

<p>Meeting of the Scientific Advice Mechanism (SAM Group of Chief Scientific Advisors) with Commissioner Hogan and Commissioner Moedas</p> <p>[Out of scope]</p> <p>[Out of scope]</p> <p>New breeding techniques</p>	<p>04 December 2018</p>
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Scene Setter

- You will speak to representatives from the Scientific Advise Mechanism (SAM). SAM is currently composed of seven members representing the areas of particle physics, bioinformatics, human genetics, sociology, political sciences and material sciences.
- SAM has prepared
 - at the request of DG SANTE: an explanatory note on New Techniques in Agricultural Biotechnology (publication February 2017)
 - at the request of SANTE: a scientific opinion on the Authorisation Processes of Plant Protection Products in Europe (May 2018)
 - at own initiative: a scientific opinion on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive in response to the European Court of Justice Decision (ECJ) of July 2018 (November 2018).
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- SAM representatives asked to explore your view on
 - [Out of scope]
- SAM's previous work on plant protection products and new breeding techniques. They will in particular ask your views in relation to the opportunities offered by new breeding techniques to balance stricter rules on approval on pesticides and challenges in relation to global food security. SAM would like his particular support for its recommendation that the GMO Directive should be revised following the ECJ ruling.

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 - | [Out of scope] [Redacted]
 - | [Out of scope] [Redacted]
 - | [Out of scope] [Redacted]
- On 2: SAM opinions on plant protection products, breeding techniques
 - The issues will give you the opportunity to focus instead on the opportunities offered by the new CAP proposal as regards comprehensive solutions for the future of food and farming systems and rural areas
 - It would be important to stress that a market oriented agricultural production should take into account societal expectations in addition to the scientific/technological dimension.
- [Out of scope] [Redacted]

[Art. 4.1 (b) - privacy]

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Commissioner's Hogan view with regard to SAMs view on the ECJ ruling and gene editing

- This is a policy area for which Commissioner Andriukaitis is better placed than me to answer. However, it is clear the ruling of the ECJ needs to be taken into account in the implementation of current provisions.
- For the time being, I am aware that the European Reference Laboratory for Genetically Modified Food and Feed and the European Network of GMO laboratories will elaborate a report on the current and future possibilities and limitations regarding the detection of food or feed obtained by new mutagenesis techniques. The report should be finalised by March 2019.
- All technological developments may offer opportunities for increasing the competitiveness hedge and doing better. However, all these need to be considered in a holistic way and long term, including societal expectation on the future of the CAP. Breeding is an important tool but needs to be seen in the overall context of production, farming systems, consumer demand or the access to breeding innovations (IP rights).
- Therefore, a market oriented agriculture focuses on a production in line with market expectations.

- Is it important to underline that the adopted proposal for the future of the CAP is providing a very open ended and comprehensive path for development: enhanced FAS, precision farming, training, digitalisation, more flexibility for MS for tailoring appropriate measures at local level, answering societal demands.

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Second key messages (defensive points)

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Potential question: What are Commissioner Hogan's views on the implications of the ECJ ruling ODoes Commissioner Hogan supports the SAM recommendation to revise the GMO legislation?

- GMO legislation is managed by my colleague Commissioner Andriukaitis. From my side I can only underline that since many year the CAP is no longer encouraging productivity in isolation. Today the CAP is market and societal oriented and farmers know that they have to take into account first societal expectations, to secure their long-term markets.

Potential question: Does Commissioner Hogan consider that gene editing can contribute to food security in the context of a growing world population and climate?

- There are no single silver bullet solutions to ensure Food security or adaptation to climate change. Instead we need a range of tools and approaches to be adapted to the variety of conditions. In this context it should be recalled that breeding and breeding technologies are important components of the toolbox. But breeding innovations should not be seen in isolation from the overall context of production, including farming systems, consumer demand or the governance and access to breeding innovations (IP rights). Similarly, technological innovations need to be matched by organizational, social and policy innovations.
- We see currently that food and nutrition security is not merely a matter of production. It is very much linked to distribution and access as well as to consumption patterns and behavior.

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Background

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NEW BREEDING TECHNOLOGIES

1) The French Council of State (Conseil d'Etat) has requested a preliminary ruling of the Court of Justice of the European Union (CJEU) to clarify:

- Whether organisms obtained by means of new mutagenesis techniques are exempted from the obligations of the GMO legislation.
- Whether Member States can regulate exempted organisms.
- Whether the validity of Directive 2001/18 can be called into question by the development of new mutagenesis techniques.

The CJEU reached the following conclusions:

- Firstly, the Court of Justice has clarified that organisms obtained by mutagenesis techniques/methods which have been conventionally used in a number of applications and that have a long safety record are exempted from the obligations of the GMO legislation. Therefore as mentioned by the Court, the GMO legislation is applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption.
- Secondly, the Court of Justice has also clarified that Member States are free to regulate exempted organisms and can subject them to the obligations laid down by the GMO Directive or to other obligations, provided that the measures adopted comply with EU law and in particular the rules on the free movement of goods.
- Finally, regarding the validity of the Directive, the Court of Justice notes that this question was only relevant in the case that all organisms produced by mutagenesis were excluded (which it is not the case on the basis of the Court ruling).

2) With reference to the CJEU ruling the **GROUP OF CHIEF SCIENTIFIC ADVISORS** issued within the Scientific Advice Mechanism (SAM) its Statement from the **Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive** (13 November 2018)

Important points raised

- New scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose
- The definition of a GMO indicates that in a GMO the genetic material is altered in a way that does not occur naturally by mating and/or natural recombination.
- This notion of naturalness can be challenged because random mutagenesis is usually more drastic than those resulting from gene editing techniques because these do not carry unwanted features.
- Targeted mutagenesis is more efficient and can speed up the generation of desired varieties
- Product characteristics are more important for safety assessments than the method used for their production. This should be a central part of the GMO legislation
- Products produced by direct mutagenesis cannot be distinguished from the ones occurred spontaneously.

Consequences identified by SAM

- The current applicable GMO Directive implies cost and labour-intensive pre-market evaluations.
- Traceability is difficult/impossible. Exporting countries market varieties they have decided not to regulate.
- Positive outcomes of gene editing for conservation, protection of biodiversity etc. are hampered.

3) On 22. November 2018, CAB Hogan received Rene Custers, Regulatory and Responsible Research Manager, of VIB, a Gent based Research Institute

Points raised by VIB:

- A vast array of knowledge about genes and genomes and their functioning had been gathered in the past years. This knowledge could be exploited by the CRISPR technology. However the Court ruling would slow down or stop certain initiatives mainly for small and medium sized companies. Only large internationals could stem the onerous pre-market evaluations as requested by EU GMO legislation. This is why they consider products produced by gene editing when introducing small amendments into the genome without foreign genetic material not being a GMO. GM labelling would be avoided.
- According to VIB such products could also be obtained by conventional techniques but to a lower speed and with higher safety concerns as unintended genetic amendments occur. The example of the pink flesh grapefruit was given. When this fruit is produced by traditional mutagenesis it is exempted from the GMO legislation. When it is produced by gene editing it is a GMO. Both fruits would be in the shelf but one would have to be labelled as GMO the other not.
- VIB is e.g. working on maize varieties with larger leaves which makes them more robust and secures harvests also under less favourable conditions. Other applications could be envisaged e.g. disease tolerant vine varieties which would not loose variety rights etc.
- Product characteristics are more important for safety assessments than the method used for their production.
- Products produced by direct mutagenesis cannot be distinguished from the ones occurred spontaneously and this leads to problems in international trade. Exporting countries market varieties they have decided not to regulate. The EU is the second biggest importer of agricultural products.
- Gene editing creates new varieties which can be used in the breeding process and would enhance biodiversity by enlarging genetic variety.
- On the initiative of the VIP, 100 research centres within the EU have signed up to a position paper.

Request by VIB:

- Small genetic changes introduced by gene edition with no-foreign genetic material shall not be considered GMO
- The definition of GMOs as contained in the Cartagena Protocol to which also the EU signed up should be applied in the EU.

The **Cartagena Protocol on Biosafety to the Convention on Biological Diversity** defines a living modified organism'(GMO) as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

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