CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

December 24, 2018

By Electronic Submission
Docket No. FSIS-2018-0036
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Ave. SW,
Mailstop 3758, Room 6065,
Washington, DC 20250

Re: Comments to Docket No. FSIS-2018-0036 Regarding the Federal Regulation of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

The Center for Science in the Public Interest (CSPI)[1] appreciates the opportunity to submit comments jointly to the United States Department of Agriculture's (USDA) and the Food and Drug Administration (FDA) on how the federal government should regulate the processes of cellular meat technology as well as the products made from those processes. These comments underscore and supplement comments made by CSPI at the FDA's public hearing on this topic on July 12, 2018, and at the USDA/FDA joint hearing on October 23rd and 24th, 2018.

I. CSPI Supports Joint Oversight by FDA and USDA of Cell-Cultured Food Products from Livestock and Poultry.

On November 16, 2018, USDA Secretary Perdue and FDA Commissioner Gottlieb issued a statement indicating that their agencies would jointly oversee cell-cultured food products from livestock and poultry. Their joint proposal is that FDA would oversee "cell collection, cell banks, and cell growth and differentiation," while USDA would oversee, including with inspections, "the production and labeling of food products derived from the cells of livestock and poultry." The transition from FDA to USDA oversight would occur "during the cell harvest stage."

The absence of a mandatory pre-market approval process at FDA for genetically engineered crops has been a factor in the low consumer acceptance of those foods. We hope this same mistake will not occur with cell-cultured food products. The best way

[1] CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by 500,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI accepts no donations from industry or government.

forward for FDA to adequately carry out its portion of any joint oversight would be for Congress to amend the Federal Food, Drug, and Cosmetic Act to add a "new technology" provision that would provide the FDA the ability to fully and publicly review new food technologies and their products for safety.

Absent such authority, CSPI still supports the proposed agreement between the FDA and USDA because it draws on the regulatory strengths of both agencies: namely, FDA's expertise in reviewing novel and cell-culture technologies, and the USDA's experience regulating meat and poultry products from the point of harvest. However, more detail is needed about how the oversight will be carried out, including: (1) a commitment from the FDA to ensure appropriate premarket review; (2) promulgation of specific regulations covering each stage in the food production process and, (3) a clearer delineation regarding when FDA oversight ends, and USDA oversight begins.

A. FDA has the Necessary Expertise to Ensure the Safety of the Cell-cultured Meat Production Process.

The FDA has the expertise necessary to oversee the production process for cell-cultured meat. The agency has a long history of overseeing substances produced using cultured cells and evaluating their safety, both as direct food ingredients (bacterial, algal and fungal forms), and when they are used to produce other ingredients, including enzymes, oils and transgenic proteins. (The Agency's Center for Biologics Evaluation and Research holds additional expertise in the basic science and regulation in this area and may provide additional scientific know-how.) In addition, the FDA regulates the health and feeding of livestock pre-harvest, through its oversight of animal feed, antibiotics withdrawal periods, and artificial insemination. The agency's expertise with biotechnology food and drug products would be particularly useful in controlling risks related to cell culture, including contamination risks and risks related to the use of novel additives and ingredients. The FDA is also best positioned to assess the safety of the inputs used in these novel food production processes, including the scaffolding and the growth media.

B. USDA Should Regulate Cell-Cultured Meat Product that Will be Sold to Consumers After its Production, Including its Labeling.

The USDA's oversight of livestock and poultry historically begins at the slaughterhouse door. The USDA inspects these products at the time of harvest and has the responsibility to ensure that meat and poultry is properly handled, stored, and transported to reduce the risk of foodborne illness prior to being made available to consumers. The agency also manages an extensive testing program to ensure that the meat meets regulatory standards for drug residues and foodborne pathogens. Finally, it provides pre-market review for the labels of meat and poultry products, to ensure that the claims made on these labels are truthful and non-misleading.

The USDA's expertise in regulating meat and poultry can be applied effectively to regulating cell-cultured meat products after the point of harvest and will complement the

capacities FDA brings to the table. While production of these products will not involve slaughter and its accompanying risks of animal disease and fecal contamination present with traditionally harvested meat, foodborne illness risks remain in the form of contamination that can occur during the production process. If drugs are used during production, the risk of drug residues must also be addressed. The USDA can apply its expertise in regulating other meat and poultry products to ensure similar risks are appropriately addressed post-harvest in cell-cultured meat.

C. USDA and FDA Will Need to Set Forth the Details of Their Joint Oversight in Promulgated Regulations, Guidelines, and Guidance Before it will Be Possible to Assess Whether the Proposed Oversight will Ensure the Safety of Cell-Cultured Meat and Poultry Products.

While we support the idea of joint oversight by FDA and USDA, CSPI reserves judgement on the overall framework until we have had the opportunity to properly assess the full, detailed proposal to determine whether it will ensure the safety of cell-cultured meat products. Detail is needed on the following questions, for example:

- What legal authority will FDA use for its oversight?
- Will FDA utilize the "food additive" provisions of the FFDCA and if so, will each cell line be considered a food additive?
- Where exactly will be the boundary in the production process between FDA and USDA oversight?

To add to the complexity of regulating this new technology and its products, it is anticipated that different cell lines might be combined in different combinations to produce different food products. Moreover, many of the products sold to consumers will involve traditional food ingredients that are being added to the cells and/or scaffolding after harvest to make products with the texture and taste that consumers expect from meat and poultry. It therefore will be important to understand which regulator will oversee these intermediary steps before there is a food product that leaves the production facility. Only with detail set forth in regulations and guidance will one be able to judge whether the proposed joint oversight assures the safety of cell-cultured food products from livestock and poultry.

II. The Regulatory Framework Must Ensure that Cell-Cultured Livestock and Poultry Products are Free of Pathogens and Drug Residues.

Proponents of cellular meat have advocated for the term "clean" meat, and the products have been represented to consumers as free of harmful pathogens and drug residues. A zero-tolerance standard for pathogens is certainly readily achievable for these products and would be a significant food safety benefit to consumers. In addition, a zero-tolerance standard for pathogens is needed because consumers have heard these claims and are likely to treat the products as if they are pathogen-free (such as eating the product raw or not refrigerating it). Therefore, both FDA and USDA need to develop a regulatory framework and system for inspection that will result in pathogen-free cell-

cultured meat. Cell-cultured meat facilities should be required to develop a Hazard Analysis Critical Control Point (HACCP) plan just like other food-producing facilities and that plan should emphasize maintaining sterility control so that products produced at these facilities are pathogen-free.

Cell-cultured meat must also be free of drug residues. The FDA has established tolerance standards for traditional meat, which are verified through USDA testing. At least some production processes involving cellular meat appear to involve the use of antibiotics. If antibiotics are used in the production of cell-cultured meat marketed in the United States, then USDA drug residue testing and FDA tolerances should be extended to cover these products, at levels identical to those for traditional meat.

III. The Regulatory Framework Must Ensure All Inputs into the Production Process and the Final Product are Safe for Human Consumption.

The cell-cultured meat and poultry industry is in its infancy and it has not yet been able to scale up its production process to produce products that consumers could purchase in restaurants or grocery stores. Therefore, the exact production process and inputs needed are not yet clear and will likely change over time. However, when that process is perfected, FDA and/or USDA must ensure that all the different inputs into the production process and the constituents in the final product are safe for human consumption. Until more information about that process is available, it is impossible for CSPI to identify specific inputs or constituents that FDA and/or USDA should focus on in its safety oversight. However, at a minimum, FDA and/or USDA will need to be satisfied that the process and product don't introduce significant new allergens into the food supply, that any hormones used in the process are not found in the product in unsafe levels, and that cell medium does not contain any compounds that have not been approved for use in food.

To be clear, the FDA should require food additive petitions for novel ingredients, as GRAS notifications are inappropriate where a consensus among knowledgeable experts regarding the safety of an ingredient or input, by definition, does not yet exist. Absent further action from Congress, the FDA should utilize its food additive petition process, and allow public comment on such petitions, for every new condition of use for innovative and novel substances added to foods. Because the production of cell-based meat is certainly a new condition of use, the FDA must use the food additive petition process to ensure that every component that is used in processing and makes its way into the final product has been vetted for safety.

IV. USDA Should Ensure that Labels for Cell-Cultured Meat and Poultry Products are Accurate, Non-Misleading, and Informative. The Use of the Terms "Meat" and "Poultry" Should be Allowed if They are Properly Qualified.

Today, consumers care more than ever about the food they eat and want information about where it came from. Any information provided to consumers should be accurate,

non-misleading, informative, and not result in consumer confusion. Cell-cultured meat and poultry products should have labels that distinguish these products from traditional meat and poultry so that consumers know that what they are buying is a different product. To do otherwise would mislead consumers and could lead to consumer suspicion about both the new and the traditional products.

However, CSPI does not believe there is any problem with labeling cell-cultured meat as "meat" or "beef" if those terms have appropriate qualifiers that make clear the product's differences (e.g., "cell-cultured beef" or "meat (cell-cultured)"). USDA should therefore allow cell-cultured meat and poultry food products to use the terms "meat", "beef", "poultry", and "chicken" if there are accompanying qualifiers that make it clear the differences from traditional meat and poultry. For example, the name Beyond Meat on the packaging for the Beyond Burger is not misleading because the front of the package also reads, in prominent green-colored text: "Plant-Based Burger Patties." USDA could set forth a labeling system that provides possible clarifying text that a cell-cultured product could use to distinguish that product in the consumers' mind. .[2]

V. There Needs to Be Sufficient and Comparable Oversight of Cell-Cultured Fish Products by FDA.

While the USDA/FDA joint hearing focused only on livestock and poultry products, there needs to be similar safety oversight for cell-cultured fish products. There are several companies exploring commercial production of cell-cultured fish and seafood products and those production processes and products will similarly need federal oversight at both the pre- and post-harvest stages. Except for catfish (and currently no company is pursuing cellular catfish), FDA has sole regulatory authority over fish and seafood products. While one could assume that FDA would draw on its expertise in cellular food ingredient production to develop similar oversight for fish and seafood products as it would develop for meat and poultry, this should be made explicit. In addition, FDA will need to establish post-harvest oversight similar to what USDA establishes for meat and poultry, especially when addressing the issue of labeling (which for fish and seafood fall under FDA jurisdiction, not USDA). It will be confusing to consumers if cellular food products from different species don't have similar labeling. Therefore, if USDA uses the terms "meat" and "poultry" with necessary qualifiers, FDA should use the term "fish" with similar, if not identical qualifiers.

---

[2] See CSPI's Letter to USDA's Food Safety and Inspection Service submitted on May 18, 2018 in response to a petition to about limiting the use of "meat" and "beef" for alternative proteins.

CSPI appreciates the opportunity to provide this comment to USDA and FDA. CSPI would welcome the opportunity to meet with the staff at USDA and/or FDA to discuss the issues addressed in this letter in more detail if that would be helpful.

Sincerely,

Gregory Jaffe
Director, Biotechnology Project
gjaffe@cspinet.org
(202)777-8369