“Risk and Reward: A new era for Agri-Food”	13/09/2019 09:30 Kilkenny, IRELAND

Scene Setter

You will address the Agricultural Science Association’s annual conference and should expect to address a whole list of different (AGRI and non-AGRI) issues:

- [redacted]
- [redacted]**/gene editing/**[redacted] These themes are (also) covered by targeted defensives and background.
- [redacted]
- [redacted]

This briefing provides key messages on the above listed issues (where possible, they have already been integrated in the narrative on the CAP reform) which is intended as an input for the speech. Defensives and background are intended as actual “briefing” part (To facilitate the use a) [redacted]/gene editing/[redacted] defensives, covering political sensitive issues, have been grouped and put in the beginning of the defensives [redacted] and b) the background has been kept concise.)

- [redacted]
- [redacted]
- New Breeding techniques, especially CRISPR, promise faster achievement of pathogen resistant crops that need less pesticide.

<u>NBT: Implications of ECJ ruling</u> of July 2018 on the regulatory status of products derived from gene editing and the implications for the GMO Directive?

- Based on the Court ruling, the GMO legislation does apply to organisms obtained by **new mutagenesis techniques**. The clarification provided by the Court is binding and does not require amending the GMO legislation.
- The Commission is discussing with the national competent authorities to ensure proper implementation of the ruling.
- I encourage all relevant stakeholders to contribute to the dialogue on potential risks and benefits of products developed through new breeding techniques and provide concrete examples of practical applications. This may facilitate genuine and open discussions and allow illustrating different views.
- The European Commission promised to come up with **a "robust response" to the EU court ruling,** and the new Commission will take initiative**.**

[redacted]

[redacted]

- [redacted]
- [redacted].

[redacted]

New Breeding Techniques

***Court ruling on new mutagenesis techniques*:** The Court of Justice of the European Union stated in its ruling of 25 July 2018 (Case C-528/16) that:

- **Directive 2001/18/EC on deliberate release of GMOs is applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption** ("new mutagenesis techniques" of **directed mutagenesis**, including those commonly known as **'gene editing techniques' (e.g. CRISPR/Cas9**).

- Organisms obtained by conventional mutagenesis[1] are excempted.

Following the CJEU ruling on mutagenesis, the **Group of Chief Scientific Advisers** of the ***Scientific Advice Mechanism (SAM)*** released a **statement**[2]**:**

- From the time of the adoption of the GMO Directive until now, extensive scientific evidence has been accumulated on spontaneously occurring genetic alterations, including point mutations, insertions, deletions and rearrangements of the genome, as well as the acquisition of exogenous genetic material across species. **New scientific knowledge and technical developments have made the GMO legislation no longer fit for purpose**.
- **The GMO Directive should be revised to be clear, evidence-based, implementable, proportionate and flexible enough to cope with future advances in science and technology in this area**. This revision should take place as part of a broad dialogue with relevant stakeholders and the public at large.
- SAM advocates for **a more inclusive discussion on how food is produced in the EU**. Ethical, legal, societal and economic considerations are also important. There is a need for providing robust and independent evidence to the Court in a systematic and transparent way.
- Mutations occur naturally / spontaneously without human intervention.
- The concept of 'naturalness' should be based on current scientific evidence of what indeed occurs naturally, without any human intervention, in organisms/ in their DNA.
- Compared to random mutagenesis, gene-editing results in much fewer unintended changes and thus fewer unintended effects and better characterised products.
- Unintended effects are not necessarily harmful they need to be addressed case by case.
- Gene editing can introduce mutations that are identical to those occurring spontaneously or through random mutagenesis. It is impossible to provide a universal detection method meeting the regulatory standards.
- The features of the final product itself must be examined regardless of the underlying technique used to generate that product. **The safety of a product depends on its features rather than the technique used.**

Reactions

Europe could lose its competitive edge in sustainable food production if the EU does not rethink its rule on genome editing crop plants.

Researchers across the EU have issued calls for the ban to be lifted. Research institutes from across Europe are calling on the EP and the European Commission to enable Europe to compete in sustainable food production and keep up with the speeding pace of innovation in agriculture. They want **to reverse the ECJ ruling that modern precision genome editing** - which does not rely on introducing DNA from other species - is nevertheless subject to the 2001 directive banning genetically modified organisms (GMOs). In a statement issued one year after the ECJ decision, researchers at 120 institutes around Europe said the EU's ban "no longer correctly reflects the current state of scientific knowledge." Scientists should be allowed to use precision genome editing, such as CRISPR/Cas, which is, in effect, a speeded-

[1] Conventional mutagenesis is often referred to as 'random mutagenesis' or 'traditional mutagenesis'

[2] https://ec.europa.eu/info/sites/info/files/2018_11_gcsa_statement_gene_editing_2.pdf

up equivalent of traditional breeding techniques. New EU legislation is needed to enable farmers to use this new technology, to produce higher yields while decreasing the use of chemicals and water, the researchers say.

According to scientists, using **CRISPR** to modify **plants to cope with higher temperatures and drought** can help in dealing with climate change. Plants would need **less chemicals and water.** Genome editing can **improve the nutritional content of food, contribute to food safety, increase yields** and **promote sustainability in agriculture**. To develop these varieties, scientists and plant breeders must have access to the widest possible array of breeding tools. The most recent addition to the toolbox is precision breeding with CRISPR. It allows scientists and breeders to develop desired crop varieties in a faster, relatively simple and much more directed way compared to previous breeding techniques.

Organic association IFOAM is pressing the European Commission to "maintain and correctly implement" the EU GMO registration Directive (2001/18) as interpreted by the EU court last year as covering products derived from new mutagenesis techniques. IFOAM argues that it is crucial to ensure that risk assessment, traceability and labelling apply to all GMOs and all genetic engineering techniques. Commercialisation of GM crops without assessment would make it "almost impossible" for organic and conventional GMO-free farmers to exclude the presence of GM material in their production process. They are strictly against any attempt to exclude plants modified with new breeding techniques (NBTs) from current EU legislation on genetically modified organisms (GMO).

The **US, China, Japan, Brazil and Australia** deem gene edited foods as safe. Scientists warn Europe could lose its competitive edge if the ECJ ruling is not overturned, as cutting-edge research in gene editing for agriculture would be pushed outside Europe. “

Boris Johnson promised to liberate UK bioscience from EU rules on genetically modified crops, if and when the UK leaves the EU.

Can the ECJ ruling be enforced?

There are also **questions about whether the EU can police the rule**, because unlike GMOs that contain foreign DNA, plants and animals modified using CRISPR contain only DNA that occurs naturally. Industry and scientists have pointed out that it is not possible to detect whether small alterations in plants are the result of precision breeding techniques, such as gene editing, or if they have arisen spontaneously in nature. Therefore, the court's ruling is impractical, as it could not be enforced on imported or domestic commodities, they argue.

The problem was acknowledged in March, when a **report from the European Network of GMO Laboratories** concluded the analytical methods they use to detect conventional GMOs cannot be applied to genome edited products.

A European Citizens Initiative petition seeking to revise Directive 2001/18[3] so that risk assessments focus on the product rather than the breeding technique opened in July to collect signatures.

[3] Grow scientific progress: crops matter!, ECI(2019)000012, Date of registration: 25/07/2019. Once formally registered, an ECI allows 1 million citizens from at least 7 of the MS to invite the European Commission to propose a legal act in areas where the Commission has the power to do so. The conditions for admissibility are that the proposed action does not manifestly fall outside the framework of the Commission's powers to submit a proposal for a legal act, that it is not manifestly abusive, frivolous or vexatious and that it is not manifestly contrary to the values of the Union.

At the **Agricultural Council in May 2019**, [redacted]

Decision-making

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The European Commission promised after the Agriculture Council that it will come up with **a "robust response" to the EU court ruling** and **draft a legislative proposal** in due time. DG SANTE "has already prepared the ground for a new initiative on gene editing to overhaul the current GMO legislation". The new Commission will take up the "initiative".

Several EU Ministers are considering **a proposal to ask the European Commission to present the "options for addressing the legal situation" of new breeding techniques (NBTs) for plants** (planned for 6 September 2019 Council Working Party).

[redacted]

[4] [redacted] Decision-making