

MEETING WITH EUROPABIO

4 September 2019, 17h00

CAB Meeting Room

1. GENERAL SCENE SETTER

- ❖ **The context:** On 4 September, you will meet the Board of Directors of CropLife International. CropLife International is the federation representing the plant science industry at global level and a worldwide network of associations. Bringing together private companies and national and regional associations, it aims at advocating for agricultural innovations in crop protection and plant biotechnology with a view to support and advance sustainable agriculture. CropLife representatives would like to exchange views on how to address key challenges at EU and global level, such as science-based decision-making, sustainability and biotechnologies.
- ❖ **The participants:** You will be meeting the members of CropLife Board of Directors. CropLife International member companies conduct innovative research and provide high technology solutions for seeds, plant biotechnology, crop protection and non-agricultural pest control. The delegation will be headed by the representatives of EuropaBio, the European association of bio-industries. The latter is itself a member of CropLife. A detailed list of the delegation members is in annex.
- ❖ **Our main messages:** The European Commission is tailoring regulatory responses to the call expressed by the society for more sustainable crop production/protection practices. Research-based companies such as the ones represented by CropLife International should focus their research efforts to provide solutions fitting with integrated crop and pest management practices. Challenges such as food safety and security, climate change and protection of the environment are calling for innovative crop varieties, e.g. through new breeding techniques, and for more sustainable crop protection practices (e.g. robotics, sensors) and products (e.g. microbial pesticides).

2. BIOTECHNOLOGY

Speaking Points

- Biotechnology has the potential to make our agri-food systems more resilient and sustainable. These are very relevant challenges.
- However, there is a lot of mistrust among EU civil society about genetic engineering. People talk about Frankenstein food and risks to the environment. New techniques are associated to increased productivity only and are not perceived as contributing to addressing climate change or reducing the use of pesticides
- This is why the use of new techniques must be translated into recognised benefits for EU society – particularly in the food area – if it is to yield public support.
- Throughout my time in office, I have said time and again that we need to speak to citizens about science, about technologies and about risk, using their language. We have to include citizens in our journey towards innovation.
- I would like to hear how you see the future of mutagenesis techniques and why - from your perspective - new techniques are important for EU citizens.
- I also encourage you to actively inform policy makers (both EU and national) on the impact of the Court ruling on the EU biotech industry - Have you already discussed the matter with the Member States authorities? What kind of feedback have you received?
- I would like to invite you to submit to Commission services substantiated information on the real and potential impacts of the Court ruling on your members.
- As you are aware, any new policy or action in this field will be for the new Commission to take forward. But it will be a very difficult decision, where the main question will be: does civil society agree that these techniques can be helpful in the context of climate change, pressure on the environment?

Background

The Court of Justice of the European Union (CJEU) ruling on mutagenesis

The Court of Justice of the European Union (CJEU) ruling of 25 July 2018 stated that Directive 2001/18/EC on deliberate release of GMOs is applicable to organisms obtained by new mutagenesis techniques.

Based on the interpretation provided by the CJEU, the French *Conseil d'Etat* has still to provide a judgement on a case submitted by a French agricultural union and eight associations related to mutagenesis and herbicide-tolerant rape varieties. The timing of the *Conseil d'Etat* judgment is unknown.

The Commission services have discussed the implementation of the Court ruling with Member States experts in several Standing Committee meetings. The Commission invited Member States to submit information on the challenges that they are facing in the implementation and enforcement of the GMO legislation as the Court has interpreted it.

Position of CropLife International

CropLife International has not issued a statement on the Court ruling on mutagenesis. However, in November 2018, CropLife International issued a statement to commend those governments that supported the International Statement on Agricultural Applications of Precision Biotechnology (<https://croplife.org/wp-content/uploads/2018/11/CLI-Statement-WTO-Precision-Biotechnology-2018-FINAL.pdf>). The statement was presented by Argentina in the World Trade Organisation Sanitary and Phytosanitary Committee meeting in early November and was co-signed by nine other countries including the US, Brazil and Canada. These countries acknowledge that precision biotechnology has a critical role in addressing challenges in agricultural production and governments should avoid unjustifiable distinctions when new techniques lead to products that can also be obtained with conventional methods. They call for minimizing unnecessary barriers to trade and exploring opportunities for regulatory and policy alignment.

Position of EuropaBio

On 29 November 2018, EuropaBio published a statement warning that the CJEU ruling will cause European life science innovation to come effectively to a halt. This would hinder the EU sustainability and competitiveness from the delivery of innovative bio-based products to sustainable food and certain healthcare solutions. EuropaBio calls for science-based, predictable and proportionate rules, instead of disproportionate regulatory requirements, when the very same product obtained with new mutagenesis could also be obtained through conventional breeding, classical mutagenesis or result from spontaneous processes in nature.

On 16 January 2019, the [REDACTED], underlined in an interview that Europe is lagging behind on breakthrough technologies, especially in the field of agricultural biotechnology. She believes that Europe can still become a world leader in the global knowledge economy if it takes action now. She proposes the following: 1) EU leaders must recognise that scientifically unjustifiable regulatory burdens have contributed to the EU's loss of competitiveness and to frictions with trading partners; 2) the EU needs a proportionate, fit-for-purpose and science-based approach to modern technologies, which reflects technical progress.

Views of the Member States

Several Member States' competent authorities have expressed at technical level the need to adapt the GMO legislation to technological progress. However, so far, only the Netherlands has adopted a formal government position. The Netherlands considers that further clarification is needed on how to implement the ruling of the EU Court of Justice. They call for a debate on the future of EU biotechnology policy and how to adapt it to technical and scientific progress.

Upon request of the Netherlands, the AGRIFISH Council of 14 May discussed this topic under any other business. 15 Member States intervened, all of them supporting – to various degrees – a debate at EU level to achieve common interpretation of the current provisions and/or to pave the way for their future modification. In addition, several Member States explicitly requested the next Commission to work on this issue.

The Finnish Presidency is organising a meeting on 6 September at the attaché level to discuss the initiative to invite the Commission to work on new breeding techniques.

ENGL report on detection of food and feed plant products obtained by gene editing techniques

The European Commission mandated the European Union Reference Laboratory to elaborate, together with the European Network of GM Laboratories, a report on the challenges to detect food and feed plant products obtained by gene editing techniques.

The report was published on 26 March 2019 and acknowledges that there are challenges to develop detection methods for some gene-edited plants. The report is based on theoretical considerations and not on experimental evidence. The identified issues will require further consideration.

The Commission has also asked EURL to address the analytical challenges for gene-edited microorganisms and animals. Outcome of this work is expected in the coming months.

Mandate to EFSA on new mutagenesis techniques

The Commission has recently mandated EFSA on the hazards and the adequacy of existing risk assessment guidance for plants developed through certain gene editing techniques. EFSA is asked to assess whether the conclusions of a previous EFSA opinion on a similar group of techniques are applicable to these plants. The outcome is expected by April 2020.

European Group on Ethics in Science and New Technologies (EGE)

EGE is preparing an opinion on gene editing which is expected by end of 2019.

The request for this opinion was made by Commissioner Moedas in July 2018. The request covers agriculture, health and environment. Specific aspects of concern relate to gene editing applied to animals and in the context of biodiversity and ecosystems. Precise scoping of the opinion is left to EGE.