



## Consumer Federation of America

December 21, 2018

Roxanne Smith, Director  
Congressional and Public Affairs  
USDA Food Safety and Inspection Service  
Office of Public Affairs and Consumer Education

*VIA ONLINE SUBMISSION*

**RE: Docket No.: FSIS-2018-0036-0001, Joint Public Meeting on the Use of Cell Culture Technology To Develop Products Derived From Livestock and Poultry**

The Consumer Federation of America appreciates the opportunity to submit comments in response to the USDA Food Safety and Inspection Service's ("FSIS") and the Food and Drug Administration's ("FDA") request for comments regarding cell cultured food products derived from livestock and poultry ("cultured meat"). CFA is an association of nearly 300 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. We commend FSIS and FDA for collaborating now to ensure that, someday, consumers may purchase cultured meat products with full awareness of the nature of these products, and with confidence that these products meet adequate safety standards.

Toward that end, CFA urges FSIS and FDA to clarify the application of the existing regulatory framework, and where appropriate to develop new guidance or rules, so that:

- Cultured meat products undergo an initial, transparent, impartial safety assessment by government regulators before going on the market.
- Government inspectors oversee the production of cultured meat products in a manner, and with sufficient frequency, to avoid the most significant risks of contamination.
- Labeling makes consumers fully aware of which products contain cultured meat, and discloses pertinent information, such as the use genetic engineering and animal-derived products such as fetal bovine serum to produce a cultured meat product, and potential allergen risks.

As many of the speakers at the October 23 and 24 public meetings elaborated on, cultured meat has the potential to alleviate many pressing environmental, food safety, labor, economic, and animal welfare concerns. Uncertainty surrounds the question of whether the technological capacity to

realize that potential will emerge anytime soon. Nevertheless, FSIS and FDA should lay the groundwork now to ensure that an economically viable cultured meat product is neither suffocated by unnecessary red tape, nor foisted on consumers without a sufficient assurance of safety, or disclosure. Ultimately, a well-designed regulatory regime will increase the likelihood that cultured meat makes a positive impact on today's most pressing public policy dilemmas.

Food safety, in particular, offers ample room for improvement. Currently, the Centers for Disease Control and Prevention estimate that meat and poultry cause 22% of foodborne illness and 29% of the deaths from foodborne illness. Pathogens like *Salmonella* and *E. coli* O157:H7 spread among live animals and from carcass to carcass in slaughter facilities, in many cases as a result of fecal contamination. Fecal contamination is a problem that would not apply to cultured meat. Some industry representatives have maintained, moreover, that microbial pathogen contamination in cultured meat facilities is more generally a non-issue because microbes grow much faster than cells, requiring an aseptic environment for the production of cultured meat that necessarily precludes the risk of pathogenic contamination. Given the resistance of the animal agriculture community to food safety regulation, particularly on-farm, widespread adoption of cultured meat could therefore result in significant public health gains. If consumers lack confidence in the safety assessment behind these products, however, they may choose to continue tolerating the food safety risks associated with traditional meat and poultry products.

To ensure consumer confidence, a pre-market approval process is essential. One obvious candidate for a pre-market approval program is the food additive petition process. According to FDA, "any substance that is reasonably expected to become a component of food is a food additive that is subject to premarket approval by FDA, unless the substance is generally recognized as safe." For several reasons we think FDA should not consider cultured meat to be "generally recognized as safe" or "GRAS." First, and foremost, most consumers simply do not consider meat produced by in vitro cultivation of animal cells to be "generally recognized as safe." Second, GRAS virtually guarantees uncertainty. An effective safety assessment needs to consider the probable consumption and cumulative effect in the diet of novel food substances—such as a synthetic growth factor—found in a company's cultured meat product. Under GRAS, however, lab meat companies need not notify the agency of their determinations, and so the extent of exposure to a given substance may be a mystery. Finally, GRAS sets up an inherent conflict of interest. Company-hired scientists rather than impartial government regulators decide what is safe. Research that does not support a safety assessment may never see the light of day.

An effective and efficient pre-market approval process would not only protect consumers directly, it would provide critical information to FDA and FSIS in the design of an appropriate inspection regime for cultured meat production facilities. At the public meetings, several speakers brought up concerns about the safety of products made from genetically engineered cell lines, of residual growth factor in cultured meat, and of the "scaffolding" on which the meat is grown. Given the immaturity of this technology, other concerns are bound to arise. Informed safety considerations must dictate how inspectors evaluate cultured meat facilities, and the safeguards that will be enforced in the industry. Relying on companies themselves, rather than impartial government regulators, to conduct the initial safety evaluations of cultured meat products (i.e. through the GRAS loophole) would run the risk of undermining safety inspection more generally.

Finally, cultured meat should carry clear labels that do not mislead consumers. However, that does not imply that federal regulators must restrict the use of the words “meat,” “beef,” “pork,” “tuna,” etc. on these products to avoid consumer confusion. Rather, labels should simply make consumers aware that the products result from cellular agriculture, not conventional slaughter or harvest, and provide pertinent information about the production process. Toward that end, we support establishing criteria for statements of identity for cultured meat products to ensure that product names are truthful, not misleading, and sufficiently differentiate cell cultured products from traditional products. We similarly support requiring some information about the methods by which animal cell cultured products are produced, including the use of genetic engineering. And we support requiring disclosure of the source of the animal cells, information that consumers would want for a variety of reasons, including to assess allergenicity risk.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion  
Director of Food Policy  
Consumer Federation of America