Human Genetic Engineering: Should Indonesia Regulate It?

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Abstract

Human genetic engineering raises pros and cons. Despite the potential to contribute to the health sector, it can cause several problems. While, in theory, it goes against nature and against other conservative beliefs, human genetic engineering gains important support from Transhumanism—a philosophy promoting the scientific evolution of the human race. This study determines the relevancy regulation of human genetic engineering on a global scope and how it affects the prospects of regulating human genetic engineering in Indonesia. The study aims to provide consideration for Indonesia in determining the legality status of human genetic engineering, through analyses of legal constructions surrounding it. The study used a comparative legal research method, using laws and legislations as the focal point to compare the legal frameworks of Indonesia and other countries. It employed secondary data and applied the qualitative method. The study reveals that some countries have already regulated the issue based on the benefits and risks, laying out the boundaries and restrictions on the issue. Indonesia has not established any regulation or showed specific interest in regulating human genetic engineering. The regulation on human genetic engineering is very important because many institutions are now increasingly carrying out human genetic engineering; and many countries oversee it. This importance is based on the theory of legal progressivity, which states that the law exists for human and not the other way around. It implies the necessity of adding progressive moves into the existing legal framework to adapt to the changes and developments in society.

Keywords: HGE, transhumanism, urgency.

A. Introduction

Every living thing has a *gene*.[1] Gene is a unit cell that can form the physical body and appearance of a creature. It carries information related to the physical body. Nowadays, technology has been able to modify genes by means of Genetic Engineering (GE).[2] GE is an advanced technology of this era. The GE has been

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1 Victoria State Government, "Genetic Information Is Found in All Living Things," Victoria State Government, accessed January 10, 2022, https://www.education.vic.gov.au/school/teachers/teachingresources/discipline/science/continuum/Pages/geneticinfo.aspx.

2 David S. Oderberg, "Towards a Natural Law Critique of Genetic Engineering," in *Philosophical Reflections on Medical Ethics* (London: Palgrave Macmillan UK, 2005), 109–134, https://doi.org/10.1057/9780230273931_6; Scott J Schweikart, "Global Regulation of Germline Genome

referred to by many terms, such as recombinant DNA technology, artificial manipulation, or gene modification.[3] The various terms, however, have similar definitions. According to the International Union of Pure and Applied Chemistry (IUPAC), GE is a process of inserting new genetic information into existing cells to modify certain organisms to change their characteristics.[4] In the development of GE, scientists originally modified plants' genetics. Over time, plants are not the only things that scientists can genetically modify. Today, GE can also be performed on animals and even GE technology "evolves" on more complex and intelligent subjects, such as humans.[5] The original goal of GE was to create a better life by tackling the food shortages of the world's population.[6] However, the goal has shifted to a higher and more complex goal.[7] Since GE has been applied to humans, its main goals have expanded to achieve a better human life, including preventing disease transmission, reducing the risk of congenital disease,[8] eliminating disability, and creating perfect cognitive humans physiologically and mentally.[9] The reasons may sound like "science fiction" but the existence of Human GE (HGE) is not a fictional story like *the X-Men* or other mutant superhero movies. HGE is the real thing. One of its products is *Clustered Regularly Interspaced Short Palindromic Repeats* (CRISPR). CRISPR is likely to be able to edit germlines in the future to improve individual traits and offspring. These traits can be resistance to disease, life expectancy, and even human intelligence.[10]

The controversy over products from both GE and HGE is still ongoing. Various global issues have made different perceptions of the existence of this technology. On the other hand, the development of modern biotechnology has made something previously impossible become possible. Since there are still many

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Editing: Ethical Considerations and Application of International Human Rights Law," *Loyola of Los Angeles International and Comparative Law Review* 43, no. 3 (2021): 279.

3 Britannica, "Genetic Engineering," accessed January 10, 2022, https://www.britannica.com/science/genetic-engineering.

4 Steven P. Bennett, "Genetic Engineering : Rearranging the Molecules of Life," accessed January 15, 2022, https://gs.ucdenver.edu/ministem/pdf/2014_miniStem_Bennett.pdf.

5 Synthego, "History of Genetic Engineering and the Rise of Genome Editing Tools," Synthego, accessed January 10, 2022, https://www.synthego.com/learn/genome-engineering-history.

6 Mahrus, "Kontroversi Produk Rekayasa GenetikaYang Dikonsumsi Masyarakat," *Jurnal Biologi Tropis* 14, no. 2 (2014): 109, https://doi.org/http://dx.doi.org/10.29303/jbt.v14i2.138.

7 G. B. Romanovsky, "Legal Regulation of Genetic Research in Russia and Abroad," *Lex Russica* 7 (2016): 93–102, https://doi.org/10.17803/1729-5920.2016.116.7.093-102.

8 Dyah Ayu Widyastuti, "Terapi Gen: Dari Bioteknologi Untuk Kesehatan," *AL-KAUNIYAH Journal of Biology* 10, no. 1 (2017): 49–62, https://doi.org/10.15408/kauniyah.v10i1.4864.

9 Second Thought, "Building the Perfect Human," accessed January 20, 2022, https://nebula.app/videos/building-the-perfect-human.

10 Lara Hersch, "Genetic Modification: The Ethical and Societal Implications Of CRISPR Technology," *NYU School of Medicine High School Bioethics Project*, accessed January 20, 2022, https://med.nyu.edu/departments-institutes/population-health/divisions-sections-centers/medical-ethics/sites/default/files/medical-ethics-high-school-bioethics-crispr.pdf.

different opinions, people need caution and vigilance. Therefore, the government and the international community handle the problem cautiously; and prepare legal instruments to protect the public from the negative consequences of the GE's products.

In 2018, Chinese researchers performed HGE on human embryos.[11] However, after their successful research, due to the absence of the permit, the researchers were sentenced to imprisonment and a fine. In addition, many scientists forbid and condemn their actions. One of the reasons for the ban was because scientists thought the researchers violated the ethics and guidelines of the scientific community. However, people will always have different opinions; scientists have various thoughts. Some will think that HGE is part of the pursuit of perfection, intelligence, and disease-free human life. However, the opinion contradicts the idea that human existence is determined by nature because HGE makes humans brutally take over the task of Nature.[12]

HE is in line with a new philosophical movement called Transhumanism.[13] Transhumanism is a movement and a current philosophical idea that seeks to break the boundaries of human existence set by nature. The main goal of the movement is to improve human abilities.[14] Transhumanism can take many forms; one of them is HGE. For conservative society, it sounds very progressive and goes beyond the limits set by nature and God. However, for a progressive society, the movement is part of a higher standard of living and a step towards achieving an ideal human life, a utopian idea.

Alternatively, the reason for performing HGE is to maintain human survival and reduce the risk of Artificial Intelligence (AI), which is predicted to have an intelligence level above the average human's intelligence. Undeniably, if humans do not try to be "perfect", humans can be controlled by their own creations like AI in the future. Apart from the strange predictions, HGE needs to be analyzed based on various aspects ranging from religious, morality, and ethics norms, which raises pros and cons. The existence of HGE is a good thing. However, it can violate essential human values if it is not regulated. HGE is also risky because, through the process, humans will be born with animal features and have physical and intelligence that are worse than normal humans. HGE is a Pandora's box if humans

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11 Henry T Greely, "CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair," *Journal of Law and the Biosciences* 6, no. 1 (2019): 111–183, https://doi.org/doi.org/10.1093/jlb/lsz010.

12 School of Medicine University of Missouri, "Gene Therapy and Genetic Engineering," Center for Health Ethics, accessed February 2, 2022, https://medicine.missouri.edu/centers-institutes-labs/health-ethics/faq/gene-therapy.

13 Nick Bostrom, "Human Genetic Enhancements: A Transhumanist Perspective," accessed February 10, 2022. https://nickbostrom.com/ethics/genetic.pdf.

14 Lamia Putri Damayanti and Priscila Asoka Kenasri, *Gerakan Transhumanisme: Etika Dalam Transformasi Manusia Di Masa Depan Gerakan* (Yogyakarta: Fakultas Ilmu Sosial dan Ilmu Politik Universitas Gadjah Mada, 2018), 4-7.

take the wrong step.[15] In addition, it is possible that through the HGE development process, many innocent human lives will be victims. In such circumstances, our morality as humans is tested. Not to mention when we talk about human rights. The dilemma of the presence of HGE needs to be considered and regulated further. The law must regulate and be a solution before bad things or conflicts happen.[16] Rahardjo, in his explanation of the progressive legal theory, implies that the law exists to serve human purposes and not the other way. It also means that the law needs to continue to adapt to changes and developments that are happening and affecting society at every level, to be able to serve its purposes. The progressive legal theory argues that taking a step into another discipline is a progressive step for the law because the law cannot only stand on the positivist ground but also expands further and serve its purposes to create order on things that have not yet been governed by positive law[17], which in this case is the development of the HGE technology. Thus, regulations need to control the HGE. At this time, many countries are in the process of making regulations related to the HGE. Since scientific progress is making its way in many countries worldwide, including Indonesia, Indonesia must essentially facilitate regulations related to HGE following the specific development of science. Thus, it can enhance society with minimum risks.

This paper is divided into two main discussions. The first part examines the HGE and the arrangement of HGE in international settings (various countries and international organizations). The second part examines the urgency and prospects of the HGE regulation in Indonesia. The study aims to identify the HGE and its regulation on a global scope and determines the urgency and prospects of the HGE regulation in Indonesia. It is expected that this study can add consideration for Indonesia to determine its position in considering the legal status of HGE and as material for designing regulations related to HGE.

This study is a comparative legal study. It analyzed the legal principles, concepts, systematics, and history of other countries and how they measure up in comparison with Indonesian legal framework. It used legislation as the primary data; and literature as the secondary data to find values to be the foundation of HGE control in Indonesia.[18] It used two approaches: comparative law and the

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15 United Nations, "Playing with Genes: The Good, the Bad and the Ugly," accessed February 5, 2022, https://www.un.org/development/desa/undesavoice/more-from-undesa/2019/06/45413.html.

16 Tuti Haryanti, "Hukum Dan Masyarakat," *Tahkim* 10, no. 2 (2014): 160–168, https://doi.org/10.33477/thk.v10i2.57.

17 Yudhi Priyo Amboro and Khusuf Komarhana, "Prospek Kecerdasan Buatan Sebagai Subjek Hukum Perdata Di Indonesia," *Law Review UPH* XXI, no. 2 (2021): 145–172, https://doi.org/10.19166/lr.v0i2.3513; Satjipto Rahardjo, *Membedah Hukum Progresif* (Jakarta: Kompas, 2006), 20-25.

18 Suteki and Galang Taufani, *Metodologi Penelitian Hukum (Filasafat, Teori Dan Praktik)* (Depok: Rajagrafindo Persada, 2018), 102-103; Irwansyah, *Penelitian Hukum (Pilihan Metode & Praktik Penulisan Artikel)* (Yogyakarta: Mirra Buana Media, 2020), 20-21.

legislative approach. The secondary data of the study was obtained through literature study techniques under legal materials related to the object of the study. The data consist of primary and secondary legal materials. There are two categories of primary and secondary legal materials laws and other regulations: foreign and Indonesian laws that are directly or indirectly related to and have the potential of being linked to future Indonesian regulation of HGE. Foreign law refers to all applicable laws and regulations outside the jurisdiction of Indonesia. Indonesian positive law is the law that is used in Indonesia and secondary legal materials act in supporting and completing primary legal material. Secondary legal material comprised previous publications, research, books, and related literature.[19] The data are then processed by using a qualitative approach and comparative analysis of law and an analysis of legislation.

B. The Existence and Regulations of HGE in Various Countries and International Organizations

HGE is a part of GE. The primary focus is genetic modification of human genes. HGE is divided into somatic and germline modifications.[20] The somatic modification only modifies the gene/subject being treated and some cells from that subject. In contrast, germline modifications affect all cells in an organism. Eggs and sperm are included in the modified cells in this case. The effects of these modifications can be passed down to the next generation.[21] However, the germline modifications that affect these hereditary conditions are still debated (the fact that genetic changes can be passed on to the next generation). There is a high chance that such conditions will occur. The effects are unpredictable. Even if germline modification therapy successfully cures disease, other mutations could potentially be introduced. Any additional mutations introduced will be passed on to the next generation because germline modification therapy targets reproductive cells. Hence, some countries, such as Austria, Australia, and Belgium, prohibit the presence of germline modifications.

The development of HGE is getting extraordinary developments. A well-known case of HGE, which is often discussed, is the birth of two babies from germline modification in November 2018 in China.[22] One year after the birth, Jiankui He, a Chinese researcher, was found guilty of committing "Illegal Medical Practice." The

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19 Joenaidi Efendi and Johny Ibrahim, *Metode Penelitian Hukum (Normatif Dan Empiris)* (Jakarta: Pranada Media, 2018), 15.

20 Bartha Maria Knoppers (et.al.), "Human Genome Editing: Ethical and Policy Considerations", accessed February 25, 2022, https://www.genomequebec.com/DATA/PUBLICATION/34_en~v~Human_Genome_Editing_-_Policy_Brief.pdf.

21 Mary Todd Bergman, "Perspectives on Gene Editing," Harvard University, accessed February 25, 2022, https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/.

22 Britta C van Beers, "Rewriting the Human Genome, Rewriting Human Rights Law? Human Rights, Human Dignity, and Human Germline Modification in the CRISPR Era," *Journal of Law and the Biosciences* 7, no. 1 (2020): 1-36, https://doi.org/doi.org/10.1093/jlb/lsaa006.

Chinese Court in Shenzhen discovered this case on December 30, 2019. The researcher's activities violate Article 336 of the Chinese Criminal Code on the non-existence of a medical license to perform a medical service.[23] Jiankui He was sentenced to prison for three years and fined 3 million RMB Yuan. Two other convicts in the case got two years in prison, and a one million RMB Yuan fine; another one got one year and six months and two years probationary and a half million RMB Yuan fine.[24] The court discovered that the three convicts did not own a doctor's license while applying the HGE technology (CRISPR). The court also emphasized that the researchers had crossed an ethical bottom line in rashly applying genome-editing technology causing the babies' genetics to change.[25]

The purpose of the project was actually good because they tried to help a couple who wanted to have a child without inheriting HIV from one of the parents. The baby's father tested HIV positive, and the mother negative. However, despite the good intentions, the research is still ethically wrong, unlicensed, and high risk. The risk of genomic editing can cause permanent damage to the baby's genome or, at worst, the entire human genome chain.[26] Regardless of the violation, the researcher carried out the process of CRISPR by extracting the ovary cell from the mother's body. Subsequently, the genome was edited to be the embryos, which are then transferred to the uterus. After the procedure, the mother had twin pregnancies. The genome was edited to delete a gene called CCR5.[27] The CCR5 gene allows cells to become infected with HIV.

After the baby was successfully born following the CRISPR-type HGE process, Jiankui He announced his team's research. However, it did not go well and did not receive significant attention. Over a hundred scientists and scholars from China agreed with the statement condemning the experiment.[28] They mentioned that Jiankui He and his team's actions were "insane."[29] They reiterated that the scientific community is still debating the validity of the CRISPR and its impact because the process of directly altering a human embryo to produce a baby without any proper tests can pose serious risks. The case has socially impacted the world community and become a concern. It is understandable that the HGE is

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23 Françoise Baylis (et.al.), "Human Germline and Heritable Genome Editing: The Global Policy Landscape," *The CRISPR Journal* 3, no. 5 (2020): 371–374, https://doi.org/10.1089/crispr.2020.0082.

24 Shuang Liu, "Legal Reflections on the Case of Genome-Edited Babies," *Global Health Research and Policy* 24, no. 5 (2020): 1, https://doi.org/10.1186/s41256-020-00153-4.

25 Shuang Liu.

26 Shuang Liu.

27 Ledford H Cyranoski D, "International Outcry over Genome-Edited Baby Claim," *Nature*, accessed February 2022, https://www.nature.com/articles/d41586-018-07545-0.

28 Akshat Rathi and Echo Huang, "More than 100 Chinese Scientists Have Condemned the CRISPR Baby Experiment as Crazy," Quartz, accessed February 25, 2022, https://qz.com/1474530/chinese-scientists-condemn-crispr-baby-experiment-as-crazy.

29 Greely, "CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair."

imminent. Any unexpected impacts can happen. It is necessary to know the relevant legal regulations related to the HGE.

Nowadays, many countries are trying to regulate HGE comprehensively. In fact, many countries have demonstrated their legal position about HGE, especially germline modification. Some countries prohibit germline-modified HE, while others permit human embryonic stem cell research. In 2014, a survey conducted in thirty-nine countries generated four categories: (1) countries that prohibit it due to the legislation; (2) countries that prohibit due to the guidelines; (3) countries that are still in an ambiguous position; and (4) countries that apply restrictions.[30] The following is a list of the countries surveyed and their positions.

Table 1. Position of Countries in Regulating Germline Modified of HGE[31]

Countries	Regulatory Position on Germline Modified HE	Relevant Legislation Guidelines and Regulations on Germline Modified of HGE
South Africa	Ambiguous	National Health Act (2003, amended in 2013)
United States of America	Restriction Policy	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2013)
Argentina	Ambiguous	Decree 200/1997: The prohibition of human cloning experiments
Austria	Prohibit (Law)	Law on Medically Assisted Human Reproduction (1992, 2004)
Australia	Prohibit (Law)	Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act (2006)
Dutch	Prohibit (Law)	Act containing rules relating to the use of gametes and embryos (2002)
Belgium	Prohibit (Law)	Act on Research on Embryos in Vitro (2003)
Bulgaria	Prohibit (Law)	Bulgarian Health Act (SG No. 70/10 2004)
Brazil	Prohibit (Law)	Biosafety Law (2005)
Chile	Ambiguous	Act No. 20.120 on Scientific Research in Humans and the Genome, and the prohibition of Human Cloning (2006)
Costa Rica	Prohibit (Law)	Decree No. 24029-S-A Regulation on Assisted Reproduction (1995)

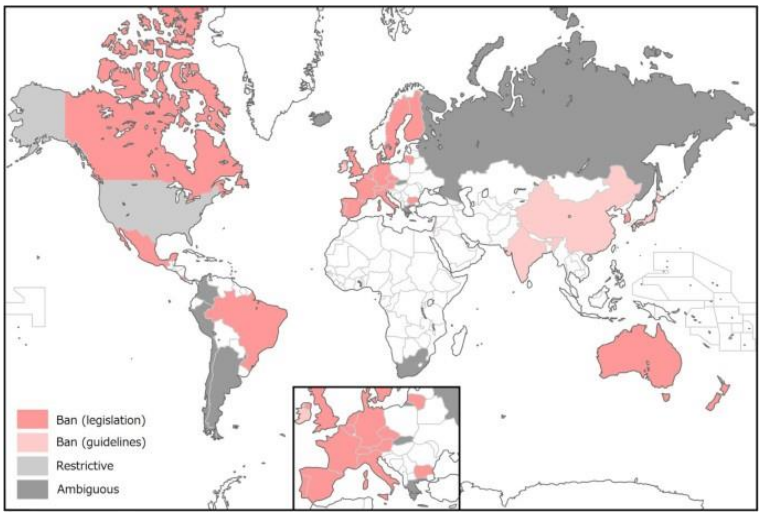
[30] Motoko Araki and Tetsuya Ishii, "International Regulatory Landscape and Integration of Corrective Genome Editing into in Vitro Fertilization," *Reproductive Biology and Endocrinology* 12, no. 108 (2014): 9, https://doi.org/10.1186/1477-7827-12-108.

[31] Araki and Ishii.

Denmark	Prohibit (Law)	Act on Assisted Fertilisation in Connection with Medical Treatment, Diagnosis and Research (1997, amended 2003)
Finland	Prohibit (Law)	Medical Research Act (488/1999,295/2004, 794/2010)
India	Prohibit (Guidelines)	Indian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Participants (2006)
Great Britain	Prohibit (Law)	Human Fertilization and Embryology Act (1990, amended 2008) and Human Fertilization and Embryology (Research Purposes) Regulations (2001)
Ireland	Prohibit (Guidelines)	Guide to Professional Conduct and Ethics for Medical Practitioners, Seventh Edition, 2009, Medical Council
Iceland	Ambiguous	Act on Artificial Fertilization and use of Human Gametes and Embryos for Stem-Cell Research (55/1996)
Israel	Prohibit (Law)	Law on the Prohibition of Genetic Intervention Act (Human Cloning and Genetic Manipulation of Reproductive Cells), (1999, renewed 2004, 2009, and valid until May 23, 2016)
Italy	Prohibit (Law)	Assisted Medical Procreation Law (2004)
Japan	Prohibit (Guidelines)	Guidelines of Clinical Research Regarding Gene Therapy (2002, amended 2004, 2008)
German	Prohibit (Law)	Embryo Protection Act (1990)
Canada	Prohibit (Law)	Assisted Human Reproduction Act (2004)
Colombia	Ambiguous	Criminal Code Law 599 (2000)
South Korea	Prohibit (Law)	Bioethics and Safety Act (2008)
Lithuania	Prohibit (Law)	Law on Ethics of Biomedical Research (VIII-1679/2000, amended 2007)
Mexico	Prohibit (Law)	General Health Law (1997)
France	Prohibit (Law)	Bioethics Law (2004, amended 2009)
Peru	Ambiguous	General Health Law (26842/1997)
Portugal	Prohibit (Law)	Law on medically assisted procreation (32/2006)

Czech Republic	Prohibit (Law)	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (96/2001) and Act on research on human embryonic stem cells and related activities and on amendment to some related acts (2006)
Republic of China	Prohibit (Guidelines)	Guidelines on Human Assisted Reproductive Technologies (2003)
Russia	Ambiguous	Law on State Regulation in the Field of Genetic Engineering Activities (1996, amended 2000, 2008, 2010); Russian Federation Citizen's Health Protection Law (22.07.1993.Reg. No5487-I) and Order 67th of the RF Ministry for Health (Reg. No4452 24.04.03)
New Zealand	Prohibit (Law)	Human Assisted Reproductive Technology Act (2004)
Singapore	Prohibit (Law)	Human Cloning and Other Prohibited Practices Act (2004)
Slovakia	Ambiguous	Health Care Act No. 277/1994
Spain	Prohibit (Law)	Law 14/2006 on Assisted Human Reproduction Techniques
Sweden	Prohibit (Law)	Genetic Integrity Act (2006)
Switzerland	Prohibit (Law)	The Federal Constitution (1999)
Greece	Ambiguous	Law No.3305 Application of Medically Assisted Reproduction (2005)

Figure 1. Distribution of germline modification regulations categories in 39 countries[32]



Based on the survey, most countries (29 out of 39) prohibit germline-modified HGE. Twenty-five countries strictly prohibit germline modification through their laws and regulations.[33] China, India, Ireland, and Japan prohibit germline-modified HGE based on guidelines.[34] Nine countries are still unclear regarding germline-modification legal status, with each legal framework not totally prohibiting HGE but has an unclear future in legal developments. The remaining country, the United States, chose a restrictive policy.

In 2020, the latest data from a survey related to the countries' policies on germline modification (heritable HGE) was published. The survey made five categories: (1) permitting; (2) prohibiting, prohibiting with particular cases, and no information on the HGE. The survey found that most countries' relevant policy documents (75 out of 96 countries) prohibit heritable human genome editing (germline modified HGE). Of the 75 countries, 70 countries prohibit germline modification. Five other countries permit germline-modified HGE with particular exceptions. However, all 96 countries do not explicitly allow the HE.[35] The following table contains a list of the countries and their categories.

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32 Araki and Ishii.
33 Araki and Ishii.
34 Araki and Ishii.
35 Baylis (et.al.), "Human Germline and Heritable Genome Editing: The Global Policy Landscape."

Table 2. List of Countries and Their Legal Positions Against Germline Modified of HE[36]

Categories	Countries
0 countries allow	-
70 countries prohibit	Austria, Albania, Argentina, Australia, Bulgaria, Bahrain, Belarus, Benin, Bosnia and Herzegovina, Brazil, Burundi, Czech Republic, Canada, Chile, China, Congo, Costa Rica, Croatia, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, India, Iran, Ireland, Israel, Japan, Kenya, Latvia, Lebanon, Lithuania, Montenegro, Malaysia, Malta, Mexico, Moldova, Netherlands, New Zealand, Nigeria, North Macedonia, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Romania, Russia, San Marino, Saudi Arabia, Serbia, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, Thailand, Tunisia, the United Kingdom, the United States, Uruguay, Vatican
5 countries prohibit with exception	Belgium, Colombia, Italy, Panama, United Arab Emirates
3 countries with uncertain regulations	Burkina Faso, Singapore, Ukraine
18 countries with no relevant information	Antigua and Barbuda, Armenia, Barbados, Central African Republic, Cuba, Egypt, Guinea, Guyana, Jamaica, Luxembourg, Namibia, Peru, South Africa, Tanzania, Trinidad and Tobago, Uganda, Vietnam, Zambia

Both 2014 and 2020 surveys show similar conclusions that countries tend to disagree with the existence of germline-modified HGE. The data show countries' consideration on the type of HGE. However, the previous data has not covered the regulation of somatic modification, which is also necessary. The following part describes the regulations of international organizations and the regulations of several countries participating in the survey.

[36] Baylis (et.al.).

1. European Union

The European Union is an international organization consisting of European countries. The organization can also issue regulations that affect its members, one of which is the HGE policy. The European Union allow some types of HGE, limited to somatic modification HE,[37] based on the Regulation (EC) No 1394/2007 of The European Parliament and of The Council of 13 November 2007 on advanced therapeutic medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.[38] According to the European Union clinical trial regulations, germline modification is prohibited,[39] based on Article 75 and Article 90 of the Regulation (EU) No 536/2014 of The European Parliament and of The Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. The regulation affirms *"(75) Directive 2001/20/EC provides that no gene therapy trials may be carried out if it causes modifications to the subject's germ line genetic identity."* It is appropriate to maintain the provision, *"(90) No gene therapy clinical trials may be carried out if it causes modifications to the subject's germ line genetic identity."*[40] based on the article, the European Union clearly forbids all kinds of gene therapy trials if they cause modification of a subject's germline genes.

In 1997, The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine - Convention on Human Rights and Biomedicine was signed in Oviedo, Spain. Most people acknowledge it as the *Oviedo Convention*. It is the first international instrument that formed legal biomedical principles. Article 13 of the Convention reads that *"modifying the human genome is only for preventive, diagnostic or therapeutic purposes and only if it has nothing to do with introducing any modification in any descendants' genome."*[41] The article implies that there is a prohibition on practicing germline-modified HGE. The prohibition comes from the idea that misusing germline-modified HGE can harm both individuals and species. It refers directly to the Preamble of the Convention, which affirms the belief that respecting humans as individuals and as members of the human species, as well as ensuring human

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37 Jennifer A. Doudna, "The Promise and Challenge of Therapeutic Genome Editing," *Nature* 578, no. 7794 (2020): 229–236, https://doi.org/10.1038/s41586-020-1978-5.

38 Regulation (EC) No 1394/2007 of The European Parliament and of The Council of 13 November 2007 on Advanced Therapy Medicinal Products and Amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

39 Miranda Mourby and Michael Morrison, "Gene Therapy Regulation: Could in-Body Editing Fall through the Net?," *European Journal of Human Genetics* 28, no. 7 (2020): 979–981, https://doi.org/10.1038/s41431-020-0607-y.

40 Regulation (EU) No 536/2014 of The European Parliament and of The Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC.

41 Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164).

dignity, is necessary. Based on these references, human dignity is the keyword and the foundation that underlie the outlawing of germline-modified HGE.

2. China

Following the previously discussed infamous case, China has become very concerned about HGE. China has made a comprehensive law on HGE. One of the principal regulations is Article 29 of the Chinese law on the Advancement of Science and Technology. The article prohibits research and development activities that endanger national security and human health, harm social and public interests, or violate ethics.[42]

Specifically, the Chinese government regulates HGE in several guidelines: the Guidelines on Human Assisted Reproductive Technologies (2003) and MOH Decree [2001] Number 14 on the Measures on Assisted Reproductive Technology. The guidelines forbid the genetic manipulation of human gametes, zygotes, and embryos for reproductive intentions. Therefore, germline-modified HGE is prohibited because relevant preclinical and clinical studies are impossible without prohibiting non-reproductive gene manipulation. On the other hand, somatic modification is not prohibited because HE, in general, is allowed. The germline modification is an exception.[43]

3. United States of America

The United States does not prohibit HGE. However, they impose moratorium policies or restrictions under the supervision of the Food and Drug Administration (FDA) and the guidelines from the National Institutes of Health (NIH). The NIH's Recombinant DNA Advisory Committee (RAC) will reject any proposal for a clinical trial of germline-modified HGE. On the other hand, the FDA regulates clinical studies.[44] The refusal by RAC can be categorized as part of a prohibition (in the form of action) but it is not literally written in the United States' law. The NIH will not fund any use of gene-editing technologies in human embryos. The concept of altering the human germline in embryos for clinical purposes has been debated for years from many different perspectives, across many medical communities, and has been viewed generally as a line that should not be crossed.[45]

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[42] The People's Republic Of China, "Law of the People's Republic of China on the Progress of Science and Technology," accessed March 5, 2022, http://english.www.gov.cn/archive/laws_regulations/2014/08/23/content_281474983042277.htm#:~:text=Law of the People's Republic of China on Progress of Science and Technology,-Updated%3A Aug 23&text=Article 3 The State guarantees, interests of scientists an.

[43] Laney Zhang, "On Gene Edited Babies: What Chinese Law Says," Law Librarian of Congress, accessed March 20, 2022, https://blogs.loc.gov/law/2018/12/on-gene-edited-babies-what-chinese-law-says/.

[44] Liu, "Legal Reflections on the Case of Genome-Edited Babies."

[45] Francis S Collins, "Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos," in *Bioethics: An Anthology* (USA: National Institutes of Health, 2015), 6.

4. The Great Britain

The Great Britain regulates and permits somatic cell therapy. However, it requires ethical approval, clinical trial license by the Medicines and Healthcare Product Regulatory Authority, and market authorization from the European Medicines Agency.[46] Thus, somatic modifications are still allowed with due regard to regulations and ethics. In Contrast, germline modifications tend to be prohibited by most countries, either through laws or regulations, and in actions such as restrictive policies or based on the guide.

C. Urgency and Prospects of HGE Regulation in Indonesia

The contemporary science and technology of GE have been significantly developed, including in HGE. It will gradually develop throughout the world; and Indonesia is not an exception due to globalization. The technology has good potential and purpose. Unfortunately, it also bears high risks. Other countries and international organizations have regulations or policies on HGE based on its urgent nature. Nevertheless, the world community is very visionary in viewing the HGE. It is in line, though indirectly, with Rahardjo's theory of legal progressivity that the law needs to adapt according to society's advancement to ensure its main purpose of creating order.

In Indonesia, the GE regulation is only limited to GE on animals and plants, as stated in the Indonesian Government Regulation Number 21 of 2005 on the Biosafety of Genetically Engineered Products. Indonesia has no specific regulations on HGE. However, Indonesia has an alternative: the Indonesian Government Regulation Number 39 of 1995 on the Health Research and Development. It does not directly refer to HGE in detail, but it is related. To use the legislation, the HGE must be a form of health research and development. Health research and development is a scientific activity that follows a systematic method to find new information and prove a hypothesis. Thus, a theory or a process of natural and/or social phenomena in the health sector can be formulated and tested for practical purposes. The HGE is essentially a human health technology and is still in the research and development stage. Therefore, the regulation can also cover the HGE indirectly. Based on the regulation, Indonesia can allow researchers to investigate the HGE for the purpose of the health of Indonesian people. the potential legal framework must be in line with the Law Number 23 of 1992 on Health.

Article 5 paragraph (1) of the Government Regulation Number 39 of 1995 on the Health Research and Development states that research and development of health can be carried out on humans or human corpses, families, communities,

[46] Postnote, "GENE THERAPY," *Postnote*, accessed March 10, 2022, https://researchbriefings.files.parliament.uk/documents/POST-PN-240/POST-PN-240.pdf.

animals, plants, micro-organisms, or the environment. Thus, HGE is a part of it because research and development can be carried out on humans. However, any studies on HGE must define some limitations. Article 5 paragraph (2) of the Regulation that the implementation of health research and development as referred to in paragraph (1) and its application is carried out by taking into account the norms prevailing in society as well as efforts to preserve the environment. In the explanation of the Regulation, norms prevailing in society are legal, religious, moral, and decency norms.

1. Religious and Morality Norms as Parameters and Sources of Material Law

The Government Regulation Number 39 of 1995 on the Health Research and Development covers the norms as a parameter to decide whether HGE is allowed or not. However, the practice can be difficult. There must be a single most relevant norm, apart from legal norms, namely religious norms. Indonesia recognizes various religions.[47] Thus, the norms are also quite complex. Furthermore, the official and foundational philosophical theory of Indonesia is *Pancasila*. The religious norms are presented because of Pancasila. The first principle of Pancasila is *Belief in the one and only God*.[48] In other words, Indonesia receives indirect intervention of religious values in the positive law. In addition, religious text can be a source of material law.[49]

In considering the HGE, if one of the religious norms is used as one of the parameters, for example, Islam, as the majority religion adopted by Indonesia, then there is a tendency for HGE not to be allowed. In Islam, changing God's creation is a sin. The HGE is a gene modification, a behavior that changes God's creation. However, an exception exists for medical purposes, such as treatment of disease.[50] Further discussions need to be held among Muslim scholars to properly define *"changing God's creation"*, because the HGE's main selling point as a field of study in genetics is its potential to prevent diseases. It also leads to another need to define the changes of Islamic rulings in the context of "prevention" and "treatment". The discussion is really important since Indonesia is the country with the biggest Muslim population.

The idea about the "norms prevailing in society" as a parameter of health research and development is also a complex matter because each norm, including

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47 I Nengah Adi Drastawan, "Kedudukan Norma Agama, Kesusilaan, Dan Kesopanan Dengan Norma Hukum Pada Tata Masyarakat Pancasila," *Jurnal Komunitas Yustisia* 4, no. 3 (2021): 928–939, https://doi.org/10.23887/jatayu.v4i3.43189.

48 Erman Sepniagus Saragih, "Analisis Dan Makna Teologi Ketuhanan Yang Maha Esa Dalam Konteks Pluralisme Agama Di Indonesia," *Jurnal Teologi Cultivation* 2, no. 1 (2018): 6, https://doi.org/doi.org/10.46965/jtc.v2i1.175.

49 Sirajuddin M, "Eksistensi Norma Agama Dan Pancasila Dalam Pembentukan Peraturan Perundang-Undangan," *Nuansa: Jurnal Studi Islam Dan Kemasyarakatan* 8, no. 1 (2015): 27-39, https://doi.org/10.29300/nuansa.v8i1.323.

50 H Hathout, "An Islamic Perspective on Human Genetic and Reproductive Technologies," *Al-Majallah Al-Sihhiyah Li-Sharq Al-Mutawassit* 12 (2006): 25, https://europepmc.org/article/med/17361675.

religious-based norms, will be different from one another. Therefore, Indonesia needs a standard rule as a parameter of the regulation on HGE. The norms prevailing in society are complex. In establishing the HGE regulation, Indonesia needs to pay attention to norms, including religious norms, as sources of material law. The norms are like Indonesian 'culture' and 'soul'.

2. Transhumanism and HGE

Contrary to the view of religious norms, a new philosophical movement called transhumanism fully supports the HGE. Transhumanism has been developing progressively since more than two decades ago. The movement assists the comprehension and evaluation of an opportunity to improve the human condition and the organism with an interdisciplinary approach. Nowadays, technologies that have full attention are genetic engineering and information technology, and future technologies, such as molecular nanotechnology and artificial intelligence.[51]

Transhumanism is a philosophical movement. According to transhumanism, humans must break the boundaries of human existence set by nature so that they can achieve an ideal condition. The boundaries (associated with HGE) are *genes determined by nature*. Transhumanism seeks to break this boundary because some genes can be harmful. Bad genes are certainly not ideal and troublesome for the development of a human body. Transhumanism also argues that what is holding humans back is not our limited imaginations, but rather the limitations of our physiology.[52] Perfectly in line with what HGE, transhumanism pushes science to expand its limits and have better contributions to the human gene pool.

Even though the term is not infamous, transhumanism affects Indonesian society, specifically the academic community, just like other academic communities across the world. Science, particularly medical science, will always consider the possible options of adopting new technologies to further develop healthcare and living standards. This has been the case with medical science throughout history. The possibilities of HGE being discussed in academic and religious communities in Indonesia show the constantly evolving curiosity and interests of the Indonesian people and heightens the urgency for more discussions.

3. Regulations, Restrictions, and Bio-Ethics as a Form of Balance Between Benefits and Risks of HGE

There are various views of religious norms and the transhumanism movement on HGE. Thus, it is necessary to remember that regulation on HGE must be

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51 Bostrom, *Human Genetic Enhancements: A Transhumanist Perspective*.

52 Allen Porter, "Bioethics and Transhumanism," *The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine* 42, no. 3 (2017): 237–260, https://doi.org/10.1093/jmp/jhx001.

immediately incorporated into the Indonesian legal system because other countries have made the regulations. Indonesia is slow in taking a policy position. It will eventually lead to a legal vacuum. Such a situation is dangerous because 'rogue' researchers can make mistakes leading to unexpected risks and harming the fabric of human life. In this case, the influence is not on a national scale, but it also has a global impact. Therefore, laws and regulations on HGE and the statement of Indonesia's position towards the HGE are mandatory and important.

In this case, Indonesia has three options to be policy: (1) permitting the existence of HGE totally, (2) prohibiting HGE in its entirety, or (3) permitting the HGE with restrictions. Each option has different consequences. Option (1) opens Indonesia to the limitless possibilities of HGE, including the possibility of becoming the forefront of the development and the possibility of being the source of biomedical catastrophe. Option (2) can make Indonesia indirectly supporting the existence of this technology but is completely free from the risks of possibly contaminating the human gene pool with problematic genes that could lead to global health crisis. On the other hand, option (3) allows Indonesia to follow scientific developments of HGE but not in its entirety, by putting restrictions on certain aspects of HGE, like other countries. The restrictive policy, as a result of option (3), also generates pros and cons because it allows Indonesia to observe carefully, in a controlled environment, the effects of HGE on the biomedical sphere and public welfare in general. Unfortunately, it also contains risks for Indonesia. Indonesia can be left out behind other countries in developing this technology, if the HGE becomes the next big thing in the biomedical industry.

The HGE is like a double-edged sword. On the one hand, the existence of HE can help humans, such as eliminating disease. On the other hand, the HGE is alleged to have *dangerous properties*. The danger is the effect of HGE, especially the Germline type, which can change future human genetics because of hereditary inheritance. Therefore, Indonesia needs to find the right balance between driving advancements in the HGE technology and managing the expected benefits and unintended consequences. According to the United Nations (UN), it can be done by maintaining a balance that will rely on three aspects: (1) consent and privacy; (2) dissemination of information and intellectual property rights (IPR); and (3) ethical boundaries.[53]

Based on the aspects mentioned by the UN, there are principles closely related to the previous three aspects. The National Academics of Sciences, Engineering and Medicine (NASEM) of the United States, in its report,[54] offered a poised collection of principles that can be used by biomedical companies or even other countries as a basic guidance in conceptualizing HGE as a field of science that is worth

[53] United Nations, "Playing with Genes: The Good, the Bad and the Ugly."

[54] National Academy of Sciences, *Human Genome Editing* (Washington, D.C: National Academies Press, 2017): 10, https://doi.org/10.17226/24623.

supporting. The following are the seven general principles of the HGE Research and Clinical Applications.

Table 3. HGE Research Principles[55]

No.	Principle	Explanation
1	**Promoting well-being**	The principle of promoting well-being supports provides benefit and prevents harm to the affected parties. It is often referred to as the principles of beneficence and nonmaleficence in the bioethics literature.
2	**Responsible Science**	The principle of responsible science underpins adherence to the highest standards of research, from bench to bedside, in accordance with international and professional norms.
3	**Transparency**	The principle of transparency requires openness and sharing of information in ways that are accessible and understandable to stakeholders.
4	**Due Care**	The principle of due care for patients enrolled in research studies or receiving clinical care requires proceeding carefully and deliberately, and only when supported by sufficient and robust evidence.
5	**Respect for Persons**	Respect for persons requires recognition of the personal dignity of all individuals, acknowledgment of the centrality of personal choice, and respect for individual decisions. All people have equal moral value, regardless of their genetic qualities.
6	**Fairness**	The principle of fairness requires cases to be treated equally. Risks and benefits shall be equitably distributed (distributive justice)
7	**Transnational Cooperation**	The principle of transnational corporation supports a commitment to collaborative approaches to research and governance while respecting different cultural contexts.

The principles also remind that there is a significant concern related to the HGE studies with all the risks and benefits while still looking at the precautionary aspect, such as through the implementation of research that still pays attention to research standards and moral values. Genuinely, the principles emphasize human existence, accountability, and supervision on the HGE without having to prohibit

[55] National Academy of Sciences.

the development of the technology. The principles can be used as the basis for an HGE regulation. However, the principles do not have legal force. Indonesia can use it as fundamental principles to regulate HGE in the future.

The HGE regulation is essential. Progressive legal theory also supports the possibility. According to the progressive legal theory of Rahardjo, the law must be at the forefront to regulate the progressivity of technology to accommodate Indonesia's future needs.[56] Therefore, the HGE is very necessary and must be regulated, despite the fact that there are differences between religious norms, as part of the norms of Indonesian society, and the progressive movement of transhumanism in viewing a change to achieve perfection. Indonesia should have chosen a firm position on the HGE. Indonesia has three options: to permit it, to forbid it, and to permit it with a limit. For instance, Indonesia may forbid germline HGE and conduct clinical trials with high standards. Indonesia has been following the HGE policies of most countries in the world on restrictive arrangements. If Indonesia is to make regulations, then Indonesia can adopt the principles recommended by NASEM.

D. Conclusion

This study concludes that most countries permit somatic modifications based on regulations and ethics. In contrast, most countries mostly prohibit germline modifications based on either regulations or actions. For instance, some countries issue restrictive policies or guidelines. Indonesia needs to regulate HGE by considering the risks. However, there are essential differences between religious norms, which are held by most Indonesian society, and the progressive movement of transhumanism, which view the change as a means to achieve perfection. Regardless of the differences, Indonesia should choose a firm position on HGE; and should not remain in *status quo*. Indonesia can take one of three options: to permit it, to prohibit it, or to limit the practice. For instance, Indonesia may ban germline HGE only; and may require high-standards clinical trials. Restrictive regulations, as the middle path, leaves a bigger room for both science and the law to fill in. Indonesia can create a legal framework under the restrictive regulation path and adopt the principles recommended by NASEM. Considering the high number of countries that have not yet accepted HGE as a possible future of biomedical science, based on the data, the development can put Indonesia in a great position as one of the prominent countries with advanced scientific development, especially in genetic studies.

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[56] M. Zulfa Aulia, "Hukum Progresif Dari Satjipto Rahardjo," *Undang: Jurnal Hukum* 1, no. 1 (2018): 159–185, https://doi.org/10.22437/ujh.1.1.159-185; Amboro and Komarhana, "Prospek Kecerdasan Buatan Sebagai Subjek Hukum Perdata Di Indonesia"; Satjipto Rahardjo, *Penegakan Hukum Progresif* (Jakarta: PT Kompas Media Nusantara, 2010), 22.

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