

ALERT

Selling Cell-Based Proteins

FSIS REQUESTS COMMENTS TO INFORM FUTURE LABELING RULEMAKING FOR MEAT AND POULTRY PRODUCTS DERIVED FROM CULTURED ANIMAL CELLS

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On September 3, 2021, the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) published an Advance Notice of Proposed Rulemaking (ANPR) on the Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells (86 Fed. Reg. 49491). The ANPR invites public comment on this topic for the next two months, through November 2, 2021.

This is far from the first bit of government outreach on this topic. As the document summarizes and discusses, there have already been thousands of such comments placed into the public record, stimulated by earlier public meetings, responses to petitions previously filed by interested parties in this area, and responses to a similar U.S. Food and Drug Administration (FDA) request for information concerning products within FDA's jurisdiction. But the publication of this particular document by FSIS, whose decisions in this area will become applicable to the majority of such products whenever they ultimately reach the marketplace, does move the process forward.

In this regard, the ANPR lists a series of fourteen specific areas where comment and supporting data would be helpful. They perhaps can be further boiled down to (1) should such products have access to the same range of terminology applied to traditional meat and poultry and (2) how, if at all, should the non-traditional nature of such products be identified.

In issuing this ANPR, FSIS is no doubt aware of the fact that achieving full public consensus on these issues will not be possible. This is perhaps best illustrated by the two prior petitions that are discussed in the document. The first, submitted by the United States Cattleman's

Authors

Bob Hibbert
Senior Counsel
202.719.4968
bhibbert@wiley.law

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

Practice Areas

FDA Regulatory Compliance
Food & Drug

Association in 2018, asserts that any such products should not be labeled as “beef” in the first instance, presumably cutting out any eligibility for other traditional terminology. On the other hand, the Harvard Law School Animal Law and Policy Clinic suggests in its 2020 petition that any such product that establishes itself as meat or poultry can and should have access to such nomenclature, and also maintains that any government requirement to differentiate such a product could be inconsistent with the First Amendment.

FSIS remains officially agnostic on such questions, ones that it will ultimately need to answer after surveying another round of comments that will undoubtedly range across this same spectrum. At this point, the ANPR is consistent with conclusions of a 2020 U.S. Government Accountability Office (GAO) report that FSIS lacks sufficient information on final product composition, as well as the technological and commercial production methods used, in order to make an informed decision on labeling requirements. FSIS is hoping to receive such information in stakeholder responses to the ANPR, but with intellectual property closely guarded for these yet-to-be-marketed products, it may not receive much more information than it already has.

In the near term, what the ANPR says about process is more instructive than what it adds to the substantive debate. First, it reiterates its federal preemption over any contrary requirements to be imposed by any state, a critical asset to this emerging industry. Second, it specifies that for the foreseeable future it intends to require specific reviews and acceptance by agency personnel of all such labeling materials.

FSIS also reaffirmed its commitment to the formal agreement between itself and FDA for these products, including the development of joint principles for product labeling and claims. Interestingly, because of its broad label approval authority, FSIS will have a hand in developing a framework for environmental/sustainable claims for these products, while similar claims for FDA-regulated products will be subject to the jurisdiction of the Federal Trade Commission (FTC) and its Green Guides. Developers of cell-cultured products continue to assert their environmental benefits, and with FTC preparing to review its Green Guides for updates in 2022, one unanswered question is whether the FSIS and the FTC will seek to harmonize their approach to such claims.

Last and by no means least, FSIS discusses how it will operate while this rulemaking activity is pending. As many readers are aware, the notice and comment rulemaking practice, particularly on issues that generate controversy, is notoriously time-consuming. Here we have an ANPR that might lead sometime next year to an actual proposal, followed by the eventual final rule with an effective date that will probably be several years hence.

There is much public discussion of the fact that many companies expect to be marketing their products much sooner than this. Regardless of when it happens, within this system any manufacturer of such a product has some ability here to force FSIS’s hand on the labeling question whenever it believes that it is ready to market a safe and wholesome product eligible for the USDA mark of inspection.

FSIS drops a few useful hints when it acknowledges this possibility, suggesting that in any such review process it would require some form of product differentiation, seemingly involving the term “cultured.” While it is then quick to note that this could change through subsequent rule, those most familiar with the FSIS labeling system

have reason to think otherwise. Given the prior approval system, the vast majority of policy in this area is made not via rulemaking but on a case-by-case basis. As such, the first few cases of this nature that appear on the FSIS's docket, and the precedents that they will set, could be of greater significance than this or any other rulemaking process.