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

May 18, 2018

Carmen M. Rottenberg
Deputy Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Ave.
S.W. Washington, DC 20250-3700

Re: Petition to Establish Beef and Meat Labeling Requirements (FSIS-2018-0016)

Dear Deputy Administrator Rottenberg:

The Center for Science in the Public Interest and Consumer Federation of America submit these comments urging you to deny the petition by the United States Cattlemen's Association (USCA) to the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) asking for the agency to amend its labeling guidance to limit the definition of the terms "beef" and "meat" on the labels it regulates.[1] The petition requests this action to distinguish alternative proteins (products derived from plants, other non-animal sources, or cultured animal cells) from meat from animals "born, raised, and harvested in the traditional manner" (traditional meat).

Alternative proteins should be subject to regulatory review to ensure that they are safe and that they carry clear, non-misleading labels. However, the federal government need not restrict the use of the words "meat" and "beef" on such products to avoid consumer confusion, provided the terms are used (as they typically are) with appropriate clarifying context. The action requested in the petition is therefore unnecessary to avoid consumer confusion. Rather than serving consumers, the petition represents a self-interested attempt to restrict healthy competition between industries vying for space at the center of the American plate.

Moreover, to the extent that any potential for confusion exists with the labeling or advertising of alternative proteins, the FSIS lacks clear jurisdiction to address this problem. Instead, any concerns related to the misleading marketing of plant-based products would be more appropriately addressed to the Food and Drug Administration (FDA) or the Federal Trade Commission (FTC). With respect to products derived from animal cells, the FDA and FSIS should come to an agreement on which agency has jurisdiction to regulate these products before either agency offers guidance on their labeling.

Should the FSIS act to define the terms "beef" and "meat," we urge the agency to provide adequate transparency and public input through a notice-and-comment rulemaking, rather than by amending its labeling guidance, as requested by the petitioners. Regardless, any agency

[1] U.S. Cattlemen's Association. Petition for the imposition of beef and meat labeling requirements. February 9, 2018. www.fsis.usda.gov/wps/wcm/connect/e4749f95-e79a-4ba5-883b-394c8bdc97a3/18-01-Petition-US-Cattlement-Association020918.pdf?MOD=AJPERES. Accessed May 17, 2018.

response should be targeted to avoid consumer confusion by taking into account the entire context of the label. The response should not be designed to favor the narrow commercial interests of one industry over another by prohibiting terminology that has not been demonstrated to lead to consumer confusion.

I. USCA Petition

On February 9, 2018, the USCA submitted a petition to the FSIS asking the agency to add definitions of the terms "beef" and "meat" to the FSIS Food Standards and Labeling Policy Book, "a guidance to help manufacturers and prepare product labels that are truthful and not misleading."[2] The USCA petition urges the FSIS to limit use of the terms "meat" or "beef" to animals born, raised, and harvested in the traditional manner.

The petition references two broad categories of alternative proteins that would be excluded from the definitions of "meat" and "beef": products grown from animal cells, sometimes called "clean meat" or "cultured meat," and alternative proteins not derived from animals, including two plant-based product lines designed to replicate meat, manufactured by Impossible Foods and Beyond Meat.

The USCA offers no direct evidence of consumer confusion (*e.g.*, consumer polling data). Instead, the group argues that these products do not meet either the dictionary definition or consumer expectations for products labeled "beef" and "meat," and it suggests that there is "facial confusion" among consumers based on recent articles and advertisements touting the similarities of certain plant-based alternative proteins to traditional meat.

II. Alternative Proteins and Traditional Meat

We generally support federal oversight of both the manufacturing and labeling of alternative proteins, to ensure that they are safe and to avoid any risk of consumer confusion. Alternative proteins can be attractive to consumers for a variety of reasons, including perceived benefits for the environment, animal welfare, and personal health. Traditional meat may be attractive for different reasons, including familiarity and taste. Therefore, while we do not support the current petition for the reasons we lay out below, we do believe that it is important for consumers to be able to easily distinguish alternative proteins from each other and from traditional meat in the food marketplace.

Nutrient Profiles

Alternative proteins often have different nutrition profiles than traditional meat, including different levels of protein, iron, vitamin B-12, sodium, saturated fat, cholesterol, and fiber. Some products, like the Beyond Burger, are similar in protein content and lower in saturated fat and cholesterol than traditional meat.[3] But grain-based burgers are typically lower in protein and higher in carbohydrates and fiber than traditional meat. In addition, many alternative proteins come pre-seasoned, which can often mean that they are higher in sodium than unseasoned traditional meat. Consumers should be able to recognize that they are purchasing a product that is different from traditional meat, understand its nutrition profile, and select a protein that meets

[2] U.S. Department of Agriculture, Food Safety and Inspection Service. Food standards and labeling policy book. August 2005.
[3] Moyer L, Liebman B. How now brown cow, *Nutrition Action Healthletter*. November 2017.

their dietary needs or desires.

Foodborne Pathogens and Novel Ingredients

Distinctions may also be important for food safety reasons. The undersigned groups have supported more stringent controls to protect consumers from pathogens on meat and poultry. For example, CSPI has twice unsuccessfully petitioned for a ban on selling traditional meat and poultry contaminated with antibiotic-resistant *Salmonella*.[4] The FSIS still permits meat to be sold with these pathogens, along with numerous other disease-causing bacteria (the sole exception being a ban on certain pathogenic *E. coli* in ground beef[5]). A zero-tolerance standard for such pathogens is potentially more readily achievable for alternative proteins, which could in turn reduce the risk of foodborne illness with those products.

At the same time, alternative proteins manufactured from plants, insects, or fungi may also contain novel proteins or other ingredients with potential food safety risks. For example, CSPI recently brokered, by way of objection to a proposed class settlement, an agreement that will require Quorn Foods to provide a warning on the label of its alternative protein products stating that the products are comprised predominately of mold, and that such mold has caused allergic reactions in the past.[6] Consumption of insects has also led to allergic reactions, which may be more likely in people with a crustacean shellfish allergy.[7] Currently, FDA requirements for allergen labeling are generally limited to the so-called "Big Eight" most prevalent allergens, and do not cover mold, insects, or other novel proteins.[8]

In addition, the FDA recently requested additional safety data to assess whether the manufacturer's determination that an apparently novel protein known as "soy leghemoglobin"[9] —an ingredient in the Impossible Burger—is "generally recognized as safe," or GRAS, is based on sufficient science. The undersigned groups have long advocated that the FDA directly review these and other new food additives for safety before they are marketed in foods. The use of a GRAS notification or self-determination process is inappropriate for novel ingredients as they typically lack a history of safe use in the food supply or adequate published and well-evaluated safety data.[10] We also believe that consumers have a right to know when they consume products containing such additives, and that shortcuts like the use of the GRAS designation will only

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[4] U.S. Department of Agriculture, Food Safety and Inspection Service. Petitions. www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions. Accessed May 17, 2018.

[5] U.S. Department of Agriculture, Food Safety and Inspection Service. USDA targeting six additional strains of E. coli in raw beef trim starting Monday. May 31, 2012. www.usda.gov/media/press-releases/2012/05/31/usda-targeting-six-additional-strains-ecoli-raw-beef-trim-starting. Accessed May 17, 2018.

[6] Center for Science in the Public Interest. Labels on Quorn meat substitutes to make products' mold content more prominent. September 6, 2017. https://cspinet.org/news/labels-quorn-meat-substitutes-make-products-mold-content-more-prominent-20170906. Accessed May 17, 2018.

[7] Ribeiro JC, Cunha LM, Sousa-Pinto B, Fonseca J. Allergic risks of consuming edible insects: a systematic review. *Mol. Nutr. Food Res.* 2018;62(1):1700030. https://onlinelibrary.wiley.com/doi/full/10.1002/mnfr.201700030.

[8] Food and Drug Administration. Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers. December 12, 2005; Updated July 18, 2006. www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm. Accessed May 17, 2018.

[9] Quora. How the 'Impossible Burger' revealed some disturbing FDA practices. August 31, 2017. www.forbes.com/sites/quora/2017/08/31/how-the-impossible-burger-revealed-some-disturbing-fda-practices/. Accessed May 17, 2018.

[10] Center for Science in the Public Interest. Groups sue FDA to protect food safety. May 22, 2017. https://cspinet.org/news/groups-sue-fda-protect-food-safety-20170522. Accessed May 17, 2017.

undermine consumer confidence in meat alternatives.

III. Consumer Confusion

While we generally agree that consumers have the right to clear information about what they are eating, most of the advertising and labeling for alternative protein products is non-misleading and will not result in consumer confusion. Indeed, such confusion would generally be counterproductive for manufacturers of alternative proteins, since consumers of those products are often motivated by a desire to avoid traditional meat. The terms "meat" and "beef" are therefore typically used in a context that readily distinguishes these products from traditional meat. Such marketing represents healthy competition between industries and should not be discouraged by a sweeping restriction on the use of specific words.

The USCA argues that both the dictionary definition of and consumer expectations for products labeled "beef" and "meat" could not include alternative proteins. While various dictionaries also offer a definition of "meat" that encompasses food of any kind (including plant tissues), it is true that many consumers today typically understand the terms "meat" and "beef" to describe animal flesh when used in isolation.[11] Yet the marketing and labeling of alternative proteins does not typically use these terms alone, but instead includes additional modifying terms that allow consumers to readily distinguish these products from traditional meat. For example, it would be rare to find a consumer who could not readily distinguish between a "veggie" burger and a ground beef patty, or tell the difference between a "meatless" meatball and a meatball made of pork and/or beef, or a "tofu" hot dog and a hot dog made of beef.

The USCA makes much of the fact that plant-based products like the Impossible Burger and Beyond Burger have been touted for their similarity to beef. They claim that this results in "facial confusion." But merely describing similarities between two products does not prove that consumers will confuse the two. That would be like saying that the plant-based spread I Can't Believe It's Not Butter causes "facial confusion" because consumers read the name and determine that the product is, in fact, butter. If anything, such comparisons have the opposite effect: they establish that the two products being compared are not actually the same thing.

Even so, there may be a small fraction of the marketing for alternative proteins that runs a risk of unnecessarily generating consumer confusion. Any potential for confusion in such cases comes not from use of the terms "meat" or "beef" to describe the alternative protein, but from the lack of additional clarifying context. For example, the USCA petition cites the website of Impossible Foods, whose page describing the Impossible Burger includes the prominent phrase "For the Love of Meat" and an image of stacked red patties that are visually indistinguishable from ground beef.[12] Consumers would have to scroll down to the next image to learn that these patties are actually "The Burger Formerly Known as Plants." The website is potentially misleading because the clarifying context is one step removed: consumers should not have to take an additional action (e.g., flipping a package over to view the back) to understand important information about the identity of a product.

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[11] We note that there is an archaic meaning of "meat," still recognized in dictionaries, that more broadly encompasses food of any kind, including nuts and other plant tissues. *See, e.g.,* definition of "meat." www.merriam-webster.com/dictionary/meat. Accessed May 9, 2018. ("Food; especially: solid food as distinguished from drink.")

[12] Impossible. www.impossiblefoods.com/burger. Accessed May 17, 2018.

The remedy in such cases (administered by the FDA or FTC, as we discuss below), would not be to prevent the use of the terms "beef" and "meat" for alternative proteins, but instead to provide the appropriate context when they are used. 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."[13] Similar clarifying language could be added to the webpage describing the Impossible Burger to avoid the risk of consumer confusion.

This is precisely the approach that the FDA recently took with respect to the vegan product Just Mayo, in an enforcement action cited by the USCA in its petition. Following complaints from competitors, the FDA issued a warning letter to Hampton Creek Foods stating that the name and imagery on the labels of the company's plant-based Just Mayo could lead consumers to confuse the product with standard egg-based mayonnaise.[14] Hampton Creek was subsequently able to resolve the FDA's concern by amending its labels to make it clearer that the product is egg-free.[15] To be clear, the FDA did not prohibit the use of the term "mayo" or require the product to be renamed in that case. Similarly, the terms "beef" and "meat" should not be prohibited on alternative plant-based proteins in this case.

IV. Lack of USDA Authority

Even assuming that the USCA has a legitimate concern with particular marketing by a competitor, the FSIS lacks the authority to take action. (In other words, the USCA has taken its "beef" to the wrong agency.)

The FSIS's authority under the Federal Meat Inspection Act (FMIA) applies only to food derived from animals, not plant-based products like the Impossible Burger and Beyond Burger, irrespective of how closely these products mimic traditional meat. Even if the FSIS were to grant the USCA petition and limit the definition of the terms "beef" and "meat" in its labeling guidance, such action would have little effect beyond preventing one FSIS-regulated product from passing itself off as another. (For example, a pork- or lamb-based product could not call itself "beef.") Therefore, if the USCA wishes to correct any potentially misleading marketing for plant-based alternative proteins, it should request action from the FDA and/or the FTC, the agencies that share oversight over the labeling and marketing of these products.

The FSIS's authority over cultured meat is unclear, largely because this type of product has not yet been made available commercially. Any petition with respect to the labeling of such products is therefore premature. At a minimum, the FDA and USDA should coordinate and determine which agency or agencies will have jurisdiction over cultured meat before either agency turns to the thorny question of how such products may be labeled.

The language of the Federal Meat Inspection Act is ambiguous with respect to cultured meat. It

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[13] Beyond Meat. http://beyondmeat.com/products/view/beyond-burger. Accessed May 17, 2018.
[14] Food and Drug Administration. Warning Letter to Hampton Creek Foods, August 12, 2015. www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm458824.htm. Accessed May 17, 2018.
[15] Strom S. F.D.A. allows maker of Just Mayo to keep product's name. December 17, 2015. www.nytimes.com/2015/12/18/business/fda-allows-maker-of-just-mayo-to-keep-products-name.html. Accessed May 17, 2018.

expressly covers "any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, *excepting* products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry."[16] While cultured meat is grown from cells harvested from animals, the portion of such cells that would remain present in any marketed product would likely be minuscule.

In addition, the FSIS regulatory framework for inspecting traditionally slaughtered meat focuses on controlling risks during the slaughter process, particularly risks of foodborne illness due to fecal contamination and animal disease. Such a regulatory framework may or may not be appropriate for cultured meat, which would be manufactured in a manner that does not involve animal slaughter and therefore entails a different set of risks.

By contrast, the FDA has more experience regulating manufactured foods and approving new technology, and also understands manufacturing processes that rely on cell culture through its regulation of biological products. However, as we stated above, we have serious concerns about the safety of products reviewed under the FDA's GRAS notification or self-determination process, and would oppose these products being marketed under FDA authority unless they undergo premarket approval as food additives.

At a minimum, any decision regarding which agency would regulate cultured meat should be hashed out as an initial step before either agency begins drafting rules on how such products might be labeled. Policy in this newly emerging field should be carefully considered, with expertise from both agencies and guided by science and public health. It should not be undertaken by a single agency in response to political pressure by members of a competing industry.

V. Recommendations

Accordingly, the FSIS should deny the USCA petition to define the terms "beef" and "meat." If the FSIS does act to influence the labeling of alternative proteins, we urge that the agency do so by notice-and-comment rulemaking, rather than by amending a guidance on food labeling. Such public rulemaking is needed to allow for appropriate transparency and public input.

Any resulting rule should be targeted to prevent potentially confusing or misleading labeling claims, rather than to favor the interests of one industry over another by arbitrarily restricting the use of specific terms.

In considering labeling for particular products, the agency should account for appropriate context, including any additional text and graphics on the label. The nature of the product should be immediately apparent to consumers, without requiring additional action (such as turning over the package to review the back panel or consulting the Internet).

Finally, while not an issue raised in the USCA petition, any marketing or labeling that states or implies benefits for health or the environment should be non-misleading and should be substantiated by accurate information. For example, should "clean meat" become commercially

[16] 21 U.S.C. 601(j)(emphasis added).

available, claims like "clean from bacteria"[17] should be substantiated by a zero-tolerance standard for *Salmonella*, *Listeria*, and other foodborne pathogens. Likewise, environmental claims like "cleaner for the environment"[18] should be supported by evidence of environmental benefits.

Thank you for the opportunity to comment on this petition.

Sarah Sorscher, J.D., M.P.H.
Deputy Director of Regulatory Affairs
Center for Science in the Public Interest

Thomas Gremillion, J.D.
Director, Food Policy Institute
Consumer Federation of America

[17] The Good Food Institute. "Clean meat": the "clean energy" of food. September 6, 2016. www.gfi.org/clean-meat-the-clean-energy-of-food. Accessed May 17, 2018.
[18] *Ibid.*