USDA/FDA Joint Public Meeting:
The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

Tuesday, October 23, 2018; 8:30 am – 4:00 pm
Wednesday, October 24, 2018; 8:30 am – 3:00 pm

U.S. Department of Agriculture - Jefferson Auditorium in the South Building
1400 Independence Avenue SW
Washington, DC 20250

Docket No. FSIS–2018–0036

AGENDA: Day 1
Oversight, Hazards, and Controls

8:00 AM **Registration**

8:30 AM **Welcome & Housekeeping/Logistics**
Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*
Carmen Rottenberg, *J.D., Acting Deputy Under Secretary for Food Safety, USDA*

8:35 AM **Opening Remarks from USDA and FDA**
Sonny Perdue, *D.V.M., Secretary of Agriculture, USDA*
Scott Gottlieb, *M.D., Commissioner of Food and Drugs, FDA*

8:55 AM **Overview of Cell Culture Technology**
Leah Stitz, *M.S., C.F.S.,* Public *Affairs Specialist, Food and Cosmetic Information Center, Center for Food Safety and Applied Nutrition (CFSAN), FDA*

Session 1: **Current Regulatory Safety Frameworks for Foods and Products of Cell Culture Technology**

9:05 AM **Current USDA Regulatory Safety Frameworks for Foods and Products of Cell Culture Technology**
Philip Bronstein, *Ph.D., Executive Associate of Regulatory Operations, Office of Field Operations, FSIS, USDA*

9:35 AM **Current FDA Regulatory Safety Frameworks for Foods and Products of Cell Culture Technology**
William Jones, *Ph.D., Acting Director, Office of Food Safety, CFSAN, FDA*
Jeremiah Fasano, *Ph.D., Consumer Safety Officer, Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, CFSAN, FDA*
Douglas Stearn, *J.D., Deputy Director for Regulatory Affairs, CFSAN, FDA*

10:05 AM **BREAK**

Session 2: **Potential Hazards for Cell Culture Technology Products Derived from Livestock and Poultry**

10:20 AM **Overview of Potential Hazards Associated with Traditional Meat and Poultry Products**
Emilio Esteban, D.V.M., M.B.A., M.P.V.M., Ph.D., Chief Scientist, Office of Public Health Science, FSIS, USDA

10:50 AM **Overview of Potential Cell Culture Technology Hazards Including Summary of Hazards Discussed at the FDA Science Board Meeting**

Jeremiah Fasano*, Ph.D., Consumer Safety Officer, Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, CFSAN, FDA*

11:05 AM **Open Public Comment on Potential Hazards**

Moderators:

Kari Barrett, *Advisor for Strategic Communications and Public Engagement, Office of Foods and Veterinary Medicine, FDA*

Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

Questions for open public comment:

- What hazards are the same between traditional meat and poultry products and products of cell culture technology, and which hazards are different?
- What are the most significant sources of potential hazards?
- Are there hazards that have not been raised, or are there aspects of the hazards that have not been discussed?

11:50 PM **LUNCH**

Session 3: Strategies to Address Potential Hazards and Provide Appropriate Regulatory Oversight Frameworks for Cell Culture Technology Products Derived from Livestock and Poultry

1:05 PM **Introduction to Strategies to Address Potential Hazards and Appropriate Regulatory Oversight Frameworks**

Philip Bronstein, *Ph.D., Executive Associate of Regulatory Operations Office of Field Operations, FSIS, USDA*

Jenny Scott, *M.S., Senior Advisor, Office of Food Safety, CFSAN*, *FDA*

1:15 PM **Open Public Comment on Addressing Potential Hazards and Providing Appropriate Regulatory Oversight**

Moderators:

Kari Barrett, *Advisor for Strategic Communications and Public Engagement, Office of Foods and Veterinary Medicine, FDA*

Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

Questions for open public comment:

- Is there an effective and efficient application of pre-market programs to ensure the safety of foods produced by animal cell culture?
- What preventive controls and other tools are best suited to managing potential hazards at each stage of production? What type and frequency of inspection will be appropriate for various stages of the manufacture of these products, given the potential hazards and assessed risks at different stages? (Stages include: seed cell procurement and selection, establishment of master cell banks, cell proliferation and passaging, cell differentiation, further processing, and packaging, in addition to culture media and scaffold element production.) Would inspection type, frequency, or other oversight activities beyond those associated with existing food products be appropriate?
- What type and frequency of inspection will be appropriate for products that combine cell cultured food products and other ingredients? Would inspection type, frequency, or other oversight activities beyond those associated with existing food products be appropriate?

- FSIS and FDA are actively working to reduce the duplicative and inefficient regulation of establishments and products under both agencies' jurisdiction. How could this be done for products of animal cell culture derived from livestock and poultry?

2:15 PM **BREAK**

Session 4: Formal Public Comment (Day 1)

2:30 PM **Public Comment Statements**
Moderators:
Kari Barrett, *Advisor for Strategic Communications and Public Engagement, Office of Foods and Veterinary Medicine, FDA*
Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

3:55 PM **Closing Remarks and Day 2 Housekeeping/ Logistics**
Carmen Rottenberg, *J.D., Acting Deputy Under Secretary for Food Safety, USDA*
Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

4:00 PM **ADJOURN**

AGENDA: Day 2
Labeling and Claims

8:00 AM **Registration**

8:30 AM **Welcome & Housekeeping/Logistics**
Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

8:35 AM **Opening Remarks from USDA and FDA**
Paul Kiecker, *Acting Administrator, FSIS, USDA*
Susan Mayne, *Ph.D., F.A.C.E., Director, Center for Food Safety and Applied Nutrition (CFSAN), FDA*

Session 5: Regulatory Frameworks for Food Labeling – Mandatory Elements

8:45 AM **Overview of Regulatory Frameworks for Mandatory Food Labeling Elements**
Douglas Balentine, *Ph.D., Director, Office of Nutrition and Food Labeling, CFSAN, FDA*
Jeffrey Canavan, *Deputy Director, Office of Policy and Program Development, Labeling and Program Delivery Staff, FSIS, USDA*

9:45 AM **Current Landscape for Food Labeling**
Matthew Michael, *Director, Issuances Staff, Office of Policy and Program Development, FSIS, USDA*
Douglas Balentine, *Ph.D., Director, Office of Nutrition and Food Labeling, CFSAN, FDA*

10:05 AM **BREAK**

10:15 AM **Open Public Comment on Mandatory Labeling Elements**

Moderators:
Malcolm Bertoni, M.S., *Associate Commissioner for Planning, FDA*
Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

Questions for open public comment:

- Should standards of identity or criteria for statements of identity be established for these products to ensure that product names are truthful, not misleading, and sufficiently differentiate cell cultured products from traditional products?
- Should the methods by which animal cell cultured products are produced (i.e., the culturing process) be considered required information for purposes of labeling? If so, what factors should be considered in accurately describing the production methods?
- Should the source of the animal cells (i.e., the species from which the cell line was initiated) be considered required information for the purposes of labeling?
- How should products containing both animal cell cultured products and traditional meat and poultry products be labeled?

11:15 AM **LUNCH**

Session 6: Regulatory Frameworks for Food Labeling- Claims

12:30 PM **Overview of Regulatory Frameworks for Claims**

Jeffrey Canavan, *Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, FSIS, USDA*
Douglas Balentine, *Ph.D., Director, Office of Nutrition and Food Labeling, CFSAN, FDA*

1:00 PM **Open Public Comment on Potential Claims**

Moderators:
Malcolm Bertoni, *M.S., Associate Commissioner for Planning, FDA*
Selena Kremer, *Ph.D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

Questions for open public comment:

- What factors should be considered in potentially allowing health, safety, and other claims in the marketing of animal cell cultured products?

Session 7: Formal Public Comment (Day 2)

1:30 PM **Public Comment Statements**

Moderators:
Kari Barrett, *Advisor for Strategic Communications and Public Engagement, Office of Foods and Veterinary Medicine, FDA*
Selena Kremer, *Ph. D., Team Lead, Congressional and Public Affairs, FSIS, USDA*

2:55 PM **Closing Remarks**

Paul Kiecker, *Acting Administrator, FSIS, USDA*

3:00 PM **Adjourn**