

**Van:** [redacted]  
**Verzonden:** woensdag 14 augustus 2019 11:20  
**Aan:** [redacted]  
**CC:** [redacted]  
**Onderwerp:** TKN FW: <geen onderwerp>  
**Bijlagen:** Position paper on the ECJ ruling on CRISPR.pdf; 19\_07\_01\_EPSO\_Genome editing - informal meeting\_Invitation\_updated.pdf

TKN

Reactie maar even afwachten... In 2e bijlage de tekst van de uitnodiging voor de informele bijeenkomst op 19 sept.

Groeten, [redacted]

-----Oorspronkelijk bericht-----

**Van:** [redacted] drs. [redacted]  
**Verzonden:** woensdag 14 augustus 2019 11:18  
**Aan:** [redacted] <[redacted]@wur.nl>; [redacted]@minInv.nl>  
**Onderwerp:** RE: <geen onderwerp>

Dag [redacted]

Ik ben vanwege familie-omstandigheden even uit de running geweest, vandaar dat ik eerder niet meer heb gereageerd. Helaas is 19 sept net de datum dat ik, maar ook onze nieuwe collega, niet kunnen. Ook de PV heeft die dag al andere verplichtingen. Ik zal de uitnodiging nog doorsturen naar I&W.

Ik zie dat de kennismaking met [redacted] pas begin oktober is gepland. Het lijkt me goed om snel een keer koffie te drinken en bij te praten over de ontwikkelingen, liefst voor de bijeenkomst in Brussel. Ik zou zelf deze week kunnen, vanaf volgende week ben ik met vakantie. [redacted], zou er toevallig deze week nog een moment zijn in jouw agenda?

Met vriendelijke groet,

-----Oorspronkelijk bericht-----

**Van:** [redacted] <[redacted]@wur.nl>  
**Verzonden:** maandag 12 augustus 2019 14:06  
**Aan:** [redacted]@minInv.nl>; [redacted]  
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**Onderwerp:** <geen onderwerp>

Beste [redacted] en [redacted]

[redacted] en ik hebben eind juni contact over een bijeenkomst die EPSO organiseert in Brussel (19 september) waarin er met meerdere ministeries gesproken gaat worden over mogelijkheden die er op dit moment liggen rond de crispr cas technologie in Europa (zie ook de bijgaande uitnodiging). [redacted] gaf aan dat er belangstelling vanuit jullie was om bij deze bijeenkomst aanwezig te zijn.

De discussie is eigenlijk nu nog relevanter geworden door het verschijnen van het IPCC klimaatrapport afgelopen week. Het is belangrijk om te bezien hoe deze nieuwe technologie een rol kan spelen in het bieden van oplossingen in de voedsel problematiek.

Er hebben inmiddels 8 landen toegezegd aanwezig te zullen zijn (BE, EE, FR, DE, NO, SE en NL). Graag zou ik van jullie willen weten wie vanuit LNV aansluit en of er wellicht ook mensen zijn die vanuit I&M willen aansluiten?

Separaat lopen er veel initiatieven vanuit de wetenschap. Vanuit het VIB in Gent is er getrokken aan een position paper wat inmiddels al door 127 kennisinstellingen binnen Europa is ondertekend. Ik weet niet of jullie dit position paper kennen, heb het voor de zekerheid maar bijgesloten,

Groet,

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## **Regulating genome edited organisms as GMOs has negative consequences for agriculture, society and economy**

On July 25<sup>th</sup>, the Court of Justice of the European Union (ECJ) ruled that organisms obtained by modern forms of mutagenesis such as CRISPR are not exempt from the EU GMO legislation. Consequently, genome edited organisms must comply with the strict conditions of the EU GMO legislation. This is in stark contrast with the opinion of the Advocate-General of the Court, which was published in January of this year and advised ruling otherwise. We regret the purely process-based interpretation of the legislation by the Court and conclude that the EU GMO legislation does not correctly reflect the current state of scientific knowledge. Organisms that have undergone simple and targeted genome edits by means of precision breeding and which do not contain foreign genes are at least as safe as if they were derived from classical breeding techniques. Therefore, we call upon all European authorities to quickly respond to this ruling and alter the legislation such that organisms containing such edits are not subject to the provisions of the GMO Directive but instead fall under the regulatory regime that applies to classically bred varieties. In the longer term, the GMO Directive should be thoroughly revised to correctly reflect scientific progress in biotechnology.

There are many reasons why agriculture in Europe and around the globe must become more sustainable. Agricultural practices put pressure on our environment, we are faced with a growing population (mounting to an estimated 10 billion mouths to feed by 2050), and climate change poses increasing challenges for crops – climate measurements from the summer of 2018 underline the urgency of this message.

Time is a luxury we don't have. Reducing the environmental footprint of agriculture and adapting farming to a changing climate are imperative. For example, crops that are more tolerant to rapidly changing and harsher environments will be crucial for the success of tomorrow's food production approaches. To address challenges like this and meet food production goals efficiently, we will need to use all knowledge and technical means available and thus also new technologies, specifically biotechnology. One of the latest breakthroughs in this field is precision breeding, an innovative crop breeding method based on genome editing. Crops developed with precision breeding could help the farmer to minimize inputs such as fertilizers and pesticides. Precision breeding can also contribute to tailoring crops to a specific area, taking into account the environmental factors of a certain region. E.g. having plants that are drought resistant could mean higher crop yields without increasing arable land.

## Taking traditional breeding to the next level

The search to introduce additional genetic variation in crops is anything but new. Plant breeding started around 8,000 BC, when farmers selected seeds from crops with the best characteristics obtained through spontaneous genetic mutations and crossbred them to produce new crop varieties with desirable properties. In more recent times, chemicals and radiation are applied to incite these mutations. This type of conventional mutagenesis is exempt from the provisions of the GMO legislation because of its long safety record. Nevertheless, this method incites hundreds or even thousands of random mutations with unknown effects and consequences. Mutations leading to non-intended changes then must be removed during the further breeding process, which is very time consuming and not always successful.

New genome editing technologies follow the same principle, but with higher efficiency and precision, as they apply only one or a few targeted mutations – the type of changes that can also occur naturally or through traditional mutagenic approaches. Recent breakthroughs in plant research allow breeders to know exactly where the change will occur and to better predict the effects of the changes. That is why these techniques are called **precision breeding**. In addition, no DNA from non-related species is present in the final crop, in contrast to GMOs.

## What the ECJ ruling means

It is generally concluded that the ECJ ruling means that the crops obtained through this type of precision breeding must comply with the strict GMO directive. In practice, the implications are far-reaching. European agricultural innovation based on precision breeding will come to a halt because of the high threshold that this EU GMO legislation presents. This will hinder progress in sustainable agriculture and will give a competitive disadvantage to plant breeding industries in Europe. The impacts on our society and economy will be enormous.

From a scientific point of view, the ruling makes no sense. Crops containing small genome edits are at least as safe as crops obtained through classical mutagenesis or conventional breeding. But more importantly, we find the ruling irresponsible in the face of the world's current far-reaching agricultural challenges.

The ruling proves that current EU GMO legislation is outdated and not in line with recent scientific evidence. As a result, it is crucial that the legislation be adapted such that organisms containing small edits are not subject to the provisions of the GMO legislation, but instead fall under the regime that applies to conventionally bred varieties. Additionally, a more



thorough revision of the legislation is necessary for GMOs and new breeding techniques to correctly reflect scientific progress in biotechnology.

### **Agricultural innovation will miss an important opportunity**

Let's make these consequences a bit more tangible. The strict legislation will make precision breeding hyper-expensive and, by consequence, a privilege of just a few large multinational companies. As such, European farmers will miss out on a new generation of hardier and more nutritious crop varieties that are urgently needed to respond to the results of climate change.

For example, diseases and pests from southern areas are rapidly spreading due to increasing temperatures. Switching off certain genes could make crops resistant to these diseases without the use of new pesticides. This applies particularly to crops that reproduce asexually, like potatoes, bananas and strawberries. These crops are more susceptible to diseases because offspring are genetically identical to their parent plants, leading to a lack of diversity. The same principle applies to drought: a significant problem many regions in the world are facing right now. On top of that, precision breeding is also ideal to improve food quality and safety, such as the breeding of new crop varieties with fewer allergens.

### **Societal and economic impacts**

Europe is in a leading position in terms of innovative agricultural research. This has led to the formation of dynamic biotech clusters consisting of numerous innovative start-ups and corporate partnerships. Many of these (small) European seed-breeding companies embrace the new technologies, as they can be implemented relatively cheaply and quickly, and because they can democratize the research and development of new agricultural products.

However, the ruling of the ECJ forces companies to go through a very long and expensive regulatory process. For entrepreneurs engaged in start-up projects involving precision breeding and their potential investors, this creates a low probability of market admission for products developed through precision breeding. Due to this significant uncertainty and additional risk, smaller biotech companies will seek refuge elsewhere. SMEs and investors might consider it too great a risk to develop activities in this hostile environment, ultimately leading to job losses in the sector. Additionally, we risk a brain drain effect when plant researchers leave Europe for better job opportunities abroad.

This also means that in Europe, developing genome-edited crops is only financially feasible for large (multinational) companies and for application in large, broad-acre crops such as maize and soy. In other words, Europe is pushing technology back into the hands of the big




market players. This is in huge contrast with countries that have adopted more flexible regulations. In such countries, universities, government institutions and small companies are poised to lead the precision-breeding revolution in agriculture. For example, US regulators have taken the view that genome-edited crops are not a problem as long as they do not contain any foreign genes and are therefore not genetically different from crops developed through traditional breeding processes. As a result, genome-edited crops will soon appear on the American market. Meanwhile, relative lower production costs in non-European areas will lead to more food and feed imports in the EU.

## Summary








Subjecting crops obtained through modern genome editing to GMO regulations will deny European consumers, producers, researchers and entrepreneurs important opportunities in sustainable agriculture. Therefore, an urgent review and amendment of the European legislation on new breeding technologies is needed. In the short term, the legislation should be altered such that crops with small DNA adaptations obtained through genome editing are **not subject to the provisions of the GMO Directive but instead fall under the regulatory regime that applies to classically bred varieties**. In the long term, new regulations for GMOs should be developed that are adapted to modern breeding techniques. This new directive should provide more legal certainty and evaluate new crop varieties on a scientific basis.



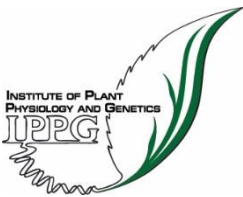
We therefore urge European policy makers to act to safeguard Europe's competitiveness on all levels.

Signatures:





From Austria:	
10.2e Scientific Director GMI	
10.2e Rector at BOKU 10.2e Vice-Rector for Research and Innovation	
10.2e Managing Directors of the AIT Austrian Institute of Technology	



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From Belgium:	
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From Bulgaria:	
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From Cyprus	
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From Czech republic:	
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10.2e [redacted] Director John Innes Centre	
[redacted] Professor at University of Cambridge	
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10.2e [redacted] Director, Institute for Infection and Immunity, St. George's Hospital Medical School	 
10.2e [redacted] Executive Director of the Sainsbury Laboratory (Norwich) 10.2e [redacted] Group Leader at the Sainsbury Laboratory (Norwich)	 
10.2e [redacted] EFB Vice-President on behalf of the European Federation of Biotechnology Executive Board	 
10.2e [redacted] Director of the Babraham Institute	

From Europe	
10.2e [redacted] EU-Life Director  EU-Life: <ul style="list-style-type: none"> <li>- Austria: Research Center for Molecular Medicine of the Austrian Academy of Sciences (Ce-M-M)</li> <li>- Belgium: Flanders Institute for Biotechnology (VIB)</li> </ul>	

<ul style="list-style-type: none"> <li>- Czech Republic: Central European Institute of Technology (CEITEC)</li> <li>- Denmark: Biotech Research and Innovation Centre (BRIC)</li> <li>- Finland: Institute for Molecular Medicine Finland (FIMM)</li> <li>- France: Institute Curie</li> <li>- Germany: Max Delbrück Center for Molecular Medicine in the Hemholtz Association</li> <li>- Italy: European Institute of Oncology (IEO)</li> <li>- Portugal: Gulbankian Institute for Science (IGC)</li> <li>- Spain: Centre for Genomic Regulation (CRG)</li> <li>- Switzerland: Friedrich Miescher Institute for Biomedical Research (FMI)</li> <li>- The Netherlands: The Netherlands Cancer Institute</li> <li>- UK: Babraham Institute</li> </ul>	
<p><i>FESPB is an umbrella organization for the European Societies of Plant Biology that encompasses 5000 plant scientists.</i></p> <p>10.2e [REDACTED], President of the Federation of European Societies of Plant Biology (FESPB)</p> <p>10.2e [REDACTED] Secretary General of the Federation of European Societies of Plant Biology (FESPB)</p>	



European Plant Science Organisation  
<https://epsoweb.org>

**Invitation**

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

Informal meeting in Brussels 19.9.2019,  
 12am – 2 pm, KoWi meeting room, European quarter

*Brussels, 1.7.2019*

**The European Plant Science Organisation (EPSO) invites 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 better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide.**

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country) and policy makers (1-2 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe.

The meeting shall be a starting point: In the coming months, we intend to broaden the discussion and invite more representatives from countries interested in the issue. We are planning such a second informal meeting towards the end of the year.

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.

Draft agenda: 12 – 2pm on 19.9.2019, Lunch will be provided

- **Welcome** – 10.2e and 10.2e
- **Legislation – how could it be improved?**
  - EPSO statement and ideas - 10.2e
  - First feedback from the CRISPRCon conference 20-21.6.2019 - [REDACTED]
  - Discussion
- **Flagships towards GE products with consumer benefits** on the market in Europe
  - EPSO first ideas – 10.2e
  - Discussion
- **Conclusions, next steps** – 10.2e and 10.2e

Please kindly **confirm your participation best by 12 July** to [REDACTED] [@epsomail.org](mailto:[REDACTED]@epsomail.org) (incl. ministry affiliation, name and email address), quoting your country (BE, EE, FI, IT, NL, NO, PT, ES, SE, DE), EPSO member research organisation or ministry affiliation, name and email address.

[REDACTED]

[REDACTED], EPSO Board; [REDACTED], EPSO Chair WG Agricultural Technologies; [REDACTED], EPSO Executive Director

**Venue:** European Liaison Office of the German Research Organisations (KoWi)  
Rue du Trône 98; 1050 Brussels; Belgium; [www.kowi.de](http://www.kowi.de)

---

**Contacts:**

+31-

@wur.nl

+49-3

@julius-kuehn.de

+32-

@epsomail.org

**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

**Van:** [redacted] <[redacted]@epsomail.org>  
**Verzonden:** donderdag 5 september 2019 08:34  
**Aan:** [redacted]  
**CC:** [redacted]@wur.nl)  
**Onderwerp:** RE: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants  
**Bijlagen:** 19\_08\_30\_EPSO\_Genome editing - informal meeting\_Participants.docx

Dear [redacted]

Thank you and please find attached the update participant list.

With best wishes  
 [redacted]

\*\*\*\*\*  
 Dr. [redacted]  
 Executive Director  
 European Plant Science Organisation, EPSO Rue de l'Industrie 4, 1000 Brussels, Belgium  
 10.2e [redacted]@epsomail.org ; T/F: +32-210.2e [redacted] www.epsoweb.org ; EU Transparency Register Number  
 38511867304-09  
 \*\*\*\*\*  
 \*

-----Original Message-----

**From:** [redacted] <[redacted]@minInv.nl>  
**Sent:** 04 September 2019 15:22  
**To:** [redacted]@epsomail.org  
**Subject:** RE: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants

Dear [redacted]

Just to quickly follow up - I can confirm that I will be present at the meeting on the 19th. Is there perhaps an updated participants list? Many thanks.

Kind regards,

[redacted]  
 Senior beleidsmedewerker biotechnologie

.....  
 Directie Plantaardige Agroketens en Voedselkwaliteit Ministerie van Landbouw, Natuur en Voedselkwaliteit  
 Bezuidenhoutseweg 73 | 2594 AC | Den Haag Postbus 20401 | 2500 EK | Den Haag  
 ..... T 06 10.2e [redacted] 070-10.2e [redacted] r [redacted]@minInv.nl  
 www.rijksoverheid.nl/Inv ..... Aanwezig ma t/m vrijdag

-----Oorspronkelijk bericht-----

**Van:** [redacted]@wur.nl>  
**Verzonden:** woensdag 28 augustus 2019 12:43  
**Aan:** [redacted]@minInv.nl>  
**CC:** [redacted]@epsomail.org>  
**Onderwerp:** FW: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants  
**Urgentie:** Hoog

Hi [redacted]

As promised you this morning I sent you some background information about the meeting in Brussels on the 19th. Great that you will join us and want to share your ideas! If you have any questions please contact [redacted] (EPSO executive director),

Cheers,

Dr. [redacted] e  
Managing Director Plant Sciences Group  
Wageningen University & Research

P.O. Box 16<x-apple-data-detectors://0/>  
6700 AA Wageningen<x-apple-data-detectors://0/>  
The Netherlands<x-apple-data-detectors://0/>

Visiting address:  
Droevendaalsesteeg 1<x-apple-data-detectors://1/>  
6708 PB Wageningen<x-apple-data-detectors://1/>  
The Netherlands<x-apple-data-detectors://1/>

T: +31 [redacted] tel:+10.2e [redacted] 46>  
M: +31 [redacted] <tel:+310.2e [redacted]>  
Email: e [redacted] @wur.nl<mailto:[redacted]@wur.nl>

www.disclaimer-uk.wur.nl<http://www.disclaimer-uk.wur.nl/>  
P Please consider the environment before printing this e-mail

-

Van: [redacted]@epsomail.org>  
Datum: woensdag 28 augustus 2019 11:28  
Aan: [redacted]@agriculture.gouv.fr>, [redacted]@kld.dep.no>,  
[redacted]@regeringskansliet.se>,  
[redacted]@bmbf.bund.de>,  
[redacted]@bmbf.bund.de>,  
[redacted]@formin.fi>,  
[redacted]@bmel.bund.de>,  
[redacted]@environment.belgium.be>  
CC: [redacted]@epsomail.org>, [redacted]@wur.nl>,  
[redacted]@julius-kuehn.de>,  
[redacted]@vib.be>,  
[redacted]@ttu.ee>,"<[redacted]@ttu.ee>,"  
[redacted]@helsinki.fi>,"<[redacted]@helsinki.fi>,"<[redacted]@ens-lyon.fr)>  
[redacted]@ens-lyon.fr>,"<[redacted]@ibba.cnr.it)>,"<[redacted]@ibba.cnr.it>,"  
[redacted]@bioteknologiradet.no>,"<[redacted]@graminor.no">  
[redacted]@graminor.no>,"<[redacted]@cnb.csic.es">,"<[redacted]@cnb.csic.es>,"<[redacted]@slu.se)>  
[redacted]@upm.es)>,"<[redacted]@upm.es>,"<[redacted]@genteknik.se>,"<[redacted]@genteknik.se>,"<[redacted]@embo.org)>  
[redacted]@embo.org)>

Onderwerp: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 - confirmed participants

Dear colleagues from national ministries,

The European Plant Science Organisation (EPSO) has the pleasure to welcome you as policy makers to join EPSO members for an 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.

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country, in cc) and policy makers (1-3 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe.

Please find attached the invitation and the list of participants – as you can see, we already have confirmation from ministry colleagues from eight countries. More are welcome and should pls confirm their participation best by 6 September to [redacted]@epsomail.org<mailto:[redacted]@epsomail.org> , quoting their country (BE, EE, FI, IT, NL, NO, PT, ES, SE, DE), ministry affiliation, name and email address.

We will send you a Handout before the event.

Should you have any dietary requirements, pls let [redacted] (in cc) know.

We very much look forward to a constructive discussion 10.2e [redacted]

[REDACTED], EPSO Board; 10.2e [REDACTED], EPSO Chair WG Agricultural Technologies; [REDACTED], EPSO Executive Director

\*\*\*\*\*102\*\*\*\*\*

Dr. [REDACTED]  
Executive Director  
European Plant Science Organisation, EPSO Rue de l'Industrie 4, 1000 Brussels, Belgium  
10.2e [REDACTED] "epsomail.org ; T/F: +32-10.2e [REDACTED] www.epsoweb.org<http://www.epsoweb.org> ; EU  
Transparency Register Number 38511867304-09

\*\*\*\*\*  
\*

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**EPSO informal science – policy meeting on genome editing in Brussels, 19.9.2019**

**List of participants - confirmed in bold – by 30.8.2019**

**Belgium**

[redacted], **Federal Ministry of Environment**  
[redacted], **VIB**

**Estonia**

t.b.a., **Ministry of Environment**  
[redacted], **Tallinn University**

**Finland**

[redacted], **Foreign Ministry**  
[redacted], **LUKE & EPSO President**

**France**

[redacted], **Ministry for Agriculture and Food**  
[redacted], **INRA**

**Germany**

**Dr** [redacted], **Ministry for Education and Research, 726 Bioeconomy**  
[redacted], **Ministry for Education and Research, 611 Ethics & Law in Life Sciences**  
**Dr.** [redacted], **Bundesministerium für Ernährung und Landwirtschaft, 222 – New Technologies**  
**10.2e** [redacted], **JKI**

**Italy**

t.b.a., **Ministry for Agriculture**  
[redacted], **University of Udine**  
[redacted], **CNR**

**The Netherlands**

[redacted], **Ministry for Agriculture**  
[redacted], **WUR**

**Norway**

[redacted], **Ministry of Climate and Environment**  
[redacted], **NO Biotech Advisory Board**  
[redacted], **Graminor and NMBU**

**Portugal**

t.b.a.

**Spain**

t.b.a., **Ministry for Research and Innovation**  
t.b.a., **Ministry for Agriculture**  
[redacted], **CBGP (UPM-INIA); AEI Gen technology Scientific advisor**  
[redacted], **CSIC**

**Sweden**

[redacted], **Min. of Enterprise and Innovation**  
[redacted], **Gene Technology Advisory Board**  
[redacted], **SLU**

**Europe**

[redacted], **EPSO**  
[redacted], **EMBO**

10.2e

**Van:** 10.2e @epsomail.org>  
**Verzonden:** vrijdag 13 september 2019 16:19  
**Aan:** 10.2e @mapa.es; 10.2e  
  
**cc:** 10.2e @nmbu.no; 10.2e  
 @helsinki.fi; 10.2e @ibba.cnr.it; 10.2e  
 @cnb.csic.es; 10.2e @upm.es; 10.2e  
 @taltech.ee; 10.2e @taltech.ee; 10.2e  
 @wur.nl; 10.2e @itqb.unl.pt;  
 10.2e @genteknik.se; 10.2e @embo.org;  
 10.2e @graminor.no; 10.2e @ens-lyon.fr;  
 10.2e @vib.be; 10.2e @bioteknologiradet.no;  
 SUNDSTRÄTM 10.2e @slu.se; 10.2e @julius-kuehn.de)  
**Onderwerp:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Handout  
**Bijlagen:** 19\_09\_13\_EPSO\_Genome editing - informal meeting\_Handout.pdf  
  
**Urgentie:** Hoog

Dear colleagues from national ministries,

Please find attached the Handout for our meeting including the updated participant list.

We very much look forward to a constructive discussion

10.2e

\*\*\*\*\*

Dr. 10.2e

Executive Director

European Plant Science Organisation, EPSO

Rue de l'Industrie 4, 1000 Brussels, Belgium

10.2e "epsomail.org ; T/F: +32-10.2e

[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09

\*\*\*\*\*

**From:** 10.2e **Sent:** 05.9.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – Updated agenda

Dear colleagues from national ministries,

Please find hereafter the updated agenda of the meeting and attached FYI the invitation and the updated list of participants.

We will send you a Handout before the event.

We very much look forward to a constructive discussion

10.2e

Updated agenda for 19.9.2019

11:30 – 12:00 Registration and lunch

12:00 – 14:00 Meeting

- 12:00 **Welcome and tour de table** – 10.2e
- 12:05 **Legislation – how could it be improved?**
  - Current regulation, EPSO statement and ideas - 10.2e
  - First short feedback from (multi-)national movements (CRISPRCon, VIB, citizens' initiative etc.)<sup>10</sup> - 10.2e and all participants
  - Discussion on the way forward – moderated by 10.2e and 10.2e
- 13:30 **Flagships towards GE products with consumer benefits** on the market in<sup>10</sup> Europe
  - EPSO first ideas – 10.2e
  - Discussion – moderated by 10.2e
- 13:50 **Conclusions, next steps** – 10.2e and 10.2e

14:00 – 14:30 Networking, continue discussions

---

**From:** 10.2e **Sent:** 28.8.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants

Dear colleagues from national ministries,

The European Plant Science Organisation (EPSO) has the pleasure to welcome you as policy makers to join EPSO members for an 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.

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Please find **attached the invitation and the list of participants** – as you can see, we already have confirmation from ministry colleagues from eight countries. More are welcome and should pls confirm their participation best by 6 September to 10.2e [@epsomail.org](mailto:10.2e@epsomail.org), quoting their country (BE, EE, FI, IT, NL, NO, PT, ES, SE, DE), ministry affiliation, name and email address.

We will send you a Handout before the event.

Should you have any dietary requirements, pls let Sofia (in cc) know.

We very much look forward to a constructive discussion

10.2e and 10.2e

10.2e, EPSO Board; 10.2e, EPSO Chair WG Agricultural Technologies; 10.2e, EPSO Executive Director

\*\*\*\*\*

Dr. 10.2e

Executive Director

European Plant Science Organisation, EPSO

Rue de l'Industrie 4, 1000 Brussels, Belgium

10.2e "epsomail.org ; T/F: +32-10.2e

[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09

\*\*\*\*\*

**Van:** [redacted]@epsomail.org>  
**Verzonden:** maandag 23 september 2019 10:41  
**Aan:** [redacted]  
**CC:** [redacted]  
**Onderwerp:** RE: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Handout

Dear [redacted]

Thank you for your active participation!  
 I will send the report and the presentations to all participants end this week.

With best wishes

\*\*\*\*\*  
 Dr. [redacted]  
 Executive Director  
 European Plant Science Organisation, EPSO  
 Rue de l'Industrie 4, 1000 Brussels, Belgium  
 [redacted]@epsomail.org ; T/F: +32-[redacted]  
[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09  
 \*\*\*\*\*

---

**From:** [redacted]  
**Sent:** 23 September 2019 10:27  
**To:** [redacted]  
**Cc:** [redacted]  
**Subject:** RE: EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Handout

Dear [redacted]

Many thanks for the interesting discussion last week. Would it perhaps be possible to receive a digital copy of the powerpoint presentations for personal use?

Kind regards,

[redacted]  
*Senior beleidsmedewerker biotechnologie*

.....  
**Directie Plantaardige Agroketens en Voedselkwaliteit**  
**Ministerie van Landbouw, Natuur en Voedselkwaliteit**  
 Bezuidenhoutseweg 73 | 2594 AC | Den Haag  
 Postbus 20401 | 2500 EK | Den Haag

.....  
 T 06 [redacted] | 070 [redacted]  
 E [redacted]@minlnv.nl  
[www.rijksoverheid.nl/lnv](http://www.rijksoverheid.nl/lnv)  
 .....

*Aanwezig ma t/m vrijdag*

**Van:** [redacted]@epsomail.org>

**Verzonden:** vrijdag 13 september 2019 16:19

**Aan:** [redacted]@mapa.es) <[redacted]@mapa.es>; [redacted]@kld.dep.no>; [redacted]@regeringskansliet.se>; [redacted]@bmbf.bund.de>; [redacted]@bmbf.bund.de>; [redacted]@formin.fi>; [redacted]@bmel.bund.de>; [redacted]@minInv.nl>; [redacted]k@environment.belgium.be>

**CC:** [redacted]@nmbu.no) [redacted]@nmbu.no>; [redacted]@epsomail.org>; [redacted]@helsinki.fi) <[redacted]@helsinki.fi>; [redacted]@ibba.cnr.it) [redacted]@ibba.cnr.it>; [redacted]@cnb.csic.es) [redacted]@cnb.csic.es>; [redacted]@upm.es) [redacted]@upm.es>; [redacted]@taltech.ee) [redacted]@taltech.ee>; [redacted]@taltech.ee>; [redacted]@wur.nl) [redacted]@wur.nl>; [redacted]@itqb.unl.pt) [redacted]@itqb.unl.pt>; [redacted]@genteknik.se) [redacted]@genteknik.se>; [redacted]l@embo.org) <[redacted]l@embo.org>; [redacted]@graminor.no) [redacted]@graminor.no>; [redacted]@ens-lyon.fr) [redacted]@ens-lyon.fr>; [redacted]@vib.be) [redacted]@vib.be>; [redacted]@bioteknologiradet.no) [redacted]@bioteknologiradet.no>; [redacted]@slu.se) <[redacted]@slu.se>; [redacted]@julius-kuehn.de) <[redacted]@julius-kuehn.de>

**Onderwerp:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Handout

**Urgentie:** Hoog

Dear colleagues from national ministries,

Please find attached the Handout for our meeting including the updated participant list.

We very much look forward to a constructive discussion

[redacted] and [redacted]

\*\*\*\*\*  
Dr. [redacted]  
Executive Director  
European Plant Science Organisation, EPSO  
Rue de l'Industrie 4, 1000 Brussels, Belgium  
10.2e [redacted]@epsomail.org ; T/F: +3210.2e [redacted]  
[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09  
\*\*\*\*\*

---

**From:** [redacted] **Sent:** 05.9.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – Updated agenda

Dear colleagues from national ministries,

Please find hereafter the updated agenda of the meeting and attached FYI **the invitation and the updated list of participants.**

We will send you a Handout before the event.

We very much look forward to a constructive discussion

[redacted] and [redacted]

## Updated agenda for 19.9.2019

11:30 – 12:00 Registration and lunch

12:00 – 14:00 Meeting

- 12:00 **Welcome and tour de table** – 10.2e
- 12:05 **Legislation – how could it be improved?**
  - Current regulation, EPSO statement and ideas - 10.2e
  - First short feedback from (multi-)national movements (CRISPRCon, VIB, citizens' initiative etc.) - 10.2e
  - and all participants
  - Discussion on the way forward – moderated by 10.2e
- 13:30 **Flagships towards GE products with consumer benefits** on the market in Europe
  - EPSO first ideas – 10.2e
  - Discussion – moderated by 10.2e
- 13:50 **Conclusions, next steps** – 10.2e

14:00 – 14:30 Networking, continue discussions

---

**From:** [redacted] **Sent:** 28.8.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants

Dear colleagues from national ministries,

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Please find **attached the invitation and the list of participants** – as you can see, we already have confirmation from ministry colleagues from eight countries. More are welcome and should pls confirm their participation best by 6 September to [redacted] [@epsomail.org](mailto:[redacted]@epsomail.org), quoting their country (BE, EE, FI, IT, NL, NO, PT, ES, SE, DE), ministry affiliation, name and email address.

We will send you a Handout before the event.

Should you have any dietary requirements, pls let Sofia (in cc) know.

We very much look forward to a constructive discussion

[redacted] and [redacted]

[redacted], EPSO Board; [redacted], EPSO Chair WG Agricultural Technologies; [redacted], EPSO Executive Director

\*\*\*\*\*

Dr. [redacted]  
Executive Director  
European Plant Science Organisation, EPSO  
Rue de l'Industrie 4, 1000 Brussels, Belgium

\*\*\*\*\*

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen.

De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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**Van:** [redacted]@epsomail.org>  
**Verzonden:** maandag 30 september 2019 17:21  
**Aan:** [redacted]@mapa.es;  
**CC:** [redacted]@envir.ee;  
 [redacted]@nmbu.no;  
 [redacted]@helsinki.fi);  
 [redacted]@ibba.cnr.it);  
 [redacted]@cnb.csic.es);  
 [redacted]@upm.es);  
 [redacted]@taltech.ee);  
 [redacted]@taltech.ee);  
 [redacted]@wur.nl);  
 [redacted]@genteknik.se);  
 [redacted]@graminor.no);  
 [redacted]@vib.be);  
 [redacted]@bioteknologiradet.no);  
 [redacted]@slu.se);  
 [redacted]@julius-kuehn.de)  
 [redacted]@itqb.unl.pt);  
 [redacted]@embo.org);  
 [redacted]@ens-lyon.fr);  
**Onderwerp:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Report - reply pls by 11 Oct 2019  
**Bijlagen:** 19\_09\_30\_EPSO\_Genome editing - informal meeting\_Report.pdf; 19\_09\_23\_EPSO\_Genome editing\_all slides\_send.pdf; 19\_09\_18\_EPSO\_Genome editing - informal meeting\_Handout\_updated.doc  
**Urgentie:** Hoog

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 availability 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 [redacted]
  - Mo 20.1.2020: yes, possible, not
  - Tu 21.1.2020: yes, possible, not
  - 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 mailing list** 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 additional ministry colleagues 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 flagship projects 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

10.2e

\*\*\*\*\*

Dr. [REDACTED]  
Executive Director  
European Plant Science Organisation, EPSO  
Rue de l'Industrie 4, 1000 Brussels, Belgium  
[REDACTED] "epsomail.org ; T/F: +32-[REDACTED]  
[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09

\*\*\*\*\*

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**From:** [REDACTED] **Sent:** 13.9.2019 **To:** Participants  
**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Handout

Dear colleagues from national ministries,  
Please find attached the Handout for our meeting including the updated participant list.  
We very much look forward to a constructive discussion  
[REDACTED] and [REDACTED]

---

**From:** [REDACTED] **Sent:** 05.9.2019 **To:** Participants  
**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – Updated agenda

Dear colleagues from national ministries,  
Please find hereafter the updated agenda of the meeting and attached FYI the invitation and the updated list of participants.  
We will send you a Handout before the event.  
We very much look forward to a constructive discussion  
[REDACTED] and [REDACTED]

---

**From:** [REDACTED] **Sent:** 28.8.2019 **To:** Participants  
**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants

Dear colleagues from national ministries,

The European Plant Science Organisation (EPSO) has the pleasure to welcome you as policy makers to join EPSO members for an 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.

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country, in cc) and policy makers (1-3 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe.

Please find attached the invitation and the list of participants – as you can see, we already have confirmation from ministry colleagues from eight countries. More are welcome and should pls confirm their participation best by 6 September to [redacted]@epsomail.org, quoting their country (BE, EE, FI, IT, NL, NO, PT, ES, SE, DE), ministry affiliation, name and email address.

We will send you a Handout before the event.

Should you have any dietary requirements, pls let Sofia (in cc) know.

We very much look forward to a constructive discussion

[redacted] and [redacted]

[redacted], EPSO Board; [redacted], EPSO Chair WG Agricultural Technologies; [redacted], EPSO Executive Director

\*\*\*\*\*

Dr. [redacted]  
Executive Director

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

[redacted]@epsomail.org ; T/F: +32-2 [redacted]

[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09

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European Plant Science Organisation  
<https://epsoweb.org>

**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 availability 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 mailing list 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 additional ministry colleagues 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 flagship projects 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.

and



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**Contacts:**

+31

[wur.nl](mailto:wur.nl)

[julius-kuehn.de](mailto:julius-kuehn.de)

[@epsomail.org](mailto:epsomail.org)

**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 Supporting literature - links**

- EPSO statement (endorsed by all EPSO Representatives for 197 institutes / universities), 19.2.2019: <https://epsoweb.org/download/epsoweb-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: <https://epsoweb.org/epsoweb-welcomes-commissioner-andriukaitis-statement-and-call-for-action-new-plant-breeding-techniques-need-new-regulatory-framework/2019/03/29/>
- 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%20editing%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: [https://www.upsc.se/documents/News/News\\_2019/2019-07-25\\_Open-letter-concerning-GMO-regulations.pdf](https://www.upsc.se/documents/News/News_2019/2019-07-25_Open-letter-concerning-GMO-regulations.pdf)
- 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](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: <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>
- 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: <https://cdn.website-editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/AFBV-WGG-Statement.pdf>



5b

EPSO:

## **Genome editing**

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

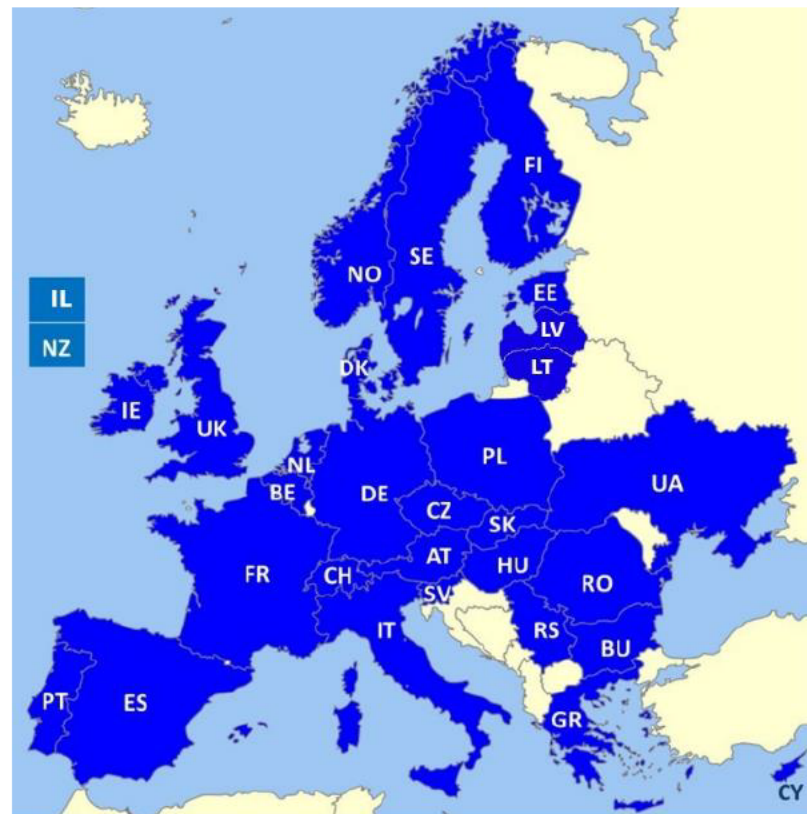
Informal science policy meeting  
European Plant Science Organisation [www.epsoweb.org](http://www.epsoweb.org)  
Brussels, 19.9.2019

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

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**
- 2) Curiosity driven plant science fosters **knowledge generation** about living organisms and the world we live in
- 3) Plant scientists **support the next generation** of scientists and entrepreneurs
- 4) 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
- ↑ food crops for better **human nutrition and health**
- Utilise bioactive **green molecules** (secondary metabolites and proteins) for renewable materials, energy, human wellbeing and health
- ↑ **resource use efficiency** and stewardship for resilient production
- ↑ **plant and crop health** for resilient production
- ↑ **forest resilience and productivity** under anticipated future climate conditions
- **Nutrient cycling** and carbon sequestration



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

- 1) **EPSO supports science and scientists** with over 10 Working Groups / meetings, workshops, conference; Briefings, analyses, web <https://epsoweb.org>, social media
- 2) **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**



Today: EPSO informal science policy meeting

**Genome editing – improve legislation and start flagships  
to better address climate, environmental, food and health  
challenges**

Brussels, 11.6.2019

**Welcome – [redacted] & [redacted]**

**Legislation – how could it be improved?**

- Current legislation, EPSO statement and ideas – [redacted]
- First feedback from (multi-)national movements – [redacted] & participants
- Discussion on the way forward – moderated by 10.2e [redacted]

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

- EPSO first ideas - 10.2e [redacted]
- Discussion – moderated by 10.2e [redacted]

**Conclusions, next steps – 10.2e [redacted]**



# This meeting is under Chatham House Rule

[www.chathamhouse.org/chatham-house-rule](http://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?

Current legislation, EPSO statement and ideas



## EPSO statements 1/2

### **On the ECJ Ruling regarding mutagenesis and the Genetically Modified Organisms Directive, 19.2.2019**

Endorsed by the EPSO Representatives for 200 institutes and universities from 31 countries. <https://epsoweb.org/working-groups/agricultural-technologies/>

The ruling disregards scientific evidence. Genome editing is not the only answer to challenges of agriculture and society, but an important tool for harnessing plant science knowledge toward a future-ready agriculture.

EPSO support for creating a future-ready regulation: EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment.

EPSO offers to collaborate with policy makers to develop an appropriate 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.

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.



## EPSO statements 2/2

**Welcoming Commissioner Andriukaitis' statement and call for action  
'New plant breeding techniques need new regulatory framework',  
29.3.2019**

<https://epsoweb.org/working-groups/agricultural-technologies/>

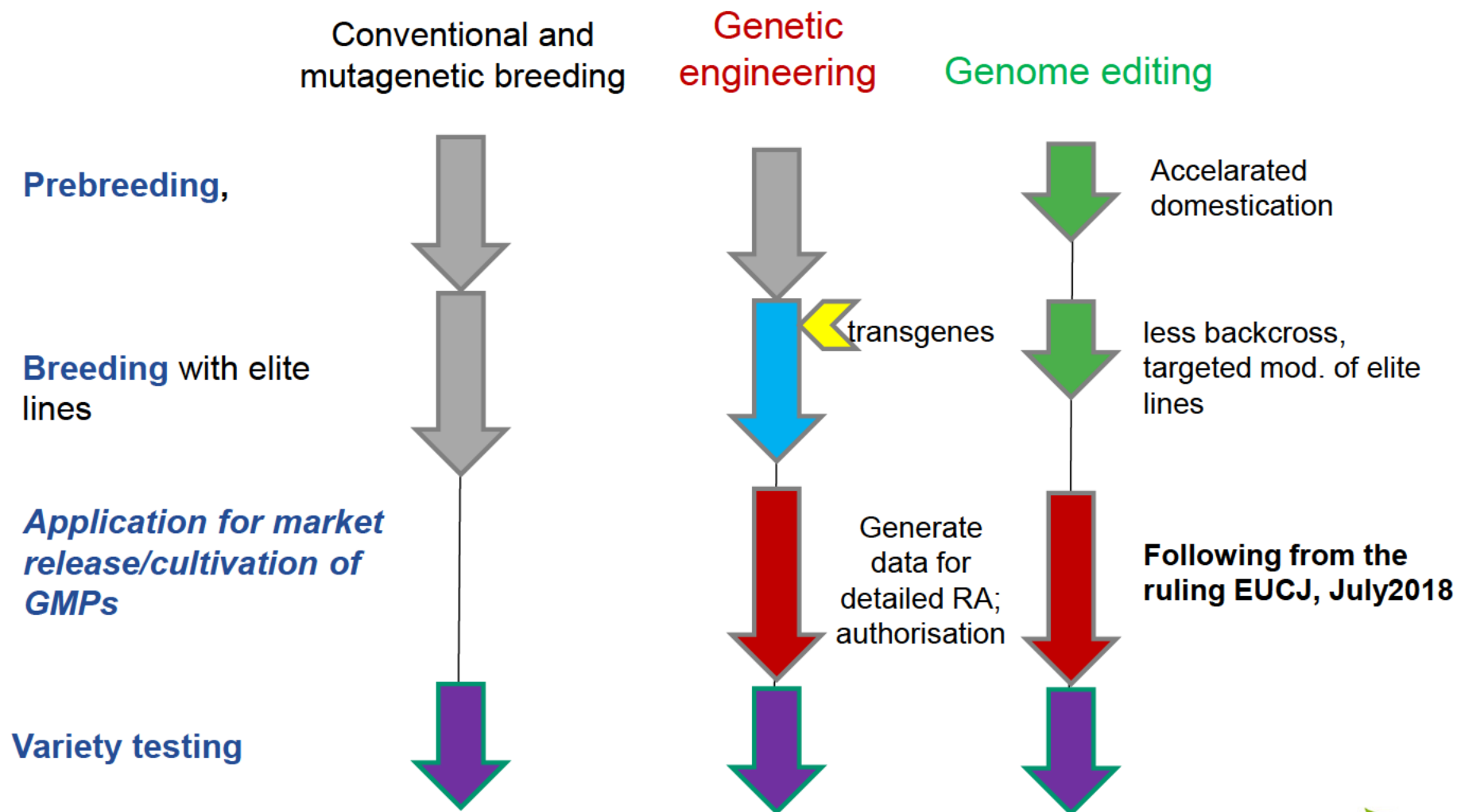
EPSO repeats its offer to collaborate with policy makers to develop an appropriate future-ready regulation to enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the 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.



# Breeding efforts & regulations



# Variety Catalogue – Variety Testing

## Regulations and obligations for conventional breeding and variety testing:

=> common catalogues of varieties for agricultural plants and vegetables

- *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

# Authorisation of GMO

## 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
    - ○ impact on non-target organisms
    - ○ impact on bio-geochemical cycles
    - ○ impact of crop management
    - ○ ...
  - Monitoring of the release
- **Labelling** of products containing or made from GMO
- Acknowledged **detection methods** (verified detection method)

# ECJ and EU regulations on GMO

## Ruling of the ECJ on July 25th 2018

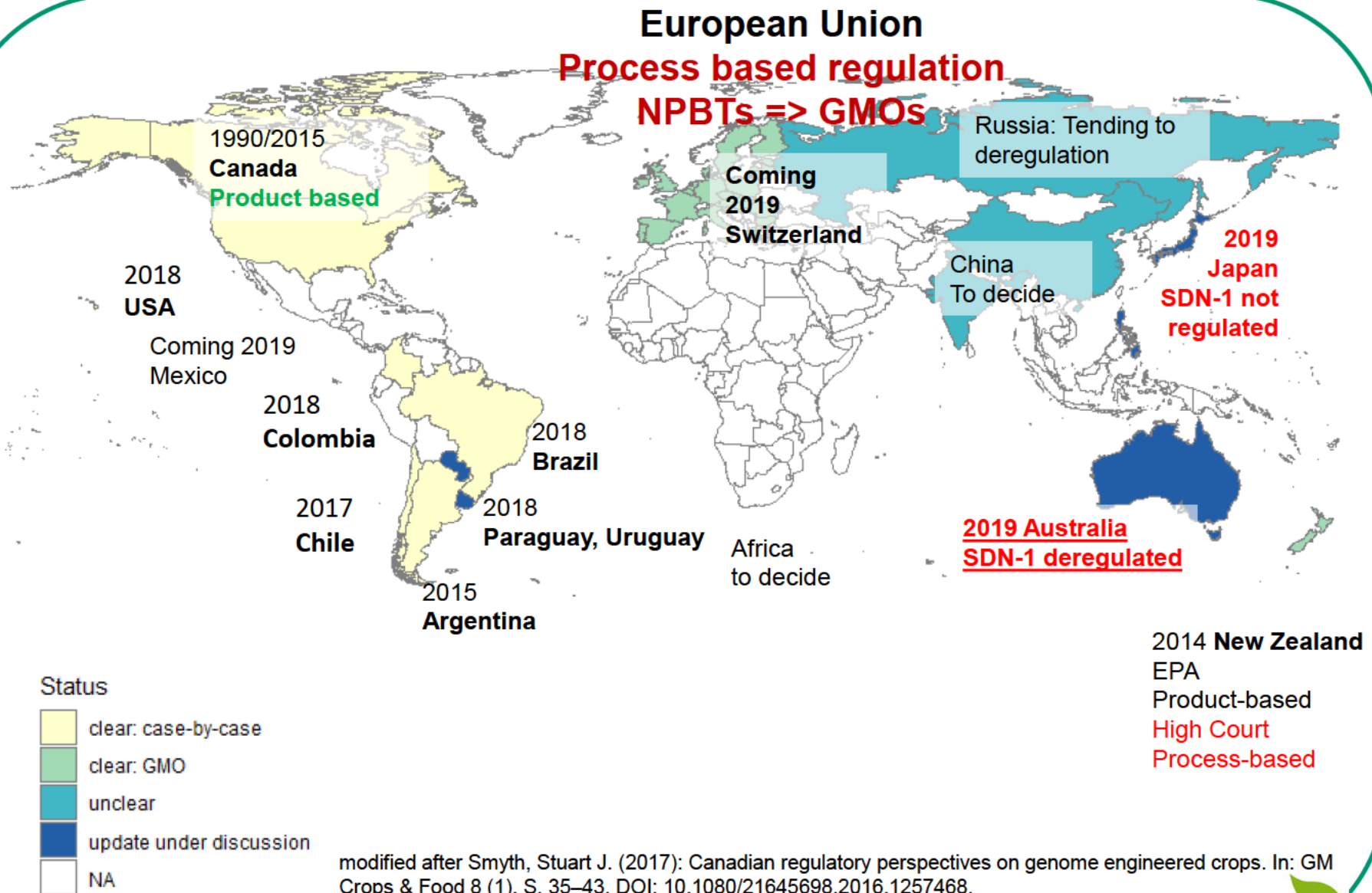
1. All organisms created by mutagenesis are GMO.
2. Mutagenesis exemption only covers organisms created by „conventional“ means of mutagenesis
3. EU member states can regulate organisms created by conventional means of mutagenesis



# GMO Regulation in the EU

	Convent. breeding	Convent. mutagenesi	Classic GMP/GMM	Genome edited P/MO
Dir. 2001/18/EC „Deliberate release“	Non GMO	<b>GMO</b> 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	-/?
Reg. (EU) 2018/848 Organic Production	Non GMO	Non GMO	GMO	GMO
Cartagena-Protocol	Non GMO	Non GMO	GMO	Non GMO; if transgenic: GMO

# How do non-European countries regulate genome editing?





# What are our concerns ?

## EPSO Statement

more than 200 research institutions mainly from Europe

**The European Plant Science Organisation (EPSO) considers that the ruling of the European Court of Justice (ECJ) on organisms obtained by mutagenesis (case C- 528/16) disregards scientific evidence...**

## Statement initiated by VIB

127 European Institutes/organisations



Open letter ESA

... über die Einschränkungen für die ... KÜHNE  
European Citizens' Initiative

Grow scientific progress: crops matter!



Support this initiative by filling in the form below

Please send the form to: [ecis@ec.europa.eu](mailto:ecis@ec.europa.eu)

Please send it by:

Support

Initiative language

English (en)

Signatures

Signature of the initiator (VIB) and the name of the initiator (VIB) are considered as the first signature. The form will be signed by the initiator (VIB) and the name of the initiator (VIB) are considered as the first signature.

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# What are our concerns ?

- ⇒ Ruling disregards scientific knowledge
- ⇒ ... counteracts scientific progress in EU// brain drain
- ⇒ Detection limits / international trade and enforcement

*Science based review of the legislation*

Open letter ESA



## How to implement a science-based legislation?

Some alternatives are:

- (i) adding modern mutagenesis methods of genome editing to the exemptions in Annex I B (2001/18/EC, Art. 3(1));
- (ii) further defining "mutagenesis" in a way that includes modern mutagenesis methods;
- (iii) modify the definition of “genetically modified organism (GMO)” (Art. 2 (2))
- adhering to the definition of living modified organisms (LMOs) of the Cartagena Protocol on Biosafety

## Support for creating a future-ready regulation

- Collaboration of scientists and policy makers to **improve the legislation**
- 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  
=> **Flagship projects**

## Where we are – steps forward



# Legislation – how could it be improved?

First feedback from (multi-)national movements

–  & participants



## **Conversations on Science, Society, and the future of gene editing**

20-21.6.2019 ; <https://crisprcon.org/crisprcon-2019/>

- Keystone Policy Centre & WUR
- Gene editing = game-changing technology that offers tremendous chances to enhance the quality of our life and causes concerns in Europe
- Stimulate open dialogue: > 400 participants from diverse stakeholders and society in Europe
- Acknowledge each other's views - opportunities and concerns when using gene editing for human health, food, agriculture and environment
- Highly interactive, the public participated via interactive media

## **Open Statement for the use of genome editing for sustainable agriculture and food production in the EU**

<https://www.psb.ugent.be/>

- Anniversary of ECJ ruling
- European scientists urge EP and EC to enable the potential of genome editing for sustainable agriculture and food production.
- Many countries choose a rational legislative framework that allows the judicious use of genome editing techniques. Europe can't stay behind.
- European agriculture can make considerable contributions to the UN SDGs. Precision breeding like genome editing potential to help reach these goals in a faster and more efficient way.
- A small revision of the EU legislation concerning genome editing will harmonize it with the legal framework in other nations and enable European scientists, breeders, farmers and producers to include genome editing as one of their tools to meet the future global challenges of sustainable development and mitigate their effects.
- The ability to use genome editing is crucial for the welfare and food security of European citizens.

# Grow scientific progress: crops matter!

European citizen initiative, 25.7.2019

<https://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2019/000012/en>



We want the EU to focus on sustainability, safety and responsible innovation when it comes to new plant breeding techniques.

Let's demand a better legal framework to reach these objectives by collecting one million signatures!

The current regulatory system results in an implicit ban of [new plant breeding techniques](#). They are valuable tools for breeding more resilient crops, with less resources and in less time: a much-needed advancement in times of climate change and prospected food insecurity - and thus something we simply cannot afford to miss out on.

We submitted a detailed [proposal](#) to the EC incl. changes to the current law that take into account important advancements in plant breeding techniques. **We propose to focus on the crop rather than the technique.** In this way safety is ensured while the valuable benefits of new techniques are not lost to illogical regulatory hurdles.



## NO Ministry of Climate and Environment -

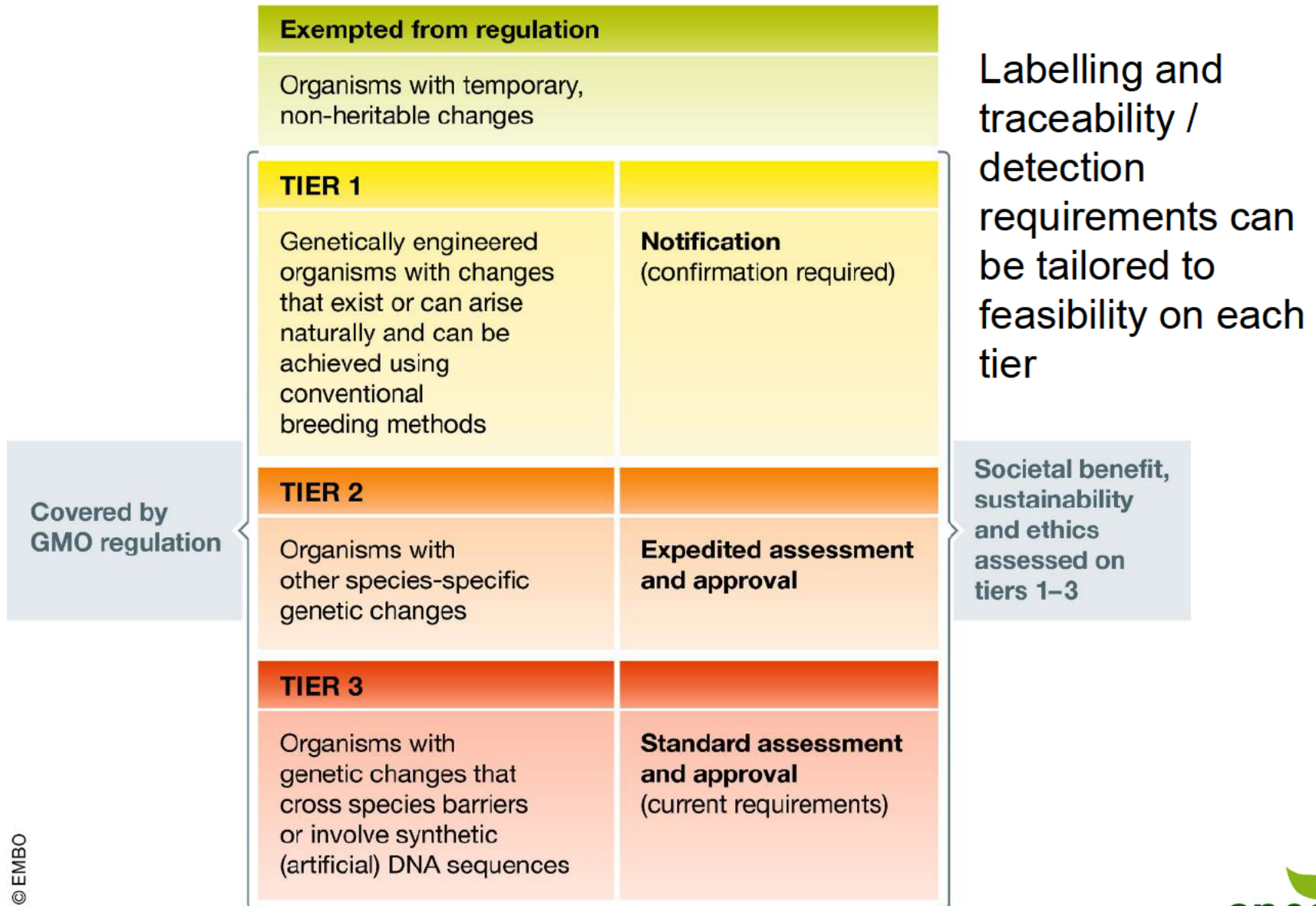
- In Norway, GMOs are regulated under the Gene Technology Act (1993)
- The Norwegian Gene Technology Act has five assessment criteria for GMOs: health impact, environmental impact, socio-economic effects, sustainable development and ethics.
- In line with signals from the Parliament, the Norwegian GMO 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



## NO Ministry of Climate and Environment -

- The Norwegian Biotechnology Advisory Board (NBAB) has recommended
  - 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 editing
    - 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)

# NO Ministry of Climate and Environment -



**More (multi)national movements  
- from participants**

**Legislation – how could it be improved?**

**Discussion on the way forward**  
- Moderated by [ ] and [ ]

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

## EPSO first ideas

—

Based on: Reports from parallel discussion groups at the EPSO 2019 General Meeting by



## Support for creating a future-ready regulation

- Collaboration of scientists and policy makers to improve the legislation
- 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

=> Flagship projects

## NBT flagships – The concept

**Improve awareness of the benefits of NBTs**, especially of Genome Editing

- bring several products using these techniques to the market in Europe
- anticipate opposing views
- demonstrate a safe and responsible handling of NBT.

(Responsiveness, Responsibility, Safety & Benefit)

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

The example products could either **benefit the population in a certain European region or a certain group of consumers** (e.g. health benefit of allergic persons)

This would likely involve **public-private risk and benefit sharing to enable SMEs** being a partner in the process.

The product should be **feasible to reach the field in a few years**.

## NBT flagship - **First ideas for examples**

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)
- 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)



## 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 projects – **Feasibility**

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**?

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

**Discussion on the way forward**

- Moderated by 

## IV – Conclusions, next steps

- Moderated by [redacted] and [redacted]

- **Keep discussion going and foster actions**
  - Among ministry colleagues – joint action(s)
  - Always contact EPSO in BRU [redacted] ) and / or in your country for support (incl. scientist from today; All representatives see <https://epsoweb.org/about-epso/representatives/> )
  - Interest in quarterly updates? Information from EPSO and from ministries you want to share
- **When meet next** – e.g. Nov'19
  - EPSO could link the next meeting(s) to the FI and DE EU Presidency subject to visibility you wish
- Suggest **more countries** to be invited in addition to the next meeting
  - Should we invite as well EC / EP?

**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](http://www.epsoweb.org)  
[epsos@epsomail.org](mailto:epsos@epsomail.org)**





European Plant Science Organisation  
<https://epsoweb.org>

**Handout**

## **Genome editing**

### **Improving legislation and start flagships to better address climate, environmental, food and health challenges**

Informal meeting in Brussels 19.9.2019,  
 12am – 2 pm, KoWi meeting room, European quarter

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**The European Plant Science Organisation (EPSO) welcomes 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 better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide.**

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country) and policy makers (1-2 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe.

The meeting shall be a starting point: In the coming months, we intend to broaden the discussion and invite more representatives from countries interested in the issue. We are planning such a second informal meeting towards the end of the year.

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.

#### **Draft agenda**

11:30 – 12:00 Registration and lunch

12:00 – 14:00 Meeting

- 12:00 **Welcome and tour de table** – 10.2e , 10.2e , 10.2e
- 12:05 **Legislation – how could it be improved?**
  - Current regulation, EPSO statement and ideas - 10.2e
  - First short feedback from (multi-)national movements (CRISPRCon, VIB, citizens' initiative etc.) - 10.2e and all participants
  - Discussion on the way forward – moderated by 10.2e
- 13:30 **Flagships towards GE products with consumer benefits** on the market in Europe
  - EPSO first ideas – 10.2e
  - Discussion – moderated by 10.2e
- 13:50 **Conclusions, next steps** – 10.2e

14:00 – 14:30 Networking, continue discussions



**This meeting is under Chatham House Rule** [www.chathamhouse.org/chatham-house-rule](http://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.

#### **Venue:**

European Liaison Office of the German Research Organisations (KoWi)

Rue du Trône 98; 1050 Brussels; Belgium; [www.kowi.de](http://www.kowi.de)

EPSO signs will point the way from the entrance to the meeting room (8<sup>th</sup> floor)

#### **Contacts**

EPSO Board

+31-10.2e  
@wur.nl

EPSO chair Agricultural  
Technologies WG

+49-10  
@julius-kuehn.de

EPSO Executive Director

+10.2e  
@epsomail.org

#### **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

## List of participants

confirmed are in bold

### Belgium

10.2e, **VIB**

### Estonia

, Ministry of Environment - apologies  
, **Tallinn University of Technology**

### Finland

, **Foreign Ministry**  
, **LUKE & EPSO President**

### France

, **Ministry for Agriculture and Food**  
, **INRA**

### Germany

Dr. , **Ministry for Education and Research, 726 Bioeconomy**  
10.2e, **Ministry for Education and Research, 611 Ethics & Law in Life Sciences**  
Dr. , Ministry of Food and Agriculture, 222 – New Technologies – apologies – will  
participate and follow up with  
, **JKI**

### Italy

10.2e, **CNR**

### The Netherlands

, **Ministry for Agriculture**  
, **WUR**

### Norway

10.2e, Ministry of Climate and Environment – apologies – 10.2e will provide information  
from CE on the status of the work on the amendment of the regulations in Norway.  
10.2e, **NO Biotech Advisory Board**  
10.2e, **Graminor and NMBU**

### Portugal

Ministry for Agriculture, Forestry and Rural Development – apologies  
10.2e, **ITQB - apologies**

### Spain

10.2e, **Ministry for Agriculture (part of the meeting)**  
10.2e, **CBGP (UPM-INIA); AEI Gen technology Scientific advisor**  
10.2e, **CSIC - apologies**

### Sweden

10.2e, **Min. of Enterprise and Innovation**  
10.2e, **Gene Technology Advisory Board**  
10.2e, **SLU**

### Europe

, **EPSO**  
, **EMBO**



## Annex I: 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

- [Council Directive 2002/53/EC](#) on the common catalogue of varieties of agricultural plant species.
- [Council Directive 2002/55/EC](#) on the marketing of vegetable seed.
- [Council Directive 2008/72/EC](#) on the marketing of vegetable propagating and planting material other than seed.
- [Commission Directive 2003/90/EC](#): Rules on minimum characteristics and minimum conditions for examining certain varieties of agricultural plant species.
- [Commission Directive 2003/91/EC](#): Rules on minimum characteristics and minimum conditions for examining certain vegetable species.
- [Commission Regulation 637/2009/EC](#) 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

- [Council Directive 1999/105/EC](#) of 22 December 1999 on the marketing of forest reproductive material
- [Commission Regulation EC 1597/2002](#) 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 [EU variety register](#) (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

- [Council Directive 2008/90/EC](#) on the marketing of fruit plant propagating material and fruit plants intended for fruit production
- [Commission Implementing Directive 2014/97/EU](#) 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:

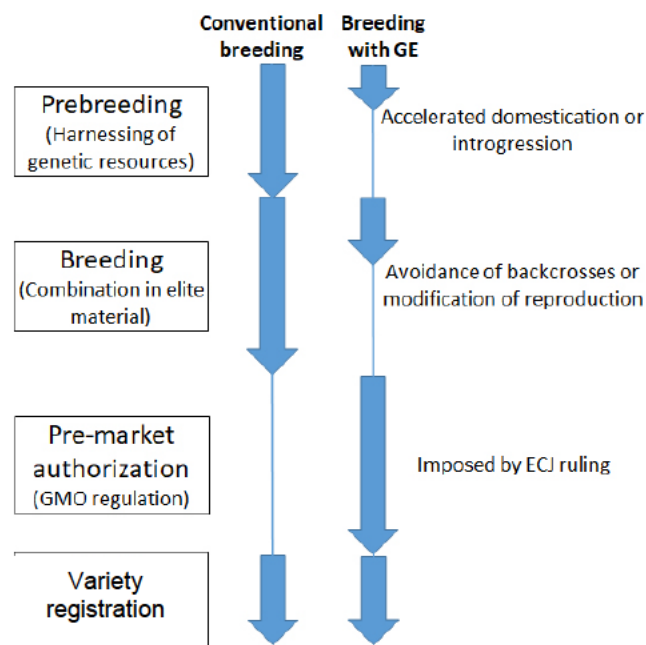
- distinctness;
- uniformity;

- 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 II: 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	- / ?
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.

## 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
    - impact on non-target organisms
    - impact on bio-geochemical cycles
    - impact of crop management
    - ...
  - Monitoring of the release
- Labelling of products containing or made from GMO
- Acknowledged detection methods (verified detection method)

### Annex III Supporting literature - links

- EPSO statement (endorsed by all EPSO Representatives for 197 institutes / universities), 19.2.2019: <https://epsoweb.org/download/epsoweb-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: <https://epsoweb.org/epsoweb-welcomes-commissioner-andriukaitis-statement-and-call-for-action-new-plant-breeding-techniques-need-new-regulatory-framework/2019/03/29/>
- 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%20editing%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: [https://www.upsc.se/documents/News/News\\_2019/2019-07-25\\_Open-letter-concerning-GMO-regulations.pdf](https://www.upsc.se/documents/News/News_2019/2019-07-25_Open-letter-concerning-GMO-regulations.pdf)
- 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](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.biotechnologiradet.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: <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>
- 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: <https://cdn.website-editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/AFBV-WGG-Statement.pdf>

**EPSO informal science – policy meeting on genome editing in Brussels, 19.9.2019**

**List of participants - confirmed in bold – by 27.8.2019**

**Belgium**

10.2e , **Federal Ministry of Environment**

10.2e , **VIB, Ghent**

**Estonia**

t.b.a., **Ministry of Environment**

10.2e , **Tallinn University**

**Finland**

10.2e , **Foreign Ministry**

10.2e , **LUKE & EPSO President**

**France**

10.2e , **Ministry for Agriculture and Food**

10.2e , **INRA**

**Germany**

Dr 10.2e , **Ministry for Education and Research, 726 Bioeconomy**

10.2e , **Ministry for Education and Research, 611 Ethics & Law in Life Sciences**

Dr. 10.2e , **Bundesministerium für Ernährung und Landwirtschaft, 222 – Neue Technologien**

10.2e , **JKI & reporting back to Ministry for Food and Agriculture**

**Italy**

t.b.a., **Ministry for Agriculture**

10.2e , **University of Udine**

10.2e , **CNR**

**The Netherlands**

t.b.a., **Ministry for Agriculture**

t.b.a., **Ministry for Infrastructure**

10.2e , **WUR**

**Norway**

10.2e , **Ministry of Climate and Environment**

10.2e , **NO Biotech Advisory Board**

10.2e , **Grainor and NMBU**

**Portugal**

t.b.a.

**Spain**

t.b.a., **Ministry for Research and Innovation**

t.b.a., **Ministry for Agriculture**

10.2e , **CBGP (UPM-INIA); AEI Gen technology Scientific advisor**

10.2e , **CSIC**

**Sweden**

10.2e , **Min. of Enterprise and Innovation**

10.2e , **Gene Technology Advisory Board**

10.2e , **SLU**

**Europe**

10.2e , **EPSO**

10.2e , **EMBO**

**EPSO informal science – policy meeting on genome editing in Brussels, 19.9.2019**

**List of participants - confirmed in bold – by 5.9.2019**

**Belgium**

10.2e [redacted], **Federal Ministry of Environment**

10.2e [redacted], **VIB**

**Estonia**

t.b.a., **Ministry of Environment**

10.2e [redacted] **Tallinn University**

**Finland**

10.2e [redacted], **Foreign Ministry**

10.2e [redacted], **LUKE & EPSO President**

**France**

10.2e [redacted], **Ministry for Agriculture and Food**

10.2e [redacted], **INRA**

**Germany**

Dr 10.2e [redacted], **Ministry for Education and Research, 726 Bioeconomy**

10.2e [redacted], **Ministry for Education and Research, 611 Ethics & Law in Life Sciences**

Dr. 10.2e [redacted], **Bundesministerium für Ernährung und Landwirtschaft, 222 – New Technologies**

10.2e [redacted], **JKI**

**Italy**

t.b.a., **Ministry for Agriculture**

10.2e [redacted], **University of Udine**

10.2e [redacted], **CNR**

**The Netherlands**

10.2e [redacted], **Ministry for Agriculture**

10.2e [redacted], **WUR**

**Norway**

10.2e [redacted], **Ministry of Climate and Environment**

10.2e [redacted], **NO Biotech Advisory Board**

10.2e [redacted], **Graminor and NMBU**

**Portugal**

t.b.a.

**Spain**

t.b.a., **Ministry for Research and Innovation**

t.b.a., **Ministry for Agriculture**

10.2e [redacted], **CBGP (UPM-INIA); AEI Gen technology Scientific advisor**

10.2e [redacted], **CSIC**

**Sweden**

10.2e [redacted], **Min. of Enterprise and Innovation**

10.2e [redacted], **Gene Technology Advisory Board**

10.2e [redacted], **SLU**

**Europe**

10.2e [redacted], **EPSO**

10.2e [redacted], **EMBO**



10.2e

**Van:** 10.2e @julius-kuehn.de>  
**Verzonden:** donderdag 19 december 2019 15:42  
**Aan:** 10.2e  
**CC:** 10.2e  
**Onderwerp:** AW: 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 10.2e  
 sounds good for me ...  
 best

10.2e

---

**Von:** 10.2e  
**Gesendet:** Donnerstag, 19. Dezember 2019 15:21  
**An:** 10.2e  
**Cc:** 10.2e  
**Betreff:** RE: 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 10.2e

As just discussed on the phone:

- We can change the agenda slightly – calling it the NL discussion proposal (2017) for example.
- It does not represent the current, formal position of NL. Even with a disclaimer, it will be difficult for me (as the NL representative) to present this within the current political context. 10.2e could you perhaps present the proposal? I would be happy to help with the preparation.

Would this be a suitable solution?

Kind regards,

10.2e

---

**Van:** 10.2e @julius-kuehn.de>  
**Verzonden:** donderdag 19 december 2019 14:52  
**Aan:** 10.2e @minlnv.nl>  
**cc:** 10.2e @wur.nl>; 10.2e @epsomail.org>  
**Onderwerp:** AW: 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

Hi 10.2e

hm, but actually the suggestion has already been circulated in 2018. So what to do with it – how to communicate it?

Nevertheless, I don't think we need to force it.

But I think, questions may arise - though it is more the general strategic view what is important and what to communicate in the future discussions.

Best wishes

10.2e

---

Von: 10.2e <[redacted]@minlnv.nl>

Gesendet: Donnerstag, 19. Dezember 2019 14:22

An: 10.2e <[redacted]@julius-kuehn.de>

Cc: 10.2e <[redacted]@wur.nl>; 10.2e <[redacted]@epsomail.org>

Betreff: RE: 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 10.2e

Many thanks for the quick reply. Considering the current, and rather political, situation around the Council decision and Commission study, I would rather not have the NL 1b proposal be examined at this point in time.

I would therefore kindly request that it is removed from the agenda the next time that the agenda is sent around. Would that be possible?

Feel free to call me at the number below if you have any questions.

Kind regards,

10.2e

*Senior beleidsmedewerker biotechnologie*

.....  
**Directie Plantaardige Agroketens en Voedselkwaliteit**  
**Ministerie van Landbouw, Natuur en Voedselkwaliteit**  
Bezuidenhoutseweg 73 | 2594 AC | Den Haag  
Postbus 20401 | 2500 EK | Den Haag

.....  
T 06 10.2e | 070 10.2e

E 10.2e <[redacted]@minlnv.nl>

[www.rijksoverheid.nl/lnv](http://www.rijksoverheid.nl/lnv)

.....  
*Aanwezig ma t/m vrijdag*

---

Van: 10.2e <[redacted]@julius-kuehn.de>

Verzonden: donderdag 19 december 2019 14:06

Aan 10.2e <[redacted]@minlnv.nl>

cc: 10.2e <[redacted]@wur.nl>; 10.2e <[redacted]@epsomail.org>

Onderwerp: AW: 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 10.2e

10.2e just passed your question.

When I prepared the agenda my sloppy entry "NL" refers to the Dutch non-paper circulated about the suggestions to modify the Directive 2001/18/EC in 2018 before the ruling. It was the first substantial suggestion how to modify the Directive. It would be nice if one from the Netherlands (my initial thought was 10.2e But you may help?) can present this (or any new suggestion that is under discussion).

Now, there are a few more proposals which we like to compare briefly. The suggestions are considered not being a final commitment of the governments but to consider an outlook during the meeting. There are some common

ideas but also some differences. The overall question is: do these different attempts provide valuable input, how should they be used. Is there another strategy ...

Feel free to get back to me.

And of course merry Christmas and a happy new year ... I 'll hope we'll meet in Brussels

10.2e

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Dr. 10.2e  
Director  
Institute for Biosafety in Plant Biotechnology (SB)  
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Federal Research Centre for Cultivated Plants  
Erwin-Baur-Straße 27, D-06484 Quedlinburg  
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**Von:** 10.2e @epsomail.org>

**Gesendet:** Donnerstag, 19. Dezember 2019 13:45

**An:** 10.2e @minInv.nl>; 10.2e @julius-kuehn.de>

**Cc:** 10.2e @wur.nl>

**Betreff:** RE: 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 10.2e

Can you pls reply to 10.2e and 10.2e our ideas regarding these short presentations?

Thank you and best wishes

10.2e

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**From:** 10.2e @minInv.nl>

**Sent:** 19 December 2019 13:13

**To:** 10.2e @epsomail.org>

**Cc:** 10.2e @wur.nl>

**Subject:** RE: 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 10.2e

I see that you placed ideas on legislation on the agenda with a contribution of the Netherlands. Would you have some more information on this for me?

Kind regards,

10.2e

Van: 10.2e <[redacted]@epsomail.org>  
 Verzonden: donderdag 19 december 2019 12:15  
 Aan: 10.2e <[redacted]@mapa.es>; 10.2e <[redacted]@mapa.es>; 10.2e <[redacted]@agriculture.gouv.fr>; 10.2e <[redacted]@regeringskansliet.se>; 10.2e <[redacted]@kld.dep.no>; 10.2e <[redacted]@regeringskansliet.se>; 10.2e <[redacted]@bmbf.bund.de>; 10.2e <[redacted]@bmbf.bund.de>; 10.2e <[redacted]@formin.fi>; 10.2e <[redacted]@bmel.bund.de>; 10.2e <[redacted]@bmel.bund.de>; 10.2e <[redacted]@bmel.bund.de>; 10.2e <[redacted]@minInv.nl>; 10.2e <[redacted]@fz-juelich.de>; 10.2e <[redacted]@fz-juelich.de>; 10.2e <[redacted]@environment.belgium.be>; 10.2e <[redacted]@envir.ee>; 10.2e <[redacted]@envir.ee>; 10.2e <[redacted]@smm.lt>; 10.2e <[redacted]@smm.lt>  
 cc: 10.2e <[redacted]@helsinki.fi>; 10.2e <[redacted]@helsinki.fi>; 10.2e <[redacted]@ibba.cnr.it>; 10.2e <[redacted]@ibba.cnr.it>; 10.2e <[redacted]@cnb.csic.es>; 10.2e <[redacted]@cnb.csic.es>; 10.2e <[redacted]@upm.es>; 10.2e <[redacted]@upm.es>; Cecilia Sarmiento <[redacted]@taltech.ee>; 10.2e <[redacted]@taltech.ee>; 10.2e <[redacted]@taltech.ee>; 10.2e <[redacted]@wur.nl>; 10.2e <[redacted]@wur.nl>; 10.2e <[redacted]@lammc.lt>; 10.2e <[redacted]@itqb.unl.pt>; 10.2e <[redacted]@itqb.unl.pt>; 10.2e <[redacted]@genteknik.se>; 10.2e <[redacted]@embo.org>; 10.2e <[redacted]@embo.org>; 10.2e <[redacted]@graminor.no>; 10.2e <[redacted]@graminor.no>; 10.2e <[redacted]@nmbu.no>; 10.2e <[redacted]@nmbu.no>; 10.2e <[redacted]@cragenomica.es>; 10.2e <[redacted]@cragenomica.es>; 10.2e <[redacted]@ens-lyon.fr>; 10.2e <[redacted]@ens-lyon.fr>; 10.2e <[redacted]@vib.be>; 10.2e <[redacted]@vib.be>; 10.2e <[redacted]@bioteknologiradet.no>; 10.2e <[redacted]@bioteknologiradet.no>; 10.2e <[redacted]@plen.ku.dk>; 10.2e <[redacted]@slu.se>; 10.2e <[redacted]@slu.se>; 10.2e <[redacted]@julius-kuehn.de>; 10.2e <[redacted]@julius-kuehn.de>

Onderwerp: 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  
 Urgentie: Hoog

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 2<sup>nd</sup> 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](http://www.kowi.de).

Those of you not confirmed yet (not in bold in the participant list), pls confirm to 10.2e 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

10.2e t and 10.2e

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Dr. 10.2e  
 Executive Director  
 European Plant Science Organisation, EPSO  
 Rue de l'Industrie 4, 1000 Brussels, Belgium

10.2e "epsomail.org ; T/F: +3210.2e  
[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09

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**From:** 10.2e **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 **2<sup>nd</sup> 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](http://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

10.2e and 10.2e

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**From:** 10.2e **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 **2<sup>nd</sup> 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](http://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

10.2e and 10.2e

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**From:** 10.2e **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 availability 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 [REDACTED]**
  - Mo 20.1.2020: yes, possible, not
  - Tu 21.1.2020: yes, possible, not
  - 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 mailing list** 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 additional ministry colleagues 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 flagship projects 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

10.2e and 10.2e

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**From:** 10.2e **Sent:** 13.9.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19.9.2019 – Handout

Dear colleagues from national ministries,

Please find attached the Handout for our meeting including the updated participant list.

We very much look forward to a constructive discussion

10.2e and 10.2e

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**From:** 10.2e **Sent:** 05.9.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – Updated agenda

Dear colleagues from national ministries,

Please find hereafter the updated agenda of the meeting and attached FYI **the invitation and the updated list of participants**.

We will send you a Handout before the event.

We very much look forward to a constructive discussion

10.2e and 10.2e

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**From:** 10.2e **Sent:** 28.8.2019 **To:** Participants

**Subject:** EPSO: Genome editing - Informal science - policy meeting in Brussels, 19 September 2019 – confirmed participants

Dear colleagues from national ministries,

The European Plant Science Organisation (EPSO) has the pleasure to welcome you as policy makers to join EPSO members for an 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.

The meeting will be an open-minded, informal discussion under Chatham House Rules between plant scientists (1 / country, in cc) and policy makers (1-3 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe.

Please find **attached the invitation and the list of participants** – as you can see, we already have confirmation from ministry colleagues from eight countries. More are welcome and should pls confirm their participation best by 6 September to 10.2e @epsomail.org, quoting their country (BE, EE, FI, IT, NL, NO, PT, ES, SE, DE), ministry affiliation, name and email address.

We will send you a Handout before the event.

Should you have any dietary requirements, pls let 10.2e (in cc) know.

We very much look forward to a constructive discussion

10.2e and 10.2e

10.2e, EPSO Board; 10.2e, EPSO Chair WG Agricultural Technologies; 10.2e, EPSO Executive Director

\*\*\*\*\*

Dr. 10.2e

Executive Director

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[www.epsoweb.org](http://www.epsoweb.org) ; EU Transparency Register Number 38511867304-09

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# Horizon Europe Strategic Planning

## Revised Orientations towards the first strategic plan

Fields marked with \* are mandatory.

With a proposed budget of 100 billion Euro from 2021 to 2027, the Horizon Europe framework programme represents the largest collaborative research and innovation investment in the world and is open to participants worldwide. The European Parliament and the Council, the co-legislators, have provisionally agreed on the Horizon Europe legislative package. A co-design process has been launched in order to optimise the targeted impacts for the first four years of implementation. It has been organised first through a web-phase consultation (28 June to 4 October) and then in the European Research and Innovation Days (24-26 September, via dedicated sessions and the village), more than 10000 contributions from stakeholders based in 99 different countries have been received. They have been taken into account and the original "Orientations" document has been modified accordingly.

The revised version of the "[Orientations towards the first Strategic Plan for Horizon Europe](#)", is now open to receive your views, focusing on a limited number of issues that had not been addressed before. Since the EU added value is the cornerstone of this survey, we particularly welcome views from organisations and networks with a cross border dimension and a mission of advocacy of relevance for research and innovation, (the so-called "umbrella organisations").

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### Section A - About you

\* Are you representing an organisation with members from different countries or a transnational network?

- ☒ yes  
☐ no

If you are representing an organisation or a network mentioned in the question, what is its name?

*1000 character(s) maximum*

European Plant Science Organisation, EPSO

Where the headquarter of the organisation or the coordinator of the network is located?

Belgium

If you are responding on behalf of an organisation or a network mentioned in the question, how many members are you representing?

*1000 character(s) maximum*

EPSO represents more than 200 research institutes, departments and universities and 3.300 individuals Personal Members, representing over 26 000 people working in plant science. <https://epsoweb.org> | EU Transparency Register Number 38511867304-09

If you are representing an organisation or a network mentioned in the question, in how many countries your members are based?

*1000 character(s) maximum*

EPSO members are based in 31 countries, mainly in Europe: AT, BE, BG, CY, CZ, DK, EE, FI, FR, DE, GR, HU, IE, IL, IT, LV, LT, NL, NZ, NO, PL, PT, RO, RS, SK, SV, ES, SE, CH, UKR, UK.

\* You or your organisation are mainly active/interested in the following areas of Horizon Europe (Please select all that apply):

- ☒ Health (cluster 1)
- ☐ Culture, creativity and inclusive society (cluster 2)
- ☐ Civil security for society (cluster 3)
- ☐ Digital, industry and space (cluster 4)
- ☐ Climate, energy and mobility (cluster 5)
- ☒ Food, bioeconomy, natural resources, agriculture and environment (cluster 6)
- ☒ Widening Participation and Strengthening the European Research Area
- ☒ Pillar I Excellent Science
- ☐ Pillar III Innovative Europe
- ☒ Other

\* Publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- ☐ Anonymous  
Only your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.
- ☒ Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

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## Section B - Questions

Which targeted impacts can be best reached (or only reached) through Horizon Europe? On the other hand, what are the targeted impacts, mentioned in the updated orientations, least likely to benefit from Horizon Europe investments?

*1500 character(s) maximum*

Targeted impacts best / only reached through HE and suggestions to the content:

ALL from CLUSTER 1 – HEALTH:

To 3.1 Staying healthy in a rapidly changing society: Add the concept of 'diverse crops for diverse diets and human health' and the goal of 'nutritional security' to healthier food choices, health promotion and disease prevention.

To 3.2 Living and working in a health-promoting environment: Add the 'importance of plants' for health and well-being in terms of agriculture, horticulture and forests.

ALL from CLUSTER 6 – FOOD ...:

To 3.4. Sustainable primary production, food and bio-based systems, FNS: Add 'Diverse crops for diverse diets, human health and resilient production will become available.' Sustainable, safe and healthy diets ...a major shift to 'diverse and' healthy diets from sustainable food production systems ....

To 4.2. Biodiversity and Natural Capital: Link to increasing 'cultured diversity' in 4.3.

To 4.3. Agriculture, forestry and rural areas: Add the concepts of 'improved crops' (in addition to management approaches) and of 'Diverse crops for diverse diets, human health and resilient production'.

To 4.5. Food systems: Link to the concepts of 'improved crops' (in addition to management) and of 'Diverse crops for diverse diets, human health and resilient production' in 4.3.

To 4.6. BBI Systems: Add to the use of nature's "biological assets" 'and improved crops, synthetic biology'...

Which common challenges between different clusters could reinforce their impacts (e.g. environment and health, green IT...)?

*1500 character(s) maximum*

Clusters 1 (Health) and 6 (Food ..) should jointly address Food and Nutritional Security (FNS) and Environmental sustainability and human health:

EPSO welcomes the link between Food and Health Clusters: 1) Crops without diseases, but with high plant secondary metabolite levels are beneficial for human health and help preventing diseases; 2) Plants in natural and cultured environments improve air quality and human wellbeing; Possibly add 3) Plant Made Pharmaceuticals contribute to novel medicines.

Keeping plants and animals healthy to supply safe food: We suggest adding 'Improving crops to prevent plant pests and diseases relevant to human health (e.g. fungi) is an important contributor.'

CLOSE THE RESEARCH AND INNOVATION CYCLE IN PILLAR 2:

EPSO urges to give more balanced consideration to basic research in relation to the other components (applied research, demonstration and innovation actions) of the research and innovation cycle in pillar 2. We currently miss potential benefits from basic research (incl. questions from innovation to basic research), hindering ground-breaking solutions addressing the SDGs. This could be better balanced by encouraging collaborative basic research as component and / or focus of RIA projects. This will widen participation incl. EU13, close gaps in collaborative research and bridge between the Excellent Science and Innovative Europe pillars. It will help private companies who need to build on the explorative research.

Beyond research and innovation, which other measures would be needed at the European level to best achieve the targeted impacts (e.g. innovation deals...)?

*1500 character(s) maximum*

Improve the innovation framework:

- o SUPPORT NEW TECHNOLOGIES – ADHERE TO INTRERNATIONAL AGREEMENTS – BY

#### IMPROVING THE LEGISLATION AND SUPPORTING FLAGSHIP PROJECTS:

Currently Europe's position on New Breeding Technologies as laid down in article 2 of directive 2001/18/EC, which is binding for NBT, is not in line with the definition of Living Modified Organism as it is defined in article 3 (g) in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, an international agreement signed by 171 countries. Europe needs to have a more balanced approach to new technologies incl. improving the legislation and start flagship projects engaging all stakeholders from scientists, companies, farmers to end-users towards products with consumer benefits on the market in Europe and globally. In parallel to such projects, new concepts for deregulation, based on public-private risk and benefit sharing, need to be developed to enable SMEs bringing such products to the market. EPSO invites policy makers to exchange 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.

What are your impressions on the co-design process and how can we improve it?

*1500 character(s) maximum*

In general, the idea is very good and most welcome. We see better links between the clusters in pillar 2 and hope this will be translated into calls that are cross-clusters (or alternating led by always one of these clusters), which would be a major improvement versus the Horizon Europe programme.

The method of co-design could be easily improved by

- 1) inviting free text contributions without set questions and only an overall text limit (e.g. 4 pages). Stakeholders would simply refer to certain chapters of the orientation paper on comment on these.
- 2) Inviting umbrella organisations to participate in or recommend experts to the upcoming workshops the respective EC colleagues will organise to further develop and translate the Strategic Plan.

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## Contact

10.2e @ec.europa.eu



European Plant Science Organisation  
<https://epsoweb.org>

## ***Invitation and agenda***

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

2<sup>nd</sup> 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](http://www.kowi.de)

*Brussels, 19.12.2019*

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, Citizen Initiative (Eur), VIB (BE), Leopoldina (DE), Norway
- 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 1<sup>st</sup> informal meeting
- Consideration of consumers' attitudes: *Nuanced attitudes to gene editing in Norway*
- Steps forward
  - Priority criteria\* / screening
  - 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: stakeholder/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 10.2e @epsomail.org** (incl. ministry affiliation, name and email address), quoting your country, EPSO member research organisation or ministry affiliation, name and email address.

10.2e and 10.2e

10.2e EPSO Chair WG Agricultural Technologies; 10.2e , EPSO President; 10.2e  
EPSO Board; 10.2e , EPSO Executive Director.

#### Attachments:

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

#### Contacts:

10.2e [ulius-kuehn.de](mailto:ulius-kuehn.de) 10.2e [@helsinki.fi](mailto:@helsinki.fi) 10.2e [@wur.nl](mailto:@wur.nl) 10.2e [@epsomail.org](mailto:@epsomail.org)

#### 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





European Plant Science Organisation  
<https://epsoweb.org>

**News items Sep-Dec'19**

## **Genome editing**

### **Improving legislation and start flagships to better address climate, environmental, food and health challenges**

2<sup>nd</sup> Informal meeting in Brussels 24.1.2020

*Brussels, 19.12.2019*

#### **News relevant to this meeting since the 1<sup>st</sup> informal meeting on 19.9.2019**

- 1-Council decision on ECJ ruling – EC study on NBTs, 14.11.2019
- 2-Denmark: Statement from the Ethical Council in DK, 2019
- 3-Germany: Leopoldina, DFG etc. joint statement, 4.12.2019
- 4-Nordic Public Private Partnership for Pre-breeding (PPP) - Workshop 5-6.2.2020 for future call
- 5-EPSO submission to EC consultation Horizon Europe Strategic Planning II, 15.11.2019

The news items were sent to EPSO by its members to bring to the attention of the participants of the informal science policy meetings on genome editing.

All participants are welcome to send us similar news items for the next quarterly update to be circulated end March 2020.

#### **1-Council decision on ECJ ruling – EC study on NBTs, 14.11.2019**

Encouraged by the Finnish presidency, on Nov 8<sup>th</sup>, 2019 the Council of the European Union requested the Commission to submit, by 30 April 2021, a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law (<https://eur-lex.europa.eu/eli/dec/2019/1904/oj>). The Council requests the Commission to submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study. In accordance with usual practice, the Council requests the Commission to ensure that the proposal is accompanied by an impact assessment.

*Attached: 19\_11\_14\_Council decision\_ECJ - NBTstudy*

Meanwhile, the European Commission already mentioned to open a consultation / call to submit information to them with a deadline in April 2020.

#### **2-Denmark: Statement from the Ethical Council in DK, 2019**

Statement from the Ethical Council in DK (in Danish):

GMO and ethics in a new time:

[http://www.etiskraad.dk/~media/Etisk-Raad/Etiske-Temaer/Natur-klima-og-foedeverer/GMO-2019/DER\\_Udtalelse\\_GMO\\_og\\_etik\\_i\\_en\\_ny\\_tid\\_m\\_baggrundsnotater.pdf#page=27](http://www.etiskraad.dk/~media/Etisk-Raad/Etiske-Temaer/Natur-klima-og-foedeverer/GMO-2019/DER_Udtalelse_GMO_og_etik_i_en_ny_tid_m_baggrundsnotater.pdf#page=27)

(© Det Etiske Råd 2019 ISBN: 978-87-92915-15-3)

The most important conclusion, summarised by EPSO colleagues in EN, is:

*7. The councils' recommendations*

7.1 It is problematic ethically to refuse to accept GMO-varieties if they can contribute to mitigate or solve important problems, if there are no good reasons not to accept them

Some of the members (Morten Bangsgaard, Anne-Marie Axø Gerdes, Kirsten Halsnæs, Mia Amalie Holstein, Poul Jaszczak, Henrik Gade Jensen, Bolette Marie Kjær Jørgensen, Henrik Nannestad Jørgensen, Rune Engelbreth Larsen, Eva Secher Mathiasen, Rico Mathiesen, Jacob Giehm Mikkelsen, Lise von Seelen, Karen Stæhr og Signild Vallgård) finds that there today exist a number examples of GMOs that are promising in this respect and they are referring to two examples (perennial wheat and fast domestication of tomato using CRISPr). These members suggest that new regulations should be implemented that does not prevent GMOs to be used only because of the technology that has been used to produce them (process requirement). Emphasis should rather be placed on the type of trait that a new variety has got, so that risk assessment should be conducted on varieties that have an increased probability to pose a risk for the environment and human health (product requirement).

The council is divided but this recommendation is from the majority

### 3-Germany: Leopoldina, DFG etc. , joint statement, 4.12.2019

"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.

The statement can be accessed by the public at: [www.leopoldina.org/en/plant-breeding](http://www.leopoldina.org/en/plant-breeding)

### 4-Nordic Public Private Partnership for Pre-breeding (PPP) - Workshop 5-6.2.2020 for future call

The Nordic Public Private Partnership for Pre-breeding (PPP) will hold a workshop on 'Nordic Plant Genetic Resources Enhancement under a Changing Climate through Public-Private Partnerships in Pre-Breeding' 5-6 February 2020 in Hyllie (Malmö), Sweden.

The main objectives of the workshop are to bring breeders, researchers and stakeholders together within the area of plant genetic resources and pre-breeding for Nordic agriculture and horticulture; continue interaction and strengthening of the current excellent network involving NordGen, academia, plant breeding entities and stakeholders; foster the evolving Nordic plant breeding through public-private partnerships on pre-breeding; and inspire the network to develop into the next level to address Grand Challenges.

Hereby, the workshop may identify new areas of collaboration and / or found relevant ideas for new projects to be financed within the Nordic PPP and to be applied for during a new call.

The Nordic PPP is a well-established public-private partnership in pre-breeding. Totally 11 breeding companies and public breeding entities from the five Nordic countries cooperate with research institutes and universities in a pre-competitive manner in these pre-breeding projects. Public breeding entities in the Baltic countries are also participating in the Nordic PPP.

See post at [https://www.plant-phenotyping.org/index.php?index=580&event=Workshop\\_Nordic\\_Plant\\_Genetic\\_Resources\\_Enhancement\\_in\\_a\\_changing\\_climate\\_Public\\_Private\\_Partnerships\\_in\\_Pre\\_Breeding](https://www.plant-phenotyping.org/index.php?index=580&event=Workshop_Nordic_Plant_Genetic_Resources_Enhancement_in_a_changing_climate_Public_Private_Partnerships_in_Pre_Breeding)

### 5-EPSCO submission to EC consultation Horizon Europe Strategic Planning II, 15.11.2019

Most relevant to this group is the following question / answer:

Question:

Beyond research and innovation, which other measures would be needed at the European level to best achieve the targeted impacts (e.g. innovation deals...)?

Answer:

Improve the innovation framework:

- SUPPORT NEW TECHNOLOGIES – ADHERE TO INTERNATIONAL AGREEMENTS – BY IMPROVING THE LEGISLATION AND SUPPORTING FLAGSHIP PROJECTS:

Currently Europe's position on New Breeding Technologies as laid down in article 2 of directive 2001/18/EC, which is binding for NBT, is not in line with the definition of Living Modified Organism as it is defined in article 3 (g) in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity,

an international agreement signed by 171 countries. Europe needs to have a more balanced approach to new technologies incl. improving the legislation and start flagship projects engaging all stakeholders from scientists, companies, farmers to end-users towards products with consumer benefits on the market in Europe and globally. In parallel to such projects, new concepts for deregulation, based on public-private risk and benefit sharing, need to be developed to enable SMEs bringing such products to the market. EPSO invites policy makers to exchange 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.

Contribution ID 666b7610-ddca-4262-b4be-dc125b7ec2cf

Attached: 19\_11\_15\_EPSO Contributionxxx.pdf

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**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

## COUNCIL DECISION (EU) 2019/1904

of 8 November 2019

**requesting the Commission to submit 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, and a proposal, if appropriate in view of the outcomes of the study**

THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 241 thereof,

Whereas:

- (1) According to the definition set out in Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>, a '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. Lists of techniques complete this definition and specify the scope of that Directive. The definition and the lists of techniques have been drafted in the light of those breeding techniques that were available and used at the time of the adoption of Directive 2001/18/EC.
- (2) Since then, there has been substantial progress in the development of new breeding techniques, leading to uncertainty on whether those new breeding techniques come under the definition of a GMO and the scope of Directive 2001/18/EC or not and, as a consequence, whether products obtained by them should be subject to the obligations laid down in that Directive.
- (3) By its judgment in Case C-528/16 <sup>(2)</sup>, the Court of Justice, after considering the overall objectives of Directive 2001/18/EC, ruled that new mutagenesis techniques fall within the scope of that Directive and are subject to the obligations laid down therein.
- (4) The ruling brought legal clarity as to the status of new mutagenesis techniques, but also raised practical questions which have consequences for the national competent authorities, the Union's industry, in particular in the plant breeding sector, research and beyond. Those questions concern, inter alia, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, from products resulting from natural mutation, and how to ensure, in such a situation, the equal treatment between imported products and products produced within the Union.
- (5) The Council considers that a study is necessary to clarify the situation, in accordance with the Interinstitutional Agreement of 13 April 2016 on Better Law-Making <sup>(3)</sup>, and in particular paragraph 10 thereof on the application of Article 225 and 241 of the Treaty on the Functioning of the European Union,

HAS ADOPTED THIS DECISION:

## Article 1

The Council requests the Commission to submit, by 30 April 2021, a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law.

<sup>(1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(2)</sup> Judgment of the Court of Justice of 25 July 2018, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, C-528/16, ECLI:EU:C:2018:583.

<sup>(3)</sup> OJ L 123, 12.5.2016, p. 1.

*Article 2*

1. The Council requests the Commission to submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study.
2. In accordance with usual practice, the Council requests the Commission to ensure that the proposal is accompanied by an impact assessment.

*Article 3*

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 November 2019.

*For the Council*  
*The President*  
L. ANDERSSON

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