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FSIS Responsibilities in Establishments Producing Cell-Cultured Meat and Poultry Food Products

FSIS DIRECTIVE

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FULL DIRECTIVE

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I. PURPOSE

This directive provides instruction to FSIS inspection program personnel (IPP) about their roles and responsibilities with regard to inspection and verification activities in establishments that harvest or process cell-cultured meat or poultry food products for human food. It also provides instruction about how to request records or other information from the U.S. Food and Drug Administration (FDA) related to the production of cell-cultured meat or poultry products.

KEY POINTS:

- *FDA and FSIS jointly oversee the production of cell-cultured meat and poultry food products and share information necessary to carry out their respective oversight responsibilities.*
- *Establishments that harvest cells for cell-cultured meat and poultry food products are dual jurisdiction establishments (DJE).*
- *Cell-cultured meat and poultry food products are subject to the same FSIS regulatory requirements and oversight authority as meat and poultry food products derived from the slaughter of amenable species.*
- *Labels applied to any FSIS-regulated products comprised of or containing cell-cultured meat and poultry food products are not eligible for generic approval.*

II. BACKGROUND

A. Animal cell culture technology is a production process used to produce meat and poultry food products without slaughter by growing the cells of livestock or poultry in a controlled environment, such as a bioreactor, and then harvesting those cells to make food. This directive refers to harvested cells derived from species amenable to the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 et seq.

<https://www.fsis.usda.gov/policy/food-safety-acts/federal-meat-inspection-act>) or Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 et seq.

<https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act>)

(hereinafter “the Acts”) and intended for use as human foods as “cell-cultured” meat and poultry food products. Cell-cultured meat and poultry food products are “meat food products” and “poultry food products” as defined under the regulations (9 CFR 301.2

<https://www.govinfo.gov/content/pkg/cfr-2022-title9-vol2/pdf/cfr-2022-title9-vol2-sec301-2.pdf>

and 9 CFR 381.2 <https://www.govinfo.gov/content/pkg/cfr-2022-title9-vol2/pdf/cfr-2022-title9-vol2-sec381-1.pdf>).

Cell-cultured meat and poultry food products are, therefore, subject to the same statutory requirements, regulations, and FSIS oversight authority as meat and poultry food products derived from slaughter.

B. FDA and FSIS have agreed https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/formal-agreement-fsis-fda.pdf to jointly oversee the production of cell-cultured meat and poultry food products and to share information necessary to carry out their respective oversight responsibilities in establishments that harvest cells for cell-cultured meat or poultry food products.

- C. FDA has jurisdiction over the preharvest production phase of the animal cell culture technology process. During this phase, living cells are collected from species amenable to the Acts and stored. These living cells are later placed in a controlled environment, such as a bioreactor, and introduced to inputs (e.g., amino acids, glucose, and inorganic salts) and other factors that encourage their growth, multiplication, and differentiation into various cell types.
- D. Jurisdiction transfers to FSIS at harvest, i.e., when the cell-culture establishment commences the process of removing the cells from the controlled environment, thereby halting their ability to further grow, multiply, or differentiate into various cell types.
- E. FSIS also has jurisdiction over the postharvest processing and labeling of cell-cultured meat and poultry food products. Postharvest, establishments that produce cells for cell-cultured meat or poultry food products may distribute the raw harvested cells in commerce or process the harvested cells into finished products that contain ingredients, such as spices, flavorings, binders, or other ingredients. Some of these establishments may send harvested cells to other establishments for further processing, rather than processing these cells at the harvest facility.

F. Ingredients, including processing aids, used in cell-cultured meat or poultry food products postharvest (including substances used preharvest that remain in the harvested cells) must be considered safe and suitable by FSIS and used in accordance with the intended use listed in 9 CFR 424.21(c) <<https://www.govinfo.gov/content/pkg/cfr-2012-title9-vol2/pdf/cfr-2012-title9-vol2-sec424-21.pdf>> or FSIS Directive 7120.1 <<https://www.fsis.usda.gov/policy/fsis-directives/7120.1>>, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products*. Ingredients listed as approved for meat in 9 CFR 424.21(c) <<https://www.govinfo.gov/content/pkg/cfr-2012-title9-vol2/pdf/cfr-2012-title9-vol2-sec424-21.pdf>> or FSIS Directive 7120.1 <<https://www.fsis.usda.gov/policy/fsis-directives/7120.1>> may be used in cell-cultured meat food products, and ingredients listed as approved for poultry may be used in cell-cultured poultry food products, provided the intended use is consistent in terms of the application (i.e., as an antimicrobial dip or as an ingredient component), product type (i.e., for use on whole-muscle or comminuted product), and any other criteria listed. FSIS Directive 7120.1 <<https://www.fsis.usda.gov/policy/fsis-directives/7120.1>> must also be compared to other requirements such as those for standard of identity to determine whether an ingredient such as an antimicrobial or binder can be used in a particular product. Ingredients not listed in 9 CFR 424.21(c) <<https://www.govinfo.gov/content/pkg/cfr-2012-title9-vol2/pdf/cfr-2012-title9-vol2-sec424-21.pdf>> or FSIS Directive 7120.1 <<https://www.fsis.usda.gov/policy/fsis-directives/7120.1>>, including processing aids and combinations of ingredients only listed individually, must be submitted for review as described in FSIS Directive 5020.2 <<https://www.fsis.usda.gov/policy/fsis-directives/5020.2>>, *The Technical Review Process*.

III. INSPECTION OF ESTABLISHMENTS PRODUCING CELL-CULTURED MEAT OR POULTRY FOOD PRODUCTS

A. Inspection: IPP are to reference FSIS Directive 5000.1

<<https://www.fsis.usda.gov/policy/fsis-directives/5000.1>>, *Verifying an Establishment's Food Safety System*, for comprehensive instructions on how to properly verify an establishment's compliance with sanitation and the Hazard Analysis and Critical Control Point regulations. In addition, IPP are to reference FSIS Directive 5000.4 <<https://www.fsis.usda.gov/policy/fsis-directives/5000.4>>, *Performing The Pre-Operational Sanitation Standard Operating Procedures Verification Task*, for instructions on how to perform the Pre-Operational Sanitation Standard Operating Procedures verification task.

B. FSIS Inspection Frequency: Cell-cultured meat and poultry food products are not derived from slaughter and thus there is no requirement for “carcass-by-carcass” inspection of cell-cultured product. IPP are to inspect establishment harvest and processing operations at a minimum of once per shift.

C. Dual Jurisdiction Establishments: Any establishment that *harvests* cells for cell-cultured meat or poultry food products is under the jurisdiction of FDA, which oversees the preharvest production phase, and FSIS, which inspects harvest and any postharvest production that may occur in the same establishment. IPP are to follow FSIS Directive 5730.1 <<https://www.fsis.usda.gov/policy/fsis-directives/5730.1>>, *Responsibilities in Dual Jurisdiction Establishments*, which provides detailed instructions for IPP responsibilities in any establishment subject to the jurisdiction of FDA and FSIS. As in any DJE, IPP are not to inspect any area of a cell-culture meat or poultry establishment not subject to FSIS jurisdiction, nor take any regulatory or administrative action concerning such areas.

IV. INTERAGENCY COMMUNICATION

A. FDA Premarket Consultation: IPP are to be aware that FDA performs a premarket consultation to evaluate the food safety implications of each domestic cell-culture meat and poultry establishment's preharvest production processes. FDA provides its consultation results and supporting documentation to the establishment and the FSIS Office of Field Operations Headquarters (OFO-HQ), in the form of a review memo and consultation dossier. OFO-HQ is to forward the documentation to the District Manager (DM) or designee responsible for the oversight of the establishment. FSIS uses this information to inform its review of the establishment's GOI application materials and otherwise guide its inspection activities, as needed.

>NOTE: If an establishment substantively alters any aspect of its preharvest production process after FDA's initial premarket consultation concludes, FDA will evaluate the modification, update its consultation results, and share this information with the establishment and FSIS as described above.

B. Requesting FDA Records: FDA has agreed to make available any records or other information to FSIS, as needed. To request such information, the DM is to:

1. Route requests for information related to FDA's premarket consultation or an establishments' preharvest production processes, equipment, materials (e.g., ingredients, including processing aids used preharvest), or manufacturing controls to FDA's premarket program for cell-cultured foods at AnimalCellCulturedFoods@fda.hhs.gov.
2. Route requests for all other types of information, including FDA inspection or enforcement records, to the FDA Office of Regulatory Affairs at ORAHAFfieldInfoAnimalCellCultureFoods@fda.hhs.gov.

V. GRANT OF INSPECTION

- A. IPP are to be aware that any establishment that intends to harvest or process cells for cell-cultured meat or poultry food products amenable to the FMIA or PPIA for distribution in commerce is to apply for a GOI or request an update to its existing GOI to include such products.
- B. OFO frontline supervisors (FLS), district managers (DM), and grant curators (GC) are not to formally review GOI applications from establishments that harvest cells for cell-cultured meat or poultry food products until the establishment has successfully completed the FDA premarket consultation process and FDA has provided FSIS with its official findings and supporting documentation.
- C. OFO FLSs, DMs, and GCs are to follow instructions in FSIS Directive 5220.1 <<https://www.fsis.usda.gov/policy/fsis-directives/5220.1>>, *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection Under the Public Health Information System*, for the processing of GOI applications.

VI. LABEL REVIEW

- A. IPP are to be aware that cell-cultured meat or poultry food product labels need to be submitted to FSIS' Labeling and Program Delivery Staff (LPDS) for review and approval before they can be used on product in commerce, along with a completed FSIS Form 7234-1 https://www.fsis.usda.gov/sites/default/files/2020-08/fsis_7234-1_approval_of_labels_2.pdf and all supporting documentation. These labels are not eligible for generic label approval.
- B. Establishments are responsible for ensuring that cell-cultured meat and poultry food product labels are not false or misleading, and for ensuring that such labels comply with all Federal meat and poultry products inspection regulations and policies. Cell-cultured meat and poultry food product labels are subject to all applicable FSIS labeling regulations, including requirements for mandatory features and recordkeeping. IPP are to reference FSIS Directive 7221.1 <https://www.fsis.usda.gov/policy/fsis-directives/7221.1>, *Prior Labeling Approval*, for additional information on the verification of general labeling requirements.

C. When a cell-cultured meat and poultry food product label does not include LPDS approval for the label, IPP are to document the noncompliance on a Noncompliance Record in the Public Health Information System, citing 9 CFR 412.1 <<https://www.govinfo.gov/content/pkg/cfr-2021-title9-vol2/pdf/cfr-2021-title9-vol2-sec412-1.pdf>> as the relevant reference. All changes to previously approved cell-cultured meat and poultry food product labels will require re-submission for LPDS approval. IPP are to retain any cell-cultured meat or poultry food product bearing a label that requires, but has not received, LPDS approval. The cell-culture establishment may take corrective action by obtaining label approval through LPDS or by replacing the noncompliant labels with labels that have received prior approval and comply with Federal meat and poultry inspection regulations and policies.

D. Final labels that are not in compliance with Federal meat and poultry products inspection regulations may still be granted temporary approval under the conditions listed in 9 CFR 412.1(f) <<https://www.govinfo.gov/content/pkg/cfr-2021-title9-vol2/pdf/cfr-2021-title9-vol2-sec412-1.pdf>>. The final label along with a completed Form 7234-1 <https://www.fsis.usda.gov/sites/default/files/2020-08/fsis_7234-1_approval_of_labels_2.pdf> and all supporting documentation, including support for conformity to the conditions in 9 CFR 412.1(f) <<https://www.govinfo.gov/content/pkg/cfr-2021-title9-vol2/pdf/cfr-2021-title9-vol2-sec412-1.pdf>>, are to be submitted to LPDS for temporary approval. Label submissions may be entered into LSAS or mailed in duplicate to LPDS.

VII. IMPORTS AND EXPORTS

A. IPP are to be aware that foreign countries may not export cell-cultured meat or poultry food products to the United States unless FSIS has determined that they have a regulatory food safety inspection system that is equivalent to that of the United States for the production of cell-cultured meat or poultry food products. When FSIS deems a country to be equivalent for such products, it will list the country as eligible to export “cell-cultured” meat or poultry food products to the United States by species in the FSIS Import Library

<https://www.fsis.usda.gov/inspection/import-export/import-export-library>.

B. Cell-cultured meat and poultry food products are subject to the same FSIS import and export regulations and policies as meat and poultry food products derived from slaughter. IPP are to reference FSIS directives in the 9000 series, which provide official communications and instruction to Agency personnel in carrying out their functions related to the import and export of meat and poultry, and FSIS Directive 13000.5 <https://www.fsis.usda.gov/policy/fsis-directives/13000.5>, *Public Health Information System Export Certification*.

VIII. QUESTIONS

Refer questions regarding this directive to your supervisor and if needed to the Office of Policy and Program Development through askFSIS <<https://www.fsis.usda.gov/contact-us/askfsis>> or by telephone at 1-800-233-3935. When submitting a question, complete the web form <<https://www.fsis.usda.gov/askfsis>> and select the “Labeling” inquiry type for labeling questions, “Import” inquiry type for questions about importing cell-cultured products into the United States, “Export” inquiry type for questions about exporting cell-cultured products from the United States, “Sampling” inquiry type for questions about sampling of cell-cultured products, or “General Inspection Policy” inquiry type for other questions about FSIS inspection of cell-cultured products.

NOTE: Refer to FSIS Directive 5620.1 <<https://www.fsis.usda.gov/policy/fsis-directives/5620.1>>, *Using askFSIS*, for additional information on submitting questions

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