

Forum: United Nations Commission on Science and Technology for Development (UNCSTD)

Issue #1: Measures to address ethical concerns regarding the development and use of biotechnology.

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Introduction



The development and use of biotechnology have been rapidly growing issues, specifically regarding ethical concerns. These concerns come from a number of different angles, whether that is GMO-grown agricultural products or animal testing for medicine development. Not all parts of the world agree on how society should pursue the opportunities in the biotechnology industry, which

can be split into multiple categories such as synthetic biology, bioengineering, and agricultural biotechnology, just to name a few. Moving forward, biotechnological advances continue at pace and present new ethical dilemmas related to human genetic modification, cloning, and data privacy. The potential of gene-editing technologies like CRISPR for treating genetic disorders is enormous but is also associated with eugenic ideals and unintended genetic consequences. Because the manipulation of genetic material with precision is possible, there is an excellent demand for consistent ethical frameworks that can prevent abuse and assure the rest of society that biotechnological innovations exist for the greater good. Consequently, the international community needs to work in partnership in a manner of guidelines that strike a balance between innovation and ethical responsibility toward humanity by respecting moral and ethical boundaries.

Definition of Key Terms

Biotechnology-Biotechnology involves using living organisms or biological systems in technological, engineering, or medical applications to develop products or processes that benefit human life and the environment.

Synthetic Biology-Synthetic biology is a new interdisciplinary area that involves the application of engineering principles to biology. It aims at the (re-)design and fabrication of biological components and systems that do not already exist in the natural world.

Animal Testing- Animal testing is the act of experimenting and developing technology on animals in order to test the product under development. Animal testing is regarded as unethical by many cultures around the world.

Bioethics- The study of the ethical issues emerging from advances in biology and medicine, including the responsible use of technology that affects

biological organisms.

Genetic Engineering: The direct manipulation of an organism's genes using biotechnology, including alterations to the genetic material (DNA) to achieve desired traits or effects.

CRISPR-Cas9: Revolutionary genetic editing technology that allows scientists to edit parts of the genome by adding, removing, or altering sections of the DNA sequence. It is one of the most precise and cost-effective methods of genetic manipulation.

Biosecurity: Measures and protocols that are put in place to protect against the misuse of biotechnology, including the containment of hazardous biological substances and the prevention of biological attacks.

GMO: Genetically modified organism, whose genetic material has been altered using genetic engineering techniques.

General Overview

GMO for Agriculture

Agricultural GMOs are made such that a plant is modified to realize some benefits, for example, resistance to pests, improved nutritional content, and increased tolerance to herbicides. For instance, GM crops include soya beans, maize, cotton, canola, and papaya. All these are engineered to confer a particular benefit on them. The general implication is that GMOs increase crop yield, lower the number of chemical sprays needed for pest control, and increase nutritional value, such as Golden rice, which contains Vitamin A. In addition, they also enhance environmental sustainability by enabling no-till farming that reduces soil erosion and carbon emissions.

Nevertheless, GMOs have received criticism and have been looked upon with skepticism. Some potential environmental impacts consist of GMO crossbreeding with wild relatives, thus leading to undesired ecological effects. Concerns about health risks like allergenicity and long-term consequences, though they remain an issue to some individuals, have otherwise been dismissed by the mainstream scientific society. Another economic consequence is that GMO seeds can be patented by large corporations, which does a disservice to small-scale farmers to some degree. GMO safety is ensured through regulatory bodies like the FDA and EFSA. Still, arguments about mandatory labeling and ethical considerations of genetic manipulation and corporate control have never seemed to be settled.

Future gene-editing technologies, such as CRISPR, offer ever-increasing precision in modification—notably offsetting many of the criticisms leveraged against traditional GMOs—as they continue to enhance crops resilient to climate change and promote general sustainability in agricultural practices.

CRISPR-Cas9 Gene Editing

This is a gene-editing technology that is quite sophisticated, and through it, scientists can carry out alterations in the DNA of an organism accurately and precisely. CRISPR-Cas9 is based on the bacterial immune system, which uses a peculiar guide RNA that guides an enzyme called Cas9 to the specific site on the organism's genome and will alter the DNA by taking breaks. Such an incision, in turn, could be repaired through native cellular processes by adding a new genetic sequence or even just by knocking out a gene. The precision, efficiency, and relative simplicity of CRISPR/Cas9 shot it forward into a robust technology not only in basic research but potentially in the treatment of genetic

diseases. Great promise exists for CRISPR/Cas9 as an essential tool for treating genetic diseases.

There is still research into applying CRISPR technology in correcting many of these mutations, causing diseases like sickle-cell anemia, cystic fibrosis, and muscular dystrophy. Clinical trials with humans have started to test and collect safety and efficacy information about such therapies. In particular, CRISPR-based therapeutics seem to hold promise in editing hematopoietic stem cells to treat blood disorders. Nonetheless, challenges still lie ahead, especially in the exact targeting for getting rid of off-target effects, which can bring about unintended mutations and long-term impact on health. Even though CRISPR-Cas9 has unearthed many potentials, it raises many ethical issues. Germline editing is the significant step forward in medical research that will result in precise DNA changes in an embryo, which will then be heritable and possibly appear in future generations.

However, it has raised issues that border on morality and fears, for example, the development of "designer babies." Concerns have also been raised about how these technologies are going to be put to use equitably and misplaced into non-therapeutic enhancements. This area will be one of global regulation, which aims to preserve a compromise between scientific advances and ethics together with public security issues. Considering the rapid pace of research developments and the actual applications of CRISPR-Cas9, the rising call for an ongoing dialogue between scientists, ethicists, policymakers, and the public remains necessary to sort out this complex landscape of gene editing.

Synthetic Biology

Synthetic biology is the design and engineering of organisms for useful means.

It is an intersection of biology and engineering, which enables the design and creation of new biological parts, devices, and systems, and the redesign of existing natural biological systems. An essential application of synthetic biology is the building of sustainable solutions—for instance, engineering microorganisms to produce biofuels, biodegradable plastics, and other materials. The inventiveness goes on to cover the creation of synthetic vaccines and newer medical therapies, including innovative ways of treating genetic disorders through pinpoint gene editing technologies like CRISPR-Cas9. The practical and ethical implications of synthetic biology cannot be overemphasized; they are enormous and multifaceted. There are concerns about biosafety and biosecurity, particularly the potential of synthetic organisms to interact in unpredictable ways with natural ecosystems or be purposely used for harmful purposes. Another problem arises in this context: the issues associated with intellectual property and access to such biotechnological innovations, as patents on synthetic organisms can curb their availability and use—more so in developing countries. Similarly, applications of synthetic biology are likely to be so expensive and complex in their development that they become practically impossible for the individual to access, asking significant ethical questions regarding equity in healthcare. With the pace at which potential synthesized impacts are materializing, it's essential to address those concerns and others as synthetic biology unfolds, both through comprehensive regulatory systems and ongoing public dialogues toward responsible development and use of the power of this technology.

Major Parties Involved and Their Views

United States of America

The United States is one of the most advanced countries in the world for biotechnology. Such sectors as medical research, agricultural biotech, and industrial biotechnology all benefit. Regulatory agencies in the United States,

including FDA (Food and Drug Administration), USDA (United States Department of Agriculture), and NIH (National Institutes of Health), promote the development of innovations and must ensure that safety and ethics regarding new products are still at a paramount level. Aside from this, the U.S. is also rich in structures for handling the ethical, legal, and social implications of biotech progress—GINA is one such example that assures protection against discrimination on the grounds of genetic information both concerning health insurance and employment. Another dimension is that the federal government in the United States will often support the private sector so that more research and development can take place.

European Union

The European Union is characterized by its cautious approach towards biotechnology, particularly genetically modified organisms (GMOs). Based on the precautionary principle, the EU is operated in such a way that when action or policy has suspected risk likely to cause harm to the public or environment, in the absence of scientific consensus, the burden of proof that it is not harmful falls on the action takers. This has the impact that GMOs are regulated more stringently, with high-level mandates of risk assessment being undertaken and provision of labels and traceability rights from farm to fork, in ensuring transparency and consumer right of choice. European Food Safety Authority (EFSA) EFSA is the European body mandated to carry out the safety and ethical assessments of products based on biotechnology.

China

China has viewed biotechnology as one of the strategic areas for development and has made enormous investments in genetic research, biopharmaceutical, and agricultural biotechnology. In China, the regulatory standards were also

perceived as being laxer than those in the West, which allowed for rapid advancements. However, the gene-edited babies of 2018 pushed the boundaries and spurred global condemnation, a backlash that has compelled Chinese authorities to rein in the guidelines since that incident. Indeed, at the core of China's approach lies a twin drive: aspiration for leadership in scientific research and the necessity to tackle significant health and food security challenges using biotechnology.

India

India is one of the countries where biotechnology has been identified as very important in achieving these health and agricultural objectives. The country has proactively enhanced the improved biopharmaceuticals, genetically modified crops, food production, and increased disease resistance. The Indian government supports initiatives promoting biotechnology and regulatory guidelines toward ensuring safe and ethical innovation. However, controversial public debate and skepticism exist about GMOs triggered by issues related to biodiversity, environmental risks, and food safety. This warrants the need for strict regulatory mechanisms. Genetic Engineering Appraisal Committee, GEAC plays a significant role in regulating these technologies.

Brazil

Brazil is one of the pioneers in applying agricultural biotechnology. The country is particularly technologically advanced in genetically modified soybeans, corn, and cotton. The overall attitude of the country toward biotechnology is very positive, as it believes that without this technology, agricultural productivity and competitiveness cannot be attained. Brazil uses a systematic biosafety law with oversight by the National Technical Commission on Biosafety (CTNBio) to carry out an assessment of GMO safety concerning agriculture and consumption.

Regulations require such technologies to benefit economic growth while protecting both the environment and human health.

Germany

As a European Union member, Germany has stringent, cautious policies regarding biotechnology. The country is famous for having stringent guidelines, especially regarding GMOs, mainly due to public awareness and political fear about the food's biotechnological alterations. High-level, developed medical and industrial biotechnology shall be promoted, taking into account high ethical standards. Public debate is carefully carried out with a clear orientation on ethical aspects, questions of environmental safety, and consumer rights and protection.

United Kingdom

The United Kingdom takes the lead in pharmaceuticals and medical biotechnology on the grounds of scientific research and development. After Brexit, its regulatory system was revised, to likely fall out of lock-step with EU biotech regulations, possibly taking up an approach to encourage innovation. It has a history of supporting leading technologies, such as CRISPR gene editing and artificial intelligence in health care, through bodies like the Human Fertilisation and Embryology Authority in ensuring robust ethical standards for reproductive technologies and research.

Timeline of Events UN involvement, Relevant Resolutions, Treaties and Events

| Date | Description of Event |
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| 1953 | James Watson and Francis Crick discovered the double-helix structure of DNA, paving the way for modern genetics |
| 1973 | Stanley Cohen and Herbert Boyer developed recombinant DNA technology, allowing genes to be spliced together and transferred between organisms. |
| 1983 | The first genetically engineered product, human insulin produced by bacteria, is approved by the FDA. |
| 1990 | The Human Genome Project is launched, aiming to map the entire human genome |
| 1994 | The first genetically modified food, the Flavr Savr tomato, is approved for sale in the United States |
| 1997 | Dolly the sheep, the first mammal cloned from an adult somatic cell, is born, demonstrating the potential of cloning technology. |
| 2002 | Researchers at SUNY Stony Brook synthesized the first complete synthetic virus, poliovirus, from scratch. |
| 2003 | The Human Genome Project is completed, with 99% of the human genome sequenced with 99.99% accuracy. |
| 2010 | Craig Venter and his team created the first synthetic cell, <i>Mycoplasma mycoides</i> JCVI-syn1.0, by assembling a bacterial genome from scratch and transplanting it into a host cell. |
| 2012 | Jennifer Doudna and Emmanuelle Charpentier developed |

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| | the CRISPR-Cas9 gene-editing technology, revolutionizing genetic engineering by allowing precise edits to DNA. |
| 2015 | The first CRISPR-edited human embryos are reported by researchers in China, sparking ethical debates about gene editing in humans. |
| 2017 | The FDA approved the first gene therapy for an inherited disease, Luxturna, which treats a rare form of inherited blindness. |
| 2020 | CRISPR-based diagnostics tests for COVID-19 are developed, demonstrating the rapid and versatile applications of gene-editing technologies. |
| 2021 | The FDA approves CRISPR-based therapy, Exa-cel, for treating sickle cell disease and beta-thalassemia, marking a significant milestone in gene therapy. |
| 2023 | The first in vivo CRISPR gene-editing treatment for transthyretin amyloidosis is administered, showing promise for treating genetic disorders directly within the body. |

Evaluation of Previous Attempts to Resolve the Issue

Previous attempts to address the ethical concerns that flow from biotechnology have settled on regulatory measures and international agreements. In this respect, both the U.S. Food and Drug Administration and the European Medicines Agency have guidelines and mechanisms of oversight to ensure that products from biotechnology are safe and efficacious. Such international agreements include the Cartagena Protocol on Biosafety, among others, which

aims to protect the world's biodiversity from real or perceived risks that arise out of GMOs. Despite these various efforts, most regulatory structures and systems find it quite challenging to catch up with the fast developments in biotechnology, especially since they usually leave multiple gaps in the regulation and enforcement of technologies. Such inconsistency in national rules has led to problems both on an individual country basis and in terms of cross-border governance.

Another approach has been the promotion of public engagement and education. Public consultation and other ethical concerns were at the core of developments for initiatives such as the Human Genome Project. Educational campaigns have been carried out to sensitize the public about the advantages and risks inherent in biotechnology. These have not often been successful, with public awareness and acceptance of the advancements in biotechnology at best being haphazard. Resistance and suspicion arise sometimes due to non-communication and lack of transparency. Moreover, socio-economic inequalities have continued to persist since most low-income regions still do not have access to the benefits of biotechnology, further exacerbating global disparities.

Possible Solutions

The ethical challenges must be met by strengthening public participation and the regulatory system. National regulatory agencies should be strengthened concurrently with biotechnological developments to ensure strict scrutiny and maintenance of ethical standards. It is possible to reinforce global governance and reduce the size of regulatory disparities by laying down comprehensive international rules. Furthermore, the organization could promote public education and engagement through forums and consultations that will help in

gathering diverse points of view, hence promote inclusive decision-making, public acceptability, and trust. Prioritization must be attached to environmental conservation and fair access to biotechnological discoveries.

Encouraging global health initiatives and creating equitable patent policies will close the gap in access to cutting-edge biotechnologies, especially in low-income areas. Ecological hazards may be mitigated by conducting thorough EIA's and promoting sustainability of biotechnology research. The incorporation of ethical considerations throughout the developmental process can lead to more responsible and beneficial innovations. This may be attained by proper promotion of ethical research practices, such as setting up ethics committees and responsible innovation.

Sustainable Development Goal (SDG)

Tackling the ethical issues in biotechnology flows well within Sustainable Development Goal 3: Good Health and Well-Being. Biotechnology has the great potential to yield better health for the globe by developing advanced treatments and diagnostics for different diseases. But to harvest that fruit, it is essential that biotechnological developments are done and used ethically. This means the bettering of regulatory frameworks, public engagement, equitable access, and environmental protection. The resolution of these ethical issues could bring us to a place where we will turn biotechnologies into tools that will strengthen global health through reducing health disparities. In view of SDG 3, it makes their use in benefit sharing.

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Appendix

Regulation and Oversight in Biotechnology

U.S. Food and Drug Administration (FDA). "Guidance for Industry: Regulation of Biotechnology Products."

This source provides detailed information on the FDA's regulatory framework for biotechnology products, including safety, efficacy, and ethical considerations.

<https://www.fda.gov/media/93174/download>

International Guidelines on Biosafety

Cartagena Protocol on Biosafety. "Convention on Biological Diversity."

This document outlines international agreements aimed at protecting biodiversity from potential risks posed by genetically modified organisms (GMOs), emphasizing the importance of global governance in biotechnology.

<https://bch.cbd.int/protocol>

The 5 Most Pressing Ethical Issues in Biotech Medicine

National Library of Medicine

This article contains other issues on biotechnology that should be addressed and

considered for this issue.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3570985/>

Developments in Biotechnology

Unacademy

This article outlines the general history of developments in biotechnology with a brief explanation. Good place to start for quick information on the topic.

<https://unacademy.com/content/kerala-psc/study-material/science-technology/developments-in-biotechnology/>