

Contribution to the briefing for the Director-General of DG SANTE for a meeting with five NGOs - IFOAM EU, GREENPEACE, ARCHE NOAH, FRIENDS OF THE EARTH EUROPE and VIA CAMPESIN, on 27.11.2019 (SANTE 4927)

New genomic techniques

State of play/background information

IFOAM EU, Greenpeace, Friends of the Earth Europe, Arche Noah and Via Campesina have been co-signatories, together with other NGOs, of an **open letter** to Vice-President Katainen on 22 May 2019 asking that during the preparations of the next work programme, the Commission ensures that the ECJ ruling is actively implemented and that newer generation of GMOs, and new techniques with no long safety record, are regulated as GMOs under the current legislation. (The open letter and DG SANTE's reply are annexed to this briefing.)

On 7 November 2019, IFOAM EU published a **press release** asking immediate action by the Commission and national authorities to ensure traceability of organisms obtained by new techniques, to develop detection methods and strategies to identify unknown genome edited products. They are concerned that the **Council study** could stall the implementation altogether, leaving European farmers, the food industry and consumers exposed to non-approved GMOs. They are against a legal proposal that would exempt the new genetic engineering techniques from the risk assessment, traceability and labelling requirements that apply to GMOs. They also ask that rapeseed and soybean imported from the US and Canada are certified as free from new unauthorised GMOs. Member States should be instructed to carry out necessary controls.

Implementation of the ECJ ruling, with an emphasis on the development of detection methods and strategies

No new developments since the last briefing on this topic.

Mandate to EFSA on new mutagenesis techniques

The Commission has mandated EFSA to assess the hazards and the adequacy of existing risk assessment guidance for plants developed through certain new mutagenesis 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.

EGE open roundtable discussion

The **European Group on Ethics in Science and New Technologies (EGE)** organised on 16 October 2019 an open roundtable discussion on the ethics of gene editing. The event brought together stakeholders from academia, industry, policy and civil society, to discuss the ethical questions raised by recent developments in gene editing, across all domains of application including human health, agriculture, and the environment. This discussion will feed into the report of EGE on gene editing, expected to be finalised in early 2020. Greenpeace [REDACTED] and Friends of the Earth [REDACTED] attended the event. DG SANTE was not consulted nor invited to the event.

Draft Council Decision on a study Article 241 of TFEU

On 8 November 2019, the Council adopted a Decision, based on Article 241 TFEU, requesting the Commission to submit a **study** regarding the status of new breeding techniques under Union law and in light of the CJEU's judgement by 30 April 2021. The study should be followed by a proposal and an impact assessment, if appropriate. DG SANTE has set up an Inter-service Steering Group to discuss the organisation of the work. The final content of the study is for the next Commission to decide on as well as any policy action based on its outcome. Targeted stakeholder consultations are also envisaged.

Lines to take

- Inform that the Commission has had several discussions with Member States on the implementation of the current legislation as the Court has interpreted it.
- Recognise that the traceability of some organisms produced with new techniques creates challenges.
- Inform that DG SANTE mandated the European Reference Laboratory to elaborate a series of reports on the detection of products obtained by new mutagenesis techniques. The first report on plants was delivered in March this year. The work continues on microorganisms and will be followed by animals and animal products.
- Recall that operators in and outside the EU are responsible for ensuring that all products placed on the market are safe and comply with the relevant regulatory requirements. Member States are responsible for enforcement and controls.
- Note that the Commission has encouraged Member States to further liaise with stakeholders to understand their concerns and needs and to monitor the evolution of the technological progress.
- Inform that the opinion from EFSA on the hazards and the adequacy of existing risk assessment guidance for plants developed through certain mutagenesis techniques is expected to be finalised by the end April 2020. This is complementary work to previous EFSA opinions from 2012.
- Clarify that the work on gene editing by the European Group on Ethics is supported by DG Research. Acknowledge that the stakeholders were consulted on this work and that their views will feed into the report of the Group.
- Enquire whether the participants see any advantages in new techniques in tackling societal challenges as compared to conventional breeding or conventional GMO techniques, in particular in the agri-food sector.
- Inform that concerning the study the Council has requested from the Commission, SANTE will need substantiated views of the stakeholders on this topic, including from the five organisations now visiting SANTE. Consultations are planned for early 2020.

- Stress that the actual content of the study is not yet decided. Confirm that any potential policy action in this field as a follow up to the study will be assessed a later stage by the new Commission.

