

Genome editing

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

5th Informal meeting, online, 4.11.2021

Brussels, 25.3.2022

The European Plant Science Organisation (EPSO) invited policy makers to join EPSO members in a 5th informal meeting exchanging views on the current situation of genome editing (GE) 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.

After an introduction, there was a tour de table: among participants from 17 countries and the European level were 17 scientists and 19 policy makers from governmental bodies. They discussed which steps could bring the discussion forward on the EU legislation and to facilitate potential flagships. The meeting was held under Chatham House Rules.

In the first part of the meeting, participants discussed the **current legislation: how it could be improved** in the short and in the longer term. A summary on the current situation and the European Commission's (EC) New Genomic Techniques (NGT) roadmap, called as well the 'Inception Impact Assessment', was given, along with views from the science and policy sides. Elements of risk analysis were discussed. The view was that the risk of *not* doing something should also be assessed.

Views from the various ministry participants were presented. These were placed in a wider perspective: In the UK, DEFRA held a consultation and received 7000 submissions, of which 50% were in favor of Genome Editing (GE). DEFRA will make a statutory instrument to make field trials easier than before. However, Scotland and Wales maintain a strict no-GE, no-GMO line. Norway is also not an EU member but is a member of the EEA, so needs to follow EU rules regarding GMO and GE. Therefore, Norway will likely wind up with rules that are consistent with the EU rules prevailing at the time. Regarding EU members, many said that they welcomed the Commission's roadmap, but that they now look to the EC for further action.

Several countries agreed with the EC's roadmap, that the current legislation has to be critically assessed, as it is outdated and no longer fit for purpose. One country maintains that there needs to be a proportionate risk assessment. The rationale for modernizing it is to protect human, animal, and plant health. Product based legislation, not method-based should be the principle. Some of these countries supported the roadmap, but had not made a submission to the process, due to their thorough involvement in various earlier phases of the process. There is a desire among the politicians for a more in-depth discussion of what is needed for the legislation. One suggestion was that GE and cisgenesis need to be excluded from the GMO legislation. Another one is hoping for a "future proofing" of the legislation.

In some countries, views are divided between ministries (welcoming the roadmap as a good starting point, favoring a revision of legislation for NGTs), between stakeholders (farmers are positive to GE, but there is reluctance from policy makers, while NGOs mobilized their supporters in opposition to

the roadmap and gave templates for public negative statements), or between regions (some regions responded positively to revising the GE legal framework).

The issue of “sustainability criteria” was discussed. One question was how to assess sustainability criteria for GE cultivars. Such an assessment should be proportionate (not so demanding that it discourages GE’s contribution to the EU Green Deal) and refer to all techniques and approaches, not just to NGTs; it would be better dealt with under the “Sustainable EU Food System new initiative” process. The two need to be interlinked.

It was **summarized** that the primary way forward is to: 1) engage with the EC to suggest ways forward to improve the legislation in Europe so that GE can be utilized to address climate change, environmental sustainability, and Food and Nutritional Security; 2) have more comprehensive communication and narratives that illustrate how GE can contribute benefits to society; 3) perform more national consumer surveys based, e.g., on the Norwegian questionnaire to compare appreciation of new technologies to address societal challenges across Europe.

In the 2nd part of the meeting, Flagships towards GE products and consumer surveys were discussed:

A brief discussion of the known national stakeholder and consumer surveys on GE was held, particularly those of Norway, Sweden, UK and Finland.

In the Swedish survey, 1000 responses were collected, the process being continued until that number was reached. This required 2000 surveys to be sent. The same was the case in Norway. One takeaway was that people want information on which breeding method was used to produce a food product. A big component of which sort of product was acceptable is the perception of risk. In essence, the traditional methods are more trusted by the public than are new (NGT) methods, but people appreciate the new technologies when used towards reducing pesticides, improving nutritional value for humans, and adapting to changing climates (drought etc.).

The published Finnish survey was a stakeholder survey, rather than one of consumers. The takeaway was that there is a lot of potential benefit seen, particularly for the forestry and agriculture sector and export markets thereof, but that industry will not take up GE until there is a different regulatory environment than currently, as well as consumer acceptance. Researchers in Finland see that expertise will move to areas where translational research and development with GE can be done, in practice meaning that innovations will take place outside and not inside the EU.

Participants were encouraged to consider a consumer survey in their respective countries similar to that made in Norway, and to use similar questions to those in Norway in order to facilitate comparison of the outcomes across Europe later on.

The ongoing projects and potential flagship products in the R&D chain were presented. Perhaps the nearest to market, based on available information, is the low-asparagine edited wheat developed in the UK, which greatly reduces acrylamide formation during baking or toasting. This has clear consumer benefits and can move towards market under the expected new regulatory regime in the UK.

Finally, IPR issues were shortly discussed. There was a brief mention that traits achieved by editing could be patented even if they could have occurred naturally. However, the patent application needs to state that they are “not essentially natural.” The question of how to simultaneously have plant breeders’ rights and open exchange while maintaining gene/trait patents was discussed. One solution would be a system such as for vegetable breeding, where there is easy access to patented lines, with arbitration if needed. The interfaces between patent law and PBR as well as with DSI and Cartagena, regarding GE, are worth examining. There will be an EMBO/EPSO workshop on the IPR question organized in January 2022.

Conclusions and actions

Participants agreed to continue the open dialogue between the science and policy participants from this meeting.

The 6th meeting will be held in May 2022 and will focus on a discussion about the EC consultation on their draft impact assessment of policy options. It will further discuss encouraging flagship projects towards genome edited products with consumer benefits for the European market and ensuring equal opportunities for all approaches to contribute to and to be combined to better address climate change, achieve food and nutritional security, and establish a sustainable agriculture in Europe and world-wide.

EPSO offers to collaborate with policy makers to develop appropriate future-ready regulations that 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 options retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.

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About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents around 200 research institutes, departments and universities from 32 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 References

EC:

- [High level event on "New genomic techniques – the way forward for safe and sustainable innovation in the agri-food sector"](#), 29.11.2021
- [Sustainable food system framework initiative – Inception Impact Assessment](#), 28.09.2021
- [Study on new genomic techniques](#), 29.4.2021
- JRC: <https://publications.jrc.ec.europa.eu/repository/handle/JRC121847> 29.04.2021

Court of Justice of the EU:

- Judgment in Case C-528/16, 25.7.2018. [EN Press Release](#); [Ruling in EN](#):
- Advocate General's Opinion in Case C-528/16, 18.1.2018. [EN Press Release](#); [Opinion in English](#)

EPSO on EC strategies, Food and Nutritional Security:

- EPSO concepts, research areas and their contributions to the EU Green Deal – the Farm to Fork and the Biodiversity Strategies – presented at the meeting
- [EPSO submission to the EC's consultation on the roadmap regarding the legislation for plants produced by novel genomic techniques \(NGTs\)](#), 25.10.2021
- Opinion paper: [Designing the Crops for the Future; The CropBooster Program](#) – mobilize the European plant research community and all interested actors in agri-food research and innovation to face the challenge, 30.7.2021
- [EPSO welcomes the European Commission's study regarding the status of novel genomic techniques \(NGTs\)](#) under European Union law, 30.4.2021
- EPSO: [Genome editing – Improving legislation and starting flagships to better address climate, environmental, food and health challenges](#), Report 3rd informal science and policy meeting, 16.2.2021
- EPSO: [Statement on the Draft Strategic Research and Innovation Strategy by the Biodiversity Partnership Consortium](#), 29.1.2021
- EPSO: [Online Workshop Implementing a Plants and Microbiomes Strategy in Europe, 13-14.1.2021 started, 13.1.2021](#)
- EPSO: [Statement on the Farm to Fork Strategy by the European Commission](#), 2.6.2020

Surveys

- The **Norwegian** Biotechnology Advisory Board (2020).
 - Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture. www.biotechnologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf
 - Questionnaire available upon request
- First outcome from the **Swedish** survey was presented at our meeting - link to the report (in Swedish): https://www.genteknik.se/wp-content/uploads/2022/02/Svenskars-installning-till-genomredigering_2022.pdf
- Survey on NGTs in **Finland**
 - report <https://julkaisut.valtioneuvosto.fi/handle/10024/163143> ;
 - Blog <https://www.vttresearch.com/en/news-and-ideas/it-time-introduce-new-genetic-techniques-europe-well>
- ETH study in **Switzerland**: Angela Bearth, ETH / CH
 - Saleh , R, Bearth, A, Siegrist, M ()2021) . How chemophobia affects public acceptance of pesticide use and biotechnology in agriculture. Food Quality and Preference 91, <https://doi.org/10.1016/j.foodqual.2021.104197>
 - The video of a workshop: https://geneticresearch.scnat.ch/en/events/uuid/i/4b5f727d-b532-5e04-8b79-02f4ad2fd78c-CRISPR_and_food_production

Please refer to the Annex II and III o the [2nd meeting report](#) for

- Regulations and obligations for conventional breeding and variety testing
- Regulations and obligations for GMO breeding and testing in the EU.