



September 24, 2018

Dr. Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-2155 for “Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments.”

Dear Commissioner Gottlieb:

On behalf of the nearly 200,000 family farmer, rancher, fisher and rural members of National Farmers Union (NFU), I am pleased to submit comments regarding “Foods Produced Using Animal Cell Culture Technology.”

NFU’s member-driven policy states “We oppose...labeling alternative protein sources as meat.”¹ We are concerned by the recent introduction of foods composed of alternative protein sources that are being labeled and marketed as “meat.” Of particular concern is the development of food products that are grown in laboratories using animal cells. These products are not derived from animals born, raised, and harvested in a traditional manner, and should not be permitted to be marketed as “meat.”

Because of rapidly evolving technologies such as animal cell culture applications, NFU urges establishment and clarification of the standard of identity for “meat” and related products to prevent mislabeling of food in the marketplace. Existing labeling and marketing laws should be consistently enforced and regulations should be updated to promote fair competition for producers and the health and safety of consumers.

¹ National Farmers Union, *Policy of the National Farmers Union*, (March 2018), henceforth “NFU Policy.”

I. Background

On April 9, NFU submitted comments to the United States Department of Agriculture (USDA) Food Safety and Inspection Services (FSIS) in support of Petition 18-01. In that letter, we argued that the definition of “meat” should be restricted “to the tissue or flesh of animals that have been harvested in the traditional manner.”² We also supported restricting the definition of “beef” to products deriving from cattle that are born, raised, and harvested in a traditional manner and urged consistent application of those standards across meat products.

FDA has stated that it is also required to regulate “both substances used in the manufacture of these products of animal cell culture technology and the products themselves that will be used for food” under the Federal Food, Drug, and Cosmetic Act (FFDCA).³ FDA also has food safety regulatory authorities under the Food Safety Modernization Act.

Given FDA’s prospective role in regulating these products, NFU urges consistent application of the principles outlined in Petition 18-01⁴ across agencies and products derived from animal cell culture technology.

II. Marketing and labeling of food produced using animal cell culture technology

NFU policy supports “thorough and accurate food labels as an important tool that helps consumers make informed decisions and allows producers to differentiate their products. We support conspicuous, mandatory, uniform, and federal labeling for food products throughout the processing chain to include all ingredients, additives, and processes” including “requiring any laboratory or artificially produced products to be labeled as such.”⁵

Furthermore, it is NFU policy that “The common names given to meat and animal products... are widely understood by consumers to be the tissue and flesh of animals that have been slaughtered for food.”⁶ Foods produced using animal cell culture technology are not slaughtered, but rather are derived from animal cells grown in a petri dish and other growing media. Thus, NFU opposes labeling of foods produced using cell culture applications as “meat” and as related products such as “beef,” “poultry” and “seafood.”

FDA has the responsibility under the Federal Food, Drug and Cosmetic Act (FFDCA) to deem a food “misbranded” if “its labeling is false or misleading in any particular... if it is offered for sale under the

² National Farmers Union. “Letter in Support of the February 9, 2018 Petition to Establish Beef and Meat labeling Requirements: To Exclude Product Not Derived Directly from animals Raised and Slaughtered from the Definition of ‘Beef’ and ‘Meat’ filed by the United States Cattlemen’s Association (USCA); Petition 18-01.” April 9, 2018.

³ “Food Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments.” <https://www.regulations.gov/document?D=FDA-2018-N-2155-0001>

⁴ United States Cattlemen’s Association (USCA). “Petition for the imposition of beef and meat labeling requirements: to exclude product not derived directly from animals raised and slaughtered from the definition of ‘beef’ and ‘meat’.” February 9, 2018.

⁵ NFU Policy.

⁶ National Farmers Union, *2018 Special Order of Business*, “Family Farming and Livestock Production.”

name of another food” or “if it is an imitation of another food.”⁷ Labeling foods produced using animal cell culture technology as “meat” and other related products is “false and misleading.”

Given rapidly evolving technologies, NFU believes the standard of identity for “meat” and related products should be properly established and clarified to prevent mislabeling of food products in the marketplace. FDA, USDA-FSIS, and other authorities should consistently enforce existing labeling and marketing laws and update regulations to promote fair competition for producers and the health and safety of consumers.

III. Industry Consolidation

Inadequate market competition is a pressing issue facing agricultural producers across the country. The number of family farms has declined significantly over the past several decades⁸, in part due to increasing horizontal and vertical integration in the agriculture and food sector. Independent producers cannot succeed in the absence of protection from unfair, anti-competitive practices.

As reported, major meat packers and processors such as Tyson Foods and Cargill have invested in cell-cultured, lab-grown animal protein products.^{9 10} These companies are implicated in the consolidation of the food and farm economy over the last several decades. The three largest firms globally in 2017 included JBS of Brazil, WH Group (Smithfield) of China and Tyson of the United States. In the U.S. market, these three companies control 63% of pork packing, and just two (Tyson and JBS) control 46% of beef packing and 38% of poultry. Cargill, headquartered in the U.S., is among the top ten meat processors globally and was ranked third in beef processing with a 19% market share in 2017.¹¹

Tyson and Cargill have invested considerable resources in cell-cultured product companies to date. Tyson participated in a \$55 million funding round for a cell cultured protein startup in December 2017¹² and a \$2.2 million funding round in May 2018.¹³ Tyson also invested in at least one additional cell cultured protein startup in January 2018, but the terms of the deal were not disclosed.¹⁴ Cargill announced in August 2017 that it participated in a \$17 million funding round in concert with a group of individuals and firms.^{15 16}

⁷ 21 U.S. Code § 343(a)-(c).

⁸ “The number of farms has leveled off at about 2.05 million.” USDA-ERS. July 26, 2018. <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58268>

⁹ Sarah Zhang. “The Farcical Battle Over What to Call Lab-Grown Meat.” *The Atlantic*. July 13, 2018. <https://www.theatlantic.com/science/archive/2018/07/lab-grown-meat/565049/>

¹⁰ Helena Bottemiller Evich. “Welcome to the turf battle over lab-grown meat.” *Politico*. June 15, 2018.

¹¹ Phil Howard. “Consolidation in global meat processing.” June 21, 2017. <https://philhoward.net/2017/06/21/consolidation-in-global-meat-processing/>

¹² Amanda Little. “Tyson isn’t chicken.” *Bloomberg*. August 15, 2018. <https://www.bloomberg.com/news/features/2018-08-15/tyson-s-quest-to-be-your-one-stop-protein-shop>

¹³ Adele Peters. “Lab-grown meat is getting cheap enough for anyone to buy.” *Fast Company*. May 2, 2018. <https://www.fastcompany.com/40565582/lab-grown-meat-is-getting-cheap-enough-for-anyone-to-buy>

¹⁴ Chloe Sorvino. “Tyson invests in lab-grown protein startup Memphis Meats, joining Bill Gates and Richard Branson.” *Forbes*. January 29, 2018. <https://www.forbes.com/sites/chloesorvino/2018/01/29/exclusive-interview-tyson-invests-in-lab-grown-protein-startup-memphis-meats-joining-bill-gates-and-richard-branson/#260346263351>

¹⁵ Jacob Bunge. “Cargill Invests in Startup That Grows ‘Clean Meat’ From Cells.” *Wall Street Journal*. August 23, 2017. <https://www.wsj.com/articles/cargill-backs-cell-culture-meat-1503486002>

¹⁶ “Protein innovation: Cargill invests in cultured meats.” *Cargill*. August 23, 2017. <https://www.cargill.com/story/protein-innovation-cargill-invests-in-cultured-meats>

Consolidation in the beef, pork and poultry industries has diminished family farmers' and ranchers' market share. Lab grown products are likely to be produced by large companies, including the major global meatpackers, exacerbating the anti-competitive practices facing family farmers and ranchers and the rural communities in which they live. Fairly and accurately labeling animal cell culture products would provide some protection for family farmers' and ranchers' market share.

IV. Conclusion

Thank you for the opportunity to submit comments on "Foods Produced Using Animal Cell Culture Technology." It is critical that a clear standard of identity for "meat" and related products is established and that this standard is implemented consistently across the federal government.

If you have any questions or would like to further discuss NFU's position on animal cell culture technology, please contact Aaron Shier, NFU's Government Relations Representative, via e-mail at ashier@nfudc.org or by phone at 202-554-1600. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Roger Johnson". The signature is fluid and cursive, with the first name "Roger" and last name "Johnson" clearly distinguishable.

Roger Johnson
President