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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, D.C. 20250-3700

Re: Use of Cellular Agriculture to Manufacture Products Derived from Livestock and Poultry Stem Cells; Docket No. FSIS-2018-0036 (November 26, 2018)

Dear Sir or Madam:

The National Chicken Council (NCC) appreciates the opportunity to provide comments on the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) Request for Public Comments on the Use of Cellular Agriculture to Manufacture Products Derived from Livestock and Poultry Stem Cells.¹ NCC represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States.

NCC appreciates USDA's and FDA's holding of a critically-important and timely joint public meeting on October 23-24, 2018, to engage industry stakeholders. Coupled with the efficiency of traditionally-derived meat and poultry production, the ongoing development of cell-cultured meat products² is evidence that U.S. food production companies are, as Secretary of Agriculture Sonny Perdue recently stated, continuing to feed people efficiently and effectively. As technological advances and consumer interest spur development of these products, it is critical that these products receive fair and proper regulatory oversight to ensure that American consumers can have the same level of confidence in the safety and labeling of these products as they do for traditionally-derived meat and poultry products.

To that end, NCC appreciates USDA's Food Safety and Inspection Service's (FSIS's) and FDA's joint statement on November 16, 2018, announcing the agreement of the two bodies on a joint regulatory framework for cell-cultured meat products. As the agencies work to refine the details of the framework, we submit these comments to emphasize the importance of coordinating regulatory efforts between FDA and FSIS to leverage each agency's knowledge and expertise. Similar to the regulation of meat and

¹ 83 Fed. Reg. 46476 (September 13, 2018)

² In using this terminology for purposes of discussion, NCC is not intending these comments to suggest a particular statement of identity or product name for these products.

poultry products derived using traditional animal production and harvest practices, the two agencies should work in collaboration to ensure the safety and appropriate regulatory oversight of cell-cultured meat products.

FSIS has the statutory authority, relevant experience, and robust regulatory frameworks for overseeing the production of a wide variety of products made using meat or poultry tissues and products represented as being of the meat or poultry industry. Through modern Hazard Analysis and Critical Control Point (HACCP) frameworks, FSIS's food safety regulatory framework is flexible enough to oversee production processes ranging from slaughter operations to extraction processes and everything in between. Moreover, FSIS has a detailed and well-developed framework for overseeing the labeling of traditionally-derived meat and poultry products, including claims about product characteristics and methods of production. These frameworks can easily be applied to cell-cultured meat products.

It is essential for protecting consumer safety and meeting customer expectations that cell-cultured meat products be regulated consistently with traditionally-derived meat and poultry products. Cell-cultured meat products will be marketed to consumers as or as near-identical substitutes for traditionally-derived meat and poultry products. It is therefore critical that consumers have the same level of confidence in the safety and labeling for these products as they do for traditionally-derived meat or poultry products.

FSIS is uniquely equipped to provide this consistency. FSIS inspectors are on-site daily to oversee processing operations. Official establishments must meet rigorous sanitation standards and have comprehensive HACCP plans. Meat and poultry products are held to various performance standards depending on the type of product. FSIS likewise has established detailed labeling regulations and policies to protect consumer expectations, clearly disclose the process by which the products were made, and ensure a level regulatory playing field. FSIS reviews and approves complex labels and special statements or claims to ensure they are truthful and not misleading. Traditionally-derived meat and poultry products have been held to the rigorous standards of FSIS inspection and oversight for decades. Cell-cultured meat products should be held to the same bar.

While FSIS has the statutory authority, relevant experience, and robust regulatory frameworks to regulate the labeling and safety of these products, FDA also may have appropriate expertise to fill a role within a comprehensive regulatory framework. NCC recognizes that FDA has long played a role in ensuring that ingredients used in meat and poultry products are safe for use in food through FDA's authority over food additive safety. Additionally, NCC recognizes that FDA has experience with similar food production technologies, such as microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients. This may lend itself to FDA addressing the technical safety of the cell-culturing technology used to create cell-cultured meat products and to determine whether the results of this technology are or are not approved food additives. It may be appropriate that shared regulatory jurisdiction draw on both FDA's and FSIS's respective expertise.

NCC believes that the same framework through which the federal government has ensured that traditionally-derived meat and poultry products are safe, wholesome, and accurately labeled can readily ensure that cell-cultured meat products are safe and truthfully labeled. Ultimately, NCC believes that

the following four core tenants are essential for ensuring that cell-cultured meat products are marketed in a safe, orderly, and truthful manner for consumers:

- The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) should regulate the labeling and safety of these products.
- It is not appropriate to refer to these products using terms such as "clean meat," nor should these products be named or described in a way that disparages conventional animal proteins.
- These products should be named or labeled in a manner that clearly discloses the process by which they are made.
- Claims that these products are superior to conventional animal proteins should be prohibited unless such a claim is substantiated by scientific evidence.

The National Chicken Council appreciates the opportunity to provide comment on the regulation of foods produced using animal cell-culture technology. Please feel free to contact us with any questions regarding the above comments. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ashley B. Peterson". The signature is written in a cursive, flowing style.

Ashley B. Peterson, Ph.D.
Senior Vice President, Scientific and Regulatory Affairs
National Chicken Council