

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 435 Cultivated Meat
SPONSOR(S): Sirois
TIED BILLS: **IDEN./SIM. BILLS:** SB 586

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Agriculture, Conservation & Resiliency Subcommittee	10 Y, 4 N	Gawin	Moore
2) Agriculture & Natural Resources Appropriations Subcommittee			
3) Infrastructure Strategies Committee			

SUMMARY ANALYSIS

The ability to take a small number of cells from living animals and grow them in a controlled environment to create food made from cultured animal cells is an emerging area of food science. Advancements in cell culture technology enable food developers to use cells obtained from livestock, poultry, seafood, or other animals in the production of food. Food products made with cultured animal cells are called a variety of names, including cultured meat, cultivated meat, cell-based meat, and lab-grown meat.

In 2019, the United States Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture agreed to establish a joint regulatory framework for human foods made from cultured cells of livestock and poultry. Under this agreement, generally, the FDA oversees the collection, growth, and the differentiation of living cells into various cell types. Regulatory authority then shifts to FSIS during the harvesting stage of the cell-culturing process, and FSIS oversight continues during the processing, labeling, and packing of cultivated meat products. Two companies have been approved to sell cultivated chicken products in the U.S.

The Department of Agriculture and Consumer Services (DACS) is the agency responsible for the enforcement of the production, manufacture, transportation, and sale of food in the state. DACS's Division of Food Safety is directly responsible for assuring the public of a safe, wholesome, and properly represented food supply.

The bill defines "cultivated meat" to mean any meat or food product produced from cultured animal cells.

The bill prohibits any person from manufacturing, selling, holding or offering for sale, or distributing cultivated meat in the state and specifies that a person who violates this prohibition commits a second-degree misdemeanor.

The bill specifies that a food establishment that distributes or sells cultivated meat is subject to fines and revocation or suspension of the food establishment's permit. Additionally, the bill specifies that the license of any restaurant, store, or other business may be suspended as provided for in the applicable licensing law upon the conviction of the owner or employee of that business for a violation in connection with that business. The bill further specifies that any cultivated meat products are subject to an immediate stop-sale order as well as embargo, detainment, or destruction.

The bill may have an indeterminate negative fiscal impact on state government.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Cultivated Meat Production

The ability to take a small number of cells from living animals and grow them in a controlled environment to create food made from cultured animal cells is an emerging area of food science. Advancements in cell culture technology enable food developers to use cells obtained from livestock, poultry, seafood, or other animals in the production of food.¹ Food products made with cultured animal cells are called a variety of names, including cultured meat, cultivated meat, cell-based meat, and lab-grown meat.²

To make food products with cultured animal cells, scientists typically start with a sample of cells from the tissue of an animal, a process that does not permanently harm or kill the animal.³ Cells are selected, screened, and grown to make a “bank” of cells to store for later use.⁴ The cell type used has a significant impact on the parameters used in the production process, as each cell type has its particular requirements that might be beneficial for or detrimental to efficient production.⁵ To make cultivated meat, a small number of cells are taken from the cell bank and placed in a tightly controlled and monitored environment that supports growth and cellular multiplication by supplying appropriate nutrients and other factors.⁶ Then, various factors, such as protein growth components, new surfaces for cell attachment, and additional nutrients, are added to the cell environment to differentiate the cells into the various cell types so they can assume the characteristics of muscle, fat, or connective tissue cells.⁷ Once the cells have differentiated into the desired type, the cellular material can be harvested from the controlled environment and prepared using conventional food processing and packaging methods.⁸

A simplified graphic of the process of cultivating meat from cells is depicted below:⁹

¹ United States Food and Drug Administration (FDA), *Human Food Made with Cultured Animal Cells*, <https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

² Food and Agriculture Organization of the United Nations (FAO) & World Health Organization (WHO), *Food Safety Aspects of Cell-based Food* (2023), 6-8, available at <https://doi.org/10.4060/cc4855en> (last visited Jan. 2, 2024).

³ United States Department of Agriculture (USDA), *Human Food Made with Cultured Animal Cells*, <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

⁴ *Id.* Examples of cells used in this process include non-differentiated stem cells, muscle precursor cells, fibroblasts, or adipose-derived cells. FAO & WHO, *Food Safety Aspects of Cell-based Food* (2023), 19, available at <https://doi.org/10.4060/cc4855en> (last visited Jan. 2, 2024).

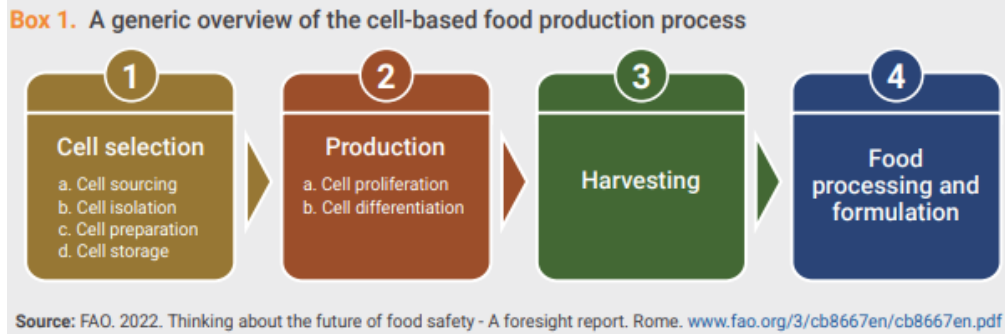
⁵ FAO & WHO, *Food Safety Aspects of Cell-based Food* (2023), 21, available at <https://doi.org/10.4060/cc4855en> (last visited Jan. 2, 2024).

⁶ USDA, *Human Food Made with Cultured Animal Cells*, <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

⁷ *Id.*

⁸ *Id.*

⁹ FAO & WHO, *Food Safety Aspects of Cell-based Food* (2023), 19, available at <https://doi.org/10.4060/cc4855en> (last visited Jan. 2, 2024).



Federal Regulation of Cultivated Meat

In 2019, the United States Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) within the U. S. Department of Agriculture (USDA), agreed to establish a joint regulatory framework for human foods made from cultured cells of livestock and poultry.¹⁰ Under this agreement, generally, the FDA oversees the collection, growth, and differentiation of living cells into various cell types.¹¹ Regulatory authority then shifts to the FSIS during the harvesting stage of the cell-culturing process, and FSIS oversight continues during the processing, labeling, and packing of cultivated meat products.¹² However, products for human consumption that are made from seafood or game meat and products for animal consumption are regulated solely by the FDA.¹³ Two companies have been approved to sell cultivated chicken products in the U. S.¹⁴ These products have been sold as prepared food on limited menus in restaurants in San Francisco and Washington, D.C.¹⁵ Currently, raw cultivated meat products are not being sold directly to consumers.

FDA Regulatory Oversight

The FDA encourages establishments interested in bringing cultivated meat products to market to do a voluntary pre-market consultation with the FDA. The pre-market evaluation assesses the production process and produced biological material, including tissue collection, cell lines and banks, manufacturing controls, and all components and inputs.¹⁶ After a successful pre-market safety consultation, the FDA conducts routine inspections on an ongoing basis, as well as other oversight activities at cell banks and facilities where cells are cultured, differentiated, and harvested.¹⁷ The FDA

¹⁰ FDA, *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species*, <https://www.fda.gov/food/domestic-interagency-agreements-food-expired/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell> (last visited Jan. 2, 2024).

¹¹ USDA, *Human Food Made with Cultured Animal Cells*, <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

¹² *Id.*

¹³ *Id.*

¹⁴ FDA, *Human Food Made with Cultured Animal Cells Inventory*, <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods> (last visited Dec. 18, 2023).

¹⁵ CNN, *Lab-grown chicken debuts in San Francisco Restaurant*, <https://www.cnn.com/2023/07/01/business/lab-grown-chicken-san-francisco/index.html> (last visited Dec. 18, 2023); NPR, *We Tried That 'Lab-grown' Chicken at One of Jose Andres' D.C. Restaurants*, <https://www.npr.org/local/305/2023/08/03/1191810646/we-tried-that-lab-grown-chicken-at-one-of-jose-andres-d-c-restaurants> (last visited Dec. 18, 2023).

¹⁶ FDA, *Human Food Made with Cultured Animal Cells*, <https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells> (last visited Nov. 29, 2023); The FDA publishes completed pre-market consultations which contain a description of the food and species origin; a file number that the FDA has assigned to the pre-market consultation; the sponsor's final submission in the consultation explaining their basis for concluding that the cultured animal cell material is safe for use as a human food; the letter the FDA sent in response to the sponsor at the completion of the pre-market consultation; and a scientific memo that documents the FDA's evaluation of the sponsor's final submission. FDA, *Inventory of Completed Pre-market Consultations for Human Food Made with Cultured Animal Cells*, <https://www.fda.gov/food/human-food-made-cultured-animal-cells/inventory-completed-pre-market-consultations-human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

¹⁷ FDA, *Human Food Made with Cultured Animal Cells*, <https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

has completed two pre-market consultations for cultivated meat, both for meat cultivated from chicken cells.¹⁸

FSIS Regulatory Oversight

Establishments that intend to harvest or process cell-cultured meat must apply for and obtain a USDA grant of inspection for such products using existing procedures.¹⁹ The establishment also must meet all applicable FSIS regulatory requirements, including the requirements for ensuring sanitation and developing and implementing the Hazard Analysis and Critical Control Points system.²⁰ The USDA directs establishments that seek to harvest cultivated meat to complete an FDA pre-market safety consultation prior to applying for a USDA grant of inspection.²¹ FSIS regulates cultivated meat products under existing food safety inspection regulations and has stated that it does not intend to establish new food safety inspection regulations specific to cultivated meat. However, FSIS has initiated rulemaking to create new labeling requirements for cultivated meat products.²²

Importing Cultivated Meat

Like traditionally produced meat, imports of cultivated meat must originate from eligible countries²³ and from establishments or plants that are certified to export to the U.S.²⁴ Countries that are eligible to export to the U.S. have gone through an equivalence process through which FSIS determines whether its inspection system achieves the same level of public health protection as is applied by FSIS in the U.S.²⁵ All imported cultivated meat products are subject to FSIS labeling requirements.²⁶ Similarly, all imported cultivated meats regulated by the FDA are subject to the same legal requirements as domestically produced food, including requirements related to unapproved additives, color additives, or other substances that may adulterate food.²⁷

Florida Food Safety

The Department of Agriculture and Consumer Services (DACs) is the agency responsible for the enforcement of the production, manufacture, transportation, and sale of food. DACs's Division of Food Safety is directly responsible for assuring the public of a safe, wholesome, and properly represented food supply.²⁸ The division accomplishes this through the permitting and inspection of food establishments,²⁹ the inspection and evaluation of food products, and the performance of specialized laboratory testing on a variety of food products sold or produced in Florida. The division also proactively monitors food from manufacturing and distribution to retail.

¹⁸ FDA, *Human Food Made with Cultured Animal Cells Inventory*,

<https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods> (last visited Jan. 2, 2024).

¹⁹ USDA, *Human Food Made with Cultured Animal Cells*, <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

²⁰ *Id.* Hazard Analysis Critical Control Point is a management system that addresses food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. FDA, Hazard Analysis Critical Control Point (HACCP), <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/hazard-analysis-critical-control-point-haccp#:~:text=HACCP%20is%20a%20management%20system,consumption%20of%20the%20finished%20product.> (last visited Dec. 20, 2023).

²¹ *Id.*

²² See Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, 86 Fed. Reg. 49,491 (Sept. 3, 2021).

²³ FSIS lists the countries, products, and establishments from those countries that are eligible to import to the U.S. on its website. USDA, *Eligible Foreign Establishments*, <https://www.fsis.usda.gov/inspection/import-export/import-export-library/eligible-foreign-establishments> (last visited Jan. 2, 2024).

²⁴ USDA, *Human Food Made with Cultured Animal Cells*, <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

²⁵ *Id.*

²⁶ *Id.*

²⁷ FDA, *Human Food Made with Cultured Animal Cells*, <https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells> (last visited Jan. 2, 2024).

²⁸ DACs, *Division of Food Safety*, <https://www.fdacs.gov/Divisions-Offices/Food-Safety> (last visited Jan. 2, 2024).

²⁹ “Food establishment” means a factory, food outlet, or other facility manufacturing, processing, packing, holding, storing, or preparing food or selling food at wholesale or retail. Section 500.03(1)(o), F.S.

DACS, as part of its responsibilities, can impose a variety of disciplinary actions against food establishments for specified violations.³⁰ This includes, but is not limited to, revoking or suspending the permit of a food establishment³¹ or imposing Class II³² administrative fines.³³ DACS, or its duly authorized agent, can also issue and enforce a stop-sale, stop-use, removal, or hold order if DACS or its agent finds that any food, food processing equipment, food processing area, or food storage area is in violation of the Florida Food Safety Act.³⁴

Effect of the Bill

The bill defines “cultivated meat” to mean any meat or food product produced from cultured animal cells.

The bill prohibits any person from manufacturing, selling, holding or offering for sale, or distributing cultivated meat in the state and specifies that a person who violates this prohibition commits a second-degree misdemeanor.³⁵

The bill specifies that a food establishment that distributes or sells cultivated meat is subject to fines and revocation or suspension of the food establishment’s permit. Additionally, the bill specifies that the license of any restaurant, store, or other business may be suspended as provided for in the applicable licensing law upon the conviction of the owner or employee of that business for a violation in connection with that business. The bill further specifies that any cultivated meat products are subject to an immediate stop-sale order as well as embargo, detainment, or destruction.

B. SECTION DIRECTORY:

Section 1. Amends s. 500.03, F.S., related to definitions in the Florida Food Safety Act.

Section 2. Creates s. 500.452, F.S., related to cultivated meat.

Section 3. Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill may have an indeterminate negative fiscal impact on DACS associated with enforcing the requirements of the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

³⁰ Section 500.121(1), F.S.

³¹ *Id.*

³² The fine for each Class II violation cannot exceed \$5,000. Section 570.971(1)(b), F.S.

³³ Section 500.121(1), F.S.

³⁴ Section 500.172(1), F.S.

³⁵ A second-degree misdemeanor is punishable by up to 60 days in jail or a fine up to \$500. Sections 775.082(4)(b), F.S. and 775.083(1)(e), F.S.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill authorizes DACS to adopt rules to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

None.