

Contribution to briefing for visit of Commissioner Andriukaitis to INRA centre in Versailles on 19-09-2019 (CAB ANDRIUKAITIS 1383)

NEW BREEDING TECHNIQUES

Speaking Points

- Biotechnology has important potential to make our societies and systems more resilient and sustainable. These are very relevant challenges.
- I would like to hear how you see the future of biotechnology in the EU and why - from your perspective - new techniques are important for European citizens.
- I also encourage you to continue communicating with policy makers (both national and EU) on the future of EU biotech research.
- As you are aware, any new policy or action in this field will be for the new Commission to take forward.
- I am very interested in hearing your experience on this topic. I have heard about your 2012 multidisciplinary project GENIUS (Genome Engineering Improvement for Useful plants for a Sustainable Agriculture), which showed challenges in the dialogue between biotechnologists and social scientists. I would be interested to hear about your experience and the challenges you have identified.
- I understand that you also carried out in 2018 a reflection on ethical, legal, societal and economic considerations. Would you also expand on your suggestions or recommendations on these aspects?
- Would you have practical examples of applications of modern biotechnologies, which could provide societal benefits?

- And what is your view on the real and potential impacts, positive and negative, of modern biotechnologies on our society?

Issue/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 the 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 INRA

INRA has developed a strategy on the use of new plant breeding technologies aiming to address scientific, regulatory and ethical challenges. This strategy, based on six major principles, aims at maintaining a high level of expertise on biotechnologies, considered as essential technologies for building knowledge and understanding of the living world. INRA considers that assessing the possibilities offered by new techniques, in addition to traditional tools, is legitimate to produce traits for the common good and to promote environmental, economic and social sustainability, for instance to reduce the use of synthetic pesticides or adapt to climate change.

INRA is committed to the principle of open research and supports multi-disciplinary and multi-stakeholder research in the area of new plant breeding techniques. INRA also defends freedom of access to all genetic resources and the non-patentability of plants derived from mutagenesis techniques.

From an internet search it appears that in March 2018, the Ethical Committee of INRA, CIRAD (the French agricultural research and international cooperation organization working for the sustainable development of tropical and Mediterranean regions) and Ifremer (the French Institute of Research for exploitation of the sea) issued an opinion on environmental, economic and ethical aspects related to the use of new breeding techniques.

In 2012, INRA and CIRAD started a multidisciplinary research project named GENIUS (Genome Engineering Improvement for Useful Plants for a Sustainable Agriculture), which included 10 public laboratories and 4 private partners. The project showed challenges in the dialogue between biotechnologists and social scientists.

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.

On 6 September 2019, at an attaché meeting, the Presidency of the Council tabled a draft Decision, based on Article 241 TFEU, requesting the Commission to submit a study in light of the CJEU's judgement regarding the status of new breeding techniques under Union law. Several Member States supported the Presidency's proposal. The Presidency's objective is to have this Council Decision adopted by the Council in a forthcoming meeting.

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

The European Commission mandated the European Union Reference Laboratory (EURL) 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 the 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 sent to EFSA a mandate on the hazards and the adequacy of existing risk assessment guidance for plants developed through certain mutagenesis techniques. EFSA has been 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 to be published by end of 2019.

Commissioner Moedas requested this opinion 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.