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

Mr. Paul Kiecker Administrator Food Safety and Inspection Service 1400 Independence Ave SW Washington, DC 20250-3700

Re: Docket No. FSIS-2020-0026: Labeling of Meat or Poultry Products Compromised of or Containing Cultured Animal Cells

Dear Mr. Kiecker:

The National Chicken Council (NCC) appreciates the opportunity to provide comments on the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS or the Agency) Advanced Notice of Proposed Rulemaking on Labeling of Meat or Poultry Products Compromised of or Containing Cultured Animal Cells. NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States.

1. National Chicken Council's Policy Regarding Cell-Cultured Meat and Poultry Products

NCC believes cell-cultured products must be marketed in an appropriate manner that clearly conveys their basic nature to consumers and avoids confusion between cell-cultured protein products and traditional animal protein products. This approach ensures a neutral playing field wherein consumers are provided truthful information about cell-cultured products so that they may make choices as they deem most appropriate. In particular, NCC's position toward cell-cultured products is as follows:

1. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) should regulate the labeling and safety of cell-cultured products;

- 2. The Food and Drug Administration (FDA) should regulate the technical safety of the cell-culturing technology used to create these products and determine whether the results of this technology are or are not approved food additives:
- 3. It is not appropriate to refer to cell-cultured products using terms such as "clean meat," nor should these products be named or described in a way that disparages conventional animal proteins;
- 4. Cell-cultured products should be named or labeled in a manner that clearly discloses the process by which they were made; and
- 5. Claims that cell-cultured products are superior to conventional animal proteins should be prohibited unless such a claim is substantiated by scientific evidence.

2. FSIS Should Establish a Codified Standard of Identity for These Products

As it relates to the Federal Meat Inspection Act (21 USC 601 et seq.) and Poultry Product Inspection Act (21 USC 451 et seq.) requirements, meat and poultry product labels must be truthful, not misleading, and approved by USDA. Having a clearly defined standard of identity for cell-cultured products would aid in the label approval process, clearly identify the requirements that products derived from cell-culture or include cell-cultured products as an ingredient must meet, reinforce an even playing field, and protect consumer expectations.

3. A Term Such As "Cell-Cultured" Should be Included in the Product Name

To ensure these products are accurately labeled and correctly identified by consumers, these products should be named or labeled in a manner that clearly discloses the process by which they were made. The product name should include the term "cell-cultured" or something similar so that it is clear that these products are not derived from traditional animal protein (skeletal muscle). This approach would be consistent with FSIS's established requirement that product produced through mechanical separation be labeled as "Mechanically Separated (Species/Kind)." Just as FSIS determined that it was important for consumers to understand that mechanical separation was used to produce that product, FSIS should protect existing consumer expectations by requiring that cell-cultured products be clearly identified as such.

Further, a term such as "cell-cultured" should also appear in the ingredient statement or any other reference to the product on the label. This labeling requirement should not only apply to single ingredient meat or poultry products but also for labels on further processed products that use cell-cultured products as ingredients. For example, while a traditional chicken and noodle soup would be labeled "chicken and noodle soup," a soup that contains cell-cultured chicken should be labeled "cell-cultured chicken and noodle soup."

4. "Cell-Cultured" Products Should not be Allowed to use Defined Parts Terms

Both products derived from cell culture as well as products containing cell-cultured material should not be allowed to use commonly defined parts terms such as breast, leg, wing, thigh, etc. These parts terms are specific to broiler chickens (and other poultry) and consumers know the meaning of these terms as referring to specific parts of the bird cut from a whole carcass.

Importantly, consumers recognize parts terms and link terms such as "wing" to "chicken." In other words, consumers understand that wings are bone-in pieces cut from the carcass of a chicken. NCC believes that it would be misleading to consumers to use the term "wing" (or other parts terms) on a product derived from cell-culture or containing cell-cultured product as they do not come from a "chicken." per se. Though these products are derived from a chicken cell, they do not originate from a

¹ 9 C.F.R. §§ 319.5 (meat), 381.173 (poultry).

live chicken and were not cut from a whole carcass. Calling them a commonly used parts term would not be truthful and would be misleading.

5. FSIS Should Require Full Sketch Approval At least Until FSIS Finalizes Applicable Regulations

To adhere to FSIS regulations, all labels used on meat and poultry products must be approved by FSIS before they can be used in commerce. Sketch-approved labels undergo a formal label application submission, evaluation, and approval process. For products derived from cell-culture or containing cellcultured products, these labels must be required to use the full sketch approval process to ensure the accuracy of the label. Cell-cultured products are novel, and neither the Agency nor industry has experience with the types of claims or information that might appear on cell-cultured meat or poultry product labels. We anticipate that significant Agency guidance will be required and that it will take a significant amount of time for the industry, especially companies without prior experience with FSIS's policies, to become familiar with claims requirements. Because companies are unlikely to be able to readily apply Agency policy to labels for these products, we do not believe it would be appropriate for FSIS to extend generic approval to labels for cell-cultured products at the outset. Cell-cultured products are simply too new, and consumers too unfamiliar with them, for there to be confidence that generically approved labels will adequately protect consumer expectations. Rather, we recommend that FSIS require these labels be submitted for sketch approval until (1) FSIS publishes regulations defining standards for cell-cultured products, (2) FSIS has gained sufficient experience with labels for these products and has published any necessary policy guidance to inform industry, and (3) FSIS through its experience conducting sketch approval concludes that applicants are able to correctly apply labeling regulations and policies to cell-cultured products.

6. FSIS Should Work with Regulatory Partners to Ensure that Retailers and Restaurants also Use Appropriate Terminology when Referring to these Products

It is important that these products be labeled in a truthful and non-misleading manner both on product labels and at the point of sale. Consumer expectations will be best protected if consumers see product names and claims presented consistently regardless of the context in which the consumer sees the product. We encourage FSIS to work with state and federal regulatory partners to ensure that FSIS policy is applied and respected at all points of interaction with these products.

Moreover, the regulatory community has a rare opportunity to ensure that cell-cultured and other alternative protein products are brought to market in a clear and consistent manner. Doing so is critical to protecting existing consumer expectations, helping consumers understand the nature of these alternative protein products, and ensuring that all market participants are competing on a level playing field. FSIS's label approval process provides one important tool, but we urge FSIS to work with other federal and state regulatory partners to ensure that all alternative protein products in the marketplace, regardless of the channel of commerce, are properly named and accompanied by appropriate claims. Achieving this goal will require articulating clear policy and, when necessary, taking clear and consistent enforcement against products that are presented to consumers in a false or misleading manner.

7. Consumer Research Would be a Valuable Tool to Understand how Consumers View these Products

NCC believes that consume research would be valuable in understanding how consumers view these products, their labels, and their identity. Such information would aid the Agency in the rulemaking process and help with defining a standard identity for these products.

Conclusion

NCC appreciates the opportunity to provide comment on the Advanced Notice of Public Rulemaking. NCC looks forward to reviewing and commenting on a proposed rule related to labeling of these products in the future, as well as any policies that FSIS may develop. Please feel free to contact us with any questions regarding the above comments. Thank you for your consideration.

Respectfully submitted,

Ashley B. Peterson, Ph.D.

Senior Vice President, Scientific and Regulatory Affairs

National Chicken Council