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Technically Food: How Innovation in Food is Presenting Unique and Complex Challenges to Regulators

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Roadmap

- Regulatory Overview and Definitions
- Labeling
- FDA-USDA Formal Agreement
- Federal Preemption
- Next Steps

Buckle Up!

Primary Federal Agencies Regulating Food in U.S.

United States Department of Agriculture

- Implements/enforces:
  - Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 301, *et seq.*)
  - Public Health Service Act (42 U.S.C. 201, *et seq.*)
  - Fair Packaging and Labeling Act (15 U.S.C. 1451, *et seq.*)
- FDA has jurisdiction over "food" which includes "articles used for food or drink" and "articles used for components of any such article." (21 U.S.C. 321(f))
- With a few exceptions (e.g., food additives), the FDCA authorizes FDA to regulate food through postmarketing mechanisms such as inspections, testing, and enforcing adulteration and misbranding standards and good manufacturing practices

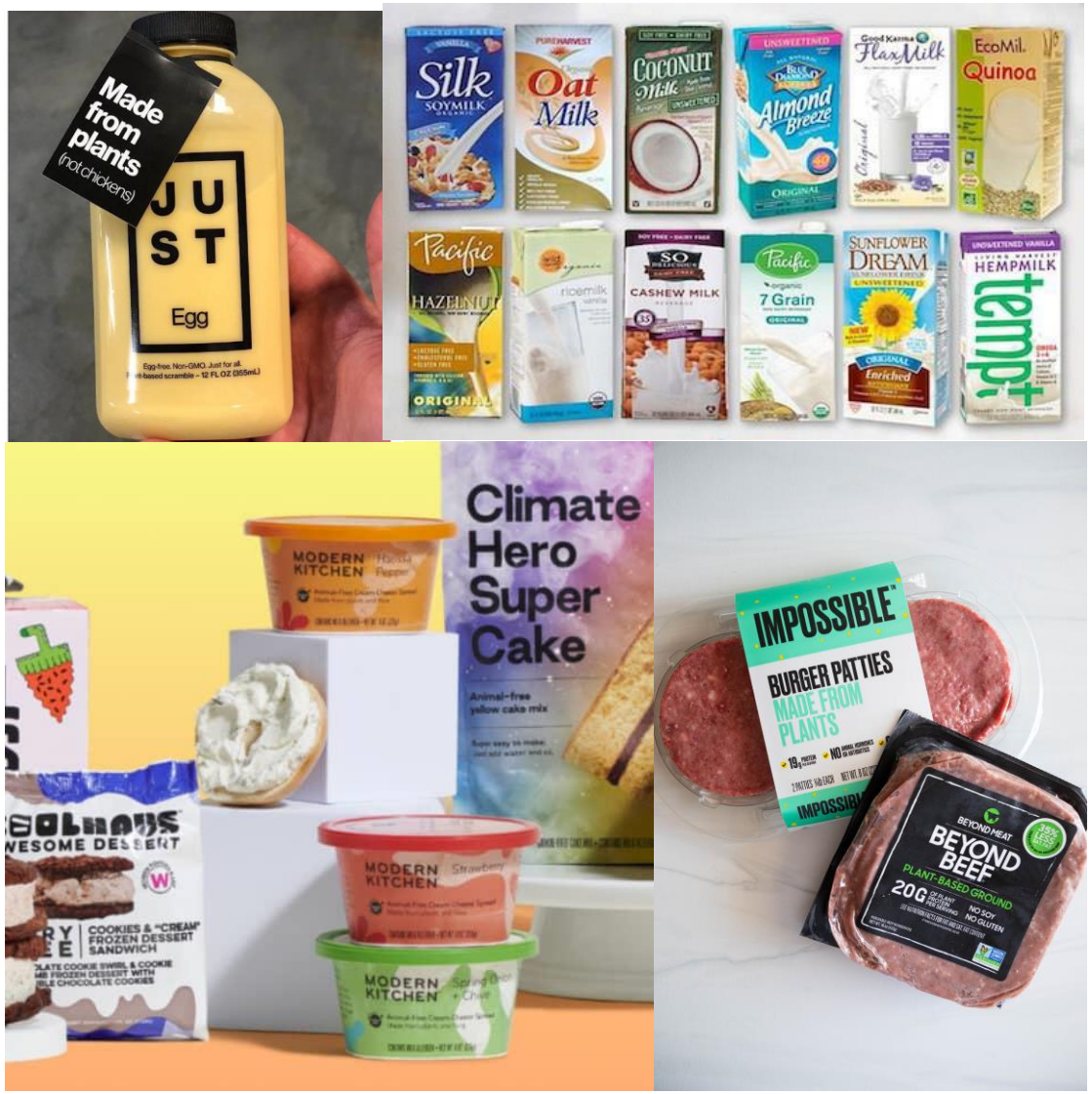
- Implements/enforces:
  - Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.)*
  - Agricultural Marketing Act (AMA)
  - Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*)
  - Human Methods of Slaughter Act (HMSA)
  - Egg Products Inspection Act (EPIA) (21 U.S.C. 1031*, et seq.*)
- Ensures U.S. commercial supply of meat (and meat products) and poultry (and poultry products) are safe, wholesome, and correctly labeled
- Places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg product processing plant
- Reviews new technologies for safety and suitability

Foods Derived from Biotechnology

- **The Coordinated Framework for Regulation of Biotechnology**
  - EPA
  - FDA
  - USDA
- **USDA APHIS Regulation of Genetically Engineered Plants**
- **FDA Regulation of Food Derived from Genetically Engineered Plants/Crops**
  - Plant Biotechnology Consultation Program
  - New Protein Consultation Program
- **FDA Regulation of Foods Derived from Genetically Engineered Animals**
- **FDA Regulation of Foods Derived from Genetically Engineered Microorganisms**

Plant-Based Foods Market Pathways

- Food additive petition
- Generally Recognized As Safe (GRAS)
- New Dietary Ingredient



FDA Foods Program Guidance Under Development

- Premarket Consultation on Cultured Animal Cell Foods: Draft Guidance for Industry
- Foods Derived from Plants Produced Using Genome Editing; Draft Guidance for Industry
- Labeling of Plant-based Milk Alternatives; Draft Guidance for Industry
- Labeling of Plant-Based Alternatives to Animal-Derived Foods; Draft Guidance for Industry

Foods Program Guidance Under Development

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Available in PDF

(Expected to publish as drafts or finals by the end of December 2022.)

Introduction

The following list of guidance topics includes possible new topics for guidance documents or revisions to existing guidance documents that the FDA Foods Program is considering. [1] We currently intend to develop guidance on each topic; however, the FDA Foods Program is neither bound by this list of topics, nor required to issue every guidance document on this list. Several factors may impact FDA's ability to issue the listed guidances, including, for example, new Administration priorities, emerging public health issues, or other extenuating circumstances. We are not precluded from issuing guidance documents on topics not on this list..

You may submit comments on the guidance topics at www.regulations.gov in Docket FDA-2021-N-0553.

Content current as of:
01/31/2022

Regulated Product(s)
Food & Beverages

FDA and Food Labeling

- Preapproval not required
- Labels must be truthful and not misleading
- Two general categories of food:
  - Standardized food (21 U.S.C. 341)
  - Non-standardized food (21 U.S.C. 343(g),(h), and (i))
- Both standardized foods and non-standardized foods are generally named by their common or usual names
  - Name by which it is known to the American public and is generally established by common usage (21 CFR 102.5(d)).

USDA and Labeling

- Must approve the labels of meat and poultry products before they enter commerce
- Labels must be truthful, accurate, and not misleading
- Generic Labels
  - Approval without submission to FSIS if criteria listed in 9 CFR 412.2(b) is met
- Certain types of labeling require submission for evaluation by FSIS (9 CFR 412.1)
  - Temporary approval
  - Products produced under religious exemption
  - Products for export with labeling deviations
  - Special statements and claims

Activities Regarding Food Standards and Labeling

- 70 Fed. Reg 29214 (May 20, 2005) - Food Standards; General Principles and Food Standards Modernization
  - 85 Fed. Reg. 10107 (Feb. 21, 2020) - Reopening of the Comment Period
- 83 Fed. Reg. 49103 (Sept. 28, 2018) - Use of the Names of Dairy Foods in the Labeling of Plant-Based Products
- Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization (September 27, 2019)
- House Committee on Appropriations Report (2021)
- FDA Fiscal Year 2022 Justification of Estimates for Appropriations

Regulation of Foods Derived from Animal Cell Lines

FORMAL AGREEMENT BETWEEN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE OFFICE OF FOOD SAFETY

1. Purpose

The purpose of this agreement is to describe the intended roles of the U.S. Department of Health and Human Services Food and Drug Administration ("HHS-FDA") and the U.S. Department of Agriculture Food Safety and Inspection Service ("USDA-FSIS") (hereinafter individually a "Party", and together the "Parties") with respect to the oversight of human food produced using animal cell culture technology, derived from cell lines of USDA-amenable species and required to bear a USDA mark of inspection.

https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell

Formal Agreement - FDA

- **Conduct premarket consultation** processes to **evaluate production materials/processes and manufacturing controls**, to include **oversight of tissue collection, cell lines and banks, and all components and inputs**. Consult with USDA-FSIS, and share results of premarket consultation processes with USDA-FSIS, as authorized by law.
- **Oversee initial cell collection** and the development and maintenance of qualified cell banks, including by issuing regulations or guidance and conducting inspections, as appropriate.
- **Oversee proliferation and differentiation of cells through the time of harvest**, including by issuing regulations or guidance and conducting inspections, as appropriate.
- At harvest, help coordinate the transfer of regulatory oversight to USDA-FSIS, including, but not limited to, **providing information necessary for USDA to determine whether harvested cells are eligible to be processed into meat or poultry products** that bear the USDA mark of inspection.
- **Ensure that covered entities comply with applicable HHS-FDA requirements**, including facility registration, the Current Good Manufacturing Practices and preventive controls regulation, and requirements applicable to substances that become a component of food or otherwise affect the characteristics of food.
- As needed, develop additional requirements for cell bank and cell culturing facility conditions and processes to ensure that biological material exiting the culture process is safe and not adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act.
- **Conduct appropriate inspections and follow-up activities**, including taking enforcement action if necessary, to ensure that cell bank and cell culturing facilities are in compliance with HHS-FDA's applicable laws and regulations. HHS-FDA shall not inspect activities solely regulated by USDA-FSIS and shall rely on the USDA-FSIS regulatory process for information regarding such activities.
- **Share information with USDA-FSIS** as authorized by law and appropriate for carrying out the respective responsibilities of the Parties, and, specifically, notify USDA-FSIS if objectionable conditions are identified, including conditions which may result in the production of adulterated or misbranded product, work collaboratively with USDA-FSIS to address such conditions with respect to harvesting, and rely on USDA-FSIS to address such conditions with respect to post-harvesting activities.

Formal Agreement - USDA

- At harvest, help coordinate the transfer of regulatory oversight from HHS-FDA, including, but not limited to, reviewing information necessary for USDA to determine whether harvested cells are eligible to be processed into meat or poultry products that bear the USDA mark of inspection.
- Require each establishment that harvests cells cultured from livestock or poultry subject to the FMIA or PPIA for the purpose of producing human food required to **bear the USDA mark of inspection, processes those cells into such human food products, or packages and labels such products, to obtain a grant of inspection**, as required by the FSIS regulations. USDA-FSIS shall not inspect activities solely regulated by HHS-FDA and shall rely on the HHS-FDA regulatory process for information regarding such activities.
- **Conduct inspection in establishments where cells cultured from livestock and poultry subject to the FMIA and PPIA** are harvested, processed, packaged or labeled, in accordance with applicable FSIS regulations (including sanitation and physical product inspection, Hazard Analysis and Critical Control Point (HACCP) verification, product testing, and records review), to ensure that resulting products are safe, unadulterated, wholesome and properly labeled. USDA-FSIS shall not inspect activities solely regulated by HHS-FDA and shall rely on the HHS-FDA regulatory process for information regarding such activities.
- **Require that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified** through inspection, as required by FSIS regulations.
- **As needed, develop additional requirements to ensure the safety and accurate labeling** of human food products derived from the cultured cells of livestock and poultry subject to the FMIA and PPIA.
- **Conduct enforcement action, as necessary**, to ensure that adulterated or misbranded human food products derived from cultured livestock and poultry cells do not enter or are removed from commerce.
- **Share information with HHS-FDA** as authorized by law and appropriate for carrying out the respective responsibilities of the Parties and, specifically, notify HHS-FDA if objectionable conditions are identified, including conditions which may result in the production of adulterated or misbranded product, work collaboratively with HHS-FDA to address such conditions with respect to harvesting, and rely on HHS-FDA to address such conditions with respect to pre-harvesting activities

Activities Regarding Regulation of Cell-Cultured Animal Protein

- **September 3, 2021**
  - USDA-FSIS published ANPRM to request comments on labeling of meat and poultry products derived from animals subject to FMIA and PPIA (86 Fed. Reg. 494941)
- **October 7, 2020**
  - FDA issued a request for information seeking comments on cell-cultured seafood subject to FDA's regulation (85 Fed. Reg. 63277)
- **July 31, 2020**
  - USDA/FDA Launches Joint Webinar on Roles and Responsibilities for Cultured Animal Cell Human and Animal Food Products
- **March 7, 2019**
  - USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry
- **October 23-24, 2018**
  - Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry
- **July 12, 2018**
  - FDA Public Meeting on Foods Produced Using Animal Cell Culture Technology

Preemption

- Based on the supremacy clause of the U.S. Constitution (U.S. Const. Art. VI, Clause 2) and "occurs when a state law is invalidated because it conflicts with a federal law." Mason et al. v. SmithKline Beecham Corp. , No. 08-2265 (7th Cir. Feb. 23, 2010).
- Three forms:
  - Express
  - Field
  - Conflict
    - Impossibility
    - Obstacle

Preemption continued…

- **USDA**
  - Language in both FMIA and PPIA explicitly states that marking, labeling and ingredients requirements in addition to or different than those required under the FMIA and the PPIA may not be imposed by any state or territory (21 U.S.C. 678 (FMIA); 21 U.S.C. 467(e) (PPIA))
    - Armour v. Ball, 468 F.2d 76 (6th Cir. 1972), cert. denied, 411 U.S. 981 (1973)
- **FDA**
  - FDCA expressly preempts state food labeling requirements that are not identical to federal requirements (21 U.S.C. 343-1(a)(1)–(5))
    - Cortina v. Goya Foods Inc., 94 F. Supp. 3d 1174 (S.D. Cal. 2015)
    - Garcia v. Kashi Co., 43 F. Supp. 3d 1359 (S.D. Fla. 2014)
    - Regan v. Sioux Honey Ass'n Co-op., 921 F. Supp. 2d 938 (E.D. Wis. 2013)

Thank you!
¡Gracias!

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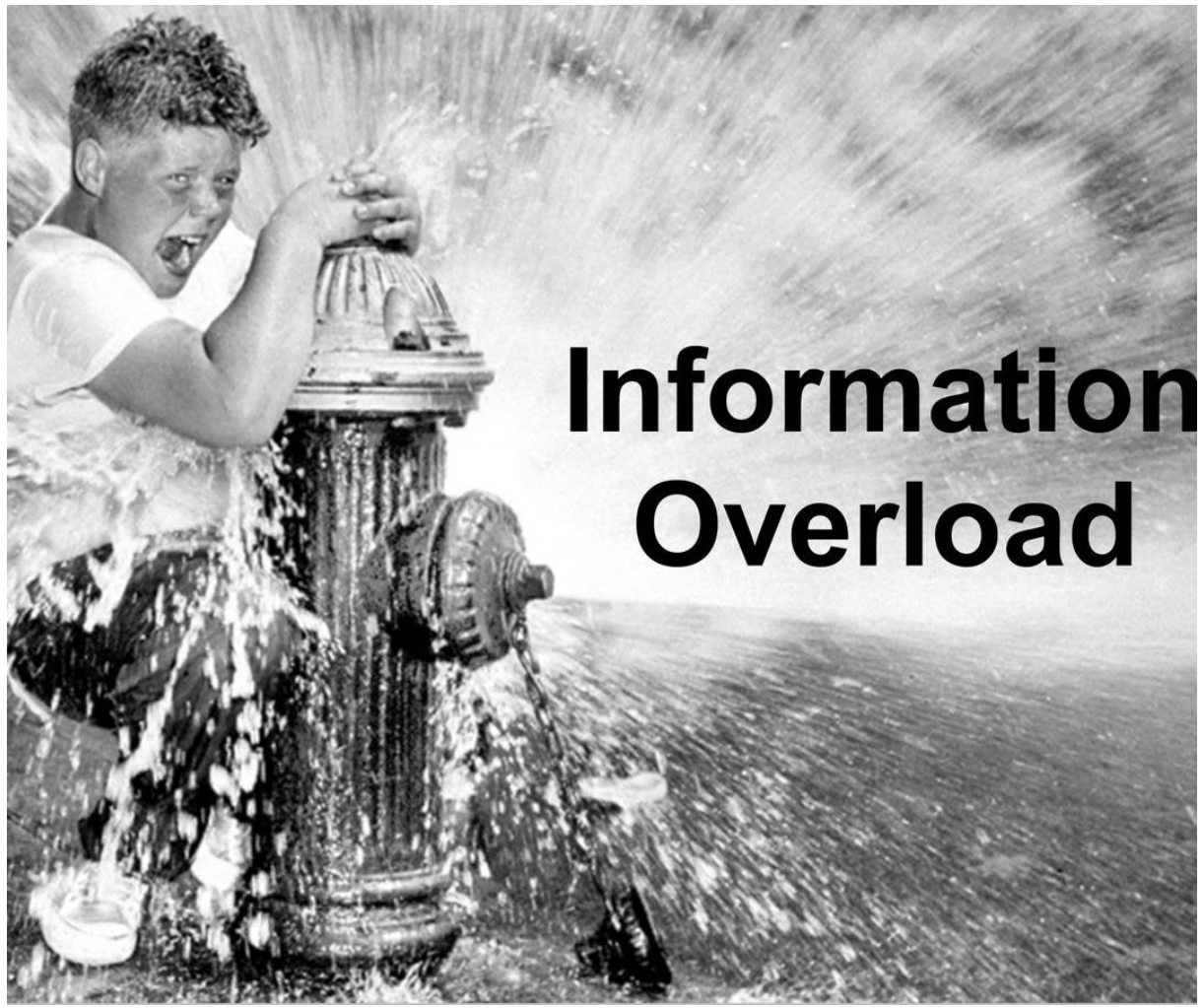
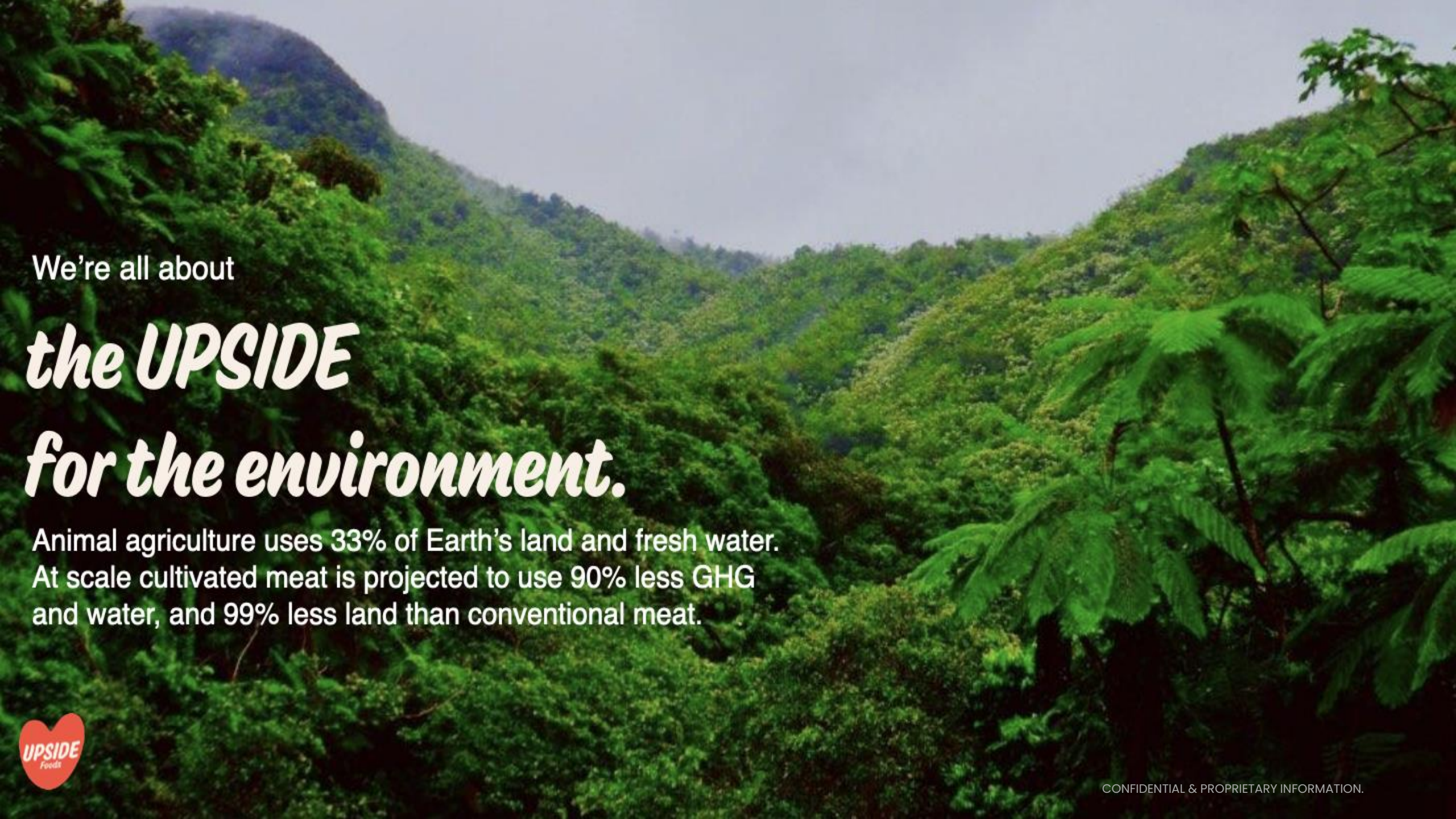


UPSIDE Foods

Eric Schulze, PhD

AT UPSIDE FOODS, WE GROW REAL MEAT DIRECTLY FROM CELLS WITHOUT THE NEED TO SLAUGHTER ANIMALS.



Overview of the science:

Step 1.

SAMPLE
Cells are the building blocks of meat, and the first step in our process. We identify and select the best cells for great tasting meat. We have the ability to cultivate, from a single cell sample, hundreds of thousands of pounds of meat.

Step 2.

NOURISH
To produce meat, we first need to nourish the cells. We feed them a blend of micronutrients optimized for our cells' needs.

Step 3.

CULTIVATE
We place the cells in a vessel called a cultivator. There they follow their natural process to form meat, just like they would grow in an animal.

Step 4.

HARVEST
After 2-3 weeks, we harvest the meat. It's then ready to be inspected, prepared, packed, served, and enjoyed.

Our technology can produce multiple types of meat — we are the only company able to create complex textures and cuts.

Regulating Cultivated Meat - Food Safety

Important:

- Regulation is the first and last pillar for building consumer trust here in the US and abroad. It will help ensure food safety, truthful labeling, and a transparent supply chain. We must get it right.

- Food is intimate and familiar – Food is expected to be safe and therefore trusted. Cultivated meat must earn that trust through effective federal regulation.

Overview:

- In March of 2019, the USDA and FDA announced a formal agreement to jointly oversee and regulate our industry.

- FDA's Role: Oversees cell collection, the development of our cell banks, as well as the scaled-up cell growth and maturation production process.

- USDA's Role: Oversees the processing , suitability of ingredients, and labeling of cultivated meat and poultry. For most seafood products, FDA will regulate the entire process.

Cultivated Meat is Regulated Under Existing Federal Authority

Important:

- FDA regulates the scaled cultivation of cells from cell isolation to cell banking all the way until the moment of harvest.

- If meat or poultry, the harvested cells or tissues are transitioned to USDA oversight where inspection begins.

- Just like any other meat or poultry product, USDA then oversees the processing of meat into a commercial food product under processing authority.

- If cultivated seafood (minus catfish), FDA continues to oversee food processing.

Food Design with Regulation in Mind

- Cultivated meat is ‘biologically-additive’ food design, which adds immense product flexibility compared to conventional products. We build our meat from the cell-up, not the animal-down - an additive process.

- Good design is constrained: Since we regulate food on an additive basis in the US, this allows us to bake regulatory affairs into our process as the primary design constraint.

- Second design constraint: familiar favorites - people want to eat familiar foods.

- Our first question was, and our last questions will be: “How are we earning consumer trust?”

- Safe, delicious, and sustainable (environmentally and operationally) guide our product decisions.

Designing with Regulation in Mind

- We ensured we developed products that came from meat and used ingredients that could be found in animals and food we consume routinely.
- We decided early to focus on familiar meat products for both consumers and regulators.
- We decided to focus on building a production facility that would be available to the public and to regulators for training while protecting IP.
- We sought out independent evaluations of our products in the press to ensure we held our flavor standards to their highest.

Cultivated Meat Regulation Will Mature as Products Hit Market

Short Term

- Products will complete federal food safety evaluation and begin making it to consumers' plates.
- Gaps to be filled:
    - Compliance programs for cultivated meat will take effect
    - Formal regulatory guidance will emerge

Mid Term

- Standards of identity may evolve as products evolve.
- Potential international harmonization efforts for export/import of cultivated products.

Long Term

- New food and non-food industries are likely to emerge off the backs of cultivated meat, sparking potentially entirely new regulatory paradigms.
- Potential statutory amendments to include cultivated meat and other 'biologically-additive' food design products.

THANK YOU!

sánchez devanny®

Legal Developments in "artificial meat" and other new food products in Mexico and challenges for its importation and marketing.

FOOD AND DRUG LAW INSTITUTE

JOSÉ ALBERTO CAMPOS VARGAS

March 31, 2022

Developments in Mexico

Mexico has currently no legal provisions in force that regulate the processes (production, preparation, packaging, marketing, etc.) related with "artificial meat".

In 2018 diverse proposals for regulation were submitted with the legislative power, however due to the COVID pandemic these were not developed nor given the necessary analysis and are not at this date at an advanced stage.

Under the current statute in force, there are no special or particular provisions that have to be followed for the use of these products as human bound food.

These products are not expressly forbidden for their use as human bound food or ingredients of other products, likewise no specific rules regarding their use or limitations exist.

Other alternative protein sources (insects and products therefrom) are commonly used and not limited or restricted in any manner.

Mexican Legal Statute

Article 4- Individuals right to food and nutrition.

Mexican Legal Provisions

FEDERAL LAWS

Food is only regulated at a Federal Level. No state or local provisions are applicable.

1. **GENERAL HEALTH LAW**
2. **FEDERAL ANIMAL HEALTH LAW**
3. **LAW ON BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS**
4. **GENERAL LAW OF THE IMPORT AND EXPORT DUTIES (MEXICAN TARIFF SCHEDULE).**
5. **FOREIGN TRADE LAW**
6. **FEDERAL LAW ON INFRASTRUCTURE QUALITY**
7. **FEDERAL CONSUMER PROTECION LAW**
8. **LAW ON BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS.**

9.?

REGULATIONS

1. **REGULATION OF HEALTH CONTROL OF PRODUCTS AND SERVICES.**
2. **REGULATION OF THE FEDERAL ANIMAL HEALTH LAW**
3. **REGULATION OF THE LAW OF BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS.**
4. **REGULATIONS OF THE FOREING TRADE LAW**
5. **REGUALTIONS OF THE FEDERAL LAW ON INFRASTRUCTURE QUALITY**
6. **REGULAIONS OF THE FEDERAL CONSUMER PROTECTION LAW**
7. **REGULATIONS OF THE LAW ON BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS.**

MEXICAN OFFICIAL STANDARDS (NOMs)

1. **MEXICAN OFFICIAL STANDARD NOM-251-SSA1-2009, HYGIENIC PRACTICES FOR THE PROCESSING OF FOOD, BEVERAGES OR FOOD SUPPLEMENTS.**

2. **MEXICAN OFFICIAL STANDARD NOM-213-SSA1-2002, APPLICABLE TO PROCESSED MEAT PRODUCTS.**

3. **MEXICAN OFFICIAL STANDARD NOM-051-SCFI/SSA1-2010, GENERAL LABELING SPECIFICATIONS FOR PREPACKAGED FOOD AND NON-ALCOHOLIC BEVERAGES - COMMERCIAL AND SANITARY INFORMATION.**

Importation and marketing.

Limitations to the importation of products.

Tariff classification and non tariff restrictions based on tariff classification.

Possible tariff classification?

Specific provisions regarding manufacturing and processing?

Provisions regarding marketing and packaging restrictions?

Labeling requirements?

Consumer Protection and information?

Practical issues

Political issues arising from the lack of information regarding safety of the products?

Cultural conception of “meat”.

Cultural perspective of a new product and risk to traditional cattle industry.

Lack of grounds for authorities to verify the products.

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