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REGULATORY CHALLENGES AND OPPORTUNITIES FOR CELL-CULTURED MEAT

A hamburger produced with zero waste and without slaughtering a single animal. A tuna sandwich prepared with no impacts on marine ecosystems.

These are among the many environmental benefits touted by advocates of innovative cellular agriculture products that may begin reaching neighborhood grocery store shelves in the next few years. "Cell-cultured" meat—alternatively described as "cell-based," "clean," "synthetic," or "lab-grown" meat—is now under development by an expanding cadre of biotechnology companies around the globe. These companies are using cutting-edge laboratory science to create a new and sustainable source of meat that promises consumers the full taste, appearance, and texture of animal products while reducing reliance on, and in some cases replacing, modern animal agriculture and industrial production practices.

As development of this technology rapidly advances, U.S. regulatory authorities have quickly recognized the need to develop a cooperative approach to oversee the production of cell-cultured meat. After months of uncertainty and reported disagreement, the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) issued a joint press release on November 16, 2018 announcing their intent to coordinate regulatory efforts through joint oversight of the cell culture development process.[1] In the absence of more details or a formal regulatory proposal, however, various consumer groups, technology proponents, and industry representatives continue to separately advocate for their own favored legal approach. Among the key controversies: can a product be considered "meat" if it is grown in a laboratory instead of derived from a slaughtered animal? A federal court is now considering that very question.[2]

Background

Cell-cultured Meat: Harvesting a Design

Cell-cultured meat is meat that is derived from an animal product. It is very close to traditional meat—or meat that is processed and derived from slaughtered animals—in taste, texture, and appearance. However, the process to develop cell-cultured meat is complex and far-removed from either traditional animal husbandry or commercial livestock production.

To create cell-cultured meat, cells are grown from either a live biopsy from a living animal, or from an embryo.[3] The collected cells are then grown in a sterile lab environment. To grow the cells into meat products, developers must differentiate cells – for example, fat from muscle – while allowing each cell to proliferate and mature.

The cells require a nutrient broth to grow, a soup that includes amino acids, salts, sugars, and growth signaling molecules. The broth must be replaced and supplemented as the cells grow. This broth and growing media is currently extremely expensive, but companies are working to produce this growing environment economically on a commercially viable scale.

As it matures, cell-cultured meat must be physically supported by a scaffolding or other structure. The scaffolding (usually made from a non-animal edible material) allows already proliferated cells to develop structure and texture. Scaffolding might become part of the product, or it may be biodegradable and break down as the meat grows. Following scaffolding, the product must be housed in a bioreactor.

This growth process is technical, expensive, and complex, but once the meat has been differentiated, matured and proliferated, it is steps from the market. Currently manufacturers are designing and growing cell-cultured meat products that mimic beef as well as poultry and seafood.

Although the process relies on modern biotechnology techniques, the process does not involve any genetic modification and therefore does not constitute "genetic engineering" under most existing regulatory definitions.[4]

Goals

Motivation for Cell-cultured Meat

Technology advocates stress the positive impacts of replacing traditional meat production through the adoption of cell-cultured meat. Greenhouse gas emissions, water usage, and land use would be reduced. Feed costs and crop footprints would be minimized. Cell-cultured meat would be grown in a sterile and sanitary laboratory and thus public health risks from exposure to bacteria and zoonotic diseases could be reduced. The lab environment would also lessen antibiotic resistance. Shelf life could be increased based on the sterile growing conditions.

Advocates also stress that food security and social economic welfare would be distributed more evenly and once cell-cultured meat can be grown on a large scale, it would presumably be available to a greater population at a lower cost.

Challenges

Technical Challenges

Cell-cultured meat is not yet available to consumers, and faces numerous challenges before large-scale production, sale, and distribution may begin. The product is currently extremely expensive to develop and produce. Additional research is still needed to develop and further innovate the process, and more technology and resources are needed to develop the product at scale. The product must also be approved by regulators in a consistent and uniform manner. Finally, consumer acceptance and demand both must grow.

Regulatory Challenges

Federal agriculture and food safety agencies have not yet have not yet addressed the status of cell-cultured meat by regulation, and such uncertainty may stifle or slow the sale and marketing of the products in the United States. Given the unique properties of cell-cultured meat, USDA and FDA announced their agreement on November 16, 2018, to participate in joint oversight over the production of cell-cultured food products, together with "robust collaboration and information sharing." Specifically, FDA will oversee the stages of growth from

cell collection to differentiation, while USDA will handle the production and labeling of cell-cultured meat.[5] This unique approach marks the cell harvest stage as the point in time in which the products will become subject to regulation as "meat," and thereby allows both agencies to operate within their conventional roles: FDA generally regulates food products (including cell-cultured foods) to ensure that they are properly labeled and safe, while USDA holds exclusive jurisdiction over the regulation and inspection of meat and poultry. Yet the suggested division of agency authority leaves key questions about the regulatory status of cell-cultured meat unanswered.

In particular, are harvested cells sufficiently covered by existing regulatory definitions of "meat," or will a new rulemaking be required to expressly address USDA's authority over the production and labeling of cell-cultured meat products? USDA's Food Safety Inspection Service (USDA-FSIS) regulates most aspects of the safety and labeling of traditional (non-game) meats, poultry, and certain egg products pursuant to its authority under the Federal Meat Inspection Act (FMIA). The FMIA does not define the term "meat," although it defines a "meat food product" as "any article capable for use as human food which is made wholly or in substantial part from meat or other portion of the carcass of any cattle, sheep, swine, or goats."[6] At the same time, it defines "prepared" meat as a product that has been "slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed."[7] A food product is "misbranded" under the FMIA if its "labeling is false or misleading in any particular."[8]

Through its implementing regulations, FSIS defines "meat" as the:

> part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing.[9]

FSIS also clarifies that a meat or meat food product is "misbranded" if:

> its labeling is false or misleading in any particular; if it is offered for sale under the name of another food; [or] if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and immediately thereafter, the name of the food imitated.[10]

The advent of cell-cultured meat was obviously not considered when these provisions were originally crafted in 1970, and the regulatory status of these new products is consequently unclear. Arguably, cell-cultured meat fits within the statutory definition of "prepared meat" under the FMIA (which broadly includes meat products that

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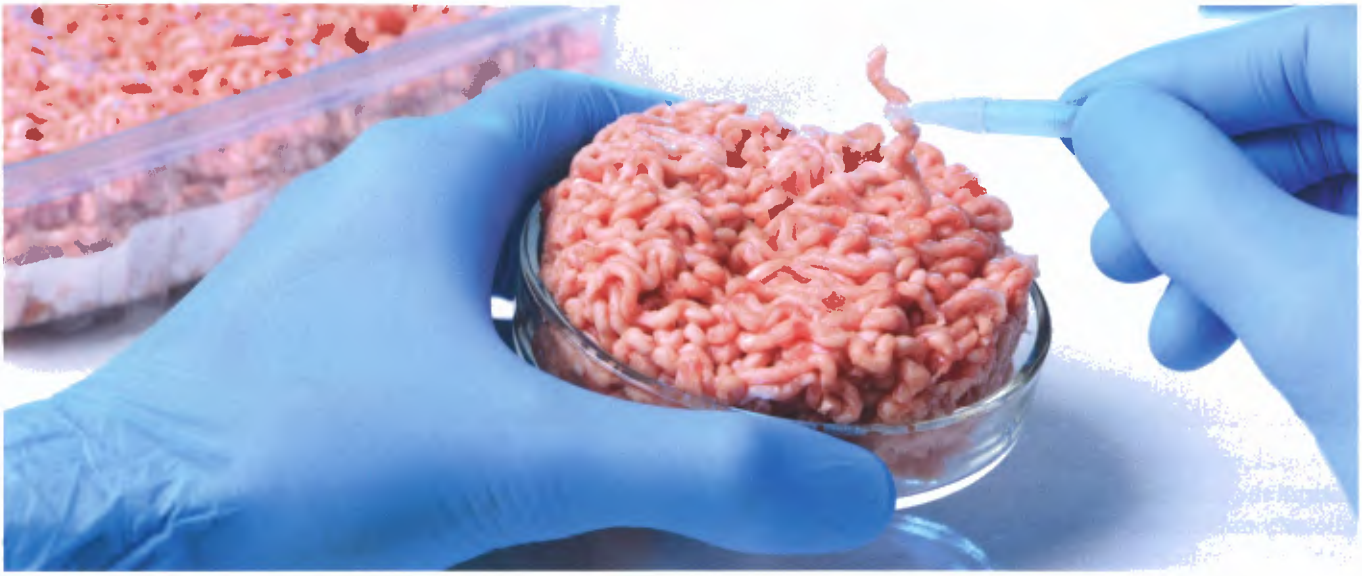

have been either "slaughtered" or "otherwise manufactured or processed"). Cell-cultured meat productions may also come within FSIS's definition of "meat," if regulators determine that the lab-grown tissues are derived from an edible "part of the muscle" of an animal.

Less clear is whether FSIS can also inspect the laboratories that produce cell-cultured meat. FSIS's existing rules apply only to establishments "in which any products of, or derived from, carcasses of livestock are, wholly or in part, prepared for transportation or sale as articles of commerce, which are intended for use as human food."[11] This provision cannot be readily applied to cell-cultured meat, which is designed to avoid the production of livestock carcasses altogether. Arguably, the types of facilities that will produce cell-cultured meat bear a much closer resemblance to food manufacturing sites and laboratories historically regulated by FDA, rather than the types of livestock slaughterhouses typically regulated by FSIS.

In the face of uncertainty over the status of new food technologies in the past, USDA-FSIS has previously attempted to use the rulemaking process to clarify its official policies. For example, public confusion arose from the term "natural" as applied to minimally processed meat and poultry products, to which the FSIS responded with an Advance Notice of Proposed Rulemaking in 2009.[12] FSIS could similarly address uncertainty over the status of cell-cultured meat production through a new rulemaking process.

At the same time, FDA is also well positioned to address the safety of cell-cultured meat pursuant to its broad authority under the Federal Food, Drug & Cosmetic Act (FFDCA). The FFDCA authorizes FDA to regulate all foods *except* meat, poultry, and some egg products. FDA's Center for Food Safety and Applied Nutrition (CFSAN) handles safety and sanitation requirements for all food introduced into or offered for sale in interstate commerce, again with the exception of meat, poultry, and some egg products. FDA also has authority to regulate certain food ingredients (such as color additives) that may be used in the production of meat.

The FFDCA requires pre-market approval of all food additives (essentially, any substance that may reasonably be expected to become a component of any food).[13] Producers may submit a petition to FDA, with data and information to show that the food additive is safe.[14] Alternatively, a food additive's safety may be established through scientific procedures to be "Generally Regarded as Safe (GRAS)" thereby avoiding the petition and approval process.[15]

On June 15, 2018, FDA announced its own jurisdictional claim over cell-cultured meat, which received immediate pushback from USDA.[16] On July 12, 2018, FDA held a day-long conference and webinar that addressed "Clean Meat," and stressed that it is very familiar with the cultured meat concept and can draw from its expertise handling other cell-cultured technology to evaluate and regulate cultured meat products. In late October 2018, USDA and FDA hosted a public meeting addressing the use of cell culture technology to develop products derived from livestock. Moreover, in its joint November 2018 statement with USDA, FDA claimed authority over the cell development stages of cell-cultured meat. Thus, it seems that FDA has assumed a future role—albeit still unclear from a regulatory standpoint—for itself in regulating at least the early development stages of the meat products that are derived from animal parts.

Legal Challenges

On February 2, 2018, the U.S. Cattlemen's Association, which represents the U.S. livestock industry, petitioned FSIS to prohibit the use of the term "beef" and "meat" for products not derived from animals that have been slaughtered or butchered.[17] The Association argued that applying these terms to cell-cultured meat products would

mislead the public and consumer, who may not be aware that the product that they purchased and consumed was derived from stem cells or animal tissues developed in a lab. The Association specifically requested that FSIS "exclude man-made or artificially manufactured products that are not derived from animals born, raised, and harvested in the traditional manner from the definition of both beef and meat." The changes, the Association urges, should be articulated in the FSIS Food Standards and Labeling Policy Book.

The petition, which remains pending, was opposed by a group of leading developers of cell-cultured meat and other meat substitute producers.[18] In their opposition, these companies analogized cell-cultured meat to well-established plant-based food products that supplement meat, poultry, and dairy products (like tofu and soy milk). The group drew expressly from an earlier petition submitted to FDA in March 2017 that had asked FDA to allow common labels for traditional foods to be supplemented by distinguishing terms for alternative plant or animal sources that replace the "main characterizing ingredient," such as "coconut milk" or "almond milk."

State Policies

Amid this controversy, and in the continued absence of more formal direction at the federal level, states may attempt to establish their own policies. For example, Missouri recently enacted a law to prohibit the labeling of products as "meat" if not derived from "harvested production livestock or poultry."[19] The state law further limits the definition of "meat" to only the "edible portion of livestock or poultry carcass or part thereof.""[20]

Cell-cultured meat industry proponents promptly filed suit in federal court, challenging the law on First Amendment grounds.[21] That case is now pending. While Missouri is the first U.S. state to modify the definition of "meat" in a way that is likely to exclude cell-cultured meat products, it is unlikely to be the last amid continuing uncertainty among federal agencies on this topic.

Potential Regulatory Framework

As the first products of modern genetic engineering became more widely available in the 1980s, federal agencies were asked to take a cooperative approach that relies on existing statutory authorities to ensure the safety of products of biotechnology. The "Coordinated Framework for the Regulation of Biotechnology" was first published by the White House Office of Science and Technology Policy in 1986 and most recently updated in 2017.[22]

Developed to clarify the roles of the primary agencies involved in the regulation of biotechnology products (USDA, FDA, and the U.S. Environmental Protection Agency), the Coordinated Framework specifically aims to address novel types of products developed through technology and science, and to coordinate regulation of both existing products and those that will be developed in the future. The 2017 update clarifies each agency's independent jurisdiction over various aspects of biotechnology products. It further outlines the roles of each agency with respect to biotechnology products that fall within the scope of multiple agencies.

A similarly coordinated cross-agency approach to the federal regulation of cell-cultured meat would provide additional clarity and certainty to the new regulatory landscape for cell-cultured meat products and clarify labeling rules to help reduce confusion for food producers and consumers alike. It may also help pre-empt a scenario in which cell-cultured meat becomes subject to a patchwork of individual and potentially conflicting state regulations.

Encouragingly, USDA and FDA have a long history of working together and consulting with each other in efforts to regulate products, like color additives, that are subject to FDA overview but may be intended for use in USDA-regulated meat products.[23] The agencies' joint November 16, 2018, statement announcing agreement to collaborate on the regulation of cell-cultured food products is an encouraging starting point, but more detailed policies and formal regulations will likely be needed to further clarify and solidify the agencies' roles.

Conclusion

As technology advances and interest grows in cell-cultured meat, federal U.S. agencies are being called upon to address key questions about the product's regulatory status under their

existing statutory authorities. A harmonized and cooperative federal approach, taken by all potentially relevant agencies, can help avoid conflicting regulatory requirements and provide much-needed certainty to developers, manufacturers, and consumers alike. While recent signals of cooperation between FDA and USDA are encouraging, both industry and consumers will benefit from more detailed legal guidance and policy direction as cell-cultured meat products enter the marketplace in the very near future.

Endnotes

1. U.S. Dep't Agric., *Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, Release No. 0248.18, Nov. 16, 2018, *available at* https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb.

2. Turtle Island Foods et. al. v. Richardson, Case No. 2:18-cv-04173-FJG (W.D. Mo. Aug. 27, 2018).

3. Liz Specht, *Is the Future of Meat Animal-Free?*, 72 Food Tech. Magazine. 16, 19 (2018).

4. *See, e.g.*, USDA 7 C.F.R. § 66.1 (proposed), defining "bioengineered food" to mean "a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature."

5. *See* endnote 1 (U.S. Dep't Agric., *Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, Release No. 0248.18, Nov. 16, 2018, available at https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb).

6. 21 U.S.C. 601.

7. *Id.*

8. 21 U.S.C. 601(n)(1).

9. 9 CFR 301.2.

10. *Id.*

11. *Id.*

12. 74 Fed. Reg. 46,951, 46,954 (Sept. 14, 2009).

13. 21 U.S.C. 348.

14. 21 CFR 170.3(i).

15. 21 CFR 170.30.

16. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610869.htm; https://www.politico.com/story/2018/06/15/lab-grown-meat-feds-turf-battle-629774.

17. http://www.uscattlemen.org/Templates/pdfs_USCA/2018-PDFs/2-9-18USCA-AMS-Petition-re-definition-of-beef-and-meat.pdf.

18. https://www.gfi.org/images/uploads/2018/04/GFIetal-Comment-FSIS-2018-0016.pdf.

19. Mo. S.B. 627.

20. 17 Mo. 265.300.

21. Turtle Island Foods, et. al. v. Richardson, Case No. 2:18-cv-04173-FJG (W.D. Mo. Aug. 27, 2018).

22. Biotechnology Working Grp., Exec. Office of the President, *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology* (Jan. 4, 2017), *available at* https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf.

23. 2015 MOU 225-00-2000 Amendment 1, Memorandum of Understanding between the United States Department of Agriculture Food and Safety Inspection Service and the United States Department of Health and Human Services Food and Drug Administration, https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomestiMOUs/ucm441552.htm.