

June 19, 2017

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

**Re: Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry
Docket FDA-2008-D-0394-0279**

Dear Ms. Epstein:

The undersigned 16 farmer, consumer, public health, environmental and public interest organizations, and businesses submit this letter on the Food and Drug Administration (FDA)'s proposed draft guidance for industry about genetically engineered animals.

Animals modified with genetically engineered DNA are currently reviewed using regulations designed for new animal drugs, not new genetically engineered animals. Last year, the FDA approved genetically engineered salmon using its outdated animal drug rules. The lack of regulations specific to GE animals facilitates the FDA overlooking major scientific concerns about environmental contamination, surprise toxins as a result of genetic engineering, unpredictable genetic responses and other unintended consequences.

The FDA is currently being sued for its inadequate review of the endangered species, environmental safety and inadequate regulations for oversight of the GE salmon called AquAdvantage. The FDA should suspend all GE animal reviews until the courts rule on the lawsuit.

The FDA needs mandatory regulations for all genetically engineered animals, corporate liability, and full health and environmental assessments.

We believe FDA should not approve any genetically engineered animals while the GE salmon lawsuit is in process, and the FDA should draft new legally binding regulations for all genetic engineering techniques for animals, including new synthetic biology and gene editing techniques.

The FDA should develop regulations that would:

1. Provide clear definitions of genetic engineering which adhere to the WHO/UN Food and Agriculture Organization's CODEX definitions of modern biotechnology. Some companies claim that the "modern breeding" techniques are not genetic engineering, but if they fall under the CODEX definition, they must be regulated as genetically engineered (GE).
2. Enact a moratorium on approvals of GE animals while the GE salmon lawsuit is in process.
3. Enforce mandatory regulations requiring safety testing for all organisms and animals that are developed using any genetic engineering processes. These should be independent tests that assess and regulate all risks, including long-term safety risks for the animals and consumers, and direct and indirect environmental harms. Instead of assuming GE animals are safe until proven harmful, government agencies should not approve or commercialize GE animals unless proven safe. Safety must be the top priority, not commercialization.
4. Require Full Environmental Impact Statements for all genetically engineered animals, including those engineered with so called "gene editing" technologies.

5. Enforce mandatory labeling of food and animals developed through any genetic engineering processes, including so called “gene drives and gene editing.” Polls are clear that Americans want to know if their food and other products have been genetically engineered.
6. Manufacturer liability for manufacturers and biotech companies that make and sell GE animals. The biotech company that made the genetically engineered product must be held liable for significant harm and costs from contamination for non-GE farmers.

Until these principles are implemented in mandatory regulations, FDA should halt the approval, commercialization, and release of any new genetically engineered animals.

Signed,

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