FDA public meeting on "Foods Produced Using Animal Cell Culture Technology"
Docket No. FDA-2018-N-2155

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July 12, 2018

Thank you for the opportunity to comment on foods produced using animal cell culture technology. My name is Michael Hansen, and I am Senior Scientist at Consumers Union, the advocacy division of Consumer Reports, an independent, nonprofit organization with 7 million members nationwide, that works side by side with consumers for truth, transparency, and fairness in the marketplace.

Without a doubt, there are potential food safety problems associated with the production of foods using animal cell culture technology. This technology involves taking cells from a food animal and getting those cells to grow and differentiate in a suitable growth medium that contains vitamins, lipids, amino acids, and growth hormones/factors, often including fetal calf serum.[1] The vats in which the lab-meat is cultured can become contaminated with disease-causing bacteria, viruses, fungi, and mycoplasma.[2] It is appropriate for the federal government to assure the safety of such foods prior to their marketing. We can see arguments for either FDA or USDA taking that responsibility.

We are concerned, however, by elements of FDA's initial explanation as to why it believes it can take on this issue under existing programs. While FDA has broad responsibility for food safety, there are some serious gaps in its safety net, which lab-grown meat could well fall through. FDA states, for example, that it "administers safety assessment programs for a broad array of food ingredients and foods derived from genetically engineered (GE) plants." But, for GE plants, this is a voluntary safety consultation—not the same as a mandatory safety assessment. To assure consumers of safety, assessments for lab-grown meat should be

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[1] Ashad MS, Javed M, Sohaib M, Saaeed F, Imran A and Z Amjad. 2017. Tissue engineering approaches to develop cultured meat from cells: A mini review. *Cogent Food & Agriculture* 3: 1320814. At: https://www.researchgate.net/publication/272522939_Cultured_meat_from_muscle_stem_cells_A_review_of_challenges_and_prospects

[2] Pauwels K, Herman P, Van Vaerenbergh B, Do this CD, Berghams L, Waeterloos G, Van Bockstaele D, Dorsch-Häsler and M Sneyers. 2007. Animal cell cultures: Risk assessment and biosafety recommendations. *Applied Biosafety* 12(1): 26-38. At: https://www.researchgate.net/publication/235932703_Animal_Cell_Cultures_Risk_Assessment_and_Biosafety_Recommendations

mandatory. FDA also states that it "has issued guidance on how to assess the effects of significant manufacturing process changes on the safety of a food ingredient." But FDA guidances are also voluntary, not mandatory.

FDA further states it "has a variety of pre- and post-market programs for evaluating the safety of substances used in the manufacture of foods, including, for example, food additive and color additive regulations." We are particularly concerned about the use of the food additive process for these food ingredients, since there is a huge loophole in the form of the generally recognized as safe (GRAS) notification process. FDA, in a Federal Register notice[3] issued in August 2016 made explicit, under the GRAS Notification process, that a company wishing to introduce a new substance into food can itself determine if it is safe. It need only assemble a small panel of scientists of its own choosing to review the substance's safety. The company need not even notify FDA of their review.[4]

Lab-meat industry representatives reportedly have already suggested they may take advantage of this loophole, including in an April 2, 2018 article in *Food Navigator*. This piece reported industry as saying that "Technically, as cultured meat is a whole food and not a food additive, no premarket approval would be required, although this would be product dependent." The article continued, "However, given the novelty of the process and the scrutiny pioneers will face, companies in the space are working closely with the FDA as they approach commercialization, and may put together GRAS determinations (which they can submit to the FDA in the hope of receiving a letter of no objection) *predicted one industry source*"[5] (*italics* added).

Finally, there is the issue of the name to give foods derived from cultured animal cells. It is important that the name informs the consumer that the food is different from conventional meat, and gives consumers some idea of how it was produced. Consumer Reports conducted a nationally representative phone survey last month of more than 1,000 people. The survey found that the vast majority of Americans think that food produced from cultured animal cells should be differentiated in some way on the label. Some 49% said it should be labeled as "meat, but accompanied by an explanation about how it is produced," while another 40% said it should be labeled as "something other than meat." Only 5% thought it should be labeled as "meat without

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[3] https://www.gpo.gov/fdsys/pkg/FR-2016-08-17/pdf/2016-19164.pdf

[4] Government Accountability Office (GAO). 2010. FOOD SAFETY: FDA Should Strengthen its Oversight of Food Ingredients Determined to be Generally Recognized as Safe (GRAS). GAO-10-246. At: https://www.gao.gov/new.items/d10246.pdf ; and Neltner T. and M. Maffini. 2013. Generally Recognized as Secret: Chemicals added to food in the United States. National Resources Defense Council. At: https://www.nrdc.org/sites/default/files/safety-loophole-for-chemicals-in-food-report.pdf

[5] Watson, E. 2018a. Rep. DeLauro to GAO: Do we need a new regulatory framework for cellular agriculture? *Food Navigator USA*, April 2, 2018. At: https://www.foodnavigator-usa.com/Article/2018/04/02/Rep.-DeLauro-to-GAO-Do-we-need-a-new-regulatory-framework-for-cellular-agriculture

any further explanation." In addition, when given a list of seven terms and asked to choose which would constitute accurate labels, the most commonly chosen terms were "lab-grown meat" (35%) and "artificial or synthetic meat" (34%). The least commonly chosen terms were "cultured meat" (11%), "clean meat" (9%), and "in vitro meat" (8%).

In sum, Consumers Union appreciates the opportunity to comment. Cultured meat products should be required to go through a premarket safety assessment, and the GRAS process is clearly inadequate to assure safety. We also urge that these types of products be named in a manner consumers will readily understand, such as "lab-grown meat," or "synthetic meat."

Thank you again for this opportunity to comment and we will submit detailed written comments to the docket.