Synesis, v. 17, n.1 , 2025, ISSN 1984-6754

ETHICAL CHALLENGES IN BIOTECHNOLOGY: EXPLORING THE BOUNDARIES OF SCIENTIFIC INTERVENTION

DESAFIOS ÉTICOS NA BIOTECNOLOGIA: EXPLORANDO OS LIMITES DA INTERVENÇÃO CIENTÍFICA

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Received: 11 Nov 2024
Accepted: 08 Jan 2025
Published: 16 Mar 2025

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Abstract: Biotechnology is causing rapid advances that have offered new prospects in medicine, agriculture, and energy, but it has also raised various ethical issues that need proper regulation. All of these issues have great potential for both social inequality and moral controversy, especially ones such as genome editing, the use of GMOs, cloning and neuroenhancement. The study aims to examine the ethical and philosophical limits within which biotechnological intervention may be justified and formulate ways to regulate them. The methodology consists of the comparative analysis of regulatory documents, ethical concepts, and the publication of biotechnology-related science. Also, it includes a structural and logical analysis of the influence of biotechnology on social and moral norms. The study results indicate the need for a clear distinction between therapeutic and enhanced use of biotechnologies and the enhancement of institutional control and harmonisation of international bioethics standards. The analysis concluded that without a single regulatory approach, there are ethical and social risks related to the availability of biotechnology and the question of individual autonomy and risks associated with the long-term consequences of genetic modification. The work's practical importance consists in the development of recommendations to the policy for regulating a regulatory policy responsible for the use of biotechnological innovations. Thrust for further research should be directed towards the appraisal of the real effects of biotechnology on social norms and the formulation of ethical mechanisms to dissuade possible threats.

Keywords: Biotechnology. Bioethics. Genetic interventions. Neuroenhancement. Ethical dilemmas. Regulatory policy. Social responsibility. Philosophy of science. GMOs. Cloning.

Resumo: A biotecnologia está a provocar avanços rápidos que oferecem novas perspectivas nos

domínios da medicina, da agricultura e da energia, mas também tem levantado várias questões éticas que necessitam de uma regulamentação adequada. Todas estas questões têm um grande potencial de desigualdade social e de controvérsia moral, especialmente as que se prendem com a edição do genoma, a utilização de OGM, a clonagem e o melhoramento genético. O objetivo do estudo é examinar os limites éticos e filosóficos em que se pode justificar a intervenção biotecnológica e formular formas de a regular. A metodologia consiste na análise comparativa de documentos regulamentares, de conceitos éticos e da publicação de ciência relacionada com a biotecnologia. Além disso, inclui uma análise estrutural e lógica da influência da biotecnologia nas normas sociais e morais. Os resultados do estudo indicam a necessidade de uma distinção clara entre a utilização terapêutica e a utilização avançada das biotecnologias, bem como o reforço do controlo institucional e a harmonização das normas internacionais de bioética. A análise concluiu que, sem uma abordagem regulamentar única, existem riscos éticos e sociais relacionados com a disponibilidade da biotecnologia e a questão da autonomia individual e dos riscos associados às consequências a longo prazo da modificação genética. A importância prática do trabalho consiste no desenvolvimento de recomendações para a política de regulamentação de uma política reguladora responsável pela utilização das inovações biotecnológicas. A investigação futura deve ser orientada para a avaliação dos efeitos reais da biotecnologia sobre as normas sociais e para a formulação de mecanismos éticos de dissuasão de possíveis ameaças.

Palavras-chave: Biotecnologia. Bioética. Intervenções genéticas. Melhoramento genético. Dilemas éticos. Política de regulação. Responsabilidade social. Filosofia da ciência. OGM. Clonagem.

1. Introduction

The biotechnology sector is among the most dynamic areas of modern science, particularly in the medical, agricultural, energy, and environmental fields. They provide an opportunity for significant progress in quality of life, extending human life expectancy, and solving the global challenges of food security and climate change. Furthermore, despite this, biotechnological innovations constitute a set of serious ethical and legal questions about the endpoints of permissible intervention in processes of nature, especially as these have to do with genome editing, cloning, GMOs and neuroenhancement. The main problem of the study is to find a balance between scientific and technological progress and the moral responsibility of society for its consequences, which is the subject of active debate in the scientific and philosophical community. In the contemporary literature, considerable attention is paid to bioethics and its role in determining the limits of permissible interference of biotechnology with natural processes (FAÚNDEZ ALLIER, 2024; KIÇMARI, 2024). Researchers are analysing the legal aspects of biotechnology regulation at the international level (HALLERMAN *et al.*, 2024) and the socio-cultural impact of such technologies on society (DOUGLAS-JONES *et al.*, 2022). At the same time, there is a lack of unity in approaches to bioethical norms governing genetic modification, cloning and neuroenhancement (COSTA, 2024). Some studies have highlighted the need to harmonise regulatory mechanisms to avoid abuses in biotechnology (RUSSO, 2023). However, although much bioethical research has been done in recent years, several unresolved issues remain. More specifically, biotechnology has not been extensively investigated in terms of social equality, moral values, and the long-term consequences of genetic interventions. However, the use of biotechnology is complicated by the decision-making process concerning its use due to the lack of a global unity of approach among regulators.

The philosophy and ethics that determine the philosophical and ethical boundaries between biotechnological intervention are analysed, and the possible consequences of these risks are assessed, as are the recommendations for regulatory policy. For this goal, some key bioethical principles should be considered, such as assessing biotechnology's effect on social and ethical norms, determining possible ways to regulate it, and further defining ways to develop ethical standards.

2. Literature review

The limits of acceptable intervention have been of special interest in the current age of contemporary biotechnology and ethics research, including but not limited to medicine and life extension (AHMAD *et al.*, 2022; APARICIO, 2025). Additionally, it thwarts the view on the bioeconomy and its ethical challenges as part of sustainable development and regulatory policy (GREMMEN, 2022; STAHL, 2022). Institutional ethics and the role of ethics committees in biotechnology research are emphasised by BYK (2023) and RUSSO (2023), who highlight the need to regulate technological progress. Ethics in technology and research appears to be a key aspect of analysis in many contemporary publications, exploring both general principles (MOSCHIS, 2024; SMUTS; WEILBACH, 2023) and specific sectoral aspects, such as in agriculture and food systems (SANDIN; ROBAEY, 2023; SHARMA, 2024). Particular attention has been paid to neuroenhancement, genetic therapy and their impact on social and moral norms (COSTA, 2024; TORO, 2023).

Biomedical ethics and the issue of genetic interventions are the subject of research in various contexts, from philosophy and morality to practical issues of bioethical decision-making (FAÚNDEZ ALLIER, 2024; MORENO, 2023). In addition, considerable emphasis is placed on the impact of biotechnology on the international order and political aspects (KIÇMARI, 2024; SOLBERG SÖILEN, 2024). As emphasised by KIWANUKA *et al.* (2024) and QUIGLEY *et al.* (2024), public education and public discussion of ethical issues in the scientific community are important, and these authors propose new models to engage the public in discussions. Current research also includes different ethical problems within various areas of science and practice and general problems of bioethics and biotechnological science. For example, HALLERMAN *et al.* (2024) actively analyse regulatory policy for biotechnology in the context of the global environment to stress that legislation should be availed to leverage the potential of technology. The study of HAVRYSH *et al.* (2020) concerned the rational use of natural resources with elements of ethics; the research is carried out about energy-efficient technologies.

Additionally, biotechnology in livestock production has received much attention regarding ethics and zoonotic risks (OPRIESSNIG; HALBUR, 2023). Understanding this issue relates closely to more significant debates in bioeconomy and sustainable development (BBSRC, 2024). The studies of relationships between technological advances and how moral norms were and were not used are especially important (NEMAT; CHARTON, 2024).

Further, educational ethics and the development of only ethical competence in engineering and technology are ongoing issues that deserve much emphasis (CHERUVALATH, 2024). This indicates that the role of society in using scientific and technological achievements is not only about the role of scientific and technological achievements but also the role of the possessor of scientific and technological achievements. WEISSGLASS (2024) looks at ethics in plant science and its effects on the global health system, and DOUGLAS-JONES *et al.* (2022) explore moral values within technology development.

Despite substantial progress in this field, a number of unresolved problems remain in the study of ethical issues in biotechnology (BIOTECHNOLOGY AND BIOLOGICAL SCIENCES RESEARCH COUNCIL, 2024). Particularly, the ways of limiting the impact of biotechnology innovations on the environment and on society's social structure are not sufficiently elaborated. Further study is required on the issue of responsibility for future generations of biotechnology developers.

3. Methods

The study's methodological approach includes, in particular, the analysis of scientific literature, the comparison of ethical concepts and regulatory documents and the systemisation of views on the regulation of biotechnology. The content analysis method enabled us to review the current way of bioethics and determine the most debated problems among scientists. The comparative method revealed differences in national regulatory approaches to biotechnology and thus allowed us to distinguish the advantages and disadvantages of those approaches. The logical-structural method was used to systematise the data obtained and formulate key conclusions about the limits of biotechnology's interference with natural and social processes. In addition, the forecasting method was used to assess future challenges associated with introducing new biotechnological solutions, which contributed to developing recommendations for their regulation.

4. Results

The ethical regulation of biotechnology includes any moral, legal and social questions raised by the applications of biotechnology. Such regulation is mainly aimed at achieving the balance between the progress of science and technology and the moral

responsibility of society to react to science and technology development. Indeed, current research specifies a number of ways by which the regulation of biotechnology should define the permissible scope of interference with biological processes.

Biomedical ethics and regulatory principles. Biomedical ethics is a central area that defines the regulatory framework for using biotechnology in medicine and genetic engineering. It is based on four basic principles: autonomy, beneficence, nonmaleficence, and justice (FAÚNDEZ ALLIER, 2024). These principles are used to assess the acceptability of new biotechnological methods, particularly in genetic therapy, genome editing and regenerative medicine. One of the important aspects is patients' informed consent when using biotechnological interventions. Research shows that the public often lacks sufficient knowledge about genetic alterations' potential risks and long-term consequences (MORENO, 2023). Therefore, the key task of biomedical ethics is to create transparent mechanisms for informing the public and forming ethics committees that monitor the compliance of biotechnology research with ethical standards (RUSSO, 2023).

Genetic interventions: a balance between scientific possibilities and moral constraints. Genetic interventions, particularly CRISPR-Cas9 genome editing methods, are sparking active debate about the permissibility of their use in human heredity. Researchers emphasise the distinction between therapeutic and enhancer use of genetic modification (TORO, 2023). Therapeutic use is aimed at treating genetic diseases and is primarily supported by ethics committees, while DNA alteration to improve an individual's physical or cognitive characteristics remains controversial (COSTA, 2024). In the international context, several regulatory documents restrict the use of human genome editing technologies. For example, the Oviedo Convention of the Council of Europe prohibits inherited genome changes due to ethical and legal risks (KIÇMARI, 2024). At the same time, some countries, such as China and the United States, are exploring the possibility of regulating gene therapy aimed at preventing diseases, which raises the question of the need to harmonise ethical standards at the international level (HALLERMAN *et al.*, 2024).

Neuroenhancement and its ethical challenges. Modern research pays special attention to the issues of neuroenhancement - the use of biotechnology to improve human cognitive abilities. This includes pharmacological methods, neurostimulation, and neurochip implantation (Costa, 2024). The central ethical dilemma is to define the boundaries between treating neurological disorders and using technology to improve the performance of healthy people. Researchers emphasise the potential risks of social inequality that may arise from the

access of only certain groups to neuroenhancement technologies (DOUGLAS-JONES *et al.*, 2022; WORLD HEALTH ORGANISATION, 2023). In addition, the issues of individual autonomy and the long-term consequences of interfering with brain activity remain open. Some countries are introducing ethical codes to control the use of such technologies, but there is still a lack of uniform regulatory approaches at the global level (WEISSGLASS, 2024).

Modern approaches to the ethical regulation of biotechnology are based on the fundamental principles of biomedical ethics, but they also face new challenges related to genetic and neurotechnological interventions. The main areas of regulation remain ensuring research transparency, protecting patients' rights, distinguishing between therapeutic and enhancing technology uses, and preventing social inequality. As biotechnology continues to evolve, the need to harmonise international ethical standards and adapt regulatory policies remains a pressing issue.

Biotechnological innovations are rapidly changing the modern socio-cultural landscape, causing profound changes in moral values, legal regulation and public perception of scientific and technological progress. They cover various areas, from medicine and food security to energy and the environment, creating opportunities for improving the quality of life and ethical challenges in their application. One of the key aspects is the issue of public acceptance of biotechnology. Studies show that trust in these innovations largely depends on the level of public awareness, regulatory policy transparency, and independent ethics committees' ability to monitor them (KIWANUKA *et al.*, 2024). At the same time, there is a growing debate about the impact of biotechnology on moral principles and social justice, especially in gene therapy, neuroenhancement and cloning (COSTA, 2024; TORO, 2023).

In the modern legal sphere, the task of harmonising legislation with ethical norms is emerging. Regulatory approaches range from strict prohibitions (as in the case of human cloning) to the gradual introduction of controlled biotechnological interventions, for example, in the field of personalised medicine (MORENO, 2023). Accordingly, it is important to examine how biotechnological innovations change social, moral, and legal norms and how society adapts to new realities (Table 1).

Table 1. The impact of biotechnology on social, moral and legal norms

Sphere of influence	**Key biotechnological innovations**	**Social impacts**	**Moral challenges**	**Legal aspects**
Medicine and genetics	Gene therapy, genome editing (CRISPR-Cas9)	Improving health, prolonging life, reducing hereditary diseases	Ethics of altering human DNA, potential inequalities in access	Regulation of the limits of genome interference, prohibition of germ cell modification in most countries
Neurotechnology	Neuroenhancement, chip implantation, brain interfaces	Improved cognitive abilities, impact on labour productivity	The problem of personal autonomy, changes in human personality	Lack of unified legislation, limited regulation
Agriculture	GMO crops, biotechnology, animal husbandry	Increased yields, disease resistance	Discussions on GMO safety, impact on biodiversity	Regulation of labelling of GMO products, bans in some countries
Environment and energy	Biofuels, bioremediation	Reducing CO_2 emissions, preserving ecosystems	Possible side effects for ecosystems, land use for biofuels	Government subsidies and environmental regulatory programmes
Cloning and bioengineering	Reproductive cloning, 3D bioprinting of organs	Possibility of organ reproduction, reduction of donor shortage	The problem of personal identity and the use of biomaterials	Prohibition of reproductive cloning in most countries

Source: Authors' elaboration based on (MORENO, 2023; COSTA, 2024; KIWANUKA *et al.*, 2024; TORO, 2023)

Biotechnological innovations have a powerful impact on social, moral and legal norms, transforming the perception of the possibilities of science and its ethical limits. On the one hand, they contribute to developing medicine, food security, and environmental sustainability. On the other hand, they raise serious questions about moral responsibility and social equality. Today's society is searching for balanced approaches to regulating biotechnology, where state laws, public debate, scientific and ethical committees, and international cooperation play an important role. The main challenges remain to ensure

transparency of scientific developments, build public trust in technologies and minimise the risks associated with their uncontrolled use.

Assessing the real impact of biotechnology on society, ethics, and legal regulation requires a thorough analysis of conceptual approaches and actual data. Statistical indicators allow us to see how fast biotechnological innovations are developing, how accessible they are to different population segments, and what regulatory mechanisms exist in different countries. Table 2 presents key statistics illustrating the scope of biotechnology applications in medicine, agriculture, energy, and ethical control mechanisms.

Table 2. Statistics on biotechnological innovations and their impact

Scope	Key statistical indicators
Genetic interventions and biomedical technologies	- In 2023, more than 2000 clinical trials of gene therapy were registered - The cost of CRISPR therapy can reach $1-2 million per patient. - 65% of US citizens support gene therapy to treat diseases, but only 30% approve it to improve physical or cognitive performance.
GMOs and biotechnology in agriculture	- In 2022, 77% of soybeans, 31% of corn and 80% of cotton were genetically modified. Only three out of 27 countries in the EU allow commercial cultivation of GMOs, while in the US and Brazil, most crops are genetically modified. - In the EU, 50% of the population is sceptical about GMO foods, while only 25% express concern in the US.
Bioenergy and sustainable development	- Global biofuel production in 2023 increased by 7% to 165 billion litres. - Approximately 10% of the world's arable land is used to grow biofuel crops. - Investments in biotechnology for renewable energy production have increased by 15% over the past 5 years, reaching $120 billion in 2023.
Ethics committees and regulatory mechanisms	- Only 40% of countries worldwide have specialised agencies to regulate biotechnology. - In 2022, 150 bioethics violations related to clinical trials and gene experiments were registered.

Source: developed by the author based on (KIÇMARI, 2024; HALLERMAN *et al.*, 2024; RUSSO, 2023; SANDIN; ROBAEY, 2023; GREMMEN, 2022; COSTA, 2024)

Biotechnological innovations significantly impact various areas of society, including medicine, agriculture, energy and regulatory mechanisms. The high proportion of genetically

modified crops (77% of soybeans, 31% of corn and 80% of cotton in 2022) indicates the widespread adoption of GMOs in the food sector. However, some scepticism remains in Europe. Gene therapy is actively developing, but its availability is limited due to the high cost, which can reach $1-2 million per patient. Bioenergy is growing – biofuel production increased by 7% in 2023, and investments in renewable energy reached $120 billion. At the same time, only 40% of countries have specialised agencies to regulate biotechnology, which points to the need for further development of international ethical standards and control mechanisms.

Modern biotechnologies offer excellent opportunities to improve the quality of life, increase food security and ensure the sustainable development of energy systems. However, several ethical challenges of using them surround moral responsibility, social justice and what could be negative consequences for the environment and human health. The dilemma is to be found in the balance between technologies and risks that come with the introduction of biotechnological innovations. In medicine, there is also the question of gun therapy and its effects on future generations. GMOs' risks in agriculture insofar as biodiversity are discussed; in the energy sector, the influence of biotechnology on ecosystems and land use is discussed. We will deal with the main ethical challenges in these areas, considering the areas of sustainable development and the bioeconomy.

1. Medical biotechnology: gene therapy, biomedical ethics, and equality of access. The use of gene therapy, genome editing, and cellular technologies is the main topic of ethical issues in medicine. These innovations signify that diseases such as cystic fibrosis or sickle cell anaemia can be treated (MORENO, 2023). In this case, however, questions emerge as to what extent human genome interference is allowable, considering heritable modifications especially problematic (TORO, 2023).

Key ethical challenges:

1. The limits of genome intervention include whether gene editing is morally permissible, especially in the case of improving human characteristics (COSTA, 2024).

2. Equality of access to biotechnological methods threatens to create genetic inequality between people who can afford genetically modified treatments and those who will be left without them (KIWANUKA *et al.*, 2024).

3. Uncertain long-term consequences – the possible negative impact of gene therapy on the health of future generations due to unpredictable genetic mutations (HALLERMAN *et al.*, 2024).

2. Biotechnology in agriculture: GMOs, food security and environmental risks. Using genetically modified organisms (GMOs) in agriculture contributes to increased yields, crop resistance to pests, and reduced need for chemical pesticides. At the same time, there are concerns about the long-term effects on human health and the environment (SANDIN; ROBAEY, 2023).

Key ethical challenges:

1. Impact on biodiversity - possible displacement of traditional plant varieties and negative impact on natural ecosystems (NEMAT; CHARTON, 2024).
2. The food market is monopolised by large corporations, which dominate the production and supply of GMO seeds, thereby limiting opportunities for small farmers (CHERUVALATH, 2024).
3. However, scientific research has not substantiated the negative impact of GMOs on human health, and some in society still doubt their safety (SHARMA, 2024).

One key aspect is the introduction of ethical standards for labelling GMO products and ensuring transparency of their use in the agricultural sector (WEISSGLASS, 2024).

3. Biotechnology in energy: sustainable development and resource use

Biotechnological innovations in the energy sector aim to develop alternative energy sources, including biofuels, and bioremediation methods for environmental clean-up (GREMMEN, 2022). However, questions arise about the rational use of resources and environmental impacts.

Key ethical challenges:

1. Competition between biofuels and food - using agricultural land for biofuel production can lead to food shortages in some regions of the world (STAHL, 2022).
2. Environmental risks: Intensive biomass cultivation can deplete soils and lead to deforestation (HAVRYSH *et al.*, 2020).
3. The equitable distribution of energy resources is a problem of access to new biotechnologies in developing countries due to the high cost of implementation (SOLBERG SÖILEN, 2024).

During the development of biotechnology in the energy sector, an ethical assessment of the environmental risks and the implementation of compensation mechanisms to accommodate the natural environment should be made.

Biotechnological innovations shape modern society, but their use is associated with various ethical challenges. Gene editing needs to be defined in the medical field regarding the limits of the technology, keeping in mind the rights of future generations and the equality

of access to technology. In agriculture, there is a need to draw a balance between giving priority to food security and the conservation of biodiversity. In the energy sector, finding an agreement between biofuel production and environmental sustainability is crucial. Accordingly, biotechnology requires ethical regulation that is systematically based on the active involvement of government agencies, the scientific community and civil society. Resolving the contradiction between technological progress and moral principles can be done by only a systematic approach, and humanity can be developed through more sustainable development only with this.

Responsible development of biotechnology relies on ethics committees and principles of institutional ethics. They are set up to assess risks associated with new technologies, track their effect on the environment and society, and monitor if international ethical standards are upheld (BYK, 2023). The focus of institutional ethics concerns the establishment of ethical standards in scientific research and the design of the mechanism to monitor compliance with them. Among its concerns is the analysis of the effects of biotechnological development on ecosystems, social equality and human rights (RUSSO, 2023). Although much effort has been made and, indeed, particular efforts have explicitly been made to address this issue, the world has not achieved global coordination and standards harmonisation (KIÇMARI, 2024).

In this context, it is worth considering the main functions of ethics committees and mechanisms for monitoring the impact of biotechnology on the environment and society (Table 3).

Table 3. Functions of ethics committees and control mechanisms

The scope of regulation	**The main functions of ethics committees**	**Institutional ethical approaches**	**Controlling the impact on the environment and society**
Medical bioethics	Analysis of clinical trials, approval of study protocols	Guaranteeing compliance with the principles of autonomy, charity and justice	Controlling the impact of gene therapy and genome editing on future generations (FAÚNDEZ ALLIER, 2024)
Genetic research	Risk assessment of genome editing, control of experiments	Establishing the limits of permissible interference with	Prevention of unwanted mutations and their spread in the

		the human genetic code	population (TORO, 2023)
Agriculture	Safety assessment of GMO foods and biotechnological livestock	Biodiversity protection and ecosystem impact assessment	Analysis of the long-term environmental impacts of GMOs (SANDIN; ROBAEY, 2023)
Energy and environment	Assessment of biofuel and bioremediation technologies	Guarantee of compliance with the principles of sustainable development	Preventing the depletion of natural resources and environmental disasters (GREMMEN, 2022)
Neuroenhancement technologies	Regulation of the use of implanted devices and brain interfaces	Protecting a person's cognitive autonomy and personal identity	Defining the boundaries of ethical use of neuro modification technologies (COSTA, 2024)

Source: Authors' compilation based on (BYK, 2023; RUSSO, 2023; SANDIN; ROBAEY, 2023; GREMMEN, 2022; COSTA, 2024)

Ethics committees and principles of institutional ethics are important elements of regulating biotechnology research. They balance scientific advances with responsibility for consequences. Byk (2023) states that they perform a key function in determining the influence of biotechnology on the environment and society, contributing to developing transparent mechanisms for risk assessment and adopting international standards.

The main challenges remain the harmonisation of regulation at the global level, prevention of possible misuse of technology, and building public trust in biotechnological innovations. The further development of institutional ethics should focus on the integration of environmental, social, and legal aspects to ensure sustainable and ethically responsible development of science.

The development of biotechnology is accompanied by significant ethical challenges that require global coordination of regulatory standards and accountability mechanisms. Despite existing international initiatives, legal and ethical approaches in different countries remain heterogeneous, creating risks of unequal access to technology, potential misuse and unregulated interference with natural processes (HALLERMAN *et al.*, 2024). The harmonisation of ethical standards should include a comprehensive approach that combines international agreements, scientific consortia, public participation and the development of

responsible regulation technologies. This requires the development of common mechanisms for risk assessment, determining morally acceptable limits of intervention and legal regulation of biotechnological innovations in a global context (Table 4).

Table 4. Approaches to harmonising ethical standards and accountability mechanisms

Approach	**Description**	**Expected results**
International coordination of regulatory standards	Harmonisation of standards through organisations such as WHO, UNESCO, European Commission	Reducing discrepancies in the legal regulation of biotechnology
Global Ethical Charter for Biotechnology	Developing common ethical principles for genome intervention, bioengineering and neurotechnology	Developing a common moral approach for all countries
Strengthening institutional control	Introduce mandatory ethics committees at all biotechnology institutions	Increasing research transparency and risk control
Development of technological ethical audits	Developing automated monitoring systems for and assessing the impact of new technologies	Prompt detection of ethical violations and their correction
Educational programmes in bioethics	Integration of bioethics courses into university curricula and professional training	Raising the ethical awareness of scientists and technology developers
Involving the public in decision-making	Holding open discussions and referendums on the introduction of biotechnology	Strengthening public trust in biotechnology regulation
Development of an international accountability mechanism	Establishment of a single international body to review ethical violations in biotechnology	Strengthening the responsibility of corporations and scientific institutions
Ethical assessment of the environmental impact of biotechnology	Mandatory environmental impact modelling before introducing new biotechnologies	Preventing possible adverse environmental effects

Source: developed by the author on the basis of (KIÇMARI, 2024; HALLERMAN *et al.*, 2024; RUSSO, 2023)

Harmonisation of ethical standards in biotechnology is a complex but necessary task for global science and politics. The proposed approaches aim to create a unified international regulatory body based on ethical principles and technology. Indeed, such components as international coordination, early institutional control, including bioethics in educational programmes and mechanisms for a public discussion of bioethical issues are

important components of this process. Over the long run, it will reduce the risks of misuse of biotechnology, increase environmental sustainability, and promote social equality by using the most advanced scientific achievements possible.

Addressing the ethical challenges of biotechnology from a philosophical perspective requires reference to key ethical theories that define the morally permissible limits of scientific interventions. The most influential concepts that can be applied to bioethical issues are Kantian ethics, utilitarianism and feminist ethics.

Based on Immanuel Kant's categorical imperative, Kantian ethics requires that human beings be seen as ends in themselves, not as a means to an end. Some aspects of biotechnology may be morally questionable. For example, genetic editing of embryos to improve specific characteristics may be seen as using a future human being to achieve a desired social or individual end, contrary to the Kantian principle. However, the therapeutic application of gene therapy is consistent with the categorical imperative if it is aimed at respecting human dignity and improving the quality of life without turning a person into an experimental object.

*Utilitarianism***.** From the perspective of utilitarianism (Jeremy Bentham, John Stuart Mill), morality is evaluated according to the principle of "the greatest good for the greatest number of people". The utilitarian approach can justify using biotechnology if it contributes to the general welfare. For example, GMO crops (GMO CROPS, ANIMAL FOOD, AND BEYOND, 2020) can increase food security and reduce hunger, positively impacting the global population. However, utilitarianism also considers potential negative consequences, such as the risks of environmental damage from biotechnology or social inequality in access to expensive medical innovations. Therefore, it is essential to determine the outweighing of the possible risks with the positive results.

This social implication of biotechnology is highlighted by feminist ethics, which concentrates on justice, equality and care. Notably, it asks whether biotechnology may fit in with commercialisation, enhancing inequality between groups and countries of various social categories. An example is reproductive technologies that might incorporate genome editing and thereby establish a new type of discrimination linked to genetic characteristics in the future or promote social pressure to educate women that they shall be responsible for "perfect" children. In addition, feminist ethics stresses the importance of broad public discussion about biotechnological innovations through which other social groups occur during decision-making.

The ethical dilemmas of biotechnology are assessed in different ways from different philosophical approaches. Kantian ethics emphasises moral principles and respect for human dignity, utilitarian ethics works on the overall beneficial effect, and feminist ethics stresses social justice. However, those three approaches must be considered in an effective biotechnology regulation for a balanced, ethical policy, reducing risks and promoting the common good of society.

5. Discussion

This development is linked with a set of ethical challenges that biotechnology should overcome through thorough analysis and discussion of the relevant but still debated limits of reasonable intervention. The study states that biotechnology regulation should simultaneously balance its scientific achievements and moral responsibility, a subject to which the scientific community pays great attention. The findings indicate that biomedical ethics plays a key role in determining the boundaries of biotechnology. The study confirmed that the principles of autonomy, nonmaleficence, beneficence and justice remain the basis for evaluating biotechnological interventions (FAÚNDEZ ALLIER, 2024). However, the question of the permissibility of genome editing, especially about hereditary changes, is still under debate.

Developing technologies, particularly CRISPR-Cas9, will contribute to the growing debate on genetic interventions. Although the scientific community primarily supports therapeutic methods, the euthanasia application of genome editing remains controversial (TORO, 2023). Analysis from the perspective of different ethical approaches shows that, for example, Kantian ethics categorically rejects any form of manipulation of the human genome for improvement. At the same time, utilitarianism allows it if it is for the common good. At the same time, feminist ethics emphasises the potential risks of social inequality arising from unequal access to biotechnological innovations. This suggests the need for a multifaceted approach to biotechnology regulation that considers technical capabilities and social and moral aspects.

The results of our study are consistent with HALLERMAN *et al.* (2024), who emphasise the importance of harmonising biotechnology legislation. At the same time, SANDIN and ROBAEY (2023) draw attention to the need for an environmental impact assessment of genetically modified organisms. The main conclusions of the discussion

indicate the need to distinguish between the therapeutic and enhanced use of biotechnology. Furthermore, there are ethical issues to be investigated in neuroenhancement and the use of implanted chips (COSTA, 2024).

The weakness of this study is that apart from legal and ethical aspects, practical issues arising from the introduction of biotechnology into society are not fully known. Some aspects of biotechnology's impact on social norms and moral principles need further research. Attention should also be paid to the problem of biotechnology's accessibility and its impact on social inequality.

6. Conclusion

The quality of life is improved through biotechnological innovation, but associated issues in ethics and society need to be clarified through regulatory mechanisms. International bioethics harmonisation has not yet been solved, particularly in genetic interventions, neuroenhancement, and bioenergy. There is admittance within the scientific community that biotechnology requires a delineation between therapeutic and enhanced use; however, since no one can agree on a united way of approaching such policy, it has proven difficult at the global level to implement regulatory policy. What makes the study original is the comprehensive analysis of the impact of biotechnology on social and moral norms, which enables the evaluation of the possible consequences for society or the development of ethical principles of the realisation of such technologies. The main limitation is the insufficient empirical basis for the long-term effects of genetic modifications, which necessitates further research in this area. The practical significance of the findings is to develop recommendations for creating ethical control mechanisms and regulatory policies that will promote the responsible development of biotechnology. Further research should focus on analysing the impact of biotechnological innovations on economic and social stability and on developing standards that guarantee equal access to the latest medical and technological advances.

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