New Genomic Techniques: a brave new world of plant breeding?

Exploring the Potential and Ethical Dimensions of New Genomic Techniques in Plant Breeding

Evangelia Daskalaki

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Swedish University of Agricultural Sciences, SLU
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Evangelia Daskalaki

Supervisor:	**Per Sandin, Swedish University of Agricultural Sciences, Department of Crop Production Ecology**
Assistant supervisor:	Jens Sundström, Swedish University of Agricultural Sciences, Department of Plant Biology
Examiner:	Martin Weih, Swedish University of Agricultural Sciences, Department of Crop Production Ecology

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Swedish University of Agricultural Sciences

Faculty of Natural Resources and Agricultural Sciences Department of Plant Biology

Department of Plant Biology

Abstract

This study is a comprehensive presentation and overview of the ethical, social, legal, technological, and regulatory aspects surrounding New Genomic Techniques (NGTs) in agricultural biotechnology. NGTs such as CRISPR/Cas and TALENs are novel methods of genome editing that offer a more precise, efficient, and sustainable alternative to traditional genetic modification methods. However, they also pose complex ethical and regulatory challenges that require a nuanced and balanced approach. The thesis delves into the evolving regulatory landscape for NGTs, especially in the European Union, and compares global perspectives on GMOs and NGTs. Ethical considerations, such as biodiversity conservation, food safety, and socio-economic equity, are examined to understand how they influence policy development. The ethical matrix is used as a tool to evaluate and analyse various points of view and potential impacts. Furthermore, the research underscores the need for continuous investigation into the long-term environmental and socio-economic impacts of NGTs and proposes future research directions and recommendations. The main aim of this thesis is to contribute to informed and responsible policy making and public discourse, supporting the responsible development and use of NGTs in global agriculture.

Keywords: New Genomic Techniques, NGTs, GMOs, GM Methods, Biotechnology, CRISPR/Cas, Ethical Considerations, Risk Assessment, Sustainability, Regulatory Frameworks

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Abbreviations

NGTs	New Genomic Techniques
CRISPR/ Cas	Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR-associated protein
TALENs	Transcription Activator-Like Effector Nucleases
DSB	Double-strand DNA break
ssDNA	Single-strand DNA
GMOs	Genetically Modified Organisms
JRC	Joint Research Centre
SMEs	Small and Medium-sized Enterprises
WGS	Whole Genome Sequencing
EFSA	European Food Safety Authority
USDA	US Department of Agriculture
FDA	Food and Drug Administration
EPA	Environmental Protection Agency
CFIA	Canadian Food Inspection Agency
OGTR	Office of the Gene Technology Regulator
CTNBio	National Technical Commission of Biosafety

1. Introduction

This thesis conducts a systematic literature review with an emphasis on the socio-economic, ethical, and legal aspects of new genomic techniques (NGTs) in agricultural biotechnology. It aims to address the characteristics, risks, ethical considerations, and policy implications of NGTs in comparison to traditional genetic modification methods, particularly conventional breeding, and transgenic techniques. Through a comprehensive analysis and a collection of credible scientific sources, the thesis draws insights into the potential benefits and challenges of fostering these techniques, through their comparison with traditional genetic modification methods. Furthermore, global regulations governing NGTs will be explored, and risk factors associated with these techniques will be assessed.

The European Union's recent proposal for a novel legal framework concerning NGT plants opens the discussion around the evolving regulatory approaches and global perspectives on GMOs and NGTs. The thesis highlights the significance of public engagement and the need for transparency and adaptability when regulatory bodies navigate the ethical complexities associated with NGTs. Additionally, it emphasizes the need for continued research into the long-term environmental and socio-economic impacts.

The first aim is to outline their nature and mode of action, considering these techniques do not introduce foreign DNA when altering the genetic material. It explores the proposed regulatory framework for NGT plants within the European Union, clarifying its core objectives of safety, sustainability, inclusivity, and innovation. A study on the evolution of genetic engineering is also important to understand the historical context and the regulatory evolution concerning GMOs. T examples of applications of NGTs in agricultural biotechnology are provided, discussing the dynamic regulatory landscape's effects on innovation, adoption, and international trade. Ethical considerations surrounding NGTs, including concerns of food safety, environmental impact, and societal acceptance, and how they influence policy development worldwide are discussed. Recommendations for future research and policy development regarding NGTs are provided.

The research questions are:

- What are the key characteristics of NGTs and how do they differ from traditional genetic modification methods, such as conventional breeding and transgenic techniques, through provided examples?
- What specific risk factors are associated with different NGTs, and how do they compare to risks in conventional breeding and transgenic methods?
- What ethical considerations are associated with NGTs and how are these considerations translated into policies within different regulatory frameworks?
- How does the ongoing GMO debate contribute to the ethical discourse surrounding NGTs, and in what ways do ethical arguments influence policy development?

1.1 Navigating the Regulatory Landscape: New Genomic Techniques in Agricultural Biotechnology

The Joint Research Centre, a service providing independent research and scientific advice to the European Commission, has published a comprehensive technical report on NGTs. These techniques are defined in the report as 'techniques that are able to alter the genetic material of an organism, developed after the publication of EU Directive 2001/18/EC' (European Commission Joint Research Centre, 2021). In 2023, the European Union acknowledged the evolving landscape of agricultural biotechnology and proposed a new Regulation for plants developed using certain NGTs. This proposal is part of a legislative package supporting the EU's Farm to Fork and Biodiversity strategies. The proposal's primary goals are to maintain a high standard of environmental and human health protection. It suggests a new legal framework for NGT plants, a departure from the current legislation that currently exists for GMOs, aiming to promote sustainable and resilient agri-food systems. (European Commission, 2023). This proposal highlights the European Union's consideration of regulating the use of NGTs and distinguishing them from GMOs.

NGT plants differ from plants developed using traditional genetic modification methods and transgenic techniques. The main differences are that NGTs are more precise and target-specific, and they operate without introducing foreign DNA (European Commission Joint Research Centre, 2021). The key elements of the new proposed regulation can be condensed in four words: safety, sustainability, innovation, and inclusivity. It primarily ensures the safety and protection of human health and the environment.

Against the backdrop of the United Nations' Sustainable Development Goals, several steps need to be taken to achieve them. As stated by the European Commission and the Study on the status of new genomic techniques under Union law (2021), the use of NGTs can make agricultural production more sustainable by creating improved plant varieties that are resilient to abiotic stress and produce higher yields. These techniques promise quicker results with fewer generations and mitigated risks associated with traditional breeding methods, such as unintended mutations. This proposed regulation focuses on the development and application of NGTs toward achieving sustainability goals within the EU. This regulation also emphasizes the importance of cultivating an inviting environment for research and innovation, particularly for small and medium-sized enterprises (SMEs). Lastly, this proposal identifies the need for a new legal framework specifically designed for NGTs, recognizing their unique nature compared to GMOs (European Commission, 2023).

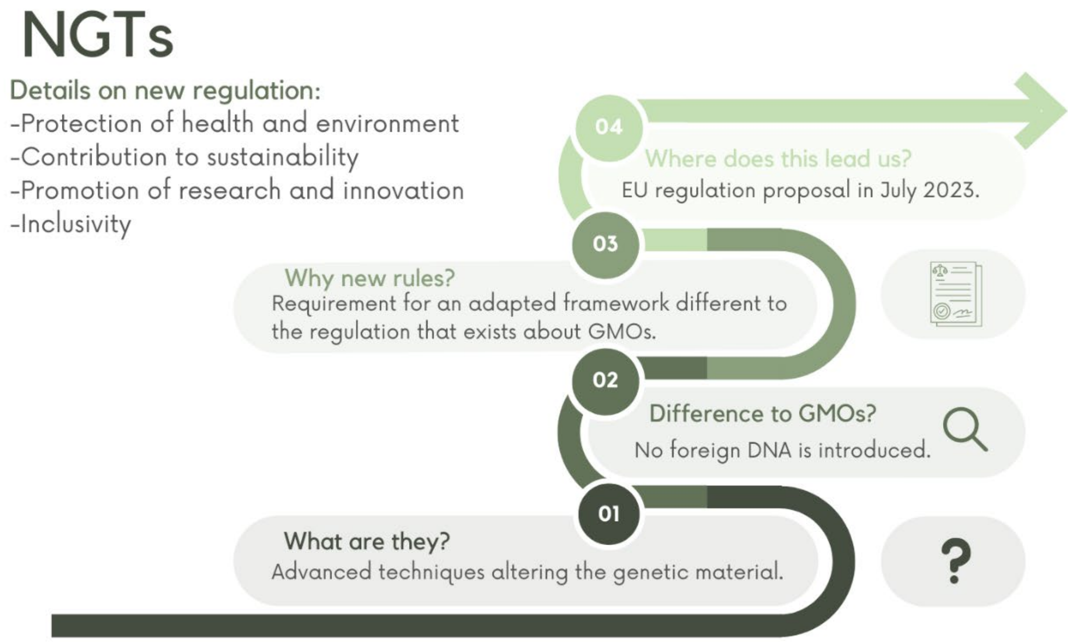

Figure 1. Infographic presenting key elements surrounding NGTs.

1.2 The Evolution of Genetic Engineering

Historically, many steps have been made in the field of genetic engineering from the discovery of the Double Helix in 1953 to the emergence of Nobel-prized CRISPR as a genome editing tool in 2012 (Doudna & Charpentier, 2014; European Commission, 2023). Farmers have unknowingly manipulated the genetic variability of their crops for centuries, through the domestication of wild species. These methods of selection and breeding took a “scientific” shape in the mid-19th century when Gregor Mendel, recognized as the father of modern genetics, established the fundamental principles of heredity. Since then, breeders have been using physical and chemical methods to induce mutations, leading to the creation of entirely new crops that did not exist before in nature, a process that has been increasingly becoming a vital factor in agricultural development.

Another major development occurred in the early 1970s, marking a pivotal point in genetic engineering: the successful crossing over of genetic barriers through breeding, allowing genetic material from one organism to another. Almost 20 years later, the European Union reacted with the adoption of new legal frameworks surrounding GMOs marking the nineties as a period of stringent regulations set by the EU surrounding GMOs. Davison (2010) characterizes EU as the strictest in GMO regulations around the world, based on that decision. One example of such stringent measures is the mandatory labelling of food and feed products containing less than 1% of GM ingredients, whereas there is zero tolerance for “unauthorized or asynchronously approved GMOs” (Davison, 2010; European Commission, 2013). These developments led to the 2023 proposal from the EU for a new legal framework for NGT plants.

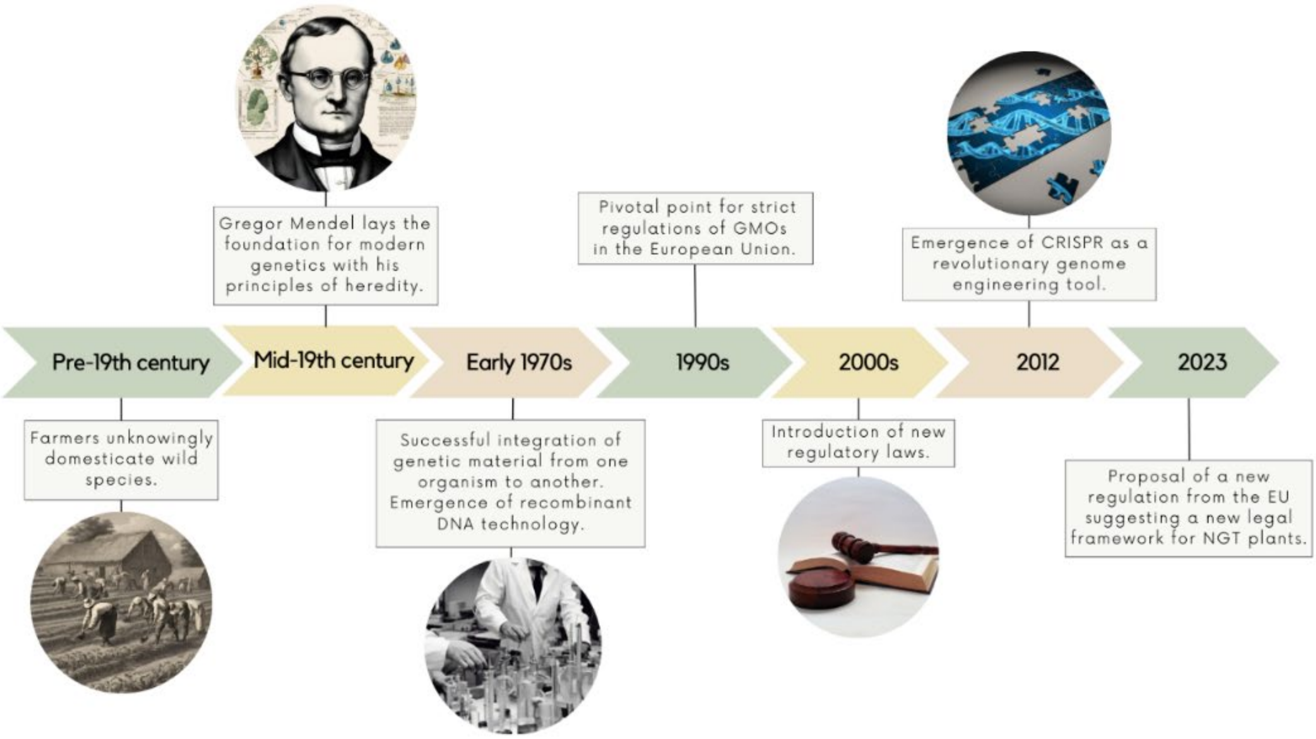

Figure 2. Timeline highlighting key milestones, scientific breakthroughs, and regulatory developments in the history of genetic engineering, leading up to the current focus on New Genetic Techniques and the evolving legal framework proposed by the European Union. This figure is created by the author.

NGTs induce non-random changes at specific target sites, with ongoing efforts to perfect experimental designs to minimize unintended modifications. Some can generate multiple changes in the genome, adding to the complexity of genetic modifications. Among these techniques, CRISPR/Cas stands out as the most prominent, especially in scientific research, lauded for its precision in DNA modification (European Commission Joint Research Centre, 2021)

1.3 Defining the New Genomic Techniques

Since 2001, advancements in high-throughput DNA sequencing and technology development have led to the emergence of various genome modification methods, including NGTs. These techniques, also applicable to animals and microorganisms, range from subtle to significant genetic alterations. Some NGTs enable precise single nucleotide changes, while others insert genes at specific locations, unlike random insertion in traditional breeding. NGTs offer target specificity but may pose off-target effects (European Commission Joint Research Centre, 2021). The European Commission's Joint Research Centre classified NGTs into four groups in their study published in 2021 based on their mode of action on the genome. The genetic changes induced can also occur naturally.

The first two groups of techniques alter the genetic material of an organism. The *first group* creates a double-strand DNA break (DSB) where both strands of the DNA molecule are broken at the same location. These breaks can be caused by environmental stresses such as radiation and chemicals as well as by endogenous cellular processes like DNA replication. DSBs can lead to mutations and chromosomal rearrangements and understanding the molecular mechanisms underlying DSB repair in plants is crucial for improving crop breeding strategies and enhancing stress tolerance. DSB-inducing techniques include CRISPR/Cas9 that introduces precise modifications in specific genes. Other techniques are TALENs (Transcription Activator-Like Effector Nucleases) and ZFNs (Zinc Finger Nucleases) (European Commission Joint Research Centre, 2021).

The *second group* induces a single-strand DNA break (ssDNA) or no DNA break. ssDNA breaks involve the cleavage of one of the two DNA strands, leaving the other intact. While less severe than DSBs, ssDNA breaks can still lead to mutations. Environmental stresses such as UV radiation, oxidative stress, and exposure to certain chemicals can induce these breaks. Genome editing techniques can also induce precise changes in the DNA without causing DNA breaks. These methods include base editing and prime editing (European Commission Joint Research Centre, 2021).

The *third group* targets the epigenome, changing the way DNA is read or transcribed into RNA. The term "epigenome" describes chemical changes on DNA and related proteins that control the expression of certain genes without changing the underlying sequence of DNA. These alterations consist of non-coding RNA molecules, histone changes, and DNA methylation. It acts as a control system, influencing which genes are turned on or off in response to environmental factors, developmental cues, and cellular signals. CRISPR/Cas systems and other techniques can also be repurposed for epigenome editing and RNA transcript modification (European Commission Joint Research Centre, 2021).

The *fourth group* modifies RNA instead of DNA. These techniques work on the RNA molecules, which are transcribed from DNA and play crucial roles in gene expression and protein synthesis. Examples include RNA interference (RNAi) and RNA editing techniques such as repurposed

CRISPR/Cas13 systems. RNA interference is a natural cellular process used for gene silencing by downregulation gene expression (European Commission Joint Research Centre, 2021).

1.4 Why NGTs matter

NGTs can become a part of agricultural biotechnology tools, helping the achievement of sustainability goals, and leading to advancements in various sectors. CRISPR/Cas crops have been introduced in countries like Japan and USA, but their legal status is still a topic of considerable discussion in various nations including the EU and New Zealand.

The regulatory landscape is dynamic and continues to evolve varying from country to country (Vora *et al.* 2023). To ensure that food and agricultural products are safe for the environment and public health in the USA, the US Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) inspect and regulate food and agricultural products (Karavolias, 2023). Canada also focuses on the product rather than the process and coined a new term for GMOs categorizing them as “novel foods” or “plants with novel traits.” There are two requirements for a GMO to be cultivated and sold as a crop according to the Canadian government. The first requirement is their approval of food safety by Health Canada and the second is the approval for livestock and environmental safety by the Canadian Food Inspection Agency (CFIA). (National Farmers Union, 2018). In Australia, the regulation of GMOs is managed by the Office of the Gene Technology Regulator (OGTR) responsible for assessing the risks “posed by or as a result of gene technology” and for the protection of health and the environment. This work is supported by other Australian government regulators who also oversee GMOs, depending on how they are used (Office of the Gene Technology Regulator, 2018). Brazil is in favour of genetic engineering and has integrated biotechnology in its regulatory framework. The National Technical Commission on Biosafety (CTNBio) is the one responsible for the technical assessment and approval of GMOs in Brazil, before the submission to other regulatory organs for access to the market (Adenle *et al.*, 2017). In Argentina, GM crops were first included in the regulation in 1991 with the first crops being approved seven years later, in 1998 (Vesprini *et al.*, 2022). China has also started taking steps towards developing a framework regulating the commercialization and production of genetically modified crops (Liang et al., 2022). In Japan, CRISPR/Cas crops have been introduced since 2019, the year when the regulation regarding gene editing technologies was updated (Vora *et al.* 2023). However, countries like Russia and African countries face challenges regarding their cultivation. Commercial cultivation of GM crops is prohibited in Russia (Chokheli *et al*., 2021). While there is an interest in cultivating GM crops in African countries, challenges and regulatory processes need to be navigated in most of them. A close collaboration between various authorities is needed to ensure the safe and effective release and cultivation of these crops (Akinbo *et al*., 2021). The development and adoption of NGTs can be influenced by variations in regulatory frameworks. These frameworks can either encourage or hinder innovation by encouraging research and development. Additionally, the approval process for NGTs and their entry into the market can time-consuming, potentially slowing down their adoption. Differences in regulations across countries can also affect international trade, as seen in past differences between the USA and Europe. These differences and variations have shaped public perception of NGT-derived products, sparking debates among the public. However, a robust and transparent regulatory system can help gain public acceptance of NGTs (European Parliament 2021, Koller *et al.* 2023). The European Union has issued a draft proposal for reformed regulation, yet there is no production of NGT-derived plants or animals in the EU due to strict legislation surrounding GMOs. The social implications of NGTs are multifaceted, involving considerations of food safety, environmental impact, ethical concerns, and regulatory challenges. The EU's regulatory approach seeks a balance between harnessing the benefits of NGTs while ensuring safety and transparency.

2. Method

This study is a systematic literature review with the aim of investigating, understanding, and comprehensively examining the existing body of research on New Genomic Techniques (NGTs). It centres on the systematic exploration of various facets of NGTs, encompassing their fundamental characteristics, practical applications, associated risks factors, ethical dimensions, regulatory frameworks, and existing knowledge gaps and policy deficiencies (Atkinson & Cipriani, 2018).

The ethical matrix is also employed in this study. It is a tool devised by Professor Ben Mepham used to assess and evaluate ethical implications and guide decision-making. It consists of various stakeholders relevant to the development and implementation of NGTs including consumers, farmers, and the environment along with the ethical principles of wellbeing, autonomy and justice. The ethical matric addresses specific concerns related to some technology, such as environmental impact, consent, and unintended consequences (Mepham, 2000).

Numerous reputable scientific databases were searched, including Web of Science, Scopus, Google Scholar, PubMed, JSTOR. The search strategy revolved around specific search terms and key words tailored to each specific research inquiry. Some examples are "New Genomic Techniques", "transgenic methods", "genetic modification", "CRISPR/Cas", "conventional breeding", "risk assessment of genetic engineering", "risks associated with NGTs", "moral standpoint on NGTs, "ethical assessment of NGTs", "GMO debate", and others (Atkinson & Cipriani, 2018; MacMillan et al., 2019).

This review included a mix of scholarly works, containing peer-reviewed articles, policy documents, technical reports, and case studies. The literature search was conducted with a commitment to remaining impartial and avoiding any personal biases (Atkinson & Cipriani, 2018; MacMillan et al., 2019).

Data extraction and synthesis followed the literature search described, to analyse and interpret the findings from the selected articles and studies. The information was systematically extracted and pertained relevant information to New Genomic Techniques (NGTs) including their characteristics, applications, risks, ethical considerations, and regulatory frameworks. This process involved carefully reviewing each study and synthesizing the extracted data to address the research questions and objectives of the study (Atkinson & Cipriani, 2018; MacMillan et al., 2019).

The selection of studies was conducted using specific selection criteria to ensure the relevance and quality of the included literature. The selection focused on the relevance to the research questions and publication date. To avoid the risk of outdated information, the review focused on literature published within the last decade, except for policies related to GMOs, which were traced back to the 2000s (Atkinson & Cipriani, 2018; MacMillan et al., 2019).

3. Results

3.1 Key characteristics of NGTs, difference from traditional genetic modification methods and examples of applications

3.1.1 Traditional Genetic Modification Methods

Traditional genetic modification methods, such as *hybridization* and *ploidy induction*, represent a valuable alternative to naturally occurring genetic alterations. These techniques involve the manipulation of breeding to achieve desired genetic outcomes.

Hybridization, where the pollen from one plant is used to fertilize the flowers of another plant, is a method that combines different varieties, species, or genera to create hybrids. The resulting hybrid plants inherit genetic material from their genetically distinct parent plants, aiding in achieving specific goals and desirable traits. Mechanisms like adaptive introgression and transgressive segregation contribute significantly to the evolution of plant lineages, generating new phenotypic diversity and potentially leading to speciation (Goulet *et al*., 2016). Hybridization techniques are particularly relevant when comparing them with site directed nuclease breeding techniques. Similarly, SDNs allow for the precise insertion of genes, which can be more controlled and targeted compared to the random mixing of genes that occurs in traditional hybridization (EFSA, 2012).

There are numerous examples of hybrid plants, like many modern maize varieties with improved traits like higher yield, disease resistance and higher nutritional content. Other similar crops are rice and wheat. Traditional modification methods like hybridization are innovative and can overcome obstacles that might complicate or make the process naturally difficult. Such obstacles can be spatial where reproductive elements are geographically separated, temporal like differing flowering times or issues of sterility. (European Commission Joint Research Centre, 2021).

Ploidy induction involves the alteration of the number of chromosomes in an organism. This can be achieved either through *autoploidy*, the multiplication of chromosomes within the same species, or *alloploidy*, combining chromosomes from different species or genera (European Commission Joint Research Centre, 2021). Depending on the species, ploidy induction can be achieved with several methods. At the cellular level, certain chemicals can have effects on cell division, leading to cells with extra chromosomes (Trojak-Goluch et al., 2021). Chemicals can also be applied to seeds before germination (Manzoor et al., 2019). Plant tissues can be grown in a nutrient medium under sterile conditions where types of stress are applied that result in polyploid cells (Niazian & Nalousi, 2020). These techniques allow for the creation of organisms carrying a combination of chromosome sets form both parents, opening doors to new genetic possibilities (European Commission Joint Research Centre, 2021).

Mutagenesis introduces several random changes within the same plant species without inserting foreign genetic material. It can occur naturally as well as artificially by exposing cells, tissues, or the whole organism to physical factors like radiation or chemicals. Phenotype selection with interesting traits and characteristics follows for further breeding (European Commission Joint Research Centre, 2021).

Genetic transformation techniques offer alternatives to traditional breeding and transgenesis. They involve the introduction and incorporation of foreign genetic material into the organism's DNA. *Transgenesis* introduces a gene from one species to another with the help of a vector, virus, or plasmid that carries the gene of interest into the plant’s cell (Low et al., 2018). *Intragenesis* refers to the rearrangement of genes within the same species or between closely related species where the relevant genes are separated, rearranged in vitro, and reintroduced into the organism. *Cisgenesis* is a process similar to *intragenesis with* the difference that the genes transferred are identical to those that could be transferred by traditional breeding (Chibage et al., 2022).

The 2023 Proposal on NGTs focuses exclusively on plants and their products that are produced by targeted mutagenesis and cisgenesis, distinguishing them from transgenic plants, which remain subject to GMO legislation (European Commission Joint Research Centre, 2021).

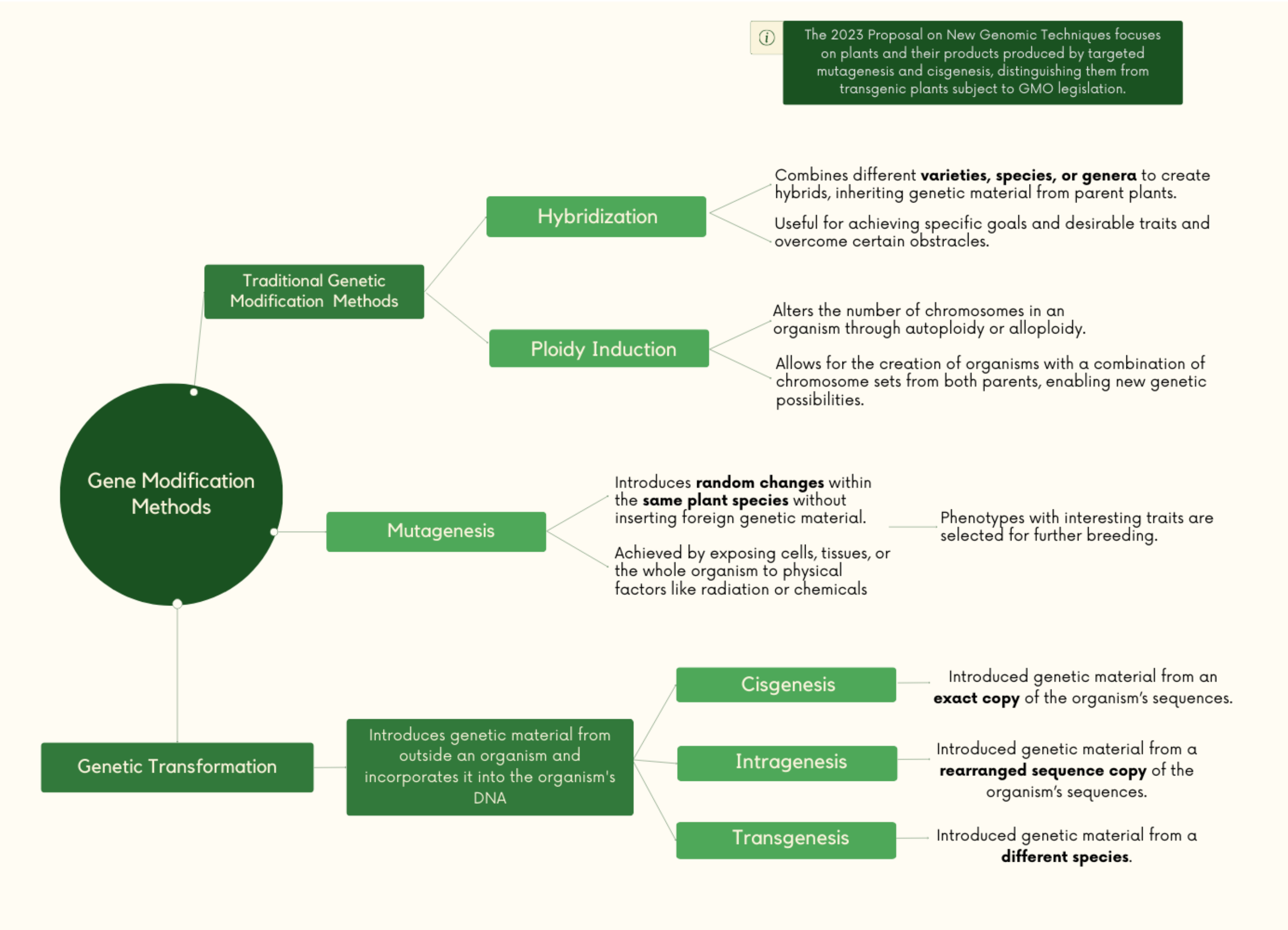

Figure 3. Infographic compiling the various gene modification methods. This figure is created by the author.

3.1.2 New Genomic Techniques (NGTs)

NGTs are distinguishable from established genomic techniques (EGTs) such as genetic transformation, hybridization, polyploidy induction and mutagenesis. Unlike EGTs, NGTs that work with cis/intragenesis and autopolyploidy induction operate within the existing gene pool, avoiding the introduction of sequencies from unrelated species, thereby minimizing the risk of introducing novel genes in ecosystems. Another characteristic is their improved accuracy, reducing the risk of unintended changes in non-targeted areas of the genome. Furthermore, these techniques can mimic natural genomic variations through small deletions, insertions, or base pair replacements. Notably, NGTs are not limited to single alterations since they can create multiple changes simultaneously. Especially, CRISPR/Cas-based techniques can perform several simultaneous alterations resulting in increased efficiency, precision, and conservation of resources. They are faster and more efficient allowing researchers to achieve desired modifications in a shorter time frame, whereas traditional breeding or transgenesis can take years to produce desired traits. (European Commission Joint Research Centre, 2021). However, the above do not give assurance that there are no risks or challenges.

3.1.3 Applications of NGTs

Several NGT plant products are already in the market or in the process of commercialization, outside the European Union. As highlighted by Campa *et al.* (2023), NGTs offer innovative solutions in fruit tree breeding, addressing climatic challenges and increasing demand. Traditional breeding techniques, though useful, are time-consuming, with fruit trees requiring up to 15 years to attain desired traits. Against the background of the growing world population, changing environmental conditions, and escalating biotic and abiotic stress, a more efficient solution is desirable, like mutagenesis, primarily using CRISPR/Cas. This technique focuses on enhancing biotic stress tolerance in fruit trees, with extensive research being conducted on combating citrus canker in citrus trees, among other applications (Campa *et al.*, 2023).

Another example is the commercial launch of modified soybeans by a U.S. company using TALEN technology. This technique specifically targets genes to alter the fatty acid composition, thereby producing a healthier plant for consumption with increased oleic acid and decreased linoleic acid contents (Haun *et al.,* 2014; Entine, 2019).

A third example comes from another American company that utilized CRISPR/Cas to develop waxy maize for industrial uses. The deletion of a 4 kb segment resulted in a modified amylopectin to amylose ratio in maize, which is valuable for industrial applications such as paper, adhesives, and lubricants. This modification simplifies and reduces the cost of amylopectin separation during production (Gao, 2020).

Nonaka *et al.* (2017) explored the use of CRISPR/Cas to increase GABA levels naturally in tomatoes. GABA (γ-aminobutyric acid), a neurotransmitter beneficial for people with conditions like ADHD, depression, hypertension, insomnia, and stress, was enhanced through a single nucleotide insertion in the GABA synthesis gene. This led to the commercial availability of a tomato variety with increased GABA (Edden, 2012; Shimada *et al.* 2009; Nonaka *et al.,* 2017).

Additionally, the development of low-gluten, non-transgenic wheat through CRISPR/Cas technology is a significant achievement. This development addresses the needs of individuals with coeliac disease by potentially enabling the production of low-gluten food products. (Sánchez-León *et al.,* 2017).

Moreover, the work of Raffan *et al.* (2021) on wheat, targeting a gene associated with the production of asparagine, showcases another impactful use of NGTs. This modification led to a significant reduction of asparagine, thereby potentially decreasing the risk of harmful acrylamide formation during food processing. This study observed consistent reductions in asparagine levels across multiple plant generations, underlining the effectiveness of this approach.

3.2 Risks of NGTs, conventional breeding and transgenic methods

3.2.1 Directive and Regulatory Framework for NGTs

Understanding the regulatory landscape for NGTs is crucial, especially when considering the associated risk factors. The EU is often the site of important policy debates regarding ethical considerations, risk assessments, and the balance between innovation and regulation. The initial focus of the EU can provide specific context allowing for a more detailed discussion in a broader global overview. The EU's approach to regulating NGTs provides a useful outlook on the challenges and opportunities associated with regulating NGTs, and the Directives provide detailed risk assessment requirements that are valuable for understanding the development of regulations and policies.

Directive 2001/18/EC primarily focuses on assessing the environmental risks posed by the intentional introduction of GMOs emphasizing that each GMO is unique and necessitating individual assessments of potential environmental impacts. This Directive aims to enhance the efficiency and transparency of the assessment process. EU member states are mandated to monitor and report on GMO releases, with a requirement to investigate and report any adverse effects thoroughly. Moreover, GMOs and products containing GMOs must be labelled to inform consumers and facilitate monitoring. The instructions in this Directive are applicable to both experimental purposes and commercial purposes. This means that both experimenting with GMOs and releasing them into the market must adhere to the same standards and regulations.

The amended Directive, Commission Directive (EU) 2018/350, adopted by the European Commission in 2018, brought necessary clarifications and updates. One significant update was the exclusion of certain genetic modification techniques, like specific mutagenesis techniques, from the Directive. This amendment aimed to strengthen the environmental risk assessment guidance for genetic modified plants intended for commercial purposes. simplifying the procedures for GMO releases in research and development.

The Commission Directive (EU) 2018/350 represents an evolution of the original 2001 Directive, aiming for a more comprehensive and adaptable framework. This Directive incorporates updated Guidance on environmental risk assessment from the European Food Safety Authority (EFSA). Established in 2002, EFSA is an independent agency of the European Union that provides scientific advice and communicates on existing and emerging risks associated with the food chain. EFSA's assessments are crucial for the development of policies and regulations to ensure food safety and protect public health. In the context of GMOs, EFSA evaluates the potential long-term environmental effects and ensures that genetically modified plants and their products are safe for commercial release. Additionally, the Directive streamlines the release process for experimental and research purposes involving GMO plants.

3.2.2 Risk Assessment and Comparative Analysis of Risks: NGTs vs Traditional Methods

The application of CRISPR/Cas has emerged as the most prominent tool among NGTs, with other methods like TALENs or variations of CRISPR nucleases also in use. The scientific focus, however, is predominantly on CRISPR/Cas (Parisi *et al.*, 2021). As a site-directed nuclease (SDN), CRISPR/Cas can target specific sequences in the genome for various purposes: knocking out genes, introducing nucleotide changes, or inserting genes to induce changes at or near the target site (Koller *et al.*, 2023).

NGTs can produce genetic changes that are similar to those obtained by conventional breeding methods. These techniques do not pose higher risks than conventional breeding and should not be subject to the same regulation as transgenesis, which involves the transfer of genes from unrelated non-sexually compatible organisms (European Commission, Directorate-General for Research and Innovation, 2021). NGTs can also have unintended effects or changes in the genome or phenotype of the modified organisms, such as off-target mutations, chromosomal rearrangements, gene silencing, or altered gene expression. These changes may affect the safety, quality, or performance of the organisms, or its interactions with the environment, health, and society. These risks may vary depending on the specific technique, organism, trait, and application of NGTs. Therefore, case-by-case risk assessment and a proportionate risk management are needed to ensure the safety and sustainability of NGTs (Koller *et al.*, 2023). The Joint Research Centre states that even though NGTs are more target-specific, unintended effects have also been found throughout various studies where NGTs were employed. These unwanted alterations should be taken into consideration when designing experiments. Off-target mutations are lower in number when it comes to NGTs and established gene modification methods. For example, traditional mutagenesis might cause more unintended modifications in comparison to NGTs (Anderson et al., 2016). The multi-step technical processes of NGTs, including non-targeted methods like transformation processes, may also induce unintended effects in genome regions other that the intended target (Morineau *et al.*, 2017; Raffan *et al.*, 2021). This emphasizes the necessity of thorough risk assessments to address possible off-target effects. The example study by Braatz *et al.* (2017) supports this assertion. It is important to note that genetic alterations observed in NGTs may also occur in conventional breeding, albeit with different likelihoods. Researchers need to meticulously distinguish and compare unintended genetic alterations induced by both NGTs and conventional breeding methods.

According to the Directive, risk assessment is mandatory for both intended and unintended genomic changes that could have potential adverse effects. Predicting such changes is challenging due to their unintended nature, which could lead to novel phenotypes or effects influenced by numerous factors. These changes can be detected post-application through whole genome sequencing (WGS) and other sequencing techniques (Chu *et al.* 2022; Park *et al.*, 2023), although some changes might require multiple methods for detection (Park *et al.*, 2023). Following sequencing, transcriptomics and metabolomics are employed to ensure safe and reliable conclusions (EFSA *et al.*, 2022).

The Directive also underscores the importance of evaluating long-term human health and environmental impacts of GMOs. These effects may be cumulative, synergistic, or antagonistic (European Commission, 2013). Researchers are advised to closely monitor the gene pool and interactions of NGT organisms with other cultivated plants (Koller *et al.*, 2023).

Unintended genetic changes may accumulate over generations, leading to diverse phenotypes. Robust safety conclusions are challenging to reach, necessitating the implementation of threshold standards (Bauer-Panskus *et al.*, 2020).

Comparing traditional breeding methods, like ploidy induction and hybridization, and NGTs, gene insertion occurs randomly in the first whereas NGTs are characterized by target-specificity. This characteristic makes them more predictable and reliable. Hybridization is generally accepted since it mimics natural processes and has been used for centuries in agriculture. It is viewed as a safe gene modification method and is not strictly regulated. Ploidy induction, occurring with application of chemicals and stress, is also relatively well accepted and regulators treat it as a conventional breeding method. Mutagenesis is also part of traditional methods. It involves exposure to physical factors like chemicals or radiation and can also occur naturally, like hybridization and ploidy induction.

The new regulatory proposal for NGT plants focuses on mutagenesis and cisgenesis. Mutagenesis is already used in ordinary breeding processes, with 75% of crop plants being mutagenic species (Ahloowalia et al., 2004). Cisgenesis bridges the gap between traditional breeding and gene modification, since the genes transferred are identical to those that could be transferred by traditional breeding. Therefore, while we cannot disregard the fact that NGT plants also need to be risk assessed, there are no special or different risks that might stem from the use of NGTs and not from conventional breeding, both because techniques included are already being used in the ordinary breeding process and because the changes induced can occur naturally as well as artificially.

In their opinion on Ethics of Genome Editing, The European Group on Ethics in Science and New Technologies (2021) highlights the need for a science-based and proportionate risk assessment that considers the characteristics and intended use of the plant, rather than the process used to create it. They also suggest criteria and methods for evaluating the potential risks of genome edited plants. More specifically, molecular characterization can be used to thoroughly understand the genetic changes introduced by genome editing and ensures precision and safety of the edited genome by detecting unintended changes. Comparative analysis compares the edited plant with its unedited counterpart and related varieties and identifies differences and potential risks related to health, environment, and agriculture. Lastly, environmental assessment evaluates the ecological consequences of releasing genome edited plants into the environment with methods like field trials and risk scenarios to ensure environmental safety and minimize unintended effects during field deployment. These assessments are crucial for responsible and informed decision-making when considering the release of genome-edited plants.

3.3 How does the ongoing GMO debate contribute to the ethical discourse surrounding NGTs, and in what ways do ethical arguments influence policy development?

3.3.1 Historical Context and Evolution of the GMO Debate

The discussion around GMOs began gaining prominence in the late 20th century, marked by key events in genetic engineering technology. Two pivotal events sparked the genesis of the GMO discussion and debate, the advent of recombinant DNA technology in 1973 and the successful introduction of an antibiotic resistance gene into a tobacco plant. This breakthrough laid the groundwork for the development of GMO crops.

The introduction of the Flavr Savr tomato in 1994, engineered for longer shelf life, marked the beginning of the commercialization of GMOs. Its release into the market ignited a widespread public and scientific debate over the safety, ethical implications, and environmental impact of GMOs. The GMO discourse has since evolved to include a broad spectrum of issues, including food safety, environmental concerns, ethical considerations, labelling and consumer choice, intellectual property rights, and the socioeconomic impacts on farmers and global food systems (Newton, 2021).

The criticism surrounding GMOs often raises concerns about safety and the potential risks to human health that can arise from their consumption. These concerns span from the emergence of new allergens to potential toxicity of GMOs. Critics also argue that the current safety assessment methods are not sufficient in regarding a GMO product as safe for consumption and suggest for more rigorous testing (Kjeldaas *et al.* 2022).The environmental impact is also an area of concern because of the possibility of impact on non-target organisms and the loss of biodiversity (Tsatsakis et al., 2017). This criticism is based on the lack of understanding of the long-term effects on the environment (Kjeldaas *et al.* 2022). Socio-economic concerns are also discussed with issues relating to corporate control over seeds and the impact on small-scale farmers (Binimelis & Myhr, 2016).

Currently in Europe, the EFSA has been instrumental in ensuring the safety of GMOs. They independently assess and provide scientific advice on potential risks associated with GMOs, covering human and animal health as well as environmental impact. EFSA issues guidance documents, such as recommendations for sequencing information in GMO applications and allergenicity assessments for GM plants. Their approach includes a comparative safety assessment, comparing genetically modified plants to non-GM varieties, contributing to GMO safety in Europe (Devos *et al*., 2013; EFSA, 2010)

Surrounding equity and justice, it is believed that while biotechnology companies and large-scale farmers will be able to yield the benefits, farmers from developing countries and low-income individuals will risk access to resources and food. It is argued that the implementation of such technologies will lead to increased inequality in the agricultural sector (Kjeldaas *et al.* 2022). Furthermore, sceptics are concerned about ethical questions revolving around ethical boundaries of scientific innovation and the power over life offered by gene modification technologies on the hands of humans (Gregorowius et al., 2011). Gene editing technologies are criticized based on the notion that changes in an organism that cannot occur naturally are ethically problematic and disrupt the natural order of life. Concerns about "playing God" highlight the suggestion that humans are risking overstepping the boundaries of nature (Feeney et al., 2021).

If an individual aims to shape a negative view on GMOs, they can easily accomplish this by sourcing numerous articles published and subsequently retracted over the years. Numerous studies, sourced from both credible and untrustworthy sources, contribute to a narrative that casts doubt on GMO safety. One example is the study led by Gilles-Eric Séralini, which claimed a specific genetically modified type of maize, resistant to herbicide glyphosate, led to the development of tumours and the early death of rats (Séralini *et al*., 2014). However, this study faced heavy criticism for methodological flaws, including a small sample size and the choice of rat strain known for being prone to developing tumours (Butler, 2012). The journal retracted the paper citing inconclusive evidence due to these flaws (Hayes, 2014). However, this study sparked arguments and debates on GMO safety and the efficacy of regulatory frameworks.

Ultimately, the journal retracted the paper, citing inconclusive evidence due to these flaws (Hayes, 2014). Despite its retraction, Séralini's study ignited debates on GMO safety and the efficacy of regulatory frameworks.
This ongoing debate over GMOs has significantly influenced the ethical discourse and policy development concerning NGTs while their negative and sceptical public perception led to a similarly cautious approach towards

NGTs (Marris, 2001). The EU's rapid and strict response to GMOs, including food product labelling, now shapes public perception and legal frameworks for NGTs. Recent studies emphasize public participation, transparency, and accountability gene editing regulation (Nielsen et al., 2021). Ethical concerns associated with GMOs also apply to NGTs, including safety, environmental impact, and socio-economic considerations (Snow *et al.,* 2005; Kloppenburg, 2004). This underscores the ned for policies and regulatory frameworks that address these shared concerns.

3.3.2 Ethical Concerns: From GMOs to NGTs

Three categories represent ethical concerns from GMOs that also affect perception and acceptance of NGTs in a broader respect. These are human health, environmental impact, and socio-economic issues. While there are many other ways to categorize these concerns, these three categories provide a comprehensive overview of the key issues. They allow for a structured analysis of the ethical landscape surrounding these technologies. Human health is one of the primary areas of debate regarding safety and risk. The questions raised revolve around the potential allergenicity, toxicity and long-term health effects. The continuity of these concerns underscores the need for comprehensive risk assessments, which were critical for GMOs and remain equally vital for NGTs, to mitigate potential health risks (Domingo and Bordonaba, 2011; Kuzma, 2016). The precision of NGTs could potentially reduce the risk of unintended consequences in comparison to GMOs, but rigorous testing and regulation are still necessary.

The ecological and environmental risks associated with GMOs are equally relevant to NGTs. These include concerns about biodiversity loss, gene flow, impact on non-target organisms and changes to ecosystems (Prakash *et al*., 2011). NGT precision could potentially mitigate some risks, but comprehensive environmental impact assessments remain essential to address these concerns. The long-term effects on ecosystems are still largely unknown, therefore the environmental impact might be considered more serious due to the irreversible nature of these changes. (European Commission; Directorate-General for Health and Food Safety, 2023).

Lastly, the intellectual property rights debate, seed sovereignty, and the impact on small-scale farmers is a shared burden in both the GMO and NGT discussions. The control of agricultural biotechnology by large corporations can exacerbate existing inequalities, impacting access to resources for smaller farmers (Kloppenburg, 2004; Graff *et al.,* 2003). This dominance by large-scale companies highlights the need for equitable policies and regulations to consider the rights and livelihoods of all stakeholders in the agricultural sector, due to the risk of increased socio-economic disparity.

The concepts of “naturalness” and “playing God” often arise in discussions on genetic modification. Critics argue that GMOs interfere with nature, but NGT precision and target specificity may alleviate some concerns, as NGTs can result in organisms that are indistinguishable from those bred using traditional methods (Kjeldaas, 2022). The 2023 Proposal for New Genomic Techniques distinguishes mutagenesis and cisgenesis from transgenic plants, highlighting that NGTs do not introduce foreign DNA. Mutagenesis induces changes within the same plant, while cisgenesis involves transferring an exact copy of an organism’s gene within the same or closely related species. The resulting organism can also be obtained with traditional breeding, a time consuming, labor intensive and spatially “expensive” process. NGTs offer faster solutions for addressing pressing issues such as food security, renewable resources, and environmental protection, which require immediate attention and action.

The “playing God” argument is often raised in discussions on genetic technologies, cautioning against the manipulation of an organism’s genetic makeup (Simons, 2022). However, since both mutagenesis and cisgenesis plants can occur naturally, this notion is confuted in the context of NGTs. NGTs can be perceived as a refinement or optimization of existing genetic material rather than the creation of entirely new organisms. While GMO and NGT plants both involve altering genetic material of an organism, NGTs offer greater precision and mitigate some ethical concerns, including risks to human health and environmental impact.

In conclusion, the ethical concerns raised by GMOs serve as a crucial framework for understanding the implications of NGTs. The ethical considerations for NGTs are still being defined and understood, and there is ongoing debate about whether the regulatory frameworks developed for GMOs are appropriate for NGTs. It is important to note that NGTs must not be confused with GMOs, neither in their mode of action nor in their potential ethical considerations.

3.3.3 Policy Development and Regional Responses

NGTs’s ethical considerations influence both the public opinion and the development of policies and regulatory frameworks. It is crucial to understand these influences to effectively address public concerns and establish efficient regulatory mechanisms.

In regions where GMOs face public scepticism, this mistrust often extends to NGTs, as they are perceived as an extension of genetic modification technologies (Frewer *et al.*, 2011). On the contrary, in areas like the United States, where such technologies are more prevalent, NGTs may be viewed more favourably. This disparity underscores the importance of transparency and public engagement, as perceptions of GMOs can affect attitudes towards NGTs (Kuzma and Besley, 2008). The EU's strict regulations on GMOs could serve as a model for NGT regulation. With NGTs being distinct from traditional gene modification techniques and GMOs, there is an opportunity for policymakers to build upon existing regulatory pathways. Tailored frameworks could balance innovation with public safety, environmental protection, and ethical considerations, ensuring responsible deployment of these emerging technologies (Smyth and Philips, 2014).

3.3.4 Global Perspectives in GMO and NGT Regulation

Understanding the global landscape of GMO policymaking necessitates an examination of how different governments and regulatory bodies have responded to the ethical challenges of GMOs and NGTs. Beyond the EU's approach, other countries like the United States, India, and Brazil showcase distinct policies and attitudes towards these technologies.

In the United States, the regulatory framework for GMOs focuses not on the modification process but on the final product. The primary concern is whether GMOs are safe for consumption and nutritionally equivalent to their non-modified counterparts. This approach aims to balance potential risks with benefits such as improved crop yields and enhanced crop resilience, reflecting a pragmatic stance towards biotechnology (Buonanno *et al.*, 2017).

India, on the other hand, demonstrates a more cautious attitude, shaped by concerns over impacts on smallholder farmers and political debates. The case of Bt cotton in India is illustrative of this approach, with its adoption having significant implications for farmer incomes, agricultural productivity, and broader socio-economic effects in the rural sector. This example underscores the delicate balance between biotechnological advancements and their implications, highlighting the need for comprehensive policy frameworks that address these multifaceted challenges (Gupta and Chandak, 2013).

Brazil adopts a more open approach towards GMOs, driven by the potential economic benefits of their application in agriculture. However, this openness does not imply a disregard for environmental and safety concerns within its regulatory framework, indicating a holistic approach that considers both economic and ecological aspects (Ramaswami *et al.*, 2012). Public perception and trust in GMOs significantly influence attitudes towards NGTs, emphasizing the need for rigorous risk assessments and enhanced transparency. Diverse national regulatory approaches illustrate the absence of a universal strategy from managing these biotechnologies. Regulatory variations in GMO cultivation and sale across countries can create challenges and disputes in international trade, due to asynchronous approvals, zero-tolerance policies, and differing labelling requirements, discouraging investment in GM technology.

3.4 Ethical, legal, and social considerations about NGT and their translation into policy

Recent technological advancements in plant genome modification have ignited considerable controversy, raising complex ethical, legal, and social issues. Specifically, the complexity of these issues lies in their level of interconnectedness and the power to influence each other. The diverse regulatory frameworks needed to address these concerns are outlined in depth by scholars such as Buch et al. (2023).

3.4.1 Ethical Considerations of NGTs

In his 2020 book "Food and Agricultural Biotechnology in Ethical Perspective", philosopher Paul B. Thompson explores the ethical dimensions, drawing insights from scientists, ethicists, and philosophers. Thompson categorizes ethical considerations into four key areas: food safety, animal welfare, environmental impact, and social consequences. Thompson emphasizes the importance of biosafety and environmental impacts in genetically modified foods. He argues that they should meet the same safety standards as non-modified foods in terms of consumption safety. This view is supported on the fact that plants qualitatively identical to NGT derived ones can also occur naturally. NGTs pose potential safety risks such as health hazards and ecological consequences, necessitating risk assessments (Kjeldaas *et al.,* 2023). Concerns also arise regarding NGTs' impact on biodiversity, which could lead to genetic bottlenecks and harm ecosystems and food system resilience (Buch *et al.*, 2023; Thompson, 2020).

When considering animal welfare, regulations often focus on reducing animal suffering and pain. Thompson (2020) expands this discussion to include implications for human health and safety, highlighting the interconnected nature of these issues.

3.4.2 Legal Considerations of NGTs

NGTs raise various legal issues that require attention in national regulations to facilitate smooth navigation for policymakers, industry stakeholders, and consumers. One legal consideration is the complexity of intellectual property rights related to NGT plants and their ownership, particularly regarding whether companies or farmers have exclusive rights. Additionally, liability for harm is debated, with implications for risk management and accountability in the agricultural sector (European Commission Joint Research Centre, 2021). The European Group on Ethics in Science and New Technologies (2021) raise traceability challenges for genome edited plants, including difficulty in distinguishing them from conventional or naturally occurring variants and the complexity of implementing traceability systems. Traceability benefits encompass safety, quality, trade facilitation and social acceptance. Solutions involve new technologies like DNA barcoding, digital sequencing information, and blockchain to enhance the identification, verification, and tracking along the supply chain. DNA barcoding analyses short DNA segments to uniquely identify species. Digital sequencing converts DNA data into a digital format for global sharing. Blockchain records supply chain history for gene edited plants, enhancing transparency and intellectual property rights management. These methods authenticate food products, trace their origin, and empower consumers with accurate information for informed decision-making, strengthening NGT regulatory frameworks.

The rapid pace of advancements in NGTs challenge existing legal frameworks, which must adapt to keep pace with scientific progress. Policy makers need to continuously evaluate and refine regulations to ensure they remain relevant and effective. This requires continuous dialogue among policymakers, scientists, and stakeholders to address issues and opportunities presented by NGTs. Current risk assessment protocols for GMOs are inflexible and difficult to update, highlighting the need for adaptive procedures to evaluate the safety and environmental impacts of evolving NGTs (Joint Research Centre, 2021).

3.4.3 Social Considerations of NGTs

Patented genetic technologies in agriculture raise questions for small-scale farmers' rights. Control over seeds, dependency on commercial seed varieties, impact on farmers' livelihoods, affordability of new technologies, and exacerbation of existing inequalities are central to these ethical considerations. Thompson (2020) notes the potential for certain technologies to favour wealthier stakeholders, creating an economic divide concentrating power and wealth in the hands of a few, thus impacting the socio-economic landscape.

While patents can drive innovation, they also risk creating monopolies and limiting access to genetic resources, raising concerns about equality, particularly in developing countries, where access to patented technologies may be limited (Buch *et al.,* 2023; Thompson, 2020).

The introduction of NGTs is also considered to pose as a threat to food sovereignty, or the right of individuals and communities to define their own food systems. Critics argue that patent control of modified crops by a few large companies could exert significant influence over global food systems. This concentration of power might weaken local food systems and restrict the autonomy of farmers and consumers in shaping their food choices and production methods (Helliwell et al., 2019).

3.4.4 Regulatory Frameworks and Policy Implications

Region-specific policies and frameworks on NGTs reflect the unique socio-economic and ethical contexts, all prioritizing human, animal, and environmental health. Common elements include rigorous risk assessments, safety testing, and post-market monitoring to ensure public safety and environmental sustainability. Additionally, the preservation of biodiversity, protection of native species, and maintenance of traditional farming practices are key priorities across these policies. Internationally, initiatives like the International Treaty on Plant Genetic Resources for Food and Agriculture play a significant role. This treaty aims to acknowledge farmers' rights and facilitate equitable benefit sharing (Louwaars and Jochemsen, 2021; Thompson, 2020). In the European Union, proposals such as the new Regulation highlight the importance of engaging small and medium-sized enterprises in the conversation, striving to strike a balance between scientific innovation, sustainable development, and social equity (Lemarié and Marette, 2022).

In Europe, the European Group on Ethics in Science and New Technologies provides the commission with independent advice on aspects like legislation and policies, specifically where ethical and societal issues intersect with the development of science and new technologies. It is an independent body of the President of the European Commission. The case studies provided shed light on the ethical and policy dimensions in plant science. These studies emphasize a balanced approach to responsible research and innovation, influencing EU policies on genome editing technologies.

Critical analyses, such as Gelinsky's and Hilbeck's commentary on the European Court of Justice's ruling, highlight the necessity of considering broader political and social dimensions in the context of NGTs (2018). Furthermore, Poort *et al.* (2022) advocate for a comprehensive ethical and policy discussion that encompasses not only scientific and technical aspects but also addresses power distribution, access to resources, and the voices of marginalized communities in the development and application of NGTs.

3.5 The Ethical Matrix

The ethical matrix, a tool used in ethical decision making, was created by Professor Ben Mepham to help decision-makers regarding technologies in the food and agricultural sector. This framework is built upon the principles described by Beauchamp and Childress, originally applied to medical issues, to assess the ethical impacts of biotechnologies in agriculture and food production. Its purpose is to systematically consider various perspectives on an issue, highlight ethical principles that might be at stake and identify potential conflicts between stakeholder interests and ethical principles to facilitate informed decision making by providing a comprehensive overview of relevant considerations (Mepham, 2000).

The structure of the ethical matrix resembles a table with stakeholders involved in the issue and columns that represent ethical principles. *Wellbeing* corresponds to utilitarianism and aligns with its "maximizing good" aspect. Utilitarianism is characterized by the view that a morally right action is the one that produces the most overall happiness or pleasure, and a wrong action is the one that tends to promote mischief, pain, evil, or unhappiness for all those affected. It is a version of consequentialism, which states that actions should be evaluated based on their consequences. Egoism and altruism are also forms of consequentialism, but utilitarianism considers the interests of all affected parties and does not discriminate between humans and all sentient beings (Viner, 1949; Mepham, 2000).

The principle of *autonomy* refers to the respect of an individuals' right to make their own choices and act independently and free from influence. It connects to deontology, a non-consequentialist ethical theory. In contrast to consequentialism, the moral rightness or wrongness of an action in deontological ethics is determined by its adherence to moral principles, duties, or rules, rather than the outcomes it produces. It emphasizes treating people with respect and dignity and avoiding actions that violate their rights. Therefore, respect for autonomy recognizes an individual's right to make their own choices and control their lives (Hughes-Warrington & Martin, 2022; Mepham, 2000).

Justice focuses on principles of justice and fairness in social institutions, aiming to create a just and equitable society. This theory is built on two ideas. First, everyone in society should have the same fundamental rights and freedoms irrespective of a person's background, wealth, or social status. The second idea is that even if social or economic inequalities exist, they should be arranged so that they benefit the least advantaged and they provide opportunities for everyone. Therefore, *justice* in the ethical matrix refers to fairness and impartiality in decision-making and the fair distribution of benefits and burdens ((Rawls, 1999; Mepham, 2000).

The ethical matrix serves as a valuable tool for evaluating the perspectives and impacts of NGTs. By considering stakeholders' viewpoints and ethical principles, it identifies concerns and promotes responsible development and use of these techniques. It collaborates with other frameworks to guide ethically sound decisions across different contexts. To facilitate this analysis, the ethical matrix for the use of NGTs is presented in Table 1.

Table 1: The ethical matrix regarding the implementation and regulation of NGTs. The table represents the various stakeholders involved in the issue and the ethical principles. This table is created by the author.

Stakeholders	Wellbeing	Autonomy	Justice
Low-income Consumers	Access to affordable and nutritious food Food security	Transparent information for Informed choice within budget constraints	Fair pricing and equitable access to NGT-derived products and benefits
High-income COnsumers	Access to high-quality and diverse food options Health and wellness	Ability to prioritize values and preferences informed decision-making	Transparency in labeling Ethical sourcing practices
Small-scale farmers	Food security Sustainable livelihoods and resilience to market fluctuations	Freedom to choose farming methods involvement in decision making processes	Equitable access to resources and fair market access Protection of traditional knowledge
Large-scale farmers	Economic prosperity and efficient production while minimizing environmental impact	Control over farming practices and adoption of technology based on informed decisions	Fair competition and transparent market practices
Farmers in developing countries	Secure livelihoods and food security through NGTs	Preservation of traditional knowledge and practices and community empowerment Provided support for implementation	Access to resources and technologies Protection of indigenous rights
Farmers in developed countries	Efficient and sustainable production Economic growth	Adoption of NGTs based on informed choices Participation in decision making processes and access to resources for implementation	Environmental stewardship and fair-trade practices
Environment	Ecological and biodiversity impacts of NGTs Promotion of ecosystem health through sustainable NGT applications	Preservation of natural balance and diversity with regulations and incentives to encourage environmentally responsible NGT use	Prevention of environmental harm and degradation NGT development prioritizing environmental sustainability and long-term ecological resilience
Researchers and plant breeders	Advanced scientific knowledge and innovation in plant breeding and genetics to develop NGTs with improved traits and characteristics More legal clarity	Autonomy in research and breeding processes and access to resources for experimentation and development of NGTs	Fair attribution of credit, recognition, and access to benefits

3.5.1 Ethical Matrix Analysis

When developing the ethical matrix, the selection of stakeholders must be approached accordingly to ensure the representation of a diverse range of perspectives and interests. This selection should emphasize inclusivity and recognition of the interconnectedness of the various stakeholders. By including a wide array of stakeholders, the ethical analysis aims to capture the complexity of the issue when considering implementing NGTs. Certain categories may overlap to some extent. One example are small-scale farmers that may exist in both developing and developed countries with similar interests or challenges. However, in this example, small-scale farmers in developing countries may face distinct challenges related to access to resources and market integration compared to small-scale farmers in developed countries. Moreover, each category represents a diverse range of experiences or perspectives that may not be fully captured by a single overarching category.

The ethical matrix analysis draws upon existing knowledge and general principles to illustrate the framework's application. The purpose is to demonstrate how this framework can inform decision-making processes by considering diverse perspectives and ethical concerns related to NGTs. Through this analysis, the complexities and interconnectedness of NGTs' ethical issues are demonstrated, while underscoring the importance of inclusive and informed decision-making in agricultural biotechnology.

Based on the level of income, low-income consumers prioritize affordable, nutritious food while being more vulnerable to food insecurity due to limited access. NGTs can improve food production, distribution, and affordability, as supported by the EU's 2023 proposal, since NGT plants can have higher yield, self-life, and resistance to stress. Providing transparent labelling and information can empower them to make informed choices that align with their dietary preferences and health needs. NGTs can also reduce production costs, benefiting low-income consumers. Brooks (2022) found GM crops increase yield, potentially aiding accessibility. Finally, equitable distribution and policies are vital to prevent further marginalization.

On the contrary, high-income consumers have greater purchasing power without budget constraints, thus seeking access to a wide range of high-quality and specialty products. They often chose organic and locally sourced options. NGT plants reduce pesticide use, promoting organic farming and enhancing food quality. The European Commission (2023) emphasizes the role of NGTs in sustainability and resilience since they can contribute to a 50% reduction in chemical pesticide use. These consumers are well-educated and seek transparent labelling and ethical resourcing. NGTs can address concerns regarding fair labour, animal welfare, and sustainability.

Small-scale farmers often rely on agriculture for their livelihoods and food security, but face challenges from market fluctuations and environmental risks. Implementing technologies that improve productivity, reduce post-harvest losses, and enhance resilience to climate change can contribute to their food security and promote sustainability. Small scale farmers value autonomy in their practices and benefit from adaptable technologies.

Policies promoting equitable access to resources and fair-trade practices are essential for their success.

On the other hand, large-scale farmers often prioritize economic prosperity, efficiency, and profitability in their farming operations. Implementing NGTs can enhance profitability and competitiveness for large-scale farming enterprises. Their aim is to maximize yields, streamline operations, and minimize waste in their production systems, which can be offered with NGT crops. They are often early adopters of agricultural technology and innovation, implementing research and development initiatives, providing, and facilitating access to resources can accelerate the adoption of innovative technologies.

One of the primary concerns of farmers in developing countries is securing their livelihoods and food security, like small-scale farmers. They face challenges related to poverty, food insecurity, and limited access to resources. Implementing NGTs can help improve agricultural productivity, increase resilience to climate change, and enhance food security for farmers in these regions. Emphasizing preservation and integration of traditional knowledge can further improve the sustainability of farming systems. However, limited access to resources hinders technology adoption and support is important for bridging the gap and fully benefit from NGTs.

Farmers in developed countries seek efficiency, productivity, and sustainability. Implementing agricultural technologies that optimize resource use, reduce environmental impact, and enhance farm profitability can improve competitiveness and resilience for farmers in these regions. Policies supporting innovation and research stimulate economic growth and rural development. Much like large-scale farmers, farmers coming from developed countries are typically early adopters of agricultural technology and innovation. Collaboration and engagement can enhance trust and transparency. Concerns about environmental sustainability and ethical sourcing drive interest in sustainable agricultural technologies, displaying commitment to environmental stewardship and social responsibility.

The study by Brookes (2022) provides compiled annual data for the impacts of GM soybean, corn, cotton, and granola. It is shown that farmers from all countries enjoy higher income both from higher yields and lower costs like less use of pesticides. This gain in incomes is almost equally divided between developed and developing countries.

When considering the environment as a stakeholder, it is important to acknowledge that NGTs can have ecological and biodiversity impacts through changes in land use and habitat loss. To mitigate harm and promote sustainability, policies should incentivize eco-friendly farming practices and enforce environmental regulations. Assessment, mitigation, and monitoring are essential for minimizing environmental risks associated with NGTs. However, NGT crops can also have positive effects, such as reducing pesticide use, as observed by Brookes (2022), with a “7.2% decrease in active ingredient use” between 1996 and 2020 due to improved GM crops and integrated management.

Researchers contribute to the advancement of scientific knowledge and innovation in plant breeding, genetics, and agricultural technology development. They can expand our understanding of technologies like NGTs and develop new techniques to enhance crop productivity and sustainability. Clear, science-based regulations are needed to support innovation in agricultural biotechnology. Autonomy in research fosters creativity and breakthroughs whereas adequate funding and resource access are essential for translating research into practical solutions. Fair recognition and reward systems, including intellectual property rights, incentivize impactful research addressing societal needs.

4. Discussion

There are two main topics of concern in food and agricultural biotechnology: safety and morality. Safety refers to physical health risks associated with consuming genetically modified products. It involves assessing potential hazards, such as allergenicity, toxicity or unintended effects. Morality encompasses ethical considerations related to manipulating the genetic makeup of organisms, like social justice issues. These concepts often overlap and are interconnected. For example, ethical considerations about the equitable distribution of benefits and risks associated with biotechnology may influence decisions about safety testing protocols, regulatory policies, and public acceptance of genetically modified foods. Conversely, safety concerns may raise ethical questions about the responsible use of biotechnology.

However, these safety and morality aspects must be viewed alongside the significant opportunities that biotechnology presents, particularly for improving sustainability, food security, and addressing environmental issues. Biotechnology can potentially aid in the development of crops with higher yields, enhanced nutritional profiles, and increased resistance to pests and diseases, contributing to more sustainable agricultural practices and greater food security. For example, genetically modified crops can reduce the need for chemical inputs, lowering environmental pollution and promoting healthier ecosystems. They can also be engineered to withstand adverse climatic conditions, expanding viable agricultural land and improving resilience to climate change.

Additionally, biotechnology can address nutritional deficiencies through biofortification, enhancing nutritional value of crops to combat malnutrition and associated diseases. Disease-resistant crops can stabilize food supplies by reducing losses due to pests and diseases, which is crucial for food security in vulnerable regions. Furthermore, advances in biotechnology can lead to more efficient use of water and fertilizers, conserving vital resources and reducing agriculture's environmental footprint.

By acknowledging and exploring the relationship between safety, morality, and these opportunities,, policymakers, researchers, and stakeholders can work towards more informed and ethically responsible decision-making in biotechnology.

Various ethical frameworks, such as utilitarianism, deontology, virtue ethics, or environmental ethics, may inform decisions about the relationship between safety and morality in biotechnology when it comes to policy development (Mepham, 2000). These frameworks offer different perspectives on how to evaluate and prioritize competing values, interests, and ethical principles in the context of food and agricultural biotechnology. While each framework offers valuable insights and perspectives, ethical decision-making often involves considering multiple frameworks and balancing competing values, interests, and principles in complex contexts and issues.

The public expresses their fears for unforeseen and unintended risks while also wrestling with the ethical implications. Evidently, many events led to shaping the view around genetic engineering with contrasting viewpoints. Rachel Schurman and William Munro focus on the clash between activists and agribusiness in their book titled “Fighting for the future of food: activists versus agribusiness in the struggle over biotechnology” (2010). Activists express concerns about potential negative social and ecological impacts, loss of democratic control and alienation, while agribusiness and scientists emphasize progress and intellectual property protection.

Louwaars and Jochemsen (2021) imply that weighing ethical concerns lies beyond scientific expertise, and rather falls on the category of “political follow-up questions”. Bioethicist Gregory Pence advocates for careful and ethical approach to biotechnology, believing in its potential for safe and humane human enhancement (Pence, 2015). Michael Reiss and Roger Straughan expanded on the ethical and moral concerns of genetic engineering in their book (2002). They emphasize the importance of understanding the science of genetic engineering to navigate its ethical considerations effectively. The main aim of their work is to educate the public and to enable readers to form their own opinions about the raised moral and ethical issues.

Philosopher Gary Comstock has extensively written about the ethical implications of agricultural biotechnology. Initially, he adopted a critical stance with raised concerns about potential negative impacts such as unintended creation of allergens and environmental catastrophe. However, he later revised his views advocating the use genetics in a careful and ethical way (Kaplan, 2012). Hugh Lacey challenges the notion of science as value-free, advocating for a consideration of ethical and societal implications in scientific inquiry. He emphasizes the need for public engagement and argues that ethical principles cannot be solely formulated based on scientific knowledge (Lacey, 2005).

The goal of crop production is to sustain humans by producing food, feed, and other products through the management of natural resources In the Anthropocene epoch, characterized by significant human impact on Earth and ecosystems, traditional agricultural practices are no longer sustainable. Crop production must adapt to minimize environmental impact and cater to the increasing global population. Plant breeding can play a significant role in advancing agriculture. In a contrasting view to the ethical discourse, the Ethics Council in Denmark questions the ethical implications of not utilizing breeding technologies to address issues like hunger and climate change (The Danish Council on Ethics, 2019)

Embracing gene editing as a tool for innovation is an important steppingstone, while ensuring informed decision-making. This coincides with Pence's views for a humane ethical application of biotechnology and Reiss and Straughan's emphasis on fostering informed dialogue. The potential benefits can be enjoyed without forgetting the need for ethical considerations and safeguards. as Alexander Pope once said, "A little knowledge is a dangerous thing" and educating the public and addressing concerns scientifically are crucial (Pope & Sargeaunt, 1909). Bridging the gap of quasi-knowledge and inaccurate or insufficient information is essential for navigating the complexities of biotechnology in agriculture.

4.1 Ethical Matrix Evaluation- Challenges and Considerations for Integrating New Genomic Techniques

One argument in favor of NGTs is the potential enhancement of food security, particularly in regions with limited access to nutritious food and fear of food insecurity, hunger and even malnutrition. NGTs can boost agricultural productivity and aid towards a more reliable and resilient food supply by enhancing crop yields, nutritional content, and resistance to pests and diseases. NGTs can also increase vitamin content or reduce allergenic compounds, thereby improving public health outcomes and addressing nutritional deficiencies. Regarding the possible environmental benefits, precision breeding techniques can reduce the need for chemical pesticides and fertilizers, reduce soil erosion, and conserve water resources, thereby promoting more sustainable farming practices and mitigating the environmental impact of agriculture. Additionally, rom an economic standpoint, investment in NGTs is seen as a driver of innovation, employment, and economic growth in the agricultural sector. By fostering scientific research and technological advancements, NGTs can stimulate innovation and competitiveness, offering success to agricultural industries in an increasingly globalized marketplace. Furthermore, the adoption of NGTs has the potential to generate new job opportunities and stimulate economic development in rural communities, contributing to broader socio-economic progress.

However, arguments against NGTs raise concerns regarding their potential risks and ethical implications. Among these concerns are the potential health risks associated with genetically modified organisms and the unintended consequences of genetic modification on human health and the environment. Critics argue that insufficient research has been conducted to fully understand the long-term impacts of NGTs on human health, necessitating safety assessments and ongoing monitoring of their effects.

Environmental concerns also participate in the debate over NGTs, with critics warning of the potential for unintended ecological consequences, such as gene flow to wild relatives, loss of biodiversity, and emergence of resistant pests. The introduction of genetically modified crops into natural ecosystems poses risks to biodiversity conservation and ecosystem health, necessitating careful consideration of the environmental impacts of NGTs and the implementation of robust regulatory mechanisms to mitigate potential harm.

In this document, NGTs have been extensively compared to GMOs and conventional breeding methods concerning health and environmental risks. While NGTs differ from GMOs by not introducing foreign DNA into an organism, they share similarities with conventional breeding techniques such as hybridization, ploidy induction, and mutagenesis. Even though these methods have been used over the years and are now considered well accepted methods in the agricultural sector, they also pose risks due to the potential introduction of unintended genetic changes arising from the mixing of substantial portions of the genome.

Considering the above, a question arises: why do we emphasize the safety and risks of NGTs over conventional breeding, especially considering the latter's lower precision and target specificity? It is crucial to recognize that both NGTs and conventional breeding methods may introduce unintended genetic changes, impacting health and the environment. However, EFSA's evaluation has indicated that no new risks are identified in NGTs compared to conventional breeding and EGTs (Mullins *et al.*, 2022). Their rigorous scientific approach ensures thorough evaluations based on health, environmental and safety aspects.

NGT organisms, when introduced into the environment and food chains on a large scale, may interact with other NGT organisms, potentially leading to cumulative effects and interactions. Applying the precautionary principle, it is essential to explore potential harm pathways and develop hypotheses regarding interactions between NGT organisms. Prospective technology assessment can aid in controlling the scale of NGT organism releases, minimizing unintended interactions (Koller *et al*., 2023). Ethical considerations further complicate the debate, raising questions about ownership and control of genetic resources, equitable distribution of benefits, and the potential exploitation of vulnerable communities. Critics argue that the commercialization of NGTs may exacerbate socio-economic disparities, favoring large-scale agribusinesses over small-scale farmers and marginalizing traditional farming practices and Indigenous knowledge systems. Additionally, the regulation of NGTs presents challenges, including defining appropriate risk assessment criteria, ensuring transparency and public participation in decision-making processes, and harmonizing regulatory frameworks across different countries and regions. Current regulations do not adequately differentiate between NGTs and traditional gene modification methods, leading to notable regulatory gaps. Not only do these gaps need addressing, but it is also crucial to consider that NGTs represent an ever-evolving field technologically. This necessitates an adjusted framework that remains relevant and effective over time. Consequently, the successful integration of these novel genome modification technologies requires careful consideration of technological, ethical, and policy dimensions. These considerations are fundamental to achieving the desired outcomes of sustainability, safety, and inclusivity.

Reflecting on the journey of this research, especially in understanding the rapid evolution of NGTs and their implications, it becomes clear that there is substantial need for further work in comprehending these techniques. As highlighted by previous studies, such as those by Frewer *et al.* (2011) and Buonanno *et al.* (2017), there is a pressing need for regulatory frameworks that are not only dynamic and responsive but also clearly distinguish NGTs from traditional genetic modification methods. The precision, possibilities and safety offered by NGTs necessitate a new regulatory approach, one that addresses all the ethical implications raised and actively includes that public in discussion regarding the implementation of NGTs. This regulatory approach must be scientifically informed and flexible enough to adapt to the rapidly changing field of technological innovation and advancements, ensuring that NGTs are integrated responsibly and effectively into our systems.

4.2 Future Research and Policy Recommendations for NGTs- Integrating Ethical Debates into Policies

Future research must prioritize understanding the long-term environmental impacts of NGTs and conducting risk assessments to prevent any gaps that might foster scepticism and mistrust. Significantly, it is important to not overlook the social aspects alongside the scientific ramifications of NGTs. Furthermore, the practical aspects of new policies should be thoroughly investigated, providing valuable insights into their potential implementation.

Continual research on NGTs' safety and risk, as underscored by previous studies and by Domingo and Bordonaba (2011), is essential. This includes studying potential off-target effects and long-term impacts on health and the environment. Policymakers must facilitate assessments to ensure NGTs pose no unforeseen risks. Additionally, ethical considerations, including biodiversity conservation and environmental impact, highlighted by Thompson (2020), should be integrated into policymaking to positively impact ecological and social systems.

Enhanced transparency and public engagement play vital roles in bridging the knowledge gap between scientists and the public, as emphasized by Frewer *et al.* (2011). Future policies should prioritize public consultation and communication, aiming to educate the public about NGTs, including their benefits and risks. This involves creating platforms for open dialogue where discussions on the benefits and risks can occur transparently. Public engagement strategies could include community forums, educational programs, and accessible online resources.

The European Union's proposal for a new regulatory framework surrounding NGTs also addresses the aspect of innovation and research. Similarly, supporting research in NGTs in critical areas like disease resistance and climate change adaptation will address global challenges such as food security and climate resilience. Recognizing the diverse approaches to GMOs and NGTs globally, international collaboration and harmonization of regulatory standards are essential, as suggested by Ramaswami *et al.* (2012). This effort will facilitate global trade and equitable NGT development. Harmonizing NGT policies across borders is vital to address the global nature of agricultural challenges and trade. It involves establishing international agreements and standards to ensure that NGT developments benefit all regions equally.

Values play a significant role in policy development, as highlighted by Macnaghten and Chilvers (2014), who emphasize the importance of public engagement in integrating societal values. Wynne (2001) emphasized the need for transparent and inclusive decision-making processes that consider diverse stakeholder perspectives. Adaptive and precautionary approaches, as advocated by Stirling (2008), are crucial for addressing scientific uncertainty and prioritizing safety and ethics. These approaches allow for flexibility and responsiveness to new scientific discoveries and societal changes, ensuring that policies remain relevant and effective over time.

In conclusion, the integration of ethical debates into NGT policies requires a multifaceted and dynamic approach. Policies need to be scientifically informed, ethically grounded, and socially responsive, addressing the complexities and evolving nature of NGTs. By considering these aspects, we can ensure that NGTs are developed and used in a beneficial and responsible way aligned with broader societal values.

4.3 Knowledge Gaps in the context of New Genomic Techniques

The long-term ecological impacts of NGTs pose uncertainties, particularly concerning their impact on biodiversity, ecosystem dynamics, and potential gene flow to non-target species. The 2021 technical report from the Joint Research Centre discusses the off-target effects of various NGTs, with some techniques showing a higher probability of creating unintended mutations than others. Extensive and prolonged research is imperative to comprehensively grasp these impacts, ensuring the ecological compatibility and sustainability of NGTs while preserving biodiversity and ecosystem integrity.

Beyond ecological concerns, knowledge gaps persist in understanding the socio-economic consequences of NGTs. This includes a thorough examination of how NGTs influence agricultural practices, alter market dynamics, and affect the livelihoods of farmers, especially in developing countries where agriculture forms the backbone of the economy. Understanding the implications of NGTs on technology access and equity among socio-economic groups is critical, determining whether these techniques act as equalizers or exacerbate existing disparities.

The role of NGTs in the global trade context remains under-explored. Research is needed to understand how these technologies affect international trade, regulatory compliance, and economic competitiveness. This includes examining NGT perception and regulation across different international markets and their implications for global agricultural trade and competition.

Additionally, public perception and understanding of NGTs represent a critical area of exploration. Enhanced transparency and active public engagement are necessary to bridge the knowledge gap between the scientific community and the broader public. Fostering an environment where the benefits and risks of NGTs are openly discussed and understood is key to their acceptance and successful integration.

To ensure that policies and regulations governing NGTs are up-to-date and effective, regulatory frameworks must be flexible and adaptable to new scientific findings and societal needs. This adaptability is crucial in accommodating the rapidly evolving nature of NGTs while ensuring safety, ethical compliance, and societal acceptance.

In conclusion, while NGTs offer considerable potential benefits, including improvements in crop yield, disease resistance, and climate change adaptation, addressing these knowledge gaps is crucial for their responsible and ethical integration into agriculture. Future research should prioritize the positive contributions of NGTs to food security, environmental sustainability, and bioethics, necessitating collaboration among scientists, policymakers, and the public to navigate the complexities of NGTs responsibly.

4.4 Source Reliability in NGT Assessments

Understanding the varying quality of sources is crucial important for informed decision-making regarding NGTs. The reliability of sources impacts the conclusions drawn about NGTs and their implementation.

The EFSA is a leading authority in the evaluation of these techniques. Their approach to assessing these techniques is grounded in rigorous scientific evidence. They utilize peer-reviewed studies, controlled experiments, and systematic analyses to draw conclusions, ensuring transparency and objectivity. Furthermore, EFSA’s evaluations include many dimensions, like health, environmental impact, and safety. This holistic approach ensures that all potential risks and benefits are considered, providing a balanced view of NGTs. Additionally, EFSA adheres to high standards in their evaluations. Their processes involve scrutiny by independent experts, minimizing biases and ensuring robust and reliable conclusions.

However, not all sources follow such methodologies resulting in varying levels of reliability. For example, industry reports can provide valuable insights but may have compromised objectivity due to vested interests. These reports may lack transparency regarding their data collection methods and underlying methodologies affecting their reliability. Opinion pieces, while contributing to the discourse on NGTs, are not equivalent to empirical evidence. Biases and personal viewpoints of the authors can influence their perspectives, possibly making these pieces more suitable as discussion points rather than definitive sources of information. Similarly, some studies that contribute to the discussion of NGTs lack the rigorous peer review process. Without this, potential flaws in methodology or interpretation may go unnoticed, reducing the reliability of these studies.

Transparency is essential in acknowledging the diversity of sources when discussing NGTs. Distinguishing between empirical evidence and other types of sources help maintain clarity. Conclusions drawn from robust studies carry more weight than those from less reliable sources can help manage expectations and promote informed discussions. This approach ensures that the benefits of NGTs are realized while addressing potential risks in a scientifically sound manner.

4.5 Conclusion

4.5.1 Conclusion of Research Questions

Traditional genetic modification methods have been the backbone of crop breeding with examples including methods like hybridization. While effective, these methods lack precision and target specificity. In contrast, NGTs including methods such as CRISPR/Cas and TALENs, allow for precise modifications, targeting specific genes without introducing foreign DNA. The application of NGTs in agriculture have resulted in disease-resistant crops, with enhanced nutritional content and improved yield and stress tolerance.

Risk assessment is an essential aspect of to ensure the safety of genetically modified organisms. The European Union has shaped the regulatory landscape of GMOs with Directives that monitor GMO releases and track their impact on the environment and human health. However, NGTs differ from what is considered traditional breeding as well as from transgenic methods due to their precision and efficiency. Compared to conventional breeding that has been practiced many years, NGTs represent a relatively newer and more precise approach to genetic modification, introducing changes to the DNA in a manner that was previously not possible. Therefore, the need for comprehensive risk assessment is important, particularly considering the potential long-term impacts and uncertainties associated with these emerging technologies. Unlike conventional breeding, which has a longer history and may have established risk profiles, NGTs introduce genetic modifications in a targeted yet unprecedented manner, necessitating thorough evaluation to ensure the safety and integrity of agricultural products derived from these techniques.

Rigorous risk assessment is necessary to evaluate specific risks posed by NGT plants and crops and their safety, quality, and performance.

The ongoing GMO debate has impacted the ethical discourse surrounding NGTs. Ethical considerations stemming from this debate are shaping policy development in the context of NGTs. GMO discussion has spanned over decades, including various issues on safety, environmental implications, and public perception. As NGTs emerge as a powerful genome editing tool, the historical perspectives from the GMO discourse shape our understanding of the ethical challenges and concerns. Some of these concerns are potential risks, moral and social implications. Policy development surrounding NGTs presents various stances in different regions. Some view NGTs as a solution to global challenges while others view them with caution. Emphasizing rigorous risk assessment and public engagement. Robust ethical frameworks are important to navigate the dynamic landscape of NGTs to embrace innovation and ensure the positive contribution of NGT implementation.

There are various ethical, legal, and social considerations regarding NGTs that are translated into policy, emphasizing the need for regulations that balance innovation with societal values. Genome editing raises questions of naturalness and ethical frameworks must balance benefits and risks, ensure informed consent, and provide equitable access and distribution. Policymakers must also define the legal implications of NGTs surrounding intellectual property rights and liability. Public perception and social acceptance influence NGT adoption. Inclusivity and engagement of diverse stakeholders along with transparency for informed decision-making influence this acceptance.

4.5.2 Ethical and Dynamic Regulation of New Genomic Techniques

As we look towards the future, the regulation of NGTs will undoubtedly continue to evolve along with scientific progress and shifting societal values. It is crucial that we approach these developments with a strong ethical compass, ensuring NGTs are utilized in a manner that is responsible and yields tangible benefits. Drawing from our experiences with GMOs, which have laid some groundwork, we recognize that NGTs introduce new, complex challenges that necessitate adaptable and forward-thinking regulatory approaches.

In this rapidly advancing field, active and ongoing dialogues among scientists, policymakers, and the public are essential. Such conversations ensure that a diverse range of perspectives are considered, enriching the policy-making process. International cooperation will also play a pivotal role, as it is vital for navigating the intricacies of NGT development. This dialogue aims to strike a balance between embracing innovation and exercising due caution. We must ensure the advantages of NGTs are effectively harnessed, giving precedence to human health, environmental protection, and social fairness.

As highlighted in this paper, NGTs have the potential to revolutionize various aspects of our lives, from healthcare to agriculture. However, this potential comes with responsibilities. The present study underscores the necessity for regulation strategies to be as dynamic and evolving as the technologies they govern. This dynamic approach is crucial, considering the ethical implications and the continuous need for vigilance in this rapidly evolving area.

The investigations into NGTs have revealed the importance of integrating ethical debates into policymaking, addressing knowledge gaps, and considering the socio-economic impacts of these technologies. The future of NGTs lies in our ability to adapt and respond to these challenges, ensuring that the development and implementation of these technologies are in harmony with ethical standards, societal needs, and environmental considerations.

In conclusion, the journey of NGT regulation is one that requires continuous adaptation, ethical mindfulness, and global cooperation. By embracing these principles, we can navigate the complexities of NGT development and ensure that these advanced technologies contribute positively to our society and the broader global community.

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Popular science summary

New Genomic Techniques for more precise and safer gene editing

The scientifical and technological advancements in the field of biotechnology and gene editing have sparked debates on the safety of NGTs. These techniques are cutting-edge tools that allow scientists to precisely edit plant genes, enhancing desirable traits like crop resilience and yield without introducing foreign DNA. By enabling faster and more efficient crop improvements, NGTs hold the promise of meeting the growing global food demand sustainably. In other words, desirable traits in crops can be enhanced more accurately with a lower risk of unprecedented and unwanted side-effects. Therefore, this evolution necessitates a new regulatory framework that caters NGTs and differentiates them from GMOs and traditional gene editing methods.

The European Union is at the forefront of this regulatory endeavour. A new proposal suggests a legal framework aimed towards NGT plants, focusing on safety, sustainability, and inclusivity. This approach highlights the EU's commitment to harvest the benefits of NGTs in a cautious way with addressing potential risks. Other than the EU's position on the matter, attitudes towards NGTs vary globally. The US emphasizes how safe the product is. In contrast, India weighs the socio-economic impact and Brazil views NGTs as an economic opportunity while considering environmental safety.

Other than the technical aspect of NGTs, NGTs come with ethical and regulatory challenges. It's crucial to ensure their safety and balance biotechnological advancements with social and economic concerns. Governments and scientists worldwide are grappling with these questions and challenges, in an attempt to develop regulations that balance innovation with ethical considerations.

As NGTs continue to advance, regulatory strategies must also evolve and adapt. This evolvement includes keeping the dialogue open and including scientists, policymakers, and the public in the discussion, ensuring international cooperation to navigate the complexities of NGT development.

By embracing ethical principles and thoughtful regulation, we can harness and manoeuvre around the full potential of NGTs for the improvement of society and the environment.

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