

Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

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Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

B a c k g r o u n d

The Council has requested [1] the Commission to submit, by 30 April 2021, “a study in light of the Court of Justice’s judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law” (*i. e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41 / E C) .

To respond to this Council’s request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed a f t e r 2 0 0 1 .

I n s t r u c t i o n s

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term “NGT-products” used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, <https://eur-lex.europa.eu/eli/dec/2019/1904/oj>

[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such as RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.

[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: <https://ec.europa.eu/eusurvey/home/helpparticipants>

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

The General Confederation of Agricultural Cooperatives in the European Union, called “Cogeca”, is the representative organisation of agricultural cooperatives in the Member States of the European Union. The Transparency Registry Number is 09586631237-74.

Please mention the sectors of activity/fields of interest of your association

Cogeca is the representative organisation of agricultural cooperatives in the Member States of the European Union. Copa and Cogeca jointly defend a common position on new breeding techniques. Copa is the representative organisation of agricultural producers from the Member States of the EU.

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

If applicable, indicate if all the replies refer to a specific technique or a specific organism

All the replies refer to agri-food, primarily and mainly to seed varieties obtained by New Breeding Techniques obtained after 2001. Like Copa, Cogeca defines New Breeding Techniques as man-made breeding techniques discovered after 2001. We know that New Breeding Techniques (NBTs) or New Genomic Techniques (NGTs) as defined for the purpose of this study can be used to insert genetic material from sexually non-compatible species into a plant genome (i.e. develop classical transgenic GMOs) as well as to induce targeted and small changes within the organism's genome (mutations). Unless stated differently, answers we provide focus on plants developed by the later application of NBTs which lead to plants that could also have been the result of earlier breeding methods, or might have been obtained from natural processes without human intervention. Plants obtained by these New Breeding Techniques cannot be distinguished from plants obtained by mutations that occur spontaneously in nature or that can be obtained through the following techniques listed in Annex I.B of Directive 2001/18: mutagenesis, cell fusion (including protoplast fusion) of plant cells of organisms that can exchange genetic material through traditional breeding methods.

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

* 1. Are your members developing, using, or planning to use NGTs/NGT-products?

- Yes
- No
- Not applicable

* Please provide details

Like Copa, Cogeca's members are not developing, using, or planning to use NBTs directly. Some Cogeca members are traders of bulk commodities, which get mixed at various stages of the supply chain, from the farms, to transport, storage and at the port. In many third countries, products obtained by NBTs are not considered as GMOs, therefore the NBT-products are not separated from non-NBT-products. Therefore, NBT-products might get into the products without our knowledge. The COVID-19 pandemic highlighted issues related to the security of food supply. Society wants very rapid scientific progress to develop a vaccine against COVID-19. We would like society to extend this vision of rapid scientific progress also to agriculture. This approach is necessary to improve the resilience of the agri-food chain. Cogeca takes the view that NBTs will help to secure global food supply, meet the sustainability goals and reduce the vulnerability of farmers to climatic variation and legislative restraints. Breeding livestock cooperatives see an interest in using NGTs for research purposes.

*** 2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- Yes
- No
- Not applicable

* Please provide details

Cogeca's members who trade commodities in bulk regularly check for transgene GMO traits at various points in the chain, to ensure that only authorized organisms, in the permitted quantity, are present in our products. However, due to it being impossible to test and distinguish whether an organism was developed using conventional breeding methods, old or new mutagenesis methods, it is not possible for us to prevent the unintentional use of such NBT-products, especially in imports from third countries. Within the EU, we make it a part of our contracts that the seller ensure compliance.

For cattle, Cogeca's member ALLICE who are involved in breeding livestock and artificial insemination are discussing the feasibility of introducing specific legal provisions in their contracts to avoid importing GMOs as well as genome edited semen from third countries and other EU partners.

* 2 bis. Have you encountered any challenges?

- Yes
- No

*** 3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- Yes
- No
- Not applicable

* Please provide details

Like Copa, Cogeca is aware that in many third countries that are major suppliers of crucial ingredients for Europe, especially for the feed industry, products obtained by new mutagenesis techniques are not considered as GMOs. Research and development are ongoing in Argentina, Brazil, USA, etc.

Cogeca has collected other examples:

the JKI (Federal Research Center for Cultivated Plants in Germany /Bundesforschungsinstitut für Kulturpflanzen <https://www.julius-kuehn.de/en/>

study has been published in a scientific journal. In addition to the slides please also see:

Modrzejewski, D., Hartung, F., Sprink, T. et al. What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map? *Environ Evid* 8, 27 (2019). <https://doi.org/10.1186/s13750-019-0171-5>

Suggestion: also list the US database on inquiries within the “Am I regulated Process”.

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/Regulated_Article_Letters_of_Inquiry

The database lists all inquiries by entities (companies, public research, etc.) developing plants/organisms that have been modified by using technology (including classical genetic engineering). It currently lists 86 letters of inquiry involving NBTs from mainly medium size companies and public research, only 6 % of inquiries come from globally active companies.

Another publicly available resource on global developments is the “gene editing tracker” operated by the Gene Literacy Project:

<https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/>

Regarding livestock breeding, there are several initiatives outside the EU, e.g. a Canadian breeding company that has announced a partnership with Recombinetics/Acceligen to produce and market genome edited hornless cows. Partly stopped after the discovery during the last summer that plasmid sequences were also integrated into the genome of their cattle. Recombinetics/Acceligen claims to be able to produce genome edited cows with improved resistance to several diseases (tuberculosis, Foot-and-mouth disease), heat tolerance / adaptation to climate change. There are also some initiative in the swine sector (e.g. Genus in China).

In addition, <https://genomebiology.biomedcentral.com/track/pdf/10.1186/s13059-018-1583-1>.

<https://www.allaboutfeed.net/Feed-Additives/Articles/2020/4/Interview-Genome-editing-can-reshape-agricultureSOFTBREAK-568550E/>

*** 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- Yes
 No
 Not applicable

* Please provide details

Like Copa, Cogeca is aware of the challenges with detecting NBTs as identified by the Joint Research Centre, numerous national experts and authorities. We are aware that written statements are being used to declare that neither GM technology nor NBTs have been used for seed samples exchanged between breeders from different organizations. At present there are not NBT-products authorized for the EU market. As far as we know, not even an application has been submitted. However, agricultural products from third countries could already contain traces of NBT-products. As long as some of these products enter the EU market without an authorization, we see it as a clear responsibility of the competent national authorities to prevent these imports and it is not the responsibility of the cooperatives.

* 4 bis. Are you aware of any challenges encountered?

- Yes
 No

* Please provide details

There are some mapping exercises at company level, to monitor the market of NBT-products. The challenge of the mapping exercise at company level can be only voluntary for the breeders and a lot of products will slip through. This will get worse with time, as more NBT-products become established in third countries that do not regulate them as GMOs.

* **5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?**

Please also see question 8 specifically on labelling

- Yes
 No
 Not applicable

* Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

When trading within the EU, Cogeca's members make it part of their contracts in the EU that the seller has to ensure compliance with the GMO legislation. However, this only shifts the problem to the part of the supply chain that is the importer.

* What best practices can you share?

Our Cogeca member, DRV can provide additional information.

* 5 bis. What challenges have you encountered?

Cogeca's members make it part of their contracts in the EU that the seller has to ensure compliance with the GMO legislation. However, this only shifts the problem to the part of the supply chain that is the importer.

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- Yes
 No
 Not applicable

* What challenges have you encountered?

Like Copa, Cogeca is not aware of any supportive actions. Interpretation and implementation of the GMO Directive is largely left to Member States and EU harmonisation is poor. Copa's member organisations in several Member States have been involved in dialogue with other stakeholders and national competent authorities regarding the interpretation of the GMO Directive and joint Copa and Cogeca actions are therefore being backed up.

*** 7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- Yes
- No
- Not applicable

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

Cogeca's members only have experience with products within the EU and identity preserved (IP) products imports as well as single-variety products where the exact circumstances of the breeding process are known. An obvious limitation is the absence of analytical methods to identify NBT-products. Thus no control mechanism can be established. This specially concerns imported raw material and products. As described above, with products of EU origin, there are contractual obligations of the seller. However, due to the impossibility of testing/distinguishing, there is no way to check, especially for the percentage level of presences.

*** 8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- Yes
- No
- Not applicable

*** 9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- Yes
- No
- Not applicable

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

B - Information on research on NGTs/NGT-products

*** 10. Are your members carrying out NGT-related research in your sector?**

- Yes
- No
- Not applicable

* Please specify including subject, type of research, resources allocated, research location

- Averis Seeds B.V. 100% subsidiary of AVEBE, an international cooperative of 2,225 Dutch and German growers, (member of COGECA via NCR see <https://www.cooperatie.nl/leden/avebe/>) develops new potato varieties that are more profitable and more resistant to disease. A crop that is more resistant to these fungal diseases needs 65-75% less crop protection agents. The result: less environmental impact and a good cost saving for the grower.
- Lyckeby Starch AB is owned by some 800 potato growing farmers in the southern parts of Sweden (member of COGECA via the LRF see <https://www.lrf.se/om-lrf/organisation/lrfs-organisationsmedlemmar/organisationsmedlemmar/>). In collaboration with the Swedish University of Agriculture (SLU), they develop new potato varieties obtained by site-directed mutagenesis CRISPR-Cas 9 , amylopectin-enriched starch potato. Amylopectin-enriched varieties would allow a reduction of energy and chemicals used in the processing of potato starch into ingredients (see above). SSF example in Q1).
- ALLICE is a French Umbrella Cooperative (Union of livestock cooperatives, a French professional livestock organization representing all sectors of cattle, goat, sheep and pig insemination), member of Cogeca via la cooperation agricole française, see <https://www.lacooperationagricole.coop/fr/allice-corporate>, they are carrying out an R&D project on Genome Editing aiming to optimize the technology, both in terms of yields and safety, and to evaluate its potential and drawbacks. Currently, no production of living animals and no commercial applications are planned. Putative applications would be for research purposes (validation of recessive mutations causing genetic defects).
- BRS (German Livestock Association see <https://www.rind-schwein.de/brs-common/brs-home-gb.html>) is a member of Copa via the DBV as BRS is an associate member of DBV. They are carrying out the following projects together with FBF: “Genome editing in the bovine embryo: Development of an efficient electroporation protocol” and “Use of DNA nucleases to generate hornless cattle”. The University of Bonn is responsible for these projects.

* 11. Are you aware of other NGT-related research in your sector?

- Yes
 No
 Not applicable

* Please specify

There is a great deal of research underway all around the world, looking into new breeding techniques related to crops. It is not possible to list all this activity here. Suggested source of information <https://www.oecd.org/environment/genome-editing-agriculture/>

a) plant sector

NBTs will also help farmers to respond to the specific demands of consumers, such as wheat with less gluten, reducing the content of saturated fatty acids, allergens, fibers, protein, or vitamins. For example, Calyxt has done so in the US with Talen technologies. See <https://calyxt.com/innovation-pipeline/>

Research in the SLU Grogrund program also involves NGTs, see SSF example in the answer to question 3. See <https://www.slu.se/en/Collaborative-Centres-and-Projects/grogrund/>

In this survey among Canadian breeders (public and private), 66% stated that they were planning to use CRISPR/CA's over the next three years. See <https://saifood.ca/gene-editing-plant-breeding-canada/>

These 3 scientific publications list multiple applications of genome editing tools in different plant species to improve yield, biotic, and abiotic stress resistance, and nutritional quality, and elaborate on future prospects for Genome Editing. See <https://www.frontiersin.org/articles/10.3389/fpls.2019.00114/full>
<https://doi.org/10.1016/j.tplants.2019.09.006>
<https://doi.org/10.3389/fpls.2018.01607>

Report of Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Julius-Kühn-Institut (JKI) and

Friedrich-Löffler-Institut (FLI): https://www.bvl.bund.de/DE/Arbeitsbereiche/06_Gentechnik/02_Verbraucher/09_Monitoring_Molekulare_Techniken/gentechnik_molekulare_techniken_node.html

Topsector Horticulture Public-Private Project H 263& KV 1509-048: A genetic analysis pipeline for polyploids, involving several breeding companies – mainly of horticultural crops:

<https://topsectortu.nl/nl/genetic-analysis-tools-polyploid>

b) Livestock sector

See previous example with Recombinetics and its subsidiary Acceligen Also cattle resistant to Bovine tuberculosis and Foot-and-mouth disease virus. The Bill Gates Foundation: modify the genes of tropical cows in order to increase their milk production and their heat resilience.

The Roslin Institute is working actively on sheep gene editing. See <https://www.ed.ac.uk/roslin>

INIA in Spain and the University of Bonn in Germany are working on genome editing of cattle embryos.

Several publications mention gene edited sheep and goats, mainly regarding muscle mass, fiber length, coat color and litter size/prolificity.

See: <https://www.ncbi.nlm.nih.gov/pubmed/3203404> for a global (non-exhaustive) overview.

The following homepage provides an overview: (<https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/european-union-animals/>)

Products/Research • Human disease research in pigs: Technische Universität München in Germany used gene edited pigs to study human diseases, including cardiovascular diseases, cancers, diabetes mellitus, Alzheimer's disease, cystic fibrosis and Duchenne muscular dystrophy. • Sheep with larger muscles: Center for Research in Transplantation and Immunology (ITUN) used gene editing to develop larger sheep with more developed muscles. • Organs in pigs: Researchers in multiple European countries (Spain, Italy) have studied how to develop humans organs for transplantation in pigs. • Gene editing research in pigs: Researchers in Germany studied how to silence genes in pigs using a gene editing technique called ZFNs as a first step to gene edited pigs for agriculture. • Virus-resistant pigs: Researchers at Edinburgh University's Roslin Institute and the UK company Genus developed pigs resistant to the virus that causes Porcine Reproductive and Respiratory Syndrome (PRRS), one of the costliest animal diseases. • Swine fever-resistant pigs: Researchers at the Roslin Institute used ZFNs to develop pigs resistant to African Swine Fever. • Influenza-resistant chickens: Researchers at the Roslin Institute and Imperial College London took first steps in developing influenza-resistant chickens to help curb the spread of avian flu to humans. • Chicken research: Researchers at the Roslin Institute used a gene editing technique called TALENs to begin developing hens that do not produce their own chicks, for use as surrogates to lay eggs from rare breeds, as well as hens that produce human proteins in their eggs for medical purposes. • Pigs with organs for humans: Researchers at the Center for Innovative Medical Models Facility of Ludwig-Maximilians University used CRISPR to begin developing pigs with organs that are more likely to be accepted when transplanted into a human.

* 12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?

Court of Justice ruling: Case C-528/16 <http://curia.europa.eu/juris/documents.jsf?num=C-528/16>

- Yes
 No
 Not applicable

* Please describe

We are aware of concerns in the scientific community that the decision is hampering its work and putting up barriers and costs that do not have a commensurate benefit for society or the environment. See <http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20editing%20for%20sustainable%20agriculture%20and%20food%20production%20in%20the%20EU.aspx> We are aware of research projects using NBTs being put on hold or delayed due to the ECJ ruling. Due to strict regulations in the EU and bleak outlook regarding possibilities in the near future, product development tends to be moved outside Europe. A particular example is a large Dutch potato breeding company that recently announced it would be moving its research on NBT potatoes with multiple resistance against phytophthora to Canada, in as far as it concerns field trials. <https://www.boerderij.nl/Akkerbouw/Nieuws/2020/2/HZPC-verplaatst-aardappelonderzoek-naar-Canada-544771E>

Even in the absence of data and information, it is obvious that the current regulatory framework is a strong deterrent for any research that our members may have undertaken, or had wished to undertake. For example, the project of Lyckeby Starch AB (SSF) on amylopectin-enriched potato varieties started in 2014. Field production should have started in 2019 and industrial production in 2022, see [AMI(19)10480rev.1 à joindre]. Field trials have so far been possible within the GMO regulation even though most of the regulation is not applicable to NBTs. To move into industrial production will not be possible with the existing legal situation because the cost of approval of a GMO classified crop is too high. Labelling requirements will also impede the projects. The logical consequence will be moving the production out of the EU.

In livestock breeding, the ALLICE research project for example has been resized and reorganized, putting less emphasis on the identification of commercial applications and technical advances compliant with routine use. Equally, research institutes like INRAE in France seem to be reluctant to produce and house products of NBTs in their experimental facilities. Many internal administrative rules are necessary requirements for allowing such experiments.

In general terms, the ECJ's ruling entails a risk that research and innovation activities may be relocated outside the EU. The EU may also have to do without the use of genetic material from third countries in order to improve plant varieties, including material for conventional cross-breeding techniques. The costs of the cultivation trials of products obtained by new targeted mutagenesis techniques commonly amount to EUR 35-50 million, like for the approval of one GM trait at EU level. These high costs are not affordable for SMEs. Innovative developments that stem from NBTs can only be shared if the costs of regulating their placing on the market are acceptable and proportionate to the size of the target markets.

*** 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- Yes
- No
- Not applicable

* Please provide concrete examples/data

Cogeca can see potential benefits from NBT related research. For example,

a) The use of NBTs in research can greatly accelerate the speed with which the genome of a crop is understood, e.g. in relation to susceptibility or resistance against a particular disease. This knowledge can then be used to develop a more targeted/efficient traditional breeding program.

b) For breeding new seed varieties, NBTs can be used to significantly reduce the time needed to breed 'traditional' new seed varieties. E.g. for fruit trees or grape wine, it takes several years to grow a tree even to the stage where it produces flowers (needed for traditional breeding). With NBTs, the genome can temporarily be altered to shorten this time to maturity, and 'switched back' afterwards before the new variety is brought into production.

a) plant sector

Potatoes: a crop that is more resistant to fungal diseases needs 65-75% less PPPs. The results: lower environmental impact and good cost savings for the growers. Amylopectin-enriched potato varieties allow for a reduction of energy and chemicals used in the processing of potato starch into ingredients.

Oilseeds: Canola: According to CIBUSTM, the new traits precisely edit the canola genome to reduce pod shatter, the tendency of canola seed pods to open pre-harvest, which can reduce yields by as much 40%, build resistance to Sclerotinia, a disease called white mold, that can reduce yields by as much as 50%, and introduce an improved weed control system, as competition with weeds for nutrients and sunlight can reduce the yield of canola. The pod shatter trait has successfully completed field trials this fall, while the white mold and weed control traits have been successful in greenhouse testing and are expected to undergo further field trials in spring and summer 2020. Beyond canola, CIBUSTM currently are working on important traits to improve farming of rice, corn, wheat, soybean and potato to address major inefficiencies in crops due to disease, insects and weeds. These traits can have significant environmental and health benefits. Producing fungus resistant plants, for instance, will reduce the need for fungicides and reduce the potential development of antibiotic resistant fungi, the rise of which is becoming a significant human health challenge. There are some canola lines with gene edited traits in development. If the trials go well, the first of these (pod shatter reduction) could be ready for launch in 2 years. It's likely these would also be sold under the Falco brand but with an additional trait identifier to clearly distinguish them.

Fruit trees: NBTs can be used to find new fruit prunus trees that resist Sharka

Olives: NBTs can provide resistance to Xyllela fastidiosa

NBTs can help to reduce anti-nutritional compounds in protein crops, such as oilseed rape, faba beans and peas, and to improve protein quality and facilitate a shift to use more vegetable protein.

NBTs can be used to speed up the domestication process in improving agronomic traits as well as quality. Domestication of wild plants increases the diversity of crops, such as field cress.

*** 14. Is NGT-related research facing challenges in your sector/field of interest?**

- Yes
- No
- Not applicable

* Please provide concrete examples/data

The biggest challenge is the European Court of Justice's ruling on 25th July 2018 in case C-528/16, which stipulates that mutagenesis techniques must be considered as pertaining to Directive 2001/18/EC on the deliberate release into the environment of GMOs .

Also, research using NBTs is currently made more expensive and time consuming, due to the demand to apply the GMO Directive on contained and confined use according to the ECJ ruling.

For example, from an SSF perspective, the current situation is stressful, as commercial production will not be possible without a change of legislation. This might force us to move some production outside of the EU. Other projects, such as disease resistance in potato, will be closed down.

As regards competition, this is of concern to the potato starch industry. We will see an increasing demand for Clean Label starch from the food industry because they do not want to label E-numbers on the final product. Without pure amylopectin potato starch, the industry will not be able to fulfil this demand, while other crops such as corn will. Potato starch will consequently lose market shares.

Also, the market has a preference for food products with no E-numbers. In a situation where the EU does not allow NBTs, imported food products will have a competitive advantage over products produced in the EU, as no analytical method exists to identify if NBT raw materials have been used.

If other modifications like disease resistance are stopped, we will have to use more pesticides and will not be able to reduce CO2 emissions to the same extent.

*** 15. Have you identified any NGT-related research needs/gaps?**

- Yes
- No
- Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

Researchers in European universities and European breeders need to have access to the same techniques as in other parts of the world.

The use of NBTs is essential for research on functional genetics. Enabling technologies, such as cell- and tissue culture, to be able to develop plants after the use of NBTs. This could be addressed by funding research in Member States.

Another example for cereals, plant breeding and research into seeds in the cereals sector are the primary levers for achieving higher protein self-sufficiency. This strategy shall encompass forage maize which has an average yield of 0.9 t of crude protein/ha. There are three priorities here:

- Increasing the cereal yields which are currently stagnating, notably by adapting wheat and barley to climate change;
- Enhancing the protein content of cereals, targeting higher physiological efficiency in the nitrogen uptake of crops;
- Improving the quality of cereal proteins, notably by increasing the content of lysine, an amino acid required in pig and poultry feed.

Regarding Detection methods: Nucleotide changes (down to single nucleotide polymorphisms (SNPs)) are detectable by standard PCR based, hybridization based or sequencing methods, but the genomic changes induced by NBTs cannot be distinguished from naturally occurring variation or from changes derived from conventional mutagenesis. The resulting organisms carry mutations, which are not distinguishable in a meaningful way from what is present in nature and existing germplasm, and from what can spontaneously arise in nature. Products generated by NBTs cannot be distinguished from products generated by other breeding practices not falling under Directive 2001/18/EC. Regulation of NBTs products under Directive 2001/18/EC therefore results in a situation in which exactly the same product (with exactly the same combination of genetic material) – one resulting from a modern technique, and the other resulting from a conventional technique –, is treated in a different manner.

In livestock breeding, NGT-related research could also help improve the efficiency and safety of the technology. Research is also valuable to elucidate gene function and validate genes and mutations of interest for both monogenic traits and QTL (e.g. when several putative causative variants have been identified in a QTL region).

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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C - Information on potential opportunities and benefits of NGTs/NGT-products

*** 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- Yes
 No

* Please describe and provide concrete examples/data

NBTs are not currently bringing benefits to European farmers because there are no products nearing commercial application. However, the EU commits itself to the Sustainable Development Goals including Zero Hunger. If European farmers do not have an appropriate toolbox, the EU will import more, putting at risk food security in other regions of the world. While PPPs have provided many good solutions, PPP resistance has increased, generating problems for farmers related to managing crop protection. There are new political movements and new market demands such as those for plant-based proteins, zero PPPs and other specific demands for industrial uses.

We see NBTs as a major part of the solution to the intractable production challenges facing our sector in its efforts to produce food, fibre, energy and other products for the market; to produce environmental goods and services; to become more resource efficient; to be part of the solution as well as to be more resilient to climate change. For the seed potato sector, NBTs are seen as the principal method for overcoming the challenges mentioned. To produce results (quickly, most importantly), other breeding methods must be used.

NBTs offer many new possibilities in plant breeding genetic enhancement, provide opportunities to speed up genetic progress for a variety of traits, including traits related to climate change, environmental footprint reduction. For instance, they make it possible to precisely edit plants, thus allowing the development of new functions to optimise existing features or identify and develop new traits within the current genetic variation of the crops. They also enable genes that present disease susceptibility in one crop to be edited. By permitting a greater use of genetic variability and a better use of existing genetics, NBTs can provide solutions to the numerous challenges that European agriculture is facing.

NBTs could thus help reduce the cost of selection programs and thus contribute to the competitiveness of the sector

By making it possible to induce more targeted genetic variations, NBTs provide more predictable genetic results than conventional traditional breeding techniques.

Conventional plant breeding takes up to twenty years. Faster plant breeding is therefore important, because market demands change considerably over a 10-year period and political ambitions create great pressure regarding the speed with which crop production need to become more sustainable. Without the availability of NBTs to develop better adapted plants, the production of healthy and safe crops cannot keep up with the speed at which the use and impacts of inputs like PPPs and fertilisers is being restricted. NBTs allow breeders to develop plants that are similar to those that derive from conventional breeding, but more quickly and in a more precise manner. They are therefore vital tools that make it possible to accelerate the process, thus replying to the various needs of farmers in a better and swifter manner. NBTs contribute to developing varieties that use fewer inputs, improving the quantity and consistency of yields, adapting to climate change, producing sufficient and high-quality food, and diversifying crops for production in order to optimise crop rotations.

NBTs go hand in hand with other technological developments, such as precision farming, digital and smart farming, and bio-control.

* Are these benefits/opportunities specific to NGTs/NGT-products?

Yes

No

* Please explain

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NBTs go hand in hand with other technological developments, such as precision farming, digital and smart farming, and bio-control.

*** 17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- Yes
 No

* Please describe and provide concrete examples/data

In the EU, the authorisation of many PPPs has not been renewed. European farmers have lost the tools that they need to protect agricultural crops. This situation seriously puts food security and safety at risk as well as the competitiveness of European agriculture. Meanwhile, new pests, such as weevils and the stink bug, are threatening crop production. Farmers need an efficient toolbox to ensure crop production and food security and safety at affordable prices for the 450 million EU consumers. NBTs are part of the toolbox that European farmers need. The EU Farm to Fork strategy calls on European farmers to significantly reduce the dependency on as well as the risks and use of plant protection products, fertilisers. Generally speaking, genetic progress provides a benefit to society in terms of food security & quality, environmental footprint and farming competitiveness... NBTs can speed up genetic progress, increasing thus these benefits. NBTs also provide opportunities to expand the naturally occurring available genetic diversity and to produce

novel alleles, conferring plant disease resistance for instance. This can help tackle challenges related to reduced use of PPPs.

Crop production starts with seeds that are more tolerant/resistant to pests, diseases and to changing climatic conditions. NBTs must feature in the breeders' toolbox. See examples below

- 1) Disease and insect resistance
 - a. Bacterial blight-resistance in rice [R. Oliva et al. Broad-spectrum resistance to bacterial blight in rice using genome editing, *Nat. Biotechnol.* 37 (2019) 1344–1350. doi:10.1038/s41587-019-0267-z.]
 - b. Viticulture is a highly conservative branch where growers and producers favour the maintenance of existing, highly popular grape varieties. However, cross-breeding for new disease-resistant varieties (that will not need to be sprayed as much) takes well over a decade and the final new variety will most likely be different from the original variety also in other aspects. New techniques for site-directed mutagenesis (e.g. CRISPR/Cas or other) will enable the introduction of disease- and pathogen resistance while maintaining original grape varieties.
 - 2) Drought-tolerant maize
 - 3) Salt-tolerant rice
 - 4) Agronomic traits
 - 5) Podshatter-resistant oilseed rape

 - 6) Food quality/food health traits
 - a. Non-transgenic, CRISPR/Cas9-developed wheat with much reduced immunoreactivity for people with coeliac disease [Sánchez-León S et al (2018). Low-gluten, nontransgenic wheat engineered with CRISPR /Cas9. *Plant Biotechnology Journal*, 16: 902-910.]
 - b. Recovering lost, wild tomato quality traits by de novo domestication of wild tomato [Zsögön A et al (2018). De novo domestication of wild tomato using genome editing. *Nature Biotechnology*, doi:10.1038/nbt.4272.]
 - c. Root chicory producing more and healthier inulin food fibre as well as medicinal terpenes (<http://chicproject.eu>)
 - d. High-amylose starch potato suitable for industrial applications [Andersson M et al, 2018. Genome editing in potato via CRISPR-Cas9 ribonucleoprotein delivery. *Physiologica Plantarum* doi: 10.1111/ppl.12731]
 - e. Vitamin A-enriched rice [O.X. Dong, et al, Marker-free carotenoid-enriched rice generated through targeted gene insertion using CRISPR-Cas9, *Nat. Commun.* 11 (2020) 1178. doi:10.1038/s41467-020-14981-y.]
 - f. Waxy maize [H. Gao et al, Superior field performance of waxy corn engineered using CRISPR–Cas9, *Nat. Biotechnol.* (2020). doi:10.1038/s41587-020-0444-0.]
 - g. NBTs are well suited to improve quality and nutritional traits in crops. These are often governed by few genes and a mutation disrupting a gene may have positive effects. Problems with obesity and demand for functional food are increasing, and NBTs can play a vital role in improving crops in these respects.
 - h. NBTs could help to reduce food waste (e.g. by enhancing shelf life of products) and to make optimal use of biomass (e.g. by utilising plant parts as much and efficiently as possible).
- NBTs could be used in a given population to increase the frequency of rare alleles of interest, which could otherwise progressively be lost (due to their low frequency, their effect is undetected or underestimated and these alleles are thus not selected). Like Cogeca, Copa sees a risk of NBT-based crops being imported into the EU at large scale, while they are sometimes not even distinguishable from 'traditional' crops. This creates unfair competition with EU domestic production. It is important to increasingly provide a level playing field.

* Under which conditions do you consider this would be the case?

an urgent need of an updated interpretation of the annex 1.B of the GMO directive

* Are these benefits/opportunities specific to NGTs/NGT-products?

- Yes
 No

* Please explain

NBTs offer many new possibilities in plant breeding genetic enhancement, provide opportunities to speed up genetic progress for a variety of traits, including traits related to climate change, environmental footprint reduction. For instance, they make it possible to precisely edit plants, thus allowing the development of new functions to optimise existing features or identify and develop new traits within the current genetic variation of the crops. They also enable genes that present disease susceptibility in one crop to be edited. By permitting a greater use of genetic variability and a better use of existing genetics, NBTs can provide solutions to the numerous challenges that European agriculture is facing.

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- Yes
 No

* Please describe and provide concrete examples/data

SMEs would develop seed varieties well adapted to local soil, climate conditions and local varieties. Multinationals focus on the main global agricultural species. Establishing a framework that allows SMEs to operate with NBTs, provided that the SMEs are not burdened with the regulatory cost, would be beneficial for maintaining competitiveness and diversity in the supply on the seed market.

As Europe wants to develop its production of grain legumes, considerable research is needed into these crops to improve yields and to reduce annual yield variation. Breeding programmes for small varieties such as clover, alfalfa, vetch, and even peas need to be improved if Europe wants to increase its protein crop production. The same applies to cover crops (mustard, radish, etc.).

The EU has an excellent reputation for its high-quality production of speciality crops. Innovation regarding crop varieties in such 'niche markets' is often dependent on investments from specialised breeding companies like SMEs. Accessibility of NBTs for these companies is essential to stay competitive and, for the respective crop production sectors, to keep up with market and societal demands

If regulated according to the GMO-directive, there are no opportunities for any businesses to market crops developed using the technology. A situation where NBTs are regulated as crops developed by traditional breeding methods, opens up major opportunities for SME/small scale operators to go into the market with NBT-products. The reason is that one or a few traits can be added to existing traditionally bred material without any new DNA inserted, which can be done quite easily at a low cost. The new situation will be that traditional breeding companies will be able to offer new varieties to all their customers as opposed to the situation we have had for any years where only huge companies can afford to use GM-technology.

* **19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?**

- Yes
 No

* Please explain why not

Like Copa, Cogeca 's position on patents on plants has been very clear for almost 30 years. In these 30 years, the European model has seen the best innovative and improved developments in terms of new plant varieties worldwide. No continent where patents control Intellectual Property (IP) rights have shown a similar level of development from a farmer's and environmental perspective. Therefore, developing patents on plants in the EU must be stopped immediately. Farmers in the EU do not want to use patented seed at all. We sincerely hope that our message is clear.

Patent law originates from the technology sector; which deals with dead matter.. Very often, biological processes cannot be predicted and the specific conditions under which agriculture and breeding function are not taken into account by patent law.

The introduction of patent law into biology has undermined the fundamental principle according to which plants and animals, and their gene pools, are not inventions.

Farmers and breeders have obtained today's species of plants and animals through centuries of work. In order for this to be possible, they have had constant access to the genetic information of previous generations. Each breeder can freely use the varieties and species obtained by other breeders for his/her own breeding purposes.

A patent, on the other hand, provides an exclusive right. Since the entry into force of Directive n° 98/44/EC on legal protection for biotechnological inventions, more and more patents applying to commercial crops, farm animals and biological processes have been granted.

Like Copa, Cogeca is very concerned by this trend which presents a risk not only for farmers but for the society in general. Free access to the entire gene pool and to all breeding processes for every breeder and every farmer is of the utmost importance for both innovation in breeding and overcoming future challenges, such as feeding a growing global population, producing biomass for renewable energy production, adapting to climate change, etc.

Experience in Member States has shown that when the farmer's and breeder's privilege was put in place, in line with the Community plant variety rights, which was an important step, farmers and breeders still had their work hampered as patent law only granted them the right to continue to carry out research on patented plants and animals . However, if they want to place on the market a new plant variety or breed of animal which contains a patented element, they must negotiate a license with the holder of the patent.

Like Copa, Cogeca believes that patent law is, therefore, an inappropriate instrument for agriculture and for the selection of plant varieties and breeds of animal. It hinders innovation and threatens progress in the breeding sector.

Patents on products, traits or genes derived from genetic engineering breeding techniques should only apply to products that contain DNA that cannot be found in nature or cannot be obtained through conventional breeding methods or mutagenesis techniques.

The Directive n° 98/44/EC on the protection of biotechnological inventions should be included in the European Commission's work programme in order to take a detailed look at the specific concerns that we have brought to your attention here. The European Commission should present a proposed modification to Directive n° 98/44/EC on these specific points so that in the future all genetic resources will remain freely available and the work carried out by farmers and breeders will not be hindered.

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D - Information on potential challenges and concerns on NGTs/NGT-products

* 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?

- Yes
 No

* Please describe and provide concrete examples/data

A situation where the EU is regulating NBTs according to the GMO-directive while other parts of the world are not will create a big challenge for the EU market.

-Lack of analysis technology will put companies and society into a situation where it will be unknown whether imported products on the market are produced with this technology.

-If European producers do not have access to NBTs, there will be a competitive disadvantage in export markets and eventually also on the EU market due to the lack of detection methods.

The Cogeca's members will not be able to ensure that imported goods on which the EU agricultural sector relies are compliant with the EU GMO-regulation. This is due to the fact that many grain/oilseed exporting countries do not regulate all NBT-products as GMOs, due to the availability of the techniques to SME-breeders around the world, who will not all be aware of or interested in EU legislation, due to the fact that they will or cannot pass on the information on their products down the chain, due to the fact that the harvests are mixed at various points in the supply chain and may contain a vast number of different varieties with unknown origin, and due to the fact that NBT-products are not detectable via tests.

Like Copa, Cogeca is concerned about the possibility of intra-EU trade barriers due to an adoption of NBT-based crops, as a consequence of the poor harmonisation of EU legislation worldwide and among Member States. Like Copa, Cogeca a risk of distortion of competition, higher business concentration and loss of genetic sovereignty and diversity.

There is a risk of distortion of competition if EU regulation doesn't apply to imported products in the same way (how to control importation when detection is impossible?). Distortion of competition is already taking place since imported products are usually not subjected to the same production constraints as they are in the EU, but the situation could be more critical with NGT products.

Risk of higher concentration of businesses in the sector, which could affect the relationship between breeders and farmers. If NGT development can not be pursued by cooperatives but only by multinational corporations. For example, Sexing Technologies or Zoetis in livestock sector, there is a risk of loss of genetic sovereignty.

There is a risk for our genomic selection system for international breeds such as Holstein if genome edited animals are imported without traceability: their progeny will introduce a bias in the reference population, resulting in a loss of genetic progress.

Each NBT should be analysed and discussed by experts on a case-by-case basis and according to strict scientific criteria. The decision on evaluating them and ascertaining the correct regulatory approach should also be proportionate to the risks. NBTs are constantly evolving and developing. Copa and Cogence therefore reserve the right to express their possible positions on these new techniques on a case-by-case basis.

Introducing NBTs into the agricultural sector should be done such that freedom of choice is maintained for all farmers. This can be achieved by providing and maintaining transparency regarding the seed varieties on a voluntary basis.

* Are these challenges/concerns specific to NGTs/NGT-products?

- Yes
 No

* Please explain why not

Some of them do already exist

*** 21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- Yes
 No

* Please explain why not

For the crop sector, as far as applications of NBTs are concerned, there is no reason to expect that NBTs that produce organisms that cannot be distinguished from those obtained by conventional breeding or natural processes would have any other impact than those latter organisms. The adaptation of new or existing seed varieties to climate change, to resist important pests and diseases, to secure yield and to maintain or improve product quality are essential to both farmers and consumers.

It is rather the opposite: effectively excluding the application of NBTs in the sense above (through regulation of products as GMOs) will deprive European farmers, as well as EU-citizens and the European society in general, from the potential benefits of those products (which in turn will raise challenges/concerns for society). In a situation where NGTs are not regulated as GMO, it is still so that new seed varieties need to be tested and approved regarding DUS in order to be sold on the market.

It is obvious that specific traits give rise to concerns in society in general. Regarding the crop sector, some European citizens are unwilling to accept GMOs with herbicide tolerance. However, this does not mean that herbicide tolerance per se is a trait with negative consequences regarding aspects such as the environment or human or plant health. If well managed, it is a trait that can be highly beneficial to the farmer as it allows for a more flexible and targeted weed management. It also promotes low-till farming practices, with benefits for the soil environment.

In the livestock sector, the presumed lack of social acceptance is of huge concern. However, this purported low social acceptance has not been substantiated by any opinion poll to date. It mainly hinges upon the low acceptance for GMOs. They still support research on Genome Editing to assess the safety (off targeting, mosaics) and efficiency (feasibility, costs compared to traditional breeding...) of this technology. As far as examples go, there are only a few known major genes of interest (from ~150 major genes identified in cattle, 90% are genetic defects!), mainly for coat color, milk proteins, muscularity, hornlessness, heat resistance (short hair)... Some mutations have been described that decrease vulnerability to tuberculosis and paratuberculosis. Most traits of interest in cattle are quantitative (QTL) and governed each by ~ 300 genes (causative mutation usually unknown).

*** 22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- Yes
 No

* Please explain and provide concrete examples and data

European farmers have serious concerns about their access to innovation in seed breeding. If the EU were to regulate all products that result from NBTs as it regulates GMOs, NBTs would cease to develop in Europe, as small and medium-sized enterprises in the sector would not be able to shoulder the costs of the requirements set out under Directive 2001/18/EC. This could lead to a higher concentration of businesses in the seed, which could affect the relationship between breeders and farmers. Similarly, it is vital for public research institutes to continue to be able to access NBTs. It is vital for farmers to have quite a wide choice of seed variety suppliers. If the seed market is concentrated between a few operators it could conduce to higher prices for varieties and lower yields as crops will not be well adapted to local conditions for all European regions.

*** 23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- Yes
- No

* Please describe and provide concrete examples/data

We support the view that the patentability of plant traits poses major risks to European agriculture.

- o Patenting plant traits will hinder innovation. Breeders are increasingly limiting their starting material to self-owned varieties, yet even this does not fully guarantee that no patents are infringed. Additionally, as more money is needed to cover patent attorneys, legal fees and transaction costs, such as license fees, less funding is available for R&D.

- o Patenting plant traits directly jeopardises many SMEs that are active in plant breeding, as they generally do not avail themselves of the necessary resources to build up their own patent portfolio or to monitor patents from third parties to ascertain whether certain materials are protected. Many SMEs are likely to be forced out of business, leading to further consolidation and/or reduced innovation in plant breeding. This would lead to the market being much more dependent on larger seed companies.

- o Patenting plant traits will reduce the freedom of choice for farmers, the industry, trade, and consumers. It may be a while before this effect is palpable, as developing varieties takes considerable time. The repercussions of cancelling breeding programmes or breeders going out of business will therefore only be felt years down the line, yet this remains an unavoidable consequence of current patenting practices for genetic traits.

- o Patenting plant traits could once again threaten agricultural biodiversity by limiting the number of breeders and breeding programmes. Seeing as the variety of biological starting material is reduced, the gene pool will become progressively more limited, thus increasing the vulnerability of crops to plagues and diseases.

We believe that patent law is an inappropriate instrument for agriculture and for selecting plant varieties because it stymies the work of farmers and breeders. Establishing the farmers and breeders' privilege in line with the CPVO was an important step forward that boosted the plant variety sector. For all of the aforementioned reasons, Copa call on you to ensure that genetic resources remain freely available in the future and that the work carried out by farmers and breeders will not be hindered. Patenting the animals / mutation makes no sense. Indeed, genetics exist within a mutual framework and the breeders and farmers are free and want to remain free to produce their next generation. Patenting a genome edited bull would imply that heifers produced by this bull would be subject to royalties when calving...

We remain concerned about the potential negative effect of patents on their day-to-day work regarding free access to plant breeding genetic material and royalty payments.

- a) Blocking effect on breeding: When a breeder wants to use a variety for further cross-breeding and to create a new variety, either he has to do away with the patented trait of the plant or he needs to get a license from the patent holder. With more patent varieties, there may be multiple patented traits which would need to be bred out or which would require a license. This would inevitably block further breeding and progress in new variety breeding.

Furthermore, patents make it possible for patent holders to exercise economic greed through their ownership of the patent rather than working in the general interest towards bringing about improved new varieties. Farmers need access to the best seed varieties at all times and are concerned about the hindrances to progress in breeding that the blocking effect of possible patents may cause. Therefore, farmers are of the view that a breeders' exemption that allows breeders to freely use any variety that contains a patented element for further breeding must be implemented in patent laws all over Europe.

- b) Royalty payments: Patents also affect farmers from the point of view of royalty payments. If the patent brings a value to the farmer, it is legitimate to charge royalties for that benefit. However, if this is not the case, it is not acceptable for farmers to pay extra royalties.

For the above reasons, we are of the view that in addition to the Commission notice and the rule change by the EPO, there is still more to do.

It is essential that any possible plant patents are subject to EU laws on plant variety protection in order to secure farmer access to the best performing varieties. It is also essential that farmers cannot in any way violate possible patents when using certified seed.

Moreover, patenting the technology may also give rise to issues, depending on the licencing strategy (high costs, exclusivity...), in particular for SMEs.

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E - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

Radiation or chemical treatments have been commonly used to create random mutations in a large number of seedlings, followed by selection and multiplication of desirable individuals. In this respect, NBTs allow us to target and monitor changes in the genome much better. In plants, as safe as plant products already produced by methods considered having a history of safe use. The techniques and their resulting products are not expected to be less safe than other plant breeding techniques.

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- Yes
 No

*** Please explain**

According to the Danish Council on Ethics [SEM(19)5061 rev.1, page 24]: "in the 20 years of cultivating herbicide- and insect-resistant plants, there have been no reports of harm to human beings or nature resulting from the use of genetic modification in itself".

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F - Ethical aspects of NGTs/NGT-products

*** 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

See useful paper: GMO and ethics in a new area, Danish Council on Ethics statement, see SEM(19)5061rev
<http://www.etiskraad.dk/~media/Etisk-Raad/en/Publications>

[/DCE_Statement_on_GMO_and_ethics_in_a_new_era_2019.pdf?la=da](#)

Many factors have changed since the GMO Directive was introduced 30 years ago.

Several sustainability problems have become more urgent.

If temperature rises are not contained, the consequences for future generations will be unpredictable. This should weigh heavily in an ethical assessment.

Plant breeding innovation 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. Accelerated variety development would be a strength in a situation with rapid climate change.

There has been substantial concern over the years regarding the products of gene technologies, voiced by certain activist groups and often also reflected in public opinion. For ethical reasons, it is important that these concerns are taken into account. However, there are also several other ethical concerns, in particular related to the policy approach towards the products of gene technologies in Europe.

First, it is problematic that science is often overlooked when it comes to making decisions for authorising the products. We appreciate the importance of aligning political decisions with the needs and expectations of all societal actors, and therefore regret that scientific advice is often overlooked when it comes to plant breeding innovations. This will impede any efforts to develop responsible governance of innovations using these techniques, particularly since many stakeholder groups do support the evidence provided by scientists. It is highly problematic from an ethical perspective to overlook scientific probabilities/facts and instead base decisions on opinions based on different agendas.

It is also highly ethically questionable that farmers who want access to improved seeds are denied this.

It is also ethically questionable from the point of view of equal access to technology. Should the products of NBT be subject to the provisions of the GMO legislation, this would result in SMEs/small scale operators being excluded from using the technology for the European market, and thus work actively against a particular segment on the market.

It is ethically problematic to not take advantage of latest technologies when these offer good benefits. There is a cost associated also with refraining from using beneficial applications.

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- Yes
 No

* Please explain

Gene editing technologies offer enormous potential for scientific advancement in fields such as medicine and agriculture, but their use also raises serious ethical and public policy concerns. Ethical consideration needs to be given to all applications of gene editing, including the non-human applications. We do not have any specific ethical considerations, since concerns are the same as with traditional selection.

NBTs are merely techniques. We believe that each NBT should be analysed and discussed by experts on a case-by-case basis and according to strict scientific criteria. The decision on evaluating them and ascertaining the correct regulatory approach should also be proportionate to the risks. NBTs are constantly evolving and developing. We therefore reserve the right to express their possible positions on these new techniques on a case-by-case basis. We call on you to fully take into account the 2012 Member State Expert Group conclusion that the legal definition of GMOs does not apply to most NBTs and that these techniques should be exempted from the rules of Directive 2001/18/EC.

Many NBTs, with mutagenesis techniques as a good example, generate mutations that are indistinguishable from those arising spontaneously in nature or through some forms of conventional breeding. Given that the communication of the European Commission has been postponed several times, we call on you to accelerate the process to clarify the legal status of NBTs; indeed, the status of mutagenesis techniques is a prime example of why this process needs to be sped up.

The focus should rather be on the products obtained by NGTs. See

<http://www.hautconseildesbiotechnologies.fr/fr/avis/avis-sur-nouvelles-techniques-dobtention-plantes-new-plant-breeding-techniques-npbt>

We believe that patent law is an inappropriate instrument for agriculture and for selecting plant varieties because it stymies the work of farmers and breeders. Establishing the farmers and breeders' privilege in line with the CPVO was an important step forward that boosted the plant variety sector. For all of the aforementioned reasons, we call on you to ensure that genetic resources remain freely available in the future and that the work carried out by farmers and breeders will not be hindered. NBTs - and access to plant varieties obtained herewith - is a key instrument, as stressed above.

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G - Consumers' right for information/freedom of choice

* 28. What is your view on the labelling of NGT-products? Please substantiate your reply

Products obtained through new mutagenesis techniques should be labelled using existing labelling schemes. It is only appropriate to label products if they are distinguishable from those produced obtained through conventional breeding. Otherwise, such labels would be misleading to the consumer and therefore violate the Food Information to Consumers Regulation. In addition, if there is no difference in the labelled product, it would not be possible to enforce the labelling.

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H - Final question

* 29. Do you have other comments you would like to make?

- Yes
- No

Please provide your comments here

In order to address the challenges presented by climate change, tackle plant diseases and protect biodiversity, a clear solution for new breeding techniques needs to be developed at European level. This is essential to avoid jeopardising the results achieved so far in the current agricultural model, which is increasingly oriented towards efficiency and sustainability.

The European Court of Justice's ruling on 25th July 2018 in case C-528/16 leads to uncertainty for European farmers. It entails a risk that research and innovation activities may be relocated outside the EU, severely hampering progress in plant breeding, depriving European farmers of the progress resulting from the use of these techniques, and negatively affecting the competitiveness of European agriculture as well as growth and employment in the EU's rural areas.

Modern mutagenesis techniques are already being used in some non-EU countries, but the products obtained using these techniques are not considered as genetically modified organisms (GMOs) and are thus not labelled as such in these countries. Besides the issue of import controls, importing agricultural products currently involves a real risk as it is impossible to guarantee their compliance with European rules. The EU may also have to do without the use of genetic material from third countries in order to improve plant varieties, including material for conventional cross-breeding techniques.

In addition, the requirements for the authorisation of GMOs in the EU and the high costs involved in the authorisation procedure prevent the European agricultural sector from benefiting from the scientific progress linked to the use of new mutagenesis techniques for breeding plant varieties. This leads to the EU being put at a competitive disadvantage compared with other regions which have a more innovation-friendly legal framework.

European farmers and agri-cooperatives need to have access to technological advancements in order to overcome a number of challenges, such as remaining competitive, adapting to and mitigating climate change, and providing an adequate supply of high-quality food. Guaranteeing legal certainty and establishing an efficient European single market for plant varieties are a basis for investments in the development of new seed varieties and are therefore of paramount importance for the future of European agriculture.

Ultimately, the objective must be to allow European farmers to take advantage of the sustainable opportunities opened up by innovation in biotechnology. Such innovation could help to enhance the uniqueness of the European agricultural model. Each NBT should be analysed and discussed by experts on a case-by-case basis and according to strict scientific criteria. The decision on evaluating them and ascertaining the correct regulatory approach should also be proportionate to the risks. See <http://www.hautconseildesbiotechnologies.fr/fr/avis/avis-sur-nouvelles-techniques-dobtention-plantes-new-plant-breeding-techniques-npbt>

We have called on the European Commission and Member States to fully take into account the findings of the Member States' expert group in 2012, which state that the legal definition of GMOs does not apply to most modern plant breeding techniques and that these techniques should be exempted from the provisions of Directive 2001/18/EC. Similarly, the conclusions of Advocate General Michal Bobek, presented on 18th January 2018, which also support this approach, should be taken on board. Since the European Commission's communication on this matter has been postponed on several occasions, we have called on the European institutions to accelerate the process to clarify the legal status of NBTs. Indeed, the status of mutagenesis techniques is a prime example of why this process needs to be sped up. Modern mutagenesis techniques are an important part of new plant breeding techniques.

Their use is necessary in order to overcome certain challenges linked to climate change, to meet society's expectations concerning the reduction in the use of PPPs, and to ensure that the EU is not left behind in the globalisation of world trade.

In addition, we would like to mention the opinion of the German Bioeconomy Council (see SEM(19)1401(rev. 1)

https://biooekonomierat.de/en/publications/?tx_rsmpublications_pi1%5Bpublication%5D=129&tx_rsmpublications_pi1%5Baction%5D=show&tx_rsmpublications_pi1%5Bcontroller%5D=Publication&cHash=4a06627d0a672591d38af91661a8a288

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Sustainability with climate focus

2019-12-02

Hans Berggren, CEO

Sveriges Stärkelseproducenter (SSF)

Sveriges Stärkelseproducenter (SSF)

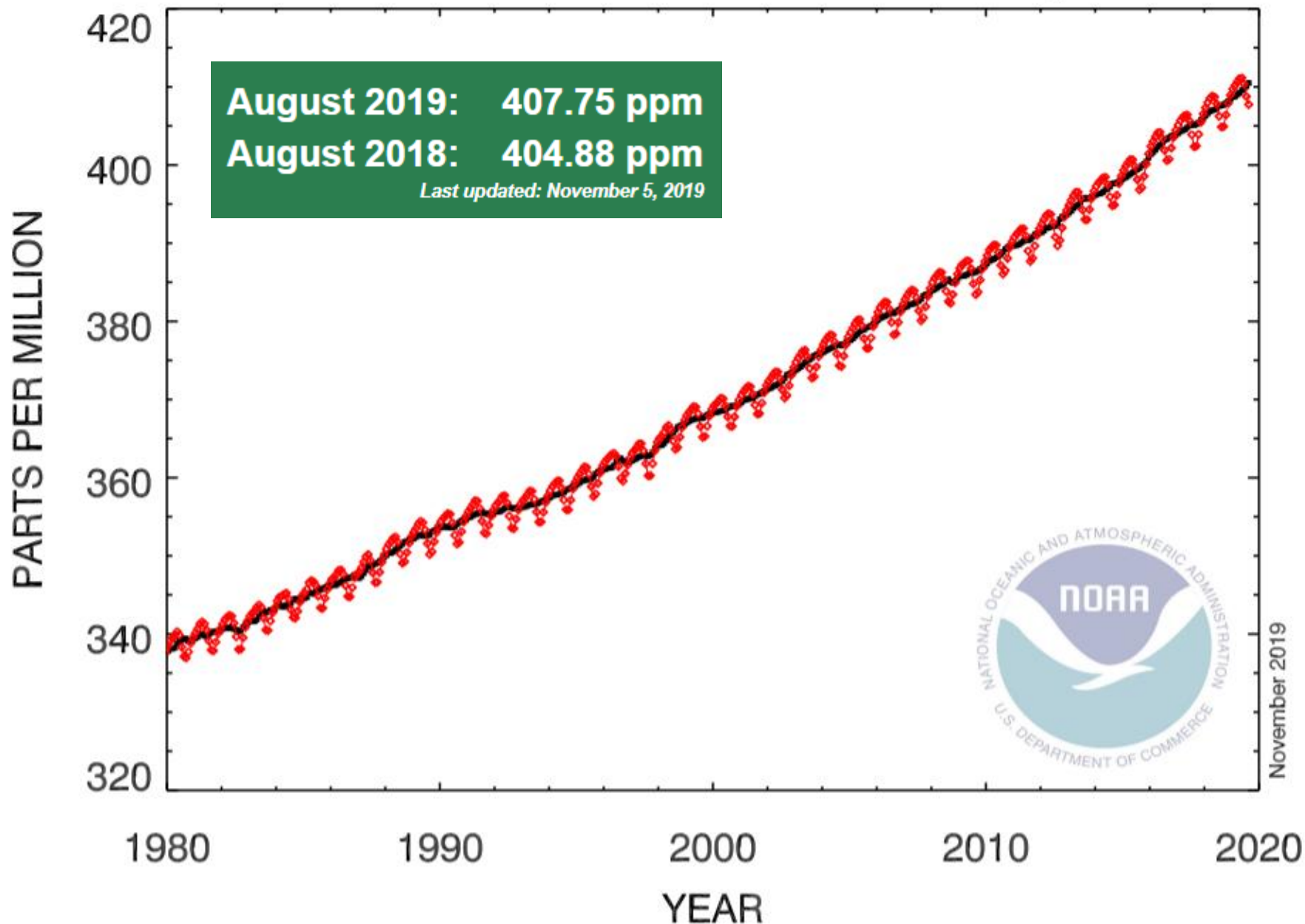


- Swedish Starch Producers Association
- Founded 1927
- Owned by 600 potato growers in southeast of Sweden
- 400 employees in Sweden + 300 employees abroad
- Represented in +50 countries
- Revenue 190 M€

Content

- What causes rising CO₂ content in the atmosphere?
- What can be done in Lyckeby?
 - **To reduce our footprint – topic of today**
 - To utilize starch replacing fossil material – topic of another day
- Need for political support

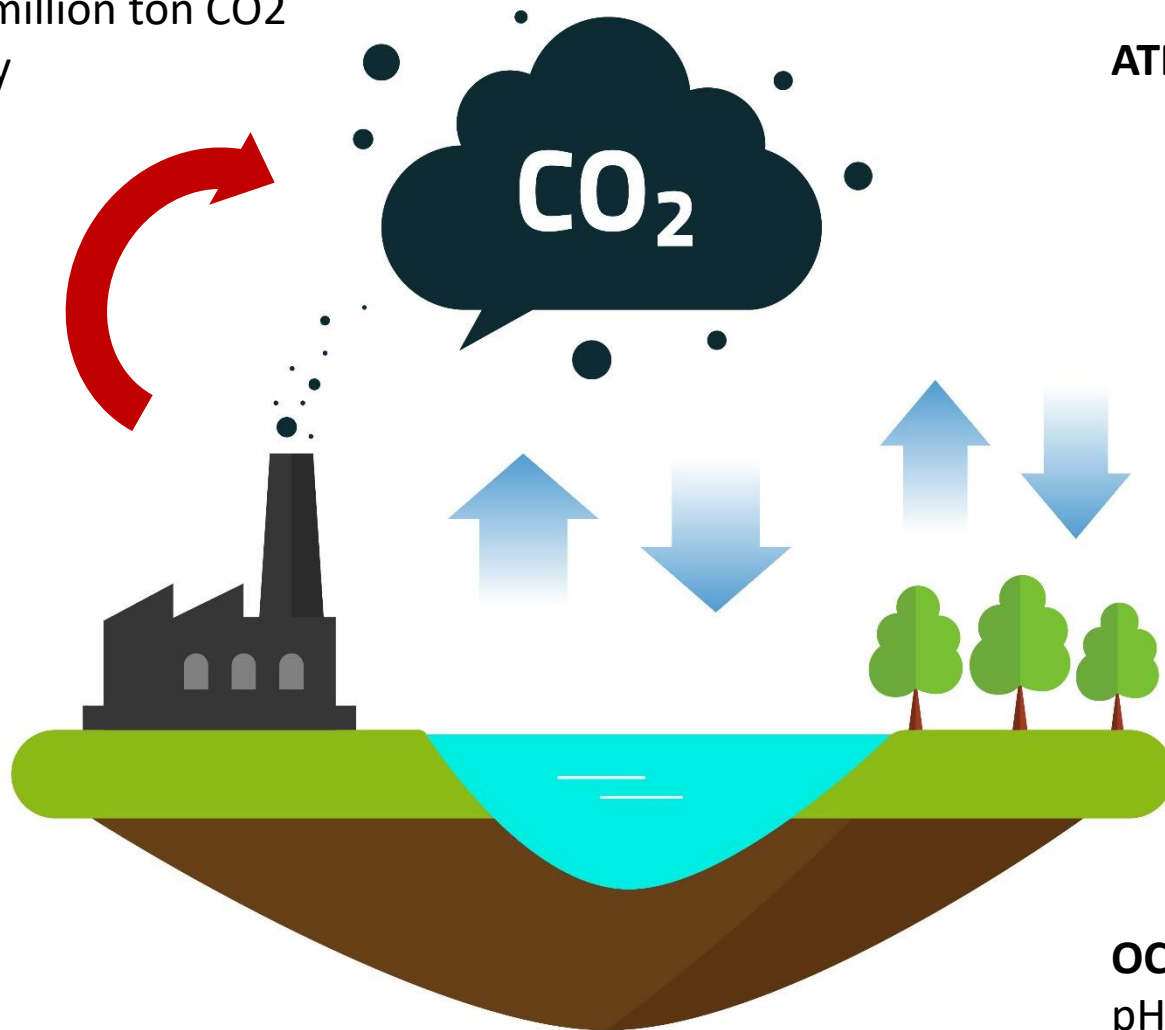
GLOBAL MONTHLY MEAN CO₂



The Carbon Cycle

FOSSIL FUEL

+ 100 million ton CO₂
per day



ATMOSPHERE CARBON

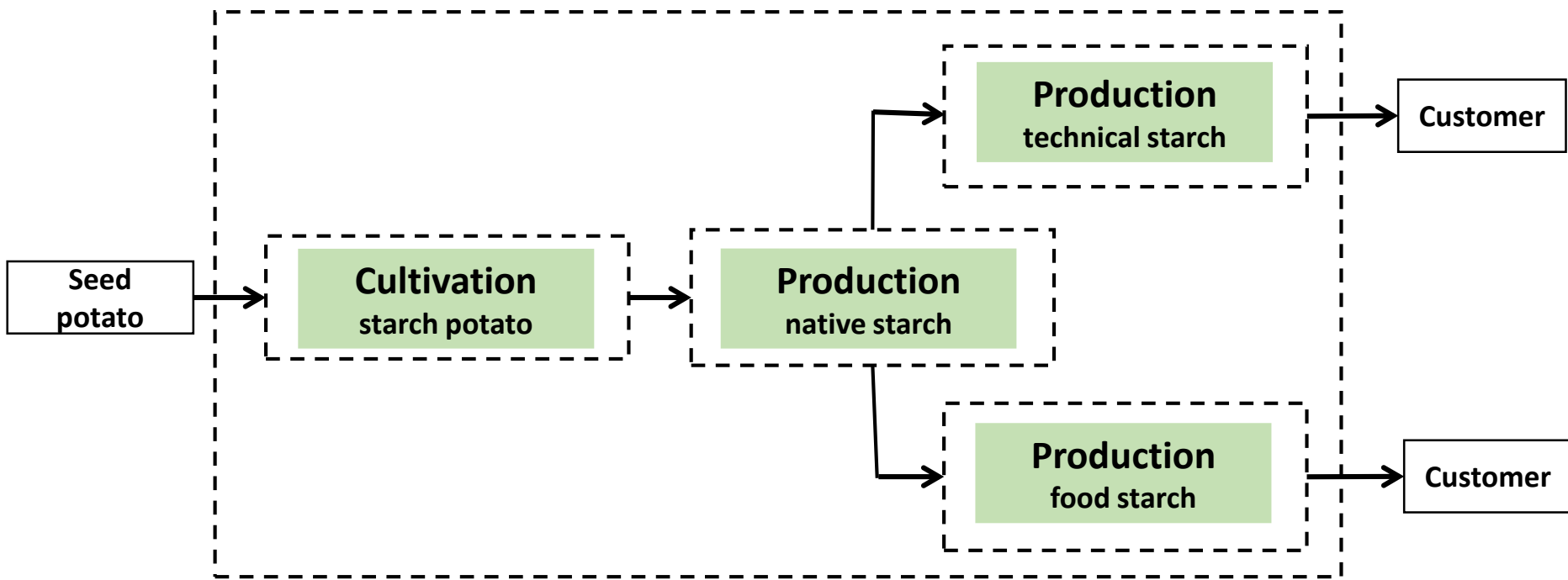
BIOSPHERE CARBON
Biomass

OCEAN CARBON
pH reduction

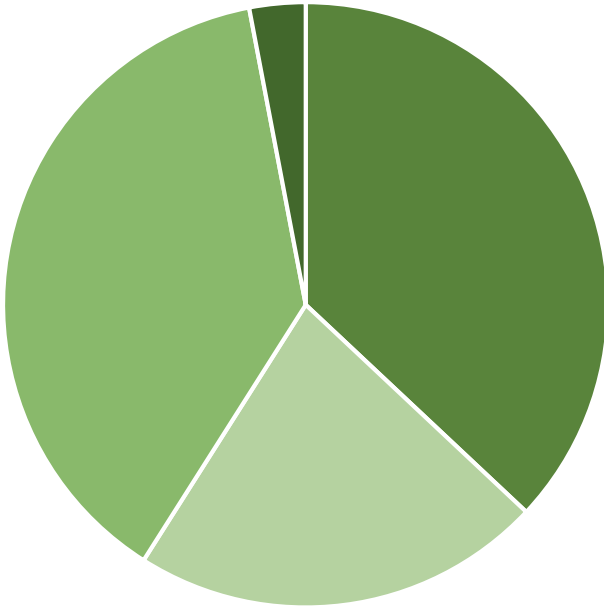
What can Lyckeby do?

Climate impact assessment with lifecycle perspective

4 connected systems from cultivation to transport to customer



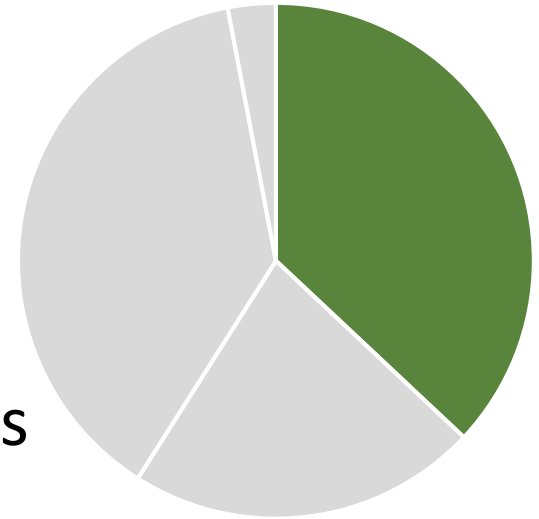
Distribution of total climate impact from our starch operations (%)



■ Fuel ■ Process energy ■ Raw material ■ Others

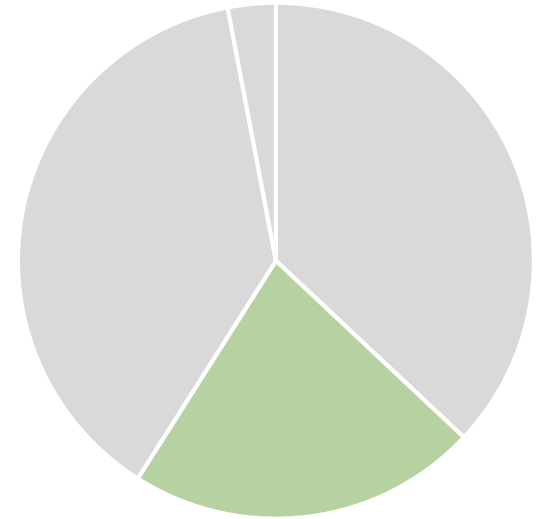
Fuel

- Cultivation process, transport of potatoes and transport to customers
- Possible actions
 - Reduce driving through better cultivation technology
 - Reduce driving through better logistics
 - Replace fossil fuel by electric power
 - Replace fossil fuel through successively substitution
 - Replace fossil fuel with HVO in own agreements



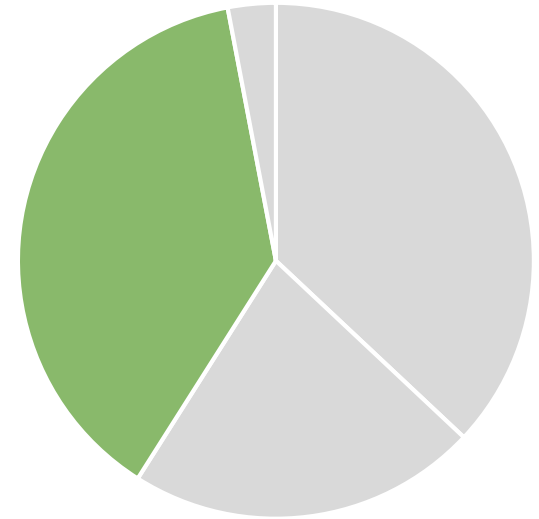
Process energy

- Production of native starch and refining of modified starch
- Possible actions
 - Reduce through optimized processes
 - Conversion of steam boilers to electricity
 - Conversion of steam boilers to renewable energy
 - Increase proportion of clean label starch



Raw material

- Commercial fertilizers, plant protection, process chemicals
- Possible actions
 - Reduce through optimal cultivation
 - Reduce through optimal process
 - Eliminate with modern plant breeding technologies
 - Renewable energy for production of raw material



Site Directed Mutagenesis for Sustainable Starch Production

Sustainable production

Today:



Chemical modification
Similar technology for 80
years

Future:



Clean label starch – product of
tomorrow
Clean label technology for
equivalent products

*Vision
"The green starch factory"*

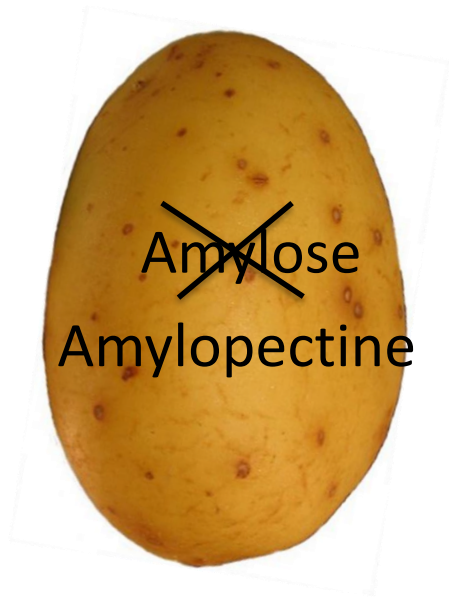
Using NBT we have managed to solve storage stability.



Research project in collaboration with



Site directed mutagenesis for improved sustainability



→
Site-directed
mutagenesis
CRISPR-Cas9

New variety:

Amylopectine starch

- ✓ Natural storage stability
- ✓ No need of chemical modification

↓
Reduction of process chemicals: 4-5000 MT/year

Reduction of energy consumption: 0,5 GWh/year



- Project started 2014
- 2019 → field production
- 2022 industrial production of new, climate friendly, starch products



Late blight resistant potato

- The use of plant protection products against leaf mold is extensive in potato cultivation
- By creating varieties that are naturally resistant to the fungus, we can reduce the use of plant protection by up to 75%
- At the same time, the use of fuel is reduced
- Breeding work is in progress, the first varieties will be evaluated in 2020

Need of political support

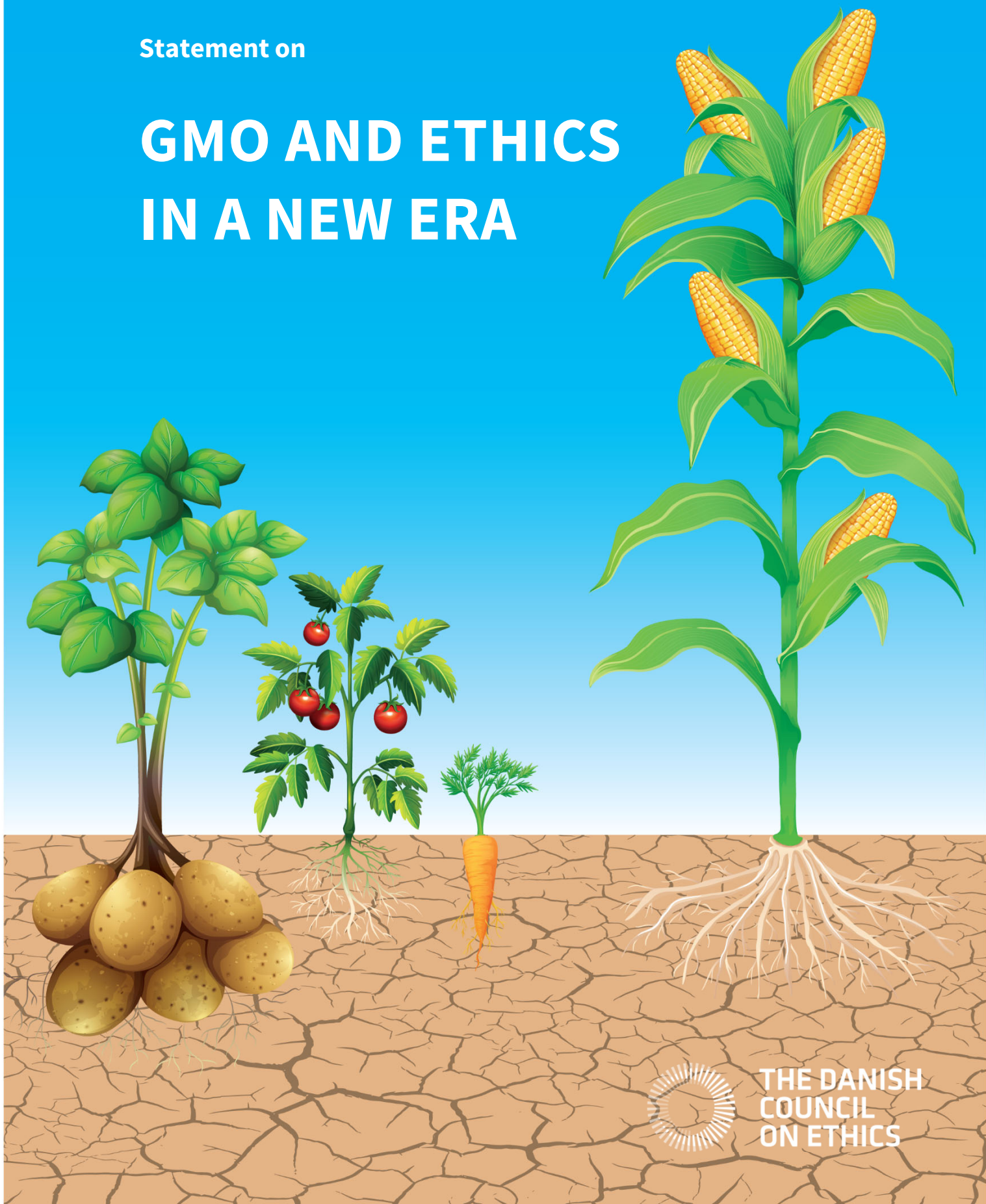
- Further policy decisions are needed to increase the availability of renewable energy sources
- Modern plant breeding is stopped by EU legislation, we need a change of the GMO-legislation

Thank you!



Statement on

GMO AND ETHICS IN A NEW ERA



THE DANISH
COUNCIL
ON ETHICS

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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:

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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 1.0°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 show 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 being edited or inserted. So far, we have almost exclusively seen types of traits that 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*

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 Roundup from Monsanto, a multinational seed and chemical company. The resistance

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

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 concerns 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

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

necessarily be 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.