Forum: Legal Committee (GA6)
Issue: Establishing a legal framework on genetic engineering methods
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INTRODUCTION

Genetic engineering is the artificial modification of an organism's genes using biotechnology. This is feasible due to the fact that the genetic code is universal, i.e. the amino acid sequence for each gene, is the same for all species. This process allows genetic engineers to introduce new characteristics to animal species and produce new varieties of plants.

Genetic engineering can be conducted at different scales. Oh the smallest scale, one base pair (Adenine-Thymine, Cytosine-Guanine) could be changed or a whole region of DNA could also be deleted. Technological developments have also allowed for the extraction of DNA from one organism and its combination with the genetic material of another.

Genetic modification (GM) has been applied to numerous fields and its multiple benefits can be broadly grouped into three categories: environmental, health and agricultural. Generally, GM can help in the production of crops which are resistant to many pests and diseases as well as in the increase of their shelf-life and vitamin content. Even though many people have expressed objections to the usage of genetically modified crops (GM-crops), most of the scientists believe that they do not cause more harm than non-GM crops.

Up to now, genetic engineering has had multiple uses that can better the lives of people with little to no harm. However, the debate surrounding the concept of GM cannot be ignored, especially because it directly pertains to human and non-human lives. Naturally, this means that scientific experiments involving such a practice need to be monitored, and a clear legal framework has to be established. However, this could be regarded as an "uncharted territory" as GM is not comparable to any other processes.

Overall, genetic engineering has proven to have substantial benefits and could greatly affect the lives of people in the following years. That is why it is important for governments not to hinder its progress but rather ensure that it is safe and ethical. Therefore, the establishment of a legal framework surrounding genetic engineering is imperative to ensure the proper usage of its methods.

DEFINITION OF KEYTERMS

Genetic Engineering

The purposive modification of an organism's characteristics by the direct manipulation of its genetic material.

Genetically Modified Organism

An organism the genome of which has been artificially engineered in order to generate desired physiological traits.

Substantial Equivalence

According to the Organization for Economic Co-Operation and Development, substantial equivalence means that the safety of a modified food may be assessed by comparing it to food the consumption of which has been proven to be harmless over time.

Transgenic animals

Animals with an altered genome, including those with genes not only from different breeds but also from different species.

Precautionary principle

An approach to possibly harmful innovations as is the case of Genetically Modified Organisms (GMOs), highlighting that the principle "caution, pausing and review" must always be used in order to ensure the public's safety.

Genome

A genome is an organism's complete set of DNA, including all of its genes.[1]

BACKGROUND INFORMATION

History of Genetic Engineering

During the 1960s, there were major discoveries regarding the structure of DNA which accelerated the advancement of genetic engineering. This contributed to the creation of recombinant DNA (rDNA), which is DNA consisted of DNA from different organisms and inserted into a host in order to produce new genetic combinations. Despite its artificiality, it replicated naturally.

Thomas Wagner at Ohio University transferred the gene of a rabbit to a mouse's genome through DNA microinjection, paving thus the way for the usage of transgenic animals. This has led to the production of the first genetically engineered human drug, synthetic insulin, the benefits of which are extremely valuable. As a result, genetic engineering became more popular. Later on, "Bt corn" was introduced which greatly contributed to the fight against pests.

The best known example of genetic engineering is Dolly, a cloned sheep. This achievement gave us the opportunity to clone endangered animals in order to save them from extinction.

Generally speaking, in recent years, there have been many developments in the field of genetic engineering ranging from the first synthetic life form to the first genetically modified salmon being introduced to markets. While such changes are likely to benefit people, it is vital to properly be monitored and strictly comply with the established legal framework.

Applications of Genetic Engineering

[1] "Genome." *Dictionary.com*, Dictionary.com, www.dictionary.com/browse/genome.

Genetic engineering methods have been applied to various fields. The artificial insulin and a hepatitis vaccine are two of the most valuable results of recombinant DNA technology. Moreover, plants may be genetically adjusted in order to be more resistant to pests, thus having a longer lifespan. Finally, dysfunctional genes can be replaced with functional ones correcting genetic diseases.

Production of insulin

In the case of insulin production, a special process is followed. More specifically, a plasmid (i.e. a small piece of circular DNA) is extracted from a bacterial cell which is then cut out by restriction enzymes. Then, the gene for human insulin is pasted into the plasmid. The plasmid is inserted into a new cell which divides rapidly and produces insulin. The more the cell divides the more insulin is produced. These cells are usually produced in large fermentation vessels that contain the nutrients which can ensure their growth. Once fermentation is complete, the mixture is filtered and insulin is then purified and placed into bottles, and may then be provided to patients with diabetes.

Cartagena Protocol on Biosafety

This protocol was introduced to ensure the protection of biological diversity from living modified organisms (LMO) resulting from GM. It is based on the aforementioned precautionary principle. The Cartagena protocol made the important distinction between organisms that are to be introduced into the environment and others that are going to be used for food or processing.

The Advanced Informed Agreement (AIA) refers to organisms that are going to be intentionally introduced into a different environment than the one that produced them. It is based on four main principles:

1. Notification by the country of production
2. Acceptance by the country of introduction
3. Decision procedure and
4. Opportunity for review of the choice

This ensures that the countries involved are aware of the risks from the transportation of these organisms. For example, a new scientific discovery may force a country to reconsider its previous stance on the transportation and/or introduction of the GM species.

It is important to note that the AIA does not include organisms that are destined for containment or for direct use, e.g. food and processing. Moreover, it is always important to take into account a country's domestic legislation which may in turn have an effect on trade.

Decisions on directly used LMOs may be taken considering either a country's domestic legislation or, in case of lack thereof, the principles of the Biosafety Clearing House established by the Protocol.

Finally, the protocol pertains to the physical transfer of LMOs by setting out what information must be included in documentation. Both the receiving and the production parties bear responsibility for the proper handling, transport and packaging of the LMOs.

Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

This Protocol provides rules concerning the liability and redress in matters of LMOs. States may also introduce civil liability rules considering the principles of this protocol. The main objectives include the fair sharing of the prospective benefits enabling and perhaps enhancing the conservation and further development of biodiversity.

The access obligations refer to the domestic-level access requiring legal transparency, clarity and certainty in order to prevent harm and reflect on food security. Generally, the access obligations mainly focus on legal transparency and proper handling of these issues.

The benefit-sharing obligations refer to the fair sharing of prospective benefits. These include monetary or other benefits as, for example, research results based on mutually agreed terms.

The compliance obligations refer firstly, to the extent to which the domestic policies of the parties involved are respected and secondly, to whether the aforementioned obligations are met or not. These mainly concern ensuring the availability of justice in case that one of the parties thinks it has been wronged and the respect for the domestic policies of all the parties. At the same time, they promote cooperation between the parties in case of a disagreement concerning the policies followed.

Genetic Engineering Risks

When setting the legal background for genetic engineering, it is important to minimize the risks that may arise because these processes involve living organisms.

As far as human health is concerned, genetic engineering bears multiple risks. Firstly, transgenic crops could also produce new allergens which will be undetectable by the average person. Moreover, some genetically modified plants contain genes that make them resistant to certain antibiotics. When those plants are consumed by animals or humans, the resistant genes could be transferred to pathogens making them resistant to antibiotics with disastrous consequences for human health. It is widely accepted that if antibiotics are excessively consumed, they are degraded and their effectiveness is reduced. This phenomenon could cause major problems in the field of medicine. Apart from that, the production of new toxins and the concentration of toxic metals are two more risks which are highly associated with GM.

There are also many risks concerning the environment. The most widely known problem is linked to the fact that genetically engineered plants might become weeds which can greatly affect crop yield and essentially disturb ecosystems. It has been observed that GM has significantly contributed to the growth of many weeds. Furthermore, a change in herbicide use patterns may greatly affect the environment. Wildlife may be poisoned resulting in environmental disturbances. Finally, the production of virus-tolerant crops may lead to the creation of new dangerous viruses which may have catastrophic effects on the environment.

Aside from the aforementioned risks, it is important to note that, since GM is a relatively new process which is constantly evolving, it includes a lot of risks that may not have been identified yet. These risks may arise from the interaction between a specific organism and its environment.

GMO Authorization

Currently, the legislation allowing GMO authorization includes a vigorous safety assessment that differs on whether the GMO is used for direct purposes or cultivation.

Firstly, the state applies for authorization and may need to carry out a risk assessment (if the purpose is cultivation). The application may include comments by the state. The European Food Safety Authority (EFSA) then carries out a risk assessment and comments on the application. It is then passed on to the European Union Commission that makes a draft decision, which is then passed on to an expert committee that decides by qualified majority (i.e. a majority that reaches a predetermined onset value of over 50%), whose decision may be appealed.

This is the policy followed by EU member states; however, it clearly includes some limitations, since on the one hand, it does not specify what happens after authorization and on the other, it does not clearly state how the process will be monitored.

Genetic Engineering on Humans

Genetic engineering on humans (also commonly known as gene editing) has significantly advanced in recent years. This process could play a major role in the treatment of genetic medical conditions, even if the cost of such treatments is currently extremely high.

In 2018, the first genetically engineered humans were produced. A pair of twins' genes was modified to ensure that they would not get HIV from their father. In view of the fact that HIV can greatly affect a person's life, there is no doubt that this is a positive advancement, but it is important to keep in mind that there are different ways to prevent HIV from being passed from parents to children. This raises serious issues, given that this could signify the start of developing "designer babies", namely babies that would have specific characteristics desired by their parents.

In Vitro Fertilization (IVF)

In Vitro Fertilization is a series of procedures which can help the conception of a child and possibly prevent genetic problems. Mature ova are fertilized by sperm in a lab and transferred to the uterus. The whole procedure takes about three weeks.

IVF may be used in case of infertility or genetic disease. When one of the parents may pass on a genetic disorder to the embryo, the ovum is screened for certain genetic problems. This allows the parents to be almost certain that the fertilized ovum will be healthy even if not all diseases are detectable.

Gene Editing

Gene or genome editing is a group of technologies which enable scientists to alter an organism's DNA. CRISPR-Cas9 is one of the most recent technologies which are much more efficient than others. It has been used for the treatment of various genetic disorders, while it has been hypothesized that, with further development, it can contribute to the revitalization of various extinct species.

Obviously, the legislation behind gene editing is more complex due to the fact that it concerns human lives. Many are opposed to gene editing because it could eventually lead to completely artificial humans. The Council for International Organizations of Medical Sciences (CIOMS) has significantly helped in the creation of guidelines for gene editing. National legislations may not follow every guideline, but those established by CIOMS can set the framework for states to work upon. However, aside from guidelines, there are also strict laws that forbid similar processes, such as cloning.

Gene Therapy

Gene therapy is a technique that utilizes genes to treat and prevent diseases. Gene therapy may include replacing a dysfunctional gene with a functional one, inserting a new gene or muting a gene that is not functioning properly.

Generally, the policy most nations follow consists in using gene therapy only if a disease cannot be cured with more "traditional" techniques, e.g. surgery, medication. Although many countries legally prohibit artificial modification, due to the alleged inefficiency of gene therapy, there are still a lot of them which have not actually established a legal framework on gene therapy.

Gene therapy may also include drugs. In most countries, those drugs are not fully controlled which may cause problems if new evidence arises and the product needs to be withdrawn from the market.

MAJOR COUNTRIES AND ORGANIZATIONS INVOLVED

United States of America (USA)

USA was the first country to introduce a genetically modified crop, the Flav-Savr tomatoes, and continues being the largest user of GM crops, with the cultivated area being roughly 70,9 million hectares. US maize production accounts for more than 60% of world production. Moreover, 39% of the total GM world production can be attributed to the US.

Brazil

Brazil uses a lot of GM crops with the cultivated area being 44,2 million hectares. It is a leading exporter of genetically modified soybeans, maize and cotton. The private sector is also largely involved.

South Africa

The GM crop varieties in South Africa represent the largest proportion of total crop plantings. In particular, genetically modified maize represents 85% of total maize plantings and GM soybeans represent 95% of total soybean production, so food sufficiency and safety are largely dependent on GM.

India

All cotton grown in India is genetically modified. Even though GM crops for food have not been introduced, field trials are being conducted in order to enable the introduction of modified crops.

European Union (EU)

While there are several European nations not allowing cultivation of genetically modified products at all and only four countries actively planting genetically modified maize, the EU is one of the largest importers of biotech grains. In fact, 70% of EU farmers are dependent on genetically modified seeds, and the halt of GM seed import would result in a loss of 30 billion euros for the European Union.

China
China has been actively involved in genetic engineering. In fact, it has banned the labelling of non-GM products as healthier, helping in the removal of the stigma against the consumption of genetically modified crops. China follows a very specific process before a product is released into the market ensuring its safe consumption by the population.

Russian Federation
In Russia, the consumption of genetically modified organisms by citizens is forbidden due mainly to the complaints of environmental organizations, which believe that there is not enough proof to ensure the safety of those crops, while it is permitted exclusively for scientific research.

World Health Organization (WHO)
Since genetically modified products may have an effect on human health, WHO has set guidelines and standards to determine the safety of GM foods.

TIMELINE OF EVENTS

DATE	DESCRIPTION OF EVENT
1953	The structure of DNA is discovered.
1973	Recombinant DNA is created by inserting DNA from one bacterium into another.
1975	The Asilomar Conference takes place, which was the first conference concerning the safe and ethical usage of genetically engineered DNA.
1980	The first GMO patent was introduced.

1982	Humulin —insulin synthesized by using modern genetic engineering techniques in a laboratory strain of Escherichia coli bacteria— is approved and introduced into the market. It is the first GM product developed for consumer use.
1994	The Flavr-Savr tomato, a GM crop with a longer shelf-life, is approved for sale in grocery stores and is considered as safe for consumption as a traditionally bred plant.
1996	Genetically modified resistant weeds are detected.
1997	The European Union rules in favor of mandatory labeling on all genetically modified food products.
2003	Genetically modified resistant pests are discovered making it obvious that the bugs have adapted. WHO and the Food and Agriculture Organization (FAO) set guidelines and standards to determine the safety of GM foods.
2011	Research finds that Bt corn toxins are passed on to fetuses.
2015	An application to genetically modify an animal is approved by the Food and Drug Administration.
2016	The United States also impose the labelling of some food that has been genetically engineered.
2017	Genetically modified apples are available for sale in the United States.
2019	Consultation on the first food from a genome edited plant takes place.

RELEVANT UN RESOLUTIONS, TREATIES AND EVENTS

UN statement on the use of GM foods as food aid in Southern Africa

In this statement, the United Nations explained how GM foods may help eradicate hunger in Southern Africa, thus highlighting the importance of their introduction in the market, as they may put an end to a problem affecting Southern African nations for years.

PREVIOUS ATTEMPTS TO RESOLVE THE ISSUE

A lot of countries have enacted their own legislation on genetic engineering. The EU has relied on its committee of experts while the US on the FDA's regulations. Moreover, the aforementioned protocols adequately regulate not only the distribution of the products but also ways to specify how those products will be safe for consumption.

The European Parliament's resolution on ethical and legal issues arising from genetic engineering aimed at highlighting the importance of this technology and establishing some principles that should be applied, but did not come to any direct decision regarding the creation of a legal background concerning genetic modification.

The Codex guidelines consisted of a set of final legal measures to ensure the safe genetic modification of plants. These include a description of the latter, including their host environment, a description of the host organism, including toxicity and allergenicity issues (which as mentioned previously may prove to be a major problem) and the genetic modifications which are expected. Moreover, they include a safety assessment that is important to avoid the negative consequences of producing genetically modified organisms.

POSSIBLE SOLUTIONS

Establishing a legal framework is a rather complicated process that needs to be viewed from different perspectives. Firstly, one should ensure that the global standards introduced will be respectful of each nation's domestic policies and not try to overrule their respective legislation. Moreover, it is important that every step of the process is carefully monitored so that no harm will be caused to the GMO producers, the GMOs themselves or the general population. Regarding the risks, since this territory is extremely unknown to most nations, it is important that the precautionary principle is always applied so that no dangerous mutations may be produced. Risk assessment, risk management and risk communication are all vital to these procedures which above all should be safe and ethical. Lastly, protection from undue harm must be an utmost priority for everyone involved.

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