

October 19, 2020

Dr. Mindy Brashears, Under Secretary for Food Safety
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Dear Dr. Brashears,

As organizations representing leading conventional and cell-based/cultured meat, poultry, and seafood companies, the Alliance for Meat, Poultry and Seafood Innovation (AMPS Innovation) and the North American Meat Institute (NAMI) write to express our support for a labeling framework that fosters transparency, consumer confidence, and a level-playing field while also aligning with longstanding law and policy.

As demand for meat, poultry, and seafood increases, the need for nutritious protein, increased productivity, and a more diversified supply chain will soon be greater than ever before. Meeting these needs will require innovative solutions and a clear, science-based regulatory system that supports new approaches to food production and enables greater consumer choice. One solution is animal cell-based/cultured technology, which allows innovators to produce additional meat, poultry, and seafood options for consumers, complementing an array of conventional products already on the market.

Although these products have not yet come to market in the United States, market entry is fast approaching, and there is significant interest in the regulation of these products, particularly regarding applicable labeling requirements. The companies developing these products are committed to supporting and complying with principles that ensure labeling is truthful and not misleading, does not disparage cell-based/cultured or conventional products, enables consumers to distinguish between such products, and is consistent with the safety and nutritional qualities of the product.¹

We understand that the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) intends to propose regulations on the labeling of cell-based/cultured meat and poultry products, and coordinate with the U.S. Food and Drug Administration (FDA) on joint principles on product labeling and claims. In addition, FDA recently issued a Request for Information on the "labeling of foods comprised of or containing" cell-based/cultured seafood, in which FDA notes that it intends to use the information and data resulting from the request "to determine what type(s) of action, if any, [it] should take to ensure that these foods are labeled properly."² We write to express our support for these important regulatory processes, and to respectfully urge FSIS to solicit the data needed to propose and ultimately establish an appropriate mandatory labeling requirement for cell-based/cultured meat and poultry products.

¹ And as with all foods, labels for cell-based/cultured products, such as seafood products, must disclose the presence of any major food allergens.

² FDA, Notice; Request for Information, *Labeling of Foods Comprised of or Containing Cultured Seafood Cells*, 85 Fed. Reg. 63277 (Oct. 7, 2020).

Historically, in evaluating the labeling of food products developed using new methods or technologies, FSIS and FDA have focused on characteristics of the finished product rather than the process by which the food was made. Where the resulting product's characteristics are substantially different from those of conventional products, FSIS and FDA have required labeling to inform consumers of such material finished product differences. For cell-based/cultured products, there are several approaches to producing these products and, depending on the approach, the characteristics of some products may vary from those of conventional products, as noted by the agencies.³ Moreover, the agencies have stated that "many of these products' characteristics will need to be reflected through the labeling of these products, which may require careful evaluation and iterative, data-driven dialogue with industry."⁴

Given this need for further data, AMPS Innovation and NAMI recommend that FSIS first issue an Advance Notice of Proposed Rulemaking (ANPR) to obtain more information and supporting data on finished product characteristics for cell-based/cultured meat and poultry products, particularly those that may require labeling. This information will provide FSIS with substantive data needed to better inform the agency's decision-making process, while also ensuring that the current labeling standards remain high. Indeed, FSIS has issued ANPRs to obtain specific data and information from industry, consumers, and other stakeholders, particularly when evaluating food labeling standards that could affect an entire category of products.⁵ The labeling of cell-based/cultured products is no different. FSIS has indicated that careful consideration of additional information relating to product characteristics is needed to inform labeling decisions for such products, and any proposed labeling standards would have industry-wide effects.

We recognize that rulemaking can be time consuming. It is possible and likely that cell-based/cultured meat and poultry products may be ready to come to market before FSIS's rulemaking process concludes. For such FSIS-regulated products, we understand that the products will be subject to FSIS prior label review and claims must be adequately substantiated.

We genuinely appreciate the speed at which FSIS and FDA have moved and we hope this pace will continue as the process moves forward. We commend FSIS and FDA for their continued leadership and encourage both agencies to continue to work in close coordination to ensure consistency in labeling across the industry. In just two years, the agencies have engaged stakeholders and taken important steps to establish a clear, predictable, and timely approach to overseeing the production of these products within the existing regulatory frameworks for meat, poultry, and seafood. In doing so, the agencies have affirmed yet again our nation's role as the world leader in protein production and responsible, science-based food innovation. As other countries look to develop principles and standards for cell-based/cultured meat, poultry and seafood products, it is critical that the U.S. government maintain its leadership role.

³ Matthew Michael & Jeremiah Fasano, Ph.D., *Animal Cell-Culture Food Technology: A New Regulatory Frontier*, Food Safety Magazine (Feb/Mar. 2020).

⁴ *Id.*

⁵ See, e.g., FSIS, ANPR, *Meat and Poultry Standards of Identity and Composition*, 61 Fed. Reg. 47453 (Sept. 9, 1996); FSIS, ANPR, *Food Labeling: Use of the Voluntary Claim "Natural" in the Labeling of Meat and Poultry Products*, 74 Fed. Reg. 46951, 46956 (Sept. 14, 2009).

We look forward to continued collaboration as FSIS and FDA clarify the final details of the regulatory framework that will govern cell-based/cultured products.

Please contact us with questions.

Sincerely,

The Alliance for Meat, Poultry and Seafood Innovation
The North American Meat Institute

CC:

Susan Mayne, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration

Paul Kiecker, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture

Jeremiah Fasano, Senior Policy Advisor, Division of Science and Technology, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration

Matthew Michael, Director, Regulations Development Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture