



December 26, 2018

Docket No. FSIS-2018-0036

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: Docket No. FSIS-2018-0036; Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived From Livestock and Poultry; Request for Comments

The Food Law and Policy Clinic (FLPC) and the Animal Law and Policy Program (ALPP) at Harvard Law School thank the FDA and USDA for the opportunity to submit these comments regarding the regulation of cell-based meat. We applaud the agencies' leadership in initiating public discussion of this important issue and encourage the agencies to develop a clear regulatory pathway that uses existing statutory and regulatory frameworks, ensures consistent and clear labeling of cell-based products, and does not include the issuance of new standards of identity or other labeling regulations.

FLPC serves partner organizations and communities by providing guidance on cutting-edge food system issues. Specifically, FLPC focuses on increasing access to healthy foods, supporting sustainable production and regional food systems, and reducing waste of healthy, wholesome food. ALPP engages with academics, students, practitioners, and decision-makers to foster discourse, facilitate research, develop strategic solutions, and build innovative bridges between theory and practice in the rapidly evolving area of animal law and policy.

As academic programs that study food system impacts on humans, animals, and the environment, FLPC and ALPP recognize the potential of cell-based foods to address a number of food system challenges. At the same time, we understand the necessity of robust regulation of these innovative products to ensure their safety and to provide clear labeling to consumers. FLPC and ALPP commend FDA and USDA for their attention to the developing field of cell-based food products and appreciate the agencies' efforts toward developing a joint regulatory pathway for these foods. The Public Meeting on Foods Produced Using Animal Cell Culture Technology on July 12, 2018 and the Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry on October 23–24, 2018 were laudable first steps, and FLPC and ALPP applaud the agencies' November 16, 2018 statement concluding that FDA and USDA should jointly regulate the production of cell-based meat and poultry products.

A joint oversight scheme with a clear procedural pathway will increase regulatory efficiency and provide clarity to American producers. FDA and USDA already have sufficient authority under existing statutes to regulate cell-based meat and poultry products. Continued collaboration between the agencies will ensure food safety and consistency in the labeling of all cell-based food products, while assuring consumer confidence and promoting innovation.

I. A Joint Regulatory Scheme and Clear Regulatory Pathway Will Increase Efficiency, Ensure Safety and Consumer Confidence, and Provide Clarity to American Producers

The commitment of FDA and USDA to a joint regulatory pathway for cell-based meat and poultry products will reduce inefficiencies and duplicative regulation, while ensuring safety and consumer confidence in these products. As the agencies acknowledged in their November 16, 2018 statement, FDA and USDA have sufficient authority under existing statutes to regulate these new products and technologies as they emerge.¹ On the basis of this ample authority, the two agencies should continue to develop the regulatory pathway they outlined in the statement, with FDA overseeing the cell culturing process and USDA regulating the further processing and labeling of cell-based meat and poultry.

Joint regulation is critical for ensuring the safety of cell-based meat and poultry products. FDA has jurisdiction over “food,” which includes “articles used for food” and “articles used for components of any such article.”² Thus, as acknowledged in the joint statement, FDA has the authority under the Food, Drug, and Cosmetic Act (FDCA), as amended by the FDA Food Safety Modernization Act (FSMA), and the Public Health Service (PHS) Act to regulate the process of collecting, banking, growing, and differentiating cells prior to harvesting. FDA should exercise this authority and leverage its expertise regulating analogous cell-cultured and fermented food products (e.g. yogurt, yeast, algal oils, cheese, rennet, beer), foods produced using biotechnology (e.g. new plant varieties), and medical products developed using cell substrates (e.g., vaccines). Leveraging this regulatory experience will help ensure the safety of the cell culturing process for cell-based meat, poultry, and seafood products, which relies upon similar source materials, ingredients, and processes as food and medical products currently on the market.

Once cells reach the harvest stage, FSIS should regulate and inspect the processing of cell-based meat and poultry products, and FDA should continue to regulate and inspect the processing of cell-based seafood products, pursuant to the agencies’ respective authorities. Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), and the agency’s implementing regulations for Hazard Analysis and Critical Control Point (HACCP) Systems (9 C.F.R. 417) and Grant of Inspection (9 C.F.R. 304 and 381), FSIS has sufficient authority to

¹ Statutes that are applicable to the regulation of cell-based meat include the Federal Meat Inspection Act; Poultry Products Inspection Act; and Federal Food, Drug, and Cosmetic Act (as amended by FDA Food Safety Modernization Act).

² 21 U.S.C. §321(f).

regulate and expertise to inspect cell-based meat and poultry (and catfish) processing facilities. As stated in the October Joint Public Meeting, two-thirds of the plants FSIS currently inspects are processing-only facilities, not slaughterhouses (4,287 of 6,433 establishments).³ Under the FDCA, as amended by FSMA, and FDA’s regulations for seafood HACCP (21 C.F.R. 123) and Current Good Manufacturing Practice (21 C.F.R. 117), Subpart B, FDA has adequate authority and expertise to regulate and inspect cell-based seafood processing facilities. Existing regulations are sufficient to ensure “a safe and wholesome product” for cell-based meats, poultry and seafood through the implementation of HACCP plans, and procedures for verification, monitoring, corrective actions, recall, and sanitation. Regulators from both agencies should collaborate with industry to identify potential hazards and clarify control and inspection procedures, following the standard industry process in which companies identify relevant hazards and lay out processes for controlling for them.⁴ Ongoing coordination with the industry is particularly important for the cell-based food industry because it will enable the industry to innovate while ensuring food safety as the technologies and methods used to develop these products emerge and evolve.

Joint regulation of cell-based meat and poultry products also will increase consumer confidence in the new products as they come to market. Consumers trust FDA’s oversight of innovative food products (as evidenced by the ubiquity of synthetic rennet and products produced by fermentation, such as baker’s yeast), and they look for the USDA inspection mark on meat and poultry products. Holding cell-based meat companies to the same regulatory and inspection standards as conventional producers will increase food safety, ensure consumer confidence, assure consistent application of regulatory authorities, and enable cell-based food companies to utilize and benefit from the USDA inspection mark on their products.

A joint regulatory pathway further will provide clarity to American companies producing cell-based meat and poultry products. Announcing a firm and clear regulatory pathway to the industry should ensure that the pace of innovation is not unnecessarily delayed by regulatory uncertainty and Congressional intervention. As both Secretary Perdue and Commission Gottlieb have rightly noted, the industry needs “bright line rules.”⁵ Both FDA and USDA can further their mission of feeding the world by embracing new technologies and techniques to produce food more efficiently and more sustainably. By creating a straightforward, single-entry regulatory pathway for emerging cell-based companies to bring their products to market, FDA and USDA will be doing precisely that—enabling the production of animal protein with fewer resources, which could help feed the planet’s growing population while preserving global resources.

³ USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry (October 23–24, 2018).

⁴ FDA, HACCP Principles & Application Guidelines (Aug. 14, 1997), *available at* <https://www.fda.gov/Food/GuidanceRegulation/HACCP/default.htm>.

⁵ Opening remarks, USDA Secretary Perdue, USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry (October 23–24, 2018); FDA Commissioner Gottlieb, Science Board to the FDA Meeting (October 22, 2018).

This regulatory scheme should not be unnecessarily arduous or restrictive that it hinders innovation, burdens producers, or incentivizes companies to seek less restrictive markets abroad. The United States currently is the global leader in the development of these products, and the cell-based meat industry, as it grows, will create new jobs, drive economic growth, and further strengthen our nation's position as a global leader in technology and innovation. Without a clear regulatory pathway, or with an overly burdensome one, the United States is likely to lose out on a major share of this industry, as producers may seek out markets with existing or more favorable regulatory pathways. This is not an imagined concern; at least one cell-based meat company is already moving away from the American market. One of the leading companies innovating in this technology, JUST, Inc., recently announced that it will be launching its first cell-based chicken product abroad, citing the current absence of a regulatory approval pathway in the United States.⁶ Additionally, a number of other cell-based meat companies already have been approached by foreign governments with incentives to move their companies abroad, including to Singapore and India.⁷ Thus, finalizing a clear and not overly restrictive regulatory pathway for these products in the near future is key to maintaining American leadership in innovation and economic growth.

II. Cell-Based Meats Should Be Labeled in a Way That Is Consistent, Does Not Limit Companies' Innovation, and Is Not Misleading to Consumers

FDA and USDA should collaborate to ensure that labeling of cell-based products is consistent across all types of products (including fish and seafood, as well as meat and poultry). This labeling should not impose unnecessary requirements, and not require the issuance of new standards of identity or other labeling regulations. While the agencies' joint statement acknowledged that USDA will take primary responsibility for the regulation of labeling of meat and poultry products, FDA will retain jurisdiction over other cell-based products, such as fish and other seafood. As with the product safety aspects outline above, the agencies should collaborate when developing guidelines and clarifying labeling requirements, so that product labels are consistent across all cell-based products that may eventually come to market.

FSIS should exercise its experience and authority regulating labeling for meat and poultry products to ensure that labels for cell-based meat and poultry products are accurate, clear, and do not mislead consumers.⁸ This should be done in the same manner FSIS pre-approves labels for any other meat or poultry product. FDA should exercise its experience and authority to regulate the labeling of cell-based fish and seafood products, similarly ensuring that labels are accurate, clear

⁶ Elaine Watson, JUST Gears Up for Late 2018 Cell-Based Meat Launch, FoodNavigator-USA (Sept. 13, 2018), available at <https://www.foodnavigator-usa.com/Article/2018/09/13/JUST-gears-up-for-late-2018-cell-based-meat-launch-but-says-more-meaningful-quantities-are-2-3-years-out>.

⁷ Public Comment, Finless Foods, USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry (October 23–24, 2018).

⁸ FSIS has the authority to pre-approve labels of meat and poultry products under the FMIA and PPIA.

and not misleading to consumers. The labeling of cell-based products should be standardized across products regulated by FDA and USDA to reduce confusion among businesses, consumers, and other stakeholders. The labels for all cell-based products also should include the source of the cells used (e.g., cattle, chicken, bluefin tuna) to account for health considerations like allergies.

The regulatory pathway should not include issuing new standards of identity for cell-based products. Because these products already fit within existing regulations, requiring new regulations would be duplicative and unnecessarily delay these products reaching the market. Cell-based meat and poultry products vary in the same way that “traditionally produced” meat and poultry products do, and they have the same or very similar nutritional content and composition. Therefore, cell-based meat and poultry products will fit under existing naming conventions and product identification schemes. Under the FMIA, “meat food product” is defined as “any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats.”⁹ Cell-based meats are meat because they are structurally and nutritionally identical or substantially similar to meat, and they are produced using animal cells extracted from the body of an animal, such as cattle.¹⁰ The agencies already have recognized this by agreeing that the USDA has joint jurisdiction over cell-based meat products. Cell-based sausage, for example, fits the existing standard of identity for sausage because it is “the coarse or finely comminuted meat food product prepared from one or more kinds of meat or meat and meat byproducts, containing various amounts of water as provided for elsewhere in this part, and usually seasoned with condimented proportions of condimental substances, and frequently cured.”¹¹ The same applies to dozens of other standards of identities the USDA has defined for meat and poultry products.¹²

Moreover, using these existing schemes will be critically important for accurately communicating the content of the products, especially to consumers who may have medical conditions such as allergies. Issuing new standards of identity, alternatively, would be burdensome and inefficient. It is a lengthy process, and it would be especially so for cell-based products given the still-emerging nature of the technology. Moreover, such standards may lock producers in to a certain form of production based on today’s technology, even though this technology is likely to continue to evolve and advance over the coming years. This could hinder innovation and create an unnecessary drain on energy resources, money, and time in contravention of the agencies’ commitments to efficiency. Labels on cell-based products should thus be clear to consumers and not unduly burdensome to producers. This will preserve American leadership in the field and avoid unnecessary government expenditures.

⁹ 21 U.S.C. § 601.

¹⁰ Stephens et al., *Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture*, 78 *TRENDS IN FOOD SCI. & TECH.* 155 (2018).

¹¹ 9 C.F.R. § 319.140.

¹² *See, e.g.*, 9 C.F.R. § 319.15 et seq.; 9 C.F.R. § 381, Subpart P.

III. Conclusion

In conclusion, Harvard Law School's FLPC and ALPP applaud FDA and USDA for announcing that they will jointly regulate cell-based meat and poultry products. We encourage the agencies to develop a clear regulatory pathway that uses existing statutory and regulatory frameworks, ensures consistent and clear labeling of cell-based products, and does not include the issuance of new standards of identity or other labeling regulations.

Thank you for your consideration.

Sincerely,

Harvard Law School Food Law and Policy Clinic
Harvard Law School Animal Law & Policy Program
