GENETICALLY MODIFIED ANIMALS: HOW SCIENCE SURPASSED THE LAW

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ABSTRACT

Genetic modification is deeply rooted in modern American agriculture. What started with barely noticeable mutations in mice has evolved to precisely editing traits for animal welfare and economic productivity. Animals bred for disease resistance, reproductive performance, and growth enhancement are just the tip of the iceberg in the twenty-first century. But regulations for modifying animals have lagged behind the leaps in the science for decades. While the FDA handles genetically modified crops like a well-oiled machine, investors looking to introduce animals to the market must clear higher hurdles. The risk in pushing for advancements in animals has seemingly stunted the United States' position globally. Other countries with more efficient regulatory schemes continue to introduce new product, while American products face market failures stemming from development times and other issues. This Note will detail the history of genetic modification technology, the abundance of potential applications in a variety of species, and suggest a reworking of the FDA's current regulations to catch up with the rest of the world.

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I. INTRODUCTION

On July 1, 2023, a Nelore cow named Viatina-19 sold for $4 million at auction in Brazil.[1] Viatina-19 weighed nearly twice as much as most adult Nelores, and shattered the record for the highest selling price for a cow at auction.[2] The aptly titled "supercow" has the potential to revolutionize the global beef market.[3] Rights for samples of her egg cells alone are worth around $250,000, and Viatina-19's owner hopes to export those cells to various regions, including the United Arab Emirates, India, and the United States.[4] Currently, Brazil leads the world in both beef exports and cattle genetics, generating billions of dollars in revenue, while conducting the highest number of in-vitro fertilizations in cows.[5]

Viatina-19, and other selectively bred animals like her, are examples of genetically modified organisms (GMOs).[6] The FDA defines a GMO as "a plant, animal, or microorganism that has had its genetic material (DNA) changed using technology that generally involves the specific modification of DNA."[7] One common form of DNA modification is known as gene editing, a process in which part of a DNA sequence is either deleted or changed.[8] A similar modification process, genetic engineering, adds new DNA from other sources in addition to removing or changing the original sequence.[9] In general, most countries treat genetically engineered organisms more harshly than genetically edited ones, subjecting genetically engineered organisms to strenuous regulatory schemes.[10]

1. David Biller, *She's the World's Most Expensive Cow, and Part of Brazil's Plan to Put Beef on Everyone's Plate*, ASSOCIATED PRESS (June 3, 2024, at 23:01 CT), https://apnews.com/article/brazil-cow-cattle-breeding-zebu-nelore-amazon-deforestation-9d58844f3e695ce878da838c10280f0d [https://perma.cc/KTG5-EK6X].

2. *Id.*

3. *See id.*

4. *Id.*

5. *Id.*

6. *See Genetically Modified Organism (GMO)*, NAT'L HUM. GENOME RSCH. INST. (Jan. 24, 2026), https://www.genome.gov/genetics-glossary/Genetically-Modified-Organism-GMO [https://perma.cc/TY9L-Z6HJ].

7. *Agricultural Biotechnology*, U.S. FOOD & DRUG ADMIN. (July 9, 2024), https://www.fda.gov/food/consumers/agricultural-biotechnology [https://perma.cc/FTD5-3HCJ].

8. Karen Steward, *Genetic Modification Techniques and Applications*, TECH. NETWORKS (Jan. 4, 2024), https://www.technologynetworks.com/genomics/articles/genetic-modification-techniques-and-applications-382001 [https://perma.cc/85XY-HE8K].

9. *Id.*

10. *Id.*

The FDA has historically treated genetically modified crops more favorably than genetically modified animals.[11] Since the 1990s, the FDA-operated Plant Biotechnology Consultation Program has provided a consistent, voluntary process for crop developers to gain approval of their product, allowing its availability into the wider marketplace.[12] Over 200 plant varieties have gone through this approval process since 1995.[13] In 2024, the FDA created an additional process for genetically modified crops through premarket meetings, giving an even faster track for crops that do not cause subjection to regulatory consideration or food safety concerns.[14] This process has already been put to use, as a crop developer met to introduce a new variety of mustard greens in August of 2024.[15] The significant support which the FDA has given to crops in comparison to genetically modified animals illustrates the gap between approved genetically modified plant species as opposed to animals, for food purposes and otherwise.

A wide variety of ethical concerns encompass the creation of GMOs, despite vast technological advancements made.[16] Both male and female species may be subject to painful surgeries, invasive biopsies, and intensive hormone injections to facilitate breeding.[17] Depending on the procedure, anywhere from 1 to 30% of targeted embryos receive the intended alteration, meaning scores of animals end up with little or no scientific value.[18] Exponential technological advancement has also led scientists to question the moral right to change fundamental characteristics

11. *See Programs on Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2024), https://www.fda.gov/food/food-new-plant-varieties/programs-food-new-plant-varieties [https://perma.cc/ZU6F-7U5D].

12. *Id.*

13. *New Plant Variety Consultations*, U.S. FOOD & DRUG ADMIN. (Dec. 10, 2025), https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=NewPlantVarietyConsultations [https://perma.cc/5XJC-FJPZ].

14. *FDA Releases Guidance on Voluntary Premarket Engagement for Foods Derived from Plants Produced Using Genome Editing*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2024), https://www.fda.gov/food/hfp-constituent-updates/fda-releases-guidance-voluntary-premarket-engagement-foods-derived-plants-produced-using-genome [https://perma.cc/8FEK-F7R4]; *Premarket Meetings for Food from Genome-Edited Plants*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2024), https://www.fda.gov/food/programs-food-new-plant-varieties/premarket-meetings-food-genome-edited-plants [https://perma.cc/L3FE-6G38].

15. *Premarket Meetings Regarding Food from Genome Edited Plants*, U.S. FOOD & DRUG ADMIN. (Jan. 13, 2026), https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GenomeEditedPlants [https://perma.cc/M8Y6-HLWV].

16. Elisabeth H. Ormandy, Julie Dale & Gilly Griffin, *Genetic Engineering of Animals: Ethical Issues, Including Welfare Concerns*, 52 CAN. VETERINARY J. 544, 544 (2011).

17. *Id.* at 546–57.

18. *Id.* at 547.

of an animal.[19] Whereas previous genetic modification had limited application and impact on a species, newer methods continue to push the upper limits and raise philosophical questions about humanity's right to reinvent an animal.[20]

II. HISTORY OF GENETIC MODIFICATION AND REGULATION OF LIVESTOCK

The first genetically modified animal was created in 1974, in a study performed by Rudolf Jaenisch and Beatrice Mintz.[21] By injecting early-stage mouse embryos with DNA from a virus, the DNA of the mice was permanently modified as the earliest known example of an animal carrying recombinant DNA.[22] Most ventures into genetic experimentation in the twentieth century were either limited to plant life or, in regard to animals, had little commercial application.[23] The early methods of gene insertion were almost entirely random and economically draining, which contributed to their lack of commercial application.[24] Throughout the twenty-first century, the discovery of new gene editing tools, including Zinc Finger Nucleases (ZFNs), Transcription Activator-like Effector Nucleases (TALENs), and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) dramatically improved procedure success rates and slashed the required costs necessary for livestock editing on a large scale.[25]

Modern genetically modified livestock are generally created by either using Somatic Cell Nuclear Transfer (SCNT) or Microinjection (MI).[26] These new modification methods have led to the creation of animals with highly desirable new traits, such as disease resistance, growth enhancement, and higher rates of feed conversion.[27] Currently, over 20 countries allow genetically modified animals for

19. *Id.* at 548.

20. *Id.*

21. Rudolf Jaenisch & Beatrice Mintz, *Simian Virus 40 DNA Sequences in DNA of Healthy Adult Mice Derived from Preimplantation Blastocysts Injected with Viral DNA*, 71 PROCS. NAT'L ACAD. SCIS. USA 1250, 1251 (1974).

22. *Id.* at 1250–51.

23. *See* Robert T. Fraley et al., *Expression of Bacterial Genes in Plant Cells*, 80 PROCS. NAT'L ACAD. SCIS. USA 4803, 4803 (1983); Xudong Ye et al., *Engineering the Provitamin A (β-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 SCI. 303, 303 (2000); Douglas Hanahan, Erwin F. Wagner & Richard D. Palmiter, *The Origins of Oncomice: A History of the First Transgenic Mice Genetically Engineered to Develop Cancer*, 21 GENES & DEV. 2258, 2258–59 (2007).

24. Dong-Hyeok Kwon et al., *Current Status and Future of Gene Engineering in Livestock*, 57 BMB REPS. 50, 50 (2024).

25. *Id.*

26. *Id.*

27. *Id.*

sale as food products to consumers, with varied levels of regulation.[28] Notably, many South American nations lack almost any unique regulations, reflected by the relatively higher number of products approved.[29] Japan and Argentina have lighter regulations, resulting in newer products hitting markets much faster compared to the United States.[30]

A. Regulation of Genetically Modified Livestock

Regulation of genetically modified animals in the United States dates back to 1986, with the publication of the Coordinated Framework for Regulation of Biotechnology (Framework).[31] The Framework indicated that the intent was to roll in existing federal regulations to apply those to the creation of new genetically modified products in "essentially the same manner" as other products.[32] From the 1990s to the early 2000s, genetically modified animals were overseen by the USDA.[33] The lack of genetically modified animals implemented into the commercial sphere did not necessitate specific regulation by the USDA.[34] This was reflected in a 2004 Pew Research Center report, which analyzed the potential issues the FDA, EPA, and USDA would specifically have with regards to genetically modified animals.[35]

Control over genetically modified animals finally shifted to the FDA upon the release of a new guidance for industry report, assuming regulation under the Federal Food, Drug, and Cosmetic Act (FD&C Act).[36] Regulation was not specifically over the animal, but rather the genetic modification processes that

28. *Gene Editing and New Breeding Techniques: Regulations, Ratings and Index*, GLOB. GENE EDITING REGUL. TRACKER (May 2024), https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org [https://perma.cc/3QWA-2TXP] (click on "Animal" tab).

29. *Id.*

30. *Id.*

31. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

32. *Id.* at 23304.

33. Alison Van Eenennaam, *Regulation of Genetically Modified Animals Part #1*, BIOBEEF BLOG (Dec. 28, 2020), https://biobeef.faculty.ucdavis.edu/2020/12/28/regulation-of-genetically-modified-animals-part-1 [https://perma.cc/2QR6-MGZA].

34. *Id.*

35. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 1–5 (2004), https://www.pew.org/-/media/legacy/uploadedfiles/phg/content_level_pages/reports/foodbiotechregulation0404pdf.pdf [https://perma.cc/8SW5-X2BL].

36. Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs; Availability, 74 Fed. Reg. 3057, 3057 (Jan. 16, 2009).

could be classified as "drugs" under the meaning of the New Animal Drug provisions added to the Act.[37] This specifically targeted genetically engineered animals because it relied on recombinant DNA, and largely ignored risks which were animal specific.[38] During this period of regulation, the AquAdvantage salmon was the only food animal granted approval by the FDA in 2015.[39]

It would take nearly a decade for the FDA to bring all genetically modified animals under their regulatory umbrella with the publication of an updated guidance for industry report in 2017.[40] By introducing a new guideline for what constitutes "altered genomic DNA" to any "genome that has been intentionally altered[,]" the FDA looped in genetically edited animals and several other proprietary technologies that had been developed since.[41] Despite pushback by lobbyists and industry leaders, the FDA rebuked urges to grant USDA jurisdiction over genetically modified animals in 2019.[42] Many critics pointed to the FDA's inefficiency in managing biotechnology with respect to animals, with only a single species to show for after the review process had existed for decades.[43] The FDA continued to show pushback against the industry in a statement released in early 2020, proclaiming the need for "maintain[ing] standards of safety and effectiveness."[44] This decision was met with resistance from genetic scientists, attacking the characterization of an error found in genetically modified animals.[45]

37. *Id.*

38. Van Eenennaam, *supra* note 33.

39. *United States: Animals*, GLOB. GENE EDITING REGUL. TRACKER (May 2024), https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-states-animals/ [https://perma.cc/MWH9-66VY].

40. Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Availability, 82 Fed Reg. 6561, 6561–62 (Jan. 19, 2017).

41. *Id.* at 6563.

42. Catherine Boudreau, *FDA Resists Livestock Lobby's Push on GE Animals*, POLITICO (July 8, 2019, at 10:00 ET), https://www.politico.com/newsletters/morning-agriculture/2019/07/08/fda-resists-livestock-lobbys-push-on-ge-animals-673570 [https://perma.cc/G7ZN-4BQ5].

43. *See* Liz Crampton, *FDA Defends Its Regulatory Prowess in Debate Over Biotech Animals*, POLITICOPRO (July 8, 2019, at 05:02 ET), https://subscriber.politicopro.com/article/2019/07/fda-defends-its-regulatory-prowess-in-debate-over-biotech-animals-1565216; Boudreau, *supra* note 42.

44. Press Release, U.S. Food & Drug Admin., FDA Expertise Advancing the Understanding of Intentional Genomic Alterations in Animals (Feb. 7, 2020, at 13:50 ET), https://www.prnewswire.com/news-releases/fda-expertise-advancing-the-understanding-of-intentional-genomic-alterations-in-animals-301001079.html [https://perma.cc/F43W-FSVL].

45. Cameron English, *FDA Defends CRISPR-Edited Animal Rules Likely to Block Most Uses: Is the Agency Trying to Avoid Litigation from Anti-GMO Groups?*, GENETIC LITERACY PROJECT (Feb. 11, 2020), https://geneticliteracyproject.org/2020/02/11/fda-defends-crispr-

The FDA subsequently approved a species of pigs for consumption by humans, bred without a gene that produced a type of sugar that resulted in allergic reactions.[46]

Despite urges from Sonny Perdue, the Secretary of Agriculture under President Donald Trump, the incoming Biden Administration rejected another request for joint oversight with the USDA.[47] Progress on the approval of new species remained slow, with an assessment performed on a cattle species resulting in a finding of "low risk," but still not resulting in approval from the FDA.[48] Biologists began to look in South American markets in search for funding after decades of roadblocks from administrative agencies in the United States.[49]

The FDA's most recent update to the approval process came in May of 2024, with yet another revision of the guidance for industry.[50] The 2024 guidance, along with a companion piece detailing the new approval process,[51] anticipated a rise in animals with heritable intentional genomic alterations (IGA), and provided

edited-animal-rules-likely-to-block-most-uses-is-the-agency-trying-to-avoid-litigation-from-anti-gmo-groups/?mc_cid=4a261d37de&mc_eid=e4eb62f6d7 [https://perma.cc/5R6Y-4UYR].

46. Press Release, U.S. Food & Drug Admin., FDA Approves First-Of-Its-Kind Intentional Genomic Alteration in Line of Domestic Pigs for Both Human Food, Potential Therapeutic Uses (Dec. 14, 2020, at 12:04 ET), https://www.prnewswire.com/news-releases/fda-approves-first-of-its-kind-intentional-genomic-alteration-in-line-of-domestic-pigs-for-both-human-food-potential-therapeutic-uses-301192244.html [https://perma.cc/TH4J-TDAD].

47. Press Release, Sonny Perdue, Sec'y of Agric., U.S. Dep't of Agric., Secretary Perdue Statement on MOU on Animal Biotechnology (Jan. 19, 2021), https://www.usda.gov/media/press-releases/2021/01/19/secretary-perdue-statement-mou-animal-biotechnology [https://perma.cc/YK4D-CC6C].

48. *See* U.S. FOOD & DRUG ADMIN., V-006378, RISK ASSESSMENT SUMMARY PRLR-SLICK CATTLE 8 (2022), https://www.fda.gov/media/155706/download [https://perma.cc/7N9W-5S6D].

49. Heidi Ledford, *Gene-Edited Animal Creators Look Beyond US Market*, NATURE (Feb. 21, 2019), https://www.nature.com/articles/d41586-019-00600-4 [https://perma.cc/QUH5-2GT4].

50. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUM. SERVS., #187A, HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS: RISK-BASED APPROACH, GUIDANCE FOR INDUSTRY (2024), https://www.fda.gov/media/74614/download [https://perma.cc/DL2X-KTT7].

51. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUM. SERVS., #187B, HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS: THE APPROVAL PROCESS, GUIDANCE FOR INDUSTRY (2025), https://www.fda.gov/media/150658/download [https://perma.cc/S9Y3-79VZ].

guidelines to determine what animals would fall under one of three categories prescribed by the FDA.[52]

Each of the categories carry a different risk analysis by the FDA receiving a different level of scrutiny.[53] Category 1 animals, the only category which does not require developer consultation with the FDA, are defined as having mitigated or understood risk.[54] Category 2 animals require a detailed application with information about the intended use of the genetic modification, which in turn may or may not require further review by the FDA.[55] Category 3 animals always require an individual inquiry from the FDA.[56] The FDA asserts that future knowledge on specific genetic modification may ultimately result in many Category 3 animals being reclassified to Category 2, but based on the current speed of regulatory processes there is no telling when this might be.[57] Animals consumed by humans only fall under Category 2 or 3, never Category 1.[58] Therefore, animals for consumption are always subject to at least a cursory review process by the FDA.[59]

Category 2 animals can potentially require a great deal of information in an application for food consumption.[60] The FDA states agencies may inquire about methodology, hormone elevation, newly produced proteins or substances, alterations to nutritional values, and changes to the animals' physiology.[61] These guidelines would apply to the vast number of products currently in production for

52. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., *supra* note 50, at 2–6.
53. *Id.* at 4.
54. *Id.*
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.* at 5.
59. *Id.* at 4.
60. *See id.* at 5–6.
61. *Id.* at 6.

agricultural purposes, including several species of cow,[62] pigs,[63] and fish.[64] The FDA's published list of risk-reviewed IGAs includes numerous examples of disease resistant pigs which have already been classified as Category 2.[65]

There have been continual updates in the technology of the field, and the latest update points to an increasing trend in granted approvals of IGAs in animals.[66] Despite this, the FDA has only approved two animals for food usage to date—pigs and salmon.[67] Although the FDA has shown marked improvements over previous regulatory systems, there is still room for improvement. For experimental scientific research, speed is the name of the game, so to encourage innovation, the FDA should not require companies to be on the hook for years awaiting approval. Companies creating animals intended for consumption must provide the FDA copious information to be approved, unnecessarily kneecapping the livestock industry.[68] The FDA should create a new regulatory category that applies to animals modified by procedures accepted as safe. This could provide a fast track for minor animal modifications to hit market, especially those that improve animal welfare like disease resistance.

62. Marc Heller, *Beef Cattle Get a Genetic Makeover for a Warming World*, POLITICOPRO: GREENWIRE (May 13, 2019, at 13:10 ET), https://subscriber.politicopro.com/article/eenews/1060326793; *Licensing Deal Will Help Genus Combat Deadly Cattle Disease*, WASH. STATE UNIV.: WSU INSIDER (July 27, 2016), https://news.wsu.edu/2016/07/27/licensing-deal-will-help-combat-deadly-cattle-disease/ [https://perma.cc/UP27-D57G]; Gregory Barber, *A More Humane Livestock Industry, Brought to You by Crispr*, WIRED (Mar. 19, 2019, at 06:00 CT), https://www.wired.com/story/crispr-gene-editing-humane-livestock/ [https://perma.cc/3XNK-9RWV]; Felix Schuster et al., *CRISPR/Cas12a Mediated Knock-In of the Polled Celtic Variant to Produce a Polled Genotype in Dairy Cattle*, SCI. REPS., Aug. 2020, at 1, 1.

63. Christine Burkard et al., *Precision Engineering for PRRSV Resistance in Pigs: Macrophages from Genome Edited Pigs Lacking CD163 SRCR5 Domain Are Fully Resistant to Both PRRSV Genotypes While Maintaining Biological Function*, PLOS PATHOGENS, Feb. 23, 2017, at 1, 1; Ed Maixner & Sara Wyant, *Protecting the Herd: New Opportunities Through Gene Editing*, AGRIPULSE (Jan. 29, 2018, at 09:14 CT), https://www.agri-pulse.com/articles/10527-protecting-the-herd-new-opportunities-through-gene-editing [https://perma.cc/8X48-4ERB].

64. Karim Khalil et al., *Generation of Myostatin Gene-Edited Channel Catfish (Ictalurus Punctatus) via Zygote Injection of CRISPR/Cas9 System*, SCI. REPS., Aug. 4, 2017, at 1, 1.

65. *Intentional Genomic Alterations (IGAs) in Animals: Risk-Reviewed IGAs*, U.S. FOOD & DRUG ADMIN. (Jan. 22, 2026), https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/intentional-genomic-alterations-igas-animals-risk-reviewed-igas [https://perma.cc/7HL4-UDQG].

66. Kwon et al., *supra* note 24, at 56.

67. *Id.* at 55.

68. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., *supra* note 50, at 10–15.

III. EFFECTS OF GENETIC MODIFICATION ON THE LIVESTOCK INDUSTRY

IGAs transplanted into livestock have the capacity to push the agriculture industry forward economically, environmentally, and socially.[69] Through increased productivity, composition, and increased nutritional benefits, IGAs would positively benefit the agriculture industry.[70]

A. Economic, Environmental, and Social Impacts

In addition to the earlier noted disease resistance, growth enhancement, and feed conversion, IGAs can lead to increased productivity, reproductive performance, carcass composition, byproduct production and composition, and hair or fur composition.[71] By using TALENs and SCNT for gene editing, cattle were successfully produced with increased muscle mass leading to higher quality meat.[72] Similar results were achieved with CRISPR/Cas9.[73] More significantly, the gene modification was found to be passed along through subsequent generations of cattle.[74] Genetic modifications generally need to be transferable in order to be mass-produced.[75] When compared with the conventional selective breeding method—which takes around 30 years to achieve desirable results—current CRISPR/Cas9 and SCNT processes introduce new traits essentially overnight.[76]

Animal byproducts, most notably milk found in cattle, sheep, goats, and pigs, can be made to produce proteins with additional nutritional benefits which do not occur naturally in that animal species.[77] The time and cost efficiency of implementing IGAs will have an enormous impact on livestock herds in a world with increasing demand and rapidly changing climates.[78]

69. *See* Matthew B. Wheeler, *Transgenic Animals in Agriculture*, NATURE (2013), https://www.nature.com/scitable/knowledge/library/transgenic-animals-in-agriculture-105646080/ [https://perma.cc/YZ8Z-XLD6].

70. *Id.*

71. *Id.*

72. Kwon et al., *supra* note 24, at 54.

73. *Id.*

74. *Id.*

75. *See id.*

76. Bhanu P. Telugu, Ki-Eun Park & Chi-Hun Park, *Genome Editing and Genetic Engineering in Livestock for Advancing Agricultural and Biomedical Applications*, 28 MAMMALIAN GENOME 338, 341 (2017).

77. Wheeler, *supra* note 69.

78. *Id.*

Holstein cows are known to absorb high amounts of light, making this breed more susceptible to heat stress.[79] Using CRISPR/Cas9, scientists have successfully introduced genes that alter both the color and length of their hair, resulting in a mitigation of heat stress.[80] These particular cows are on track for FDA approval and show one of the many examples of how gene modification can lead to increased productivity in animals.[81]

With the recent advent of pandemic diseases affecting humans and livestock alike, the need for quick adaptation in herds to combat disease is greater than ever.[82] Disease resistance lessens the need to quarantine herds and care for sick animals, two substantial economic costs when dealing with infected livestock.[83] Both factors reduce the amount of distributed antibiotics and the time the herd is affected by the disease.[84] One notable example is a gene introduced via SCNT to pigs to create a resistance to porcine reproductive and respiratory syndrome (PRRS), a disease notable for its negative impact on the livestock industry.[85]

An important secondary effect of an increase of IGA in livestock is the benefits to public health and nutrition.[86] Animal species may be modified to provide higher levels of protein or increased levels of fatty acids to provide higher quality food products.[87] The World Agricultural Organization projects the demand for animal proteins to reach 1.8 billion tons.[88] This number will continue to rise, with an estimated 70% increase in the requirement for animal products by 2050.[89] The continued urbanization of developing countries strips away available farmland and requires livestock farmers to become more efficient.[90]

79. Kwon et al., *supra* note 24, at 54.

80. *Id.*

81. *Id.*

82. *See id.* at 54–55.

83. *Id.*

84. *Id.* at 54.

85. *Id.* at 55 (noting that PRRS is a respiratory infectious disease, which geneticists combatted by the introduction of a mutation introduced via SCNT known as CD163).

86. Wheeler, *supra* note 69.

87. *Id.*

88. Kwon et al., *supra* note 24, at 53.

89. Telugu, Park & Park, *supra* note 76, at 341.

90. *See id.*

B. Potential Future Applications in Livestock

CRIPSR/Cas9's explosive improvements to previous genetic modification technology have made previously unthinkable changes to species possible.[91] In addition to the species mentioned earlier, IGAs have been evaluated for horses, chickens, goats, sheep, and buffalo.[92]

In addition to meat and milk, sheep and goats play a significant role in the production of cashmere.[93] Targeting genes relating to hair follicle density, length, quality, and growth rate, CRISPR/Cas9 could push sheep and goats' impact on the textile industry.[94] Even the color of the wool is able to be altered, a significant factor in the value of the raw material.[95] Similar adaptations to other livestock species concerning growth rate, muscle development, reproductive prowess, and milk composition show promising results.[96]

Chickens would benefit greatly from increased egg production and immunity allowed by CRISPR/Cas9.[97] Their biological differences from mammals have presented unique challenges but would benefit from increased funding and further experimentation.[98] Because of the severe vulnerability of chickens to common avian virus variants, disease resistance to combat massive losses of poultry would greatly benefit the industry.[99]

Although research is more limited on horses due to their fewer applications in the agricultural field, CRISPR/Cas9 has still been used to eliminate a gene that increases the likelihood of skin diseases.[100]

As the supply of the livestock market continues to be challenged by increasing demand, the optimizations IGAs create in animals are needed to support the industry's economic feasibility. Without access to greater land area, each animal will need to provide greater output, and IGAs are the most feasible method due to the speed of change being demanded.

91. Dalia M. Aboelhassan & Hesham Abozaid, *Opportunities for CRISPR-Cas9 Application in Farm Animal Genetic Improvement*, MOLECULAR BIOLOGY REPS., Oct. 30, 2024, at 1.
92. *Id.* at 2.
93. *Id.* at 5.
94. *Id.* at 5–6.
95. *Id.*
96. *See id.* at 6–7.
97. *Id.* at 7.
98. *Id.*
99. *See id.* at 8.
100. *Id.*

C. Public Criticism of Genetically Modified Animals

American consumers and society at large may present an even larger hurdle to the industry than current FDA regulations.[101] Concerns with food safety, environmental issues, animal welfare, and other various controversies might implicate the FDA's unwillingness to lessen restrictions on animals with IGAs.[102] Despite most Americans believing that genetic modification should be used to prevent the spread of disease or growing organs for human transplant, a clear divide exists as to whether increased nutritional value is acceptable.[103] These views vary widely on both the basis of scientific knowledge and religious commitment.[104] Despite current studies showing IGAs present very little risk for humans, fear of potential future consequences ranks as the highest reason for those who oppose the technology.[105] Another common concern pertains to upsetting the general balance of nature, or "God's plan."[106] Continued education to the public at large about genetically modified animals is only half the battle, as it seems the technology itself presents a hard-to-swallow pill regardless of the risks.[107]

Studies which address the concerns of a novel toxin or allergen being introduced into an SCNT genetically modified animal are nearly 20 years old, concluding no discernible difference existed in cattle created using the method.[108] Indeed, the FDA's Center for Veterinary Medicine came to the same conclusion in 2003 when proclaiming, "the current weight of evidence suggests that there are no biological reasons . . . to indicate that consumption of edible products from clones . . . poses a greater risk than consumption of those products from their nonclone

101. *See* Ali Saeed, Muhammad Abubakar & Sehrish Kanwal, *Future Challenges Related to Animal Biotechnology*, *in* THE ROLE OF BIOTECHNOLOGY IN IMPROVEMENT OF LIVESTOCK: ANIMAL HEALTH AND BIOTECHNOLOGY 135, 135 (Muhammad Abubakar, Ali Saeed & Oguz Kul eds., 2015).

102. *See id.* at 145.

103. Cary Funk & Meg Hefferon, *Most Americans Accept Genetic Engineering of Animals That Benefits Human Health*, *But Many Oppose Other Uses*, PEW RSCH. CTR. (Aug. 16, 2018), https://www.pewresearch.org/internet/2018/08/16/most-americans-accept-genetic-engineering-of-animals-that-benefits-human-health-but-many-oppose-other-uses/ [https://perma.cc/U9YN-YVLU].

104. *Id.*

105. *Id.*

106. *Id.*

107. *See id.*

108. Saeed, Abubakar & Kanwal, *supra* note 101, at 138.

counterparts."[109] The continued efforts of the global scientific community remain unified in this conclusion, and little to no evidence exists to the contrary.[110]

A major concern with genetically modified animals' potential effects on our greater ecosystem comes from the potential to escape confinement and interbreed.[111] This would be especially prevalent for species with quick maturation cycles, such as fish or insects, many of which have the potential to become invasive species with accelerated growth rates.[112] While not unfounded, many of these concerns are limited with respect to the majority of common livestock animals, like pigs and cattle, which generally would not find crossbreeding candidates in the wild.[113] Certain genetic traits, such as the introduction of novel proteins or other nutrients, likely will not have a large impact on the American ecosystem.[114]

IV. CURRENT FDA REGULATION

Despite the FDA's claims that the risk-based approach is "based on sound science,"[115] geneticists tend to agree that modern genetic technology risks equal those of conventionally-bred animals.[116] Despite continued enhancements in procedures and CRISPR/Cas9 IGAs being considerably more precise than the technologies these guidelines initially regulated, FDA approval remains inflexible and unyielding.[117] Because each category merely relies on the type of genetic change and restricts transgenic IGAs that would create the most profitable and beneficial new products, the new review process will continue to be an obstacle for researchers.[118] Genomic data is burdensome to generate, both economically and timewise, while the FDA's slow approval process discourages developers from funding projects.[119] Despite genetically modified plants receiving widespread

109. *Id.*

110. *Id.*

111. *Id.* at 139; *see also* Inst. for Fisheries Res. v. U.S. Food & Drug Admin., 499 F. Supp. 3d 657, 660–61 (N.D. Cal. 2020) (showing the court agreed with the FDA's conclusion that AquAdvantage's salmon were highly unlikely to escape, however, they should have conducted a risk assessment to determine the effect on normal salmon).

112. Saeed, Abubakar & Kanwal, *supra* note 101, at 139.

113. *Id.*

114. *Id.*

115. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., *supra* note 50, at 2.

116. Saeed, Abubakar & Kanwal, *supra* note 101, at 138.

117. Emma Kovak, *New Livestock Biotechnology Guidance Misses the Mark*, THE BREAKTHROUGH INST. (May 2, 2024), https://thebreakthrough.org/blog/new-livestock-biotechnology-guidance-misses-the-mark [https://perma.cc/S442-HAZ9].

118. *See id.*

119. *Id.*

exceptions for similar IGAs, the FDA maintains a harmful double standard for livestock.[120] In the latest guidance for the industry, the FDA promised the continuation of updating guidelines with the emergence of new technologies,[121] which rings hollow when current regulations are already decades behind.[122]

A. Inadequacies of Current Regulations

Scientists are far from the only interested parties in pushing these innovative technologies. In 2024 alone, the Biotechnology Innovation Organization spent millions of dollars lobbying to deregulate genetically modified livestock.[123] The National Pork Producers Council, the largest agricultural lobbying group, attempted to shift regulatory powers from the FDA to the USDA towards the end of the first Trump Administration.[124]

FDA regulation is not without its merits; despite the USDA holding oversight over some agricultural animals, they lack general authority to regulate non-livestock animals.[125] The USDA also lacks the current infrastructure for any sort of review process for genetically modified livestock, a particular hinderance in an already inefficient system.[126] Other proponents of the FDA point to their human-health-centric mandate, as opposed to the USDA's industry focus, to ensure that decisions are more socially conscious rather than economically driven.[127]

120. *Id.*

121. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., *supra* note 50, at 2.

122. Kovak, *supra* note 117.

123. *See, e.g.*, BIOTECHNOLOGY INNOVATION ORG., LD-2 DISCLOSURE FORM, LOBBYING REPORT (July 22, 2024, at 11:04 CT), https://lda.senate.gov/filings/public/filing/991dd04b-1c9c-48bf-a6de-1cff187913c7/print/ [https://perma.cc/L3KV-KQ7E]; BIOTECHNOLOGY INNOVATION ORG., LD-2 DISCLOSURE FORM, LOBBYING REPORT (Oct. 21, 2024, at 15:05 CT), https://lda.senate.gov/filings/public/filing/8994dbbd-d832-4697-a411-d6b4ed7ce1eb/print/ [https://perma.cc/94ZU-3YBS]; BIOTECHNOLOGY INNOVATION ORG., LD-2 DISCLOSURE FORM, LOBBYING REPORT (Apr. 26, 2024, at 16:06 CT), https://lda.senate.gov/filings/public/filing/667f7787-301d-404d-9120-ab3b7502afc6/print/ [https://perma.cc/4WAZ-9FZ5].

124. Adam Cancryn & Liz Crampton, *11th-Hour Deal Strips FDA Oversight of Genetically Modified Animals*, POLITICO (Jan. 19, 2021, at 18:00 ET), https://www.politico.com/news/2021/01/19/fda-hhs-genertically-modified-animals-460486 [https://perma.cc/G2WQ-QLJL].

125. Zachary Goldstein, *Genetically Engineered Animals to Be Regulated by FDA*, CTR. FOR SCI. IN THE PUB. INT. (May 21, 2024), https://www.cspinet.org/cspi-news/genetically-engineered-animals-be-regulated-fda [https://perma.cc/BS5B-HX7Q].

126. *Id.*

127. *See* Cookson Beecher, *FDA to Steer Regulations for Genetically Edited Meat Animals*, FOOD SAFETY NEWS (June 4, 2024, at 18:14 CT), https://www.foodsafetynews.com/

B. The Failure of AquAdvantage

AquaBounty and its genetically modified salmon are now infamous, being the subject of a lawsuit attempting to remove regulatory power of genetically modified animals from the FDA.[128] In *Institute for Fisheries Resources v. Hahn*, the court rejected the contention that the FDA's authority over genetically modified animals was outside of its purview.[129] Finding that a tool used for genetic modification falls squarely under the FD&C Act's[130] definition of drug, "articles . . . intended to affect the structure or any function of the body of man or other animals[,]" the court upheld the FDA's authority.[131]

In the second phase of the case, *Institute for Fisheries Resources v. United States Food and Drug Administration*, advocacy groups contested the FDA's approval of AquAdvantage as an abuse of authority.[132] Much of the Plaintiff's basis for the abuse of discretion claim was derived from the FD&C Act's language requiring drugs be "safe for use" if the health of humans is implicated.[133] Finding the requirements for evaluating environmental factors to be extremely broad, the court ruled that the FDA must assess the potential impact of AquAdvantage on wild salmon.[134] Despite requiring further review from the FDA, the court declined to vacate the approval because of the potential harm to the company's stock of salmon.[135] The FDA subsequently amended the statement to allow for continued approval of the salmon.[136]

The ultimate success in court was not enough for AquAdvantage to succeed in the market.[137] In part due to national retailers refusing to sell genetically

2024/06/fda-to-steer-regulations-for-genetically-edited-meat-animals/#google_vignette [https://perma.cc/7R8Z-C8DW].

128. *See* Inst. for Fisheries Res. v. U.S. Food & Drug Admin., 499 F. Supp. 3d 657, 661 (N.D. Cal. 2020); Inst. for Fisheries Res. v. Hahn, 424 F. Supp. 3d 740, 744 (N.D. Cal. 2019).

129. *Inst. for Fisheries Res.*, 424 F. Supp. 3d at 758.

130. 21 U.S.C. § 360b (conferring power of enforcement to the FDA through the Secretary of Health and Human Services).

131. *Inst. for Fisheries Res.*, 424 F. Supp. 3d at 751, 755 (quoting 21 U.S.C. § 321(g)(1)).

132. *Inst. for Fisheries Res.*, 499 F. Supp. 3d at 661.

133. *Id.* at 663 (quoting 21 U.S.C. § 360(b)).

134. *Id.* at 665–66.

135. *Id.* at 669–70.

136. U.S. FOOD & DRUG ADMIN., AMENDED FINDING OF NO SIGNIFICANT IMPACT (FONSI) 6 (2024), https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFonsi/4710, [https://perma.cc/5N7P-V5RT].

137. *Genetically Engineered Salmon Production Ends as AquaBounty Shutters Last Facility*, FRIENDS OF THE EARTH (Dec. 12, 2024), https://foe.org/news/aquabounty-ge-salmon-ends/ [https://perma.cc/GM4H-DCAF].

modified salmon, AquaBounty closed all facilities relating to the salmon after operating at a loss for several years.[138] Environmental organizations denounced AquaBounty's disregard for the ecological impact of the salmon, making broad sweeping statements about the undesirability of genetically modified animals for consumption.[139]

C. Genetically Modified Animals' Potential Future

The future success of genetically modified animals will turn on three factors: (1) the adoption of a more efficient regulatory scheme; (2) a change in public perception; and (3) continued financial investment. AquAdvantage is a perfect study for how all three factors worked against bringing the product to market.[140]

The science behind the salmon was completed by 1989, but the process for approval by the FDA did not exist until 2009, subsequently taking another six years before approval.[141] AquaBounty had approached the FDA as early as 1993 to gain approval, but consistent legislative roadblocks prevented the salmon from generating revenue until the 2020s.[142] As of May 2024, the FDA's new risk evaluation process has only resulted in a single cattle species that will not require further review before marketing.[143] Without a consistent process modeling of genetically modified crops, which continue to churn out new variations, research into modifying animals for human consumption will likely stifle.[144]

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138. *Id.*; *see also Company Commitments on GMO Salmon*, FRIENDS OF THE EARTH (Nov. 20, 2025, at 12:28 CT), https://foe.org/company-commitments-on-gmo-salmon/ [https://perma.cc/VJ9R-V2RD] (listing companies that have pledged to not sell GMO salmon); Edward Carver, *Campaigners Celebrate as Firm Making First-Ever GMO Fish Ceases Operations*, MONGABAY (Dec. 31, 2024), https://news.mongabay.com/2024/12/campaigners-celebrate-as-firm-making-first-ever-gmo-fish-ceases-operations/ [https://perma.cc/VK89-3F5G] (discussing the closing of the AquaBounty facilities).

139. *Genetically Engineered Salmon Production Ends as AquaBounty Shutters Last Facility*, *supra* note 137.

140. *See* Carver, *supra* note 138.

141. Dave Conley, *AquAdvantage Salmon's Journey to Market: Still Making History*, AQUACULTURE MAG., Aug.–Sep. 2018, at 12, 13, https://aquabounty.com/wp-content/uploads/2018/08/AQUABOUNTY-AQM_44-4.pdf [https://perma.cc/P4N5-GYXF].

142. *Id.* at 12–14.

143. *Intentional Genomic Alterations (IGAs) in Animals: Risk-Reviewed IGAs*, U.S. FOOD & DRUG ADMIN. (Jan. 22, 2026), https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/intentional-genomic-alterations-igas-animals-risk-reviewed-igas [https://perma.cc/7HL4-UDQG].

144. *See Premarket Meetings for Food from Genome-Edited Plants*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2024), https://www.fda.gov/food/programs-food-new-plant-varieties/premarket-meetings-food-genome-edited-plants [https://perma.cc/L3FE-6G38].

Public perception is likely to continue being the largest roadblock to widespread acceptance of genetically modified livestock. Leaders of environmental advocacy groups continue to assert that "[g]enetically engineered food is a losing investment."[145] As biotechnology firms have been quick to point out, AquAdvantage's failure was essentially caused by these advocacy groups.[146] The opposition to genetically modified animals tends to disagree with current research and prioritize ecological concerns over human health concerns.[147] As with most new technology, only time will tell if eating genetically modified animals will eventually become more acceptable. There must be demand before developers can continue to invest in new products.

As with all economic operations, especially scientific research, continued funding is necessary to spur progress.[148] Both the FDA and the USDA appear to be on the right track, having recently issued grants to a variety of universities for the purpose of researching genetically modified animals.[149] AquaBounty suffered greatly by operating on the market for over three decades without a return on investment, and new products cannot face these same barriers.

V. CONCLUSION

Genetically modified animals have the potential to turn the livestock industry on its head. The environmental, economic, and practical effects of altering animal DNA to best fit market conditions cannot be overstated.[150] Genetic modification has fallen victim to a two-pronged attack of ineffective administration and a vocal minority of moral opponents.[151] The FDA has made progress in the last few decades by attempting to catch up to genetically modified crops, but the recent failure of AquAdvantage caused by factors outside of its control will deter future

145. *Genetically Engineered Salmon Production Ends as AquaBounty Shutters Last Facility*, *supra* note 137.

146. *See* Carver, *supra* note 138.

147. *See, e.g.*, *Genetically Engineered Salmon Production Ends as AquaBounty Shutters Last Facility*, *supra* note 137.

148. *See* Lynnette Harris, *USDA Funds Developing a Network to Advance Genetic Research in Agricultural Animals*, UTAH STATE UNIV.: UTAH STATE TODAY, (Dec. 5, 2024), https://www.usu.edu/today/story/usda-funds-developing-a-network-to-advance-genetic-research-in-agricultural-animals [https://perma.cc/5CQK-CWGP].

149. *Id.*

150. *See* discussion *supra* Sections III.A, III.B.

151. Conley, *supra* note 141, at 12–13; Carver, *supra* note 138; FUNK & HEFFERON, *supra* note 103.

investors.[152] While salmon presented a unique ecological concern unlikely to translate to other livestock, past reactions from advocacy groups seem to suggest that future products are likely to be met with the same hostility.[153] The science backing genetic modification will continue to improve, as previously impossible feats become the new norm. The needed change in public opinion remains to be seen, but as newly funded projects continue to show results that lower consumer costs and increase profits for farmers, a push for their consumption could very well follow. A new regulatory scheme and increased funding will pave the way for realizing the infinite possibilities of genetically modified livestock.

152. *Genetically Engineered Salmon Production Ends as AquaBounty Shutters Last Facility*, *supra* note 137.

153. *See* discussion *supra* Section III.C.