

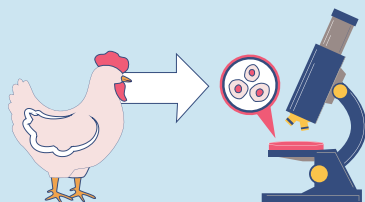
What the FDA Evaluated During the First Completed Pre-Market Consultation

The complex process of taking a small number of live cells from livestock, poultry, seafood, or other animal species and growing them in a controlled environment to create a food can be broadly summarized in a few steps. Below is an example of what we reviewed at each production step during the firm's pre-market consultation:

Firm's Production Steps

What the FDA Reviewed

1



Cell Collection

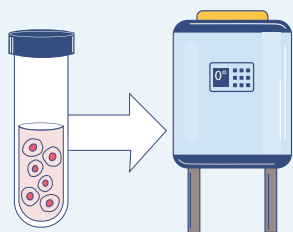
Collected samples of cells once from two different chicken tissues.



How the cells are isolated, including:

- How cells are taken from an animal
- How cells are confirmed to be from the right animal species
- How cell lines are selected
- What measures are taken to ensure the cells are free of contaminants, including microbes or viruses

2



Cell Line and Cell Bank

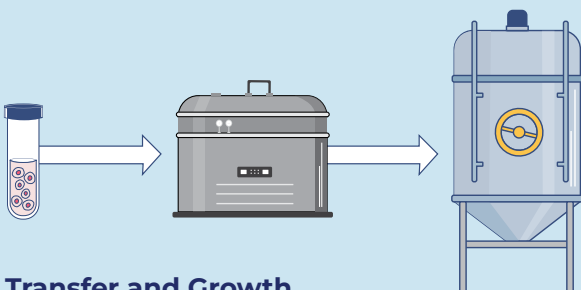
Cells from the sample are screened, adapted to culture conditions, and grown to make a "bank" of cells that are frozen and stored for later use.



How the cell bank is made, including:

- How the cells are adapted to culture and can sustain growth
- The firm's quality control measures for the cell bank, including checking the cell identity, checking for contaminants including microbes and viruses, and measuring cell growth and behavior

3



Transfer and Growth

A small number of cells from the cell bank are placed in tightly controlled environments (sealed vessels) that support growth and multiplication by supplying nutrients and other factors. Cells are transferred to larger vessels over time to reach the amount of material needed for food production.



Substances used in the culture process as the cells multiply and differentiate:

- Nutrients for cells to grow
- Growth factors (substances found in animals that send signals for cells to grow or change)
- Substances that manage properties of the medium such as pH or foaming

4

Differentiation

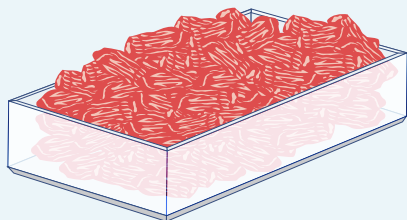
After the cells have multiplied many times over, into billions or trillions of cells, the environment is changed in ways that allow the cells to assume muscle-specific characteristics.



Consideration of potential risk factors in the production process, including:

- The firm's assessment of hazards at each production step
- How the firm plans to apply food safety control measures based on its assessment
- How the firm monitors the growth and health of the cell cultures during production

5



Harvest

Harvest the material to prepare further using conventional food processing and packaging methods.



Product that is harvested for use in conventional food processing, including:

- Identity of the cell material
- Makeup of the cell material
- Potential residues from the culture process
- Specifications for food contaminants such as lead, cadmium, mercury, arsenic, and pathogens

During the harvest process, when the firm begins removing the chicken cells from the sealed vessels, the FDA and USDA coordinate regulatory oversight as jurisdiction transitions to [USDA](https://www.usda.gov). USDA oversees the conventional processing and packaging of the food material, as well as labeling of products made from this material.

The FDA's Ongoing Evaluation

In addition to the voluntary pre-market consultation, the FDA's inspectors have been on site at the firm's facility where cells are cultured, grown, and harvested for an inspection. The FDA intends to conduct another inspection after commercial distribution starts. These inspections will help ensure that potential risks are being managed and that the food exiting the culture process is safe and not adulterated within the meaning of the Federal Food, Drug & Cosmetic Act and the FDA's regulations. Get more information about Human Foods Made with Cultured Animal Cells at <https://www.fda.gov/food/food-ingredients-packaging/food-made-cultured-animal-cells>