

BEEF BUSINESS

by Julie Mais, editor

In this month's "Beef Business," we present the FDA's first low-risk determination for enforcement discretion for an intentional genomic alteration in an animal for food use.

FDA Low-Risk Determination for Marketing of Products from Genome-edited Beef Cattle

The U.S. Food and Drug Administration (FDA) announced March 7 it has made a low-risk determination for the marketing of products, including food, from two genome-edited beef cattle and their offspring after determining the intentional genomic alteration (IGA) does not raise any safety concerns (low-risk determination).

The IGA results in the equivalent genotype (genetic makeup) and short-hair coat trait seen in some conventionally bred cattle, known as a "slick" coat. This is the FDA's first low-risk determination for enforcement discretion for an IGA in an animal for food use.

"Today's decision underscores our commitment to using a risk and science-based, data-driven process that focuses on safety to the animals containing intentional genomic alterations and safety to the people who eat the food produced by these animals," said Steven M. Solomon, director of the FDA's Center for Veterinary Medicine.

Based on the agency's review of scientific data, the FDA has determined the product is low-risk and does not raise any safety concerns, and the FDA does not

expect the product developer of the IGA to pursue the FDA's approval prior to marketing (enforcement discretion). To date, the FDA has made low-risk determinations for enforcement discretion for many other IGAs in animals for non-food uses and also has approved applications for five IGAs: in groups of goat, chicken, salmon, rabbit and, most recently, a line of pigs.


IGAs are alterations made using molecular technologies that introduce changes to the genome of an animal. The IGA in these cattle, known as PRLR-SLICK cattle, was introduced using a genome-editing technique known as CRISPR (clustered regularly interspaced short palindromic repeats). The IGA can be passed on to offspring, allowing the trait to be shared through conventional breeding. There are conventionally bred cattle with naturally occurring mutations that result in the same extremely short, slick-hair coat. Reports in scientific literature indicate cattle with this extremely short, slick-hair coat are potentially able to better withstand hot weather. Cattle that are comfortable in their environment are less likely to experience temperature-related stress and may result in improved food production.

Although PRLR-SLICK cattle have an equivalent trait to those cattle

with a naturally occurring short hair coat, they are not currently in commerce. The product developer plans to use the genetic products from these two animals with select customers in the global market soon, and anticipates meat products will be available for purchase by general consumers as early as two years.

The FDA reviewed genomic data and other information submitted by the product developer confirming the IGA in genome-edited PRLR-SLICK cattle is equivalent to naturally occurring mutations that have arisen in several breeds of cattle as an adaptation to being raised in tropical or subtropical environments.

The data also confirmed the IGA results in the same slick-hair trait as in cattle found in conventional agricultural settings. Further, the food from the cattle is the same as food from conventionally bred cattle that have the same slick-hair trait.

The FDA does not expect farms or facilities not owned or operated by the developer that are producing and breeding these low-risk PRLR-SLICK cattle using conventional breeding techniques to register with the agency. The low-risk determination was provided to Acceligen. 

Source: FDA