Genetic Engineering and its Implications for Biosecurity: Risk Assessment and Management

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Abstract

Genetic engineering is a variety of methods that use molecular biology technology to change DNA sequences in genomes. The effectiveness of homology-directed repair could be enhanced to facilitate future developments in CRISPR/Cas9 gene editing. As part of the One Health idea, biosecurity—which includes minimizing the spread to animals, people, plants, and the environment—is particularly important? To reduce the likelihood that animal diseases could endanger society, disease prevention techniques such as biosecurity, surveillance, and traceability are essential. Some people have strong moral and religious opinions about genetically modified organisms (GMOs), which raises several problems. The marketing of genetically modified organisms raises biosafety concerns that are increasingly being addressed by national and international agencies and regulatory bodies. It examines strategies used to reduce the danger that has been identified by science and may take into account additional considerations (such as socioeconomic or ethical).

Keywords: Genetic Engineering; Biosecurity; Risk Management; GMOs; CRISPR; TALENS; Bio-Pharming

Cite this Article as: Noor M, Qamar U, Sharif H, Aiman T, Saeed S, Saeed MT, Qayyum U, Tariq I, Khanam M and Rafiq S, 2025. Genetic engineering and its implications for biosecurity: Risk assessment and management. In: Farooqi SH, Kholik K and Zaman MA (eds), One Health Horizons: Integrating Biodiversity, Biosecurity, and Sustainable Practices. Unique Scientific Publishers, Faisalabad, Pakistan, pp: 280-289. https://doi.org/10.47278/book.HH/2025.169

A Publication of Unique Scientific Publishers

Chapter No: 25-038

Received: 02-Jan-2025
Revised: 25-March-2025
Accepted: 17-May-2025

Introduction

Introduction to Genetic Engineering

Since DNA was discovered to be the unit of heredity and the basis for the fundamental tenet of molecular biology—that DNA generates RNA and RNA generates proteins scientists have looked for methods and tests to gain a better understanding of how DNA affects inheritance. Researchers soon started examining chromosomal DNA in organisms and animals after the invention of molecular biology methods including restriction enzymes, DNA sequencing, and DNA cloning. The use of selectable markers in plasmids was a development of previous studies that employed the co-incubation of viral DNA with cultured cell lines. From physically co-incubating DNA with cultivated cells to electroporation and microinjection of cultured cells, delivery techniques for random DNA integration have changed throughout time (Nicholl, 2023). Alongside physical methods of transferring DNA to cells, the use of viruses to transfer DNA to cultivated cells has also developed. The mouse genetics community swiftly employed homologous recombination in animal cells to create gene-modified mouse ES cells and, consequently, gene-modified whole animals. Specifically, the 2014 discovery of bacterial CRISPR-mediated adaptive immunity and its use in genetically editing human and mouse cells marked a turning point in contemporary research (Ahmad et al., 2021). Moreover, transgenic mouse development has changed since the advent of CRISPR/Cas9 technology. Differences in the need for ES cell microinjections into blastocysts and nucleic acid microinjections into zygotes are indicative of this paradigm change. The CRISPR/Cas9 techniques have greatly simplified the process of producing genetically modified model animals in mice, rats, and other species, even though the previously established principles of genetic engineering using mouse ES cell technology are still applicable (Ren et al., 2021).

Gene therapy pursues to treat hereditary illnesses by replacing defective genes, while genetically engineered bacteria and yeast are utilized to produce pharmaceuticals like insulin and human growth hormone. Moreover, in industrial biotechnology, genetically tailored microorganisms are employed for the production of biofuels, bioplastics, and other sustainable materials, signifying the vast potential of genetic engineering in solving global challenges. Animals and organisms can have extra genetic material inserted into their chromosomes using a variety of methods. Currently, single-copy gene insertion at a specified place is the most attractive approach.The ability to alter the genome at single nucleotides is demonstrated by the invention of CRISPR/Cas9 base editing technology. The CRISPR technology, which prevents chromosome breaks when modifying the genome, is critical in therapeutic applications where unintentional alterations might harm patients (Grama et al., 2022). Some examples are as follows:Genetic Engineering using CRISPR/Cas9 and TALENS,Gene Editing in Immortalized Cell Lines, Viruses and Transposons as Vectors, Retroviruses.

1. CRISPR/cas9
2. TALENs

1. CRISPR/cas9

The most important scientific breakthrough of the decade is generally agreed to be the CRISPR/Cas9 genome editing method.Due to its versatility and ease of manufacturing, the Cas9 (CRISPR-associated) enzyme, which is a component of the type II CRISPR system that comprises the innate immune system of the *S. Pyogenes* bacterium, has brought about this generation of genome editing.The arrangement of the guide RNA (gRNA) sequence must be such that the 5′ end is complementary to the target site to instruct Cas9 to knock out a particular target DNA.The targeting of Cas9 is easier to program than that of the more complex genome editing tools (TALENs, ZFNs, and MNs) (Bhardwaj & Nain, 2021).To accurately cleave DNA, the CRISPR-Cas9 system's endonuclease is regulated by a brief gRNA sequence (20 bp).Because it provides specificity in Cas9-mediated targeting, the 5′-NGG-3′ proto spacer-associated motif (PAM) interaction domain is in charge of identifying the precise binding position on target DNA.There is a wide range of Cas enzyme diversity among species with different PAM needs. Human cells as well as a variety of other cells and creatures have been successfully treated using CRISPR-Cas9 technology.But a major drawback of the CRISPR/Cas9 platform is the significant risk of off-target mutations (Bessoltane et al., 2022) (Figure 1).

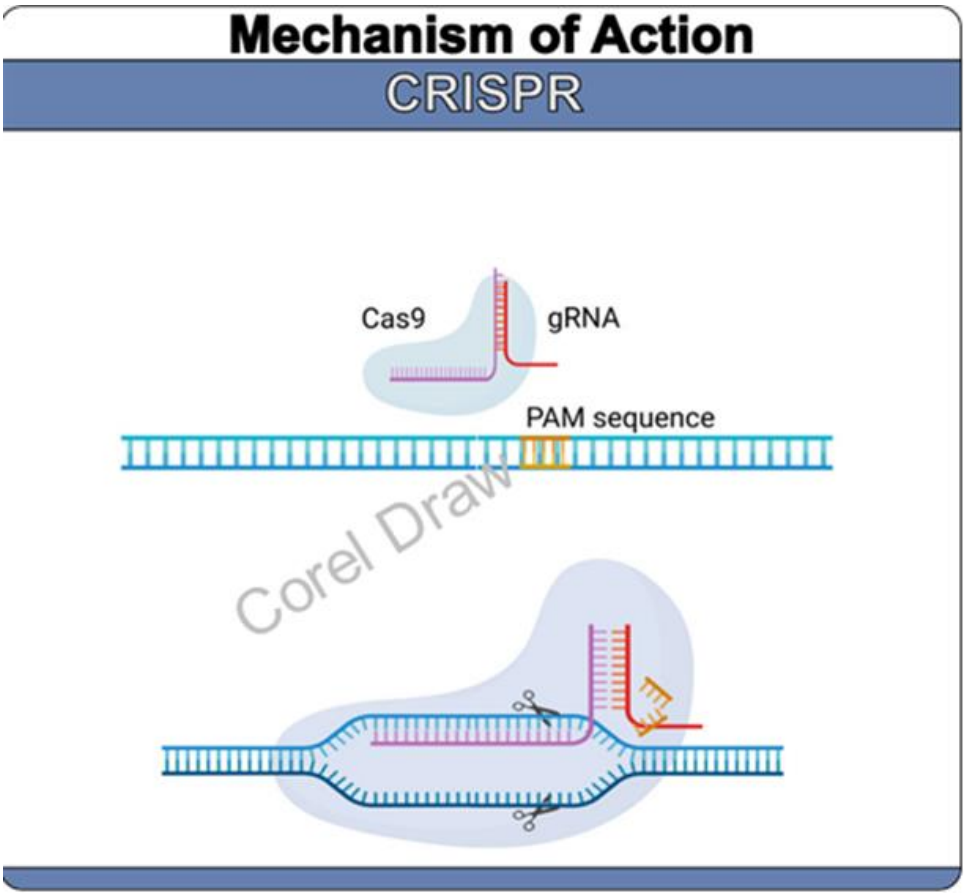

Fig. 1: CRISPR mechanism of action

2. TALENs

2009 saw the first description of TALEN proteins, which come from the bacterial species Xanthomonas, which is responsible for plant illnesses. Because TALEs are compatible with a variety of functional domains, they offer flexible applications in genetic engineering. From transcriptional regulators to tools for genome editing, TALE proteins can evolve through a variety of combinations with transcriptional activators, repressors, or endonucleases (Shamshirgaran et al.,2022). The components of a typical TALEN unit include the Fok1 nuclease, an acidic region that activates target gene transcription, a nuclear localization signal (NLS), and a core DNA binding domain with 12–28 repetitions. TALE proteins provide the two DNA binding domains (DBDs) that make up the commonly used TALEN system. Each unit is connected to a catalytic domain that is taken from the restriction enzyme Folk1. However, it is very easy and versatile to modify TALE-based techniques to alter any genome (Table 1). According to the crystal structure of TALE proteins bound to target DNA, each repeating unit forms a v-shaped structure composed of two alpha helices that join to form a solenoid-like structure that encircles the main groove of DNA through the hypervariable amino acids (Wani et al.,2023) (Figure 2).

Role of Genetic Engineering In Several Fields

In Medical Field

The application of gene transfer techniques can be applied at many different levels. A genetic defect in somatic cells is addressed by somatic cell gene therapy (Demirer et al., 2021). Replacement of a missing or defective enzyme or protein, as well as an inadequate circulating protein, is the most effective use of this type of gene therapy. To fix the condition in the progeny, a gene must be inserted into the patient's reproductive tissue using germline modification. The introduction of a gene to enhance a certain characteristic, like height, is known as enhancement genetic

engineering (Saha et al., 2021). The endeavor to modify or enhance complex human traits, including personality or character, that are usually polygenic is known as eugenic genetic engineering (Karunarathna et al., 2024).

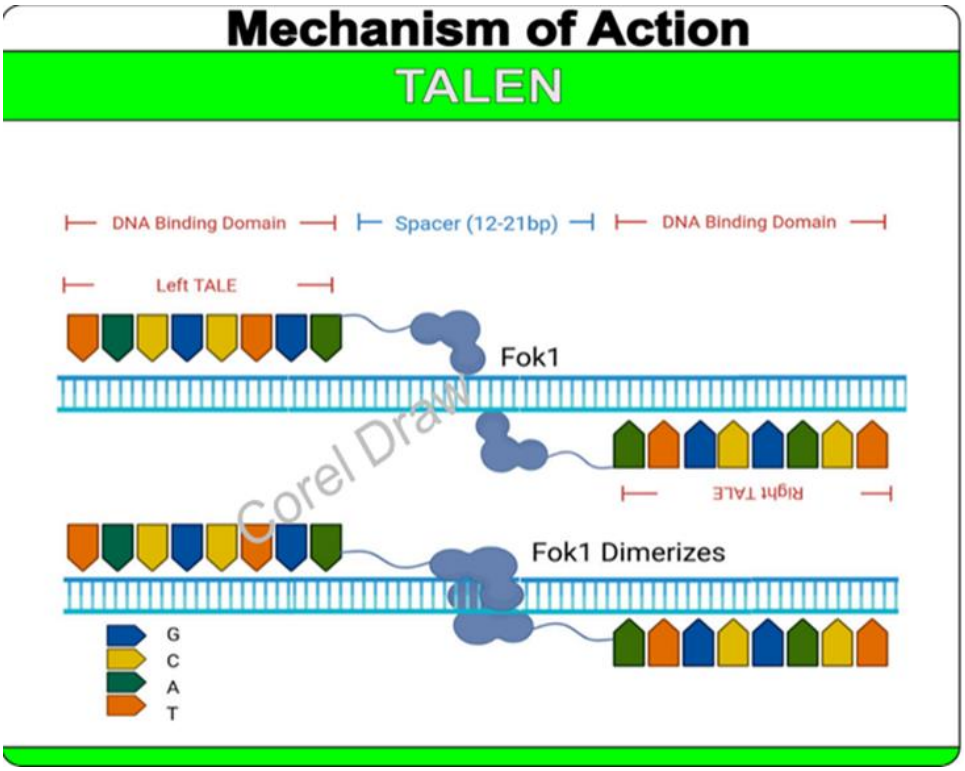

Fig. 2: TALENS mechanism of action

Table 1: TALENS vs CRISPR

Feature	TALEN	CRISPR/Cas9	
Recognition type	DNA-Protein	DNA-RNA	(Wani et al.,2023)
Target site length Endonuclease	30-36 bp	23 bp	(Shamshirgaran et al., 2022)
Dimerization	Fok1	Cas9	
Off-target	Required	Not required	
Design and Assembly	Low	High	
Target Range	Labour intensive	Easy	
Degenerate Recognition	Unlimited	Limited by PAM	
Specificity	Yes	No	
DNA methylation sensitive	High, few mismatches tolerated	Moderate	
Mitochondrial Genome Engineering	Yes	No	
Precision of Genome Editing	Easy	Complex	
	High	Moderate	

Gene Therapy for AIDS

Monocytes and lymphocytes infected with the human immunodeficiency virus (HIV) develop HIV as a component of their DNA. HIV replication in T cells and monocytes gradually reduces CD4 cell counts, leading to immunodeficiency and death from cancer and other opportunistic infections. Three approaches to gene therapy for AIDS are possible: increasing the immune system, changing cells to create a material that may aid or impede the body's defenses against HIV infection, and changing HIV-infected cells to either kill them or stop HIV replication within them (Sayed et al., 2022). To get the desired response, some researchers have proposed injecting genes encoding HIV antigens directly into the muscle. Success or failure depends on the ability to functionally introduce gene-coding nucleic acids into somatic cells and maintain those genetically modified cells at a significant fraction of the total number of cells in a tissue for a long period. These principles are currently being tested in several trials (Zhang, 2021).

Role of Genetic Engineering in Agriculture

Numerous, if not the majority, of the globe's farmers are confronting an agricultural crisis. In the industrialized nations, the number of individuals involved in agriculture has been declining for much of the twentieth century. It is possible that genetic engineering might be utilized in a manner that could assist in alleviating the farm crisis. If, for instance, genetic engineering enabled farmers to lower their operating expenses, it could have a positive effect. Ultimately, the development of insect-resistant (*Bacillus thuringiensis* or Bt) maize and potatoes (*Solanum tuberosum*) appears to reduce costs that would otherwise go towards pesticides (Yan et al., 2022).

Do Genetically Engineered Crops Offer an Avenue for Reducing Poverty?

It should be emphasized from the beginning that technology by itself cannot reduce poverty. The Green Revolution began with this technology-driven strategy, and it serves as a remarkable example of the outcomes of implementing such measures. If genetic engineering is applied to solve issues unique to the poorest farmers, it appears logical that their circumstances may be enhanced. These specific interventions have proven effective in the area of food policy (Kavhiza et al., 2022). By reducing the costs of foods usually eaten solely by the impoverished, the advantages of the assistance are aimed at the population segment that requires it most. Therefore, it appears logical to assume that if genetic engineering were directed in the same way, it could benefit those who are impoverished and starving (Smyth, 2022).

Application of Genetic Engineering in Industries

The management of industrial wastewater can be especially challenging when toxic substances are involved. The biological elimination of heavy metals through the use of natural and genetically modified microorganisms has garnered significant attention due to its reduced environmental impact. Al *caligeneseutrophus* is an*L Proteo bacterium* that inhabits industrial wastewater rich in heavy metals. The aforementioned bacteria can be quite beneficial for the bioremediation of chromium from industrial wastewater (El-Sheekh et al., 2022).

Bio Pharming

With genetic engineering, conventional crops might be utilized to generate valuable chemicals, including pharmaceutical proteins, at an agricultural level—a concept known as 'bio pharming'. Producing antibodies serves as a good illustration. Antibodies are proteins created by the immune systems of animals when they encounter an infection caused by an antigen. Every antibody identifies and attaches to the antigen that triggered its creation. This interaction between antibodies and antigens has been widely utilized in both diagnostic and therapeutic medicine (Eidenbergeret al., 2023). At present, the large-scale cultivation of cells is frequently utilized in the mass production of antibodies. Nevertheless, tobacco plants modified with a mouse antibody gene generated the antibody at a concentration exceeding 1% of the overall leaf protein produced. In theory, antibodies and various pharmaceutical proteins like hormones, growth factors, and enzymes can be generated in different crops, harnessing the benefits of elevated production levels and reduced operational costs through existing agricultural methods (Jiang et al., 2020).

Biosecurity

"The sum of risk management practices in the defence against biological threats" refers to the avoidance of abuse through loss, theft, diversion, or purposeful release of diseases, poisons, and any other biological materials. To prevent misuse through loss, theft, diversion, or intentional release of diseases, poisons, or other biological materials, "the sum of risk management practices in the defence against biological threats" is used. The term was first used in the 1980s in the agricultural sector (Huber et al., 2022). Although the term "biosecurity" was first used about animal health and production systems in the 1980s, it was defined as "the vital work of strategy, efforts, and planning to protect human, animal, and environmental health against biological threats" by the U.S. Association of State Departments of Agriculture. Biosecurity encompasses all actions done to prevent illnesses from entering the environment (bioexclusion) and from spreading (bio-containment) (Renault et al., 2021). The One Health approach makes biosecurity—which includes limiting the spread to humans, animals, plants, and the environment—especially important. The other actors should therefore use the FAO and WHO definition of biosecurity, which considers these variables, as a guide to emphasize the importance of biosecurity for environmental and public health in addition to animal health (Figure 3) (Saegerman et al., 2023).

Biosafety Levels

Only certain biological laboratories are subject to a set of safety measures known as Biological Safety Levels (BSL). There are four biosafety levels: BSL-1, BSL-2, BSL-3, and BSL-4. The greatest (maximum) level of containment is BSL-4 (Figure 4).

BSL-1

- Standard microbiological practices
- Handwashing sinks and waste decontamination facilities
- No special containment equipment required (Renault et al., 2021)

BSL-2

- Laboratory access is restricted when work is being conducted
- Additional safety measures such as the use of biological safety cabinets (Class II)
- Autoclaves available for decontaminating waste
- Use of PPE, including lab coats and gloves (Huber et al., 2022)

BSL-3

- Controlled access to the laboratory
- Directional airflow to prevent contamination
- Exhaust air not recirculated
- Use of Class II or III biological safety cabinets (Huber et al., 2022)

BSL-4

- Isolated facility with independent air supply
- Chemical showers for personnel before exiting

Full-body, air-supplied suits for researchers (Huber et al., 2022)

Fig. 3: Holistic Biosecurity Approach

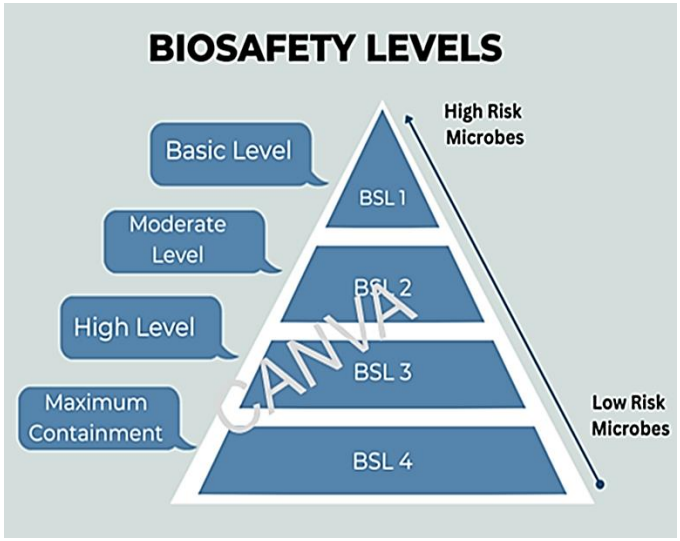

Fig. 4: Biosafety Levels

Identifying and Evaluating Biosecurity Risks in Genetic Engineering

To reduce the likelihood that animal diseases may endanger society, disease preventive measures such as biosecurity, surveillance, and traceability are essential. The diseases that require biosecurity vary depending on the species of interest, such as avian influenza, foot-and-mouth disease, and African swine fever. Disease prevention, including surveillance, biosecurity, and traceability, was emphasized by the European Animal Health Law (Regulation (EU) 2016/429) to lessen the possibility that animal diseases could pose a threat to society. Biosecurity's main objective is to safeguard against threats from organisms and illnesses. The three primary biosecurity techniques are exclusion, eradication, and control. Proficient system administration, practical protocols, and the prompt and efficient exchange and safeguarding of vital information support them. Biosecurity is distinct from biosafety, even though the terms are commonly used interchangeably in the scientific literature. A supplemental concept to biosecurity, biosafety is defined as "the application of laboratory practices and procedures, specific construction features of laboratory facilities, safety equipment, and procedures, specific construction features of laboratory facilities, safety equipment microorganisms and other biological hazards" (Moritz et al., 2020).

Biosecurity Risks Related to Synthetic Biology

Risks of Producing Genetically Engineered Species

Often used to screen genetically modified microbes, antibiotic resistance genes are acquired and constantly increased by other bacteria through horizontal gene transfer in natural environments. *E. coli* developed resistance to tetracycline, amikacin, and piperacillin by 140, 80, and 15 times, respectively, after just two weeks of ALE (Serwecińska, 2020). If these altered or evolved microbes were to infiltrate the natural environment, the likelihood of superbug formation would grow. It should be mentioned that the WHO believes that by 2050, superbugs might kill 10 million people annually, surpassing the number of fatalities from cancer (Sun et al., 2022).

Risks of Altering Species Diversity

A strong tolerance to salt, high temperatures, and alkaline conditions are just a few of the survival benefits that genetically modified organisms may have over natural ones. Through competition for ecological niches, these modified species could upset the natural ecological balance and biodiversity if they were to reappear in the wild (Rafeeq et al., 2023). Moreover, even though gene drive can be used to lower populations of harmful species like mosquitoes, creatures carrying the devices may escape from the release site or there may be cross-species transfer to other organisms. For instance, the extinction of species that feed on insects may eventually result from the loss of mosquitoes (Ferraguti et al., 2022)(Figure 5).

Risks of Abusing Synthetic Biology Products as Biological Weapons

The potential use of synthetic biology products as biological weapons has recently raised concerns about biosecurity since it is now able to fully synthesize viruses, including those that infect humans. To paralyze limb relaxation, for example, the poliovirus can penetrate the central nervous system and damage the motor nerve cells in the anterior horn of the spinal cord (Trump et al., 2020). The variola virus is the subject of another example of virus production. Even though the WHO declared the variola virus to be dead worldwide in 1980, research on the virus is still ongoing. Since most people do not now have effective immunity to the virus, a smallpox pandemic would be extremely dangerous if it were to recur. Since late 2019, SARS-COV-2 has infected around 300 million individuals globally. Although the creation of vaccines has benefited from the use of synthetic viruses, the possibility of their leakage is still a major worry, particularly since the inclusion of manmade mutations in synthetic viruses may result in changed infectivity (Shen et al., 2023).

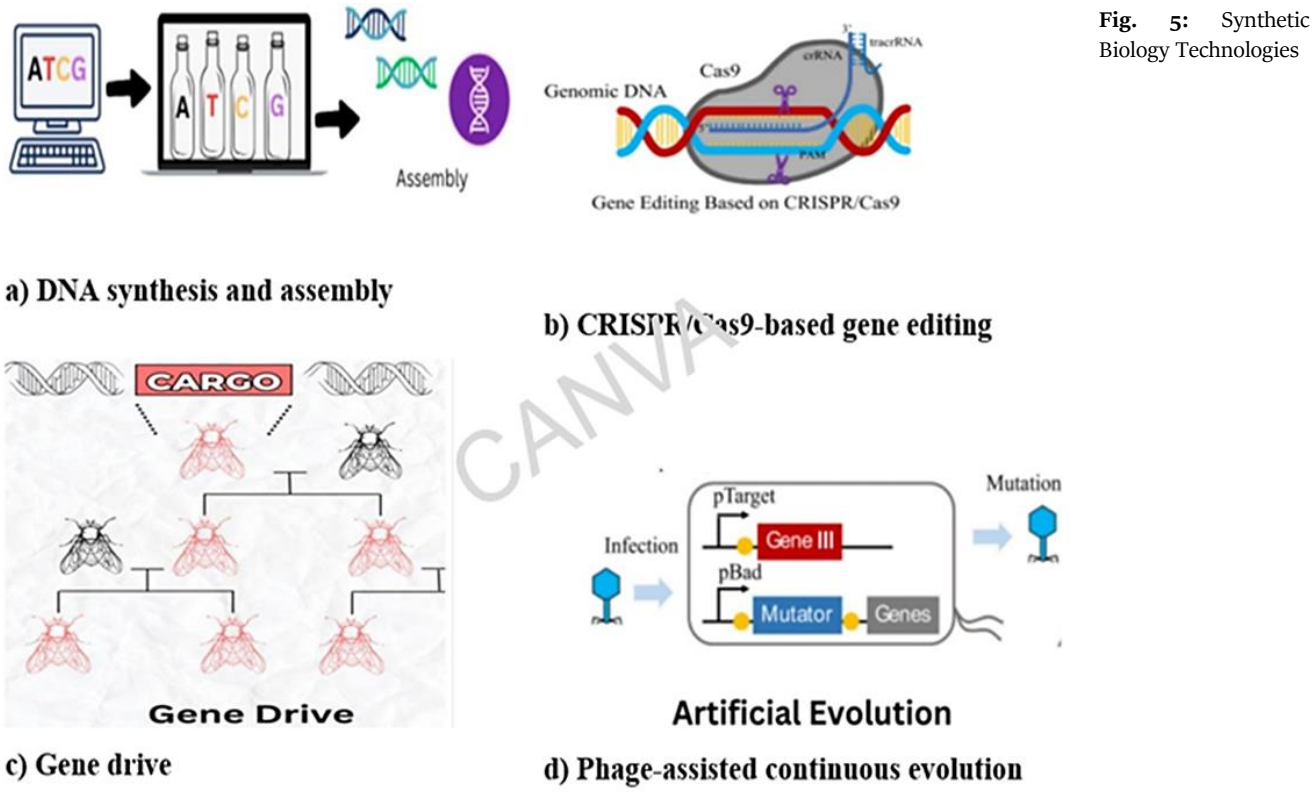

Fig. 5: Synthetic Biology Technologies

Managing Biosecurity Risks of Platform Vaccine Advancement

Dual-use evaluations must balance the advantages and disadvantages of a particular technology. The use of platform vaccination techniques to combat COVID-19 and Ebola shows how effective they are at combating emerging illnesses. Since they have shown encouraging qualities like quick development times and effectiveness in combating COVID-19, novel platform vaccine techniques like RNA vaccines are probably going to receive a significant rise in funding over the next several years. Viral vectors provide the basis for some of the most cutting-edge and promising COVID-19 vaccines (Lundstrom, 2021). Importantly, virally vectored vaccines demonstrated effective and rapid development during the Ebola outbreaks in the Democratic Republic of the Congo and West Africa. Crucially, vaccines containing viral vectors elicit strong T-cell responses, which may be necessary to effectively produce immunity against encapsulated viruses with intricate pathophysiology, such as filoviruses or poxviruses. Perhaps the most promising vaccination platforms based on viral vectors are those that may produce protective immune responses with a single injection. However, wherever feasible, the hazards connected to the creation of vaccines vectored by viruses should be minimized (Musunuri et al., 2021). To lessen biosecurity concerns, researchers and funders should consider the dual-use potential of different approaches to creating viral vector-based platforms. Priority work should be given to vectors with comparatively low dual-use potential of associated technological capabilities and insights.

Priority should be given to identifying low dual-use solutions to overcome certain technical obstacles like anti-vector immunity. This could entail, for example, selecting non-genetic strategies to get beyond anti-vector immunity rather than genetic ones. These nongenetic strategies could include creating methods for synthetic surface modifications that are not transmissible to viral progeny or expanding the vector portfolio to include viruses with low seroprevalence, such as non-human adenoviruses (Berger, 2021).

Rise of Monocultures and Effects on Biodiversity in the Food Supply

The cultivation of GM crops supports an industrial agriculture model that has reduced crop diversity. Intensive farming methods and advancements in agricultural technology have led to intricate, lasting transformations in traditional agriculture. Farmers cultivating GM crops apply pesticides to manage insects that the GM transgenes fail to regulate and utilize broad-spectrum herbicides (Suarez & Gwozdz, 2023). Excessive dependence on biotechnological solutions can hasten pest resistance and disrupt natural ecosystem balances, fostering a cycle that increases the demand for additional pesticides and herbicides and eventually results in monocultures. For instance, growers depending on Roundup for weed control restrict themselves to a limited selection of GM-resistant crops (Renard & Tilman, 2021). Cultivating just a limited number of crop types can result in soil depletion and foster conditions that are detrimental to the natural predators of pests—like birds and insects that depend on diverse weeds, seeds, and microhabitats absent in monocultures. A decline in the population of natural pest enemies increases the demand for additional GM products and pesticides. GM monocultures may also heighten the likelihood of widespread crop failures. Reduced biodiversity heightens the susceptibility of crops to diseases and pests, implying that a single blight or infestation could wipe out hundreds of thousands of acres of crops. Monocultures may also lead to poor nutrition by limiting the variety of food options for consumers. For instance, corn, which is largely genetically modified in the United States, has become a part of nearly all our food (Mukhovi& Jacobi, 2022).

Contained Use of GMOs

In actions involving GMOs, the term "contained use" describes measures taken to limit their interaction with people or the environment. It pertains to the genuine process of genetic alteration, as well as the utilization, storage, transportation, and elimination of GMOs. Both biological and physical methods can be used to contain GMOs. Barriers used in physical confinement are designed to prevent organisms from accidentally exiting the lab and being released. This could entail the use of specifically designed laboratories, disinfection methods, limited access, and similar measures. Biological containment means creating the organism in a way that prevents it from growing outside the laboratory (Beeckman &Rüdelsheim, 2020).

Genetic Engineering and Perceived Levels of Risk

Genetic engineering stands apart from other food technologies due to ethical issues brought up by the public concerning its development and use. For many years, genetic engineering has served as a production tool in the creation of consumer products like medicines and detergents. The phrase "genetically engineered food products" refers broadly to foods and food components that include or are made from genetically modified substances, even if they do not contain genetically modified material (Spök et al., 2022). The labeling of genetically modified foods and the perceived risk to consumers is a significant and contentious topic. In 2000, the Food Standards Council of Australia and New Zealand decided to mandate the labelling of foods that contain genetically modified ingredients. Like any new technology, the public might link both advantages and dangers with the technological methods used in food production and the final product. Consumer responses to biotechnology and the subsequent acceptance of products can be influenced by how risks and benefits related to the technology and its use are perceived (Siegrist & Árvai, 2020).

Moral and Religious Objections to Genetic Engineering

A group of concerns arises from certain individuals who strongly hold moral and religious beliefs. Some argue that changing an organism's genetic structure in a way that could never happen through natural reproduction immorally “play[s] God” or turns living beings into commodities. According to this perspective, the inherent value of the natural boundaries of the genetic code signifies that producing entirely new species in a lab undermines both nature and society. Some worry that GMOs might disrupt the dietary laws set by their faith — for instance, genes from prohibited foods could be inserted unknowingly into the foods they are allowed to consume (Babale&Atoi, 2021).

Ethical Concerns

Several ethical issues have been brought up concerning HGT from GMOs, such as the perceived threats to the integrity and intrinsic value of the organisms involved, the idea of natural order and species integrity, and the stability of the ecosystems in which the genetically modified organism lives (Thompson & Oosting, 2020). The environment and human health are at clear risk from GMOs, according to several scientific studies that have emerged in recent years. The capacity to position the gene in a particular area is lost when genetic engineers create transgenic or genetically modified plants. The position of the gene, which is usually unknown, is found at random within the genetic material (Sandler, 2020). In the US, numerous examples of these undesirable impacts have already been identified after approval (e.g., heightened lignin in GM soya, deformed cotton bolls in GM cotton, etc.) (Rahman et al., 2023). Invasiveness, effects on non-target species, gene flow to wild relatives or conventional crops, and other unintended consequences might result from the introduction of genetically modified plants or crops into the ecosystem. Furthermore, certain indirect effects of GMOs were also noted that could potentially damage the environment. In addition to crop pests, some transgenic traits, such as the pesticidal poisons generated by Bt genes, can also affect non-target species. Long-term effects on non-target species or weed assistance are most likely to result from transgenes that guarantee resistance to pests and environmental stress and/or encourage higher seed production (Tilgam et al., 2021).

Importance of Risk Management in Genetic Engineering

Risk Assessment

Risk is ubiquitous and unavoidable. Agencies and regulatory authorities both domestically and internationally have been paying more and more attention to Biosafety concerns related to the marketing of genetically modified organisms. Based on the body of experience and scientific knowledge accumulated over the previous few decades, these are founded on a shared set of principles (Brookes & Barfoot, 2020).

The goal of risk assessment is to use scientific data to estimate risks and determine the likelihood of certain outcomes. It is essential to raising quality, whether it be in life or products, and it is crucial to the innovation needed to optimise advantages. Environmental risk evaluation (ERE) examines the effects of introducing a genetically modified plant into a specific ecosystem (Kaikkonen et al., 2020). The ERA focuses on assessing the risk of damage to ecosystem elements considering the exposure to the GM plant. Importantly, as the range of environmental release advances from small-scale confined field trials to larger trials and seed increases across diverse environments, ultimately leading to unrestricted commercial release, the focus and intensity of attention on aspects of the ERA will change as the GM plant develops. Due to the vast array of potential issues related to ERA, the problem formulation stage is crucial to ensure that the risk assessment is appropriately structured and executed (Hubbard, 2020). The GM plant is widely used with little consideration for containment due to commercialization. As a result, the environmental risk assessment is done in a tiered manner, with the problem formulation determining the precise questions that need to be addressed and collecting pertinent data, as well as the data synthesis required to complete the applicable ERA.

Risk Management

After evaluating a risk, it needs to be handled. The handling of risk is purely a political act, leading to a choice about whether to accept the risk that was assessed earlier. It may consider extra factors (such as socioeconomic or ethical) and address approaches employed to mitigate the scientifically recognized risk (Devos et al., 2022). Numerous frameworks for risk assessment methodology distinguish between risk

assessment and risk management. However, some frameworks simply distinguish certain aspects of risk management (such as monitoring) from risk assessment, whereas other aspects of risk management (such as evaluating risk mitigation options) are deemed part of the risk assessment process, as a comprehensive understanding of risks must incorporate the impact of any mitigation strategies that lessen risks. In order to regulate, manage, and control risks identified by risk assessments, the protocol establishes and maintains appropriate structures and tactics (Leonelli, 2020). The three key components were designed for risk management. The key elements include impact evaluation, public engagement/participation, and the creation of regulatory frameworks. Managing GMO-related concerns requires an understanding of several ideas, all of which are vital in this field (Saxena et al., 2020) (Table 2).

Table 2: Risk Types, Their Sources, and How to Manage Them in the Use of GMOs

Category	Risks	Management Strategies
Environmental Risks	• Gene flow to non-target species Impact on biodiversity Ecological disruptions	• Biological containment (Devos et al., 2022) Environmental impact assessments • Post-release monitoring
Human Health Risks	• Allergenicity in GM foods • Toxic byproducts Gene transfer risks	• Allergenicity/toxicity testing (Brookes & Barfoot, 2020) Avoid antibiotic resistance markers
Ethical and Socioeconomic Risks	• Ethical concerns Inequity and monopolization	• Public engagement (Thompson & Oosting, 2020) • Fair access and anti-monopoly rules
Laboratory and Industrial Risks	• Biohazards from GMO release Worker exposure	• Biosecure facilities (Spök et al., 2022) Safety protocols and training
Regulatory Challenges	• Lack of global guidelines Weak enforcement	• Follow international protocols (Musunuri et al., 2021) Strengthen regulatory bodies
Monitoring and Surveillance	• Long-term impact detection Limited post-release checks	• Traceability systems (Kaikkonen et al., 2020) Continuous monitoring
Communication Gaps	• Public mistrust Limited stakeholder input	• Transparent communication (Hubbard, 2020) Stakeholder collaboration

Conclusion

Biosafety issues surrounding the marketing of genetically modified organisms are receiving increasing attention from national and international authorities and regulatory bodies worldwide. It examines strategies used to reduce the danger that has been identified by science and may take into account additional considerations (such as socioeconomic or ethical). Since DNA was discovered to be the unit of heredity and the basis for the fundamental tenet of molecular biology—that DNA generates RNA and RNA generates proteins—scientists have looked for methods and tests to gain a better understanding of how DNA affects inheritance. Researchers soon started examining chromosomal DNA in organisms and animals after the invention of molecular biology methods including restriction enzymes, DNA sequencing, and DNA cloning. The power to alter individual nucleotides in the genome is demonstrated by the invention of CRISPR/Cas9 base editing technology. The use of gene transfer techniques can be applied at a wide range of levels. Gene therapy for somatic cells treats a genetic defect in somatic cells.The crucial task of strategy, planning, and effort to safeguard the health of people, animals, and the environment from biological dangers is known as biosecurity. A group of concerns arises from certain individuals strongly held moral and religious beliefs. Some argue that changing an organism's genetic structure in a way that could never happen through natural reproduction immorally “play[s] God” or turns living beings into commodities. Globally, national and international agencies and regulatory bodies are paying more and more attention to biosafety concerns related to the marketing of genetically modified organisms. The handling of risk is purely a political act, leading to a choice about whether to accept the risk that was assessed earlier.

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