

Human Food Made with Cultured Animal Cells

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 are enabling food developers to use cells obtained from livestock, poultry, seafood, or other animals in the production of food.

There is currently no food made from cultured animal cells available for sale in the U.S. market. Manufacturers are generally working on scaling up their processes to consistently produce amounts large enough to be competitively priced. As these products come closer to market, the FDA is closely coordinating with the United States Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS), which shares jurisdiction over these human food products for certain animal species to ensure that they are safe and accurately labeled. Both agencies are working with manufacturers to ensure these products meet all applicable FDA and USDA-FSIS requirements.

The FDA is continuing to work with firms that are developing food made from cultured animal cells to ensure that the processes used to produce them are safe and lawful under the Federal Food, Drug, and Cosmetic Act. While it is a shared responsibility for the FDA and industry to ensure food is safe, it is the manufacturer's responsibility to ensure they are marketing food that meets all applicable FDA requirements.

The Science of Making Food with Cultured Animal Cells

There is a long history of scientific advances in biology, biochemistry, and engineering that have led to the innovations enabling the growth of animal cells outside of the animal itself, in a controlled environment, for food. The complex process can be broadly summarized in a few steps.

- Step 1: Manufacturers typically start with a sample of cells from the tissue of an animal, a process that does not require harm to or death of the animal. Some cells from the sample are selected, screened, and grown to make a "bank" of cells to store for later use.
- Step 2: A small number of cells are taken from the cell bank and placed in a tightly controlled and monitored environment (typically, a number of sealed sterile vessels of increasing size) that supports growth and cellular multiplication by supplying appropriate nutrients and other factors.
- Step 3: After the cells have multiplied many times over into billions or trillions of cells, additional substances (for example, protein growth factors, new surfaces for cell attachment, additional nutrients) are added to the controlled environment to enable the cells to differentiate into various cell types and assume characteristics of muscle, fat, or connective tissue cells.
- Step 4: 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.

Regulatory Approach for Human Food Made from Cultured Animal Cells in the U.S.

The FDA regulates human food made from cultured cells of livestock and poultry jointly with USDA-FSIS, following the [formal agreement \(/food/human-food-made-cultured-animal-cells/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell\)](#) we established in March 2019. Under this agreement, the FDA oversees cell collection, cell banks, and cell growth and differentiation. We transition oversight to USDA-FSIS during the harvesting stage of the cell culture process. USDA-FSIS oversees the further production and labeling of these products. As part of the agreement, the FDA and USDA-FSIS are working to develop detailed procedures to facilitate coordination of shared regulatory oversight related to the harvest of the cultured livestock and poultry cells.

The formal agreement reflects that human food made from cultured animal cells are regulated based on the animal species used as the original source of cultured cells. It is informed by the agencies' existing jurisdiction over traditionally produced products from the same species:

- The FDA regulates live animals to be used as food up until they are presented for slaughter.
- USDA-FSIS regulates the slaughter and processing of animals intended for human consumption and regulated under the Federal Meat Inspection Act (FMIA) (that is, cattle, sheep, swine, goats, and fish of the order Siluriformes) or the Poultry Products Inspection Act (PPIA) (that is, chicken, turkeys, duck, geese, guineas, ratites, and squab).
- For cell-cultured food, the FDA regulates the cell collection, banking, growth and differentiation of the cells, with a regulatory transition to USDA-FSIS, for the species covered under FMIA and PPIA, at harvest through processing and labeling.

Other applications of this food production technology that are not included in the formal agreement are within the FDA's jurisdiction:

- The FDA regulates processing for food, as well as the food themselves, made from the cultured cells of animals not regulated under the FMIA or PPIA (for example, seafood other than Siluriformes and game meat). The FDA has applicable requirements under both the Federal Food, Drug, and Cosmetic Act and Public Health Service Act.
- The FDA regulates all food for animal consumption, regardless of the animal species from which the food or cells are obtained.

The FDA's Role in Regulating Human Food Made from Cultured Animal Cells

As described in the [formal agreement \(/food/human-food-made-cultured-animal-cells/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell\)](#), the FDA's approach to regulating products derived from cultured animal cells involves a thorough pre-market consultation process and inspections of records and facilities as applicable. ^

Pre-market Consultations

The FDA's voluntary pre-market consultation process evaluates the safety of food made from cultured animal cells before it enters the market. The pre-market consultation allows developers to work with the FDA on a product-by-product basis and informs them of issues they must consider to produce safe food that does not violate the Federal Food, Drug and Cosmetic Act's requirements. As part of the pre-market consultation process, we evaluate the production process and the cultured cell material made by the production process, including the establishment of cell lines and cell banks, manufacturing controls, and all components and inputs. Our goal is to support innovation in food technologies while always maintaining as our priority the production of safe food.

We encourage firms to have conversations with us often and early in their product and process development phase. We are already engaged in discussions with multiple firms about various types of food made from cultured animal cells, including seafood and food destined for animal diets. Information about all completed consultations is available in the [FDA's inventory of completed pre-market consultations for human food made with cultured animal cells \(/food/human-food-made-cultured-animal-cells/inventory-completed-pre-market-consultations-human-food-made-cultured-animal-cells\)](#).

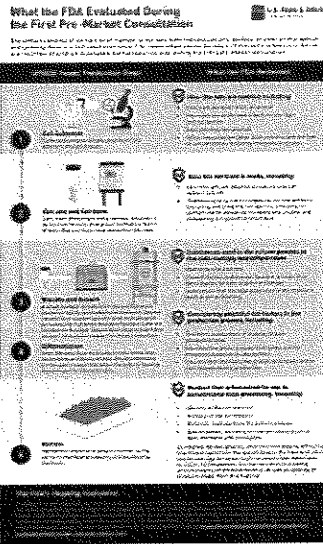
On November 16, 2022, the FDA completed its first pre-market consultation for a human food made from cultured animal cells.

We evaluated the information the firm submitted to the agency and have no further questions at this time about the firm's safety conclusion.

The FDA is committed to sharing information about our oversight of human food made from cultured animal cells and released:

- The FDA's [response letter \(/media/163260/download?attachment\)](#) to the firm
- The FDA's [scientific memo \(/media/163261/download?attachment\)](#) that describes our evaluation of the data and information provided by the firm
- The firm's [own assessment \(/media/163262/download?attachment\)](#) that their food product is safe

Example of the Information the FDA Evaluated for this Pre-market Consultation



[Enlarge in PDF \(546KB\) \(/media/163026/download?attachment\)](#)

For questions about the pre-market consultation process for **human food**, firms may contact the Center for Food Safety and Applied Nutrition, Office of Food Additive Safety at AnimalCellCultureFoods@fda.hhs.gov (<mailto:AnimalCellCultureFoods@fda.hhs.gov>).

The FDA intends to [issue guidance \(/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development\)](#) on the pre-market consultation process, and the draft guidance will represent a formal opportunity for public comment.

If firms intend to market the cultured animal cell food products, or any of the byproducts generated during the production of process, for **animal food**, firms should contact the Center for Veterinary Medicine, Division of Animal Food Ingredients, at Animalfood-premarket@fda.hhs.gov (<mailto:Animalfood-premarket@fda.hhs.gov>).

Inspections and Other FDA Oversight Activities

The FDA intends to conduct routine inspections at cell banks and facilities where cells are cultured, differentiated, and harvested. These inspections will help ensure that potential risks are being managed and that biological material exiting the culture process is safe and not adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act. The FDA will ensure that covered entities comply with applicable requirements for facility registration and for Current Good Manufacturing Practices and other food safety regulations.

In conducting inspections and other oversight activities, the FDA will be able to draw on the results of the pre-market consultation and a thorough assessment of records maintained by the facility. If our inspections uncover areas of noncompliance, we will take appropriate action. The FDA also will ensure that labeling of cell cultured products derived from animal species not subject to USDA jurisdiction is truthful and not misleading, consistent with coordinated FDA and USDA-FSIS principles for product labeling and claims.

USDA-FSIS' Role in Regulating Human Food Made from Cultured Animal Cells

USDA-FSIS and the FDA work together to transition regulatory oversight from the FDA to USDA-FSIS during harvest when the establishment removes the cells from the active growth environment to be prepared for traditional food processing. USDA-FSIS will carry out inspections at establishments where cells derived from livestock and poultry are harvested. These establishments will be required to have a USDA grant of inspection and meet the USDA-FSIS regulatory requirements, including the requirements for ensuring sanitation and developing and implementing Hazard Analysis and Critical Control Points systems. USDA-FSIS will ensure that any human food made from cultured animal cells are labeled truthfully and consistent with coordinated FDA and USDA-FSIS principles for product labeling and claims. Under the requirements of the FMIA and PPIA, all labeling of human food made from the cultured cells of livestock or poultry must be preapproved by USDA-FSIS.

Learn more about USDA-FSIS' regulatory oversight and activities on [USDA's Foods Made with Cultured Animal Cells \(https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells\)](https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells) page.

Imports of Human Food Made from Cultured Animal Cells

For food made from cultured animal cells that is produced in other countries, the FDA collaborates with USDA-FSIS and other U.S. regulatory agencies to ensure manufacturers meet U.S. import regulations before allowing them on the U.S. market. For example, these imports also will be subject to applicable requirements of the [USDA Animal and Plant Health Inspection Service \(APHIS\) \(https://www.aphis.usda.gov/aphis/ourfocus/importexport\)](https://www.aphis.usda.gov/aphis/ourfocus/importexport) and U.S. Customs and Border Protection.

Imports of FDA-Regulated Food Made from Cultured Animal Cells

Like all FDA-regulated food, imported human food made from cultured cells from fish, seafood, or [other species not subject to USDA jurisdiction \(https://ask.usda.gov/s/article/What-are-nonamenable-species\)](https://ask.usda.gov/s/article/What-are-nonamenable-species) (for example, bison and quail) must meet the same legal requirements as domestically produced food, including requirements related to the absence of unapproved food additives, color additives, or other substances that may adulterate the food.

Imported food comprising or containing cells from fish, seafood, or other non-amenable species must also meet specific agency requirements and are subject to oversight through multiple programs, including:

- registration of foreign facilities that engage in manufacturing, processing, packing, or holding of the food,
- prior notice to the FDA that the food is being imported or offered for import, and
- establishment and implementation of verification procedures by the importer to provide assurance that the foreign processor is following applicable food safety requirements.

Imported food is subject to FDA inspection when offered for import at U.S. ports of entry. The FDA may detain shipments of products offered for import that appear to be in violation of FDA requirements.

More information about the FDA's requirements for imported food can be found here:

- [Importing Food Products into the United States \(/food/food-imports-exports/importing-food-products-united-states\)](#)
- [Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507: Guidance for Industry \(/media/110317/download?attachment\)](#)
- [What do importers need to know about the Foreign Supplier Verification Programs \(FSVP\) rule? FDA Strategy for the Safety of Imported Food \(/food/conversations-experts-food-topics/what-do-importers-need-know-about-fsvp\)](#)

Imports of USDA-FSIS Regulated Meat and Poultry Products

Countries seeking eligibility to export to the U.S. products made from cultured meat or poultry cells must undergo a separate equivalence process by USDA-FSIS. Like imports of traditionally produced meat and poultry products, imports of meat and poultry products made from the cultured cells of livestock and poultry must originate from eligible countries and from establishments that are certified to export to the United States. A country becomes eligible to export to the United States following an [equivalence \(https://www.fsis.usda.gov/inspection/import-export/equivalence\)](https://www.fsis.usda.gov/inspection/import-export/equivalence) process, through which USDA-FSIS determines whether its food safety inspection system achieves the same level of public health protection as is applied by USDA-FSIS in the United States. Additionally, the foreign food safety inspection system must provide standards equivalent to the USDA-FSIS to ensure other non-food safety requirements (such as accurate labeling, and assurance that meat and poultry products are not economically adulterated) are met.

Imports of meat and poultry products made from the cultured cells of livestock and poultry will also be subject to all the other [USDA-FSIS requirements for imports \(https://www.fsis.usda.gov/inspection/import-export/import-guidance\)](https://www.fsis.usda.gov/inspection/import-export/import-guidance), including labeling requirements and reinspection by USDA-FSIS at an [official import establishment \(https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory\)](https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory). At this time, USDA-FSIS has not determined any country as equivalent for the export to the U.S. of products made from meat and poultry cultured cells; therefore, commercial imports of products made from meat and poultry cultured cells are not allowed.

Human Food Made with Cultured Animal Cells Inventory



The inventory of completed pre-market consultations for human food made with cultured animal cells provides the following information about any human food that has completed a pre-market consultation with the FDA:

- Description of the **food** and **species of origin**
- **File number** that the FDA has assigned to the pre-market consultation
- **Sponsor's final submission** in the consultation explaining their basis for concluding that the cultured cell material is safe for use as human food
- **Letter that the FDA sent in response** to the sponsor at the completion of the pre-market consultation
- **Scientific memo** that documents the FDA's evaluation of the sponsor's final submission

Inventory (<https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods>)


FDA Announcements, Meetings, and Webinars

We are committed to engaging stakeholders and sharing information about our approach to regulating human food made from cultured animal cells. The FDA and USDA-FSIS have held public meetings to better understand the science of animal cell culture technology, discuss potential hazards and labeling considerations, and to listen to consumer concerns. We will continue to engage stakeholders as we provide clarity to industry and consumers about the requirements for producing, distributing, and selling this food in the U.S.

Announcements

- [Constituent Update: FDA Completes Second Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology \(/food/hfp-constituent-updates/fda-completes-second-pre-market-consultation-human-food-made-using-animal-cell-culture-technology\)](#) (March 21, 2023)
- [Constituent Update: FDA Completes First Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology \(/food/hfp-constituent-updates/fda-completes-first-pre-market-consultation-human-food-made-using-animal-cell-culture-technology\)](#) (November 16, 2022)
- [Press Release: FDA Spurs Innovation for Human Food from Animal Cell Culture Technology \(/about-fda/page-not-found\)](#) (November 16, 2022)
- [Constituent Update: FDA Seeks Input on Labeling of Food Made with Cultured Seafood Cells \(/food/hfp-constituent-updates/fda-seeks-input-labeling-food-made-cultured-seafood-cells\)](#) (October 6, 2020)
- [Constituent Update: USDA/FDA Launch Joint Webinar on Roles and Responsibilities for Cultured Animal Cell Human and Animal Food Products \(/food/hfp-constituent-updates/usdafda-](#)

[launches-joint-webinar-roles-and-responsibilities-cultured-animal-cell-human-and-animal-food](#)
(July 31, 2020)

- [Article: Animal Cell-Culture Food Technology: A New Regulatory Frontier](https://www.food-safety.com/articles/6470-animal-cell-culture-food-technology-a-new-regulatory-frontier) (<https://www.food-safety.com/articles/6470-animal-cell-culture-food-technology-a-new-regulatory-frontier>) 
(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (February 20, 2020)
- [Constituent Update: USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry](#) ([/news-events/press-announcements/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food-products-cell-lines-livestock-and](#)) (March 07, 2019)
- [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](#) ([/news-events/press-announcements/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb-regulation-cell-cultured-food-products](#)) (November 16, 2018)
- [Press Release: USDA and FDA announce joint public meeting on use of animal cell culture technology to develop products derived from livestock and poultry](#) ([/news-events/press-announcements/usda-and-fda-announce-joint-public-meeting-use-animal-cell-culture-technology-develop-products](#)) (September 10, 2018)

Public Meetings and Webinars

- [Overview of FDA and USDA Roles and Responsibilities for Cultured Animal Cell Human and Animal Food Products Webinar](#) ([/food/workshops-meetings-webinars-food-and-dietary-supplements/overview-fda-and-usda-roles-and-responsibilities-cultured-animal-cell-human-and-animal-food-products](#)) (July 31, 2020)
- [USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry](https://www.fsis.usda.gov/news-events/events-meetings/usda-and-fda-joint-public-meeting-use-cell-culture-technology-develop) (<https://www.fsis.usda.gov/news-events/events-meetings/usda-and-fda-joint-public-meeting-use-cell-culture-technology-develop>) (October 23-24, 2018)
- [October 22, 2018: Science Board to the FDA Meeting Announcement](#) ([/advisory-committees/advisory-committee-calendar/october-22-2018-science-board-fda-meeting-announcement-10222018](#)) (October 22, 2018)
- [FDA Public Meeting on Foods Produced Using Animal Cell Culture Technology](#) ([/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-foods-produced-using-animal-cell-culture-technology](#)) (July 12, 2018)