Southern China International MUN

Official Background Guide

Human Rights Council: On measures to ensure ethical use of biotechnology

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1. Description of the Issue

1.1 History of the Issue

Biotechnology is a multidisciplinary field aiming to improve human health, and ultimately, the environment [1]. Selective breeding, the act of breeding animals or plants to obtain the desired trait, is arguably the first practice of biotechnology [2]. Its underlying mechanisms were figured out by Gregor Mendel when he observed the breeding behaviors of peas in 1866 [46]. Fermentation, exploiting microorganisms to produce the desired products, is also human's first try at biotechnology. With the ability to convert sugar into carbon dioxide and alcohol, microorganisms are often used to make bread and alcoholic beverages for commercial purposes [44]. Realizing these benefits brought by the use of biotechnology, humankind soon started to advance the field of biotechnology.

In the year 1928, Alexander Fleming discovered Penicillin, extracted from the Penicillin mold. He found that this substance has the ability to fight off bacterial infection, thus marking a milestone of human medical achievement, and was a pivotal point in the history of biotechnology [3]. This antibiotic was later mass-produced during World War II, bringing tremendous effects on the war as the French and Dutch actively tried to produce penicillin. The Nazi Germany then, later in the same year, successfully produced penicillin for its purposes. The impact of the discovery and production of Penicillin led to the awarding of a Nobel Prize to Fleming and other significant figures. Using similar techniques, other researchers soon found a plethora of other antibiotics [4].

Soon after, in 1953, the structure of DNA was discovered. Rosalind Franklin, a female British scientist, was collecting data about the structure of DNA. With her data leaked, Franklin's credit for revealing the structure was taken by James Watson and Francis Crick, who were later awarded a Nobel Prize for their discovery [5].

The period from the 1970s to the 2000s witnessed the rapid growth of the field called synthetic biology. In 1973, Stanley N Cohen and his fellow researchers became the first to succeed in making recombinant DNA in *E. coli*. They did so by transforming or making the bacteria take up a foreign piece of the gene, the bacteria using plasmids, or circular DNA [6]. This success led to rapid advancement in synthetic biology. With the ability to express foreign genes in bacteria, Genetech in 1982 successfully produced human insulin using E. coli. Such a product was approved by the Food and Drug Administration (FDA) [7]. In 1983, the human race saw another advancement in biotechnology. The technique called Polymerase Chain Reaction (PCR) allowed the amplification of a specific genetic fragment, allowing researchers to dig into the function of a particular gene. It was also used in forensic medicine and the medical field in general [8].

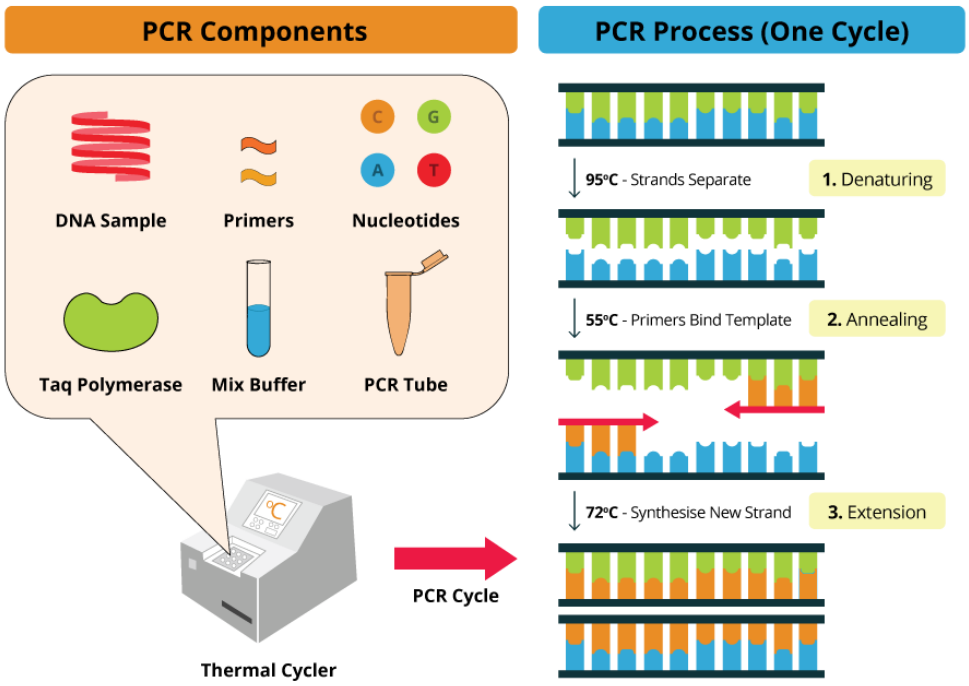

Figure 1. Polymerase Chain Reaction. Image by: BioNinja

The first project receiving numerous doubts from the public was The Human Genome Project (HGP), conceived in 1984 and began in 1990, aiming to determine the nucleotide sequence of the entire human genome [45].

Figure 2. The Human Genome Project. Image by: National Institutes of Health

The first step is to catalog human genes, allowing future studies on the functions of a particular gene, studies on genetic diseases, and the development of measures to treat such diseases. Despite these alluring benefits, problems were raised regarding this ambitious project. The project's practicality was doubted in the scientific community, as the formation and acquisition of genetic diseases is a complex process. At the same time, the working mechanisms for replication, RNA splicing, and the final gene expression were kept unanswered. The public, likewise, raised concerns over the practice of this research project. Fearing privacy infringements and violations against data confidentiality, the public was dissatisfied with this project [9]. Some also were afraid that the collected data would be used for discriminatory purposes [10], as data might be manipulated for personal or institutional benefits. Some held beliefs that the research is the remnant of eugenic theories [11]. The HGP is a failure in the outcomes it produces. With its promise at the very start that HGP would provide a complete understanding of the human genome and the function of each gene, its results failed to accomplish the goals due to the superficial understanding of gene expression.

Another cautionary tale about biotechnology arose from the cloning of a sheep, later known as Dolly the sheep. Deriving cells from sheep, researchers developed the clone sheep Dolly [12, 13]. Shortly four years after the cloning, Dolly began to find difficulties in walking; its condition of arthritis was later found in 2002 [14]. Arthritis is never uncommon to see in sheep, but Dolly's onset was premature, denting public confidence about cloning. Also, the telomere, the DNA fragment indicating longevity, was found to be abnormally short in Dolly. The decreasing rate was found to be consistent with the age of the donor tissue that was used to create Dolly [15]. With all these problems found, Dolly was euthanized in 2003 [16].

Figure 3, Dolly the sheep. Photo by: Canapress

The creation of a cloned sheep also evoked the fear of a cloned human. This concern was heavily discussed among biologists and policymakers. Ending three years of failure in reaching a binding agreement, the United Nations (UN) declared the ban on all forms of human cloning [17]. Nevertheless, the debate over human cloning still arose among researchers and the public. As the embryo produced by cloning still had to undergo the developmental process in a uterus, people started to argue whether an artificial uterus should be made. Opponents to this argued that artificial uteri would be unable to establish the natural maternal-embryonal dialogue, thus depriving the embryo of an essential condition of being a human [18]. Supporters of human cloning claimed that the bearing of a twin was essentially the same as cloning a human. Such a debate continues even now.

1.2 Recent Developments

With the rapid development of biotechnology, ensuring ethical use becomes increasingly important. CRISPR was first found in E. coli by Ishino et. al in 1987 [19]. The year 2013 saw a major breakthrough in the application of CRISPR, as different groups of researchers almost simultaneously successfully genetically edited human and animal cells with the help of CRISPR [20] [21]. CRISPR was also recognized for its potential in gene therapy, the treatment of disorder or disease by a transfer of engineered materials into human cells [22]. A group of researchers at Sun Yat-sen University tried to publish their work in 2015 in which they used the CRISPR-Cas9 system on human embryonic cells. Though they emphasized that they used non-viable cells in their work, their work was largely unaccepted in the scientific community. It was finally accepted

by a domestic journal and evoked an "epic" debate as a result [23]. The first clinical human test on CRISPR gene editing was conducted in China in 2016, which was proven to be a success [24]. The first use of CRISPR-Cas9 in the United States was in 2019 when researchers tried to use it to treat sickle cell disease, also demonstrating a major success [25]. The Nobel Prize in 2020 was awarded to Emmanuelle Charpentier and Jennifer Doudna for their accomplishments in the development of CRISPR technology [26]. Despite these exciting achievements brought by CRISPR, criticisms and ethical concerns were not absent. Despite the high precision of CRISPR-Cas9, off-target effects were still a considerable risk. The unintended genetic modification can provoke excessive immune responses, leading to adverse health impacts in patients [27]. CRISPR also has the ability to eradicate all future hereditary disorders. However, the ethical issue of this was heavily debated and aroused public concerns over the health impact [28]. Also, CRISPR allows people to "customize" the skin tone, eye colors, and other physical features of babies, sparking the debate over "designer babies" and its moral implications [29]. Though with a large number of concerns, a comprehensive regulatory framework is still not in place.

From a broader view, gene therapy in general also raises ethical concerns. Gene therapy was administered for the first time in 1990 to treat adenosine deaminase (ADA). While the result looked positive initially, adverse health impacts showed up later both in humans and other animals [30]. The tragic story of Jesse Gelsinger shocked the world and caused widespread skepticism against gene therapy [31]. Four days after the gene therapy operation, a large-scale autoimmune response led to a sharp increase in body temperature, renal and pulmonary failure, jaundice, impaired blood clotting, and the subsequent death of Gelsinger [32]. A conference on scientific, medical, legal, and ethical issues about genomic modification was then held in 2015 in California. The report of the conference carried recommendations to strongly discourage work on introducing heritable changes in human embryonic cells [33]. Concerns were also raised by researchers that the attempt to introduce heritable changes in humans will hinder the progress of gene therapy in general, and set back the works on treating genetic diseases [34]. Some countries nowadays have their own regulatory frameworks for therapies and medical products [35]. Biotechnology, especially genetically modified organisms (GMOs) is also used in agriculture. Genetically modified (GM) crops were seen as a promising means to mitigate problems in commercial agriculture. China was among the first to commercialize the use of GM crops when it grew GM tobacco for insect resistance [36]. In 1994, the United States had its first GM crop, GM tomatoes, for human consumption, approved by the FDA. GM crops have been proven to be beneficial to the economy. However, questions over safety and efficacy were raised. New proteins can potentially be produced with new genes by pleiotropic effects, bringing unprecedented allergic reactions [37]. Mutagenesis can also be present in GM crops, disrupting or modifying the original genetic expression of the host DNA. Also, with disruptions brought by the newly inserted

genes, fusion proteins expressing the inserted DNA and original DNA can be made. Abnormal expression of genes can also happen, leading to a high yield of downregulated genetic pathways, consequently making toxins in edible plants [38]. Also, consumers also held the perpetual fear that the edited genes will one day be horizontally transferred, the transfer of genetic materials regardless of species, to themselves. The ability of GM crops to maintain their insect resistance was also under doubt. Researchers also feared that the pest-resistant characteristic would horizontally gene transfer to their weedy relatives and create "superweeds."

Key Terms

Biotechnology – The multidisciplinary field using knowledge from biology to benefit the world in general.
Selective breeding – The act of breeding plants or animals to gain the desired trait.
Cloning – Making an organism by duplicating the host's DNA.
Gene editing – The artificial editing of genes to acquire a desired characteristic.
Gene therapy - The treatment of a disorder or disease by a transfer of engineered materials into human cells.
Synthetic biology – A multidisciplinary field using genetic editing to make desired products from bacteria.
Genetically modified (GM) crops – Crops undergo genetic modification to amplify a wanted characteristic.
CRISPR – A genetic editing tool using a DNA segment and its associated proteins.

2. Emphasis of the Discourse

2.1 Right-Wing Approach

The use of biotechnology is highly likely to encounter negative voices from the conservative. This opposition may come from the fear that the use of new biotechnology can lead to negative, unintended consequences. Right-wing politicians and policymakers will likely go hand-in-hand against the use of biotechnology in everyday life, promulgating policies to restrict the use of the latest biotechnology. Right-wing policymakers generally want to see more rounds of testing and a more comprehensive understanding of possible outcomes.

Nevertheless, acknowledging the advantages of biotechnology, many right-wing politicians and policymakers are becoming more open to it. Italy is a major right-wing country. In the late 20th

century, Italy had arguably a conservative perspective on the use of biotechnology, putting emphasis on the rights of life, human health, and the preservation of nature [39]. In the early 21st century, however, Italy became the third-largest bioeconomy in Europe [40]. With a focus on agriculture, Italy employs the new genomic techniques (NGTs), and breeding techniques by altering the genetic materials of plants, in producing fruits [41].

The right-wing is more aware of the possible drawbacks brought by the incautious use of newly developed biotechnology. It pays more attention to scandals and adverse impacts of biotechnology, in both the medical and agricultural fields.

2.2 Left-Wing Approach

Recognizing the potential benefits and costs of the use of biotechnology, more liberal politicians generally will open the debate for the public. Policymakers will also promote the use of biotechnology as it raises the productive efficiency dramatically. In these left-wing countries, thorough regulations regarding biotechnology will be made, yet the attitude towards biotechnology will generally be positive.

The left-wing will more likely emphasize the benefits of biotechnology while paying less attention to the drawbacks. Therefore, scandals and public opposition may arise since additional costs may manifest as a larger crowd uses biotechnology.

China is an interesting example of this side of the issue. China is generally tolerant of the use of newly invented medical devices. While the government played an active role in investing in GM crops, several scandals regarding GMOs led to public disapproval of GMOs in China [42 43]. Regardless of these early pushbacks, the Chinese government has made the development of biotechnology a priority in its policymaking since 2007 [44]. China was the fastest-growing country in synthetic biology between 2004 and 2008, having the largest percentage of increase in SCI publications, and issued patents, compared with Germany, Japan, the UK, and the US [45]. Currently, China focuses on the CRISPR technology.

2.3 Stance of Intergovernmental Organizations

Intergovernmental organizations (IGOs) generally have similar perspectives on this matter as they want to push the development of biotechnology while holding doubts about some technologies, especially GMOs.

The United Nations strives to establish a binding, international regulatory framework for biotechnology. It has successfully banned human cloning in all forms. However, up until this point, the UN has not succeeded in making a universal regulatory framework for biotechnology. The International Center for Genetic Engineering and Biotechnology (ICGEB) is established by the UN to promote international cooperation, strengthen countries' capabilities in genetic engineering, and serve as a forum for information exchange. The ICGEB is generally very open to innovations in biotechnology and also has advisors to oversee the regulations for the development of biotechnology. The Food and Agriculture Organization (FAO) of the UN strives to combat hunger and improve nutrition. The FAO calls for more innovations and applications of agricultural biotechnology. It also urges countries to improve on the existing regulatory frameworks for agricultural biotechnology, especially on the use of GM crops.

Likewise, the European Group on Ethics in Science and New Technologies (EGE) has called for inclusive debates on the ethical implications of biotechnology. It also advocates for joint monitoring of regulatory developments. The European Food Safety Authority (EFSA) opened a panel for the use of GMOs in agriculture, assessing risks from GMOs.

2.4 Stance of Developed Countries

Developed countries have different opinions on this naturally polarizing issue. The United States and countries in the European Union (EU) are major stakeholders in this debate, having opposing views.

The United States is generally very permissive in biotechnology. While it was not the first one to commercialize GM crops, it soon became the pioneer in GM crops in many ways. The US is more tolerant of the consumption of GM crops on a state level, and the approval process is generally easy. Apart from GM crops, the use of other biotechnology has advanced rapidly in the US. Lately, in January 2024, the U.S. Environmental Protection Agency (EPA) approved the use of biopesticides using the RNA interference technique in the fields.

The EU takes a more precautionary measure on this matter. The EU strives to protect human health, animal rights, and the environment in the face of GMOs. Eight member states (Austria, Bulgaria, Greece, Germany, Hungary, Italy, Luxembourg, and Poland) have banned the cultivation of GM crops since 2013[47]. Its regulatory frameworks led to criticisms from the scientific community, claiming that the entire framework is botched [46].

2.5 Stance of Developing Countries

Developing countries generally are active players in biotechnology as they prioritize biotechnology research and are refining their regulatory frameworks for it.

Brazil is a good example of an active country in biotechnology. In 2005, the National Biosafety Technical Committee (CTNBio) became the central body for biosafety regulation, responsible for supervising the research and commercialization process of GMOs. Brazil is quite generous in its regulation of research programs. Suffering from mosquito bites, researchers developed the idea to genetically modify male mosquitoes (making them infertile), and got this project approved by the government [47]. Currently, researchers are still not allowed to release these GM mosquitoes, but the government's attitude is generally bright towards GMOs.

India is also an active country in biotechnology. Regulation was created in 1989 to regulate research, biologics, confined field trials, food safety assessment, and environmental risk assessment[48]. Several committees were soon formed to review biosafety, approve commercialization, and assess genetic engineering [48]. Currently, the release of GMOs is still strictly prohibited.

3. Possible Solutions

3.1 In Favor of Developed Countries

Developed countries have different perspectives on this matter. While some states may want a more permissive regulatory framework, those in the EU generally prefer a stricter one.

The United States, Canada, Australia, and New Zealand are likely to prefer a permissive set of regulations. The United States recognizes the cost-effectiveness of biotechnology and wants to gain advantages in the market by prioritizing biotechnology development. Canada, Australia, and New Zealand prioritize innovations. Australia, in particular, is very involved in agricultural biotechnology, thus reducing regulatory barriers to such biotechnology. A possible solution that can potentially please these stakeholders is to legislate looser regulations, especially for GM crops.

Most European countries favor a stricter set of regulations for biotechnology. Aware of the risks

of the spread of GMOs and the risks of gene engineering, the EU has developed a strict set of regulations. They are also aware of the intense debate over ethical problems with the use of agricultural and medical biotechnology. Therefore, these stakeholders may want regulations that are inclusive, binding, and strict. They may want increased public engagement in policymaking.

3.2 In Favor of Developing Countries

Likewise, developing countries also favor diverse solutions.

Countries such as Argentina, Brazil, and China may want looser regulations. Argentina and Brazil generally want to see the use of GM crops in agriculture so as to increase farming efficiency and the economy, as disease- and pest-resistant crops have been proven to improve crop yields. China is constantly developing its agricultural biotechnology, especially GM staple food. Also, China is part of the initiative to tackle the mosquito problem by genetic modification. These stakeholder countries generally want regulations that permit research and commercialization of GMOs to improve their national economic statuses.

Countries such as India, Kenya, and South Africa are likely to prefer stricter regulations. A strong public sentiment against GMOs is present in India, affecting policymaking [49]. In Kenya and South Africa, whose regulations regarding biotechnology are still incomprehensive, people share an apprehension about GMOs. Hence, these countries may prioritize developing a binding and effective set of regulations. For instance, they may want to ban the commercialization of GM crops completely to ensure public health.

4. <u>Keep in Mind the Following</u>

When researching this topic, make sure to dig into the specifics. You should understand which aspects their countries focus most on. You should also pay close attention to the composition of their countries' economy, medical system, and agriculture. Some questions to guide your research are the following:

1. *What is your country's perspective on scientific research?*
2. *What is your country's main focus on biotechnology? Is it agricultural, medical, or something else?*
3. *What are some existing regulations for biotechnology in your country? Are they effective?*
4. *What are the primary concerns over biotechnology in your country?*

5. *How do public opinions shape policymaking in your country?*
6. *What are some potential costs and benefits of GMOs?*
7. *What are some environmental impacts of biotechnology that are relevant to your country?*
8. *How can countries collaborate to establish harmonized and binding regulations for biotechnology?*

5. Evaluation

Countries have different preferences when it comes to regulations for biotechnology. While some may prioritize innovations and economic growth, some may pay closer attention to public opinions and potential risks. Biotechnology is a relatively young, rapidly evolving field. An advancement comes with a risk. When evaluating possible solutions, be sure to consider the risks and benefits of biotechnology. We still do not have an international regulatory framework for biotechnology yet. New voices should be heard. Be innovative. Consider both sides of the debate. Good luck.

6. Bibliography

1. V. Gupta, M. Sengupta, J. Prakash, and B. C. Tripathy, 'An Introduction to Biotechnology', *Basic and Applied Aspects of Biotechnology* (2016), 1-21.
2. S. T. Harbison, 'What Have We Learned About Sleep from Selective Breeding Strategies?', *Sleep,* 45 (2022).
3. S. Y. Tan, and Y. Tatsumura, 'Alexander Fleming (1881-1955): Discoverer of Penicillin', *Singapore Med J,* 56 (2015), 366-7.
4. R. Gaynes, 'The Discovery of Penicillin—New Insights after More Than 75 Years of Clinical Use', *Emerg Infect Dis,* 23 (2017), 849-53.
5. A. Stasiak, 'Rosalind Franklin', in *Embo Rep* (Copyright © 2001 European Molecular Biology Organization., 2001), p. 181.
6. S. N. Cohen, A. C. Chang, H. W. Boyer, and R. B. Helling, 'Construction of Biologically Functional Bacterial Plasmids in Vitro', *Proc Natl Acad Sci U S A,* 70 (1973), 3240-4.
7. N. A. Baeshen, M. N. Baeshen, A. Sheikh, R. S. Bora, M. M. Ahmed, H. A. Ramadan, K. S. Saini, and E. M. Redwan, 'Cell Factories for Insulin Production', *Microb Cell Fact,* 13 (2014), 141.
8. L. Garibyan, and N. Avashia, 'Polymerase Chain Reaction', *J Invest Dermatol,* 133 (2013), 1-4.

9. R. L. Zimmern, 'The Human Genome Project: A False Dawn?. Interview by Judy Jones', *Bmj,* 319 (1999), 1282.
10. Ruth Hubbard, *Exploding the Gene Myth: How Genetic Information Is Produced and Manipulated by Scientists, Physicians, Employers, Insurance Companies, Educators, and Law Enforcers* (Beacon Press, 1999).
11. Theresa Marteau, and Martin Richards, *The Troubled Helix: Social and Psychological Implications of the New Human Genetics* (Cambridge University Press, 1996).
12. K. H. Campbell, J. McWhir, W. A. Ritchie, and I. Wilmut, 'Sheep Cloned by Nuclear Transfer from a Cultured Cell Line', *Nature,* 380 (1996), 64-6.
13. I. Wilmut, A. E. Schnieke, J. McWhir, A. J. Kind, and K. H. Campbell, 'Viable Offspring Derived from Fetal and Adult Mammalian Cells', *Nature,* 385 (1997), 810-3.
14. O. Dyer, 'Dolly's Arthritis Dents Faith in Cloning', *Bmj,* 324 (2002), 67.
15. P. G. Shiels, A. J. Kind, K. H. Campbell, I. Wilmut, D. Waddington, A. Colman, and A. E. Schnieke, 'Analysis of Telomere Length in Dolly, a Sheep Derived by Nuclear Transfer', *Cloning,* 1 (1999), 119-25.
16. N. Williams, 'Death of Dolly Marks Cloning Milestone', *Curr Biol,* 13 (2003), R209-10.
17. S. Mayor, 'Un Committee Approves Declaration on Human Cloning', *Bmj,* 330 (2005), 496.
18. C. Tannert, 'Thou Shalt Not Clone. An Ethical Argument against the Reproductive Cloning of Humans', *EMBO Rep,* 7 (2006), 238-40.
19. Y. Ishino, H. Shinagawa, K. Makino, M. Amemura, and A. Nakata, 'Nucleotide Sequence of the Iap Gene, Responsible for Alkaline Phosphatase Isozyme Conversion in Escherichia Coli, and Identification of the Gene Product', *J Bacteriol,* 169 (1987), 5429-33.
20. P. Mali, L. Yang, K. M. Esvelt, J. Aach, M. Guell, J. E. DiCarlo, J. E. Norville, and G. M. Church, 'Rna-Guided Human Genome Engineering Via Cas9', *Science,* 339 (2013), 823-6.
21. L. Cong, F. A. Ran, D. Cox, S. Lin, R. Barretto, N. Habib, P. D. Hsu, X. Wu, W. Jiang, L. A. Marraffini, and F. Zhang, 'Multiplex Genome Engineering Using Crispr/Cas Systems', *Science,* 339 (2013), 819-23.
22. E. L. Scheller, and P. H. Krebsbach, 'Gene Therapy: Design and Prospects for Craniofacial Regeneration', *J Dent Res,* 88 (2009), 585-96.
23. D. Cyranoski, and S. Reardon, 'Embryo Editing Sparks Epic Debate', *Nature,* 520 (2015), 593-4.
24. D. Cyranoski, 'Crispr Gene-Editing Tested in a Person for the First Time', *Nature,* 539 (2016), 479.
25. S. H. Park, and G. Bao, 'Crispr/Cas9 Gene Editing for Curing Sickle Cell Disease', *Transfus Apher Sci,* 60 (2021), 103060.

26. L. Westermann, B. Neubauer, and M. Köttgen, 'Nobel Prize 2020 in Chemistry Honors Crispr: A Tool for Rewriting the Code of Life', *Pflugers Arch,* 473 (2021), 1-2.
27. Q. Yi, X. Ouyang, G. Zhu, and J. Zhong, 'Letter: The Risk-Benefit Balance of Crispr-Cas Screening Systems in Gene Editing and Targeted Cancer Therapy', *J Transl Med,* 22 (2024), 1005.
28. N. H. Evitt, S. Mascharak, and R. B. Altman, 'Human Germline Crispr-Cas Modification: Toward a Regulatory Framework', *Am J Bioeth,* 15 (2015), 25-9.
29. B. M. Knoppers, and E. Kleiderman, '"Crispr Babies": What Does This Mean for Science and Canada?', *Cmaj,* 191 (2019), E91-e92.
30. C. T. Deakin, I. E. Alexander, and I. Kerridge, 'Accepting Risk in Clinical Research: Is the Gene Therapy Field Becoming Too Risk-Averse?', *Mol Ther,* 17 (2009), 1842-8.
31. I. Gostimskaya, 'Crispr-Cas9: A History of Its Discovery and Ethical Considerations of Its Use in Genome Editing', *Biochemistry (Mosc),* 87 (2022), 777-88.
32. B. Sibbald, 'Death but One Unintended Consequence of Gene-Therapy Trial', *Cmaj,* 164 (2001), 1612.
33. D. Baltimore, P. Berg, M. Botchan, D. Carroll, R. A. Charo, G. Church, J. E. Corn, G. Q. Daley, J. A. Doudna, M. Fenner, H. T. Greely, M. Jinek, G. S. Martin, E. Penhoet, J. Puck, S. H. Sternberg, J. S. Weissman, and K. R. Yamamoto, 'Biotechnology. A Prudent Path Forward for Genomic Engineering and Germline Gene Modification', *Science,* 348 (2015), 36-8.
34. E. Lanphier, F. Urnov, S. E. Haecker, M. Werner, and J. Smolenski, 'Don't Edit the Human Germ Line', *Nature,* 519 (2015), 410-1.
35. D. Drago, B. Foss-Campbell, K. Wonnacott, D. Barrett, and A. Ndu, 'Global Regulatory Progress in Delivering on the Promise of Gene Therapies for Unmet Medical Needs', *Mol Ther Methods Clin Dev,* 21 (2021), 524-29.
36. R. Raman, 'The Impact of Genetically Modified (Gm) Crops in Modern Agriculture: A Review', *GM Crops Food,* 8 (2017), 195-208.
37. D. Butler, and T. Reichhardt, 'Long-Term Effect of Gm Crops Serves up Food for Thought', *Nature,* 398 (1999), 651-6.
38. A. J. Conner, and J. M. Jacobs, 'Genetic Engineering of Crops as Potential Source of Genetic Hazard in the Human Diet', *Mutat Res,* 443 (1999), 223-34.
39. M. Ballmaier, 'Italian Government Rebuffs Emerging Biotechnology Industry', *Nat Med,* 5 (1999), 363.
40. F. Fava, L. Gardossi, P. Brigidi, P. Morone, D. A. R. Carosi, and A. Lenzi, 'The Bioeconomy in Italy and the New National Strategy for a More Competitive and Sustainable Country', *N Biotechnol,* 61 (2021), 124-36.

41. L. Nerva, L. Dalla Costa, A. Ciacciulli, S. Sabbadini, V. Pavese, L. Dondini, E. Vendramin, E. Caboni, I. Perrone, A. Moglia, S. Zenoni, V. Michelotti, S. Micali, S. La Malfa, A. Gentile, S. Tartarini, B. Mezzetti, R. Botta, I. Verde, R. Velasco, M. A. Malnoy, and C. Licciardello, 'The Role of Italy in the Use of Advanced Plant Genomic Techniques on Fruit Trees: State of the Art and Future Perspectives', *Int J Mol Sci,* 24 (2023).
42. Jane Qiu, 'China Sacks Officials over Golden Rice Controversy', *Nature* (2012).
43. Ji-kun Huang, and Bo-wen Peng, 'Consumers' Perceptions on Gm Food Safety in Urban China', *Journal of Integrative Agriculture,* 14 (2015), 2391-400.
44. Z. Chen, 'Introduction. China in the Era of Life Science and Biotechnology', *Philos Trans R Soc Lond B Biol Sci,* 362 (2007), 945.
45. L. Pei, M. Schmidt, and W. Wei, 'Synthetic Biology: An Emerging Research Field in China', *Biotechnol Adv,* 29 (2011), 804-14.
46. G. Tagliabue, 'The Eu Legislation on "Gmos" between Nonsense and Protectionism: An Ongoing Schumpeterian Chain of Public Choices', *GM Crops Food,* 8 (2017), 57-73.
47. P. P. Andrade, M. A. da Silva Ferreira, M. S. Muniz, and A. de Casto Lira-Neto, 'Gm Insect Pests under the Brazilian Regulatory Framework: Development and Perspectives', *BMC Proc,* 12 (2018), 16.
48. V. Ahuja, 'Regulation of Emerging Gene Technologies in India', *BMC Proc,* 12 (2018), 14.
44. National Research Council (US) Panel on the Applications of Biotechnology to Traditional Fermented. "Biotechnology for Production of Fruits, Wines, and Alcohol." *Www.ncbi.nlm.nih.gov*, National Academies Press (US), 1992, www.ncbi.nlm.nih.gov/books/NBK234683/.
45. Brown TA. Genomes. 2nd edition. Oxford: Wiley-Liss; 2002. Chapter 1, The Human Genome. https://www.ncbi.nlm.nih.gov/books/NBK21134/
46. Genetic Alliance; District of Columbia Department of Health. Understanding Genetics: A District of Columbia Guide for Patients and Health Professionals. Washington (DC): Genetic Alliance; 2010 Feb 17. Appendix B, Classic Mendelian Genetics (Patterns of Inheritance). https://www.ncbi.nlm.nih.gov/books/NBK132145/
47. "Questions and Answers on EU's Policies on Cultivation and Imports of GMOs." *European Commission - European Commission*, 2024, ec.europa.eu/commission/presscorner/detail/en/memo_13_952. Accessed 17 Dec. 2024.
48. Ministry of Environment & Forests. *ANNEX-4 MINISTRY of ENVIRONMENT & FORESTS NOTIFICATION RULES for the MANUFACTURE, USE/IMPORT/EXPORT and STORAGE of HAZARDOUS MICRO ORGANISMS/ GENETICALLY ENGINEERED ORGANISMS or CELLS*. 1989, geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf. Accessed 18 Dec. 2024.
49. The Hindu Bureau. "South Indian Farmers' Organisations Oppose Genetically Modified Crops." *The Hindu*, 29 Sept. 2024, www.thehindu.com/news/national/telangana/south-

indian-farmers-organisations-oppose-genetically-modified-crops/article68697867.ece. Accessed 18 Dec. 2024.