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Fellowship Capstone | Policy Brief

Editing the Future: The Need for Regulating Genetic Modification

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I. Executive summary

The rapid advancement in genetic modification technologies, especially CRISPR and gene editing, has transformed our ability to perform accurate changes to DNA, with applications in medicine, agriculture, and environmental science. These technologies, however, have raised ethical, safety, and societal concerns. The question is whether governments should regulate genetic modification in humans, animals, and food. This policy briefing considers the ethical issues, global views, risks of inaction, and other possible policy options regarding genome editing. It recommends that governments implement regulations to guarantee that such technologies are being used responsibly. Some of the key stem include banning non-therapeutic human germline editing, requiring strict ethical screening for genetic alteration in animals, and genetically modified food being clearly labeled. Effective regulation will help to balance the promise of these technologies with the need to protect public health, safety, and ethical standards.

II. Overview

CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) and other gene-editing technologies have transformed the ability to modify DNA with unprecedented precision, speed, and affordability. Gene editing has quickly entered fields involving human health, agriculture, and the environment, but it also raises serious questions, concerns, and ethical issues that need to be addressed.

In the medical field, gene editing holds potential for treating over 7,000 single-gene disorders, including sickle cell disease and cystic fibrosis. However, many concerns arise when these tools are used to enhance human traits rather than treat diseases. Most of the ethical debate centers on the use of CRISPR-Cas9 to edit human germlike cells and embryos, as future generations can inherit these changes.

In agriculture and animal science, gene editing has been used to increase crop yields, reduce the need for pesticides, and improve livestock resistance to disease. For example, GM crops have been associated with yield increases of 20–22% and pesticide reductions of nearly 37% globally. Despite these benefits, critics warn of potential ecological disruption, reduced biodiversity, and ethical issues related to animal welfare and corporate control of food systems.

The long-term effects of genetic modification are still poorly understood, with unpredictable consequences that could disrupt ecosystems, harm biodiversity, or introduce new health risks. Technologies like gene drives, which can spread

genetic changes rapidly across populations, pose serious environmental threats that might be irreversible. The uncertainty around these risks raises ethical concerns, especially when decisions are made with limited knowledge of their potential impact on future generations.

Given these uncertainties, there is a need for stronger, global regulations on genetic modification. Policies should prioritize safety, transparency, and ethical responsibility, ensuring that biotechnology is developed in ways that protect both the environment and public health.

A. Relevance

The debate around genetic modification is no longer theoretical. Real-world events have shown just how urgent regulation has become. In November 2018, Chinese scientist He Jiankui shocked the world by announcing the birth of twin girls whose genes he edited using CRISPR to make them resistant to HIV. The experiment, which disabled the CCR5 gene, was conducted in secrecy and without clear medical necessity or proper oversight. Although China had existing guidelines, they lacked legal enforceability and detailed protocols, allowing a major ethical breach to occur. This case demonstrates the dangers of moving forward with powerful biotechnology in the absence of strict regulation, transparency, and accountability.

Without global standards, genetic modification policies vary wildly. What's banned in one country may be legal in another. This inconsistency can lead to cross-border ethical disputes, trade conflicts (especially involving genetically modified food), and even scientific "tourism," where individuals seek out countries with the weakest regulations. For example, He Jiankui's gene-editing experiment in China sparked international outrage, showing how one nation's oversight can have global implications. Establishing shared standards would reduce international friction and ensure a more cooperative and ethical approach to gene editing.

Similarly, in agriculture, genetically modified organisms (GMOs) are widely used in food production, but transparency remains limited. Many consumers are unaware of what they are eating due to unclear labeling policies. As more CRISPR-edited crops enter the market, the line between "natural" and modified food becomes increasingly blurry, raising concerns about informed consent and consumer rights. Without mandatory labeling and oversight, public trust in food safety and biotechnology could erode.

III. History

A. Current Stances

Stances on Human Gene Editing Across Countries

Policies on human gene editing vary widely across the globe, ranging from permissive to restrictive, with many countries falling into ambiguous legal gray areas. A 2023 study published in The CRISPR Journal analyzed national policy documents from 106 countries and found that most restrict or prohibit heritable genome editing:

- **Only 11 countries** explicitly permit research on genetically modified embryos

without allowing implantation.
- **No country** permits the clinical use of heritable genome editing (i.e., transferring edited embryos into a uterus).

These findings underscore a growing global consensus that germline editing should be cautiously treated. However, the study also found that many nations either lack comprehensive regulations or operate under vague, outdated frameworks, and the pace of scientific development often far exceeds legal reform

An example of this is South Korea, where the Bioethics and Biosafety Act (BioAct) governs gene-related research. The BioAct does not explicitly regulate "gene editing" as a category; instead, gene therapy is addressed indirectly through drug laws or human subject research guidelines. Gene therapy is classified into two types:

Type 1: Alter genes inside the human body, potentially affecting offspring.
Type 2: Transfers genetic material or altered cells into the body, with less risk of heritability.

While germline gene therapy is fully banned(including interventions involving embryos, sperm, eggs, or fetuses), the BioAct still permits limited embryo research, such as for infertility treatment or using surplus IVF embryos. This regulatory gray area has led to legal ambiguity, raising concerns that certain research could enable germline modifications without being prohibited. Legal scholars have called for clearer distinctions between heritable and non-heritable interventions and revisions to laws like BioAct §47 to explicitly address technologies like CRISPR.

The 2018 case of Chinese researcher He Jiankui, who edited embryos to create genetically modified babies, highlighted the urgent need for global policy frameworks surrounding heritable genome editing. His actions sparked international outrage, as they demonstrated the risks of advancing powerful genetic technologies without sufficient ethical oversight and regulatory safeguards. In response, influential scientists like Emmanuelle Charpentier and Feng Zhang called for a global moratorium on germline editing, stressing that it should not proceed until robust scientific, ethical, and legal guidelines are established

National policies on gene editing reflect a balance between scientific progress, ethical considerations, and public trust. As Na-Kyoung Kim argues, clear and proactive legislation is crucial to prevent misuse and foster responsible innovation.

Stances on Animal Gene Editing Across Countries

The global regulatory landscape for animal gene editing (GnEd) varies widely. The U.S. FDA treats all gene-edited animals as GMOs, imposing strict regulations, while Japan, Argentina, Brazil, and Colombia exempt animals with naturally possible edits, enabling the commercialization of products like fast-growing fish and disease-resistant pigs. Australia takes a similar approach, with lighter regulation for edits that don't involve foreign DNA. In contrast, the EU enforces strict GMO rules on all gene-edited organisms, stalling most applications, and Norway bans cloning-related methods on welfare grounds. China leads in research output and

appears to have fewer barriers, though its policies remain opaque. Overall, while some countries are moving toward trait- and technique-based classifications, the lack of global consistency highlights the need for clearer, harmonized standards.

Stances on Genetically Modified Food (GMOs) Across Countries

Globally, GMO regulations vary widely depending on a country's economic priorities, consumer attitudes, and political climate. In the United States, where around 70–80% of processed foods contain GMOs, labeling remains largely voluntary despite increasing consumer demand for transparency,63% of Americans supported the FDA's current voluntary policy in a 2014 survey, while states like Vermont, Connecticut, and Maine have pushed for their own mandatory labeling laws. In fact, the U.S. led the world in 2015 with 43% of all global "GMO-free" product launches, compared to just 4% from the EU. The European Union, in contrast, has one of the strictest and most centralized GMO regulatory systems. GMO approval involves multi-step evaluations through the European Commission and European Food Safety Authority, and all foods containing more than 0.9% GMOs must be labeled. The EU's restrictive stance stems from consumer skepticism, environmental activism, and protectionist trade policies, causing delays and higher costs for GMO adoption and biotechnology development. Japan takes a middle-ground approach: GMOs are regulated under the Cartagena Protocol, and labeling is mandatory if GM ingredients are among the top three by weight and make up over 5% of the product. Oversight is split between ministries, including Health, Agriculture, and the Environment, with risk assessments conducted by the Food Safety Commission. China also requires mandatory GMO labeling under its updated 2015 Food Safety Law, and violators can face fines or license suspensions. However, implementation has been inconsistent, and labeling specifics (like font size or display format) remain unclear. Despite early regulatory efforts since the 1990s and over 300 approvals for GMO research by 2000, public trust remains low in China due to poor government communication and incidents like the 2012 Golden Rice controversy. These differences in regulation have consequences for global trade: countries with highly divergent GMO policies trade significantly less with each other, and researchers have called for more harmonized regulations to reduce costs and ease compliance in international markets.

IV. Policy Problem

A. Stakeholders

A wide range of stakeholders are directly affected by or involved in the regulation of genetic modification technologies. First and foremost, governments are responsible for creating and enforcing the legal frameworks that determine how gene editing can be used. Their role is critical in ensuring that these technologies are applied safely, ethically, and transparently across sectors. Without clear laws and enforcement mechanisms, there is a risk of unethical experiments, as seen in the CRISPR baby case in China.

Scientists and researchers are at the forefront of gene editing innovation, developing tools like CRISPR-Cas9 that have revolutionized biotechnology. While many are driven by the

potential to cure diseases and solve agricultural problems, the scientific community has also expressed strong concerns about premature or unregulated applications. For example, following the 2018 germline editing scandal, leading researchers called for a global moratorium on heritable human genome editing.

The medical community functions both as a key implementer of gene editing therapies and as a safeguard for patient safety, informed consent, and health equity. Organizations like the World Health Organization and the National Academies of Science have emphasized the importance of ethical guidelines and robust clinical oversight before gene editing is applied to patients, especially in reproductive contexts.

Agricultural corporations are heavily invested in genetically modified crops and animals, aiming to boost yield, reduce disease, and cut costs. Companies like Bayer and Corteva have developed CRISPR-edited crops resistant to pests and climate stresses. However, these entities may resist strict regulations that could slow commercialization or reduce profits (Shukla-Jones et al., 2018). This has raised concerns about corporate influence over the food system and the marginalization of small farmers.

Consumers, meanwhile, are demanding greater transparency and accountability in both medicine and food. In agriculture, CRISPR-edited crops may not always be labeled under current laws, leaving many people unaware of what they are eating. According to a 2022 Pew Research Center survey, a majority of Americans support mandatory labeling of genetically modified foods.

Lastly, youth and future generations are perhaps the most important, yet most voiceless, stakeholders. Germline editing can result in irreversible genetic changes passed down through generations, and environmental uses of gene editing (like gene drives) could permanently alter ecosystems. These long-term effects make it imperative that policy decisions today account for those who will live with the consequences tomorrow.

B. Risks of Indifference

Failing to regulate genetic technologies could lead to consequences across multiple domains. In humans, unregulated gene editing, especially of heritable traits, raises the risk of irreversible genetic alterations, widening social inequality, and the resurgence of eugenics-like ideologies. The Nuffield Council on Bioethics warns that germline editing without ethical safeguards threatens dignity, justice, and informed consent.

In animals, lack of oversight could cause unintended suffering, harm biodiversity, and destabilize ecosystems. The National Academies of Sciences, Engineering, and Medicine note that such changes can disrupt food chains and alter habitats. Similarly, genetically modified crops without clear labeling can erode public trust and limit consumers' ability to make informed decisions

Globally, the absence of shared rules could cause conflict if countries follow very different standards or exploit weak regulations. This could lead to “ethics dumping” or “regulation shopping,” where researchers seek permissive jurisdictions to bypass safeguards.

Finally, misused tools like gene drives could cause lasting damage to wild populations. Esvelt and Gemmell warn that such genetic changes may be

impossible to reverse. Without coordinated global oversight, the cost of inaction may be permanent harm to both ecosystems and society.

C. Nonpartisan Reasoning

Regardless of political beliefs, gene editing raises concerns that demand shared, responsible oversight. Protecting public health and safety is a universal priority, not a partisan issue. Democratic values like transparency and informed consent should guide decisions on biotechnologies. Long-term risk management helps prevent unintended harm to future generations. Scientific progress also depends on maintaining ethical boundaries to preserve public trust and research integrity. Moreover, unregulated gene editing can pose national security risks, such as bioweapons or genetic surveillance. To lead globally in biotechnology, nations must prioritize responsible innovation over unregulated competition. Upholding these principles strengthens both global cooperation and domestic resilience in the face of rapid technological change

V. Tried Policy

In the United States, gene editing is governed by several agencies under the Coordinated Framework for the Regulation of Biotechnology (first issued in 1986 and updated in 2017). The Food and Drug Administration (FDA) regulates gene therapies as biologics under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. The U.S. Department of Agriculture (USDA) oversees genetically engineered plants through its SECURE Rule (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient), finalized in 2020. However, these rules don't address human germline editing directly, and critics argue the system lacks oversight.

Globally, China revised its gene-editing regulations in 2023 after the He Jiankui scandal. The new "Measures for the Ethical Review of Life Science and Medical Research Involving Humans" includes clearer penalties for unauthorized gene editing and mandatory ethical reviews for research involving human embryos.

The European Union, under Directive 2001/18/EC, bans most GMOs and prohibits human germline editing except in rare, controlled medical exceptions.

The World Health Organization (WHO) launched a Human Genome Editing Registry in 2021 as a step toward transparency, but participation is voluntary, and there is no enforcement mechanism to ensure compliance or ethical standards.

Labeling laws for genetically modified foods also vary widely: for example, the U.S. National Bioengineered Food Disclosure Standard (2016) requires GMO food labeling, but critics argue it lacks clarity and excludes some processed products. In contrast, EU countries require clear GMO labeling, while others, like Canada, have voluntary systems.

VI. Policy Options

Ban Non-Therapeutic Germline Editing To prevent irreversible genetic risks and ethical violations, the U.S. should enact a federal ban on non-therapeutic germline editing. Unlike somatic editing, germline changes affect future generations and raise concerns about eugenics. A clear prohibition, similar to the EU's stance under Directive 2001/18/EC, would safeguard against eugenics-like outcomes and protect future generations until long-term risks are better understood.

Enact Stronger GMO Transparency Laws The current National Bioengineered Food Disclosure Standard (2016) lacks clarity and allows QR codes or digital links instead of direct on-package labeling. Updating the law to require plain-text labels on all genetically modified food would increase consumer choice and trust. This would align with EU regulations that require comprehensive transparency for bioengineered products.

Increase Funding for Bioethics and Public Engagement Federal investment in bioethics research and public education through agencies like the NIH and NSF is crucial for fostering informed dialogue and guiding responsible innovation. This support should fund school-based programs, community outreach, and research on the societal impacts of gene technologies. Strengthening public understanding not only builds long-term trust but also helps prevent misuse and political polarization.

VII. Conclusions

In this paper, I examined the ethical and regulatory challenges posed by genetic modification technologies, particularly CRISPR and gene editing. While these innovations hold transformative potential in medicine, agriculture, and environmental science, they also raise significant concerns related to safety, equity, and long-term impact. Without clear government oversight, the misuse of these tools, whether through non-therapeutic human germline editing or unregulated genetic changes in animals and food, can lead to ethical and societal consequences. To ensure these technologies are used responsibly, governments must enact strong, science-informed policies that prioritize transparency, public trust, and global cooperation.

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