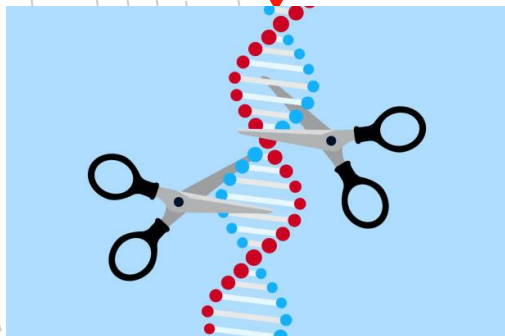


EGE

The EGE (European Group on Ethics in Science and New Technologies) has been working on an Opinion on the ethics of gene editing for some years – at the request of the European Commission.

<https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6d9879f7-8c55-11eb-b85c-01aa75ed71a1>

Genome editing



- This Opinion addresses the profound ethical questions that arise when editing modifies the genomes of higher organisms - humans, animals (insects) and plants
- It analyses various domains of application, from humans (health and enhancement) to animal experimentation (including research and livestock breeding) to crop variety and gene drives.

Genome Editing

How can our language be honest about the uncertainties in how we will develop and use the technologies, and what promise and risk their use holds, without employing terms that trigger gut reaction rather than thoughtful deliberation?

Words do have consequences and they need to be used 'responsibly' in order to help ensure that the public and public policy stakeholders are well informed, since words influence how we act upon and shape the world in which we live.

Diversity

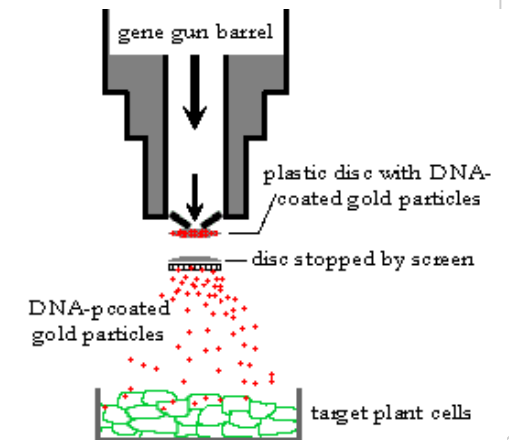
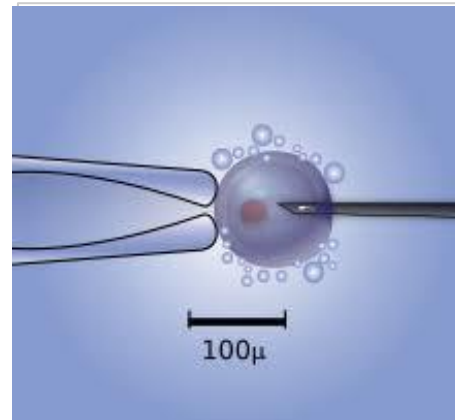
Diversity is commonly understood as the richness and variety of distinct objects or types, whether that be at the level of genomes, organisms, species or ecosystems. Measures of diversity consider not only the variety but also the rarity of a species, trait or object. In many contexts, diversity has risen to the status of an accepted 'good', and a social goal to be protected and promoted, often against a background of its perceived precariousness due to human activity. What kinds of values are being attached to a multiplicity of life forms?

Precision

Genetic modification of living material has been imprecise, both in terms of the location of the modification and of the modification that was achieved. New genome editing technologies have improved the precision on both accounts.

Modifying human embryos requires 'absolute' precision if they are to be implanted – especially if any errors are likely to be carried through generations

The techniques of producing a viable plant for commercial use mean that unwanted or unexpected mutations can be identified and discarded, hence absolute precision is not a requisite



Safe Enough?

The 'safe enough' narrative limits reflections on ethics and governance to considerations about safety; it purports that it is sufficient for a given level of safety to be reached in order for a technology to be rolled out unhindered, thereby eschewing ethically important questions such as whether genome editing is in fact necessary, acceptable, and under what conditions.

Those who are using the technology must ensure that they are monitoring for unpredicted and unintended events, and act upon them accordingly and without delay. This also extends to questions of coordination, inequalities and power relations. In fact, 'safety' or 'trustworthiness' do not pertain solely to technologies but also to institutions and forms of governance in societies – including matters of oversight as well as of democracy and rule of law.

Governance

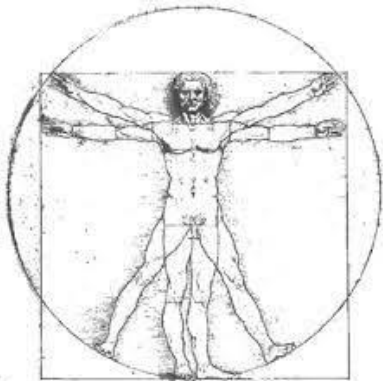
- There is a lack of structures of global governance. We recognise that genome editing technologies, particularly their application in humans require a global governance approach. It is difficult to take regulatory measures of worldwide scope that are efficient and respected by all States. (moratorium?)
- Proposing criteria for the governance of genome editing, particularly where the modification is in the human germline, is not an easy task. Reflection is required on the rights and values involved (notably human dignity, solidarity, right to identity); on the expectations generated by these techniques, and on the limits and principles that should govern its application (safety, effectiveness, efficiency, transparency, common good, accountability, proportionality, etc.).

Humans

Given the powerful technologies available today to edit the human genome there is a requirement to assess their impact on shared ethical principles and fundamental rights and freedoms, including the dignity of every human being, the right to life, health and bodily as well as mental integrity, respect for autonomy, freedom of research, justice, non-discrimination and solidarity.

If we permit the modification of the human genome, we must consider whether this is for **enhancement** or **therapeutic** reasons. Is it possible to differentiate between these?

Assuming that the desired modification can be done with **precision** and **safely**, should we permit modifications only to **somatic** cells, or could the modification of the **germline** be acceptable?



Humans

- There is a longstanding practice of weighing potential benefits and risks in clinical research (and even in clinical practice) and in healthcare for somatic genome editing, but with regard to germline editing the question of safety is more complex.
- We must consider the impact on shared ethical principles and fundamental rights and freedoms, including the dignity of every human being, the right to life, health and bodily as well as mental integrity, respect for autonomy, freedom of research, justice, non-discrimination and solidarity.

Recommendations

- Establish a public registry for research on germline genome editing. The registration should be compulsory regardless of funding mechanism
- Protect social justice, diversity and equality
- Proactively safeguard against enhancement or dis-enhancement of traits
- Ensure that investments in research on germline genome editing have the purpose of protecting health.
- Ensure adequate competencies in expert bodies

Animals

Genome editing of animals is still primarily within the research domain. Millions of animals are used ranging from zebra fish embryos to non-human primates. The EGE Opinion stresses research over animals used for food and other products

In 2017:

- 10,664,752 animals used for research in the EU
- Mice, fish, rats and birds account for 92% of animals used
- Cats, dogs, and primates account for 0.25%
- The UK, France and Germany were the highest user of animals
- 45% are for basic research, 23% for translational and applied research and 23% for regulatory purposes

In 2019, there were 143 million pigs, 77 million bovine animals and 74 million sheep and goats in the **EU-27**. Just over half of the **EU-27's** meat production was from pigs (22.8 million tonnes) in 2019.

Animal Research

- **Strengthen oversight of genome editing in animals for scientific experiments according to, and beyond, the 3Rs**
 - the EGE recommends reinforcing reporting requirements with respect to scientific experiments using genome edited animals, including documenting their purposes;
 - the EGE urges research ethics committees and bodies in charge of project evaluation to carefully evaluate the costs/benefits of genome editing experimentation taking the 3Rs framework into account;
 - the EGE recommends that researchers be required to ensure transparency, sharing of data and tissues, and the publication of negative results in order to minimise uncoordinated duplication of experiments
 - The EGE recommends that ethical oversight of practices involving reduction of animals natural abilities be instituted
- In addition, It is recommended that regulation of the use of animals modified with human genetic material be imposed

A red speech bubble graphic with a white outline, containing the text 'Animals commercial'. The bubble has a tail pointing downwards and to the right.

Animals commercial

Ensure the wellbeing of genome edited livestock animals

Genome editing of animals will be used to modify or insert traits for commercial purposes. The EGE expects the EU and its Member States to ensure that the health and wellbeing of the concerned animals is assured during all stages of the procedures and of the animals' life.

Reconsider ethically contested industrial farming practices

The debate on genome editing also raises general questions around ethically contested industrial farming practices. The EGE considers wider reflection around sustainable and ethical food production models necessary.

Gene editing in agriculture

- The use of gene editing in plants is already happening, and, in Europe particularly, may be controversial.
- Science provides almost unlimited power to modify our environment. The problem is no longer as to what can be done, but rather what should be done
- **The economic impact of choosing to use or not use plants produced using ANY new technologies is likely to be significant and should be addressed by public authorities and society at large**

Precaution and safety?

- Should concerns that harm could occur affecting human health, the agricultural environment or the natural environment due to the introduction of genome edited organisms result in a complete ban on such products?
 - “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation” (Rio Declaration 1992)
- Proportional to the chosen level of protection
- Precaution dictates that case-by-case consideration of the products of genome editing and of their use in particular environments is required. **Should this analysis identify both risk and benefit to humans and the environment?**

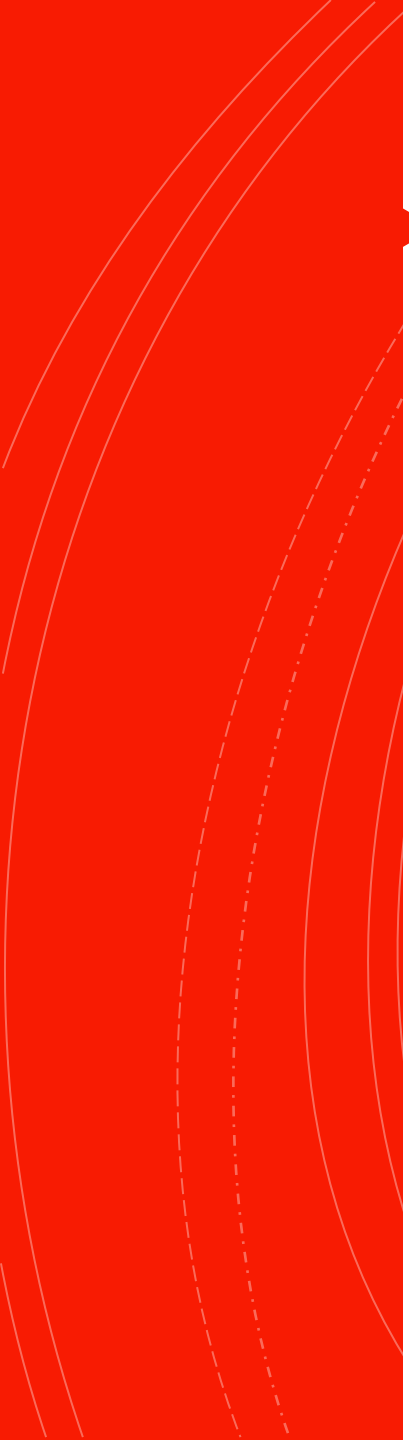
Industrialisation of Agriculture

- Changes to agricultural practices, including increasing size of farms is of concern to many in society, who mourn the loss of small farms and the increasing size of field impacting on the natural environment. Does the introduction of new (genome edited varieties) exacerbate this process?

Availability of new improved varieties

- Many, in Europe in particular, question the need for new varieties. They argue that the rapid pace of development of new varieties given modern tools will have a deleterious effect on plant genetic resources. Older methods of enhancement took time, and their impact was thus probably lower on the agricultural environment

Impact on biodiversity – positive and negative

- 
- **The impact of patents on availability of traits and on cost to farmers**
 - Restrictions on farming practices with the introduction of patented varieties
 - ‘sharing’ of patented traits across the industry
 - **Biosecurity**
 - “a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk”
 - **Justice**
 - **Exclusion of small seed producers due to regulatory burden**

Improve the agricultural environment

- **Improve quality of produce in water scarce environments and adaptation to climate change**
- **Improve availability of plants suited to a particular environment**
- **Improve efficiencies in farming to increase yields, quality and create consistency**
- **Reduce cost of production**
- **Conserve natural resources**
- **Reduce post-harvest losses**
- **Improve access to local and international markets**
- **Protect the natural environment**
- **Improve compliance with legislation and other regulations**

What and Why?

- **Precaution** dictates that case-by-case consideration of the products of genome editing and of their use in particular environments is required. Should this analysis identify both risk and benefit to humans and the environment?
- Why limit case-by-case consideration to varieties produced using new technologies?
- Where a change in the genome involves many new protein and enzyme genes (e.g. synthetic biology), or where the position of changes is random, it may mean that the risk assessment is very detailed and deliberate, in order to avoid or minimise the risk of serious and irreversible harm to either the environment or to human health.
- Should companies introducing new varieties, regardless of method of provenance, be required to identify the impact of their use on biodiversity and the environment?

What and Why?

- Food security has become an important issue, particularly with a growing urban population, the impact of climate change, limited land available for agricultural expansion and the need to have an efficient distribution system where losses during transportation are minimised. The new techniques may have a role to play. What incentives could be introduced to ensure that new varieties address biosecurity and security of supply for food, feed, fibre and fuel?
- Should consideration be given to structures that support smaller actors to undertake risk assessments and enter the market?



Hence

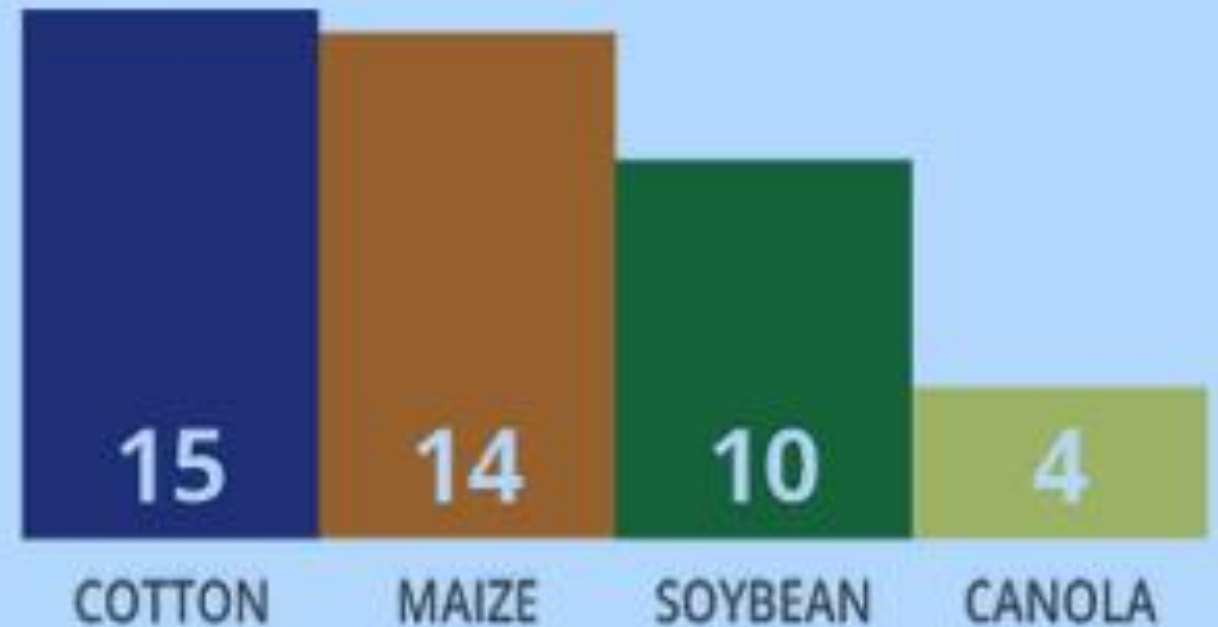
There is a need to ensure food security, provide renewable resources for fuel, feed and fibre, safeguard the retention of biodiversity and protect our environment.

Genome editing technologies could, with appropriate and proportionate control, enhance our ability to achieve these goals

Although gene technology has been successfully applied in many countries, it is still not globally accepted – is this an ethical issue?

Relatively few commercially grown food plants are GM or edited

NUMBER OF COUNTRIES GROWING MAJOR BIOTECH CROPS IN 2018



Society

- Understanding the impact of climate change, including desertification, drought or even excess water provides an impetus for producing new varieties of plants
- There is a need to examine the agricultural techniques currently used to facilitate the growing and distribution of plant products.
- The needs of the different kinds of farmer and of the consumer need to be addressed

“Agriculture contributes nearly one-quarter of global greenhouse gas emissions, uses 37 percent of landmass (excluding Antarctica), and accounts for 70 percent of all freshwater withdrawn from rivers, lakes, and aquifers