Van:	@epsomail.org>
Verzonden:	vrijdag 17 januari 2020 10:32
Aan:	@mapa.es);
	@regeringskansliet.se);
	@fz-juelich. de @fz-juelich.de);
	@bmel.bund.de);
	@fz-juelich.de); @envir.ee)
	@smm.lt)
CC:	@helsinki.fi);
	@ibba.cnr.it);
	@upm.es); nto@taltech.ee);
	@taltech.ee); @wur.nl);
	@itqb.unl.pt);
	@genteknik.se); @embo.org);
	(@graminor.no);
	(@nmbu.no); @cragenomica.es);
	(@ens-Iyon.fr); (@vib.be);
	@bloteknologiradet.no);
Onderworp:	EPSO: Genome editing 2nd Informal science policy meeting in BRU 24.1.2020; Invitation +
ondernerp.	updated agenda: List of participants: Pending confirmations by 20 Jan pls
Biilagen:	20.01.16 EPSO Genome editing 2nd informal meeting Invitation and agenda.pdf: 20.01.17
	EPSO Genome editing 2nd informal meeting Participants.docx: 19 09 30 EPSO Genome
	editing informal meeting Report.pdf
Urgentie:	Ноод
Dear colleagues	from national ministries,
Thank you for yo our 2 nd Informal	our replies. Pls find attached the Invitation with the updated agenda and the List of Participants for science - policy meeting in Brussels next Friday, 24.1.2020.
The meeting will	l be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the
German Researc	ch Organisations), Rue du Trône 98; 1050 Brussels; Belgium; <u>www.kowi.de</u> .

Those of you not confirmed yet (not in bold in the participant list), pls confirm to best by 20 January.

FYI, we attach as well the report form the 1st informal meeting 19.9.2019.

Looking forward to a most interesting discussion

European Plant Science Organisation, EPSO Rue de l'Industrie 4, 1000 Brussels, Belgium

psomail.org ; -

www.epsoweb.org ; EU Transparency Register Number 38511867304-09

From: Sent: 19.12.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation + agenda; List of participants; News; Pending confirmations by 17 Jan pls

Dear colleagues from national ministries,

Thank you for your replies. Pls find attached the **Invitation with the draft agenda**, the **List of Participants** and **News** (relevant publications) since our September meeting for our 2nd **Informal science - policy meeting in Brussels as Friday**, **24.1.2020**.

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; <u>www.kowi.de</u> .

Those of you not confirmed yet (not in bold in the participant list), **pls confirm to best by 17 January**. FYI, we attach as well

- 19_11_14_Council decision_ECJ NBTstudy (news item 1)
- 19_11_15_Contribution666b7610-ddca-4262-b4be-dc125b7ec2cf.pdf (news item 5)
- Wishing you a Merry Xmas and all the best for 2020

Looking forward to a most interesting discussion

From: Sent: 09.12.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020 (11am - 4pm); List of participants; Pending confirmations ASAP pls

Dear colleagues from national ministries,

Thank you for your replies. Pls find attached the **updated List of Participants** for our 2nd **Informal science - policy meeting in Brussels as Friday, 24.1.2020.**

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; <u>www.kowi.de</u>.

Those of you not confirmed yet (not in bold), pls confirm to me ASAP, latest by 17 January.

We will send you the draft agenda and relevant publications since our last discussion next week. Looking forward to a most interesting discussion

From: Sent: 22.10.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020 (11am - 4pm) - block; Pending confirmations by 25 Nov pls

Dear colleagues from national ministries,

Thank you for your replies. We are happy to confirm the date for our 2nd Informal science - policy meeting in Brussels as Friday, 24.1.2020 – pls block this in your agenda.

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; <u>www.kowi.de</u>.

Pls find attached the list of participants. **Those of you not confirmed yet (not in bold), pls confirm to me before 25 November**. Upon your recommendation we already added two ministry colleagues to the list – pls feel free to suggest more colleagues from your country / other countries' ministries we should invite.

Most of you confirmed as well to be included in a **mailing list** to receive quarterly (if appropriate monthly) updates regarding genome editing legislation and efforts to improve the legislation from among the participants. Again – if you did not confirm yet, you may do so at any time.

We will send you more information before the Xmas break.

Looking forward to a most interesting discussion

From:

Sent: 30.9.2019 To: Participants

Subject: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Report - reply pls by 11 Oct 2019

Dear colleagues from national ministries,

Thank you for a very open and constructive meeting!

Please find attached

- The Report you may use publicly
- The Presentations you may use internally to discuss with your colleagues
- The Handout including the updated participant list Chatham House Rule only for participants.

Actions:

- All participants (this always includes those that apologised to due to overlapping activities) kindly provide to us best by 11 October 2019 their <u>availability</u> to meet in Brussels in the European quarter (if possible at KoWi) on suggested dates in January – pls delete what not applicable and send back to
 - Mo 20.1.2020: yes, possible, not
 - o Tu 21.1.2020: yes, possible, not
 - o Th 23.1.2020: yes, possible, not
 - Fr 24.1.2020: yes, possible, not
 - Th 30.1.2020: yes, possible, not
 - Fr 31.1.2020: yes, possible, not.
- All participants kindly reply to us best by 11 October if they agree to be on a <u>mailing list</u> to receive quarterly (if appropriate monthly) updates regarding genome editing legislation and efforts to improve the legislation from among the participants.
 - Colleagues who have the Finnish proposal that the EC should perform a study on the impact of the ECJ ruling, pls provide this to us to send it to the list clearly stating the level of confidentiality we need to apply.
- Ministry participants kindly suggest to EPSO best by 11 October which <u>additional ministry colleagues</u> to invite (providing name, ministry, email)
 - o from your own country e.g. from the other key ministries involved in the discussion
 - from additional countries.
 Should this not be possible under GDPR, please recommend such colleagues to contact EPSO expressing their interest to join the next such informal meeting.
- All participants are welcome to brainstorm with their colleagues further ideas for <u>flagship projects</u> or already started initiatives that could become a flagship and send to us by early December to include in the preparatory material for the next meeting.

We very much look forward to your replies and to continue the discussion

European Plant Science Organisation, EPSO Rue de l'Industrie 4, 1000 Brussels, Belgium

"epsomail.org;

www.epsoweb.org; EU Transparency Register Number 38511867304-09



Invitation and agenda

Genome editing Improving legislation and start flagships to better address climate, environmental, food and health challenges

2nd Informal meeting in Brussels 24.1.2020 11 am – 4 pm European Liaison Office of the German Research Organisations (KoWi) Rue du Trône 98, 1050 Brussels, Belgium, www.kowi.de

Brussels, 19.12.2019, updated 16.1.2020

The European Plant Science Organisation (EPSO) invites policy makers to join EPSO members in an 2nd informal meeting exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide.

Draft agenda: 11 - 4pm on 24.1.2020, Lunch will be provided

11:00 - 11:30 Registration

11:30 Welcome and tour de table

12:00 Legislation – how could it be improved?

Introduction of the already available substantial suggestions to update or replace current EU-legislation on GMO:

- Detailed introductions (5'-10' each) to ideas from the NL discussion proposal 2017 Citizen Initiative (Eur)
- Comparative summary

12:50 Discussion

- Perspectives (small modifications or fundamental changes ...)
- Consideration of the upcoming study by the European Commission
- How to support policy makers

13:30 Lunch

14:00 Flagships towards GE products with consumer benefits on the market in Europe

- Summary from the 1st informal meeting
- Consideration of consumers' attitudes: Nuanced attitudes to gene editing in Norway
- Steps forward
 - Priority criteria* / screening
 - o Consider stakeholder concerns
 - Next steps

15:30 Conclusions, next steps

16:00 Closing

	*Flags	hips	priority	criteria
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- status: ongoing or de novo?
- feasibility: target identified or not?
- novelty: novel or copy of existing mutation (same species or other species)?
- type of benefit: crop culture (less intrants, resilience, adaptation, diversification, productivity) or quality of the product (health benefit, technical improvement for processing industry)?
- beneficiary: farmer, consumer and/or citizen?
- impact: region or country or climatic zone or all of EC?
- impact: field crop or niche market?
- Impact: stakleholder/consumer concerns

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country) and policy makers (1-3 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe. The meeting shall build on the 1st one. We will continue to broaden the discussion and invite more representatives from countries interested in the issue.

EPSO offers to collaborate with policy makers to develop an appropriate future-ready regulation to enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the environmental impact of agriculture. Notwithstanding the technical option retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.

Those still pending (not in bold in attached participant list), please kindly confirm your participation best by 17 January to provide the personal of the persona of the personal of the personal of the pers

Attachments:

- List of participants only for meeting participants (Chatham House Rules)
- News relevant to his meeting since the 1st informal meeting on 19.9.2019



About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 31 countries, mainly from Europe, and 2.600 individuals Personal Members, representing over 26 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science including science advice to policy, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science. https://epsoweb.org/



Apologised count	tries:
Denmark	
,	Ministry of Environment and Food - apologies
	, University of Copenhagen - apologies
Lithuania	
	. Vice-minister of Education, Science and Sport - apologies
	, LT Research Centre for Agriculture and Forestry (LAMMC) – apologie
Portugal	
	, Forestry and Rural Development - apologies
	, ITQB - apologies

Report



Genome editing Improving legislation and starting flagships to better address climate, environmental, food and health challenges

Informal meeting in Brussels 19.9.2019

Brussels, 30.9.2019

The European Plant Science Organisation (EPSO) invited policy makers to join EPSO members in an informal meeting exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe to better address climate change, achieve food and nutritional security, and establish a sustainable agriculture in Europe and world-wide.

The meeting was an open-minded, informal discussion under the Chatham House Rule between plant scientists (1 / country) and policy makers (1-2 / country) from governmental bodies, which already indicated interest in an innovative approach for agriculture and plant breeding in Europe.

Participants discussed the **current legislation - if and how it could be improved** in the short and in the longer term. Following an introduction by EPSO and examples from movements in the various countries, ministry participants provided information about the status of discussion in their respective country.

The Finnish proposal via the Council of the European Union that the EC should perform a study on the impact of the ECJ ruling was mentioned, which is foreseen to be on the agenda of the AGRI Council meeting in November / December. The study is intended to be accomplished end April 2021. It should look into how the Court of Justice ruling affects genome editing technologies. The discussion on the legislation and possible improvements is expected to be on the agenda of the incoming Commissioners who would take office earliest on 1.11.2019, subject to their approval by the European Parliament.

The various countries are having internal discussions. It is likely that one country is going to publish a position in the near future. In other countries, recommendations / positions of governmental advisory boards have already been published. As an example of a possible way forward, the proposal of the Norwegian Biotechnology Advisory Board (Bratlie et al. 2019), was presented.

During the discussion the following general issues were highlighted for further consideration to improve the legislation: i) better address global challenges such as climate change, environmental impact, food and nutritional security, ii) arrive at a legislation adhering to international law (Cartagena protocol), iii) enable implementation of the ECJ ruling (for example a simple notification for the class of genome editing products that could be achieved by classical mutagenesis, breeding or evolution, but not additionally regulating these), iv) strengthen European competitiveness, and v) offer a free choice to developing countries to use the technology without restrictions when exporting their products to Europe. In addition, in a future meeting concerns raised by parts of society should be addressed as well.

In the second part of the meeting, the concept of **flagship projects towards genome edited products with consumer benefits for the European market** and initial ideas for such flagships were debated. Each flagship should address at least one global challenge – climate change / environmental sustainability, food and nutritional security, human health AND have a benefit for a certain group of consumers (regional, health condition – e.g. allergic people, etc.), and / or

improve European competitiveness. Taking all flagships together, ideally all parts of Europe would benefit.

Such flagships should be based on public-private risk and benefit sharing. They have to engage, from start to finish, scientists, industry (focus on SMEs), farmers, policy makers, regulatory agencies and citizens. The presentation of flagship ideas needs to specify and later on demonstrate how they address global challenges / societal questions, legislative requirements, economic and consumer benefits.

Flagship ideas can target different levels of technology readiness, ranging from theoretical concepts, to proof-of-concept in confined environments and field trials, to actual market release. Ideally one should be market-ready to be further developed to market release and authorisation might be envisaged in the medium term to actually have a product on the market in Europe (to demonstrate benefits while testing the legislative burdens if not already benefiting from respective improvements); others should complete field trials (to show benefits and encourage further steps towards the market), and some could be at the laboratory / greenhouse stage (to demonstrate feasibility and potential benefits).

The meeting was a starting point: In the coming months, we intend to continue the open dialogue between the science and policy participants from this meeting and invite representatives from other countries interested in the issue, possibly as well from the European Commission and/or the European Parliament. We are planning such a second informal meeting around January 2020.

At the second meeting we will continue the discussion on options to improve the regulation, taking into account developments across Europe (best with some insight into the EC priorities / agenda) and beyond, and hearing more ideas / proposals for possible flagship projects, discussing how prepare implementation of such an initiative at national or if possible multi-national level.

Actions:

- All participants (this always includes those that apologised to due to overlapping activities) kindly provide to us best by 11 October 2019 their <u>availability</u> to meet in Brussels in the European quarter (if possible at KoWi) on suggested dates in January (Mo 20., Tu 21., Th 23., Fr 24., Th 30., Fr 31.1.2020).
- All participants kindly reply to us best by 11 October if they agree to be on a <u>mailing list</u> to receive quarterly (if appropriate monthly) updates regarding genome editing legislation and efforts to improve the legislation from among the participants.
 - Colleagues who have the Finnish proposal that the EC should perform a study on the impact of the ECJ ruling, pls provide this to us to send it to the list - clearly stating the level of confidentiality we need to apply.
- Ministry participants kindly suggest to EPSO best by 11 October which <u>additional ministry</u> <u>colleagues</u> to invite (providing name, ministry, email)
 - from your own country e.g. from the other key ministries involved in the discussion
 from additional countries.
 - Should this not be possible under GDPR, please recommend such colleagues to contact EPSO expressing their interest to join the next such informal meeting.
- All participants are welcome to brainstorm with their colleagues further ideas for <u>flagship</u> <u>projects</u> or already started initiatives that could become a flagship and send to us by early December to include in the preparatory material for the next meeting.

EPSO offers to collaborate with policy makers to develop an appropriate future-ready regulation to enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the environmental impact of agriculture. Notwithstanding the technical option retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.



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Annex Supporting literature - links

- EPSO statement (endorsed by all EPSO Representatives for 197 institutes / universities), 19.2.2019: https://epsoweb.org/download/epso-statement-on-ecj-ruling-regarding-mutagenesis-and-gmo/
- EPSO welcomes Commissioner Andriukaitis statement and call for action 'New plant breeding techniques need new regulatory framework', 29.3.2019: <u>https://epsoweb.org/epso/epso-welcomescommissioner-andriukaitis-statement-and-call-for-action-new-plant-breeding-techniques-need-newregulatory-framework/2019/03/29/</u>
- VIB statement (including signatories for 109 institutes / universities and 18 associations), 25.7.2019: http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20ed iting%20for%20sustainable%20agriculture%20and%20food%20production%20in%20the%20EU.aspx
- Open letter from Swedish Vice chancellors of Umea University and representatives from funding agencies, 25.7.2019: <u>https://www.upsc.se/documents/News/News_2019/2019-07-25_Open-letterconcerning-GMO-regulations.pdf</u>
- ESA Open Letter to Member States on the EU Court Ruling on Mutagenesis, 9.5.2019: https://www.euroseeds.eu/app/uploads/2019/07/Letter-to-Member-States-at-Scopaffs-July-2019.pdf
- Grow scientific progress: crops matter! European citizen initiative, 25.7.2019: https://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2019/000012/en
- Statement by the Group of Chief Scientific Advisors, 13.11.2018: https://ec.europa.eu/info/sites/info/files/2018 11 gcsa statement gene editing 2.pdf
- Bratlie et al. 2019: A novel governance framework for GMO. EMBO Reports (2019) 20: e47812; DOI 10.15252/embr.20194781 [Suggestion from Norway to modify legislation on genetic engineering] http://www.bioteknologiradet.no/filarkiv/2019/03/2019-04-16-Genteknologiloven-komplett-ENGELSK-siste.pdf
- Paper from the NL suggesting the modifications in the Annexes of 2001/18/EC prior to the ruling, 21.3.2019: <u>https://www.cogem.net/index.cfm/nl/publicaties/publicatie/voorstel-voor-aanpassing-van-de-vrijstelling-in-de-ggo-regelgeving-aanvullende-criteria-voor-het-vrijstellen-van-gg-planten?order=relevance&g=&category=&from=30-09-1998&to=21-03-2019&sc=fullcontent
 </u>
- Curia Judgement of the court in case C-528/16, 25.7.2018: http://curia.europa.eu/juris/document/document.jsf?docid=204387&doclang=EN
- Wasmer 2019: Roads Forward for European GMO Policy—Uncertainties in Wake of ECJ Judgment Have to be Mitigated by Regulatory Reform. Front. Bioeng. Biotechnol. 7:132. doi: 10.3389/fbioe.2019.00132
- Joint Statement of AFBV and WGG, 13.9.2019: <u>https://cdn.website-</u> editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/AFBV-WGG-Statement.pdf

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Van: Verzonden:	donderdag 23 januari 2020 11:50
Aan:	
Onderwerp:	RE: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation updated agenda; List of participants; Pending confirmations by 20 Jan pls
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Van: Verzonden: dond	@wur.nl> lerdag 23 januari 2020 11:49
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Van:	@wur.nl>
Verzonden: do	nderdag 23 januari 2020 09:55
Aan:	

Could we have contact by phone today?

Groet,

Op 23 jan. 2020 om 09:48 heeft @epsomail.org> het volgende geschreven:

Dear

Thank you, this is unfortunate indeed. I will add your apologies in the agenda. Should I add that participates on your behalf and will you provide any information to **see a**/get feedback from him?

With best wishes and see you next time

From: @minlnv.nl>
Sent: 23 January 2020 09:38
To: @epsomail.org>
Cc: @wur.nl>

Subject: RE: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation + updated agenda; List of participants; Pending confirmations by 20 Jan pls

Dear

Unfortunately I will not be able to attend tomorrow due to other pressing matters in the Hague. Apologies for the inconvenience.

Kind regards,

Van: @epsomail.org<mailto: @epsomail.org>> Verzonden: vrijdag 17 januari 2020 10:32 Aan: @mapa.es<mailto: @mapa.es>) @mapa.es<mailto: @mapa.es>>; @agriculture.gouv.fr>>; @agriculture.gouv.fr<mailto: @regeringskansliet.se<mailto</pre> @regeringskansliet.se>) @regeringskansliet.se<mailto: @regeringskansliet.se>>; @kld.dep.no<mailto: @kld.dep.no>>; @regeringskansliet.se<mailto: @regeringskansliet.se>>; @bmbf.bund.de<mailto: @bmbf.bund.de>>; @fz-juelich. de (@fz-juelich.de>) @fz-juelich.de<mailto: @fz-juelich.de>>; @fz-juelich.de<mailto @bmbf.bund.de<mailto:</pre> @bmbf.bund.de>>; @formin.fi<mailto: @formin.fi>>; @bmel.bund.de<mailto: @bmel.bund.de>>; @bmel.bund.de<mailto: @bmel.bund.de>) @bmel.bund.de<mailto: @bmel.bund.de>>; < @minInv.nl<mailto: @minInv.nl>>; @f7juelich.de<mailto @fz-juelich.de<mailto @fz-juelich.de>) <</pre> @fz-juelich.de>>; @environment.belgium.be<mailto: @environment.belgium.be>>; @envir.ee<mailto: @envir.ee>) @envir.ee<mailto: @envir.ee>>; @smm.lt<mailto: @smm.lt>) @smm.lt< @smm.lt>> CC: @epsomail.org<mailto: @epsomail.org>>; @helsinki.fi<mailto: @helsinki.fi>) @helsinki.fi>>; @helsinki.fi<mailto @ibba.cnr.it<mailto: @ibba.cnr.it>) @ibba.cnr.it<mailto: @ibba.cnr.it>>; @cnb.csic.es<mailto: @cnb.csic.es>) @cnb.csic.es<mailto: @cnb.csic.es>>; @upm.es>) @upm.es<mailto @upm.es<mailto: @upm.es>>; @taltech.ee<mailto @taltech.ee>) @taltech.ee<mailto: @taltech.ee>>; @taltech.ee<mailto: @taltech.ee>) @taltech.ee<mailto: @taltech.ee>>; @wur.nl<mailto: @wur.nl>) @wur.nl<mailto: @wur.nl>>; 2

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Onderwerp: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation + updated agenda; List of participants; Pending confirmations by 20 Jan pls

Urgentie: Hoog

Dear colleagues from national ministries,

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FYI, we attach as well the report form the 1st informal meeting 19.9.2019.

Looking forward to a most interesting discussion

Transparency Register Number 38511867304-09

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From: Sent: 19.12.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation + agenda; List of participants; News; Pending confirmations by 17 Jan pls

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European Plant Science Organisation, EPSO Rue de epsomail.org ; Transparency Register Number 38511867304-09	'Industrie 4, 1000 Brussels, Belgium www.epsoweb.org <http: www.epsoweb.org=""> ; EU</http:>

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Dear colleagues from national ministries,

Thank you for a very interesting meeting and apologies for the delay in sending the report, you will receive it later in April.

As we are all busy with the EU survey on NGTs, you may find the report useful towards which presented first outcome at our meeting:

The Norwegian Biotechnology Advisory Board (2020). Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture. <u>www.bioteknologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf</u>

With best wishes and have a nice Easter

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From: Sent: 17.1.2020 To: Participants

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Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture







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1. Preface

The aim of this report has been to investigate Norwegian consumers' attitudes towards the use of gene editing in livestock and crop plants in Norwegian agriculture and aquaculture. The knowledge obtained here will be used as a steering tool for the industry-led research project GENEinnovate, of which the survey is a part. In addition, a good knowledge base can contribute to an informed public debate and future-oriented policy.

GENEinnovate is a collaboration between Norsvin, Geno, AquaGen, Graminor, the Norwegian University of Life Sciences (NMBU) and the Norwegian Biotechnology Advisory Board to establish research collaborations and build expertise on gene editing in livestock, fish and plants in Norway. The project is funded by the Norwegian Research Council (project no. 281928) and by the industry partners in the project. The study on which the report is based was carried out as part of the work package for which the Norwegian Biotechnology Advisory Board is responsible. The Norwegian Biotechnology Advisory Board is an independent body appointed by the government that gives advice on issues concerning the use of biotechnology and genetic engineering and contributes to public information and debate.

Sigrid Bratlie (former senior advisor at the Norwegian Biotechnology Advisory Board, now special advisor at the Norwegian Agricultural Cooperatives and project member of GENEinnovate) has led the work and had the main responsibility for designing the questions and content for the focus group interview guide and the survey questionnaire, analysed the survey data, prepared the results and wrote the report. Hilde Mellegård, senior adviser of the Norwegian Biotechnology Advisory Board, has also contributed to the development of the interview guide and survey questionnaire as well as editing the report. The rest of the GENEinnovate project group contributed with scientific advice during the preparation of the study and the completion of the report.

Data collection, both in focus groups and in the population survey, was carried out by Ipsos, a company that performs market analyses and opinion polls. The project manager was Arild Sæle. Ellisiv Bergheim was responsible for the qualitative study. She led the discussions in the focus groups and compiled the results afterwards. Linn Sørensen Holst was responsible for the quantitative population survey. Jan Behrens contributed to the development and quality assurance of the content of the questionnaires.

Thanks to Knut Liestøl, Professor of Bioinformatics at the University of Oslo, for providing guidance in choosing statistical methods. Thanks also to researcher Audun Fladmoe at the Institute of Social Research, Oslo, for guidance in the study design and to former Director of the Norwegian Biotechnology Advisory Board Ole Johan Borge for his helpful reflections on the planning of the study.

Published 2 April 2020

2. Summary

This report presents results from a population survey of Norwegian consumers' attitudes towards the use of gene editing in Norwegian agriculture and aquaculture. The data are from 2016 respondents, nationally representative of age, gender and geographical region, from the Ipsos online panel.

The key findings are:

• Norwegian consumers know quite a lot about genetically modified food, but only about half have heard about gene editing (often called CRISPR).

• Norwegian consumers' attitudes toward the use of gene editing (which in this context is defined as targeted genetic changes without insertion of new DNA) depend on the purpose and what the product it is used for. The majority are positive about using gene editing in Norwegian agriculture and aquaculture for purposes that are perceived to promote societal benefit and sustainability. Examples include reducing pesticide use and crop losses in plants, climate adaptation of crop plants, increasing nutrient content in crop plants, increasing crop plant yields, improving animal and fish health and reducing the environmental impact of the aquaculture industry. However, most consumers are negative about using gene editing for purposes that are not perceived to be of significant benefit to society or which may impact animal welfare negatively, such as changing the appearance of animal and plant products or enhancing production traits in livestock.

- Most Norwegian consumers are in favour of using gene editing in organic food production if it allows crops to be cultivated without pesticides.
- Most are somewhat or very worried that the use of gene editing in plants or livestock could pose risks to health and the environment.
- Consumers' attitudes and levels of trust depends on who is behind the development of products. Consumers are more positive about gene edited products developed by Norwegian researchers and breeding companies for the Norwegian market than they are about genetically modified products developed by international producers for the global market.
- Consumers have a fairly high level of trust that gene edited products developed by Norwegian researchers and breeding companies are beneficial to society and that they are safe for health and the environment when they have been approved by Norwegian authorities.
- A large majority of consumers think that labelling is important, but the label should also contain information about which genetic technology has been used, why it was used and which trait has been changed.

• Consumers prefer foods that are not gene edited if they can choose from relatively similar products, but they are not willing to pay very much extra for non-gene-edited foods. Consumers' willingness to pay extra for gene edited foods with benefits that they think are important is also fairly low.

• More consumers think that it may be unethical not to use gene editing to address important societal challenges than those who do not.

• Norwegian consumers regard gene editing and genetic modification as more unnatural than traditional breeding, but they do not distinguish between the two types of genetic technology in terms of naturalness. Perception of naturalness is linked to acceptance of gene editing in crop plants and livestock, and the level of knowledge affects this perception.

• Knowledge is crucial for acceptance and trust. Our results indicate that Norwegian consumers with the most knowledge about genetic engineering and genetics are the most positive about using gene editing in agriculture and aquaculture and have the most trust in product developers and authorities that approve products.

The main conclusions from the population survey are that the majority of Norwegian consumers are positive about sustainable and societally beneficial use of gene editing in Norwegian agriculture and aquaculture. However, many consumers are concerned about risk, although they have fairly high confidence that gene edited products approved by the Norwegian authorities are safe for health and the environment. Consumers also want information about product traits that makes it easier for them to choose. The results also show that there is a need for knowledge building about genetic technology and food in the general population.

4. Introduction and background

Gene editing has the potential to contribute to sustainable food production. Possible benefits of gene editing in livestock and crop plants include increased yields and better utilisation of resources, improved plant and animal health, reduced need for pesticides and fertilizers and increased nutritional content and durability of the food. However, there is considerable debate about the consequences of using genetic engineering for health, the environment and global food power. The public debate impacts research, technology development, policy and regulations and should therefore be knowledge based. The aim of this report is to contribute to such knowledge by surveying Norwegian consumers' attitudes toward the use of gene editing in livestock and crop plants in Norwegian agriculture and aquaculture.

4.1 Genetically modified food in a historical context

The public debate about genetically modified food has a decades-long history. Genetic engineering of plants, animals and microorganisms was first developed in the 1970s, and genetically modified crops have been on the international market since the 1990s. Most often, such 'classical' genetic modification involves transferring genes from one organism to another, often from one species to another. Most genetically modified organisms (GMOs) on the global market today are crop plants that tolerate different types of pesticides and/or produce toxins against insects. These are developed for large, commercial markets.

Genetically modified food currently is and has long been a contentious issue, especially in Europe. There is a widespread notion that European consumers oppose GMOs. A Eurobarometer survey from 2010 showed that 61 per cent of Europeans disagreed that the development of genetically modified food should be encouraged, and a similar percentage responded that genetically modified food worried them [1]. A survey carried out by Consumption Research Norway (SIFO) in 2017 on behalf of the Network for GMO-Free Food and Feed, hereafter named the SIFO study, showed that most Norwegian consumers are opposed to genetically modified food [2]. The focus of these surveys has been on 'classical' genetic modification and commercial products currently available on the international market but not in Norway.

4.2 Gene editing - new technology and changing attitudes

In recent years, new genetic engineering techniques termed gene editing have been developed. The most well-known of these, which is also the focus the GENEinnovate research project, is CRISPR. Since its development in 2012, the technology has been adopted rapidly in both academia and commercial research and development. Gene editing is cheaper and simpler to use than 'classical' genetic modification and enables a greater range of genetic changes to be made. Gene editing is also more targeted than older techniques. In principle, gene editing allows any change in the genetic sequence in any cell type or organism. Multiple changes can also be made in parallel [3,4]. The simplest and most widespread application of gene editing in crop plant and livestock research and development today is genetic alterations that mimic naturally occurring changes or changes that can or in theory could be obtained by conventional breeding methods. Such changes may improve a number of traits in plants and animals. Much of the on-going research is on applications for improved plant and animal health. These developments have also led to a diversification and increase in the number of stakeholders involved in research and innovation in the field. See the box below for further information on gene editing, genetic modification and traditional breeding as well as a brief description of regulations.

BOX: Methods for developing crop plants and livestock, and products thereof, with new traits

Traditional breeding through crossing:

For organisms that propagate through sexual reproduction, the offspring is a genetic mix of its two parents, with half of its DNA coming from each. This enables beneficial traits from different individuals to be combined. At the same time, other undesirable properties are also inherited. These can be removed over time through new crossings over several generations. New traits often arise from spontaneous mutations – random changes in the genetic sequence caused by, for example, UV radiation from the sun or errors that occur when a cell divides in two. In animals and plants, usually a few dozen mutations occur from one generation to the next. Some mutations lead to functional changes, which can be either positive or negative for the organism, while most have little or no effect.

Regulation: Plants and animals, as well as products thereof, produced by traditional breeding are not regulated specifically, but they are subject to general provisions on food safety, animal welfare, etc.

'Classical' genetic modification:

The first methods of genetic modification, developed in the 1970s and 1980s, are based on isolating and inserting genes into the DNA of a cell. Different methods are available for getting the gene into the cell. In plants, bacteria are often used as carriers of the genetic material, or it can be transferred using chemicals, electricity or a so-called 'gene gun'. In animal cells, chemicals or electricity are also used, or the genetic material can be injected through microinjection or transferred using a virus. It is often difficult to control where in the DNA a gene is inserted and how many copies are inserted.

Regulation: In addition to general regulations that apply to all food-producing plants and animals, genetically modified plants and animals are regulated under specific regulations for GMOs. This involves assessment of health and environmental risk. In Norway, GMOs must also be assessed according to the criteria of societal benefit, sustainability and ethics under the Gene Technology Act.

Gene editing with CRISPR:

Gene editing enables more targeted changes to be made to the genetic material than are possible with classic genetic modification. The process involves enzymes that recognise a specific DNA sequence and create a cut in the DNA. During the subsequent repair process initiated by the cell, DNA can be removed, replaced or inserted in the cut zone, thus enabling specific changes to be made. In this way, genetic traits from different individual organisms can be combined without other undesired traits that occur during traditional crossbreeding. In this study, we have defined gene editing as genetic changes that mimic those that arise spontaneously in nature or changes that can be obtained through traditional breeding (e.g. inserting genes from one potato variety into another potato variety). In these cases, no genetic sequences from other species are inserted, and the result therefore differs from that of 'classical' genetic modification. The precision of the gene editing depends on the type of organism, the sequence that is targeted and which CRISPR method variant is used.

Regulation: There are different regulations for gene-edited organisms in different parts of the world. In some places, such as the US and Australia, gene edited plants without inserted DNA are not regulated differently from plants produced by traditional breeding. In Norway and the EU, however, all gene edited organisms are classified as GMOs and must be approved according to the same criteria as 'classical' GMOs.

Developments in both the technological possibilities and the range of applications have renewed the public debate about genetically modified food, and important nuances are emerging. For example, public perceptions depend on whether or not the genetic change crosses species barriers as well as on product characteristics [5,6,7,8]. Recent findings also indicate that the purpose of genetically engineering plants and animals is important. For example, a substantial majority (71 per cent) of UK consumers are positive about using genetic engineering for improving animal health or for reducing the environmental impact of agriculture, whereas a minority (33 per cent) are positive about using genetic engineering when the purpose is primarily to increase the producer's profits. The study, conducted in 2017 by The Royal Society in the UK [9], is, as far as we know, the only published survey that specifically looks at consumer attitudes toward new genetic technologies such as gene editing. Norwegian consumers' attitudes about gene editing have not yet been studied. Such knowledge could be an important element in the public debate and for research and innovation in Norway.

4.3 GENEinnovate – gene editing for innovation in the Norwegian breeding industry

In the research project GENEinnovate, scientists, bioindustries and the public sector are working together to investigate whether gene editing can contribute to sustainable food production in Norwegian agriculture and aquaculture.

The four industry partners, Norsvin, Geno, AquaGen and Graminor, are leading bioindustries in crop plant and livestock genetics in Norway and represent both the agricultural and aquaculture sectors. Several of them also have significant international markets. All use genomics (information about the genetic sequence) in their breeding programmes and have several research programmes for better understanding the genetics underlying different traits. Breeding and genetics are important tools for the development of sustainable food production, increased food security and to ensure competitiveness.

To better understand which gene variants are important and possibly integrate them into their breeding programs, the industry partners want to build expertise and develop gene editing technology. If successful, the method can make breeding more efficient and more precise than it is today. The main aim of GENEinnovate is to conduct research to improve plant and animal health. Examples are potatoes that are resistant to late blight, pigs and cattle that are resistant to infectious disease and salmon that are resistant to sea lice. The Norwegian University of Life Sciences (NMBU) is a key partner that will lead the work on developing technology platforms that can be used in the various work packages.

Since gene editing is a controversial topic, GENEinnovate will also engage in public dialogue and promote transparency and open communication about on-going research and related aspects. The Norwegian Biotechnology Advisory Board is responsible for this part of the project. This collaboration could help the breeding companies to understand and build competence on gene editing in a way that is in line with societal values and political and regulatory guidelines. The survey presented here is part of this work.

5. Methods

In this chapter, we describe the methods and data collection in the study. We conducted two surveys: a qualitative survey with focus groups and a quantitative population survey.

5.1 Qualitative survey (focus groups)

The qualitative study was first and foremost exploratory with the aim of uncovering relevant nuances and causes of different attitudes towards genetic technologies. It was also used to inform the design of the population survey questionnaire.

The focus groups were conducted on 23–24 October 2019 at the Oslo, Norway office of the market analysis company Ipsos. The sample consisted of a total of 20 respondents from the Oslo area, recruited through Ipsos' online panels and Facebook campaign. The criterion for participation was that the respondents must have heard about genetic technology. The selection was made to ensure even distribution between respondents who were initially positive, neutral or negative about the use of genetic technology. The respondents were divided into four groups of five with participants of both genders:

- Group 1: Men/women aged 20–34 years, Low to medium education
- Group 2: Men/women aged 20-34 years, Higher education
- Group 3: Men/women aged 35-55, Low to medium education
- Group 4: Men/women aged 35–55, Higher education

5.2 Quantitative population survey

The sample consisted of 2016 respondents, randomly drawn from Ipsos' online panel of approximately 50,000 people aged 18+. The sample was nationally representative for gender, age and geographical region. However, the level of education was somewhat higher than the population average, which is common for a standard sample from Ipsos' online panel. Furthermore, the sample cannot be assumed to be representative in terms of ethnicity, culture and minority groups.

In cases where respondents were asked to respond to several questions on the same topic, the questions were presented in random order to avoid order effects.

After an initial mapping of background knowledge, the respondents were presented with three brief informational texts explaining the principles behind traditional breeding, genetic modification and gene editing. The purpose was to ensure that the respondents had a sufficient knowledge base to be able to answer questions on various issues related to the use of gene editing in Norwegian agriculture and aquaculture. However, we wanted to keep the information to a minimum and avoid technical details to ensure that the respondents' attitudes were as representative as possible for what can be expected in the general population. The texts were as follows:

Traditional breeding, used since the Stone Age

All plants, animals and microorganisms contain thousands of genes (DNA) that determine their traits. In nature, genetic changes arise naturally that cause the traits to change. This is used to breed crops and livestock with desirable traits, which is done by crossing individuals with different desired traits. This is

the way humans around the world have adapted plants and animals to agriculture for thousands of years.

'Classic' genetic modification from the 1970s and 1980s

This method was developed by scientists in the 1970s and 1980s. It involves transferring genes from one organism to another, often between species. The method has mostly been used to transfer genes from bacteria to plants to make the plants more tolerant to herbicides or resistant to insects, which allows bigger crops.

Gene editing, the latest method

This method makes it possible to make targeted changes to the DNA, for example, removing, adding or exchanging genes or parts of genes (a common method is called CRISPR). In the examples in this study, gene editing refers to making genetic changes that mimic those that can happen by themselves in the wild or the changes one could get through traditional breeding (e.g. inserting genes from one potato variety into another potato variety). In these cases, no genes from other species are inserted. The purpose of gene editing is to adapt plant and animal traits.

The full questionnaire from the population survey can be found in the Appendix. Tables with complete frequencies for all questions, distributed across demographic variables, are available in Norwegian upon request.

5.3 Statistical analyses

Various statistical tests were used to estimate the extent to which the results of the survey can be assumed to be valid for the general Norwegian population.

- A repeated measures ANOVA was used to measure variations in the attitudes of each respondent.
- A one-way ANOVA (multivariate, corrected with Fischer's LSD), paired samples t-test or independent samples t-test (bivariate) was used to compare the average values in different groups.
- Correlation analyses (Pearson parametric test or Spearman non-parametric test) were used to
 examine the correlation between attitudes and age as well as between self-reported knowledge
 of and actual knowledge of genetic modification and related topics.
- A Chi-square test was used to compare sample frequencies.

Where numerical values calculated from graded variables (e.g. degree of positivity/negativity) formed the basis for the analyses, 'don't know' responses were excluded because the variable cannot be attributed to a meaningful value.

In all figures, the significance level is set to * = p < 0.05, ** = p < 0.01, *** = p < 0.001

All analyses and figures were made in SPSS Statistics 26 from IBM [10].

6. Results

In this study, we wanted to survey Norwegian consumers' attitudes toward different uses of gene editing relevant to Norwegian agriculture and aquaculture in general, and to GENEinnovate in particular. We also wanted to explore consumer attitudes and trust levels towards researchers, producers and relevant authorities as well as aspects related to knowledge level, risk perception, product labelling, willingness to pay and ethics. The results presented below are mainly from the population survey. Some findings from the focus groups are included where they are considered particularly relevant to elaborate or complement the quantitative data. The most interesting and relevant findings are presented below.

6.1 Norwegians' knowledge of genetics and genetic engineering

Before going into specific attitudes toward gene editing, we wanted to map what basic knowledge the respondents had about genetics, traditional breeding methods and genetic technology.

6.1.1 Genetically modified food is a well-known concept, but only half have heard about gene editing (CRISPR)

In the population survey, the respondents were first asked to classify their own knowledge of genetically modified food and gene editing (Figure 1). Over 96 per cent have heard about genetically modified foods, and over half state that they have some or a lot of knowledge. However, only about half the respondents have heard about gene editing, and only 21 per cent state they have some or good knowledge about this technology.



6.1.2 Self-reported knowledge about genetically modified foods correspond well with actual knowledge about genetically modified foods and related topics

To assess whether there is a correlation between respondents' self-reported knowledge about genetically modified foods and their actual knowledge of genetically modified foods and related topics, they were asked to rate the trueness of four different items on a ten-point scale from mostly untrue to mostly true. They could also choose the option 'impossible to judge'. In general, there is good agreement between the respondents' self-reported knowledge of genetically modified food and their actual level of knowledge (Figure 2).



Figur 2: Agreement between self-reported knowledge of genetically modified food and actual knowledge of genetic modification and related topics. On the X-axis is the ten-point scale ranging from mostly untrue to mostly true (to the left of the dotted line), plus the option 'impossible to judge' (to the right of the dotted line). For each item, the respondents aswers are distributed according to their self-reported knowledge of genetically modified food (per cent). Grey arrows indicate the most correct answer for each item according to the best scientific knowledge base.

The items 'traditional breeding has nothing to do with genes' and 'ordinary tomatoes have no genes, while genetically modified tomatoes have genes' are both false, and the respondents are more likely to respond correctly the higher they rate their own knowledge of genetically modified foods. The item 'research shows that the genetically modified products currently found on the international market are safe to eat' is — according to the majority of the scientific literature and food safety authorities mostly true [11], which is more often the response when the respondents report knowing more about genetically modified foods. The exception is the item 'there are approved genetically modified foods in Norwegian food stores', which many — regardless of their reported knowledge of genetically modified foods — believe to be true, when in reality there are no legally sold genetically modified foods in Norway. Although there is generally a good correlation between self-reported knowledge and actual knowledge of genetically modified foods, it is worth noting that, within the group of those who answer incorrectly on several of the items (those who specify a value at the opposite end of the scale than the answer that is most correct), there is a majority who state they have good knowledge about genetically modified foods. This indicates that there is a small sub-group that reports good knowledge of genetically modified foods but has low actual knowledge or low trust in the science. We will return to this group later in the report. It is also worth mentioning that, the less respondents report knowing about genetically modified foods, the more often they respond that the items are impossible to judge, or they place their answer in the middle of the scale. The results show that, with some exceptions and variations, there is good agreement between self-reported knowledge about genetically modified foods and related topics and their actual knowledge, noting certain reservations and limitations discussed in Chapter 7.2 on the use of simplified measurement variables.

6.2 Attitudes toward the use of gene editing in Norwegian agriculture and aquaculture depend on the purpose and product

As described initially, studies have shown that Norwegians and other Europeans have long been sceptical about genetically modified foods. However, few of the studies have differentiated between different types of use of genetic engineering for different purposes, and the few that have done so have largely focused on the specific GMOs that are on the international market. These products have not been considered relevant for Norwegian agriculture and aquaculture, and they have not been produced with new genetic technologies such as gene editing. However, recent studies have suggested that there are important nuances in attitudes. For instance, it has been reported that consumers' attitudes depend on the purpose the technology is used for, what trait is being changed and the type of organism. We wanted to investigate the attitudes of Norwegian consumers toward the use of gene editing for purposes relevant to Norwegian agriculture and aquaculture in general, and to the GENEinnovate project in particular. Therefore, the respondents were presented with ten different hypothetical cases to evaluate. Both the purpose of the gene edit and a concrete example of a product relevant to Norwegian agriculture or aquaculture were described for each case. It was important to have a wide range in both purpose and type of product in order to find relevant nuances in attitudes and to cover the fields of interest of all the different partners in GENEinnovate. We therefore chose five cases for crop plants and five cases for livestock, and in both groups the cases covered a range of purposes: plant and animal health, sustainability (e.g. climate adaptation or reduced environmental impact), production traits (yield) and traits that can be perceived as more 'trivial' (colour).

Because there is varying knowledge of different breeding methods –traditional breeding, genetic modification and gene editing – we presented the respondents with an informational text on each of the three methods before asking questions about their attitudes (see description in section 4.2). In particular, we wanted to point out that the type of gene editing that is relevant in GENEinnovate does

not involve inserting genes from other species, which is how 'classic' genetic modification has most commonly been used, but rather genetic changes that can also be achieved with conventional breeding methods.

Below we present the most important findings about Norwegians' attitudes toward different uses of gene editing in Norwegian agriculture and aquaculture.

6.2.1 The majority of consumers are positive about using gene editing for purposes that benefit society and contribute to sustainability in Norwegian agriculture and aquaculture

There is considerable variation in the respondents' attitudes toward different uses of gene editing in Norwegian agriculture and aquaculture (Figure 3). Overall, the majority are positive about applications with a clear sustainability or societal benefit profile, in both crop plants and livestock.

The majority of the respondents are positive about using gene editing in crop plants for several purposes. They are most positive about using gene editing to reduce pesticides and crop losses, such as creating potatoes with improved resistance to late blight. In this case, over a quarter of the respondents are very positive and almost 70 per cent are positive overall. Only about 13 per cent are negative. Climate adaptation of crop plants, such as wheat that can better withstand drought or rainfall, is another purpose that many respondents are positive about, with scores almost as high. Over half of the respondents are also positive about using gene editing to improve the nutrient content of crop plants, such as tomatoes with higher levels of vitamin C or antioxidants. A little under a quarter are negative in this case.

Several purposes of gene editing in livestock also receive support from the respondents. The majority, about 60 per cent, are positive about using gene editing to improve animal health, such as cows and pigs resistant to infectious disease or salmon resistant to sea lice. Fewer than 20 per cent are negative in these cases. Additionally, more than half of the respondents are positive about using gene editing to reduce the environmental impact of aquaculture, such as sterile farmed salmon that cannot interbreed with wild salmon if they escape. About 20 per cent are negative.

However, using gene editing for purposes that can be perceived as more 'trivial', in this case changing the appearance of the products, was something a large majority of respondents feel negative about for both crop plants and livestock. For example, 63 per cent are negative about changing the colour of fruits and vegetables, and almost 70 per cent are negative about changing the fillet colour of salmon.

In most cases, the respondents do not distinguish between animals and plants in their attitudes when the purpose was the same, i.e. the purpose of the use of the technology is more important than the type of product in question. However, one purpose stood out: production traits. Nearly half of the respondents are very or somewhat positive about using gene editing to develop high-yielding crop plants, such as wheat with larger or more grains, while only 27 per cent say they are negative. In contrast, only 20 per cent have positive attitudes toward using gene editing for increasing production traits in livestock, such as cattle with increased muscle mass or milk production, while over half are negative.





Figure 3: Different attitudes toward gene editing for different purposes in crop plants and livestock in Norwegian agrigulture and aquaculture among Norwegian consumers (weighted by gender, age and geopgraphical region). There are significant differences in attitudes for each individual respondent (p<0.001, Repeated measures ANOVA). The findings from the population survey largely reflect the findings from the focus groups, in which the respondents' attitudes also varied according to the purpose of the gene editing. Most of the participants in the focus groups were, for example, positive about gene-edited late blight-resistant potato and disease-resistant livestock but negative about increasing production traits in livestock.

However, some of the cases divided the respondents in the focus groups. One example is gene editing to increase yield. Several respondents had negative attitudes toward using gene editing for applications that primarily sought to increase the producer's profit, which many perceived productivity/yield improvements to represent. Others argued that high productivity/yield in livestock and crops is necessary to limit land use for food production, which is important for sustainable development. It is possible that the respondents in the population survey have similarly different perceptions of what benefits or disadvantages increased production traits may have. There were also different views on gene editing to improve nutritional content or increase shelf life in food products in the focus groups, although the majority were positive. One concern was about the health effects of changing the nutritional composition and shelf life of foods, for example, on the gut microbiota. Some also expressed concern that a few 'super foods' could end up dominating the market and negatively impact food product diversity.

The respondents in the focus groups emphasized different arguments in their assessments of gene editing for different purposes, but some were prevalent: animal welfare, sustainability and consumer benefit are aspects most of them were concerned about. The respondents also emphasized that technologies such as gene editing can be used for both desirable and undesirable purposes, and its use must be viewed in the context of larger policy issues related to, for example, food security, population growth and the impact that various food production systems have on ecosystems, biodiversity and sustainability in general.

In conclusion, the results from the population survey indicate that the majority of Norwegian consumers have positive attitudes toward using gene editing for purposes that clearly contribute to sustainability and societal benefit.

We also wanted to investigate whether there are relevant differences in attitudes between different demographic groups. There is little variation and correlation between groups with different levels of education and geographical distributions in our sample. However, there are other demographic factors that influenced attitudes to some extent. The most relevant findings are listed below.

6.2.2 Younger consumers are slightly more positive about gene editing than older consumers

The distribution of attitudes toward different purposes/products across different age groups reveals a weak but significant correlation between age and attitudes (Figure 4). In some cases, younger consumers tend to be more positive than older ones. This is most evident in the cases in which the majority of the respondents are negative (i.e. in cases where gene editing is used for purposes that can be perceived as 'trivial', such as changing the appearance of plant and animal products, and for improving production traits in livestock). A similar but somewhat weaker trend is also found in the cases in which the majority of the respondents are positive (i.e. cases in which gene editing is used for purposes that are more clearly beneficial to society or contributes to sustainable development). In these cases, the younger consumers are also more positive than the older ones, but the differences are smaller. In some cases, however, the positivity seems to first decrease and then subsequently increase in the highest age groups.



Figure 4: Age affects attitudes toward gene editing. In all cases exept one, there is a weak but significant correlation between age and attitudes (**= p<0.01, ***= p<0.001, Spearman non-parametric correlation analysis). The data are normalised to 100 per cent in each age group. N is between 294-397 in each group



The correlation between age and attitudes holds for all cases with one exception. In the case where gene editing is used to reduce pesticide use and crop losses (e.g. potatoes that better resist late blight), we find no significant differences: all age groups are about equally positive.

The findings largely reflect the attitudes of the focus groups, in which there were also differences between the age groups. However, there are some nuances that emerged during the discussions that are worth noting. For instance, younger participants were more concerned about animal welfare than older ones, whereas older participants were more concerned than younger participants with direct consumer benefits.

Our findings are consistent with those of other studies, which have also shown that younger consumers are more positive than older consumers about using genetic modification and gene editing for various purposes, including food production [2,9,12].

6.2.3 Women are slightly more sceptical about gene editing, but not for the purposes the majority are most positive about

We next investigated whether gender has an impact on attitudes toward gene editing in Norwegian agriculture and aquaculture. The results (Figure 5) show that women are slightly more sceptical than men, but these differences are largest in the cases in which the majority of respondents are negative (i.e. in cases where gene editing is used for purposes that can be perceived as more 'trivial', such as changing the appearance of plant and animal products or increasing production traits in livestock). Women are also slightly more negative than men about using gene editing to increase production traits in plants, to reduce the environmental impact of the aquaculture industry and to increase the nutrient content of plants, but the majority of both women and men are positive in these cases. For the other cases the majority of the respondents have positive attitudes towards — gene editing to reduce pesticides, climate adaptation of plants and improvement of livestock and fish health — there are no significant differences between genders. These are purposes that can be perceived to have a clear societal benefit or to contribute to increased sustainability and animal welfare. The findings correspond well with the dialogue in the focus groups, where women expressed a somewhat greater scepticism about the use of gene editing than men, but primarily for purposes that were perceived as negative or that could be perceived as less useful to society. The SIFO study [2] showed that, amongst Norwegians, women are generally more negative than men about genetically modified foods. Our results indicate that the picture is in fact more nuanced.


6.2.4 Those with the most knowledge about genetically modified food are most positive about gene edited food

In the SIFO study [2], the researchers concluded that scepticism about GMOs increases with increasing educational level. Our results show no such relationship. In fact, there is no correlation between positivity or negativity toward various purposes for using gene editing between different educational groups (data not shown). However, the level of education in our sample is not representative of the population. Therefore, we rather wanted to investigate whether the level of knowledge about genetic engineering and related topics is influential on attitudes toward the use of gene editing. Because there is a good correlation between actual knowledge about genetically modified food' as a proxy (substitute variable) for a broader level of knowledge. We also chose 'knowledge of genetically modified food' rather than 'knowledge of gene editing (CRISPR)' as our primary measurement variable, as only about half of the respondents have heard of the latter, which could present challenges in the statistical analyses. Furthermore, there is good agreement between the attitudes of these two groups, so the results are assumed to be valid for the level of knowledge of both technologies.

The results from the two example cases are presented below, in which the majority of respondents are positive and negative, respectively: gene editing for climate adaptation of crop plants and for changing the appearance of animal products (Figure 6). In both cases, the respondents' attitudes correlate with their knowledge of genetically modified foods: the more knowledge they have about genetically modified foods: the more knowledge they have about genetically modified foods, the more positive the respondents are. The greatest impact can be seen in the proportion of those who are 'very positive', which is significantly higher in the good knowledge group in both cases. We also found a similar correlation in the other cases (data not shown).



each knowledge group. N is indicated in the figure.

Meanwhile, we also observe that the percentage who are 'very negative' about using gene editing for climate adaptation is also highest among those who report having good knowledge about genetic engineering and genetics. A 2019 study showed that, among Americans, the degree of resistance to GMOs is correlated with increasing self-reported knowledge but decreasing actual knowledge [13]. Our results indicate a similar trend (Table 1): Within the group that reports having good knowledge about genetically modified foods, there is a difference in the actual knowledge level or trust in science between those who are positive and negative about the use of gene editing. In this group, those who are very negative about, for example, the use of gene editing for climate adaptation of plants know the least about genetic engineering or have the least trust in science. In this sub-group, less than 20 per cent state that it is mostly true that 'research shows that GMO products found on the international market are safe to eat' (the three highest values on the truth scale), while nearly 70 per cent believe this item to be mostly untrue (the three lowest values on the truth scale). These results differ clearly from those of the sub-group who report having good knowledge of genetically modified foods and who are positive about using gene editing for climate adaptation of plants, where the level of actual knowledge or trust in science is significantly higher. In this group, over 70 per cent of the respondents indicate that the item is mostly true, compared with only 5 per cent who say it is mostly untrue. Differences in knowledge levels within the group reporting good knowledge of genetically modified food are also present, but smaller, when the purpose of gene editing is one that the majority of respondents feel negatively towards, such as changing the appearance of animal products. In these cases, an equal proportion of those with negative attitudes judge the item about safety to be mostly true and mostly untrue. Our results suggest that increased actual knowledge increases the acceptance of gene edited products, especially for products that the majority of consumers perceive as positive. However, it must be considered that there is a relatively small sample in the group of respondents who have good knowledge of GMOs (N = 141). Further, we cannot make a definitive conclusion regarding the causality of this correlation.

Table 1: Within the group of respondents who score their knowledge of genetically modified food as good, positivity towards use of gene editing is related to actual knowledge level and/or trust in the science (*=p<0.05, Chi Square).

Adapt a crop plant to a	Item: Research shows that GMO products found on the intern market are safe to eat									nationa	Impossible
changing climate *	Mostly true	<							\rightarrow	Mostly untrue	to judge
Very positive	1,7 %	0,0 %	3,4 %	3,4 %	0,0 %	6,9 %	10,3 %	15,5 %	5,2 %	51,7 %	1,7 %
Somewhat positive	7,7 %	10,3 %	5,1 %	2,6 %	7,7 %	2,6 %	7,7 %	12,8 %	12,8 %	25,6 %	5,1 %
Neither positive nor negative	0,0 %	7,1 %	0,0 %	0,0 %	14,3 %	14,3 %	7,1 %	14,3 %	21,4 %	7,1 %	14,3 %
Somewhat negative	15,4 %	15,4 %	0,0 %	7,7 %	0,0 %	15,4 %	0,0 %	15,4 %	0,0 %	30,8 %	0,0 %
Very negative	12,5 %	18,8 %	37,5 %	0,0 %	0,0 %	0,0 %	6,3 %	18,8 %	0,0 %	0,0 %	6,3 %
Don't know	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	100,0 %	0,0 %	0,0 %	0,0 %
Change cosmetic traits in animal products *	Mostly true	÷				_			>	Mostly untrue	Impossible to judge
Very positive	0,0 %	0,0 %	5,6 %	5,6 %	5,6 %	11,1 %	0,0 %	11,1 %	16,7 %	44,4 %	0,0 %
Somewhat positive	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	13,3 %	6,7 %	20,0 %	13,3 %	46,7 %	0,0 %
Neither positive nor negative	4,0 %	0,0 %	0,0 %	0,0 %	12,0 %	4,0 %	16,0 %	20,0 %	4,0 %	36,0 %	4,0 %
Somewhat negative	0,0 %	11,1 %	7,4 %	0,0 %	0,0 %	3,7 %	11,1 %	14,8 %	7,4 %	40,7 %	3,7 %
Very negative	12,5 %	12,5 %	12,5 %	5,4 %	1,8 %	5,4 %	5,4 %	14,3 %	5,4 %	17,9 %	7,1 %
Don't know	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %	0,0 %

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6.2.5 All political party voter groups have nuanced attitudes toward gene editing in Norwegian agriculture and aquaculture, but there are also differences between them

Next, we wanted to examine how the attitudes toward gene editing in the sample are distributed according to political party affiliation. Thus, we asked the respondents which party they would vote for if there were a parliamentary election on the coming Monday. The proportion of respondents in each voter group in the sample reflect the national average of opinion polls for the same period in December 2019 (within a 95 per cent confidence interval), with the exception of the voters of the Red Party (Rødt), who are slightly over-represented. A summary of some of the most interesting findings is presented below.

Generally:

Regarding attitudes toward different uses of gene editing between voter groups, we find several overall trends (Figure 7). The majority of the respondents in all voter groups are positive about using gene editing for most of the purposes/products that the majority of the total sample are positive about — i.e. the 'desired' products. The voters of the Green Party (MDG) and the Liberal Party (V) are the most positive in these cases. The groups that stand out in the opposite direction are those who would vote for the Center Party (Sp) and the Christian Democratic Party (KrF). Although these voters are also more positive than negative about the 'desired' purposes/products, in several cases less than half of them are positive — and the proportion was consistently lower than in the other voter groups. Similarly, the majority of all voter groups are negative about purposes/products that the majority of the total sample are negative about — i.e. the 'unwanted' products. For example, there are few differences in attitudes toward using gene editing for purposes that can be perceived as 'trivial', such as changing the appearance of plant and animal products. In these cases, all voter groups are largely equally negative.

Other groups that stand out are respondents who do not state a clear party affiliation, either because they are uncertain who they would vote for, do not want to give this information, or cannot or will not vote in an election. These groups are more negative than other groups and have a larger proportion of members who report that they do not know how they feel about using gene editing (data not shown). However, it is not possible to say whether the differences in these groups are due to differences in political values. Therefore, the analysis and conclusions that follow only focus on the differences between groups with a stated party affiliation.

To go more in-depth and map nuances within and between the different voter groups, we looked at variations in attitudes towards different purposes/products. Here, we have chosen four cases of particular political relevance (Figure 7), and we comment on and discuss the findings in light of overall political trends.

Climate adaptation of plants:

All constituent groups are positive about this use of gene editing, but to varying degrees. The Green Party and Liberal Party voters are the most positive, in line with the general tendencies in the voter groups described above. Almost 80 per cent of the respondents in these groups report that they are 'very' or 'somewhat' positive. The proportion of respondents who report that they are 'very positive' is highest among Green Party voters, while none of the Liberal Party voters are 'very negative'. Both parties have a clear and proactive climate policy. Those who would have voted for the parties of the political left — the Labour Party (Ap), the Socialist Left Party (SV) and the Red Party — take a relative middle position on the use of gene editing for climate adaptation of plants. Between 60 and 70 per cent are positive, while a fairly small proportion are negative. We find a similar distribution among those who say they would vote for parties to the political right — the Conservative Party (H) and the Progress Party (Frp).

On average, the Christian Democratic Party and Center Party voters are least inclined to favour the use of gene editing for climate adaptation of plants. Nevertheless, the majority of respondents in these groups are also positive about this purpose/products. Thus, the benefits also appear to outweigh the disadvantages for the voters of parties that, in general, have restrictive policies on the use of biotechnology compared to other parties. However, it seems that this theme can be polarizing, especially among the Christian Democratic Party voters: about two-thirds are positive while one-third is negative. No one in this group answered 'don't know', and only four per cent are neither positive nor negative. Among the voters for the Center Party, the main agricultural party, more than half have a positive attitude toward the use of gene editing for climate adaptation of plants, while about 20 per cent are negative.

High-yielding plants:

This is the purpose for which the voters' views diverge the most. In several voter groups, the majority are positive, but not by the same margin as for the other 'desired' purposes. The Center Party and Christian Democratic Party voters are more or less divided down the middle, with the same proportions expressing negative and positive attitudes. In all voter groups, a greater proportion of respondents also state that they are neither positive nor negative about this purpose, compared to their attitudes about other purposes. The results from the focus groups indicate that the respondents have different perceptions about the potential benefits and disadvantages of increased yields in plants, as discussed in section 6.2.1, which may also be relevant to the population survey.

Animal (livestock) health:

The use of gene editing to improve animal health is a purpose that the majority of all voter groups are positive about, although there are interesting nuances here as well. Of note, the Green Party voters are the group with the second most 'very positive' responses but also the most 'very negative' ones. Thus, gene editing in animals appears to be a polarizing theme among these voters. The attitudes of the Green Party and Liberal Party voters differ regarding gene editing in animals. Among the other parties, attitudes follow the general trends: most are positive, but with a slightly higher proportion of positive voters to the political right.

Increased productivity in livestock:

In this case, the majority of all voter groups are negative. However, there are some relevant nuances. Again, the Green Party and Liberal Party voters separate regarding the use of gene editing on animals, as the voters of the former are significantly more negative than the voters of the latter. This may be related to the Green Party's clear policies on both animal welfare and reduced meat consumption. Otherwise, the voters on the political right were somewhat less negative than the voters on the political left.



6.3 Most consumers think gene editing could be used in organic food production if it allows a plant to be cultivated more easily without pesticides

Organic food is an alternative to conventionally produced food, and in Norway it accounts for about two per cent of total food sales where there is an organic alternative [14]. Organic food also has a significant market globally, especially in the Western world. Moreover, the market for organic food is growing, both in Norway and throughout the world. Studies have shown that consumers particularly emphasize health aspects when choosing organic food, and concerns about pesticides is one of the most important considerations [15]. Currently, genetic engineering of plants and animals is not permitted in organic food production, and the use of chemical pesticides is prohibited. However, the development of gene editing has renewed the debate, both because it can be used to make genetic changes that can also be achieved with traditional breeding and because some of the applications are aimed at purposes that are important in organic food production, such as reduced pesticide use. In GENEinnovate, one of the sub-projects is focused on developing potatoes that are resistant to late blight and therefore do not need to be sprayed with pesticides. We wanted to investigate attitudes toward using such a product in organic food production. In the total sample, a majority (58 per cent) of the respondents are slightly or very positive about using a gene edited crop plant in organic food production if it can more easily be cultivated without pesticides (data not shown). Only 16 per cent report that they are slightly or very negative. More important, however, is understanding what consumers who actually buy organic food think. When we look at the distribution of attitudes across categories regarding the type of food the respondents usually prefer to buy, we see that a majority in all sub-groups are positive about such use of gene editing in organic food production (Figure 8). In the group of respondents who prefer organic food, just over half are positive, while about a quarter are negative.



Imagine that gene editing makes it easier to cultivate crop plants without pesticides. How positive or negative are you towards using such a plant in organic food production?

What type of food do you prefer when you go food shopping?

Figure 8: The majority are positive toward using gene editing in organic food production if it allows crop plants to be cultivated more easily without pesticides, also among those who prefer to buy organic food in the store. (***p<0.001, Chi-square – within groups).

6.4 Consumers worry about risk and long-term consequences

Central to both GMO regulation and the public debate on genetically engineered food are questions about whether products are safe for human health and the environment. We therefore wanted to understand the consumers' concerns about the risks and long-term consequences of gene editing in Norwegian agriculture and aquaculture.

6.4.1 Most consumers are worried about health and environmental risks

Similar to the SIFO study [2], the respondents in our survey have some concern about the consequences for health and the environment of using genetic engineering in plants and animals. The largest group — just over 40 per cent in both cases — state that they are somewhat worried that gene edited products could pose a risk to both health (when consumed) and the environment (Figure 9). In total, around 60 per cent respond that they are somewhat or very worried. Less than 20 per cent are somewhat or entirely unworried.



The level of concern about risks from gene edited products is relatively stable across different demographic groups, but with some differences. For example, women are slightly more worried about both health and environmental risks than men, and those with lower education are more worried about health risks than those with higher education (data not shown). The first of these findings corresponds to findings from the SIFO study, while the latter is an opposite finding. The differences may be due to sampling effects. For instance, in our survey, there is a slight over-representation of highly educated respondents compared to the national average. The SIFO survey does not indicate whether the sample is representative of education. However, our sample was twice as large as the SIFO sample, which makes our analyses more robust. The differences may also be due to differences in how the questions are formulated and the thematic focus, e.g. we focus on gene editing in Norwegian agriculture and aquaculture while the SIFO study focused on 'classical' genetic modification and international food production.

6.4.2 Those with the most knowledge are least worried about health risks, but everyone is equally worried about environmental risks

We sought to identify whether knowledge of genetic engineering and genetics influences the level of worry about health and environmental risks associated with the use of gene editing. In our survey, we find a significant and negative correlation between knowledge about genetically modified food, which we again use as a proxy for general knowledge about genetic engineering and genetics and worry about health risks (Figure 10). The less knowledge respondents have about genetically modified food, the higher their average level of worry (among those who did not respond 'don't know'). The proportions of those that are entirely unworried and those that are very worried (i.e. those with the most extreme attitudes) are both highest in the group with good knowledge about genetically modified foods. The relative relationship between these proportions (percentage entirely unworried divided by the percentage of very worried) is also negatively correlated with knowledge level: The more knowledge about genetically modified food the consumers have, the larger the proportion of consumers that are entirely unworried to the proportion of consumers that are very worried (data not shown).

However, there is no significant correlation between the level of knowledge and worry about environmental risk: Although the proportions of those who are very worried and entirely unworried are both higher among respondents with more knowledge about genetically modified food, all knowledge groups were equally worried on average. Furthermore, there is no significant correlation between the level of knowledge and the relative ratio of those who are entirely unworried and very worried.



Figure 10: Knowledge of genetically modified food is inversely correlated with worry that gene edited food is risky to health but not to worry about risk to the environment. (**= p<0.01, ***= p<0.001, Pearson parametric correlation analysis). The data are normalised to 100 per cent in each knowledge group. N is indicated in the figure.

These results from the population survey show that many Norwegian consumers are somewhat or very concerned about the health and environmental risks associated with gene edited foods. Also, in the focus groups, several respondents stated that genetic modification and gene editing sounded 'scary'. However, they emphasized that it seems less scary if the genetic changes are smaller or less extensive, for example, removing genetic material or adding genes that exist within the species, compared to adding something entirely new, such as genes from other species.

Today, there is broad consensus in the scientific community and among competent authorities that perform risk assessments of GMOs that the genetically modified products currently on the international market are safe to eat. However, health concerns related to genetically modified foods have been documented in several studies and in surveys in Norway and in other countries [5, 15, 16, 17,18]. In a Eurobarometer on biotechnology from 2010, 59 per cent of respondents disagreed with the statement that genetically modified food is safe for their own and their family's health [1]. In a more recent Eurobarometer on food safety from 2019 [19], however, genetically modified ingredients in food and drink were placed quite far down on the list when respondents were asked to choose a maximum of five topics that they had heard of and were concerned about. Higher on the list of concerns were antibiotics, hormones, steroids, pesticide residues, environmental toxins, additives, food hygiene, food poisoning caused by bacteria and infectious disease agents in the food products. A total of 27 per cent of respondents cited genetically modified food and drink as a concern in this Eurobarometer. However, in the Norwegian SIFO study from 2017 [2], a larger proportions of respondents (53 per cent) believed that GMOs would have negative environmental effects, compared with those who believed that GMOs would pose a health risk (45 per cent).

Of note, the safety of gene edited and genetically modified products are determined by production, use and product properties, and it is therefore not possible to make any general assumptions based on which technology is used. Therefore, the approval of GMOs is based on a case-by-case assessment.

In our population survey, a significant majority of the respondents state that they trust that gene edited and genetically modified products are safe to eat and safe for the environment if approved by the Norwegian authorities, as presented in the next chapter. Moreover, in the focus groups, trust and knowledge were highlighted as important topics: Most of the respondents were positive about gene edited products that contribute to societal benefits and sustainability if the development and commercialization of the products is based on thorough research. They also emphasized that the products should be approved by authorities before they are allowed into the market and that assessments of benefits and risks must be knowledge based.

With regard to other concerns that are not directly related to health and environmental risks, the participants in the focus groups particularly highlighted aspects related to animal health and welfare. Many expressed a positive attitude towards gene editing to improve animal health but emphasized that this depends on the availability of knowledge about what other consequences the genetic changes could have for the animal. Another recurring topic was concern about the consequences that are not related to the gene edited products as such but rather the food production systems in which they are used and how such use can amplify the negative effects associated with the management of natural resources. For example, they emphasized that gene editing (and other technologies) must be used in ways that do not create less biodiversity in food or in natural ecosystems.

6.5 Attitudes and trust depend on who is behind the development of genetically engineered products

The public debate about genetically modified and gene edited food is not only about the specific products but also often about who is behind them. We therefore wanted to examine consumers' attitudes toward and trust in different actors involved in bringing products to market.

6.5.1 Consumers are most positive about gene edited products developed by Norwegian producers for the Norwegian market

Previous surveys on Norwegian consumers' attitudes toward genetically engineered food have focused on products that already exist on the international market or are under development and intended for the international market. The conclusion has been that Norwegian consumers are generally quite negative about such products. We thus wanted to investigate whether it matters who develops the products and for which markets the products are primarily developed. We first asked the respondents how positive or negative they generally are about the existing GMO products developed by international producers intended for the international market (Figure 11, upper panel). Over twice as many are negative as positive (45 per cent vs. 20 per cent). We then asked how positive or negative they would generally be if gene edited products were developed by Norwegian researchers and breeding companies for the Norwegian market (Figure 11, lower panel). In this case, the ratio was the opposite: about twice as many respondents are positive as are negative (45 per cent vs. 23 per cent). This indicates that who is behind the development of the products and which market they are intended for influence consumer acceptance. It is also possible that consumers' opinions are influenced by which technology is used, that is, 'classical' genetic modification versus gene editing. However, it is difficult to determine the extent to which this affects their attitudes towards producers/products, which is the topic of this question. As far as possible, we want to compare the current situation (i.e. previously documented attitudes towards GMO) with attitudes toward the uses of genetic engineering that are relevant for GENEinnovate (i.e. gene editing without inserting genes from other species). The comparison is therefore performed across technologies/technology applications.



Figure 11: Attitudes toward genetically engineered products depend on who is behind the development of the products. The respondents are more positive about gene edited products developed by norwegian researchers and breeding companies intended for the Norwegian market than about the genetically modified products that are developed by international companies for the international market (***= p<0.001, Paired samples t-test).

6.5.2 Most consumers trust that gene edited products developed and approved in Norway are safe and beneficial to society

Another relevant aspect to the GENEinnovate partners is whether consumers trust that the products that may come to the market — if the research and development process is successful — are both safe and beneficial to society. We therefore asked the respondents how much they trust that Norwegian researchers and breeding companies would use gene editing in ways that benefit society (Figure 12, upper panel). We also asked them how much they trust that genetically modified/gene edited products approved by the Norwegian authorities are safe to eat and safe for the environment, as all products should be before they come to the market (Figure 12, lower panel). In both cases, the results are quite similar: The majority respond that they have some, a lot or complete trust (67 and 71 per cent, respectively). At the same time, a non-negligible proportion of respondents (just under a quarter) have little or no trust in either case. Among the respondents that indicated they have no trust in product developers or Norwegian authorities (N = 127 and N = 118, respectively), a high proportion (56 and 66 per cent, respectively) state that they are very worried that gene edited products are risky for health and the environment (data not shown).



who do not have such trust (low or no trust). (***= p<0.001, Chi square – within groups).

Looking at how trust is linked to knowledge about genetically modified food, we see that there is a clear correlation: the better the respondents' knowledge about genetically modified food, and thus the better their actual knowledge about genetic engineering and genetics, the more they trust both Norwegian product developers and that products approved by the Norwegian authorities are actually safe to eat and for the environment (Figure 13).



In the focus groups, the respondents also said that they would be more positive about gene edited products developed in Norway for the Norwegian market than about products developed by international producers for the international market. They were also fairly trusting of Norwegian products being both beneficial to society and safe if approved by the authorities. However, the focus group participants emphasized that they would be most positive and have more trust if the research and product development were financed through public funds. This is informative for GENEinnovate, which is an industry-led innovation project co-financed with public funds from the Norwegian Research Council. When asked about what level of knowledge about risks they need to be reassured about the safety of a product, the focus group participants mostly responded that they trust the quality of the research conducted by Norwegian researchers and the judgement of the Norwegian authorities about risks and consequences as long as a reasonable risk assessment is done.

6.6 Most think that labelling is important, but also that the label should say something about which technology is used and what it is used for

An important aspect of the public debate on genetically modified and gene edited food is labelling. Under current regulations in Norway and the EU, all genetically modified and gene edited products must be labelled as GMOs, in the interest of consumer choice. However, the consumer does not receive information about the type of genetic technology used, the trait that has been changed or the purpose for which it has been changed. As we have seen earlier, these are aspects that are influential on consumers' attitudes toward gene editing. Here, we examine attitudes towards the labelling of gene edited products as well as what kind of information consumers want.

As many as 76 per cent of the respondents say that it is very or fairly important that gene edited products are labelled to indicate that they have been produced by genetic engineering (Figure 14).



However, a large majority want the label to contain additional information (Figure 15). More than 60 per cent of the respondents believe that the label should distinguish between gene editing and 'classical' genetic modification. Even more important, in the respondents' opinion, is knowing which trait has been changed and for what purpose. Over 80 per cent respond that the label should contain this type of information.



6.7 The majority of consumers prefer non-gene-edited products if they can choose between relatively similar products. Price influences their choices

For GENEinnovate, it is useful to know not only about attitudes toward products in general but also about what products consumers will actually choose when they buy food in stores. We therefore wanted to investigate consumer preferences and willingness to pay for gene edited and non-edited foods.

6.7.1 Most prefer foods that are not gene edited over foods that are gene edited if they have a choice between similar products

First, we asked the respondents what they would choose if they could choose between two fairly similar food products, one of which had been produced using gene editing and the other by traditional breeding (Figure 16). A majority (just over half) answer that they would choose the non-gene-edited product. About 40 per cent say that it does not matter, or they do not know what they would choose. Only six per cent reported that they would deliberately choose the gene edited product. Considering the varying attitudes toward different purposes for gene editing (Figure 3), this may indicate that consumers will be more likely to choose gene edited products if they have significant benefits.



6.7.2 Consumers' willingness to pay is fairly low for both gene edited and non-gene-edited foods

Although consumers have general preferences for certain types of products, their actual choices will be influenced by the price of the product. We therefore wanted to investigate the respondents' willingness to pay for both gene edited and non-gene-edited foods. First, we asked those who had indicated that they prefer products made without gene editing, given a choice between two fairly similar products, the degree to which they are willing to pay extra for such non-gene-edited products. Of these respondents, just over half state that they are willing to pay extra to some or to a very large extent (data not shown). These respondents represent 28 per cent of the total sample. This finding is in line with a survey conducted by the Norwegian University of Life Sciences (NMBU) in 2018, which also found that the willingness to pay to avoid GMOs was relatively low: Approximately 40 per cent of Norwegian consumers were not willing to pay anything extra to avoid GMOs in food, and only about every tenth consumer would pay more than a 20 per cent premium to avoid, for example, genetically modified salmon [20].

Next, we asked the all the respondents in the survey whether they are willing to pay extra for a gene edited food product that has a benefit they think is important. Twenty-eight per cent respond that they are to some or to a very large extent willing to do so (Figure 17). About 58 per cent are to a small extent or not at all willing to pay extra for gene edited food, even if it has a benefit they think is important. This result also indicates that price plays an important role in Norwegian consumers' product choice. Although most people are positive about using gene editing in Norwegian agriculture and aquaculture for certain purposes, their willingness to pay is relatively low.



6.8 It may be unethical not to use gene editing to solve major societal challenges

Ethics is at the heart of the debate about genetically modified and gene edited foods. So far, the debate has largely focused on whether it is ethically acceptable to genetically engineer animals and plants. However, in the spring of 2019, the Danish Ethical Council published a statement in which they turned the question around: The majority of Council members argued that it can be ethically problematic *not* to use GMO products if the products can help solve important societal problems [21]. The examples used were genetically engineered crop plants that are adapted to climate change or could contribute to the prevention of climate change. Accordingly, we wanted to investigate what Norwegian consumers think of such a statement. We asked our respondents to consider the following claim: 'It can be unethical not to use gene editing in crop plants and livestock if it can contribute towards solving important societal challenges, such as climate adaptation of crops' (Figure 18).



Almost half (48 per cent) of the respondents entirely or somewhat agree with the statement. Almost one-third (29 per cent) do not know or neither agree nor disagree, while just over one-fifth (22 per cent) somewhat or entirely disagree. The degree of agreement is inversely correlated with age; that is, younger respondents agree more than older ones, whereas there was no significant difference between genders (data not shown). Even more interesting is a significant correlation between the level of knowledge and agreement with the statement. The more knowledge respondents have about both genetically modified foods and gene editing, the more they agree that it would be unethical not to use gene editing in livestock and plants if it can help solve important social problems (Figure 19).



The correlation is significant both for the mean values in each knowledge group and for the ratio between the proportion who entirely agree and entirely disagree in each knowledge group. In particular, the groups with good knowledge about genetically modified foods and gene editing stand out, where the proportion who entirely agree with the claim is high (31 and 33 per cent, respectively). However, the percentage of respondents that entirely disagree is also somewhat higher among those who rate their knowledge of genetically modified foods as good compared to other knowledge groups. Within this specific sub-group, however, a high proportion (60 per cent) report that they believe that the item 'research shows that GMO products on the international market are safe to eat' is mostly untrue (the three lowest scores on the trueness scale).

6.9 Consumers' perception of naturalness is related to their attitudes toward and worry about the use of gene editing

One aspect that often comes up in the public debate about technology in general and genetically modified foods in particular is the concept of naturalness. In the focus groups, several of the participants stated that they associate genetic modification with something unnatural. Others argued that genetic modification is no more unnatural than the breeding of plants and animals, which humans have been doing since the origins of agriculture. We thus wanted to investigate consumers' perceptions of naturalness in relation to the use of gene editing more closely.

6.9.1 Genetic engineering is more unnatural than traditional breeding, but there is no difference between genetic modification and gene editing

First, we wanted to compare the perception of naturalness of the different breeding methods. Thus, we asked the respondents to rate the different methods on a ten-point scale from completely unnatural to completely natural. Looking at the average values for each method (Figure 20), we see that traditional breeding is regarded as quite natural and more natural than genetic engineering. However, the consumers do not distinguish between the naturalness of genetic modification and gene editing and place both these methods in the middle of the scale on average.



This finding is interesting given that, in this study, we have defined gene editing as 'making genetic changes that mimic those that can occur by themselves in the wild or the changes that could be achieved through traditional breeding', while genetic modification is defined as 'transferring genes from one organism to another, often across different species'. This may indicate that the degree of genetic change does not affect consumers' perception of naturalness. However, we do not know what the respondents have placed emphasis on in this context. The concept of naturalness is complex, and the question can also be perceived as a question about values. Other studies have also found that consumers perceive genetically engineered foods as unnatural [22].

6.9.2 Attitudes toward the use of gene editing and worry about risk are related to the perception of naturalness

We next wanted to examine whether views on naturalness are related to attitudes toward the use of gene editing. We find a clear correlation between these variables, as shown in the case of the use of gene editing to reduce pesticides and crop loss (e.g. potatoes that better resist late blight): The more negative the respondents are, the more unnatural they perceive gene editing to be (Figure 21, upper panel). We also observe a clear correlation between the respondents' perception of naturalness and their worry about risk: The more worried the respondents are that a gene edited product is risky to eat, the more unnatural they perceive gene editing to be (Figure 21, lower panel). We find an almost identical connection between perceptions of the naturalness of genetic modification and attitudes and worry about risk. The respondents' perceptions of the naturalness of traditional breeding, however, are independent of these factors, and all groups scored traditional breeding as approximately equally natural (data not shown).



6.9.3 The perception of naturalness is related to knowledge about genetic engineering and genetics

We also wanted to investigate whether knowledge affects the perception of naturalness. Looking at the average values for naturalness of gene editing, we find a weak but significant correlation with knowledge of gene editing and genetically modified foods: The better the knowledge, the more natural the consumers think that gene editing is. However, the difference between these average values is small: In all the knowledge groups, the average values are in the middle of the naturalness scale (data not shown). However, the true variation and differences are not well reflected in the average values, as many of the respondents indicate naturalness values at the extremes of the scale. We therefore found it more appropriate to look at the distribution within certain sub-groups. It is especially relevant to look at the group who state that they have good knowledge of gene editing.

Among the respondents who score their knowledge of gene editing as good but simultaneously say it is mostly untrue that 'research shows that GMO products on the international market are safe to eat', the

average value for the naturalness of gene editing is 3 (out of 10) – thus fairly unnatural. In comparison, the average value for the naturalness of gene editing is 6.5 (out of 10) in the group who score their knowledge of gene editing as good and say it is mostly true that 'research shows that GMO products on the international market are safe to eat'. Similar percentages apply to the group who say they have good knowledge of genetically modified foods (data not shown). Thus, there is a connection between knowledge about genetic engineering/genetics and the perception of naturalness.

Overall, our results suggest that the perception of naturalness is an important factor for Norwegian consumers' attitudes toward the use of gene editing in plants and animals, and their level of knowledge is related to this perception. However, it is not possible to determine whether the perception of naturalness influences acceptance or whether acceptance influences the perception of naturalness. Consumers do not distinguish between genetic modification and gene editing in terms of naturalness. The purpose of making a genetic change thus seems to be more important to consumers than which genetic technology has been used.

7. Conclusions

In this study, we have investigated Norwegian consumers' attitudes toward the use of gene editing in Norwegian agriculture and aquaculture. The report is based on a quantitative population survey with a sample size of just over 2,000 respondents, who are nationally representative in terms of age, gender and geographical region. It is also based on findings from a qualitative study with focus groups. However, the qualitative study was primarily exploratory and was used to inform the design of the quantitative survey questionnaire, and the findings cannot be generalized to the population. The following includes a brief summary of the most important findings, a discussion of the limitations of the survey and methods and a look forward at possibilities for follow-ups and further research.

7.1 Summary

Overall, our results show that the majority of Norwegian consumers are positive about using gene editing in plants and animals if the purpose can be perceived as beneficial to society and to contribute to sustainable development. Examples are climate adaptation of crop plants, reduction of pesticides and crop losses and improved animal and fish health. Meanwhile, consumers have negative attitudes toward the use of gene editing for purposes such as changing the appearance of plant and animal products or increasing the productivity of livestock. Although most people are positive about using gene editing for several purposes, many are worried about the risks and consequences of using the technology. Nevertheless, the majority of consumers have fairly high trust in products developed by Norwegian researchers and breeding companies and that are approved by the authorities. However, consumers want information through labelling which should include information about which technology has been used and for what purpose. For GENEinnovate, these results are informative in terms of project orientation and future innovations. They can also give an indication of what can be expected if the innovation process succeeds and products are considered for commercialization.

Our findings show that there are many nuances in consumers' attitudes toward gene edited foods. In contrast to several previous studies, in which the approach often is 'for or against' the use of genetic engineering, our results show that the picture is much more nuanced. It is important to emphasize these nuances in the public debate: What can the technology be used for? Who is behind the development of the products? For which countries' food production systems are the products intended? How can consumer trust be safeguarded?

A central theme of the survey is knowledge. We consistently observe that the respondents' attitudes and trust depend on their level of knowledge. At the same time, our findings show that the actual knowledge about gene editing in the population is limited. Only about half of the respondents in the sample have even heard of the topic of the study — gene editing. Although that is a larger proportion than in the Eurobarometer from 2019 [19], in which 21 per cent stated that they had heard about gene editing, few claim to have much knowledge about the technology in our survey. This underlines the importance of knowledge building in order for consumers to make informed choices and the need for a nuanced public debate on this topic. Our results suggest that there is a connection between knowledge about genetic engineering and trust in the underlying science as well as trust and attitudes toward the use of the technology and those developing the products.

7.2 Reflections on the methods and limitations of the survey

The survey sample was representative of the Norwegian population in terms of gender, age and geographical region. However, their attitudes may not be fully representative of Norwegian consumers' attitudes and reactions to gene edited products that may come to the market in the future. First, the sample is drawn from Ipsos' online panel, not randomly from the population. Online panels offer an easy way to conduct population surveys, and the sample is weighted on demographic variables such as age, gender and geographical region. Still, there is underlying bias in such a selection. For example, the respondents must have access to the Internet to participate, they are often more educated than the national average and certain minority groups are often under-represented. All these factors affect representativeness. The respondents in the survey were also presented with information on gene editing and other breeding methods before answering questions about their attitudes to ensure that they all had a sufficient understanding of what we were asking them. Such information will not be available to consumers who have to decide between products in a store. The way gene edited and all other genetically engineered products must currently be labelled in Norway and the EU, consumers will only be informed that the product is classified as a GMO. Limited access to further information about the product, such as the purpose of making the genetic change and the trait that has been changed, will likely be a relevant factor to consider in the commercialization of gene edited products and preassessment of the market. Given the large differences in consumers' attitudes toward the use of gene editing for different purposes, as we have clearly shown in this study, it is likely that consumers' choices will not match their actual attitudes toward a gene edited product due to the lack of sufficient information.

In this study, we have placed considerable emphasis on the relationship between knowledge and attitudes. However, there are several limitations that are worth discussing. The topic of this study is complex, and many consumers have no prior knowledge about it. Thus, the attitudes revealed here are not based on in-depth knowledge of the topic. It is also likely that some respondents guessed when answering the questions rather than answering 'don't know' for the four knowledge items in order to appear more knowledgeable — a known dilemma with this type of knowledge questions. Such guessing can cause the frequency of answers with middle values on the scale to increase, even though several of the items have a right and a wrong answer. To further investigate this, we first let the respondents score their own knowledge about genetic modification and then distributed the answers from the knowledge items over these self-reported knowledge groups. The tendency to answer 'don't know' or to enter a middle value is relatively low in the total sample. More importantly, it is lowest in the groups with good self-reported knowledge and highest in the groups with low self-reported knowledge, especially among those who say they have never heard of genetic modification. We therefore have confidence that the connection between self-reported and actual knowledge is real, and the conclusions about the connection between attitudes and knowledge are valid. However, there are certain limitations to the use of simplified measurement variables as the basis for our conclusions. We often use the variable 'knowledge about genetically modified food' as a proxy for a broader level of knowledge, as there is a relatively good correlation between self-reported knowledge and actual knowledge about genetic engineering and genetics based on the trueness scores of the four items related to the topic. Simplifying knowledge measurements into one variable was also necessary for feasibility. However, it is not possible to define an absolute level of knowledge for each respondent based on our data since the knowledge part of our survey is of limited scope. The respondents may also have different knowledge of different aspects related to the same overall topic. The conclusions are therefore drawn with the proviso that the respondents' true knowledge might be more varied and different than what we find in our analyses. Ideally, we would also have preferred to use 'knowledge of gene editing (CRISPR)' as our primary measurement variable rather than 'knowledge of genetically

modified food', as the study is mainly about gene editing. However, since a significantly lower proportion of the respondents have knowledge of gene editing, this would have weakened the statistical analyses.

We will also comment on some general perspectives on food and technology. Often, the debate about genetically engineered food is not about technology itself but rather about larger political and societal aspects. For example, conversations in the focus groups revealed that several participants are concerned with issues of sustainability and animal welfare related to meat consumption and the livestock industry. Hence, their attitudes toward the use of gene editing in livestock could largely be linked to such overall views. Several respondents in the focus groups expressed that they were negative about the use of gene editing in livestock because they were principally opposed to the livestock industry.

A related issue concerns the population's knowledge about food production in general. In the focus groups, it was challenging to discuss, for example, the use of gene editing to develop pigs that do not have to be castrated (by affecting hormonal sex development) because most of the focus group participants were unaware that male pigs are currently surgically castrated and why it is done (to prevent boar taint, which gives the meat a pungent taste and smell). The topic of pig castration itself generated so many negative reactions that it was difficult for the respondents to evaluate the case, and it was unclear whether several of them understood that gene editing could actually help reduce the need for surgical castration or whether they thought it would lead to more castration. The word hormones also resulted in immediate negative associations, regardless of the scientific rationale of the effects of the gene editing. We therefore chose to exclude this case from the subsequent population survey because it would have been particularly difficult to judge what the respondents placed emphasis on in their answers and whether they understood the purpose of the gene editing. It is also evident from both the focus groups and the population survey that many consumers have limited knowledge about genetics and breeding in general. For example, 35 per cent of the respondents in the population survey score the item 'ordinary tomatoes do not have genes, while genetically modified tomatoes do' as more true than untrue or indicate that it is impossible to judge. Additionally, over 40 per cent thought it was more true than untrue that 'traditional breeding has nothing to do with genes' or that this item is impossible to judge. This highlights the need for knowledge building regarding how the development of livestock and crop plants is done, both with and without genetic engineering, and how food is produced.

7.3 A look ahead

This survey has given us new knowledge about the Norwegian population's attitudes toward the use of gene editing in Norwegian agriculture and aquaculture. Finally, we highlight some opportunities for further studies that could help build even better knowledge about the topic.

The data collected from the survey make it possible to perform many more analyses than were feasible within the scope of this report. This applies both to questions that have not been used and to relationships between variables that have not been analysed. For example, it is possible to investigate the relationships between attitudes and consumer habits more closely, such as diet and food shopping preferences. These are aspects we have gathered information about but not included in the analyses. Furthermore, it is also possible to take a closer look at how attitudes are divided into sub-groups in the sample. For example, it would have been interesting to examine how political views are linked to trust, knowledge and views on ethics. It would also be useful to supplement the study with other methods to consider the complex issues related to the use of genetic engineering in more detail. Lay conferences and other more complex dialogue formats could provide a more representative information base on,

for example, perspectives on values in the population. It would also be interesting to conduct a followup study in which half of the respondents are presented with information texts about gene editing and other methods for developing crop plants and livestock while the other half does not receive such information before evaluating cases of different uses of gene editing and other questions. In this way, we could estimate the effects of receiving prior information on attitudes toward the use of gene editing.

In this study, we specifically wanted to examine Norwegian consumers' attitudes toward the use of gene editing for the development of products intended for production in Norway. Thus, it is not possible to generalize the results to other populations. It would be interesting to see results from similar studies in other countries, especially in Europe, with questions adapted to the national context in each case. In order to facilitate such comparisons, we refer to the Appendix, which includes the complete questionnaire where central questions on which the conclusions of this analysis are based are highlighted.

Through this study and other project activities, GENEinnovate aims to contribute to knowledge building in the population about the opportunities and challenges related to gene editing. Broader efforts and focused strategies for strengthening public knowledge are nevertheless important, as we expect that technological possibilities, knowledge management, policy and public dialogue on gene editing will become increasingly important for Norwegian agriculture and aquaculture and society overall in the future.

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9. Appendix

Questionnaire used for population survey about Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture

(translated from Norwegian)

Questions used for analyses:

qage	What is your age?	
range:*		
Years:		1

qgender	Are you						
range:*							
Male		O 1					
Female		O 2					

qregion	What region in Norway do you live in?	
range:*		
Østfold		O 1
Akershus		O 2
Oslo		O 3
Hedmark		O 4
Oppland		O 5
Buskerud		O 6
Vestfold		O 7
Telemark		O 8

qregion	What region in Norway do you live in?	
Aust-Agder		O 9
Vest-Agder		O 10
Rogaland		O 11
Hordaland		O 12
Sogn og Fjord	dane	O 14
Møre og Rom	nsdal	O 15
Trøndelag		O 50
Nordland		O 18
Troms		O 19
Finnmark		O 20

qedu	What is your highest completed education?						
range:*							
Primary scho	ool (up to 10 years education)	O 1					
High school ((11-13 years education)	O 2					
College/unive	ersity, undergraduate (1-3 years)	O 3					
College/unive	ersity, postgraduate (4 years or more)	O 4					

qstud	Are you currently in education?	
• range:*		
No		O 1
Yes, in schoo	ol/ high school	O 2
Yes, reading	for a bachelor or similar	O 3
Yes, reading	for a masters degree or higher	O 4
Yes, other ed	lucation	O 5

Information

This is a survey about development of plants, animals and other organisms through different methods of changing their DNA.

How much do you know about the following?							
◆ range:*							
	l have good knowledge	I have some knowledge	I have only heard of this	I have never heard of this			
	1	2	3	4			
Genetically modified food	0	0	0	0	1		
Gene editing (often called CRISPR)	0	0	0	0	2		

	No tru unt	w yo e. Fo true.	ou wi or ea	ll be pr ch item	esented with a few stateme , please evaluate whether i	ents th it is m	at ca ostly	n be true	or i	re or mostl	less y	
range:*	Most ly untr ue									Most ly true	Impo ssibl e to judg e	
1.1.1	1	2	3	4	5	6	7	8	9	10	11	
• rot:r Ordinary tomatoes do not have genes, while genetically modified tomatoes have genes.	0	0	0	0	0	0	0	0	0	0	0	1
There are approved genetically modified foods in Norwegian food stores	0	0	0	0	0	0	0	0	0	0	0	2
Traditional breeding has nothing to do with genes.	0	0	0	0	0	0	0	0	0	0	0	3
Research shows that the	6											

Research shows that the genetically modified products currently found on the international market are safe to eat.	0	0	0	0	Ο	0	0	0	0	0	04

Information

> Over the next three pages you will get explanations about three different methods for developing novel traits in crop plants, livestock and fish that can be used in agriculture and fish farming.

Please read through each explanation and click next when you are done.

Information

Traditional breeding, used since the Stone Age

All plants, animals and microorganisms contain thousands of genes (DNA) that determine their traits. In nature, genetic changes arise naturally that cause the traits to change. This is used to breed crops and livestock with desirable traits, which is done by crossing individuals with different desired traits. This is the way humans around the world have adapted plants and animals to agriculture for thousands of years.

Information

'Classic' genetic modification from the 1970s and 1980s

This method was developed by scientists in the 1970s and 1980s. It involves transferring genes from one organism to another, often between species. The method has mostly been used to transfer genes from bacteria to plants to make the plants more tolerant to herbicides or resistant to insects, which allows bigger crops.

Information

Gene editing, the latest method

This method makes it possible to make targeted changes to the DNA, for example, removing, adding or exchanging genes or parts of genes (a common method is called CRISPR). In the examples in this study, gene editing refers to making genetic changes that mimic those that can happen by themselves in the wild or the changes one could get through traditional breeding (e.g. inserting genes from one potato variety into another potato variety). In these cases, no genes from other species are inserted. The purpose of gene editing is to adapt plant and animal traits.

	Based on w positive or crop plants purpose is	hat you kn negative an and livest to:	ow and the ce you to us ock in Norv	e informatio sing gene edi wegian agric	n you have now i iting (the newest culture and fish f	read, how method) or arming, if t	n the
range:*						1.1.2	
	Very positive	Somewhat positive	Neither positive nor negative	Somewhat positive	Very negative	Don't know impossible to answe	v, e r
	1	2	3	4	5	6	
• rot:r							
Adapt a crop plant to a changing climate, e.g. whea that better tolerates drought or precipitation?	. 0	0	0	0	0	0	1
Improve nutritional content of a crop plant, e.g. tomatoes with more Vitamin C or antioxidants?	0	0	0	0	0	0	2

I I I I I I	Based on wi positive or i crop plants purpose is t	hat you kn negative an and livesto o:	ow and th re you to u ock in Nor	e informatio sing gene edi wegian agric	n you have now iting (the newest culture and fish f	read, how method) of farming, if	n the
Reduce pesticides and crop loss, e.g. blight resistant potato?	0	0	0	0	0	0	3
Develop high yielding crop plants, e.g. wheat with more or larger seeds?	0	0	0	0	0	0	4
Change cosmetic traits in plant products, e.g. fruits or vegetables with a different colour?	0	0	0	0	0	0	5
Improve animal (livestock) health, e.g. cattle or pigs that are resistant to infectious disease?	0	0	0	0	0	0	6
Reduce the environmental impact of aquaculture, e.g. sterile salmon that does not interbreed with wild salmon if it escapes?	0	0	0	0	0	0	7
Improve fish health, e.g. salmon that are resistant to sea lice?	0	0	0	0	0	0	8
Develop high yielding livestock, e.g. cattle with increased muscle mass or milking capacity?	0	0	0	0	0	0	9
Change cosmetic traits in animal products, e.g. salmon with more brightly pink coloured meat?	0	0	0	0	0	0	10

	Ho	w na	atura	l or u	nnatural do you consider th	e follo	wing	g met	thod	s to b	e?	
* range:*								6				
	Com plete ly unna tural 1	2	3	4	5	6	7	8	9	Com plete ly natu ral 10	Impo ssibl e to ans wer 11	
• rot:r												
Traditional breeding, used since the Stone Age	0	0	0	0	0	0	0	0	0	0	0	1
'Classic' genetic modification from the 1970s and 1980s	0	0	0	0	0	0	0	0	0	0	0	2
Gene editing, the latest method	0	0	0	0	0	0	0	0	0	0	0	3

1	Fo what ex	tent do you	agree or	disagree wit	h the following sta	atement?
range:*						
	Entirely agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Entirely disagree	Don't know
	1	2	3	4	5	6
* rot:n						
It can be unethical not to use gene editing in crop plants and livestock if it can contribute towards solving important societal challenges, such as climate adaptation of crops.	0	0	0	0	Ο	O 1

Information						
13 C 1 C 1 C 1 C 1	W. L. L. K	1.	T	111201110	1000	_

The rest of the questions are about gene editing (the latest method)

	How worried or unworried are you that gene edited p to your health (when eaten)?	products present risks
• range:*		
Very worried		0 1
Somewhat wor	ried	O 2
Neither worried	nor unworried	O 3
Fairly unworried		O 4
Entirely unworr	ied	O 5
Don't know		O 6

		•
Entirely unwo	orried	0 5
Don't know		0 6
	How worried or unworried are you that gene ed to the environment?	lited products present risks
range:*		1.4
Very worried	y	0 1
Somewhat w	orried	0 2
Neither worri	ed nor unworried	0 3
Fairly unworr	ied	0 4
Entirely unwo	orried	0 5

	Imagine that gene editing makes it easier to cultivate crop pesticides. How positive or negative are you towards using organic food production?	plants without such a plant i	n
• range:*			
Very positive		0	1
Somewhat p	ositive	0	2
Neither posit	ve nor negative	0	3
Somewhat n	egative	0	4
Very negativ		0	5
Don't know.	mpossible to answer	0	6

	The genetically modified products currently developed by international companies. How towards such products?	on the international market positive or negative are you	are
range:*			
Very positive		0	1
Somewhat p	ositive	0	2
Neither posit	tive nor negative	0	3
Somewhat n	egative	0	4
Very negativ	e	0	5
Don't know,	impossible to answer	0	6

	How positive or negative would you be if ge for the Norwegian market by Norwegian re companies?	ne edited products are developed searchers and breeding
• range:*		
Very positive		O 1
Somewhat po	ositive	O 2
Neither positi	ve nor negative	O 3
Somewhat ne	egative	O 4
Very negative	3	O 5
Don't know, ii	mpossible to answer	O 6

	How much do you trust that Norwegian researchers and breeding companie would use gene editing in ways that benefit society and the environment?
range:*	
Complete trust	t O 1
A lot of trust	O 2
Some trust	O 3
Low trust	O 4
No trust	O 5
Don't know	O 6

	In Norway, all genetically modified/gene edited products must be approved by the authorities after health and environmental risk assessments. How much do you trust that such approved food products are safe to eat and safe for the environment?
range:*	
Complete trust	O 1
A lot of trust	O 2
Some trust	O 3
Low trust	O 4
No trust	O 5
Don't know	O 6

	How important or unimportant is it to you store are labelled to indicate that they have engineering?	that gene edited products in the been produced with genetic
+ range:*		
Very import	tant	O 1
Somewhat	important	O 2
Not particul	larly important	O 3
Not importa	ant at all	O 4
Don't know	, ,	O 5

	Should the label also distinguish between gene editing (the latest m and 'classical' genetic modification (from the 1970s and 1980s)?	nethod)	
 filter:\q14= range:* 	1:2		1
Yes		0	1
No		0	2
Not important		0	3
Don't know		0	4

	Should the label also contain information about the trait that has be changed and the purpose for making it?	en	
 filter:\q14=1:2 range:* 	2		
Yes		0	1
Should the label also contain information about the trait that has been changed and the purpose for making it?			
--	---		
O 2	1		

No

Not important

Don't know

Imagine that you could choose between two fairly similar food products, one produced by gene editing and the other without gene editing (by traditional breeding). Which of the two would you prefer?

• range:*

Not important to me	O 1
The food product made with gene editing	O 2
The food product made without gene editing	O 3
Don't know	O 4

To what extent would you be willing to pay e edited?	xtra for food that is non-gene-
 filter:\q17=3 range:* 	
To a very large extent	O 1
To some extent	O 2
To a small extent	O 3
Not at all	O 4
Don't know	O 5

	To what extent would you be willing to pay extr has a benefit you think is important?	ra for gene edited food that
range:*		
To a very large	e extent	O 1
To some exter	nt	O 2
To a small ext	ent	O 3
Not at all		O 4
Don't know		O 5

Information	
And finally some questions for statistical purposes.	

O 3

0 4

What type of food do you prefer when you	go food shopping?
* range:*	
Organic food	O 1
Conventionally produced food	O 2
Varies between different food categories	O 3
Doesn't matter	O 4
Don't know	O 5

	Which political party would you vote for i election on the coming Monday?	f there were a parliamentary	
range:*			
The Red Par	ty (Rødt)	0	1
The Socialist	Left Party (SV)	0	2
The Labour F	Party (Ap)	0	3
The Center P	Party (Sp)	0	4
The Green P	arty (MDG)	0	5
The Christian	Democratic Party (Krf)	0	6
The Liberal P	Party (Venstre)	0	7
The Conserv	ative Party (Høyre)	0	8
The Progress	s Party (Frp)	0	9
Other Party		0	10
Don't know	Don't know		11
Do not wish t	o say	0	12
Would not / c	annot vote	0	13

E	Hvor enig eller uenig er du i følgende utsagn?						
 range:* rot:r 	Helt enig 1	Litt enig 2	Hverken enig eller uenig 3	Litt uenig 4	Helt uenig 5	Vet ikke 6	
'Classic' genetic modification (from the 1970s and 1980s) of livestock can be ethically acceptable	0	0	0	0	0	0	1
'Classic' genetic modification (from the 1970s and 1980s) of crop plants can be ethically unacceptable	0	0	0	0	0	0	2
Gene editing (the latest method) of livestock can be ethically acceptable	0	0	0	0	0	0	3
Gene editing (the latest method) of crop plants can be ethically unacceptable	0	0	0	0	0	0	4

Questions that were asked but not used in the analyses:

Would you accept that Norwegian politicians to a larger extent than today facilitate the use of gene edited (the latest method) products, if it will enable more Norwegian researchers and breeding companies to develop products for Norwegian food production?
* range:*

Yes, that is acceptable	O 1
No, that is unacceptable	O 2
Unsure, don't know	O 3

	Which of these statements best describes your current diet? ONLY ONE CHOICE POSSIBLE		
 range:* I regularly ea 	t animal and non-animal products (omnivorous)	0	1
I don't eat m	eat or fish, but I eat other animal products (e.g. eggs, cheese and milk) (vegetarian)	0	2
I don't eat ar	ything that comes from animals, fish or other sea food (vegan)	0	3

	Which of these statements best describes your current	diet?
	ONLY ONE CHOICE POSSIBLE	
I sometim	es eat meat or fish (flexitarian)	O 4
I don't eat	meat, but I eat fish (pescetarian)	O 5
Other:		Open

How important is it to you that the food yo	u eat is natural?
* range:*	
Very important	O 1
Somewhat important	O 2
Not particularly important	O 3
Not important at all	O 4
Don't know	O 5

What best describes the area in wh	ich you live?
◆ range:* _arge city	O 1
Suburb	O 2
Small or medium sized town	O 3
/illage	O 4
Sparsely populated area	O 5

Are there children under 18 currentl	currently living in your household?		
* range:*			
No	0	1	
Yes, one child	0	2	
Yes, two children	0	3	
Yes, three children	0	4	
Yes, four or more children	0	5	

Comments	Do you have comments about these topics that you think are relevant for us to know?	
	Oper	

Van:	@epsomail.org>	
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	editing_FINAL_excl study NO_send.pdf; 20_01_2	4_EPSO_Genome editing - 2nd informal
	meeting_Handout.doc; 20_01_23_EPSO_Genom	e editing - 2nd informal
	meeting_Participants.docx	
Urgentie:	Ноод	

Dear colleagues from national ministries,

Thank you for a very open and constructive meeting!

Please find attached

- The Report you may use publicly
- The Presentations Chatham House Rule you may use internally to discuss with your colleagues
- The Handout and the participant list Chatham House Rule only for participants.

As we agreed at the end of our 2nd meeting, the 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.

Actions:

- All participants (this always includes those that apologised to due to overlapping activities) kindly provide to us by 8 May their <u>availability</u> to meet in Brussels in the European quarter (likely at KoWi) between 19.10. and 6.11.2020 and Ministry / funders participants kindly <u>indicate if they wish to present</u> ongoing, approved or possible future opportunities regarding flagship projects:
 - o I am interested to join the 3rd meeting: yes / no
 - o Availability between 19.10. and 6.11.2020:
 - I am available all dates yes / no*
 - *I am NOT available on these dates: list
 - I would be interested to present ongoing, approved or possible future opportunities regarding flagship projects: yes (keyword) / no

Based on your availability, we will let you know mid-May 1-3 dates to pencil in for the 3rd meeting. Monitoring the corona developments we will let you know by 4th September if the meeting can already take place and on which of the reserved dates.

- All participants are welcome to send us <u>news items for a quarterly update regarding genome</u> editing legislation and efforts to improve the legislation from among the participants.
- Ministry participants kindly suggest to EPSO which <u>additional ministry colleagues</u> to invite (providing name, ministry, email). Should this not be possible under GDPR, please recommend such colleagues to contact EPSO expressing their interest to join the next such informal meeting.

We very much look forward to your replies and to continue the discussion Stay safe!

Sent: 09.04.2020 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Norwegian consumers' attitudes toward gene editing

Dear colleagues from national ministries,

Thank you for a very interesting meeting and apologies for the delay in sending the report, you will receive it later in April.

As we are all busy with the EU survey on NGTs, you may find the report useful towards which presented first outcome at our meeting:

The Norwegian Biotechnology Advisory Board (2020). Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture. <u>www.bioteknologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf</u>

With best wishes and have a nice Easter

From:

From:

Sent: 17.1.2020 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation + updated agenda; List of participants; Pending confirmations by 20 Jan pls

Dear colleagues from national ministries,

Thank you for your replies. Pls find attached the **Invitation with the updated agenda** and the **List of Participants** for our 2nd **Informal science - policy meeting in Brussels next Friday, 24.1.2020.**

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; <u>www.kowi.de</u>.

Those of you not confirmed yet (not in bold in the participant list), **pls confirm to best by 20 January**. FYI, we attach as well the report form the 1st informal meeting 19.9.2019.

Looking forward to a most interesting discussion

From: Sent: 19.12.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Invitation + agenda; List of participants; News; Pending confirmations by 17 Jan pls

Dear colleagues from national ministries,

Thank you for your replies. Pls find attached the Invitation with the draft agenda, the List of Participants and News (relevant publications) since our September meeting for our 2nd Informal science - policy meeting in Brussels as Friday, 24.1.2020.

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; www.kowi.de .

Those of you not confirmed yet (not in bold in the participant list), pls confirm to best by 17 January. FYI, we attach as well

- 19_11_14_Council decision_ECJ NBTstudy (news item 1)
- 19_11_15_Contribution666b7610-ddca-4262-b4be-dc125b7ec2cf.pdf (news item 5)

Wishing you a Merry Xmas and all the best for 2020

Looking forward to a most interesting discussion

From:

Sent: 09.12.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020 (11am - 4pm); List of participants; Pending confirmations ASAP pls

Dear colleagues from national ministries,

Thank you for your replies. Pls find attached the updated List of Participants for our 2nd Informal science - policy meeting in Brussels as Friday, 24.1.2020.

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; www.kowi.de .

Those of you not confirmed yet (not in bold), pls confirm to me ASAP, latest by 17 January.

We will send you the draft agenda and relevant publications since our last discussion next week.

Looking forward to a most interesting discussion

From:

Sent: 22.10.2019 To: Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020 (11am - 4pm) - block; Pending confirmations by 25 Nov pls

Dear colleagues from national ministries,

Thank you for your replies. We are happy to confirm the date for our **2nd Informal science - policy meeting in** Brussels as Friday, 24.1.2020 – pls block this in your agenda.

The meeting will be from 11 am to 4pm including a lunch break, again at KoWi (European Liaison Office of the German Research Organisations), Rue du Trône 98; 1050 Brussels; Belgium; www.kowi.de .

Pls find attached the list of participants. Those of you not confirmed yet (not in bold), pls confirm to me before 25 **November**. Upon your recommendation we already added two ministry colleagues to the list – pls feel free to suggest more colleagues from your country / other countries' ministries we should invite.

Most of you confirmed as well to be included in a mailing list to receive quarterly (if appropriate monthly) updates regarding genome editing legislation and efforts to improve the legislation from among the participants. Again - if you did not confirm yet, you may do so at any time.

We will send you more information before the Xmas break.

Looking forward to a most interesting discussion

Report



Genome editing Improving legislation and starting flagships to better address climate, environmental, food and health challenges

2nd Informal meeting in Brussels 24.1.2020

Brussels, 24.4.2020

4a

The European Plant Science Organisation (EPSO) invited policy makers to join EPSO members in a 2nd informal meeting exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe to better address climate change, achieve food and nutritional security, and establish a sustainable agriculture in Europe and world-wide.

The major change compared to last the meeting is the European Commission study. The Council of the EU requested the EC to submit a study regarding the status of new genomic techniques under Union law. The EC will perform this study until April 2021, covering all new genomic techniques developed after 2001. In a first step EU-level Stakeholders, including EPSO, and the Member States were invited to provide their experiences through a questionnaire. EPSO will provide input.

The meeting focused on exchanging insights between scientists (1 / country) and policy makers (1-2 / country) from governmental bodies, again no industries involved. We discussed legislation, which steps could we take to bring the discussion forward (parallel with the study of the EU). Secondly, we discussed potential flagships. The meeting was held under Chatham House Rules.

<u>In the first part of the meeting</u>, participants discussed the **current legislation - if and how it could be improved** in the short and in the longer term. First, several participants gave detailed introductions of already available substantial suggestions to update or replace current EUlegislation.

The citizens' initiative started in July 2019, will end in July 2020 and they hope to collect 1 million signatures to "stimulate" the EC to take actions. Next to this they came up with a new legal proposal: 1) Introduce additional definition of long safety record and a new definition of mutagenesis; 2) Add an annex 1C, specifically for NBTs; 3) Organisms made using new mutagenesis techniques would only be exempted if the modification could also have been achieved by traditional breeding methods.

Comments:

This is not a small alteration. It is not very realistic to set up an all-encompassing crop trait database, it remains discriminatory.

It is important to underline that the number of signatures relates to this specific proposal, many more would sign up to a general improvement of the legislation as asked by many scientists.

Another Northern country proposal focusing on product-based legislation instead of process based, was mentioned as a long-term approach.

Policy makers explained the need for an improved legislation to be clear and simple.

: there is a difference in the GMO definition between Europe and the Cartagena Protocol on Biosafety (no exemptions for classical mutagenesis). The EU is focused,

on the other hand, on "conventional organisms." Originally, the differences in focus were not seen to create "operational differences", so the EU did not change its legislation. However, after the ECJ case it creates a difficult situation (slide 18).

It would be very good to 1) harmonize between Cartagena and other GMO legislation, 2) avoid discrimination between products with the same genetic properties, 3) achieve enforceable legislation, 4) enable genome editing for sustainable agriculture and food production.

envisages four options: 1) Change the definition of a GMO (align with Cartagena LMO); 2) Expand annex 1A part 2 (techniques that do not lead to GMO; favored by **100**; 3) Introduce a definition of mutagenesis (including modern techniques); 4) Expand annex 1B (add additional techniques that are exempted), or create an annex 1C with these new techniques.

The VIB position is focusing on short term options, in order to harmonise with the rest of the world. The long-term approach might only work on a global scale and this makes it difficult to achieve at the moment.

Comments:

This proposal should be discussed with colleagues from regulatory bodies. Changing the GMO definition will be very difficult, so in the opinion of certain people we should take out mutagenesis techniques from the GMO definition. Mind you: nature offers the best and powerful mutagenetic techniques...

In summary: option 2, expand annex 1A. However, we have to be careful how we rewrite recitals, so as to overcome Recital 17.

2) or the area of exemption (either amend annex IA part 2 or amend annex IB), 2) Additionally an introduction of a preliminary examination procedure in individual cases.

Comments:

There are some similarities with the VIB proposals. It underlines again the need to change the GMO definition.

It is doubtful if the proposed preliminary examination will work from a legal perspective. Probably therefore this proposal will only work within Europe.

Always remind people that regulations exist (Annex II) that apply to any new plant variety and are successfully used for conventional breeding. Therefore, varieties exempt from GM legislation are still subject to these other regulatory requirements by default, ensuring safety.

The Norwegian Biotechnology Advisory Council proposal is a short term solution suggesting a three - tiers approach, assessing not only risks but as well benefits (see www.bioteknologiradet.no/a-forward-looking-regulatory-framework-for-gmo/). Tier 1 is equal to VIB option 2 and would trigger a notification (similar to the Leopoldina proposal), but no need for final approval. It includes assessments of societal benefits, sustainability and ethics. For GMO medicinal products separate regulations should be considered. *Comments:*

Working with the differences between tiers would also offer solutions for the problem around detection -e.g. tier 1 only document based.

More countries in Europe, Asia and America are working on similar approaches.

The proposal could benefit from definitions from others like VIB.

Tier 1 definition, difficult part is "what can arise in nature".

This could be included in the 2001/18 regulation similar to adding Annex 1A part 2 (Option 2).

Spanish Inter-ministerial Council of GMO preliminary report on GMO legislation and NBT: On the ministry website: www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/. As a result, Competent Authorities call on the European Commission to carry out a broaderranging revision and modernization of the EU biotechnology policy. Policy and regulation must continue to ensure a maximum level of safety and environmental protection, but they also have to be aligned with the advances in science and technology and flexible to cope with future challenges. The approach of this review should be based on giving priority to the safety of the final products, over techniques. We acknowledge that factors other than scientific evidence are inherent to policy-making procedures. These must be also considered, identified and communicated in a transparent way. *Comments*: An English translation would be most appreciated.

ask for a strong focus on plants and small changes in the legislation. They choose a science-based approach and fully agree that we need new tools to achieve sustainability and want to concentrate on plants and possibly exclude animals.

During the discussion the following **general issues** were highlighted for further consideration to improve the legislation: 1) better address global challenges such as climate change, environmental impact, food and nutritional security, 2) arrive at a legislation adhering to international law (Cartagena protocol), 3) enable implementation of the ECJ ruling (for example a simple notification for the class of genome editing products that could be achieved by classical mutagenesis, breeding or evolution, but not additionally regulating these), 4) strengthen European competitiveness, and 5) offer a free choice to developing countries to use the technology without restrictions when exporting their products to Europe. In addition, in a future meeting concerns raised by parts of society should be addressed as well.

We need to start a short term AND a longer-term improvement of the legislation almost in parallel: There is an urgency to come up with short term solutions to better address societal challenges and to be competitive globally - gene edited products will enter the European market from outside countries in increasing quantity over time. Even short-term solutions might take up to five years. In addition, we need a long-term paradigm shift from mainly process- to mainly product-based legislation in Europe.

Policy makers need to know which problems we can help to solve with these new technologies, e.g. reducing pesticide use as stated in the European Green Deal, contribute to Food and Nutritional Security in Europe and globally in future. A coordinated effort by scientists and policy makers across Europe would be appreciated – one of the ideas of the informal science and policy meetings.

Regarding the EU study, there was agreement of its high importance and that we need to take action to coordinate our inputs.

In the second part of the meeting, the concept of flagship projects towards genome edited products with consumer benefits for the European market and initial ideas for such flagships from the 1st informal meeting were followed up.

First outcome from a study by the Norwegian Biotechnology Advisory Board on the Norwegian consumers' attitudes towards gene editing in Norwegian agriculture and aguaculture was presented. which has been published in the meantime at www.bioteknologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-andaqua-FINAL.pdf. The study is based on more than 2000 representative responses. Two main conclusions were: 1) Use of the technology matters! It would be unethical not to use genome editing for addressing the Sustainable Development Goals (SDGs). The use connected with organic food would be appreciated. Labelling different to GM would be appreciated indicating which trait(s) were improved. 2) Who developed it matters! National / small breeding companies are appreciated, whereas multinationals are seen more negatively. Similar for cultivation by farmers. Many consumers trust national companies and safety authorities. Comments:

It would be useful to carry out similar studies in other countries across Europe.

In the **discussion on possible flagship projects** it was suggested to start some which can lead to products on the European market in some years. A second waive could develop products for the longer-term. Challenges to address could include e.g. reducing pesticide use, improving drought tolerance, stop and revert insect decline.

Several policy makers suggest using existing multinational collaborations of funders, such as Nordic countries combined with some central European countries. This could be a focus of a third informal science and policy meeting later in 2020.

Conclusions and actions

Participants agreed to continue the open dialogue between the science and policy participants from this meeting and invite representatives from other countries interested in the issue and a member of the European Parliament.

The 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.

Actions:

- All participants (this always includes those that apologised to due to overlapping activities) kindly provide to us their <u>availability</u> to meet in Brussels in the European quarter (if possible at KoWi) between 19.10. and 6.11.2020 (see email text) and Ministry participants kindly <u>indicate</u> <u>if they wish to present</u> ongoing, approved or possible future opportunities regarding flagship projects.
- All participants are welcome to send us <u>news items for a quarterly update regarding genome</u> editing legislation and efforts to improve the legislation from among the participants.
- Ministry participants kindly suggest to EPSO which <u>additional ministry colleagues</u> to invite (providing name, ministry, email). Should this not be possible under GDPR, please recommend such colleagues to contact EPSO expressing their interest to join the next such informal meeting.
- All participants are welcome to brainstorm with their colleagues on further ideas for <u>flagship</u> projects or already started initiatives that could become a flagship and send to us by August to include in the preparatory material for the next meeting.

EPSO offers to collaborate with policy makers to develop an appropriate future-ready regulation to enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the environmental impact of agriculture. Notwithstanding the technical option retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.



About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 31 countries, mainly from Europe, and 2.600 individuals Personal Members, representing over 26 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science including science advice to policy, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science. https://epsoweb.org EU Transparency Register Number 38511867304-09

Annex I Supporting literature - links

- The Norwegian Biotechnology Advisory Board (2020). Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture. <u>www.bioteknologiradet.no/filarkiv/2020/04/Report-</u> <u>consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf</u>
- EPSO Statement on the Horizon Europe Strategic Plan, 18.2.2020. <u>https://epsoweb.org/epso/epso-statement-on-the-horizon-europe-strategic-plan/2020/02/18/</u>
- Nordic Public Private Partnership for Pre-breeding (PPP) Workshop 5-6.2.2020 for future call <u>https://www.plant-</u> <u>phenotyping.org/index.php?index=580&event=Workshop Nordic Plant Genetic Resources Enhance</u> <u>ment in a changing climate Public Private Partnerships in Pre Breeding</u>
- "Towards a scientifically justified, differentiated regulation of genome edited plants in the EU", joint statement from the German National Academy of Sciences Leopoldina, the Union of the German Academies of Sciences and Humanities, and the German Research Foundation, December 2019, 84 P., ISBN: 978-3-8047-4064-8. www.leopoldina.org/en/plant-breeding
- The Council of the EU requested on 8.11.2019 the Commission to submit, by 30.4.2021, 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 <u>https://eur-lex.europa.eu/eli/dec/2019/1904/oj</u>.
- EPSO statement (endorsed by all EPSO Representatives for 197 institutes / universities), 19.2.2019: <u>https://epsoweb.org/download/epso-statement-on-ecj-ruling-regarding-mutagenesis-and-gmo/</u>
- EPSO welcomes Commissioner Andriukaitis statement and call for action 'New plant breeding techniques need new regulatory framework', 29.3.2019: <u>https://epsoweb.org/epso/epso-welcomescommissioner-andriukaitis-statement-and-call-for-action-new-plant-breeding-techniques-need-newregulatory-framework/2019/03/29/
 </u>
- VIB statement (including signatories for 109 institutes / universities and 18 associations), 25.7.2019: <u>http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20ed</u> <u>iting%20for%20sustainable%20agriculture%20and%20food%20production%20in%20the%20EU.aspx</u>
- Open letter from Swedish Vice chancellors of Umea University and representatives from funding agencies, 25.7.2019: <u>https://www.upsc.se/documents/News/News_2019/2019-07-25_Open-letter-</u> <u>concerning-GMO-regulations.pdf</u>
- ESA Open Letter to Member States on the EU Court Ruling on Mutagenesis, 9.5.2019: https://www.euroseeds.eu/app/uploads/2019/07/Letter-to-Member-States-at-Scopaffs-July-2019.pdf
- Grow scientific progress: crops matter! European citizen initiative, 25.7.2019: https://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2019/000012/en
- Statement from the Ethical Council in DK (in Danish): GMO and ethics in a new time: <u>http://www.etiskraad.dk/~/media/Etisk-Raad/Etiske-Temaer/Natur-klima-og-foedevarer/GMO-2019/DER Udtalelse GMO og etik i en ny tid m baggrundsnotater.pdf#page=27</u> (© Det Etiske Råd 2019 ISBN: 978-87-92915-15-3)
- Statement by the Group of Chief Scientific Advisors, 13.11.2018: <u>https://ec.europa.eu/info/sites/info/files/2018_11_gcsa_statement_gene_editing_2.pdf</u>
- Bratlie et al. 2019: A novel governance framework for GMO. EMBO Reports (2019) 20: e47812; DOI 10.15252/embr.20194781 [Suggestion from Norway to modify legislation on genetic engineering] <u>http://www.bioteknologiradet.no/filarkiv/2019/03/2019-04-16-Genteknologiloven-komplett-ENGELSK-siste.pdf</u>
- Paper from the NL suggesting the modifications in the Annexes of 2001/18/EC prior to the ruling, 21.3.2019: <u>https://www.cogem.net/index.cfm/nl/publicaties/publicatie/voorstel-voor-aanpassing-van-de-vrijstelling-in-de-ggo-regelgeving-aanvullende-criteria-voor-het-vrijstellen-van-gg-planten?order=relevance&q=&category=&from=30-09-1998&to=21-03-2019&sc=fullcontent
 </u>

- Curia Judgement of the court in case C-528/16, 25.7.2018: <u>http://curia.europa.eu/juris/document/document.jsf?docid=204387&doclang=EN</u>
- Wasmer 2019: Roads Forward for European GMO Policy—Uncertainties in Wake of ECJ Judgment Have to be Mitigated by Regulatory Reform. Front. Bioeng. Biotechnol. 7:132. doi: 10.3389/fbioe.2019.00132. <u>https://www.frontiersin.org/articles/10.3389/fbioe.2019.00132/full</u>
- Joint Statement of AFBV and WGG, 13.9.2019: <u>https://cdn.website-</u> editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/AFBV-WGG-Statement.pdf

Annex II: Regulations and obligations for conventional breeding and variety testing

EU database of registered plant varieties

The common catalogues of varieties of agricultural plant and vegetable species list the varieties which can be marketed in the EU.

Catalogues are based on the registration of plant varieties in EU countries after they have been technically examined there and notified to the Commission.

Variety registration is a precondition for the certification of seed.

To be listed, varieties must meet standards on:

- Distinctness
- Uniformity
- Stability
- Value for cultivation and use for agricultural crops.
 - This value is based on:
 - Yield
 - Resistance to harmful organisms
 - Response to the environment
 - Quality characteristics

Legislation

- <u>Council Directive 2002/53/EC</u> on the common catalogue of varieties of agricultural plant species.
- <u>Council Directive 2002/55/EC</u> on the marketing of vegetable seed.
- <u>Council Directive 2008/72/EC</u> on the marketing of vegetable propagating and planting material other than seed.
- <u>Commission Directive 2003/90/EC</u>: Rules on minimum characteristics and minimum conditions for examining certain varieties of agricultural plant species.
- <u>Commission Directive 2003/91/EC</u>: Rules on minimum characteristics and minim conditions for examining certain vegetable species.
- <u>Commission Regulation 637/2009/EC</u> of 22 July 2009 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species.

Forest tree species

Legislation

- <u>Council Directive 1999/105/EC</u> of 22 December 1999 on the marketing of forest reproductive material
- <u>Commission Regulation EC 1597/2002</u> of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the format of national lists of the basic material of forest reproductive material

Fruit genera and species

FRUMATIS (Fruit Reproductive Material Information System) 7 <u>EU variety register</u> (updated 2-Sep-2019) to improve the traceability and promote the dissemination of information on the varieties that can be marketed in the EU. The EU variety register contains the varieties with an official description - which need to be officially registered - as well as varieties with an officially recognised description. Before official registration the variety's identity is tested for:

- Distinctness;
- Uniformity;
- Stability

Legislation

- <u>Council Directive 2008/90/EC</u> on the marketing of fruit plant propagating material and fruit plants intended for fruit production
- <u>Commission Implementing Directive 2014/97/EU</u> implementing Council Directive 2008/90/EC as regards the registration of suppliers and of varieties and the common list of varieties

Vine propagating material of the genus Vitis

Common catalogue of varieties of vine propagating material: Before a variety is listed in a national catalogue of vine varieties the variety's identity is tested for:

- distinctness;
- uniformity;
- stability.

Legislation

- Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of vines
- Commission Implementing Decision (EU) 2017/478 of 16 March 2017 releasing certain Member States from the obligation to apply to certain species Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC and 2002/57/EC on the marketing of fodder plant seed, cereal seed, material for the vegetative propagation of the vine, forest reproductive material, beet seed, vegetable seed and seed of oil and fibre plants respectively, and repealing Commission Decision 2010/680/EU

Timeline for conventional breeding and optimal application of genome editing in the breeding process



Annex III: Regulations and obligations for GMO breeding and testing in the EU

	Convent. breeding	Convent. mutagenesis	Classic GMP/GMM	Genome edited P/MO
Dir. 2001/18/EC "Deliberate release"	Non GMO	GMO exempted from further obligations	GMO	GMO
Reg. (EG) 1829/2003 "GM Food / feed"	Non GVO	Non GMO	GMO	GMO
Reg. (EG) 1830/2003 "GMO Traceability"	Non GMO	Non GMO	GMO	GMO
Dir. 2009/41/EG "Contained use "; GMM	+	Non GMO	- /GMM	-1?
Reg. (EU) 2018/848 Organic production and labelling	Non GMO	(Non GMO)	GMO	GMO
Cartagena-Protocol	Non GMO	Non GMO	GMO	Non GMO; if transgenic: GMO
Dir. 2002/53 Plant varieties Catalogue	Non GMO	Non GMO	GMO / -	GMO / -

GMP = genetically modified plant; GMM = genetically modified microorganisms

Definitions in Directive 2001/18/EC

Recitals

(17) This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.

Article 2 - Definitions

For the purposes of this Directive: [...]

(2) "genetically modified organism (GMO)" means 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;

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

Article 3 - Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

EPSO: Genome editing – 2nd informal science - policy meeting 24.1.2020 – Report

ANNEX I A - TECHNIQUES REFERRED TO IN ARTICLE 2(2) PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B: (1) in vitro fertilisation.

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

ANNEX I B - TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Obligations for GMO other than generated by classical mutagenesis

- Authorisation procedure (step by step: lab -> field trial -> market release; case by case: each event)
- Authorisation for field releases (at national level; limited risk assessment; essentially prevent spreading, protect environment)
- Authorisation of deliberate release to the market requires a detailed risk assessment comprising
 - Description of the organism(s) and modifications
 - Compositional analysis
 - Toxicological and allergological evaluation
 - ...
 - Environmental risk assessment
 - o impact on non-target organisms
 - impact on bio-geochemical cycles
 - o impact of crop management
 - o ...
 - Monitoring of the release
 - o Labelling of products containing or made from GMO
 - o Acknowledged detection methods (verified detection method)



EPSO:

Genome editing Improving legislation and start flagships to better address climate, environmental, food and health challenges

Informal science policy meeting European Plant Science Organisation <u>www.epsoweb.org</u> Brussels, 24.1.2020



I - EPSO – The European Plant Science Organisation, the voice of plant science in Europe -

Independent academic organisation

Mission:

- Promote plant science and support plant scientists
- Discuss future plant science programmes across Europe
- Provide authoritative independent information on plant science → science advice to policy
- Promote training to meet the challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science → help reaching SDGs

Members:

- > 200 research institutes, universities, departments (>26 000 researchers and staff in plant science) from 31 countries – mainly in Europe
- + > 3.600 Personal members



What can plant science contribute to society (in Europe) today and in future?

- 1) Plant science can help to address global challenges incl. SDGs
- Curiosity driven plant science fosters knowledge generation about living organisms and the world we live in
- Plant scientists support the next generation of scientists and entrepreneurs
- Plant scientists support Open Science Free collaboration and movement of scientists



1 - Plant science can help to address global challenges

FNS, climate change, human health, energy security, sustainability – all benefiting from NBTs

- ↑ yield (stability) in changing environments
- $\circ \uparrow$ food crops for better human nutrition and health
- Utilise bioactive green molecules (secondary metabolites and proteins) for renewable materials, energy, human wellbeing and health
- ↑ plant and crop health for resilient production
- Nutrient cycling and carbon sequestration





EPSO helps plant scientists to engage with policy and society [in Europe] to contribute

- EPSO supports science and scientists with over 10 Working Groups / meetings, workshops, conference; Briefings, analyses, web <u>https://epsoweb.org</u>, social media
 EPSO provides science advice to policy mainly at European level (EC, EP, MSs) and at national & global levels
- 3) EPSO fosters science with society approaches









2 – EPSO provides science advice to policy

Agricultural technologies – e.g. on NBTs

- EPSO statement on ECJ ruling regarding mutagenesis and GMO directive, 19.2.2019
- EPSO informal science policy meetings
- o EC study on NBTs
 - The Council of the EU requested the <u>EC to submit by</u> <u>30.4.2021 a study</u>, regarding the status of new genomic techniques under Union law [<u>Council Decision (EU) 2019/1904</u>].
 - EC will perform study covering all new genomic techniques developed after 2001.
 - <u>EC invites contributions from MS and EU Stakeholders</u> (SHs): targeted consultation of EU level SHs that could be directly or indirectly impacted and/or have potential interest in new genomic techniques (list consulted SHs soon on EC web) – incl. EPSO

Agricultural technologies – e.g. on NBTs cont.

EC study on NBTs – contributions from MS and EU-level SHs cont.

- EC consultation process:
 - <u>Draft questionnaire</u> distributed to <u>selected EU-level SHs</u> (incl. EPSO)
 - SH meeting 10.2.2020 in Brussels discussing draft questionnaire
 - Invitations to this meeting after confirmation of your interest (max. 2 participants representing your organisation in the consultation process, their functions and contact details. Consultation launched via EUSurvey in 2nd half of February.
 - SHs have until 30.4.2020 to reply to the EUSurvey <u>questionnaires</u>.
- Brussels 15.1.2020 MS Committee meeting (2001/18, 1829/2003, 2009/41) on the EU Council/Commission task on new techniques and the GMO regulation. Member states will have a lot to follow up on

Today: EPSO 2nd informal science policy meeting Genome editing – improve legislation and start flagships to better address climate, environmental, food and health challenges

Brussels, 24.1.2020

; updates –

Welcome –

Legislation – how could it be improved?

- Available suggestions –
- Comparative summery -
- Discussion on the way forward moderated by

Flagships towards GE products with consumer benefits on the market in Europe

- Summary from 1st meeting EPSO –
- Consumers' attitudes to genome editing in Norway -
- Discussion moderated by

Conclusions, next steps –



This meeting is under Chatham House Rule

www.chathamhouse.org/chatham-house-rule :

'When a meeting, or part thereof, is held under the **Chatham House Rule**, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.'

The rule originated at Chatham House with the aim of encouraging openness of discussion and facilitating the sharing of information. It is now used throughout the world as an aid to free discussion of sensitive issues. It provides a way for speakers to openly discuss their views in private while allowing the topic and nature of the debate to be made public and contribute to a broader conversation.



II Legislation – how could it be improved?

- chaired by



Introduction of available suggestions to update or replace current EU-legislation on GMO







Citizen's initiative proposal, 25.7.2019 -

Core concepts in the citizens' initiative legal proposal



- **1**. Introduce additional definitions of:
 - Long safety record
 - Mutagenesis, making a differentiation between conventional and new mutagenesis techniques
- 2. Add an annex IC specific for organisms made using new mutagenesis techniques
- Organisms made using new mutagenesis techniques would only be exempted if the modification could also have been achieved by traditional breeding methods.
 - For compliance to this requirement a database will be set up with established/known croptrait combinations



Citizen's initiative proposal, 25.7.2019 -

What the citizens' proposal means:





Citizen's initiative proposal, 25.7.2019 -

Pros and cons of the citizens' initiative legal proposal:

- It is not a small alteration
- Is setting up an all-encompassing crop-trait database realistic?
- It remains discriminatory: you can generate new traits with conventional mutagenesis that will not be covered, while generating the same trait with new mutagenesis would still be covered









Exempted GMOs



Goals

- Harmonization with Cartagena and other GMO legislation
- 2. Avoid discrimination between products with the same genetic properties
- 3. Achieve enforceable legislation
- Enable genome editing for sustainable agriculture & food production



Option 1 Change the definition of a GMO


Replace the current definition of a GMO, by:

"GMO means a living organism, with the exception of human beings, that possesses a novel combination of genetic material obtained through the use of modern biotechnology"

-> As a result article 3 and Annex IB can be deleted



Option 2 Expand Annex IA part 2



Add to Annex IA part 2:

(4) Mutagenesis resulting in the formation of permanent genetic alterations that could otherwise also have occurred spontaneously in nature or result from conventional breeding activities, and does not result in the insertion of sequences in that organism that are foreign to the organisms' gene pool.

[[[(5) Allele replacement
(6) Cisgenesis]]]



Option 3

Introduce a definition of mutagenesis



Add to article 2, the following:

•••

(9) 'mutagenesis' means the delibaterate induction by humans by any physical, chemical or biological means of permanent alterations to the genome of an organism [that could otherwise also have occurred spontaneously in nature or result from conventional breeding activities], and does not result in the insertion of sequences in that organism that are foreign to the organisms' gene pool.

-> Need to introduce a recital that over-rules the current recital 17



Option 4 Expand Annex IB



Replace 'mutagenesis' in Annex I B by:

- (1) Conventional random mutagenesis techniques using physical or chemical means such as ionizing radiation and ethylmethylsulphate (EMS),
- (2) Targeted mutagenesis techniques using chemical or biological means such as oligo-directed mutagenesis and site-directed nuclease technology that generate permanent alterations to the genetic material that could otherwise also have occurred spontaneously in nature or result from conventional breeding activities and which do not result in the insertion of sequences in that organism that are foreign to the organisms' gene pool
- (3) ...

-> Need to introduce a recital that over-rules the current recital 17



Pros and cons of options

- Options 1 and 2 have a full harmonizing effect while options 3 and 4 may still lead to different legal approaches in EU member states
- Option 1 clearly alignes with CPB
- Option 2 avoids changing the current definition, but opens this definition to a more product-oriented interpretation
- Option 4 may be perceived as the smallest change

















• Analyses of the European GMO legislation

vs. scientific knowledge and scientific perfomance

 "... due to the mounting divergence between scientific progress and legal standardisation, the primarily process-based European regulatory approach is no longer justifiable."

Accordingly, the science academies and the DFG see an urgent need to reassess the products of the much more precise and efficient methods of genome editing and, as a **first step**, to amend European genetic engineering law in the short term. In a second, long term step, the legal framework should be fundamentally overhauled to place the focus on novel traits and features of an organism that are relevant to the environment, health, and nature conservation, not on the underlying breeding process.



➤ Aim:

Limiting the scope of the GMO regulatory framework so that it does not apply to GEd organisms,

- in which no foreign genetic information has been inserted, or
- in which there is a combination of genetic material which *could also result naturally or by conventional breeding* techniques

Recommended measures:

- Change in the GMO definition or the area exemption
- Additionally: Introduction of a *preliminary examination procedure* in individual cases



Primary suggestion - Revision of Article 2: (=> GEdO is not a GMO)

⇒ Describing a genome state of an organisms rather than a process of its modification

⇒ Focus on genome modifications that more likely enable assignation to a technical process

"For the purposes of this Directive: ...

'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material **has been is** altered **in the shape of insertion of genetic information into the genome** in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;"



1st alternative suggestion – Amendment to Annex I A Part 2 Directive 2001/18/EC: (=> GEdO is not a GMO)

"Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of **recombinant nucleic acid molecules or** genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

- 1. in vitro fertilisation,
- 2. natural processes such as: conjugation, transduction, transformation,
- 3. polyploidy induction,

4. targeted molecular techniques which, when applied, effect a genetic modification that may have occurred naturally, in particular techniques that

a) cause deletions of DNA,

b) exchange individual base pairs,

c) cause the insertion, inversion or translocation in the genome of genetic information known to occur, or can occur with high probability, in the natural gene pool of the same species or closely related species."



2nd alternative suggestion -

Amendment to Annex | B Directive 2001/18/EC: (=> GEdO is a GMO but exempted)

"Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

1. mutagenesis,

2. cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods,

3. targeted molecular techniques which, when applied, effect a genetic modification that may have occurred naturally, in particular techniques that

a) cause deletions of DNA,

b) exchange individual base pairs,

c) do not cause stable insertion of genetic information,

d) cause the insertion, inversion or translocation in the genome of genetic information known to occur, or can occur with high probability, in the natural gene pool of the same species or closely related species."



Additional suggestion - Preliminary examination/consultation procedure:

 \Rightarrow Information about GEdO in the EU

⇒Ensure absence (of remnants) of foreign DNA (compliance to 2001/18/EC)

>> The preliminary examination procedure, in particular its scope and the requirements for applications for preliminary examination, should be regulated in a new Article, possibly in conjunction with a new Annex I C, in Directive 2001/18/EC. The European Food Safety Authority (EFSA) should be involved in this preliminary examination procedure in the form of a binding scientific opinion. <<



Recommendation 2. A fundamentally new legal framework

- Triggers of risks for humans, nature and the environment
 - Not: methods of genetic modification
 - *but: products* resulting from genetic modification, e.g. plant with certain characteristics, and their use
- Completely new legal framework
 - *Product-related*: Linking regulation to novel characteristics of an organism
 - *Science-based*: Adaptation of the "if" and "how" of a risk assessment to traits and their novelty
 - Upstream clarification procedure: Assessment of the regulatory status
 - Adaptation to the state of the art: *review and, if necessary, revision* of the legal framework at least every five years





Recommendation 4. Differentiated discussion of breeding methods

Recommendation 5. Securing freedom of choice

Recommendation 6. Responsible exploitation of innovation potential

Recommendation 7. Increasing market competition







- In Norway, GMOs are regulated under the Gene Technology Act (1993)
- The Norwegian Gene Technology Act has five assessment criteria for GMOs: health impact, environmental impact, socio-economic effects, sustainable development and ethics.
- In line with signals from the Parliament, the Norwegian GMO regulation has been rather strict.
- Norway has implemented parts of the EU GMO regulation through the EEA Agreement
 - Directive 2001/18 is implemented
 - Regulation 1829/2003 is to be implemented
- Although Norway has some adaptations to National regulation (EEA Agreement), the Norwegian GMO management can hardly deviate substantially from the one in the EU. In particular, this is true when it comes to the definition of a GMO.
- Hence, the EU Court of Justice ruling from July 2018 is relevant also for Norway



- The Norwegian Biotechnology Advisory Board (NBAB) has recommended
 - o a softening-up of the Norwegian GMO-management/legislation
 - that a panel or committee is appointed by the Norwegian government in order to publish a Norwegian Official Report (in Norwegian, an NOU) on gene technology and genome etiting
 - establishment of such a panel is also supported by a variety of interest groups and organisations (Nettverk for GMO-fri mat og fôr)
- The Norwegian Government follows the international development closely, in particular the latest developments within the EU.
- The Norwegian Ministry of Climate and Environment (Competent Authority for GMOs) and the Government are in the process of deciding on the next steps, among them,
 - whether a panel is to be appointed (NOU)
 - specific changes in the Gene Technology Act (a public hearing is expected shortly)







What is needed?

- Appropriate regulatory framework – innovation in governance
- Openness and transparency in research and development
- Knowledge-based, goaloriented and inclusive public dialogue







http://www.bioteknologiradet.no/a-forwardlooking-regulatory-framework-for-gmo/



	Exempted from regulation Organisms with temporary, non-heritable changes		Final tier placement can be affected by
			aspects concerning the genetic change, the organism or the trait.
Covered by GMO regulation	TIER 1	E.g. move up if suspected risk, or move down if similar product previously	
	Genetically engineered organisms with changes that exist or can arise naturally and can be achieved using conventional breeding methods	Notification (confirmation required)	approved.
	TIER 2	Societal benefit, sustainability	
	Organisms with other species-specific genetic changes	Expedited assessment and approval and ethics assessed on tiers 1–3	
	TIER 3		Standard assessment and approval (current requirements)
	Organisms with genetic changes that cross species barriers or involve synthetic (artificial) DNA sequences	Standard assessment and approval (current requirements)	

Bratlie et al. (2019). Embo Reports 20: e47812







Labelling and traceability/detection requirements can be tailored to feasibility on each tier



JRC TECHNICAL REPORTS

Explanatory Note

Challenges for the detection of genetically modified food or feed originating from genome editing

- Enforcing legislation will be very challenging.
- Detection only possible when previous information about genetic change is available (but even then not definitive).
- Can be difficult to clear imported food and feed at the EU-border in time.
- Detection method is a prerequisite for application for approval of a GMO – catch 22.



Tier 1

Notification with information on:

- The methods used,
- Which genes/traits have been changed
- Intended and unintended changes
- The specific organism that has been modified
- The environment into which the organism is to be released
- Experimental data, where available.
- A self-assessment of health and environmental risks, sustainability, societal benefit and ethics should also accompany the notification.

Tier 2

- Remove requirement for toxicity testing where no foreign DNA intoduced?
- Reduce requirements for documentation on specific release conditions and recipient environments, such as individual time-points for release, the duration of the release?
- Reduce requirements for field trials: e.g. approval for groups of GMOs, multiple edits that are expected to give same phenotype etc.

Tier 3 Standard assessment



Directive 2001/18/EC

Article 7

Differentiated procedures

1. If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems and the GMOs concerned meet the criteria set out in Annex V, a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs.

2. Following its own initiative or at the latest 30 days following the receipt of a competent authority's proposal, the Commission shall,

(a) forward the proposal to the competent authorities, which may, within 60 days, present observations and at the same time;

(b) make available the proposal to the public which may, within 60 days, make comments; and

(c) consult the relevant Scientific Committee(s) which may, within 60 days give an opinion.

3. A decision shall be taken on each proposal in accordance with the procedure laid down in Article 30(2). This decision shall establish the minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release, in particular:

However!

- No scope for derogation from approval requirement?
- No scope for derogation from labelling / detection requirement?
- Implementing Regulation no 503/2013 does not lay down procedures to derogate from requirements under Regulation No 1829/2003 (Food and feed)





Public dialogue at the heart



- Enabling framework that lowers hurdle
- Science based / risk proportionate
- More predictability

- Lack of experience with new technologies
- Impact on ecosystems when rapid development
- Need for precaution

- Value of regulatory oversight and public trust
- Gene editing and other gene technologies can contribute to sustainable agri- and aquaculture
- Competitiveness on the international market is crucial
- Importance of health, environment, societal benefit, sustainability and ethics



Lowering regulatory hurdle

Oversight and control

Public Trust

Science based policy Political willingness



Genome editing: Call for new EU legislation

Germany and EU should help to shape bio-innovations



Home / New & Common Japanese Authorities Recommend Not Regulating Gene Editing

Unlike judges in the European Union, a government panel in Japan says transgenic modification and genome editing are not the same.

Aug 22, 2018 KERRY GRENS



ASSIVE & ISTOCK VISUAL SPACE

A Japanese government panel announced Monday (August 20) that it A recommends regulating only genetically modified organisms that have had foreign genes permanently introduced into their genomes and

not those whose endogenous genes have been edited, according to NHS World-Japan. This means that developers will not have to get approval from the government to produce gene-edited organisms, The Maintchi reports.

The only stipulation is that researchers and businesses will have to register their modifications to plants or animals with the government, with the exception of microbes cultured in contained environments. "We judged that there needed to be some kind of management system in place to earn consumers' trust," a panel member tells *The Mainichi*. Draft Document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment



Government of India Ministry of Science & Technology Department of Biotechnology

In view of the recent developments in the field of Genome Editing Technologies a need was felt to bring out guidelines. After series of expert consultations, draft guidelines titled "Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment" has been prepared. The draft guidelines accommodates applicable laws. Acts, and procedures governing Genome Editing, general considerations and tiered approach for risk assessment of genome edited organisms and products derived thereof, regulatory approval road map, data requirement for risk assessment and institutional mechanism for governance and oversight.









Spain -

- Spain has received national applications for conducting activities of confined use with genome-edited products before and after the judgement. All the applications have been processed in accordance with the case by case principle.
- They are subjected to the <u>same risk assessment process included in the</u> <u>GMO legislation</u>. The evaluation includes both the activity to be performed and the facilities in which they are going to be conducted. Where appropriate, they are authorized according to GMO national legislation and included in the national register of GMO activities.
- The <u>national competent authority in Spain is the Interministerial Council</u> of GMO. This Council includes representatives from the different ministries agriculture, environment, research, trade, health ... The decision on GMO are based on the risk and also on the interest for the agriculture, industry, research and trade sector.
- The priority is to work with the EU commission and other MS to clarify the legal situation and legal options for products derived by genome editing techniques. An important issue is the challenge of controlling products from novel genomic techniques.

Spain -

 The Interministerial Council of GMO have published a preliminary report on GMO legislation and NBT. The report is available on the Ministry of Agriculture, Fisheries and Food website:

www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/.

- This document presents an analysis of the consequences of the European Court ruling on new mutagenesis techniques. General issues and other focused on Spain are included.
- As a result, <u>Competent Authorities call on the European Commission</u> to carry out a broader-ranging revision and modernization of the EU biotechnology policy. Policy and regulation must continue to ensure a maximum level of safety and environmental protection, but they also have to be aligned with the advances in science and technology and flexible to cope with future challenges. The approach of this review should be based on giving priority to the safety of the final products, <u>over techniques</u>. We acknowledge that factors other than scientific evidence are inherent to policy-making procedures. These must be also considered, identified and communicated in a transparent way.


Spain -

- Since the publication of the judgement of new mutagenesis techniques, the Competent Authorities have increased their participation in different for a, <u>meetings</u>, workshops on new genomic techniques.
- A recent example of bringing information to the public was a workshop on 'New Breeding Techniques' in Madrid in May 2019 aimed at stimulating an open debate among scientists and other relevant stakeholders about opportunities and challenges arising from the use of new breeding techniques. Presentations: <u>www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica</u>.
- <u>Academics and scientific are perceived as trusted communicators and</u> they are doing great things to explain these technologies to the society, showing the differences between these technologies and traditional DNA recombinant technologies in terms of precision, safety, detection
- The <u>National Commission of Biosafety</u> is the scientific advisory body. Two <u>scientific opinions</u> regarding novel genomic techniques have been published. The conclusions concurred with those from the report of the Scientific Advisory Group of the European Commission. The reports are available on the Ministry for Ecological Transition website: www.miteco.gob.es/es/calidad-y-evaluacion-Ambiental/temas/biotecnologia/organismos-modificados-geneticamente-onte-/commission-naciona-bioseguridad/.





Sweden

Ministry of Enterprise and Innovation

- 2015-2018, Field trials with GE plants allowed without special permits
- Court case C-528/16 Confédération Paysanne
 - Genome Editing is a form of mutagenesis
 - In agreement with the concept of naturalness
 - In agreement with the precautionary principle
- Now:
 - SE supported the study on GE that the EC now is now conducting
 - Argued that the EC should also study the economic consequences of the EC court ruling
 - A small change in the legislation takes less time to achieve and is more predictable













Comparative summary

New legislation ("long term")				Yes, => novelty, product based		Tiered assessment; process triggered
Modification Dir 2001/18/EC ("Short term" ?)	Yes	extended add.	Yes	Yes	Yes	



Comparative summary

GMO definition (Dir 2001/18/EC Art 2) => Exclude GEdO			focus <i>novelty</i> ~ <i>CPB</i>	focus ~ likely also occur naturally, conv. breeding, etc.		GEdO ~ natural
Other Definitions (Dir 2001/18/EC Art 2)		Add def. "Long safety record", "Mutagenesis"	include <i>modern</i> <i>mutagenesis</i> in definition of <i>mutagenesis</i> ~ recital 17	natively	include modern mutagenesis in definition of mutagenesis	occuring = Her 1
GMO definition (Dir 2001/18/EC Annex 1 A part 2)			extend list ~ <i>natural occuring</i> => exclude GEdO	alternatively extend list ~ natural occuring => exclude GEdO	extend list ~ <i>natural</i> <i>occuring</i> => exclude GEdO	Species specific changes = Tier 2 = expedited assessment
GMO exemption (Dir 2001/18/EC Annex 1 B)	extend list 4 <i>plants</i> => exempt <i>GEdP</i> ; Applicant: justification on request; review		extend list, ~ recital 17 ⇒ exempt GEdO; ~ natural occuring	alternatively extend list ⇒ exempt GEdO; ~ natural occuring	extend list, ~ recital 17 ⇒ exempt GEdO; ~ natural occuring	Cross species modifications = GMO = Tier 3;
"Annex 1 C"		"Positive list" of exempted GEdO; => int. data base				

Comparative summary

Notification			GEdO ~ natural occuring = Tier 1
Pre-evaluation	[post: justification on request by authorities]	Consultation; => Presence of transgenes	





Legislation – how could it be improved?

Discussion on the way forward

- Moderated by

- Perspectives (small modifications or fundamental changes)
- Consideration of the upcoming study by the EC
- How to support policy makers

- from participants



III - Flagships towards GE products with consumer benefits on the market in Europe

chaired by







Support for creating a future-ready regulation

- Scientific engagement in the societal debate on genome editing
- Communicate in a fact-based and yet accessible manner about innovative plant science and its societal role
- Collaboration of scientists and policy makers backing discussion to improve the legislation

=> Flagship projects



NBT flagship - What does it take?

- Flagship project
 - story to tell: scientists' / SMEs' commitment
- Communication
- Policy support
- · Funding throughout the pipeline: lab to field to market

NBT flagship - Feasability?

Which are appropriate **subjects/topics**? What is a realistic **scale** (EU, national)? What are the necessary **resources**? What are **potential risks** - how to **tackle** these? Who will **support** it? What are the **next steps**?



First ideas (non exhaustive):

- Resistance to fungi (e.g. mildew diseases) that are a problem in organic and or conventional farming (e.g. in grapevines in Italy, France, Spain, Germany)
- o Reduction of allergens in wheat (Gluten) or apple
- Diversify taste of crops that has been unified (e.g. tomato, pepper e.g. according to regional preferences)
- Altering the fatty acid or protein composition of food crops or crops for industrial production (the latter must provide an obvious benefit for the public)

o Fungi resistant banana ...



The example products could either **benefit the population in a certain European region or a certain group of consumers** (regional, health condition – e.g. allergic people, etc.), and / or improve European competitiveness

Challenge: The **benefit of such a product for the consumer** should be obvious and reasonable.

Projects should specify and later on demonstrate how they address global challenges / societal questions, legislative requirements, economic and consumer benefits.

The whole set of flagship projects (with consumer benefits) should cover Europe.



Public-private risk and benefit sharing to enable SMEs being a partner in the process.

Engage, from start to finish, scientists, industry (focus on SMEs), farmers, policy makers, regulatory agencies and citizens.

Flagship ideas can target **different levels of technology readiness**, ranging from theoretical concepts, to proof-of-concept in confined environments and field trials, to actual market release.

Ideally **one should be market-ready** to be further developed to market release and authorisation might be envisaged in the medium term to actually have a product on the market in Europe.



Picking up the stake - priority criteria

- status: ongoing or de novo?
- feasibility: target identified or not?
- novelty: novel or copy of existing mutation (same species or other species)?
- type of benefit: crop culture (less intrants, resilience, adaptation, diversification, productivity) or quality of the product (health benefit, technical improvement for processing industry)?
- beneficiary: farmer, consumer and/or citizen?
- impact: region or country or climatic zone or all of EC?
- impact: field crop or niche market?
- impact: stakeholder/consumer concerns







Flagships – Discussion on the way forward - Moderated by

- Priority criteria* / screening
- Consider stakeholder concerns
- Next steps

- from participants



Flagships – possible priority criteria -

- Status: ongoing or de novo?
- Feasibility: target identified or not?
- Novelty: novel or copy of existing mutation (same species or other species)?
- Type of benefit: crop culture (less intrants, resilience, adaptation, diversification, productivity) or quality of the product (health benefit, technical improvement for processing industry)?
- o Beneficiary: farmer, consumer and/or citizen?
- Impact: region or country or climatic zone or all of EC?
- o Impact: field crop or niche market?
- Impact: stakleholder/consumer concerns



IV – Conclusions, next steps

Moderated by

Keep discussion going and foster actions

- Among ministry colleagues joint action(s)
- Always contact EPSO in BRU and / or in your country for support (incl. scientist from today; All representatives see <u>https://epsoweb.org/aboutepso/representatives/</u>)
- Continue quarterly updates? Information from EPSO and from ministries you want to share
- When meet next e.g. autumn 2020
 - EPSO could link the next meeting to the DE EU Presidency subject to visibility you wish
- Suggest more countries to be invited in addition to the next meeting
 - Invited EC / EP (short notice) next time earlier

This is our future we have to engage in it

Scientists can help to build an inclusive collaborating Europe / world



Thank you for your collaboration

www.epsoweb.org epso@epsomail.org





Handout

Genome editing Improving legislation and start flagships to better address climate, environmental, food and health challenges

2nd Informal meeting in Brussels 24.1.2020 11 am – 4 pm European Liaison Office of the German Research Organisations (KoWi) Rue du Trône 98, 1050 Brussels, Belgium, www.kowi.de

Brussels, 24.1.2020

The European Plant Science Organisation (EPSO) invites policy makers to join EPSO members in an 2nd informal meeting exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide.

Draft agenda: 11 - 4pm on 24.1.2020, Lunch will be provided

11:00 - 11:30 Registration

11:30 Welcome and tour de table

12:00 Legislation – how could it be improved? [chaired by

Introduction of the already available substantial suggestions to update or replace current EU-legislation on GMO:

Detailed introductions (5'-10' e	each) to ideas from t	he Citizen Initiative (Eur)	VIB (BE)
, Leopoldina	, Norway	updates from Spain	
, Sweden	and E	stonia	
Comparative summary	1		

Comparative summar

12:50 Discussion

- Perspectives (small modifications or fundamental changes ...)
- Consideration of the upcoming study by the European Commission
- · How to support policy makers

13:30 Lunch

14:00 Flagships towards GE products with consumer benefits on the market in Europe

- Summary from the 1st informal meeting
- · Consideration of consumers' attitudes: Nuanced attitudes to gene editing in Norway
- Discussion on the way forward
 - Priority criteria* / screening
 - o Consider stakeholder concerns
 - Next steps

15:30 Conclusions, next steps

16:00 Closing

*Flagships priority criteria

- status: ongoing or de novo?
- feasibility: target identified or not?
- novelty: novel or copy of existing mutation (same species or other species)?
- type of benefit: crop culture (less intrants, resilience, adaptation, diversification, productivity) or quality of the product (health benefit, technical improvement for processing industry)?
- beneficiary: farmer, consumer and/or citizen?
- impact: region or country or climatic zone or all of EC?
- impact: field crop or niche market?
- Impact: stakleholder/consumer concerns

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country) and policy makers (1-3 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe. The meeting shall build on the 1st one. We will continue to broaden the discussion and invite more representatives from countries interested in the issue.

EPSO offers to collaborate with policy makers to develop an appropriate future-ready regulation to enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the environmental impact of agriculture. Notwithstanding the technical option retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.



- List of participants only for meeting participants (Chatham House Rules)
- News relevant to his meeting since the 1st informal meeting on 19.9.2019
- Report from the 1st informal EPSO science and policy meeting on 19.9.2019, 30.9.2019
- Document with information on novel genomic techniques in Spain, AJ Martin dIF, 21.1.2020 & From the Spanish report online the EN introduction (p 3-4) and summary (p 8-10) (<u>https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/informeciomgsentenciamutagenesisdiri</u> gida11 02 2019 tcm30-496814 tcm30-512235.pdf), Q1 2019



About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 31 countries, mainly from Europe, and 2.600 individuals Personal Members, representing over 26 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science including science advice to policy, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science. https://epsoweb.org/



Apologised countries:

Denmark

, Ministry of Environment and Food - apologies , University of Copenhagen - apologies

Italy

t.b.a., Ministry for Environment , CNR - apologies

Lithuania

, Vice-minister of Education, Science and Sport - apologies , LT Research Centre for Agriculture and Forestry (LAMMC) – apologies

Portugal

, Forestry and Rural Development - apologies , ITQB - apologies

, ALLEA - apologies