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What's at Steak: USDA Solicits Comments on Cultured Meat Labels

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Using recent advances in cell culture technology, numerous companies are developing meat products produced in vitro using cultured cells derived from living animals. As such companies get ready to market their products to consumers, regulators are asking for industry input.

FSIS advance notice of proposed rulemaking

In an advance notice of proposed rulemaking (ANPR) published on September 3, 2021, the US Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) seeks comments from stakeholders regarding the labeling of meat and poultry products comprising or containing cultured cells derived from animals. Comments submitted in response to the ANPR will "inform future rulemaking to establish labeling requirements for these products." **The deadline to submit comments in response to the ANPR is November 2, 2021**. Topics covered by the ANPR include, among others:

1. Naming convention and disclosure of animal cell culture technology, and use of such terms (e.g., "cell-cultured" vs. "cell-cultivated").
2. Labeling requirements for "combination" meat products comprised of slaughtered meat or poultry and cultured animal cells.
3. Product names and labeling terms that could be considered false or misleading, or harmful to industry or consumers.
4. Whether to establish a standard of identity under the USDA's authority in the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 607(c) and 457(b)) for foods comprised of or containing cultured animal cells?
5. Whether to establish common names or naming conventions for cell-cultured products, whether to include these naming conventions in the standards of identity for such products, and whether to define the names by common usage, statute, regulation or some other administrative process.
6. Nutritional, organoleptic (e.g., appearance, odor, taste), biological, chemical or other characteristics material to consumers' purchasing and consumption decisions, and whether they vary between slaughtered meat or poultry products and those comprised of or containing cultured animal cells.
7. Whether the creation of a category of cell-cultured meats requires amendments to the definitions for "meat," "meat byproduct," "poultry product," "poultry food product" or "meat food product" to specifically include or exclude foods comprised of or containing cultured animal cells.
8. Whether to require listing cultured animal cells in ingredient sublistings, or elsewhere on the label.

Intra-agency cooperation for regulation of cultured meat products

The ANPR is a significant step toward the establishment of a US federal regulatory system for labeling meat and poultry products

comprised of cultured cells. In general, the US Food and Drug Administration (FDA) has jurisdiction to regulate food products, including cell-cultured foods,[1] while the USDA regulates meat and poultry.[2] On March 7, 2019, the FDA and FSIS **signed a formal agreement to jointly oversee production of cell-cultured food products**. Pursuant to this agreement, the FDA will oversee those aspects of manufacturing that occur prior to cell harvest – including collection, growth, and differentiation of livestock and poultry cells. Subsequently, FSIS will oversee the processing, packaging, and labeling of the resulting meat and poultry products using the cells. The FDA and FSIS have also agreed to develop joint principles for product labeling and claims, with the goal of producing a labeling scheme that is consistent and transparent.

Misbranding, standards of identity and enforcement authority

Under the USDA and FDA governing statutes, a product may be considered misbranded if, for example, its labeling is false or misleading,[3] if it is offered for sale under the name of another food,[4] or if it is an imitation of another food that is not labeled as such.[5] A product may also be misbranded if it is represented as a food for which a standard of identity has been established, and it does not adhere thereto.[6] A standard of identity establishes specific names, terms and information to be used on products labels, and may require the presence of certain ingredients and amounts, or it may specify how products must be formulated, processed or manufactured. Both FSIS and the FDA have the power to establish standards of identity – FSIS for meat and poultry products, and the FDA for all food within its jurisdiction.[7]

Although the potential for standards of identity in the cultured meat space is raised in the ANPR, several stakeholders have already commented on this issue, focusing on how cultured meat products will be similar to traditional, slaughtered meat.[8] In this rapidly evolving space, establishment of any standard of identity needs to be evaluated carefully, with an eye toward rapidly developing technology. This is particularly true given the diversity of products that may be achieved using cell culture techniques, with each potentially having different compositions and organoleptic properties.

Any formal regulatory framework established in the cultured-cell space will necessarily include enforcement provisions. The formal agreement between the FDA and FSIS authorizes the FDA to take enforcement action to ensure that cell bank and cell culturing facilities are in compliance with applicable FDA laws and regulations. It also states that the FDA will notify the FSIS if "conditions which may result in the production of adulterated or misbranded product" are identified pre-harvest and will "rely on FSIS to address such conditions with respect to post-harvesting activities." The FSIS, in turn, is authorized to conduct enforcement action as necessary "to ensure that adulterated or misbranded human food products derived from cultured livestock and poultry cells do not enter or are removed from commerce." It is unclear how well this division of labor will play out in practice, and how effectively the two agencies will cooperate to effect enforcement actions.

Insights from the debate on labeling of cultured seafood products

The FDA regulates food,[9] including fish, shellfish, and seafood.[10] In October 2020, the FDA issued a request for information (RFI) **related to labeling of foods made from cultured seafood cells**, which covered many of the same issues as the FSIS ANPR. In response to the RFI, the FDA **received more than 35 comments** from consumers and industry stakeholders. Most comments were in favor of product identity statements to differentiate products comprising cultured cells from traditional seafood. Some commenters advocated for the "adoption of a single, science-based qualifier to be used for cell-cultured seafood products as well as for cell-cultured meat and poultry products."[11] Others asserted that "the consumer must know what they are eating" – and emphasized the need for consumer educational outreach and consistency and clarity in labeling.[12] It is likely that comments received in connection with the FSIS ANPR will raise similar concerns as the FDA's RFI, and may also raise new issues specific to the development of cultured meat products.

Looking forward

While the FDA and the USDA are in the beginning stages of regulating food derived from cultured animal cells, many questions may arise. In addition to the current solicitation for comments on labeling issues, we anticipate that the agencies may seek similar input on issues related to the "manufacture" of cell-cultured food,[13] as well as the impact of any US-based regulatory scheme on imported (and exported) foods, given the global nature of the food supply chain and the efforts by other countries to regulate in this space.[14]

Cooley is actively monitoring the issues impacting the cultured-cell meat and seafood industries, including regulatory oversight and updates. Companies interested in understanding more about the cultured cells, or with a desire to provide formal comments for submission to FSIS, are encouraged to contact our team. Cooley's lawyers bring decades of experience helping agtech and foodtech companies navigate complex legal issues involving intellectual property; litigation; FDA regulatory; licensing, collaboration and M&A deals; and capital raises including venture financing and public and private capital markets.

Notes

1. See Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, *et seq.*), the Public Health Service Act (42 U.S.C. 201, *et seq.*), and the Fair Packaging and Labeling Act (15 U.S.C. § 1451, *et seq.*)
2. See Federal Meat Inspection Act (FMIA; 21 U.S.C. § 601 *et. seq*); Poultry Products Inspection Act (PPIA; 21 U.S.C. § 451, *et seq.*)
3. 21 U.S.C. §§ 601(n)(1) and 453(h)(1); 21 U.S.C. § 343(a).
4. 21 U.S.C. §§ 601(n)(2) and 453(h)(2); 21 U.S.C. § 343(b).
5. 21 U.S.C. §§ 601(n)(3) and 453 (h)(3); 21 U.S.C. § 343(c).
6. 21 U.S.C. §§ 601(n)(3) and 453 (h)(7); 21 U.S.C. § 343(g).
7. 21 §§ U.S.C. 607(c) and 457(b); 21 U.S.C. § 341; *infra* n. 11.
8. See, e.g., United States Cattlemen's Association Petition dated Feb. 9, 2018, which seeks to limit the definition of "beef" to exclude food comprising cultured animal cells.
9. The only foods not regulated by FDA are meat products subject to regulation under the Meat Inspection Act, see 21 U.S.C. § 392(b).
10. With the exception of catfish, which falls under the UDSA's jurisdiction.
11. See comment by the National Fisheries Institute.
12. See comment by the Seafood Product Association.
13. The FDA announced in 2019 that its approach to regulating products derived from cultured animal cells will involve a thorough pre-market consultation process and inspections of records and facilities.
14. In December 2020, **Singapore became the first country to approve the commercial sale of meat made from cultured cells**.

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