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USDA/FDA Joint Public Meeting on

The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

Docket No. FSIS-2018-0036

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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.

I am primarily commenting today on assuring the safety of lab-grown, or *in vitro*, meat.

There are two basic ways to produce lab-grown meat: 1) by proliferating existing muscle tissue (e.g., skeletal muscle explants) *in vitro*, as suggested by Benjaminison and colleagues[1], or 2) via a scaffold-based system, which involves growing cells around a specific structure that the cells attach to, as described by Dr. Mironov and Dr. van Eelin[2]. The former system, using skeletal muscle explants is not presently economically viable for a number of technical reasons, such as lack of a blood/nutrient circulation in the explants. The latter, or scaffold-based system, is more technologically feasible and often involves culturing suitable stem cells from various tissues—usually embryonic myoblasts or adult skeleton muscle satellite cells—so that they proliferate, attach to a scaffold and then grow and differentiate into muscle cells (e.g., myofibrils) when perfused with a culture medium in a bioreactor. This method appears to be the one that is moving toward commercialization today.

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[1] Benjaminson M, Gilchriest J and M Lorenz. 2002. In-vitro muscle protein production system (MPPS): Stage 1, Fish. *Acta Astronautica,* 51(12): 879-889. At: https://vdocuments.site/in-vitro-edible-muscle-protein-production-system-mpps-stage-1-fish.html.

[2] van Eelen WF, van Kooten WJ and W Westerhof. 1999. Industrial scale production of meat from *in vitro* cell cultures. Patent description. At: ; Sharma S, Thind SS and A Kaur. 2015. In vitro meat production system: why and how? *Journal of Food Science and Technology* 52(12): 7599-7607

The source of cells may pose safety problems. The primary cells (e.g., stem cells and satellite cells) can be derived from repeated biopsies of select animals, which means that a collection of animals will be needed. These primary cells can also be derived from cells lines, particularly ones that are immortal and can proliferate indefinitely. As a team of UK scientists pointed out in a paper published this year, research is needed on "the safety of ingesting genetically-modified cell lines, as these lines exhibit the characteristics of a cancerous cell which include overgrowth of cells not attributed to the original characteristics of a population of cultured primary cells."[3] FSIS does not allow cancerous lesions or tumors to enter commerce or the food chain.[4] Regulators should request data on whether lab meat will contain oncogenes that are expressed, and if so, make a determination as to the appropriateness of consumption.

In order to assure the safety of lab-grown meat, three things must be assured. First, the safety of all the chemicals and other ingredients needed to get the animal cells to grow and differentiate—nutrients, growth factors/hormones, differentiation factors, often including fetal calf serum or horse serum, antimicrobials (commonly added to cultured cells to prevent bacterial and fungal contamination , particularly in long-term cultures), materials to make the bioscaffold, etc.[5]—should be evaluated and their use regulated, perhaps as food additives or processing aids.

Second, since there is a huge potential problem from contamination of the cell lines and/or growth/culture medium with pathogenic bacteria, viruses, fungi and mycoplasma,[6]—cell cultures, unlike living animals, do not have a functioning immune system—there needs to be continuous monitoring of the cell lines and growth media/bioreactor for these contaminants and some sort of standards established to assure safety. Our position is that bacteria, fungi and mycoplasma that are human pathogens should all be considered adulterants.

Third, there should be close oversight— continuous inspection—of production facilities to insure they are operating in a safe manner.

How regulatory responsibilities should be divvied up between FDA and USDA is an open question. The safety of the production inputs may best be handled by FDA. However it is

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[3] Stephens N, Di Silvio L, Dunsford I, Ellis M, Glencross A and A Sexton. 2018. Bringin cultured meat to market: Technical, socio-political, and regulatory challenges in cellular agriculture. *Trends in Food Science & Technology* 78: 155-166. At: https://bura.brunel.ac.uk/bitstream/2438/16451/1/Fulltext.pdf

[4] Schweihofer J. 2016. Are things like cancerous tumors allowed by meat inspection. At: https://www.canr.msu.edu/news/are_things_like_cancerous_tumors_allowed_by_meat_inspection

[5] 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

[6] 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

extremely important that FDA should not allow these inputs through the generally recognized as safe (GRAS) notification process. FDA, in a Federal Register notice[7] 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.[8] It is essential that these inputs, especially the ones that may be produced via genetic engineering, should go through the food additive process, not the GRAS notification process. As for monitoring the safe operation of production facilities, this may be an appropriate role for USDA/FSIS who has inspectors in all slaughter facilities during production. Production facilities will require continuous inspection.

Finally, based on our own survey, we urge that these types of products be named in a manner consumers will readily understand, such as "lab-grown meat"or "synthetic meat".[9]

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 should not be used. Cultured cell lines and growth/culture media should be continuously monitored for contaminants and standards set to assure safety. There should be continuous inspection of production facilities to ensure they are operating in a safe manner.

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

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

[8] 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

[9] https://consumersunion.org/wp-content/uploads/2018/07/CU-cmmts-to-FDA-on-lab-grown-meat-7.12.18.pdf