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Health Commission

What are the constraints necessary to genetic modifications of the human gene pool?

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Summary:

WHAT IS GENETIC MODIFICATION AND ENGINEERING?

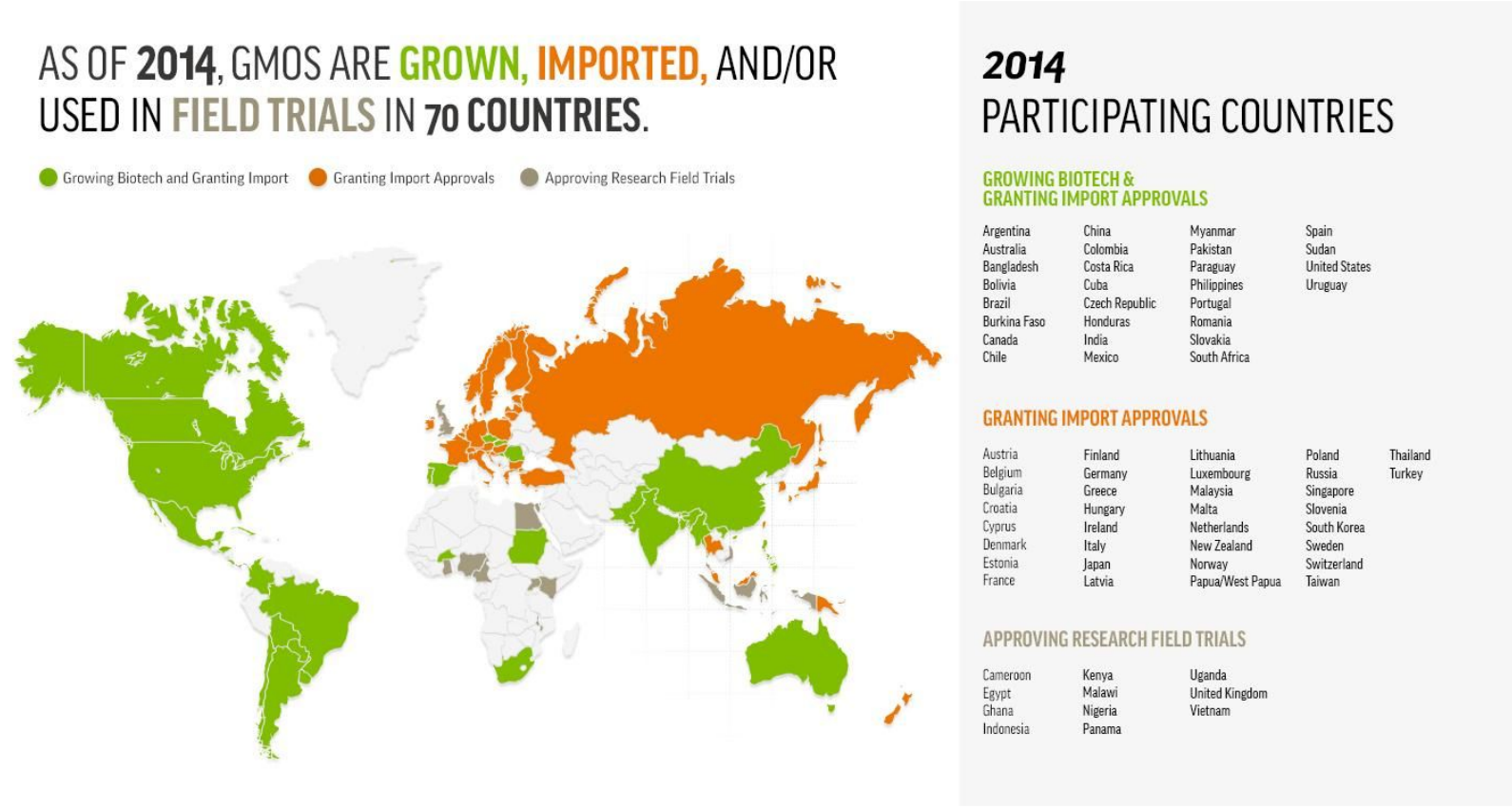
Genetic modification is to change a living being's DNA, therefore altering its body. This may have consequence over the immune system, genetic diseases, and attributes, such as strength and eyesight. It has been in practice long before the discovery of natural evolution, mainly with breeding of both crops and livestock. In the 1970s, both the first genetically engineered animal and the first genetically engineered plant appeared; and the technology was then commercialised.

But how does the process work ? Certain *enzymes* can cut pieces of DNA from one organism, and join them into a gap in the DNA of another organism. This means that the new organism with the inserted genes has the genetic information for one or more new characteristics. For example, the organism might produce a useful substance, or be able to carry out a new function. The organism has then been genetically modified.

Nowadays, genetically engineered bacteria produce hormones and proteins such as somatostatin and insulin, necessary for certain medications (insulin is used to treat diabetes). Before genetically engineered bacteria, ingredients were extracted from corpses of animals, a much more unsustainable and unsanitary method. Genetic engineering may also be called genetic modification or GM. It is not the same as cloning, although cloning techniques may be used in genetic engineering.

In the last couple decades genetic engineered has become present in everyone's life with the recent addition of GMOs *(Genetically Modified Organism)*, present as of 2014 in 73 countries.

But the goal of the Health committee is not to enter in the controversy of GMOs, but to establish what measures are to be taken to regulate the modification of the human gene pool.



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WHY is GENETIC ENGINEERING POLICYMAKING NEEDED? AND WHY NOW?

As of September 2017, genetic engineering has become both cheaper and easier thanks to a new technology that has emerged in the last decade called CRISPR. CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats, which are the hallmark of a bacterial defense system that forms the basis for genome editing technology. Pronounced "*crisper*", it is a biological system for altering DNA. Known as gene editing, this technology has the potential to change the lives of everyone and everything on the planet. CRISPR was co-discovered in 2012 by molecular biologist Professor Jennifer Doudna whose team at Berkeley, University of California was studying how bacteria defend themselves against viral infection. Prof. Doudna and her collaborator Emmanuelle Charpentier are now among the world's most influential scientists. The natural system they discovered can be used by biologists to make precise changes to any DNA. Indeed, Doudna told BBC news:

"Since we published our work four years ago laboratories around the world have adopted this technology for applications in animals, plants, humans, fungi, other bacteria: essentially any kind of organism they are studying."

With these systems, researchers can permanently modify genes in living cells and organisms and, in the future, may make it possible to correct mutations at precise locations in the human genome in order to treat genetic causes of disease. The cost in particular has been reduced to a tenth of the expensed of previous methods, and new commercial uses of genetic engineering have appeared beyond the absolute necessity of treating diseases and improving sustainability, such as the sale of modified animals like glowing fish.

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CONSEQUENCES OF CRISPR

So how and when might we begin to see treatments from CRISPR? Given that the technology is just a few years old it is not surprising that trials have yet to begin in patients, but several are in the planning stage. As a first example, the Boston biotech firm Editas Medicine is hoping to have a gene-editing treatment ready for clinical testing in 2017 to treat Leber congenital amaurosis, a rare retinal disease that causes blindness. The gene mutation causes the gradual loss of photoreceptor cells in the eye.

Modification of the human gene pool could potentially cure every single genetic disease, ranging from mild conditions (like colour-blindness) to life-threatening diseases, like haemophilia or Huntington's disease, not to mention other common diseases in-between like trisomy.

Other non-genetic diseases could be cured as well. HIV has already been removed in more than 50% of the body cells of a rat, potentially curing it, and the immune system can be improved to cure cancers or the flu. Both the People's Republic of China and the United States of America have already started governmental research into curing cancer thanks to

CRISPR, and there are several recently-formed biotech firms which are hoping to take CRISPR technology into the clinic. They are working on the theory that CRISPR might be used to boost the function of the body's T cells so that the immune system is better at recognising and killing cancer. Disorders of the blood and immune system are other potential targets. One cloud hanging over all this effort is a big patent fight over CRISPR. On one side are Prof Doudna's team, on the other a group based in Boston, Massachusetts. The patent row is unlikely to prevent academic researchers from using CRISPR, but it could have a profound impact on who reaps the financial returns of this emerging technology. Two earlier forms of gene editing have already made it into the clinic. Last year a technique known as TALENs was used to help reverse cancer in a patient at London's Great Ormond Street Hospital. The patient in question, Layla Richards had an aggressive form of leukaemia, and all previous treatments had failed. She remains the first person to date whose life has been saved by gene editing.

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OPINIONS AND STANCES ON HUMAN GENETIC ENGINEERING

There are strong arguments for and against cloning and genetic engineering. It is possible to produce genetically modified animals and plants. For instance, sheep that produce human proteins for treating the symptoms of cystic fibrosis - a disease which causes sufferers to produce abnormally thick and sticky *mucus* in their lungs - have been produced, and even tobacco plants that glow in the dark when they need watering. However, genetically modifying the human embryos seems to be a massive no, for the moment. No scientist is suggesting - yet - that gene-edited human embryos should be born. But several teams in China have done some basic research and the UK is the first country to formally approve gene editing in human embryos, for research only. This will be done at the Francis Crick Institute in London. When it opens in a few months it will be the biggest biomedical laboratory in Europe and will be a centre for gene editing. A team led by Kathy Niakan - recently named by Time magazine as one of the world's 100 most influential people - will use CRISPR to edit out key genes from the embryo, to try to identify the genetic faults which

lead many women to repeatedly miscarry. The embryos will be allowed to develop for just a few days. She told BBC News:

> *"What I'm hoping is that it provides us with a really crucial insight into early human development. I think it could help in identifying ways in which we could improve IVF to identify those embryos that are likely to continue to develop and thrive and, and give rise to healthy babies."*

As mentioned, all these modifications and cures can be performed as genetic treatment or by modifying an embryo's DNA. The difference between these two applications is that the cures applied with the former will perish when the patient perishes, but the ones applied with the latter will be inherited by the patient's offspring, which would change the human gene pool forever.

Some people are excited by the almost limitless possibilities genetic engineering, while some people believe the process is unethical and should be banned. Others are concerned about what might happen in the future.

A distinction must be made between modalities and principles. Today, manipulating the human genome of germ cells may be premature: these techniques may not be safe enough. Another major concern could be our current understanding of the human body: improvements or corrections may cause undesired changes, so how much testing should genetic treatments go through before they're actually administered to patients? Whatever the case, these techniques will surely become more and more secure over time. What will we do then? Should standards change?

At any rate, this research rings ethical alarm bells for Marcy Darnovsky of San Francisco's Center for Genetics and Society. She believes human embryo editing research may not be adequately controlled, leaving it open to a lab somewhere to create the first gene-edited babies. She states:

> *"You could find wealthy parents buying the latest offspring upgrades for their children. We could see the emergence of genetic haves and have nots, leading to even greater inequality than we already live with".*

Some of the key scientists in this field have concerns about the potential misuse of a technology that could be used for eugenics, to create genetic discrimination. Professor Doudna told CNN of a nightmare she had where she was led into a dark room where a man was seated with his back to her. She said:

> *"When he turned I realised with horror that it was Hitler and I was being expected to discuss this technology with him and he eagerly wanting to use it".*

She says that that while it is very hard to regulate the use of CRISPR technology, it is important to find a consensus about how people should proceed. All being said and done, the scientist's last words were :

> *"I never want to over-promise but I feel diseases will be cured and we want to enable clinicians and scientists to bring that to a reality".*

From WHO's *(World Health Organisation's)* website:

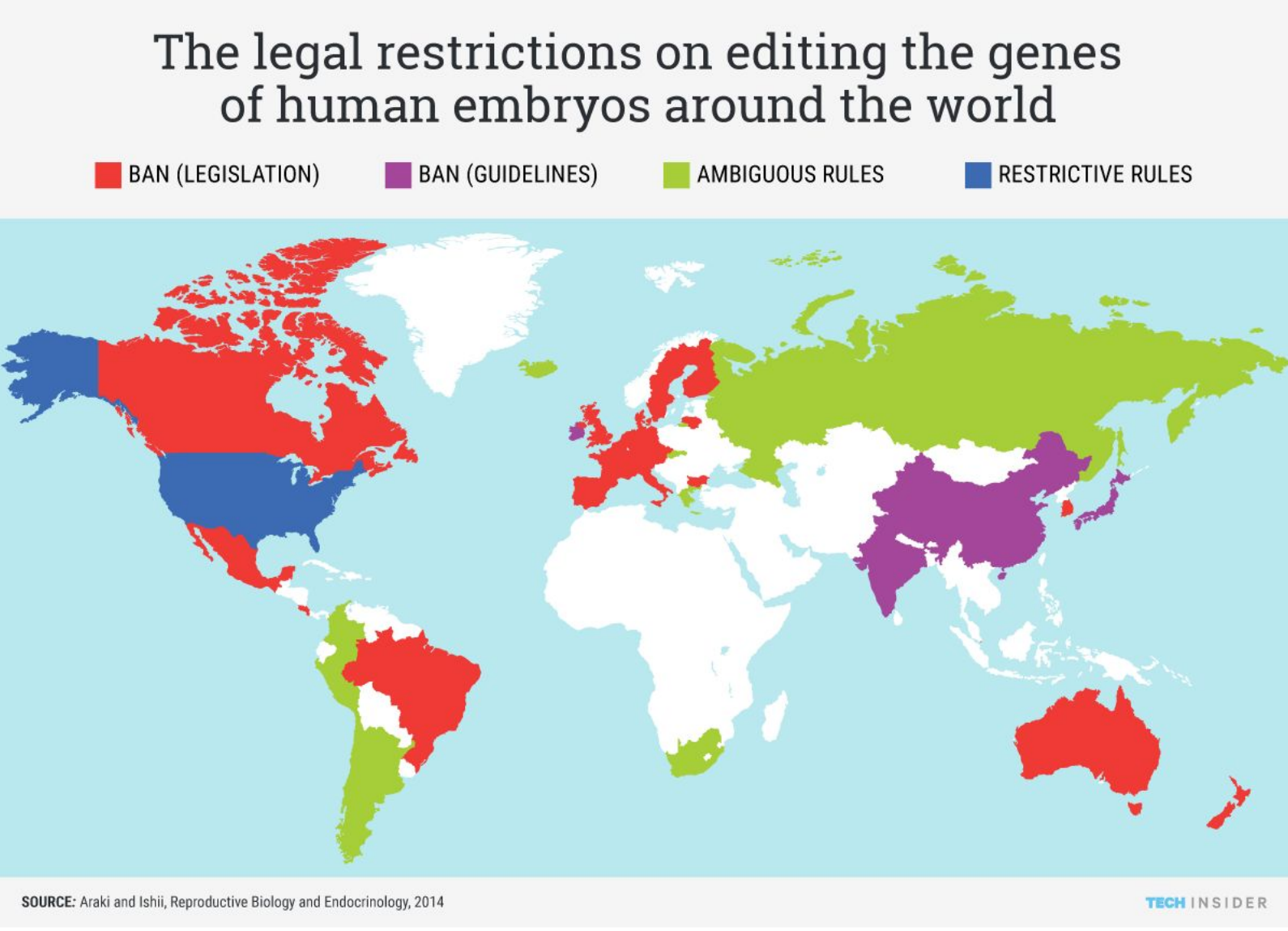
> *"WHO recognizes the role of human genomics research and related biotechnologies to achieve a number of public health goals, such as to reduce global health inequalities by providing developing countries with efficient, cost-effective and robust means of preventing, diagnosing and treating major diseases that burden their populations."*

Indeed, WHO is currently working alongside many Collaborating Centres that are highly valued mechanisms and try to implement its implemented work around the world (China, Cuba, India, Iran, Jordan, Russia, UK, Brazil).

On the other hand, many non-governmental nonprofit organisations founded in the late 20th century (such as GeneWatch UK, ETC Group and the Center for Genetics and Society) strongly oppose gene patents as well as the genetic modification and cloning of animals. The Center for Genetics and Society in particular does encourage genetic research as long as it aims to eradicate diseases and improve health in general, but opposes genetic modification that would "fundamentally change the nature of the human species"–in other words, anything involving alteration of the "germ line." The existence of such organisations are proof of how divided public opinion is in a number of countries and of how big is the spectrum of all possible solutions.

The fact that there are major differences between legislations of many countries is also proof of the existence of such spectrum. Many countries have outright bans on editing human embryos, but in other cases, the rules aren't so clearly defined. Even when they are, those rules are rarely legally binding.

In 2014, Motoko Araki and Tetsuya Ishii of Hokkaido University in Japan analyzed the rules on human embryo editing in 39 countries around the world. Here's what they found:



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AIM OF THIS YEAR'S HEALTH COMMITTEE

The fruit of our debating session lies within the ethical aspect of the subject. Morally, can the human race afford to let genetic modifications of the human gene pool be the norm? If so, to what extent? If not, the what other measures can be taken? It has to be said that, once the human embryo is modified, there's no turning back: offspring will undoubtedly inherit modifications. Mankind will start directing its evolution. Is this wise? "Respectful" towards mother nature? God? If so, which god? LICs *(Low Income Countries)* countries have a strong disadvantage since there is less genetic research provided. However, some countries would benefit enormously from possible HIV, Malaria, Zika cures. The question is can ethics be compromised to heal the human race? How far can this go? Treatments can range from curing life-threatening pandemics only to curing merely annoying genetic defects (like colour-blindness), not to mention improvements to existing attributes, such as eyesight. Yes, this surely sounds like sci-fi, but whatever legislation is decided now will most likely still be valid when genetic engineering has gone beyond current expectations, both in cost and efficiency. An important decision has to be made, soon.

In short, the stance on human genetic engineering varies wildly across institutions, experts, countries and NGOs. The aim of this year's Health Committee assembly is to reach a consensus - or at least to begin to do so - since this is a debate that will probably remain an issue for decades to come, and as a technology developing fast *now*, policymaking needs to be implanted soon. Whatever the house decides, it will change the lives of generations to come and the direction of future medical research.

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Sources, further reading and documentation

General information on CRISPR, its history and patent issues:
https://www.wired.com/2015/07/crispr-dna-editing-2/

World Health Organization (WHO) home page on genomics:
http://www.who.int/genomics/about/en/

EU Stance on genomics (relevant to all EU countries and to the **EU seat** itself):
https://ec.europa.eu/research/ege/pdf/gene_editing_ege_statement.pdf

Britain's situation in the Brexit context (research funds came from the EU until now and the UK is leading research on the genomics field. No funds, no research, no genomics):
https://www.genomeweb.com/research-funding/brexit-britain-genomics-community-anxious-about-future-eu-funding-collaboration