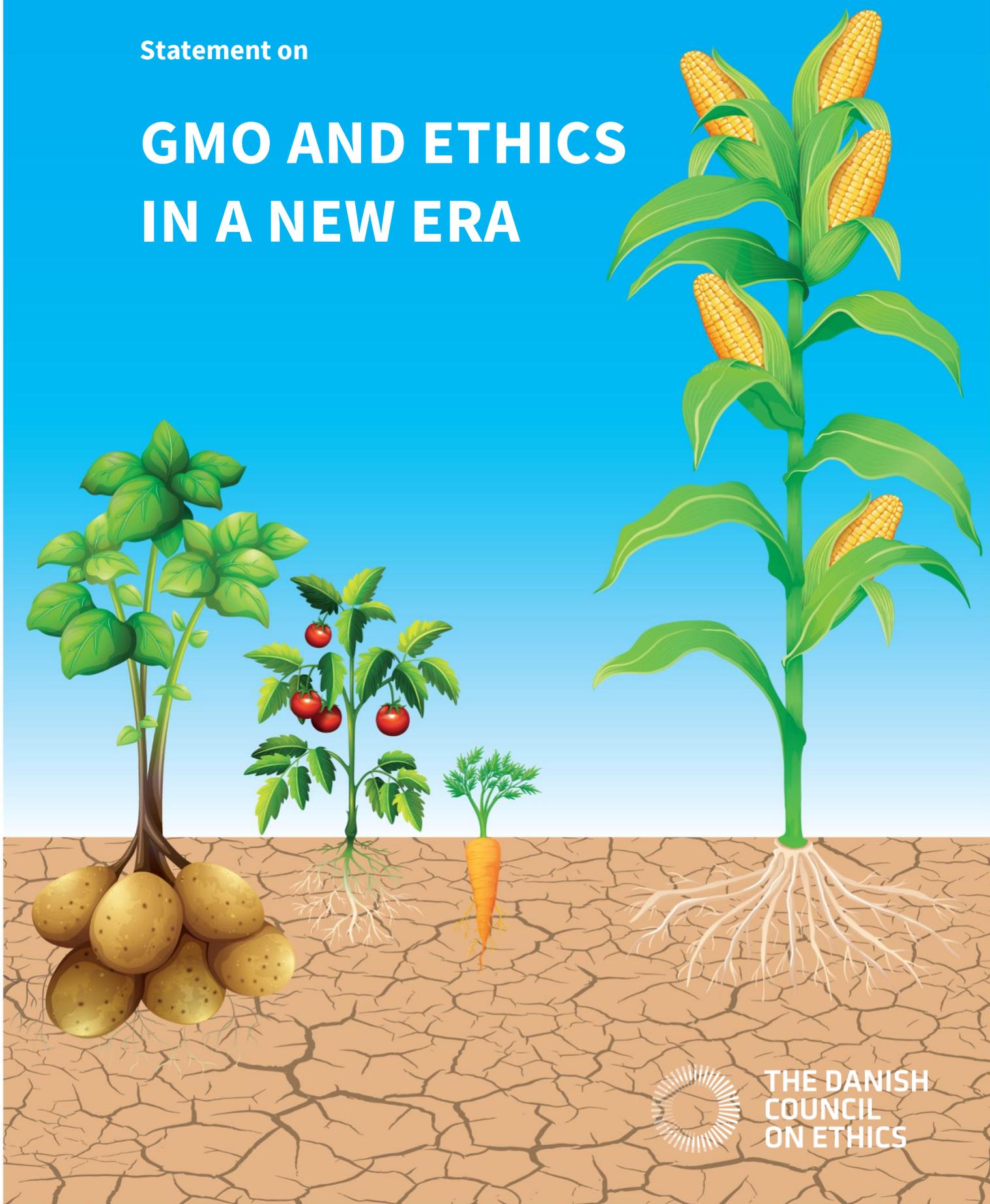


Statement on

GMO AND ETHICS IN A NEW ERA



THE DANISH
COUNCIL
ON ETHICS

TABLE OF CONTENTS

Preface	3
Statement on GMO and ethics in a new era	4
1. Introduction	4
2. Why are fast changes to the plants we eat necessary?	6
2.1 Conventional breeding	7
2.2 Gene technology and CRISPR	8
3. European opposition to GMO.....	9
4. CRISPR as a tool to introduce positive climate traits	12
5. EU GMO legislation and the mutagenesis exemption.....	16
6. Ethics: Is genetic modification of plants wrong in itself – wrong in every case?.....	17
6.1 Genetic modification of plants is wrong because it is particularly risky	19
6.1.1. Gene modification is particularly risky	19
6.1.2. Gene technology should not (always) be considered risky.....	19
6.2 Genetic modification of plants is valuable if it can help achieve e.g. the UN Global Goals	20
6.2.1. Positive consequences for the climate and sustainability should be included in the assessment of a GMO.....	20
6.2.2. Positive contributions to sustainability cannot outweigh the problems of GMO:.....	21
6.3 Genetic modification of plants is wrong because it is unnatural.....	21
6.3.1 It is not wrong to change nature even though nature is valuable in itself	22
6.3.3. Changing nature is at odds with the inherent value that nature possesses	23
7. The Council's recommendations	23
7.1 It is ethically problematic to reject GMO varieties if they can help alleviate or solve significant problems and there are no good arguments for rejecting them.....	23
7.1.1 Absence of particular risks.....	25
7.1.2 Contribute to sustainable development	25
7.2 It is ethically problematic to use gene technology to change plants	27

PREFACE

This statement has been prepared by a working group established by the Danish Council on Ethics in the winter of 2018-2019.

The Council would like to thank the following experts for having contributed to the working group:

Mickey Gjerris, Associate Professor of Bioethics at the University of Copenhagen;
Rikke Bagger Jørgensen, Senior Researcher Emeritus at the Department of Environmental Engineering, Technical University of Denmark;
Klemens Kappel, Professor of Philosophy at the University of Copenhagen;
Jørgen E. Olesen, Professor at the Department of Agroecology, Aarhus University and
Michael Broberg Palmgren, Professor of Plant Physiology at the Department of Plant and Environmental Sciences, University of Copenhagen.

Participating from the Danish Council on Ethics were Anne-Marie Axø Gerdes, Henrik Nannestad Jørgensen and Morten Bangsgaard (chair of the working group).

The Council would also like to thank Andreas Christiansen, Postdoc from the Department of Media, Cognition and Communication, University of Copenhagen for having prepared the background paper on ethical restrictions on GMO (*Danish title: Baggrundsnotat om restriktioner på GMO*) and the paper on whether GMO opposition is based on the perception that naturalness is good in itself (*Danish title: Skyldes GMO-modstand at naturlighed opfattes som godt i sig selv?*) We are also grateful to Torben Chrintz, Scientific Adviser at the think tank Concito; June Rebekka Bresson from Noah, Friends of the Earth; and Arne Holst-Jensen, member of the Norwegian Biotechnology Advisory Board and Senior Scientist at the Norwegian Veterinary Institute for their presentations at the Council meetings.

Morten Andreasen and Anne Lykkeskov have prepared the statement in the Council's secretariat.

The statement has been transacted by the Council on three meetings in October 2018 and January and February 2019.

Anne-Marie Axø Gerdes
Chairperson of the Danish Council on Ethics

Christa Kjøller
Head of Secretariat

STATEMENT ON GMO AND ETHICS IN A NEW ERA

Many factors have changed since genetically modified organisms made their entry in Europe more than 30 years ago, and the Danish Council on Ethics therefore finds that the time has come for a renewed debate on GMO. New types could potentially play a positive role in achieving several of the UN's Sustainable Development Goals from 2015. In this statement, the question of whether GMO's technology could and should be used to develop plants with traits beneficial to achieving the goal of taking urgent action to combat climate change is used as an example of the potentials of GMOs'. Other examples could be the goals to end hunger, to promote sustainable use of ecosystems and to achieve food security and ensure sustainable consumption and production patterns. The Council provides recommendations on the question of whether it would be ethically problematic to reject GMOs with beneficial traits provided they are not assessed as posing a higher risk to humans or the environment than similar varieties developed by conventional methods. The Council's opinion moreover implicates recommendations for a change of the EU's authorisation system for GMOs and other plants with new traits

1. Introduction

The public opposition that has been levelled against genetically modified organisms (GMOs), and especially GM plants, since their introduction in Europe more than 30 years ago¹, has largely been based on arguments of ethics. Genetic modification was looked upon as a particularly invasive technology that would change nature in unprecedented ways. Since no experience had been gained with such invasive changes before, people were afraid of the risks in the form of unintended events that could arise in the short and long term.

Several things have changed in these 30 years, however, and the Danish Council on Ethics therefore finds it relevant to call for a renewed debate on the ethical implications of genetically modified plants:

- **The techniques have improved**, and especially the CRISPR technology, developed in 2012, has made it far more simple to quickly and more accurately alter genes without inserting genetic material from other species. In addition, it is possible to make small changes like turning genes on and off²

¹ Genetic modification of crop plants was developed in the 1970s, and since the 1980s, the technology has been used to add novel traits to plants, see National Academies of Sciences, Engineering, and Medicine. 2016. *Genetically Engineered Crops: Experiences and Prospects*. Washington, DC: The National Academies Press, 5

² A change could cover one or more of the following features of a gene: the gene's code (the bases of the DNA), its functional product (amino acids and/or protein folding structure), or its activity level (from completely turned off to hyperactive)

- We now have more than 20 years of research into **risks** which shows that there is no scientific evidence that GMO in itself entails a greater risk than conventional plant breeding technologies^{3,4}
- **Benefits to societies:** Some developers, e.g. universities and small seed breeders, have started developing GMOs which are of relevance to the handling of serious societal problems, including the climate challenge and the biodiversity challenge

It seems today that not all GMOs should be assessed in the same way from an ethical point of view. There is nothing to suggest that gene modification per se has any bearing on how risky new plants are. This makes it relevant to question if the EU's Deliberate Release Directive⁵ is up-to-date given that it requires all genetically modified organisms to be subjected to the same comprehensive and costly authorisation procedure before being released for cultivation in the EU. It also raises the question of whether it is ethically problematic if the legislation obstructs the development and marketing of GMOs, e.g. those with positive effects, if they are not deemed more risky than similar conventional varieties.

The EU defines a GMO as: an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Both plants and animals can be GMOs, but this statement focuses solely on genetically modified plants.

In the following we use the climate challenge as an example of a serious threat to which GMO could contribute positively. The same principled considerations could be applied to the use of GMOs in other areas. Climate change is an acute threat to the foundations of life for human beings now and in the future, and the window for action in relation to avoiding temperature increases of more than 1.5°C above pre-industrial levels is quite narrow. It is obvious that neither GMO nor any other single solution will be enough to solve the problem of climate change. More and more, however, indicates that we are in a situation where we cannot afford to turn down any measure that can contribute to mitigating or limiting the impacts of climate change, unless there are good reasons for doing so. The Council therefore finds that the time has come for a renewed debate on GMO.

³ National Academies of Sciences, Engineering, and Medicine. 2016

⁴ EU Commission. 2010. A decade of EU-funded GMO research (2001-2010), 16

⁵ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

2. Why are fast changes to the plants we eat necessary?

In October 2018, the Intergovernmental Panel on Climate Change, IPCC issued their report⁶ on the measures needed to limit global warming to 1.5°C above pre-industrial levels – the target set by the global leaders in Paris in 2015.⁷ The report concluded that this can still be achieved but that it will, among other measures, require unprecedented transitions in the use of global land areas. Large areas should be converted into permanent vegetal cover, e.g. planted or self-sown forest and other natural habitats, thus reducing the area for agricultural production immensely. Since the industrialisation, CO₂ emissions from human activities have already caused the temperature to increase by 1°C, causing the changes we are already experiencing in the form of extreme weather events, melting ice in the Arctic Region, rising sea levels, etc.

The Paris Agreement 2015

At Paris COP21 in December 2015, 196 member states of the UN ratified the UN Framework Convention on Climate Change (UNFCCC), which is a legally binding climate agreement known as the Paris Agreement.

The Paris Agreement's long-term goal is to keep the increase in global temperature to below 2°C – and to work towards limiting the increase to 1.5°C above pre-industrial levels.

The IPCC report on global warming of maximum 1.5°C

After the Paris Agreement was ratified in 2015, the member states asked the Intergovernmental Panel on Climate Change (IPCC) to prepare a report by 2018, detailing the possibilities of achieving the goal of keeping global warming at 1.5°C above pre-industrial levels.

The 91 experts responsible for the report make it clear that if the goal is to be achieved, CO₂ emissions must reach net zero around 2050. But it is not enough: CO₂ must be removed from the atmosphere as well. One approach could be to plant more forest in very large areas, combining it with so-called BioEnergy Carbon Capture and Storage (BECCS) where the wood is combusted at power plants and the CO₂ is captured and pumped into the underground. Another approach could be to develop even more high-yielding crops for biomass production, for example via CRISPR technology and in conjunction with BECCS. It is, however, debated whether this technology would work adequately.

⁶ IPCC. 2018. *Global Warming of 1.5°C, an IPCC special report on the impacts of global warming of 1.5°C above pre-industrial levels and related global greenhouse gas emission pathways, in the context of strengthening the global response to the threat of climate change, sustainable development, and efforts to eradicate poverty. Summary for Policymakers*

⁷ UN. 2015. The Paris Agreement, see: <https://unfccc.int/process-and-meetings/the-paris-agreement/the-paris-agreement>

If temperature rises are not to accelerate, it is not enough to reduce future greenhouse gas emissions; we will also need to remove CO₂ from the atmosphere. Since trees and other plants absorb CO₂, a central approach would be to increase the areas of natural habitats on a large scale, including self-sown and planted forest.⁸ The protection of a number of habitats, such as peat bogs, rain forest and seagrass beds, could have a positive effect in terms of limiting climate changes by absorbing and storing carbon, thus reducing the amount of carbon dioxide in the atmosphere.⁹ The global area utilized for the cultivation of food would thus need to be reduced significantly.¹⁰ This is an enormous challenge, which only grows bigger as the global population will increase from 7.5 billion in 2017 to 11.2 billion in 2100 according to the UN estimate.¹¹ We will need to feed a rapidly growing global population while reducing agricultural land considerably. It must be achieved concurrently with climate changes that are challenging agricultural production in many places, causing droughts and seawater floods which make cultivation of the soil no longer tenable.

One of the conditions for being able to produce more food in a smaller area and under more extreme weather conditions caused by climate change, is the ability to develop very efficient and **higher yielding plants** that can yield more in a smaller area. It will also be beneficial to develop plants that are better at **binding CO₂** in the soil or can do with less fertilisation or ploughing since both of these activities increase the emission of CO₂ from fossil fuels (**climate mitigation**). In addition, we must develop plants that can adapt to the climate changes we are already experiencing, even in Denmark, and which will only become more common in the future, e.g. by being able to adjust to major variations in precipitation, etc. (**climate adaptation**). It may be possible to develop such types of plants via conventional processing techniques, but with the CRISPR technology such varieties can in many cases be developed quicker and more accurately.

2.1 Conventional breeding

Throughout the thousands of years where humans have cultivated land, farmers have selected the best specimens among their harvested crops and have crossed them with each other to combine the best traits. Thus, the natural genetic variations in plants have been the basis of the alterations in traits – and thus the genetic composition – of

⁸ IPCC. 2018, s 22

⁹ Barfod, A et al. 2019. Vi kan stadig nå at bremse klimakrisen, men uddør en art, er den væk for altid. [There is still time to slow down the climate crisis, but once a species is extinct, it is gone forever] *Politiken*, 24 February.

¹⁰ IPCC reports that the area no longer to be used for agricultural production is the size of the USA (10 million km²), adding that energy crops will need to be planted in an area the size of Australia (up to 7 million km²)

¹¹ UN. 2017. World population prospects. 2017 revised

the crop plants. Developing new plant varieties through crossbreeding takes a long time, normally 12-16 years.

The development of new, more valuable plant varieties is called plant breeding. A distinction is traditionally made between *conventional* and *biotechnological* plant breeding. However, this is somewhat misleading as conventional plant breeding also makes use of biotechnology, e.g. so-called DNA marker assisted selection (MAS), chromosome doubling, etc.

The traditional mutagenesis techniques, which are still being used, were developed in the 1940s in response to the challenge that it was often impossible to find the genetic variant in the species itself that would enable the needed progress through traditional plant breeding. Scientists began altering the genome of living organisms by introducing mutations, for example by irradiating them with a radioactive source or exposing them to mutagenic chemicals.¹² Both spontaneous and induced mutations increase the genetic variation that the plant breeder bases his work on. In both cases, the results are random mutations, meaning that it is not possible to control where they occur. Induced mutagenesis is thus an "inaccurate genetic modification".

The vast majority of mutations are either neutral or undesirable, both for the plant's ability to survive in nature and as a crop plant. Once an attractive trait/mutation is identified, several rounds of *backcrossing* are therefore necessary, crossing the mutant plant with high-yielding varieties and selecting the offspring that has retained the attractive trait and, as far as possible, has not inherited any of the bad mutations. This technique is usually time-consuming, and there is no guarantee that all bad mutations are removed. The types of genetic modification that does not introduce genes from other species are collectively referred to as **mutagenesis**.

2.2 Gene technology and CRISPR

When gene technology entered the scene, it was revolutionary in enabling a more targeted alteration of plant genes. For example, it became possible to introduce genes from other plants of the same or closely related species – so-called **cisgenesis** – thus reducing or eliminating the subsequent plant breeding processes. And it became possible to introduce DNA from organisms with whom the plant cannot reproduce in nature – so-called **transgenesis**.

The first gene modification techniques were inaccurate and time-consuming, so initially the progress was much slower than expected. However, in recent years,

¹² van Harten AM. (1998) *Mutation Breeding: Theory and Practical Applications*, 353 pp. Cambridge: Cambridge University Press.

technological advances have been fast and comprehensive. Especially the **CRISPR** technology, developed in 2012, has made it far simpler, quicker and more accurate to alter genes without inserting genetic material from other species. The **CRISPR** technology can be applied to all the three types of modifications, but it enables a more accurate modification than the previous techniques. Many people therefore use the term 'gene editing' or, when the changes do not introduce external genetic material into the plant but merely knocks out selected genes, the term 'precision mutagenesis' about changes produced by CRISPR.¹³

3. European opposition to GMO

When the general public became aware that scientists were working on changing what was considered the "basic ingredients" of organisms, the genes, it caused widespread concern. In particular, the thought of inserting genes from completely different organisms into plants was troubling. Did scientists want to redesign nature entirely, and would they ever be able to grasp what the long-term consequences of what they had started would be?

It was also feared that GM foods would be dangerous to consume and that the edited plants would spread uncontrollably in nature. However, in 2016 an extensive US review of 20 years of GMO research was published. It documented that the existing GM plants had neither caused health damage to the livestock they had been fed to, nor to the people who had consumed them.¹⁴ Other major studies have shown similar results: the application of genetic modification does not in itself involve higher risks than, for example, conventional plant breeding technologies.¹⁵ It has been argued by GMO opponents that feeding animals with GM food has caused diseases such as infertility, tumours and premature death. In none of the cases, however, did the documentation presented by the opponents live up to the requirements for scientific studies.¹⁶

Nonetheless, it should be noted that the existing risk assessments are based on only a few types of GMOs. The fact that no risks have been shown in these particular types is therefore no guarantee that no risks will be found in other types of GMO in the future. For example, the problem of spreading (invasiveness) depends on which traits are

¹³ Danish Agricultural Agency. 2018. *Hvad kan de nye planteforædlingsteknikker bruges til og hvordan skal de reguleres? [What is the potential of the new plant breeding techniques, and how should they be regulated?]*

¹⁴ National Academies of Sciences, Engineering, and Medicine. 2016. *Genetically Engineered Crops: Experiences and Prospects*. Washington, DC: The National Academies Press,

¹⁵ EU Commission. 2010. *A decade of EU-funded GMO research (2001-2010)*, 16

¹⁶ American Association for the Advancement of Science. 2012. *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods*

being edited or inserted. So far, we have almost exclusively seen types of traits that are advantageous only in the cultivated ecosystem where, for example, herbicides are applied. Such alterations would not do well outside the fields. But other traits such as salt and drought tolerance might grant the plant an advantage in the wild and thereby increase its potential to spread.

Therefore, the risk assessments completed so far show that *not all* GMOs pose a risk to human beings or to nature – i.e. there is no basis to reject all GMOs as risky. However, the studies cannot be used to argue that *no* GMOs are risky. It is conceivable that at some point in time GMOs will be developed with different traits that will pose a risk to humans or to nature. Similarly, it is conceivable that in the future new varieties developed by means of conventional technologies could turn out to be risky.¹⁷ This indicates a need to establish an authorisation system that does not treat all GMOs as risky and all other new varieties as not risky. A system that to a higher degree looks at the type of alteration that has been introduced as the basis of deciding which varieties needs to be subjected to risk assess.

The public opposition to GMO, especially in Europe, has not diminished over time. Whereas the acceptance of gene technology to develop new treatments for diseases in humans has risen since first introduced, the same cannot be said for applying gene technology to plants. There are several reasons for this tendency, which we will return to.

The strongest opposition is in Europe, and until 2017, only one single crop has been authorised for cultivation in the EU. It is a type of maize (MON810), which is grown in approximately 100,000 hectares every year in a number of southern European countries.¹⁸

In the rest of the world GMO is gaining ground. So far, four types of crops (soya beans, maize, cotton and oilseed) and two types of traits (herbicide tolerance and insect resistance) have been dominant. Among them, GMOs with either of these two traits made up 99% of the GMO-covered area in 2017.¹⁹ The GMO crop that is used most widely in the world is RoundupReady soya that, by means of genetic modification, has been made resistant to the herbicide glyphosate, which is the active substance in

¹⁷ The Lenape potato is an example of conventional breeding leading to serious and unintended effects, see Zitnak A and Johnston GR. 1970. Glycoalkaloid content of B5141-6 potatoes. *American Potato Journal*, Vol 47, no 7: 256–260

¹⁸ Danish Agricultural Agency. 2018. *Hvad kan de nye planteforædlingsteknikker bruges til og hvordan skal de reguleres? [What can the new plant breeding techniques be used for, and how should they be regulated?]*

¹⁹ ISAAA. 2017. *Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years*. ISAAA Brief 53, 105

Roundup from Monsanto, a multinational seed and chemical company. The resistance implies that the genetically modified soya is not affected when farmers spray it with Roundup whereas other plants, weeds, etc. are killed.

Bt cotton is an example of an insect-resistant crop that carries a gene from a bacterium that makes the plant produce Bt toxin. Bt toxin is harmful to certain insect pests, which are thus controlled without the farmer having to use pesticides. This is an advantage because it avoids the spread of toxins that would affect several organisms in and outside the field and not just those insects that damage the crops.²⁰

There are, however, also problems associated with these uses of GMO. There have been reports of insects and weed plants that have developed resistance to a herbicide, likely as a result of local excessive use of that particular substance.²¹

What many of the reported problems generally have in common is that they are not the result of genetic modification in the sense that they will be present in any genetically modified organism. The problems concern only *certain GMOs*, more specifically those that are dominant today which have been developed for a certain type of farming characterised by monoculture. The widespread use of GMO plants with, for example, Roundup-tolerant traits has even given rise to monocultures of plants with this transgene.

This has made many critics not impressed by this type of GMO. They consider it a problem that the varieties have been developed by the agrochemical industry, which appeals to large-scale farming, monoculture and a high requirement of external resources and where the sale of seed corn is linked to the sale of chemicals, which essentially is not sustainable. The fact that these GMO varieties are covered by patents, while Europe has had no tradition for patenting new varieties, has also led to widespread criticism. Because of the patenting system, farmers who would wish to set aside seed corn for next year's sowing, cannot do so because they are forced to buy the seeds from the seed company. This can be a problem for farmers in developing countries in particular.

The fact that GMO with these two traits are so dominant has made many critics regard GMO as inseparable from the use of pesticides, dependence on multinational seed and chemical companies, less diverse cultivation systems and patenting. All of this had

²⁰ ISAAA. 2017. *Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years*. ISAAA Brief No. 53. ISAAA: Ithaca, NY, p 3

²¹ National Academies of Sciences, Engineering, and Medicine. 2016, 144

made it difficult for Europeans to consider GMO as progress, and the opposition has been consistently strong throughout all these years.

4. CRISPR as a tool to introduce positive climate traits

In recent years, quite a lot of research has been carried out by universities and smaller manufacturers to develop genetically modified plant varieties with entirely different traits than the two mentioned above. They for example develop plants that are more resistant to disease, that are healthier to eat, that can keep for longer (so reducing food waste), etc.²²

In addition, varieties with beneficial climate traits are developed, including:

- Varieties that are **high-yielding** and thus area-efficient while being able to survive with **less fertilisation, spraying or ploughing** (e.g. *de novo* domesticated tomato) or **store more CO₂** in the roots (e.g. perennial grains) (**climate mitigation**),
- Varieties that can adapt to the climate changes, e.g. by being **drought resistant or salt tolerant (climate adaptation)**.

Both conventional and organic production still have far to go before they meet the need for making plant production better adapted to a changing climate. Conventional production is high-yielding, but is a burden to the climate and the environment. Organic production is in many cases better for the environment²³, but produces a lower yield per hectare or per animal. It therefore requires a larger area that could have been used for natural habitats, e.g. forest. Both production types could turn out to suffer substantial reductions in yield if climate-resilient varieties are not developed. Gene technology is one of many means that appears capable of offering solutions.²⁴

A new field of research departs from the fact that many of the traits required to achieve the above-mentioned goals are already present in the plants' wild relatives from which the commercial variants were once developed. Or in wild plant species that so far have not been developed for modern food production. This has inspired researchers to start with these wild species and refine them rather than continue breeding on the present crops. Only this time make the improvements in a more

²² Norwegian Biotechnology Advisory Board 2018. *Genteknologiloven – invitasjon til offentlig debatt. Sammendrag [Gene technology legislation – invitation to public debate. Summary]*.

²³ However, a knowledge synthesis from 2015 has indicated that the nitrogen load from organic pig farms was significantly higher compared to conventional pig farms.
http://icrofs.dk/fileadmin/icrofs/Diverse_materiale_r_til_download/Vidensynte_WEB_2015__Fuld_laengde_400_sider.pdf

²⁴ Other methods include contemporary MAS and changed agricultural practices – e.g. crop rotation practices, choice of crops, two varieties per season, etc.

targeted way through so-called *de novo* domestication.^{25,26} This process is based on mutating so-called domestication genes in the not yet cultivated plant^{27,28}.

A domestication gene is a gene that, once mutated, results in a plant with desirable traits for human use of the plant. The result of the mutation is often the destruction of the gene or its delicate regulation. This leads to the loss of a trait that is important to the wild plant but might be undesirable from a cultivation perspective. For example, wild rice drops its ripe seeds in the blowing wind while cultivated rice has been bred to avoid this. Whereas this is a loss for the wild plant because it makes it difficult for it to spread, it is an advantage for farmers who want to harvest the rice. We know of many domestication genes today, although the number of domestication genes is still debated.²⁹ Research published in the autumn of 2018 has shown that wild tomatoes can be *de novo* domesticated by introducing only six mutations. This allows wild or semi-cultivated crops which already possess the desirable positive traits to be *de novo* domesticated, in principle, by mutating genes that show similarities with domestication genes in close relatives. For example, it is doubtful whether transgenesis or mutation technologies can be used to tweak a given plant to store more CO₂ in its roots. But if a wild plant is known to have this trait already, it should, in principle, be possible to use mutation technology to domesticate the plant while preserving its ability to store CO₂ in its roots. However, the increased carbon capture in the roots will ultimately require improved photosynthesis for the plant to maintain its yield.

Domestication genes

Recent years' sequencing of the plant genome has led researchers to identify the genes – so-called domestication genes – that make the plants commercially attractive, e.g. in terms of fruit size and fruit yield, shelf life and form.

The background paper describes an example of such a *de novo* domesticated variety developed by means of the CRISPR technology. This is the result of entirely new

²⁵ Østerberg JT, Xiang W, Olsen LI, Edenbrandt AK, Vedel SE, Christiansen A, Landes X, Andersen MM, Pagh P, Sandøe P, Nielsen J, Christensen SB, Thorsen BJ, Kappel K, Gamborg C, Palmgren M. (2017) Accelerating the domestication of new crops: Feasibility and approaches. *Trends in Plant Science*. 22(5):373-384.

²⁶ Zsögön A, Cermak T, Voytas D, Peres LE. (2017). Genome editing as a tool to achieve the crop ideotype and *de novo* domestication of wild relatives: Case study in tomato. *Plant Science*. 256:120-130.

²⁷ Doebley JF, Gaut BS, Smith BD. (2006) The molecular genetics of crop domestication. *Cell*. 127(7):1309-21.

²⁸ Comai L. (2018). The taming of the shrub. *Nature Plants*. 4(10):742-743

²⁹ Torkamaneh D, Laroche J, Rajcan I, Belzile F. (2018). Identification of candidate domestication-related genes with a systematic survey of loss-of-function mutations. *Plant Journal*. 96(6):1218-1227.

research^{30,31} and involves studies where wild tomato yielded more, larger and more resilient fruits (the fruits of wild tomatoes are rather small, so they are low-yielding) merely as a result of a few and minimal CRISPR-induced mutations in the plant's DNA. The wild tomato itself has a number of the traits that are desired and are difficult to breed in modern tomato varieties:

- Resilience to drought, which could limit the need for irrigation and increase yields in periods of drought
- Resilience to pests, which could limit the need for pesticides
- A high content of lycopene, which is considered to have positive health effects
- Salt tolerance, corresponding to tolerance to water shortage, as salt extracts water from the plant³²

CRISPR technology is thus used to perform precision mutagenesis, i.e. 'internal' editing of the plant's genes, but carried out with higher accuracy compared to traditional mutagenesis. Genes from other organisms are not added.

The other example concerns work done to modify the wild grass *Thinopyrum intermedium* (or *Intermediate wheatgrass*) where conventional plant breeding has so far been a very slow process, and where the CRISPR technology is thought to be able to accelerate the breeding process. This is another variety that has a lower yield than its developed modern varieties, but on the other hand has several climate-friendly features, first and foremost because it is a perennial and has a large root system (up to 3 m deep). It can be 'cut' like lawn grass, which means no harvesting of the roots and no ploughing. This offers several advantages to farmers, the environment and the climate.³³

- the plant can survive long periods with limited precipitation and is thus better adapted to weather fluctuations caused by global warming
- the plant is better at absorbing nutrients, which limits the requirements for fertilisation and reduces nutrient leaching

³⁰ Li T, Yang X, Yu Y, Si X, Zhai X, Zhang H, Dong W, Gao C, Xu C. (2018). Domestication of wild tomato is accelerated by genome editing. *Nature Biotechnology*. doi: 10.1038/nbt.4273

³¹ Zsögön at al. 2018. De novo domestication of wild tomato using genome editing. *Nature Biotechnology* 1. October, doi:10.1038/nbt.4272

³² Zsögön at al. 2018

³³ Lubofsky, E. 2016. The promise of perennials: Working through the challenges of perennial grain crop development. *CSA News* Vol. 61 No. 11, p. 4-7

- the plant binds more carbon in the soil, which is good for the climate
- it becomes harder for weed plants to take hold, which reduces the need for herbicides or manual weeding
- farmers can avoid many rounds in the fields whether it is fertilising, spraying, ploughing, harrowing, etc., which emit CO₂ and are time-consuming
- the soil quality is improved because the roots reduce erosion and add carbon and structure, and because the soil is not compressed by the frequent passage of machinery

With the first mapping of the *T. intermedium* genome in 2018³⁴ and knowledge of the wheatgrass' domestication genes, a much more targeted breeding process looks achievable. It can prove difficult and time-consuming to use conventional breeding means to develop a variety with all the traits that makes it both commercially useful and climate-friendly. Crossbreeding of *T. intermedium* with other wheat variants such as spelt has been tried in various forms, but those variants that gained a remarkably better yield lost their perennial qualities. This is yet another example where it is conceivable that the CRISPR technology could be used to domesticate the crop through targeted mutations in domestication genes, and without losing good genes in the crossing process. It might be easier to breed already perennial grass into a perennial grain than turning a modern annual grain, such as wheat, into a perennial.

Even with the use of CRISPR technology, it is not certain that we can produce varieties that are at the same time climate- and environment-friendly, high-yielding and commercially attractive. But no matter the technology, we should be able to make progress. As indicated above, the use of CRISPR technology to perform precision mutagenesis, will likely allow progress to be made far quicker than the use of traditional technologies.

Because of CRISPR, even small research environments and companies can now get much more involved in gene technological processing with the potential of making food production significantly more adapted to the climate. The problem in terms of developing GMO that benefits society is, however, that, in Europe, universities and small-scale manufacturers cannot get their plants authorised for deliberate release

³⁴ Kantarski, T, Larson, S, Zhang, X et al. 2017. Development of the first consensus genetic map of intermediate wheatgrass (*Thinopyrum intermedium*) using genotyping-by-sequencing. *Theoretical and Applied Genetics*, Vol 130, no 1: 137-150

into the environment because they cannot afford to go through the comprehensive safety assessments required by EU legislation.

5. EU GMO legislation and the mutagenesis exemption

In 2001, the public opposition in the EU against GMO resulted in the adoption of the so-called Deliberate Release Directive,³⁵ which establishes that genetically modified organisms must undergo an authorisation procedure before they can be released for cultivation in the EU. Thus, they must satisfy multiple requirements that new varieties created through other means must not. Among other things, the manufacturer must carry out extensive assessments of risks to human health and the environment posed by the deliberate release of the specific GMO.

Since the conduct of these risk assessments is a major economic expenditure, it is a paradox that only the multinational seed companies can afford risk assessing their GMOs. Researchers at universities and small companies are in reality prevented from seeking authorisation of their plants in the EU due to the cost of conducting these risk assessments.

Lately, another paradox of the legislation has been discussed. In the directive, new varieties whose genes have been edited through irradiation or chemical treatment have been exempted from the authorisation procedure through the directive's so-called mutagenesis exemption. The reason is that they "have conventionally been used in a number of applications and have a long safety record."³⁶

This seems to indicate that organisms developed by mutagenesis are not considered risky. In response to this, researchers have pointed out that the type of genetic changes involved in employing CRISPR technology e.g. to introduce domestication genes as described above are much more limited and controlled than mutations introduced by traditional mutagenesis. In other words, you cannot credibly claim that the uncertainty associated with the use of CRISPR makes the technology more risky than the practices we are already using and have used without any significant problems for centuries – on the contrary, the uncertainty seems to be far smaller. This will be elaborated on in the background paper (available only in Danish on the website of the Danish Council on Ethics).

³⁵ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

³⁶ Ibid, whereas-clause 17

The European Court of Justice was requested to decide on these considerations, and it delivered its judgment on 25 July 2018. To many people's surprise, the court upheld that only organisms obtained by traditional mutagenesis should be exempt from the directive's requirement for safety approval. The grounds cited by the court was that "the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis."³⁷

Whereas opponents of GMO were generally satisfied with the judgment, the research communities have demanded that the legislation be changed. They want the legislation to no longer be based on *which technique* has been used to develop the plant, but to focus instead on *which traits* have been added to the plant.³⁸ It are good reasons to continue risk assessing organisms that have been added certain traits – for example, traits with particular risks of undesirable effects on the environment and health – before we start using them. But other types of changes that add traits that we know carry no increased risks should not be subjected to such extensive risk assessment requirements.³⁹

6. Ethics: Is genetic modification of plants wrong in itself – wrong in every case?

Today, we face a challenge where both sides of the debate claim that ethical concerns support their views: The opponents make the claim that it is ethically problematic to make such fundamental changes to nature as is done by gene technology, and that it is wrong to expose human beings and the nature to the risks of GMO cultivation. Advocates stress that if a technology can help to solve very serious problems that could potentially cost human lives, and if no special risks have been identified from its use, it would be wrong not to make use of the technology.

From an ethical point of view, it is relevant to distinguish between whether something such as a technology is *wrong or problematic in itself*, regardless of its application. Some of the criticism raised against GMO has been characterized by deeming *all* applications of gene technology with plants as wrong. Other critics find that the use of

³⁷ Judgment of the court, case C-528/16, 25 July 2018

³⁸ It is important here to distinguish between a purely physical change, e.g. if it involves a major insertion or a replacement of a single base pair on one side, and the functional (phenotypic) change (the trait being added) on the other. For example if the trait is well known and already present in the concerned food product plant, or if it concerns a completely novel trait that has been obtained from another species or produced synthetically.

³⁹The European Societies of Plant Biology. 2018. *Regulating genome edited organisms as GMO's has negative consequences for agriculture, the society and economy*

gene technology on plants is wrong, but that in some situations other concerns still make it ethically acceptable to apply the technology.

Another approach could be to consider gene technology as being wrong or problematic when used in certain ways that *lead to wrong outcomes*. In much the same way that most people would not consider knives to be problematic in themselves, but obviously considers it wrong if a knife is used to stab another person. This type of GMO criticism would not object to GMO applications that can serve societal objectives, e.g. by helping to fight climate change, or for purposes that are not risky. While applications that, for example, are risky because they have undesirable effects on the environment or the health of humans and animals would be considered wrong – because they are risky, not because they are the result of gene technology.

Much of the criticism directed at GMOs – e.g. that they promote the use of pesticides, are subjects to patenting, are developed by multinational companies or planted in areas where rain forest used to grow – is not criticism of GMO as such, but of the conditions that surround certain applications of certain GMOs. In other words, these problems concern *certain particular* GMOs. The problem arises when these considerations are used to argue against *all* GMOs.

This is problematic because a GMO might very well be developed at a university, have no patent, not require the destruction of rainforest, not be pesticide-resistant, etc. The criticized properties are not the result of genetic modification in the sense that all GMOs would possess them. Consequently, this criticism cannot justify a general opposition to GMO. Instead they can be used as arguments for the far less extensive claim that some GMOs are problematic, e.g. those that are tolerant to pesticides. What makes them problematic, then, is their ability to tolerate pesticides. Since not all GMOs tolerate pesticides, this is not an argument that can be used against GMOs in general; it is irrelevant for GMOs that do not tolerate pesticides.

In the following, we will focus on the general arguments against GMOs, i.e. arguments that are often put forward as reasons to reject the use of GMO as such because genetic modification of plants is considered problematic in itself. We shall, however, also consider the ‘opposing’ argument that, morally, we ought to use the types of GMOs that could be beneficial, e.g. by advancing the UN global goals, if there are no strong arguments not to use them. The three arguments thus are: 1) Genetic modification of plants is wrong because it is particularly risky, 2) Genetic modification of plants is valuable if it can help achieve the UN Global Goals, and 3) Genetic modification is wrong because it is unnatural.

6.1 Genetic modification of plants is wrong because it is particularly risky

A majority of Europeans consider it unsafe to consume GMO (59%) and say GMO is harmful to the environment (53%).⁴⁰ If it is a characteristic of all genetically modified plants that they are risky in this way, GMO development should always be considered wrong. However, the known uses of GMO have so far not been shown to cause harm to human beings or the nature that was a result of the genetic modification. Of course, this does not mean that in the future, no GMOs that could turn out to be harmful to consume or could spread uncontrollably in nature will be developed. Some will also argue that long-term effects of the GMOs which have already been risk assessed might still emerge at a later point in time, while others will claim that 20 years is long enough to safely say that there is no evidence to consider all genetically modified plants as risky – although they will admit that there could still be reasons to risk assess some types of GMO before use. The most frequent arguments for and against are:

6.1.1. Gene modification is particularly risky

The fact that no risks have been observed for genetically modified plants so far does not mean that problems will not emerge in the long term. Changing the genes of plants with gene technology is hazardous in ways that breeding using other processing techniques are not. And if, along the way, diseases in humans or damage to the ecosystems occur that researchers did not anticipate, it will be too late to reverse the development.

It is an inherent quality of the technology that it moves into territory beyond the comprehension of human beings. We should therefore avoid using it in plant breeding based on the so-called *precautionary principle*. The interpretation of this principle is often that if there is reasonable suspicion that an activity could seriously harm human beings or the environment, measures against it must not be delayed on the sole ground that there is scientific uncertainty when it comes to the risks of a technology.⁴¹

6.1.2. Gene technology should not (always) be considered risky

As mentioned earlier, 20 years of GMO risk assessments have not established that GMO is risky in general. Obviously, it cannot be guaranteed that no damage will emerge in future if other types of changes are made than those we have experience in today. But this is also the case if other changes are introduced using irradiation or chemistry for example.

It seems groundless today to continue claiming that there is scientific uncertainty as to whether genetic modification in itself entails particularly high risks. It is the type of

⁴⁰ European Commission. 2010. *Biotechnology report – Special Eurobarometer*

⁴¹ Peter Pagh in the Danish encyclopaedia 'Gyldendals Store Danske' (http://denstoredanske.dk/Samfund,_jura_og_politik/Jura/Landboret_og_milj%C3%B8ret/forsigtighedsprincip)

modification – the trait added – that determines the risk, not the technology used to obtain it. Equal things should be judged equally, and a given change introduced with CRISPR technology is no more risky than the same change introduced with irradiation or chemistry (the use of which even produce unintended mutations with unknown consequences). The question of whether to carry out risk assessments before the introduction of a new variety should therefore depend on the trait being added, not the technology used to achieve it.

6.2 Genetic modification of plants is valuable if it can help achieve e.g. the UN Global Goals

The focus of GMO discussions often concerns avoiding negative traits (such as unnaturalness), or undesirable consequences (such as health risks or undesirable effects on nature).

Those who find that genetic modification is an inherently risky or unnatural technology and therefore problematic to apply, may still consider whether beneficial effects of using GMO could, in some situations, outweigh these concerns. Positive impacts on the climate or sustainability in general could represent such beneficial qualities. If genetic modification could contribute considerably to mitigating the sustainability problems that in many areas, including the climate area, are serious, this could in some perceptions outweigh the problems that follow from the lack of naturalness.

Another approach could be to weigh the overall consequences of introducing GMO by comparing the consequences of using a given GMO with the consequences of not using it. If the consequences for sustainability (and thus for the conditions of human life) of using a given GMO are better compared to not using it, then we ought to use it.

Whether – and if so to what extent – positive features such as sustainability should be included in the assessment of given GMOs is debated, the arguments for and against often being:

6.2.1. Positive consequences for the climate and sustainability should be included in the assessment of a GMO

If the global temperature increase is to be kept below 1.5°C above pre-industrial levels, we will need to produce much more food in a much smaller area and with fewer resources. Used in the right way, genetic modification could contribute to this although, obviously, the technology cannot single-handedly solve the problems of reducing the agricultural CO₂ impact and the challenge of feeding a rapidly growing

global population. However, the current situation is so severe that we cannot refrain from using *all* available means to ensure food production in the future. It is not a question of whether to use gene technology *or* rather introduce dietary changes; in the current situation, we need to use all means available if there are not very good reasons not to do so. Similarly, if a given GMO can help solve other serious problems, it should be brought to use.

6.2.2. Positive contributions to sustainability cannot outweigh the problems of GMO:

It is true that in many areas it is a problem that our way of living is not sustainable, meaning that for example climate changes are threatening the conditions for human life and the nature. There could, therefore, be situations where it would be necessary to accept solutions that are otherwise considered problematic as the lesser evil. But using such a fundamentally unnatural technology like genetic modification entails problems that are so serious that, in the bigger picture, they cannot be outweighed by the modest contribution to climate change mitigation offered by some GMOs. It is untrustworthy to rely on gene technology to make an important contribution to the climate and sustainability when 30 years with GMO have given no convincing results to that effect. Other means, such as changing consumption patterns towards more plant-based diet will contribute far more to sustainability compared to genetic modification of plants. There is a tendency to pin unrealistic hopes on technology to solve all problems so that we will not have to give up a lifestyle that we have become accustomed to, which is based on a non-sustainable high consumption. It clouds the acknowledgement that we need to make fundamental changes to the way we live and to get used to a much lower and more sustainable consumption.

6.3 Genetic modification of plants is wrong because it is unnatural

A survey shows that 70% of the European public consider GM food as unnatural.⁴² Other surveys indicate that many people link the perception that something is unnatural to the belief that it is wrong.⁴³ This type of opposition can be substantiated in the belief that nature and naturalness possesses a value that makes it problematic for humans to interfere with it. There are differing understandings of what it is precisely that human beings should not interfere with. One view is that human beings violate nature if they seek to control nature and exploit it for their own purposes in any way. Another and more moderate view is that certain processes in nature should be allowed to take place without human intervention. Therefore, a forest planted by humans can still be considered natural if the plants are then allowed to develop without human interference. In this understanding, then, it should not necessarily be

⁴² European Commission. 2010. *Biotechnology report – Special Eurobarometer*

⁴³ Scott S, Inbar Y, Wirz C, Brossard D and Rozin P. 2018. An Overview of Attitudes Toward Genetically Engineered Food. *Annual Review of Nutrition* no 38: 459-79

considered unnatural if plants were modified through conventional breeding because the changes brought about would be considered similar to the changes nature itself could have created. In this view, what humans ought to abstain from would therefore be to completely deviate from natural processes, e.g. by inserting genes from different species into an organism.⁴⁴

Although this argument has a wide appeal, it is difficult to pin down exactly why it is considered wrong to change nature or radically break with its normal evolution (see Annex on natural food products – available in Danish only on the website of the Danish Council on Ethics). The reason for this is that human beings change nature every day, e.g. through treatment of diseases or plant and animal breeding without it being considered as wrong. This raises the question why genetically modifying plants it is considered unnatural in a way that is seen as wrong while other unnatural acts are not considered wrong. Below we summarise some of the key arguments, which state that it is wrong to radically change nature, followed by a number of counter arguments, which state that it is not in itself wrong to do so.

6.3.1 It is not wrong to change nature even though nature is valuable in itself

We constantly change nature, for example through conventional breeding. And if clearly natural things such as cancerous tumours or tsunamis are seen as negative, while clearly unnatural things like appendectomies or computers are seen as positive, it becomes clear that naturalness cannot be used as a measure for whether things are good or bad. At the same time, it is not clear how to understand 'the natural' let alone draw a clear line and say that what lies beyond it is 'too unnatural'. For example, it is not necessarily the case that changes induced by means of gene technology are extremely comprehensive, or that the same change could never spontaneously emerge in nature. While CRISPR technology can be used to make major changes, it can also be used to make changes equivalent to those obtained by conventional breeding (mutagenesis), or changes that can occur spontaneously in nature.

But the fact that nature has inherent value does not mean that human beings should never make changes to it. It is a fact of life that we exploit nature, but we must of course at the same time take good care of it. So impacting nature to the extent that the livelihood of current and future human beings is put at risk, e.g. by causing temperature rises above 1.5°C above pre-industrial levels, or to cause species extinction at the current speed of the biodiversity crisis, is morally problematic to a serious degree.

⁴⁴ An account of a gradualistic perception of naturalness can be found in: Sandin, Per. 2017. How to Label 'Natural' Foods: a Matter of Complexity. *Food Ethics*, Volume 1, Issue 2, pp 97–107

6.3.3. *Changing nature is at odds with the inherent value that nature possesses*

Humans should do more to adjust their way of living to the given nature rather than constantly trying to transform it to match their desires and treat nature merely as a resource. It is inherently wrong to constantly attempt to subordinate nature and change it, and it is this conduct that has brought us to where we are today with a climate crisis and other sustainability crises. It is true that human beings cannot avoid changing nature and exploiting it to survive, but the more we depart from the natural and the more high-technological tools we develop, the more problematic it is.

Gene technology is wrong because it is more unnatural than conventional breeding and thus a further step in the wrong direction. When it comes to the climate crisis and the other manmade crises, gene technology is part of the problem rather than part of the solution. The only way forward is for human beings to commit to the fact that we are part of nature, not its masters. We should find a way to live with it rather than increasingly change the natural balances with the serious consequences that we witness today.

The Act on the Danish Council on Ethics provides that “Respect for nature and the environment is based on the premise that nature and the environment are inherently valuable.” The members of the Council adhere to this at an overall level. However, this does not reflect a commitment on the part of the individual members to specific philosophical approaches.

7. The Council's recommendations

7.1 It is ethically problematic to reject GMO varieties if they can help alleviate or solve significant problems and there are no good arguments for rejecting them

Some members (Morten Bangsgaard, Anne-Marie Axø Gerdes, Kirsten Halsnæs, Mia Amalie Holstein, Poul Jaszczak, Henrik Gade Jensen, Bolette Marie Kjær Jørgensen, Henrik Nannestad Jørgensen, Rune Engelbreth Larsen, Eva Secher Mathiasen, Rico Mathiesen, Jacob Giehm Mikkelsen, Lise von Seelen, Karen Stæhr and Signild Vallgård) find that there are today several examples of GMOs that show promising signs of alleviating or solving significant problems, and we have here shown two.

The members find that an authorisation system should be introduced that does not put obstacles in the way of GMOs based on the technology used to produce them (process requirement). Instead, the focus should be on the type of trait being added to a new variety. The requirement for risk assessment should therefore apply to varieties that are considered to pose an increased risk to human health or the environment (product requirement).

Many factors have changed since GMO was introduced more than 30 years ago: genetic modification technologies have improved and have become much more accurate. In the 20 years of cultivating herbicide- and insect-resistant plants, there have been no reports of harm to human beings or the nature resulting from the use of genetic modification in itself.

Meanwhile, in the 30 years that have passed, several sustainability problems have become more urgent. For example, global warming is threatening the life conditions of millions of people even in the short term, and if temperature rises are not contained, the consequences for our children and grandchildren will be unpredictable. This should weigh heavily in an ethical assessment. GMO alone cannot solve the climate challenge, but the situation today is so serious that all measures should be employed unless there are substantial arguments not to do so.

Here, we have described two types of GMOs: de novo domestication of wild tomato and intermedium wheatgrass with several beneficial climate features. We have found no compelling arguments against bringing them into use.

The wild tomato has been modified by CRISPR technology by 'turning off' genes in the plant without inserting any genes from other species (precision mutagenesis). The wheatgrass could be developed in the same way, but is not there yet.

Such changes are very close to the mutations that occur spontaneously in nature, which makes it difficult to see why they should be perceived as radically unnatural. They need not under controlled conditions collide with nature's inherent value or worsen the effects of the general, negative effects of humans in a geologic epoch that more and more researchers refer to as the Anthropocene. That is the era where humans influence nature more than the other way around – rather than the Holocene which is the official term for the period after the last ice age.

In principle, the changes could have been achieved with traditional mutagenesis techniques (although the changes made by these techniques would typically be more inaccurate and slow) and should therefore not be seen as more risky than the changes we already accept without demanding risk assessments because experience has shown that they are not risky. The fact that new varieties could be developed faster with CRISPR could potentially be problematic if their traits are not risk assessed. On the other hand, accelerated variety development could be considered a strength in a situation with rapid climate change where a need for short term development of new varieties may arise.

As mentioned, several other arguments often raised against GMOs are not relevant to the GMOs described in this statement: they are not developed or patented by multinational companies, they would presumably reduce rather than promote the use of pesticides, water and other natural resources, and they also have other beneficial environmental effects such as their ability to improve soil quality, limit erosion and add carbon and structure to the soil.

These examples refute the arguments that genetically modified plants in any form are more unnatural or more risky than plants developed by traditional means.

7.1.1 Absence of particular risks

Some of these members (Morten Bangsgaard, Anne-Marie Axø Gerdes, Mia Amalie Holstein, Poul Jaszczak, Henrik Gade Jensen, Bolette Marie Kjær Jørgensen, Henrik Nannestad Jørgensen, Rune Engelbreth Larsen, Eva Secher Mathiasen, Jacob Giehm Mikkelsen, Lise von Seelen, Karen Stæhr and Signild Vallgård) *find* that the absence of particular risks is sufficient to allow the authorisation of new varieties.

7.1.2 Contribute to sustainable development

Other of these members (Kirsten Halsnæs, Rico Mathiesen) find that it ought to be an actual requirement when new GMOs are authorised that they are both deemed not to be risky and that they will contribute to sustainable development overall. They emphasise that GMO must be assessed in terms of their potential positive consequences for example in the form of increased access to food products, contribution to poverty reduction, health and other of the UN Global Goals, and in terms of a positive impact on the climate in the form of new crops with a high carbon-binding potential. The reason for this is that democratic societies should take into account when public opposition against a technology is persistent for such a long period as we have seen in the GMO area. The politicians should not ignore such opposition and ease the GMO requirements unless there are very good arguments to do so. In this situation, the absence of increased risk is not sufficient to derogate from the requirement for an extended risk assessment. In addition, it should be a requirement that the variety can contribute to sustainable development.⁴⁵ Such an authorisation requirement is found in the Norwegian gene technology act.⁴⁶

⁴⁵ See also Zetterberg, C and K Björnberg. 2017. Time for a New EU Regulatory Framework for GM Crops? *J Agric Environ Ethics* 30:325–347

⁴⁶ Lov om framstilling og bruk av genmodifiserte organismer m.m. (genteknologiloven) [Act on production and use of genetically modified organisms, etc. (the Gene Technology Act)] from 1993. Section 10 provides that "The deliberate release of genetically modified organisms can only be authorised when there is no risk of harmful effects on the environment and health. Furthermore, the assessment must attach

A large majority of the Council members thus find that not all GMOs should be prohibited solely because of the process, gene technology, used to produce them. Some GMO types are compatible with both the absence of particular risks and the contribution to sustainability and respect for nature's own processes. GMOs such as these should not be rejected or obstructed by subjecting them to risk assessment requirements that are not imposed on similar new varieties developed by conventional means.

Consequently, Denmark should work towards changing the authorisation procedures to a product-based system (looking at the organism's traits and risks regardless of creation method), thus moving away from a process-based system (looking at the method or technology used to modify the plant). It should be the end-product – a combination of trait, plant species and breeding area – which decides if a new variety should be subjected to a risk assessment process or if it can be introduced upon an administrative assessment.

Such a system can be designed in various ways, and different versions have emerged in the recent years. The authorisation system used in Canada is based on an assessment of the end-product. All so-called plants with novel traits must be authorised regardless of the technology used to produce them.⁴⁷ Norway has long had an authorisation system where requirements for societal benefits, sustainability and ethics are of key importance to the authorisation of GMOs. The Norwegian Biotechnology Advisory Board has just submitted a proposal for a new authorisation procedure for GMOs (plants and animals). It has three levels of authorisation requirement depending on the genetic modification being made.⁴⁸ Other proposals for changing the authorisation procedures have come from the Dutch government, which proposes to exempt plants obtained with so-called New Plant Breeding Techniques, including CRISPR, if they are considered at least as safe as plants obtained with traditional breeding.⁴⁹

particular importance to whether the deliberate release is beneficial to society and is suited to promote sustainable development"

⁴⁷ See the criteria here: <http://www.inspection.gc.ca/plants/plants-with-novel-traits/eng/1300137887237/1300137939635>

⁴⁸ Norwegian Biotechnology Advisory Board 2018. *Forslag til oppmykning av regelverket for utsetting av genmodifiserte organismer [Proposal for easing the regulations for the release of genetically modified organisms]*. Also see Bratlie, S. et al. 2019. A novel governance framework for GMO. *EMBO reports*

⁴⁹ The Netherlands Ministry of Infrastructure and the Environment. 2017. *Proposal for discussion on actions to improve the exemption mechanism for genetically modified plants under directive 2001-18-EC*. See also the proposal from Bioökonomierat, the German Bioeconomy Council. 2018. *Genome editing, Europe needs new genetic engineering legislation - preliminary version*

When assessing which new varieties to subject to risk assessment, the Danish Council on Ethics stresses that the main focus should be on the nature of the added change, not on the technique used to obtain it.

7.2 It is ethically problematic to use gene technology to change plants

One member (Herdis Hansen) finds that gene technology is the exponent of a way of thinking that fundamentally sees the goal of the human race as continuously extending their control over nature, enabling a far more extensive interference with nature's own processes, compared to conventional breeding.

This form of control of nature is wrong because it does not respect the inherent value of nature. The technology should therefore not be used, and politicians in Europe should listen to the national majorities and respect their wishes of avoiding genetically modified foods.

This member acknowledges that the climate changes are serious and that it is important to find ways of keeping the global temperature rise below 1.5°C over pre-industrial levels. However, this does not mean that genetic modification would be a suitable technology to achieve this goal.

Throughout history, human beings have continuously increased their control of nature, and we have reached a stage where it has been suggested to name our age the Anthropocene – the age where humans change nature more than the other way around. Climate change is only one of the results of this approach to nature and the disrespect for its balances. It is the incessant attempts of human beings to subordinate and change nature that have brought us where we are today. Gene technology is an expression of this approach to nature; it is more unnatural than conventional breeding, because it makes it possible to break with the processes that take place in nature. Using gene technology, humans can 'short-circuit' the evolutionary mechanisms, and introduce changes, that would not occur in nature without human interference. By moving further away from the natural processes, gene technology is taking one further step in the wrong direction.

Nature and 'the natural' have inherent value, and as human beings we should do more to adjust the way we live to the given nature rather than try to transform it again and again to match our desires.

Combating climate change requires a radically different perspective on nature and a much less materialistic way of life. It is necessary that we overcome the way of thinking that sees the 'good life' as dependent on a consumption, which is completely

detached from what the natural foundation can sustain. The only solution is for us to start adjusting our way of life to the natural balances and to respect the limitations that is set by the natural foundation. A fundamentally unnatural technology such as genetic modification does not offer any solutions to these problems, because the technology itself is an expression of a way of thinking that wishes to exploit nature to meet our needs.

There are no easy solutions or technological fixes to solve the problem of climate change or any of the other complex crises that the UN climate goals address. Pretending that gene technology can offer such a technological fix runs the risk of shifting the focus away from the actual problems and delaying the realization that truly fundamental changes are needed.

Therefore, this member cannot support measures to ease the authorisation system for GMOs. A system that is based on product authorisation rather than process authorisation will inevitably lead to the release of several GMOs into nature on the basis of superficial risk assessments. This is not consistent with the precautionary principle and does not respect the major opposition to genetically modified food products from populations in the EU.