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IT'S GETTING HOT IN HERE: FDA CLEARS FOOD PRODUCTS FROM GENE-EDITED HEAT TOLERANT BEEF CATTLE

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On March 7, 2022, the U.S. Food and Drug Administration ("FDA") announced its "low-risk determination" to clear the marketing of food products derived from beef cattle that have been genetically altered to be more tolerant of hot weather. The director of the FDA's Center for Veterinary Medicine ("CVM") said that the "decision underscores our commitment to using a risk and science-based, data-driven process that focuses on safety to the animals and safety to the people who eat the food produced by these animals." The FDA's low-risk determination is the first use of its enforcement discretion for intentional genomic alterations ("IGAs") in animals for food use.

IGAs in animals are regulated by the FDA as animal drugs under section 201(g) of the Food, Drug and Cosmetic Act ("FD&C Act"), because such IGAs are "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The animal itself is not regulated by the FDA, but instead the regulated article is the specific gene cassette and alteration sequence, including the specific genome site where the insertion, substitution, or deletion occurs. A new animal drug is "deemed unsafe" unless the FDA has approved a new animal drug application ("NADA") for its intended use. Food derived from an animal using an unsafe new animal drug is considered to be "adulterated" under section 501(a)(5) of the FD&C Act. Accordingly, the use of IGAs in animals has generally first required FDA approval of a NADA. The FDA approved the first such NADA for a food-producing animal in 2015—the AquaAdvantage Salmon, an Atlantic salmon genetically engineered to grow faster.

In 2017, the FDA issued draft revised guidance #187—Regulation of Intentionally Altered Genomic DNA in Animals. This draft revised guidance clarified the FDA's approach to the regulation of IGAs in animals. The FDA reinforced its position that animals with IGAs are subject to premarket approval requirements based on the risks they pose. However, the FDA clarified that it may exercise enforcement discretion regarding the NADA requirements "[b]ased on evaluation of risk factors." The FDA further clarified by stating that "it may exercise enforcement discretion on a case-by-case basis if, after a risk-based review, it determines that the product or category of products is low risk to humans, animals and the environment." To date, the FDA has exercised enforcement discretion through low-risk determinations for IGAs in animals, but only for non-food uses. The FDA has also approved many IGAs in animals for food uses, such as goats, chicken, salmon, rabbit, and pigs, but

only through the formal NADA process. The FDA's low-risk determination for gene-edited beef cattle is the first determination of its kind for an IGA in an animal for food use.

The beef cattle at issue are genetically altered using the clustered regularly interspaced short palindromic repeats (CRISPR) gene-editing technique. This introduces a trait expression for an extremely short, slick-hair coat, which allows the cattle to better withstand hot weather. The FDA confirmed that the IGA utilized here was "equivalent to naturally occurring mutations that have arisen in several breeds of cattle as an adaptation to being raised in tropical or subtropical environments." Moreover, it determined that "the food from the cattle is the same as food from conventionally bred cattle that have the same slick-hair trait."

The director of CVM touted the determination as "demonstrate[ing] our ability to identify low-risk IGAs that don't raise concerns about safety, when used for food production." He further echoed the hope that FDA's determination "will encourage other developers to bring animal biotechnology products forward for the FDA's risk determination in this rapidly developing field, paving the way for animals containing low-risk IGAs to more efficiently reach the marketplace."

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