

ANIMAL BIOTECH

ANIMAL BIOTECHNOLOGY

Animal Biotechnology is the use of molecular biology techniques to modify the genome of animals in order to improve their health, well-being, agricultural production, and protection against diseases. More recently, genome editing technologies (Zinc Finger Nucleases, TALENS, and CRISPR-Cas systems) have opened up new opportunities to easily create genetic variations in animals that can easily be obtained through conventional genetic selection and breeding.



Key Points

- Biotechnology plays a critical role in meeting a number of producer, consumer, and societal needs;
- Animal Biotechnology is currently being regulated as an “animal drug” under FDA authority granted by the Federal Food and Drug Cosmetic Act (FFDC);
- Each specific genomic alteration is considered to be a separate new animal drug subject to new animal drug approval and requirements;
- FDA is currently reviewing “Guidance for Industry 187”, which describes the process the FDA will take in regulating biotechnology-derived animals;
- Not a single food animal derived from biotechnology is currently available in the United States. To date AquAdvantage Salmon is the only animal biotechnology food product approved in the United States and sold in Canada

Our Message

NASDA urges a concerted effort by federal and state agency partners, as well as impacted stakeholders, to ensure that animal biotechnology products are approved in a timely manner, while supporting and encouraging education to consumers to increase understanding and acceptance of the technology.

NASDA supports the Coordinate Framework principles that guide federal regulatory policy for biotechnology:

- Federal oversight should focus on the characteristics and risks of the product, not the process, used in its development;
- Regulatory review should be designed to minimize burden while ensuring protection of public health and welfare;
- Regulatory programs should be responsive to rapid advances in biotechnology.



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