August 23, 2018

President Donald J. Trump
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

Memphis Meats and the North American Meat Institute respectfully request that your Administration clarify the regulatory framework for cell-based meat and poultry products, based on the existing comprehensive system that ensures U.S. consumers enjoy the safest and most affordable food in the world.

Existing law and practice, as well as longstanding precedent, demonstrate that both the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have roles to play in regulating cell-based meat and poultry products. To ensure the regulatory system protects consumers while fostering innovation, it is imperative that the agencies coordinate and collaborate in their efforts, consistent with established policy.[1]

As leaders and partners in meeting the world's protein needs, we know that large-scale production methods, small-scale farming, and cell-based meat and poultry production methods will all play a role. Cell-based meat products are meat produced from animal cells in cell culture. They are an "and," not an "or," solution, and the latest in a long history of innovation in American agriculture. Recognizing a shared desire to support innovation and feed the world, moving forward we will use the term "cell-based meat and poultry" to describe the products that are the result of animal cell culture.

As an industry, we are uncompromising on product safety and we recognize the importance of consumer transparency. We support a fair and competitive marketplace that lets consumers decide what food products make sense for them

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[1] *See, e.g.,* Formal Agreement between USDA and FDA Relative to Cooperation and Coordination (Jan. 30, 2018) ("In the interest of regulatory efficiency and the effective execution of their respective responsibilities . . . USDA and FDA share the goals of identifying and potentially reducing the number of establishments subject to the dual regulatory requirements of USDA and FDA, bringing greater clarity and consistency to jurisdictional decisions under USDA and FDA's respective authorities, including transition period, and decreasing unnecessary regulatory burdens."); Memorandum of Understanding between USDA Food Safety and Inspection Service (FSIS) and FDA (MOU 225-00-2000) (establishing a working relationship between FSIS and FDA's Center for Food Safety and Applied Nutrition for the use of food additives, generally recognized as safe (GRAS) substances, prior-sanctioned substances, and color additives used in the production of meat and poultry products).

and their families, and the existing regulatory framework can achieve these goals.

As is the case for other new or novel foods or food ingredients, including those made from or otherwise used in meat and poultry products, FDA should have oversight over pre-market safety evaluations for cell-based meat and poultry products. Historically, for evaluations relating to meat or poultry products, USDA has provided input to FDA as part of this process. Given USDA's expertise in regulating meat and poultry, that role should continue. After pre-market safety has been established with FDA, USDA should regulate cell-based meat and poultry products, as it does with all other meat and poultry products, applying relevant findings from FDA's safety evaluation to ensure products are safe, wholesome, and properly labeled.

Such a regulatory framework is not new and plays into the strengths and experience of FDA and USDA: FDA has extensive expertise regarding products produced using cell culture technology and USDA has a longstanding role in inspecting meat and poultry products. We nonetheless understand that decisions made regarding a regulatory framework must be made with the input of all stakeholders.

The United States is currently the world leader in protein production, including cell-based meats. But we will not maintain that position without regulatory clarity. As a next step, we respectfully request a combined meeting between the White House, USDA, FDA, and both conventional and cell-based meat and poultry industry stakeholders, including the undersigned.

Thank you for your thoughtful consideration of this critical topic. We look forward to continued collaboration as we move forward.

Respectfully submitted,

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