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Where's th Beef? Hot Topics In The Regulation of Food Disruptors:
Lab-Created Protein

American Agricultural Law Association: October 27, 2018

New Technologies: ~~Lab-Created Protein~~ Cell Cultured Technologies

Federal Regulation of food: ensures quality and safety.

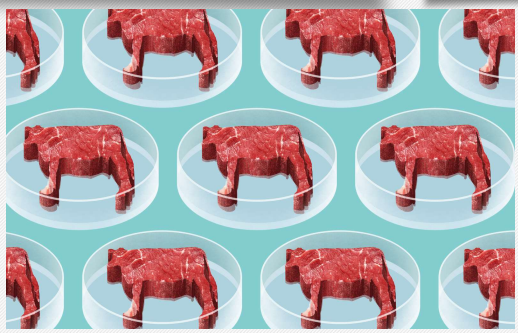
Agencies with food regulation authority are the USDA and FDA.

→USDA regulates meat → FDA regulates food

Are existing regs adequate for new technologies?

Benefits

Food Safety Regulation:
Where do lab proteins fit?



1. What to call it?
   - Cellular agriculture
   - Lab protein
   - Clean meat
   - Fake meat
   - Cultured meat

2. Is it meat?
   - Cattlemen's Association says "no!"
   - Industry say "yes!"

3. If it's meat, doesn't the USDA have jurisdiction?

Benefits

Food Safety Regulation:
Where do lab proteins fit?

What is it?

- production of agricultural products from cell cultures
- grown from the same cells that produce meat in the animal from which they are taken
- uses meat, poultry, and fish cells to produce edible protein *ex vivo*—outside the animal
- finished product replicates the characteristics of muscle harvested from food-producing animals, yielding a meat product that does not require animal slaughter

Benefits

Food Safety Regulation:
Where do lab proteins fit?

What is it?

Production of cell types present in meat – muscle cells, fat cells, connective tissue, etc. - through a cell culture platform, using cells derived from meat-relevant species including avian, mammalian, and piscine cell lines

Benefits

Food Safety Regulation:
Where do lab proteins fit?

How is it produced?

Four core elements of the production process:
(1) cell cultures;
(2) scaffolds;
(3) media, and
(4) bioreactor (cultivator)

→ cells from USDA-inspected animals via biopsy
→ separated and transferred in a sterile environment and placed in a bioreactor, or cultivator
→ fed nutrients referred to as “media” or “growth medium”
→ cells grown on a scaffold until maturation into cell types required for meat

Benefits

Food Safety Regulation:
Where do lab proteins fit?

February 9: US Cattlemen's Association filed a petition with the USDA to exclude cultured meat from being labeled as "meat" or "beef."

May 14: Ag appropriations bill included regulation section.

June 15: FDA announced hearing on Foods Produced Using Animal Cell Culture Technology.

June 14: Aleph Foods Ltd (Israeli company) called on USDA to promote clean meat for compelling safety advantages (antibiotic and pathogen free).

June 27: First Congressional Briefing on lab proteins was hosted by R&D Caucus co-chairs, Representatives Bill Foster and Barbara Comstock.

Benefits

USDA – vs - FDA

July 12 FDA hearing (reported as "power grab")

Gottlieb: promotion of innovation + protecting consumers

FDA experience with novel technologies, and medical regulation → extensive knowledge of cell culture technologies →

FDA should regulate; in best position to evaluate safety of cell-based food

4 "ities"

USDA – vs - FDA

"… extensive expertise and experience in relevant scientific areas. Currently, FDA evaluates microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients, administers safety assessment programs for a broad array of food ingredients and foods derived from genetically engineered plants, manages safety issues associated with animal cell culture technology in therapeutic settings, and manages risks associated with the processing, manufacture, and packaging of food incorporating seafood tissues."

4 "ities"

July 12: Foods Produced Using Animal Cell Culture Technology

Questions:

What considerations specific to animal cell culture technology are appropriate to include in evaluation of food produced by this method of manufacture?

What kinds of variations in manufacturing methods are relevant to safety for foods produced by animal cell culture technology?

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July 12: Foods Produced Using Animal Cell Culture Technology

Questions:

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 hazards associated with production of foods using animal cell culture technology different from those associated with traditional food production/processing (such as, for example, insanitary conditions, improper temperature controls, or control of contaminants)? Is there a need for unique control measures to address the hazards associated with production of foods using animal cell culture technology?

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Food Safety Regulation:
Where do lab proteins fit?

August 23: Memphis Meats, a leader among the lab-created protein start-ups, and the North American Meat Institute (NAMI) joined forces and called for both agencies—FDA and USDA—to have regulatory jurisdiction over lab-created protein.

Letter to President Trump:
- Agreed on naming as "cell-based meat and poultry."
- Goal is to protect consumers while foster innovation || imperative that agencies coordinate and collaborate in their efforts, consistent with established policy.
- FDA should have oversight over pre-market safety evaluations for cell-based meat and poultry products.

Benefits

Food Safety Regulation:
Where do lab proteins fit?

August 23: Memphis Meats and NAMI Letter (cont'd)

- USDA should regulate cell-based meat and poultry products, as it does with all other meat and poultry products, applying relevant findings from FDA's safety evaluation to ensure products are safe, wholesome, and properly labeled.

They also called for a joint meeting involving the White House, USDA, FDA, and farm-raised and lab-created meat industry representatives.

Benefits

USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 and 24

USDA + FDA

Day 1—Oversight, Hazards, and Controls

Day 2—Labeling and Claims

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - 24

Groups Commenting:

→Consumer Advocates
→Animal Advocates
→Big Animal Operation Advocates
→Cell Cultured Technology Advocates
+ The Rationals

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- **Current Regulatory Safety Frameworks for Foods and Products of Cell Culture Technology**

  USDA + FDA

- **Potential Hazards for Cell Culture Technology Products Derived from Livestock and Poultry**

  HACCP, SSOPs, FSMA, good manufacturing, hazard analysis, preventive controls

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- **Potential Hazards for Cell Culture Technology Products Derived from Livestock and Poultry**

Questions for public comment:

- What hazards are the same between traditional meat and poultry products and products of cell culture technology, and which hazards are different?
- What are the most significant sources of potential hazards?
- Are there hazards that have not been raised, or are there aspects of the hazards that have not been discussed?

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- **Strategies to Address Potential Hazards and Provide Appropriate Regulatory Oversight Frameworks for Cell Culture Technology Products Derived from Livestock and Poultry**

Open Public Comment:

- Is there an effective and efficient application of pre-market programs to ensure the safety of foods produced by animal cell culture?
- What preventive controls and other tools are best suited to managing potential hazards at each stage of production?

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- What type and frequency of inspection are appropriate for various stages of the manufacture of these products, given the potential hazards and assessed risks at different stages?
- (Stages include: seed cell procurement and selection, establishment of master cell banks, cell proliferation and passaging, cell differentiation, further processing, and packaging, in addition to culture media and scaffold element production.)

4 "ities"

USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- Would inspection type, frequency, or other oversight activities beyond those associated with existing food products be appropriate?
- 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?

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- Consumers: GMO analogous (industry and regulators-v-consumers)
- GRAS is a defective process; self-policing, no peer review, no confidence for consumers
- Comprehensive and mandatory review that is independent and transparent—not GRAS
- Need new process for new technologies-v-need clear regulatory process with single point of entry; existing pre-market system is fine
- scaffold-based = cells attach to scaffolding to grow and differentiate when infused with growth medium in bioreactor; source of cells via repeated biopsies and can be derived from cell lines that are immortal and can proliferate indefinitely; "research is needed on safety of ingesting as they exhibit characteristics of a cancerous cell which includes overgrowth of cells not attributable to original characteristics of a population of cultured primary cells"

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- Safety of all chemicals and other ingredients necessary to promote cell growth should be evaluated: nutrients, growth hormones, antimicrobials, bioscafolding materials
- Huge potential problem is contamination of cell lines via growth of bacteria, fungi and mycoplasma; continuous monitoring for contaminants and standards for safety; and bacteria, fungi and mycoplasma should be considered adulterants.
- Close oversight and continuous inspection of production sites; GRAS is not appropriate; shared oversight between FDA and USDA;

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- American Meat Science Association: to be considered meat cultured animal tissue must result in a product that is comparable in composition functionality and sensory characteristics to meat naturally derived from animals; there is no process to determine if the product meet specific characteristics similar in composition; meat science unanswered questions because have not been able to evaluate. How the conversion from muscle to meat? Amino acid content? Micronutrients. PH. Not fully characterized. Not enough scientific information to determine that should be called meat. Research is urgently needed to characterize.
- There is a willingness to do so.

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 23 - Day 1

- Current framework is insufficient to regulate novel technologies and their risks.
- Update existing framework. Outdated tools predate first wave of GE products.
- Should be regulated as food additives and not as GRAS
- FDA should conduct its own risk assessment on products and each ingredient. USDA inspection of factories to ensure safety and help prevent outbreaks.
- Risks are not hypothetical:
  - Process requires antibiotics
  - Novel ingredients may pose allergic risks
  - Need EPA risk assessment of environmental contamination

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Regulatory Frameworks for Food Labeling - Mandatory Elements

- Nutritional composition
- Statement of Identity/Product Name
- Statement of Quantity of Contents – also in metric
- Ingredient Statement = order of descending amounts in regulatory of common and usual name, not process aids because not ingredients in final product
- Allergens – big 8: milk, egg, fish, crustacean shellfish, peanuts, tree nuts, wheat, and soybeans
- Principal Display Panel / Inspection Legend / Safe Handling

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Open Public Comment on Mandatory Labeling Elements

- 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?

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Open Public Comment on Mandatory Labeling Elements

- 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?
- How should products containing both animal cell cultured products and traditional meat and poultry products be labeled?

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Regulatory Frameworks for Food Labeling-Claims

FSIS animal production claims | feed claims | FDA nutrient content | health claims

Open Public Comment on Potential Claims

- What factors should be considered in potentially allowing health, safety, and other claims in the marketing of animal cell cultured products?

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Public Comment on Labeling

- Consistent labeling and oversight; full transparency in labeling; should be the same.
- Safe, healthy and accurately labeled for human consumption
- Transparent labeling and safe practices for all: cell culture AND slaughterhouse
- Claims such as "clean" meat misrepresents as sterile; environment is conducive to growth of all pathogens; if contaminated there will be contamination in the ultimate product; scaffolding elements may have hazardous effects on public and has to be labeled;
- How do you label growth medium?
- if marketed as environmentally sustainable do we have a labeling process for that? Takes 5,000 liters of fluid to produce 1 to 2 kilograms of product; where are byproducts of process going to go;

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Public Comment on Labeling

- Altered nutrition potential; FDA doesn't do prior label approval is a more natural fit for FSIS
- Consumers Union: survey of 1018 random adults, demographic and geographic representative of US population;
  - should be labeled "meat" with explanation, or something else entirely
  - 7 choices on what it should be called; lab-grown meat 35%; artificial meat 34%; clean meat 9%; cultured meat 11%
  - Needs to be clearly labeled

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USDA/FDA Joint Public Meeting: The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | October 24 - Day 2

Public Comment on Labeling

- allergens, e.g., fish
- Need standards of identity that identify cell cultured products as something other than beef; consumers will want to know.
- Methods should be communicated.
- Source of cells should be on label.
- Antibiotic use must be on label.
- Need "real" consumer research before labeling.
- Labeling is a problem for entire food system but consumers care more.

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Submit Comments

https://www.regulations.gov/

Due November 26, 2018

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Only The Beginning …

Multiple applications of cellular technology

For example:

"Peter Thiel pet food startup aims to make lab-grown mouse meat"

Business Insider—August 2, 2018

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QUESTIONS?

We would love to hear your questions.

Thank you for your attendance and participation.

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