Report



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

Informal meeting in Brussels 19.9.2019

Brussels, 30.9.2019

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

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

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

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

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

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

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

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

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

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

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

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

## Actions:

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

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

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**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. <a href="https://epsoweb.org">https://epsoweb.org</a> EU Transparency Register Number 38511867304-09

## Annex Supporting literature - links

- EPSO statement (endorsed by all EPSO Representatives for 197 institutes / universities), 19.2.2019: <a href="https://epsoweb.org/download/epso-statement-on-ecj-ruling-regarding-mutagenesis-and-gmo/">https://epsoweb.org/download/epso-statement-on-ecj-ruling-regarding-mutagenesis-and-gmo/</a>
- EPSO welcomes Commissioner Andriukaitis statement and call for action 'New plant breeding techniques need new regulatory framework', 29.3.2019: <a href="https://epsoweb.org/epso/epso-welcomes-commissioner-andriukaitis-statement-and-call-for-action-new-plant-breeding-techniques-need-new-regulatory-framework/2019/03/29/">https://epsoweb.org/epso/epso-welcomes-commissioner-andriukaitis-statement-and-call-for-action-new-plant-breeding-techniques-need-new-regulatory-framework/2019/03/29/</a>
- VIB statement (including signatories for 109 institutes / universities and 18 associations), 25.7.2019:
   <a href="http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20ed">http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20ed</a>
   iting%20for%20sustainable%20agriculture%20and%20food%20production%20in%20the%20EU.aspx
- Open letter from Swedish Vice chancellors of Umea University and representatives from funding agencies, 25.7.2019: <a href="https://www.upsc.se/documents/News/News">https://www.upsc.se/documents/News/News</a> 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
- o Grow scientific progress: crops matter! European citizen initiative, 25.7.2019: https://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2019/000012/en
- Statement by the Group of Chief Scientific Advisors, 13.11.2018: https://ec.europa.eu/info/sites/info/files/2018 11 gcsa statement gene editing 2.pdf
- Bratlie et al. 2019: A novel governance framework for GMO. EMBO Reports (2019) 20: e47812; DOI 10.15252/embr.20194781 [Suggestion from Norway to modify legislation on genetic engineering] http://www.bioteknologiradet.no/filarkiv/2019/03/2019-04-16-Genteknologiloven-komplett-ENGELSK-siste.pdf
- Paper from the NL suggesting the modifications in the Annexes of 2001/18/EC prior to the ruling, 21.3.2019:
  <a href="https://www.cogem.net/index.cfm/nl/publicaties/publicatie/voorstel-voor-aanpassing-van-de-vrijstelling-in-de-ggo-regelgeving-aanvullende-criteria-voor-het-vrijstellen-van-gg-planten?order=relevance&g=&category=&from=30-09-1998&to=21-03-2019&sc=fullcontent</p>
- 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: <a href="https://cdn.website-editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/AFBV-WGG-Statement.pdf">https://cdn.website-editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/AFBV-WGG-Statement.pdf</a>