FDA STATEMENT

Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner Anna Abram on emerging food innovation, "cultured" food products

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Food safety is at the core of the agency's mission to protect and promote public health for our nation's consumers. We take seriously our commitment to the consumers and industry who look to the FDA for important guidance when it comes to our nation's food supply, including the pathway for bringing forward safe, emerging food innovations. A key part of our mission is helping enable innovation and technological advances in the food sector, ensuring the safety of the products. As part of this mission, the FDA is constantly evaluating new areas of food innovation and establishing guidelines on how new technology can safely advance. One such area is the development of products that are intended to resemble conventional meat, poultry and seafood. These "cultured" products are generally made from cells collected from animals that are multiplied using non-traditional food technologies. These technologies could offer certain new opportunities over conventionally developed food products.

The use of animal cell culture technology as a method of food production and manufacturing raises many important considerations from a technical and regulatory perspective. In order to help foster dialogue regarding these emerging food technologies, and the considerations they raise, today the FDA announced a public meeting (https://www.federalregister.gov/documents/2018/06/18/2018-12939/meetings-foods-produced-using-animal-cell-culture-technology) to discuss the opportunities and challenges of this new space.

Under the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over "food," which includes "articles used for food" and "articles used for components of any such article." Thus, as a starting point, both substances used in the manufacture of these products of animal cell culture technology and the products themselves that will be used for food are subject to the FDA's jurisdiction.

This is a dynamic space that's gaining interest among companies for various reasons, including appealing to consumers motivated by animal welfare concerns and commercial incentives, including environmental impact, for replacing traditional animal-derived materials for non-animal derived components. At the same time, the technological considerations for these products are complex and evolving.

We expect that most or all starter cells for food applications will come from living animals for the foreseeable future for commercial and marketing reasons. While currently, animal cells can be produced from the starter cells in bioreactors (a scaled-up application of traditional cell culture techniques) businesses are also working to commercialize processes by which cells can be cultured using biocompatible scaffolding or other techniques to permit the formation of complex tissues, similar to strategies being explored for therapeutic organ or tissue replacement.

In either case, a significant technical challenge with respect to the use of animal cell culture technology to develop foods intended to resemble conventional meat, poultry and seafood products involves the development of the growth medium used to multiply the cells and ensure that they differentiate into the correct cell types. Finally, after creation, both suspension-cultured (unstructured) and scaffold-cultured (structured) products would be further processed using traditional food manufacturing processes that fall under FDA regulations such as the Food Safety Modernization Act's preventive controls framework.

The FDA has a long history of ensuring food safety and applying our statutory framework while supporting rapidly evolving areas of technological innovation in food. The agency currently evaluates microbial, algal and fungal cells generated by large-scale culture and used as direct food ingredients. The agency administers safety assessment programs for a broad array of food ingredients, including foods derived from genetically engineered plants, and also manages safety issues associated with cell culture technology in therapeutic settings. In addition, the FDA manages the potential risks associated with the processing, manufacture and packaging of many foods, including most seafood products. The FDA remains committed to using our expertise in relevant scientific areas to evaluate the safety of emerging food technologies, such as foods generated by animal cell culture technology. But as we mentioned, in addition to leveraging the existing expertise of our staff, we're also investing in making sure we are considering all the unique attributes and challenges of this specific area.

The July 12 meeting will provide an important opportunity for the FDA to share our experiences in evaluating and ensuring the safety of novel technologies in the food sector. We will share our initial thinking for how we intend to appropriately apply our existing regulatory tools and policies to this novel area of technology. The forum will also provide an opportunity to discuss with stakeholders potential benefits and challenges of developing and regulating these products.

While the primary focus of the meeting is food safety, and we encourage stakeholders to share their information and data, we also want to have a dialogue around other areas of interest related to foods produced through animal cell culture technology, such as labeling. Our intent is to engage in a public discussion on this evolving technology to ensure we understand and consider all aspects as we determine the FDA's approach to these novel products. In addition, we plan to leverage the expertise of the FDA Science Board during their regularly scheduled meeting in October to further inform our efforts.

As this field continues to advance, it will be important for the FDA to provide timely information to consumers and industry given the agency's expertise and role in advancing food safety. The FDA is committed to working with stakeholders to foster innovation while ensuring the safety of our nation's food supply. We look forward to this upcoming public meeting and the continued dialogue in gathering information and exchanging ideas about this new sector and possibilities for innovations on behalf of consumers.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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