



December 2, 2021

Submitted electronically via regulations.gov

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Mailstop 3758, Room 6065
Washington, DC 20250-3700

Re: FMI Comments on the Food Safety and Inspection Service Advance Notice of Proposed Rulemaking on Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells; Docket No. FSIS-2020-0036

Dear Sir or Madam:

FMI appreciates the opportunity to provide comments on the Food Safety and Inspection Service's (FSIS or "the Agency") Advanced Notice of Proposed Rulemaking on Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells (ANPR).¹ FMI applauds FSIS for engaging in the ANPR process to ensure a deliberate, evidence-based approach to labeling meat and poultry products comprised of or containing cultured cells derived from animals ("cell-cultured meat and poultry products").

As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at www.FMI.org.

¹ 86 Fed. Reg. 49491 (Sept. 3, 2021), Advance Notice of Proposed Rulemaking on Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells; Docket No. FSIS-2020-0036, hereinafter "ANPR."



FMI Supports A Deliberate Approach to Product Labeling

FMI supports taking a deliberate, evidence-based approach to labeling cell-cultured meat and poultry products. As this new category matures, all stakeholders will benefit from a clear and fair set of product labeling expectations. FMI encourages FSIS to engage in a transparent, evidence-based process that engages all stakeholders. As FSIS develops a labeling policy for cell-cultured meat and poultry products, FMI offers several recommendations.

- Any labeling framework ultimately developed should promote transparency, build consumer confidence, and provide an even playing field for all market participants.
- FMI encourages FSIS to develop a labeling framework that is rooted in and builds on FSIS's existing regulatory framework and policies. Fundamentally, labeling must be truthful and not misleading. FSIS has experience with ensuring that products are labeled in a way that is meaningful to consumers, that clearly delineates between products, and that protect established consumer expectations. We encourage FSIS to draw on that experience.
- In evaluating whether and how cell-cultured meat and poultry products should be differentiated from traditional meat and poultry products, we encourage FSIS to consider key factors such as consumer expectations for the sourcing, content, or method of production for the product; nutritional qualities or characteristics; safety profiles; product performance or organoleptic attributes; product ingredients or components; the production method; and other relevant characteristics. We encourage FSIS to conduct or consider consumer research in evaluating these criteria.
- To the extent that FSIS determines that cell-cultured meat and poultry products should be differentiated from traditional products through labeling, we encourage FSIS to consider or conduct research into what terms most clearly and appropriately convey the differences to consumers. FMI believes that labeling should be clear, simple, not misleading, and non-disparaging (both to the labeled products and other products in the marketplace).



- Labeling requirements and policies should be consistent, well publicized, and applied in a manner that is fair to all market participants. Clear, fair rules and policies provide an even playing field while also providing the regulatory clarity needed to foster innovation. Importantly, FMI encourages FSIS to ensure that any labeling requirements are sufficiently flexible to facilitate continued product innovation while still protecting consumer expectations.
- We encourage FSIS to evaluate what type of product claims are likely to appear on the labels of cell-cultured meat or poultry products and to develop clear policies around those claims and to continue closely monitoring the marketplace to provide further guidance as this product category matures.
- FSIS should consider the entire value chain—including point of sale materials at retail stores and menus or menu boards at restaurants—when developing labeling policies and providing labeling guidance. Even though retail establishments and restaurants are not regulated as official establishments, FSIS’s labeling policies will be informative for these channels.
- FMI appreciates FSIS providing clarity around its expectations for label approval for cell-cultured meat and poultry products, including FSIS’s preparing for the possibility that cell-cultured meat or poultry products might come onto the market before FSIS is able to complete rulemaking around product labeling. FMI believes that FSIS’s label review program is capable of ensuring that such products are labeled in a truthful and non-misleading manner. Should labels begin to be submitted for sketch approval, FMI encourages FSIS to monitor applications carefully to identify areas where further guidance may be needed and to ensure any policies adopted are well publicized to enable clarity and consistency for all market participants.
- FMI urges the Agency to consider all existing regulatory frameworks, such as Country of Origin Labeling, coordinating with its sister agencies to determine how these should be applied to cell-cultured products in a manner that is consistent and fair to products from both traditional and cell-cultured sources.
- FMI encourages FSIS to take a similarly proactive approach in addressing inspectional oversight for the manufacturing of cell-cultured meat and poultry products. FMI agrees that HACCP concepts likely are sufficiently flexible to



address the unique production steps involved in producing these products, but we recommend that FSIS develop industry guidance to help establishments understand FSIS's expectations around manufacturing safety and oversight. We also encourage FSIS to collaborate with the Food and Drug Administration to provide clear guidance around how the agencies plan to coordinate and transition their jurisdiction over cell-cultured meat and poultry products.

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FMI supports FSIS's consideration of labeling regulations for cell-cultured meat and poultry products, and we encourage FSIS to continue efforts to engage with industry as it moves forward.

Should you have questions about these comments, please feel free to contact us.

Sincerely,



Stephanie Harris
Chief Regulatory Officer & General Counsel



Dana Graber
Senior Counsel, Legal and Regulatory Affairs

