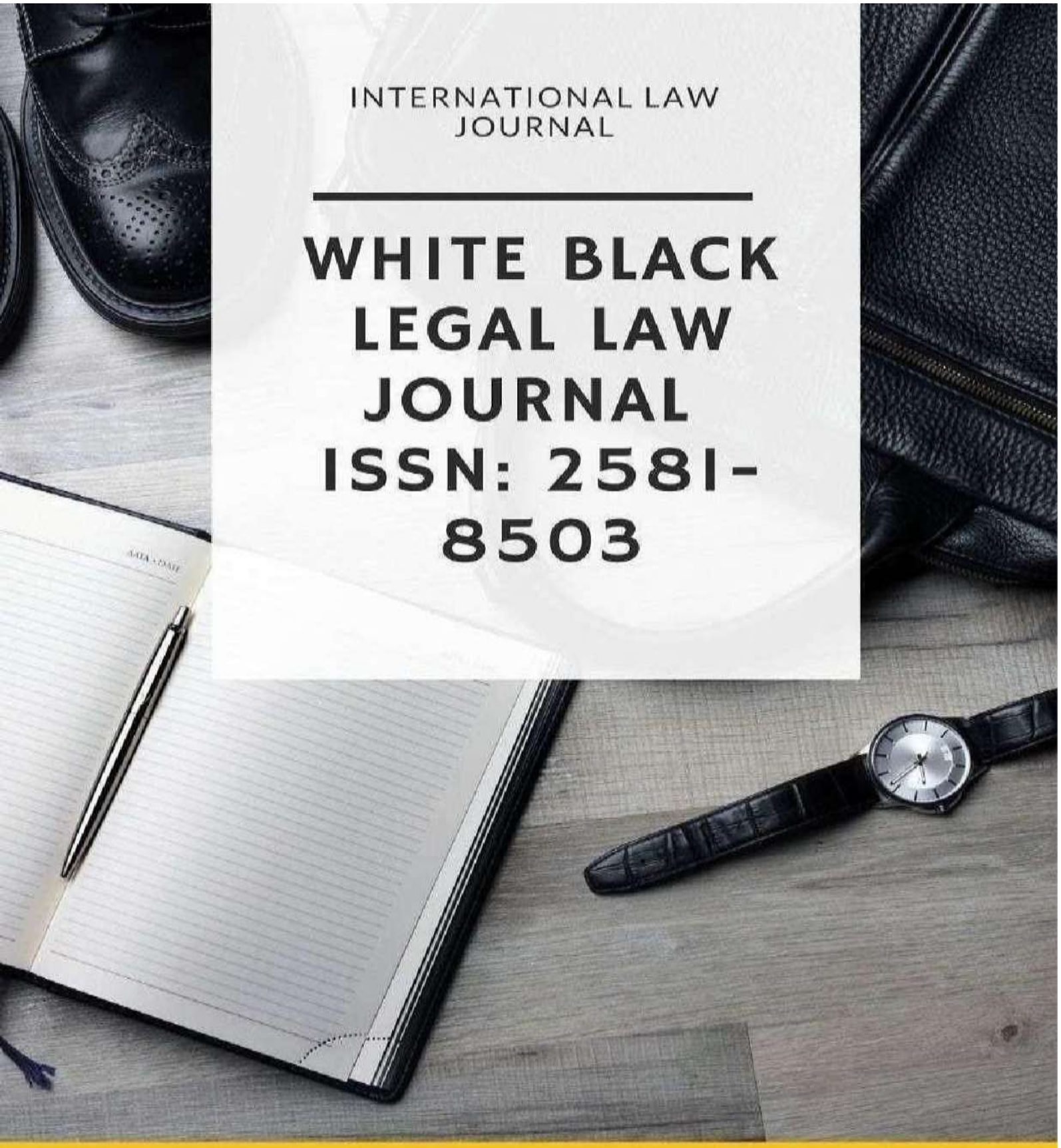

INTERNATIONAL LAW JOURNAL

WHITE BLACK LEGAL LAW JOURNAL

ISSN: 2581-8503

Peer - Reviewed & Refereed Journal

The Law Journal strives to provide a platform for discussion of International as well as National Developments in the Field of Law.

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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and

refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

REGULATION OF GENETIC ENGINEERING IN ANIMALS: LEGAL AND ETHICAL CONSIDERATIONS: A CRITICAL EXAMINATION

AUTHORED BY - RANJANA PAUL[1]

Abstract:

In contrast to conventional breeding, which involves indirectly transferring advantageous genes from one animal species to another, genetic engineering involves the unbroken manipulation of an organism's genes. By modifying animals to reach maturity more quickly, genetic engineering can boost the production of agricultural animal species. Transgenic lambs and pigs that have had their genes changed to express more growth hormones are two examples. To improve the quality of food, farm animals can be genetically modified. To produce a variety of textiles, animals can be altered to produce more milk, develop more muscular mass, or develop different coats. In contrast to traditional breeding, which involves manipulating an organism's genes, genetic engineering involves the continuous manipulation of an organism's genes. Genetic engineering threatens the natural ecosystem, biodiversity, and the natural rights of animals. Genetically modified animals suffer from unforeseen health consequences, including genetic disorders, experience reduced lifespan, or other physiological problems. Genetic Engineering reduces the nutritional value of products and also shortens the lifespan of animals at the same time. The ultimate objective of this paper is to find out the legality of the genetic engineering of animals, to reach a conclusion regarding ethical implications, and to solve the ethical implications associated with the genetic engineering of animals. The laws dealing with it are also discussed in this paper in detail.

Keywords: Genetic Engineering, Animals, Animal Rights, Animal welfare, Legal-Ethical Considerations

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Introduction:

Genetic Engineering is the direct manipulation of an organism's genes which is different from traditional breeding where the organism's genes are manipulated indirectly for transferring beneficial genes from one animal species to another. A subfield of biotechnology known as genetic engineering entails directly modifying an organism's DNA to change certain aspects of it. By using the genetic material from one animal species, scientists can now create new ones. A subfield of biotechnology known as genetic engineering entails directly modifying an organism's DNA to change certain aspects of it. Through genetic engineering, scientists can now create new animal species by introducing genetic material from one or more plants or animals into the genome of another animal. This enables scientists to produce animals that are entirely alien to the planet and specially bred to have only the characteristics that people want in animals. Thus, science can create agricultural animals that have healthier meat and flesh and are less able to feel the pain and suffering often associated with the conditions present in modern factory farms. Critics contend that by genetically modifying farm and research animals, we might be reversing the millions of years of labor that nature has put into creating them. Natural animals have evolved to live in particular environments, and when scientists alter the DNA of a few species, the ecosystem's delicate balance may collapse, leading to the extinction of an undetermined number of natural animal species. Advocates for animal rights argue that animals possess an inherent right to exist without human-induced genetic modifications. This perspective is rooted in the belief that each species should maintain its natural integrity and evolutionary adaptations, which have developed over millions of years. [2]Manipulating animal genomes questions significant ethical issues regarding how humans should alter other species and the potential suffering involved. There is no explicit clause in the Indian Constitution that forbids genetic engineering, hence it is controlled but not strictly criminalized there for several reasons. Important tenets of ethical genetic engineering include non-maleficence, beneficence, justice, fairness, respect for autonomy, and precaution. To aid medical researchers in their hunt for treatments for genetic illnesses like breast cancer, genetically modified animals are also produced. Last but not least, cloning endangered animal species can help wildlife management achieve its objectives of protecting wild populations of the planet's biological variety and guaranteeing that the genetic information of endangered animals will not be lost when the last of the species passes away.

[2] Genetic Engineering and Animals | Animal Legal & Historical Center, https://www.animallaw.info/intro/genetic-engineering-and-animals (last visited Oct 23, 2024).

Genetically modified animals

AquAdvantage salmon (fast-growing, disease-resistant), GloFish (genetically modified luminous fish), Enviropig (reduced phosphorus waste), and Spider-goats (generating silk proteins) are a few examples of genetically modified animals. AquAdvantage fish is a genetically engineered fish that can reach market size in roughly 18 months rather than three years because it possesses a growth hormone gene from Chinook salmon, which causes it to grow more quickly than ordinary salmon. Researchers created silk-spinning goats in 2012 so that their milk would include spider silk proteins, which could be extracted and used in a variety of materials science and medical applications. Researchers have created allergy-free cows that don't produce milk that contains proteins like β-lactoglobulin, which can trigger allergic reactions. The goal of this change is to give people with dairy allergies a safer milk substitute. The aforementioned instances demonstrate the various uses of genetic modification in animals, ranging from agricultural improvements to medical advancements and environmental sustainability.[3]

Techniques in Genetic Engineering

Transgenesis: The transfer of genes from one organism to another, initially the primary method for creating GM animals. This involves integrating foreign DNA into the host genome.[4]

Genome Editing: CRISPR and TALENs (Transcription Activator-Like Effector Nucleases) are examples of contemporary techniques that allow for targeted changes without the need to introduce extraneous DNA. As a result, genetic modifications are now more widely used than with conventional transgenic techniques.

Gene Targeting: Methods that use natural cellular repair processes to facilitate gene insertion or deletion by causing double-strand breaks in DNA. This approach decreases undesired consequences and improves specificity.

Societal benefits

It may result in the creation of animal models to investigate human illnesses, speed up medical research, and enhance existing therapies. Animals that have undergone genetic engineering can produce useful medications and proteins, including hormones and antibodies, that are essential

[3] Genetic Modification (GMOs): Animals | SpringerLink, https://link.springer.com/referenceworkentry/10.1007/978-3-319-09483-0_209 (last visited Nov 3, 2024).

[4] Genetic engineering of animals: Ethical issues, including welfare concerns - PMC, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078015/ (last visited Oct 5, 2024).

for the treatment of a variety of illnesses. By enhancing growth rates, illness resistance, and feed efficiency, genetic alterations can improve cattle attributes and contribute to more productive and sustainable agriculture. Genetic engineering can aid in the conservation of endangered species by enhancing genetic diversity and resilience, potentially helping to preserve biodiversity. Genetically modified animals can assist in environmental cleanup efforts by breaking down pollutants or contributing to waste management. These benefits demonstrate how genetic engineering can contribute to advancements in medicine, agriculture, conservation, and environmental management.

Industrial benefits

Genetic engineering can enhance growth rates, feed efficiency, and disease resistance in livestock. This leads to increased meat, milk, and egg production, improving overall food security. By modifying genes, animals can be made resistant to specific diseases, reducing the need for antibiotics and lowering healthcare costs in farming. Genetic modifications can enrich the nutritional profile of animal products. For instance, engineering animals to produce milk with higher levels of omega-3 fatty acids can contribute to healthier diets. Genetic engineering can help reduce the need for certain painful procedures or treatments. For example, creating animals that are less prone to certain genetic disorders can enhance their overall well-being. Genetically modified animals can be used to produce pharmaceuticals, antibodies, or hormones, which can be harvested from their milk or blood. This biopharming approach can lead to more efficient production of medical products. Genetic engineering can help develop animals that are more efficient at converting feed into protein, reducing resource consumption and environmental impact. Genetically modified animals, such as mice engineered for specific human diseases, provide valuable models for medical research, leading to advancements in treatments and understanding of various conditions. Genetic engineering can enhance fish and shellfish growth rates, disease resistance, and environmental adaptability, promoting sustainable aquaculture practices. Genetic engineering may aid in conservation efforts by enhancing the resilience of endangered species or helping restore populations impacted by habitat loss.

Ethical Issues of Genetic Engineering of Animals

Concerns about animal welfare and other ethical issues can surface at any point during the development and lifespan of a single genetically modified animal. In the pharmaceutical sector,

genetically modified animals are now frequently used for risk assessment, therapeutic development, and discovery. Concerns around intellectual property and patenting produced animals and/or the methods utilized to produce them are also raised by genetic engineering. The scientific community may develop a culture of secrecy as a result of protecting intellectual property, which restricts the sharing of data and animals. Such restrictions on data and animal sharing could lead to scenarios where genetically modified animal lines are needlessly duplicated, which would go against the reduction principle. Farm animals that have undergone genetic engineering can be produced to improve food quality. For example, pigs have been genetically engineered to express the Δ12 fatty acid desaturase gene (from spinach) for higher levels of omega-3, and goats have been genetically engineered to express human lysozyme in their milk. Such advances may add to the nutritional value of animal-based products. Modifications are seen as violations of an animal's integrity and natural state. Many argue that tampering with an animal's genome undermines its essence and capacity to thrive in its natural environment.[5] The argument posits that humans should not interfere with natural processes, as doing so could lead to unintended moral and ecological consequences. Critics believe such interventions reflect a hubristic attitude towards nature.[6] Unexpected health complications, such as genetic abnormalities, shortened lifespans, or other physiological problems, may affect genetically modified animals. The release of genetically modified animals into the environment may have unanticipated consequences for ecosystems, including upsetting ecological equilibrium and local biodiversity. Genetic engineering procedures can cause physical and psychological stress to animals. It is challenging to evaluate the possible hazards and unforeseen repercussions over time because the long-term effects of genetic changes are frequently unknown. Genetic variety, which is essential for a species' flexibility and resilience, can be diminished by an overemphasis on particular genetic features. These drawbacks emphasize the necessity of thorough risk assessments and strict ethical considerations in animal genetic engineering procedures.

Ethical Boundaries in Genetic Engineering

Products made from genetically modified animals do not now have to be labeled, so consumers are not aware of what they are buying. Tracking possible health effects linked to these items is made more difficult by this lack of transparency. Interbreeding between GE animals and

[5] Ethical perspectives on modifying animals: beyond welfare arguments | Animal Frontiers | Oxford Academic, https://academic.oup.com/af/article/10/1/45/5699797?login=false (last visited Nov 3, 2024).
[6] Genetic Modification (GMOs): Animals | SpringerLink, *supra* note 3.

domesticated or wild populations may have unforeseen implications, such as introducing novel features into wild species. [7]Local ecosystems and biodiversity may be threatened by this gene flow, especially if GE features provide these animals an edge over native species.[8]

The ethical concerns surrounding biopiracy the practice of corporations asserting ownership of genetic resources without paying Indigenous groups or nations that have historically nurtured these organisms are brought up by the patenting of genetically modified animals. The livelihoods of those who depend on these resources as well as the local biodiversity may be threatened by this activity.[9]Animal genetic alteration raises questions regarding potential social impact and animal welfare. Pain and suffering during the experiment, uncertain outcomes and unanticipated repercussions, the potential for heightened vulnerability to illness, and the disturbance of social structures and natural behavior are all effects. Certain DNA sequences that are not typically present in an animal's genetic composition can be added, changed, or removed to genetically edit it. It aims to modify specific animal characteristics or introduce new ones, such as enhanced growth or disease resistance. An organism's genetic material, or DNA, contains the instructions for every characteristic it develops. Changes made to an animal's genetic makeup can therefore be inherited by the next generation.

Legal Framework

Genetic engineering and biotechnology, especially about animals, are governed by several laws and regulations in India. The following are some important legal frameworks designed to stop unlawful genetic engineering practices: The 1986 Environment Protection Act regulates dangerous materials, including genetically modified organisms (GMOs), and establishes a framework for environmental protection. It requires evaluations of how biotechnology applications affect the environment. Conserving biological diversity and controlling access to biological resources, such as genetic material, are the goals of the Biological Diversity Act of 2000. It guarantees the sustainable use of biological resources and demands local populations' prior informed consent.[10]

[7] Genetic engineering of animals: Ethical issues, including welfare concerns - PMC, *supra* note 4.
[8] Center for Food Safety | Government Regulations | | Government Regulations, CENTER FOR FOOD SAFETY, https://www.centerforfoodsafety.org/issues/680/ge-animals/government-regulations-278 (last visited Oct 23, 2024).
[9] BBC - Ethics - Animal ethics: Biotechnology, https://www.bbc.co.uk/ethics/animals/using/biotechnology_1.shtml (last visited Nov 3, 2024).
[10] Vibha Ahuja, *Regulation of Emerging Gene Technologies in India*, 12 BMC PROCEEDINGS 14 (2018).

The Animal Welfare Act, 1962-This act focuses on the humane treatment of animals and includes provisions related to experimentation and genetic manipulation. It aims to ensure that any genetic engineering practices comply with animal welfare standards.[11]

The Food Safety and Standards Act, 2006- This act regulates food safety and standards, including genetically modified foods. It mandates labeling and safety assessments for GM food products, ensuring consumer protection.

The Genetic Engineering Appraisal Committee (GEAC)- Under the Ministry of Environment, Forest and Climate Change, the GEAC is responsible for assessing and approving proposals for the release of GMOs into the environment. It plays a critical role in ensuring compliance with regulations. The main regulatory agency that assesses and authorizes applications for genetically modified organisms (GMOs) is the GEAC, which is housed inside the Ministry of Environment, Forests, and Climate Change. It supervises field testing and commercial GMO releases and performs evaluations to guarantee adherence to environmental safety standards. The main regulatory agency that assesses and authorizes applications for genetically modified organisms (GMOs) is the GEAC, which is housed inside the Ministry of Environment, Forests, and Climate Change. It supervises field testing and commercial GMO releases and performs evaluations to guarantee adherence to environmental safety standards.

The Indian Patent Act, 1970- While primarily focused on intellectual property rights, this act also addresses issues related to biotechnological inventions, including genetic engineering. It prohibits patents on certain living organisms to prevent misuse.

Violations of these laws can lead to penalties, including fines and imprisonment, depending on the severity of the infraction. Enforcement is carried out by various government agencies. These laws collectively aim to regulate genetic engineering practices, promote ethical treatment of animals, and prevent illegal activities in biotechnology. Enforcement of Indian laws regarding genetic engineering on animals involves several agencies and frameworks designed to ensure compliance with regulations. Here's an overview of how enforcement is structured:

[11] National Research Council (US) Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology, *Regulatory Framework for Animal Biotechnology*, *in* ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS (2002), https://www.ncbi.nlm.nih.gov/books/NBK207580/ (last visited Nov 8, 2024).

Ministry of Animal Husbandry and Dairying

This ministry is in charge of managing and caring for cattle. To make sure that genetic engineering procedures adhere to animal welfare regulations, it collaborates with other departments.

Central and State Pollution Control Boards

These organizations keep an eye on the effects of biotechnology on the environment and enforce laws pertaining to the control of hazardous waste and pollution from genetic engineering operations.

Department of Biotechnology (DBT)

The DBT creates rules and guidelines about the study and advancement of biotechnology. It works in tandem with the GEAC to guarantee adherence to safety and ethical standards.

Animal Welfare Board of India (AWBI)

This board oversees adherence to the Animal Welfare Act and advocates for the ethical treatment of animals. It contributes to the evaluation of the moral ramifications of genetic engineering procedures. Penalties, such as fines and jail time, may follow violations of genetic engineering regulations. Inspections are carried out by enforcement agencies, and those who violate the law may face legal punishment. The public, NGOs, and civil society are essential in reporting illicit activity.

The Department of Biotechnology, the Genetic Engineering Approval Committee (GEAC), and other organizations are part of the regulatory system. Research is encouraged, entrepreneurs are incubated, and biotechnology is regulated by the Department of Biotechnology (DBT). GMO safety is supervised by GEAC. The Recombinant DNA Advisory Committee (RDAC) ensures that genetic research is conducted ethically. The Food Safety and Standards Authority of India (FSSAI) is in charge of food safety, whereas the Drugs Controller General of India (DCGI) oversees biopharmaceuticals. Before conducting field tests or releasing GMOs for sale, developers must get GEAC approval. Thorough scientific analysis and public consultation are part of the review process. GMO goods that are prepared for sale or release must be properly labeled to ensure consumers understand their use. Additionally, a traceability mechanism is in place to monitor GMOs across the supply chain. Strict containment procedures must be followed by labs and establishments handling genetically modified

organisms to avoid unintentional releases. India's biosafety laws contain clauses addressing accountability and remedy if GMOs cause harm to the environment or human health. To make sure that GMO-related activities follow biosafety regulations, ongoing monitoring, and compliance checks are carried out.

Landmark judgments on genetic engineering

Animal Legal Defense Fund v. Hormel Foods Corp. (2020) In this instance, Hormel Foods was sued by the Animal Legal Defence Fund for genetically modifying pigs, claiming that this was against animal welfare regulations. It raised questions regarding the moral treatment of genetically engineered animals, even though it was not a decision that directly addressed genetic engineering. Japan's Supreme Court ruled against the use of gene-edited animals in the food industry, reflecting the country's cautious approach to genetic modifications in livestock and emphasizing the need for stringent regulatory oversight. The U.S. Food and Drug Administration established guidelines for the regulation of genetically engineered animals, particularly focusing on those intended for food. This regulatory framework has been influential in setting standards for the approval and monitoring of such animals.

On June 16, 1980, the United States Supreme Court rendered a landmark decision in Diamond v. Chakrabarty, which significantly altered the field of patent law, especially as it related to living things. The dispute started when General Electric microbiologist Ananda M. Chakrabarty created a genetically modified bacteria that could degrade crude oil, which was important for environmental cleanup initiatives. Chakrabarty filed for a patent on this bacterium, but the U.S. Patent Office first denied the application, claiming that since living things were regarded as natural goods, they could not be patented.

Legal Consideration of Genetic Engineering on Animals

GE animals can contribute to the biological contamination of wild populations and organic farms through crossbreeding or other means. This contamination can lead to the loss of genetic diversity in natural populations, posing risks to ecosystem resilience and stability. Current laws such as the Animal Health Protection Act provide limited authority over the environmental release of GE animals, focusing primarily on livestock diseases rather than broader ecological implications. There are serious worries over genetic pollution due to the possibility of crossbreeding between wild or domesticated populations and genetically modified organisms (GMOs). This might lead to a decline in genetic diversity and the possible emergence of alien

species that could displace native species. Genetically engineered animals' intellectual property concerns draw attention to a crucial point where ethics and innovation converge. Patents raise issues with animal welfare and environmental sustainability even though they offer crucial protections that promote scientific research and development. Future policies will probably be shaped by ongoing discussions as society considers the effects of animal genetic modification.

Counterbalance of Innovation and Regulation

In genetically modified animals, even the same gene change can produce a variety of phenotypes; some have no welfare issues, while others have negative consequences. Since it's sometimes difficult to predict the effects of a particular genetic mutation on a single animal, genetically modified animals must be closely monitored to address any unanticipated welfare concerns as they arise. Newly created genetically modified animals need more observation than typical animals because of their unpredictable nature. Once a genetically modified animal line has been established and the welfare concerns are recognized, it would be possible to reduce the levels of surveillance if the animals are not exhibiting a phenotype that has negative welfare impacts. The main piece of federal law governing animal property in the US is the Animal Welfare Act (AWA). The creation and upkeep of federal standards and rules for the humane treatment of non-human animals are usually regarded as having been unsuccessfully accomplished by the AWA. Dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, and other warm-blooded animals that are being utilized or are planned to be employed for research, education, testing, experimentation, or display are all protected by the AWA.

Cultural Perspective

Animal genetic alteration is a complicated topic that is influenced by many cultural norms and beliefs. While some cultures may welcome the potential advantages of biotechnology for enhancing productivity and well-being, others are adamantly against it due to historical injustices connected to scientific interventions, spiritual convictions, or worries about the integrity of the natural world. Many Asian civilizations, especially those in nations like India and Japan, have a spiritual perspective on genetic alteration. Harmony with nature and the idea that changing an animal's genetic makeup upsets the natural order are highly valued. Religious convictions that support the sanctity of life might occasionally serve as the foundation for these opinions. A common utilitarian viewpoint that highlights the potential advantages of genetic modification for boosting food security, improving animal welfare, and furthering medical research is found in many Western nations, especially in the US and portions of Europe.

Supporters contend that such changes can lessen an animal's suffering or enhance its health. Some Eastern societies are skeptical about the use of technology in animal husbandry and agriculture.

Future Prospects

With technological developments that may result in more effective production techniques and better animal welfare, the future of genetic engineering in animals appears bright. However, the global adoption of these technologies will be influenced by continuing debates on ethics, public acceptance, and regulatory actions. In conclusion, animal genetic engineering is a quickly developing area with important ramifications for ethics, medicine, and agriculture. Its development will need to be properly guided by rigorous consideration of ethical concerns and regulatory frameworks as techniques improve and applications expand.

Limitation of the study:

Current laws present several serious obstacles to the regulation of genetically altered (GE) animals, chiefly because of antiquated frameworks, insufficient risk evaluations, and a dearth of regulations specifically designed for this technology. Outdated legislative frameworks, a lack of clear rules, and the complexity of the technology itself make it difficult to regulate genetic engineering (GE) in animals. GE animals are not specifically governed by any laws; rather, they are covered indirectly by current statutes. Instead of creating specific laws for genetically modified animals, organizations such as the FDA and USDA have relied on broad principles that fall short of addressing the particular hazards involved with genetic alterations. Since applications filed under the Investigational New Animal Drug (INAD) program are kept private, the licensing procedure for genetically modified animals sometimes lacks transparency.

Recommendations:

1. Existing regulatory frameworks often lack comprehensive ethical guidelines. The Asilomar Conference and other international agreements have laid foundational principles for responsible research; however, gaps remain regarding transparency, informed consent, and environmental responsibility. There is a pressing need for

updated legislation that addresses both the ethical implications of genetic modifications and the potential risks associated with GMOs escaping into natural environments. [12]

2. Development of emergency response plans for unintended consequences.
3. Investigation of the long-term consequences of genetic engineering.
4. Training of researchers on animal welfare.
5. Strengthening animal welfare laws.
6. Encouragement of public-private partnership.
7. Addressing concerns regarding food safety and labeling.
8. Coordination between numerous regulatory agencies.
9. Establishment and Conduct of public surveys, consultations, and advisory committees.
10. Animal welfare boards or committees focus on ensuring that genetic engineering practices adhere to ethical and humane standards.

Conclusion:

Recent animal welfare laws are insufficient to mitigate the issue regarding the long-term effects of scientific advancement on animal health and well-being. There is a requirement for vigorous harmonized standard regulatory guidelines ensuring safety efficiency and minimization of unexpected consequences for upholding scientific integrity. To address problems, a more robust regulatory structure is needed. This could entail creating clear ethical standards for genetic engineering practices that prioritize the welfare of animals, involving stakeholders in discussions about genetic engineering regulations, including the general public and animal rights organizations, establishing monitoring systems, and establishing protocols for ongoing assessment of the impacts of genetically modified animals on human health and biodiversity. The morality and legality of regulating animal genetic engineering must be addressed immediately in India. Existing frameworks provide a foundation, but they are insufficient to manage the complexity resulting from biotechnology advancements. To guarantee the responsible application of genetic engineering technology while preserving animal welfare and environmental integrity, a thorough strategy that combines moral concerns with strong legal requirements is necessary. There is no denying that we cannot afford to watch helplessly while this technology drastically alters every aspect of our lives. We must not wait to observe the consequences. We must develop informed viewpoints, encourage legislative regulation, and

[12] The Ethical and Security Implications of Genetic Engineering, ORFONLINE.ORG, https://www.orfonline.org/research/the-ethical-and-security-implications-of-genetic-engineering (last visited Nov 3, 2024).

hold out hope that bioengineering will ultimately lead to greater environmental sustainability, less animal suffering, and a more caring attitude.

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