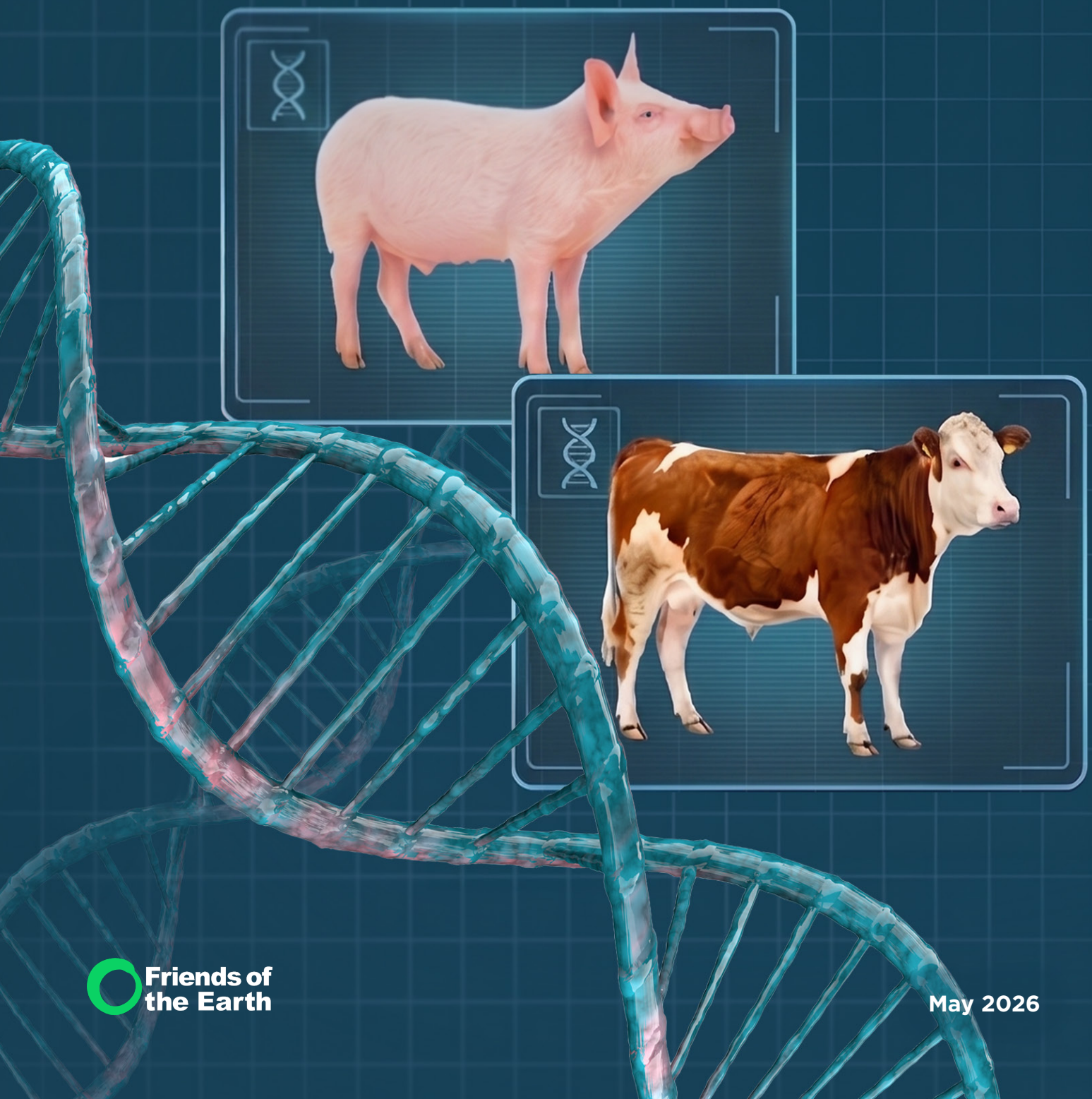
Engineering Harm:

Why Genetically Engineered Animals Deepen Risks to Public Health and Animal Welfare



Friends of the Earth

May 2026

Overview

This brief is an update to Friends of the Earth's 2019 report, *Genetically Engineered Animals: From Lab to Factory Farm*. Since that report was published, the U.S. Food and Drug Administration (FDA) has approved three genetically engineered (GE) animals for human consumption. This update summarizes emerging scientific research and documents serious public health, animal welfare, and regulatory concerns associated with these approvals.

Introduction

At a moment defined by accelerating climate change, biodiversity loss, and mounting public health crises driven by industrial agriculture, we urgently need a transition to sustainable, just, and humane food systems. Instead, the development of genetically engineered animals is pushing agriculture further in the wrong direction—reinforcing the factory farm model by redesigning animals to better endure its inherently harmful conditions, including disease, pollution, and animal suffering.

Rather than solving the problems of industrial animal agriculture, genetically engineering animals risks compounding them. Independent research has shown that genetic engineering—including newer gene-editing techniques like CRISPR—can result in unexpected genetic mutations and physical abnormalities in GE animals, calling into question industry claims of precision and safety.

Even more alarming, genetically engineered animals face little meaningful regulatory oversight. FDA approvals rely heavily on company-generated data, with minimal transparency and virtually no opportunities for independent scientific review or public input. Despite regulatory sign-off, independent studies continue to identify risks to animal health and welfare and food safety.

Recently Approved GE Animals

Since 2020, the U.S. government has approved three genetically engineered animals for human consumption. Together, these animals illustrate how genetic engineering is being used to accommodate industrial farming systems rather than transform them.

Genetically Engineered Animals Approved in the U.S. between 2020-2025				
Company	**Animal**	**Application**	**FDA approval**	**Market arrival**
Acceligen	Cattle	The 'PRLR-SLICK' cattle is engineered to have a thinner coat, intended to be more heat-resistant.[1]	2020	FDA approval allows live GE cattle, semen, embryos, and meat from bulls and their offspring to be sold on the market. It is not clear whether any of the products are yet being sold.
Revivicor	Pig	The 'Galsafe pig' is engineered to remove a protein associated with allergic reactions to pork.	2022	Being marketed online.
Genus PLC	Pig	The 'PRRS-resistant pig' is engineered to resist porcine reproductive and respiratory syndrome.[2,3,4]	2025	The company plans to sell young and mature pigs, eggs, and sperm to pork-producing facilities across the US and its territories but it has not been marketed as of report publication.[5]

Animal Welfare Concerns

Extending the Factory Farm Model

Rather than reducing crowding, pollution, stress, and disease prevalent on factory farms, genetically engineered animals are being designed to survive these conditions. GE cattle engineered for heat tolerance and pigs engineered for disease resistance normalize factory farming's cruelty by modifying animals instead of reforming harmful production systems. This approach perpetuates the very practices responsible for widespread animal suffering, antibiotic overuse, and environmental contamination.

Harm in the Development Process

The techniques used to create GE animals—cloning and micro-injection[i]—are inherently invasive and inefficient, resulting in high rates of failure as well as unnecessary animal suffering and death.[6,7,8]

- **GalSafe pigs:** Thousands of cloned embryos resulted in only two successful pregnancies.[9,10] One piglet died shortly after birth with abnormalities, an enlarged tongue and kidneys. Further rounds of cloning were likely undertaken to establish the five founder pigs reported to the FDA.[11] Mortality rates before weaning were double those of conventional pigs (25% vs 12.6%).[12]
- **PRRS-resistant pigs:** These pigs were created using micro-injection.[13,14,15] Only about 20% of piglets (90 of 435) carried the intended genetic edit, many had additional unintended mutations. Numerous animals were discarded due to genetic abnormalities.
    - **PRLR-SLICK cattle:** These cattle were created using micro-injection. After extensive failures, including a calf that died unexpectedly from a heart defect, only two bull calves were approved.[16]

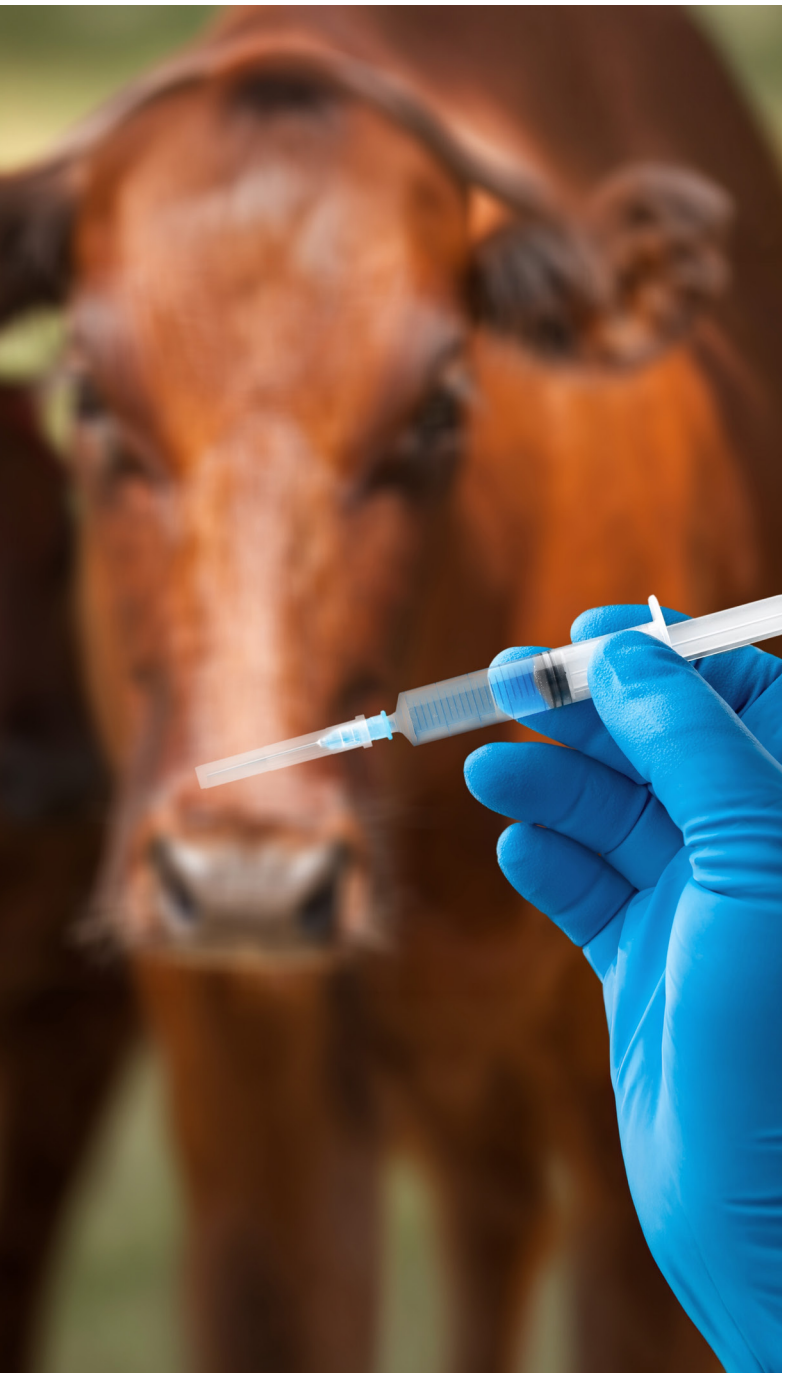
Scaling these animals for commercial production would require further experimentation and breeding—raising additional animal welfare and genetic health concerns.

i Animal cloning is the process of creating a genetically identical copy of an animal by transferring the nucleus of a somatic (body) cell into an egg cell whose own nucleus has been removed. In microinjection, foreign DNA (like genes or CRISPR tools) are injected into the zygote using a super-fine needle.

Unintended Genetic Changes

Unintended genetic changes are not rare anomalies; they are a known and persistent outcome of genetic engineering.[17] These off-target effects can disrupt normal biological functions, leading to chronic pain, developmental defects, compromised immune systems, fertility problems, and early death.[18]

In the case of PRLR-SLICK cattle, the genetic modification disrupts the prolactin hormone receptor—which has a role in more than 300 biological processes, including liver function and milk production. It is not known what potential impacts on the resulting animals might be.



Public Health Concerns

All three recently approved GE animals pose unintended and potentially significant risks to human health.

Antibiotic Resistance

The GalSafe pig contains an antibiotic-resistant marker gene, a feature that raises public health concerns. The marker gene makes the pig cells resistant to some antibiotics; this resistance could transfer to bacteria in the pig's gut.[19,20] From there it could spread in the environment via manure or into the food chain via bacteria on the pig meat—potentially making certain infections in humans harder or impossible to treat.[21,22,23,24,25] Yet online marketing for the GalSafe pig fails to disclose the presence of this antibiotic resistance gene.[26]

Virus Evolution and Spillover Risks

Virus-resistant animals, such as the PRRS-resistant pig, may increase long-term disease risks. By placing evolutionary pressure on pathogens, these animals could drive the emergence of more virulent or transmissible viruses.[27] When viruses are partially suppressed rather than eliminated, they may evolve to become more virulent, more transmissible, or capable of bypassing engineered resistance. Notably, the PRRS-resistant pigs were not resistant to all virus strains, demonstrating that resistance can be overcome.[28]

The National Academy of Sciences has warned that while the likelihood of such evolution may be "low to medium," the potential consequences for human populations could be severe.[29] These risks are not merely theoretical. In past research efforts in the United Kingdom attempting to genetically engineer chickens to be resistant to avian influenza, viral mutations emerged that raised concerns about increased potential for the disease to jump to human populations.[30,31]

Disturbingly, FDA reviews do not meaningfully address these risks.

Food Safety

One food safety concern associated with GE animals is the possibility that novel or altered proteins produced through genetic engineering—whether intentionally or unintentionally—could cause allergic reactions in humans.[32] This concern is relevant to the two GE pigs examined in this report, as their genetic modifications alter biological pathways with implications for molecules present in edible tissues, requiring FDA evaluation of potential allergenicity.

The PRLR-SLICK cattle have a disruption in the prolactin receptor (PRLR) gene, which is structurally similar to the human receptor. Yet, this was not considered in food safety assessments since the engineered change in the cattle did not introduce a new protein; it modified the function of a naturally occurring protein already present in cattle. Thus, the safety of resulting milk was not evaluated, underscoring the FDA's failure to apply comprehensive regulatory safeguards.[33,34]

Regulatory Failures

Regulatory oversight of genetically engineered animals in the U.S. is deeply inadequate. The process prioritizes corporate convenience over precaution, allowing risky technologies to move forward without adequate safeguards, transparency, or public consent.

Fragmented oversight

Federal oversight is divided among multiple agencies under the Coordinated Framework for the Regulation of Biotechnology, resulting in fragmented and incomplete regulation. The FDA takes the lead by regulating genetically engineered animals as "animal drugs" through the Center for Veterinary Medicine (CVM).[35] The U.S. Department of Agriculture (USDA) plays a limited role in assessing risks to livestock health and disease transmission through its Animal and Plant Health Inspection Service (APHIS) and food inspection through the Food Safety and Inspection Service (FSIS). The Environmental Protection Agency (EPA) has only a minimal role, focused narrowly on ensuring that any new substances or chemicals

produced by genetically engineered organisms do not harm human health or the environment.

Critically, no single agency is responsible for evaluating the full range of cumulative and long-term impacts—including animal welfare, ecosystem effects, and public health risks—leaving major regulatory gaps and allowing genetically engineered animals to move forward without comprehensive oversight.

Shortcomings of FDA oversight

Regulatory review of GE animals is further undermined by serious gaps in the FDA's assessment process. Safety determinations are based almost entirely on data generated and submitted by the companies developing the animals, with no requirement for independent scientific review or verification. The FDA does not require an assessment of harm to the experimental "founder" animals used in genetic engineering and cloning experiments, effectively ignoring animal suffering that occurs during development. In addition, the agency fails to fully evaluate risks related to antibiotic resistance and the potential evolution of more dangerous viruses in response to disease-resistant animals.

What's more, not all applications of genetic engineering are regulated with the same level of scrutiny. The difference comes down to FDA regulatory discretion. In the case of the PRLR-SLICK cattle, the FDA determined that the edit mimics conventional breeding outcomes. Thus, the FDA chose not to require a full premarket approval, instead issuing a "no safety concerns" determination based on a risk assessment summary, not a complete formal risk assessment.[36,37]

Shortcomings of USDA GE food labeling rule

The USDA is responsible for labeling GE animal products under the National Bioengineered Food Disclosure Standard. While mandatory labeling requirements went into effect in 2025, the USDA rule limits consumer understanding because it requires disclosure only when genetically engineered DNA is *detectable*, meaning many products from genetically engineered animals or using gene-editing techniques may carry no label at all. In addition, the rule allows disclosures via QR codes or text links instead of clear on-package language, reducing transparency and creating barriers for consumers who want immediate, accessible information at the point of purchase.

Lack of transparency and public participation

Compounding these shortcomings, there is no meaningful public participation process, leaving consumers, farmers, and independent scientists without a formal opportunity to review data, raise concerns, or challenge approvals before genetically engineered animals enter the food system. Much of the safety information submitted by developers is treated as confidential business information, resulting in limited publicly accessible data, abbreviated risk summaries, and few opportunities for independent verification of FDA's conclusions. In cases like the PRLR-SLICK where the agency exercises regulatory discretion—such as issuing a "no safety concerns" determination rather than conducting a full premarket approval—public transparency is further reduced, exacerbating concerns about accountability, scientific rigor, and public trust in the regulatory process.[38,39]

Need for a precautionary approach

Given the scientific uncertainties and potential for unintended consequences in genetically engineered animals, a precautionary approach to regulation is essential. Genetic modifications can have unpredictable effects on animal health, ecosystems, and human food safety, as evidenced by off-target mutations, incomplete resistance to pathogens, and welfare problems in some GE and cloned animals. Applying a precautionary framework would prioritize thorough, independent risk assessment, transparency, and monitoring before products enter the food system, rather than relying on abbreviated reviews or assumptions of equivalence to conventional animals. This approach helps minimize harm, protect public and animal health, and maintain public trust, acknowledging that scientific understanding of long-term ecological and health impacts is still incomplete.

Conclusion

Genetically engineered livestock represents a false solution to the crises caused by industrial animal agriculture. Rather than confronting overcrowding, pollution, disease, and exploitation, these technologies entrench the factory farm model and shift risk onto animals, consumers, and ecosystems.

At a time when we need bold solutions to transform our food system, engineering animals to better fit factory farming is not progress—it is a dangerous distraction.

Friends of the Earth calls for a fundamentally different path—one rooted in agroecology, animal welfare, environmental justice, and public health. Well-managed pasture-based and organic systems can support healthy soils, protect biodiversity, reduce climate impacts, improve animal welfare, and eliminate routine antibiotic use.

Friends of the Earth urges policymakers to halt approvals of genetically engineered animals, close regulatory loopholes, and invest instead in farming systems that protect public health, respect animal welfare, and restore the environment. The future of food must be rooted in justice and sustainability—not corporate-driven shortcuts that deepen harm.

Endnotes

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