PROPOSAL ON REGULATION ON PLANTS OBTAINED BY CERTAIN NEW GENOMIC TECHNIQUES AND THEIR FOOD AND FEED

-5 JULY 2023-

A new initiative in an highly regulated sector

- All seeds put on the market follow strict **registration** and **certification** processes, with distinctiveness, uniformity, stability and Value for cultivation and use to be proven.

- At EU level, the seed sector is regulated mainly via the Directive on the common **catalogue of varieties** of agricultural plant species as well as **more than 10 sectoral directives** (beets, cereals, fooderplants, forest material, fruit plants, oil and fiber plants, ornamental plants, potatoes, vegetables, wine).

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A new way of doing an old job: improving agriculture via improved plants

Faster, and more targeted

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Much-awaited text: a long story

- July 2018 : EU **Court of Justice**: *"organisms produced by targeted mutagenesis are GMOs"*
- November 2019: the Council requests the Commission to prepare a **study on the status of NGTs** under EU law.
- May 2020: **Farm to Fork Strategy**
- April 2021: The EC study recognizes that plants obtained from **NGTs have the potential to contribute to the objectives of the European Green Deal** and in particular to the Farm to Fork and Biodiversity Strategies and the United Nations' Sustainable Development Goals (SDGs) for a more resilient and sustainable agri-food system.
- Sept – Oct 2021: EC Road map
- April –July 2022: EC Public Consultation

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Objectives of the proposal

General objectives

- Maintain a high level of protection of **human and animal health** and of the **environment**, in accordance with the **precautionary principle**;

- Enable the development and placing on the market of plants and plant products contributing to the **innovation and sustainability objectives of the European Green Deal** and of the Farm to Fork and Biodiversity strategies;

- Ensure the effective functioning of the internal market and enhance the **competitiveness of the EU agri-food sector** at the EU and global level, providing a level-playing field for its operators.

Specific objectives

- Procedures for the deliberate release and placing on the market ensure that **NGT plants and their food and feed are as safe** as their conventional counterparts, while not entailing **unnecessary regulatory burden**;

- Deliberate release and placing on the market of NGT plants and their food and feed that feature a wide range of **plant species and traits by various developers**;

- NGT plants released or placed on the market feature traits that can **contribute to a sustainable agri-food system**.

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Scope of the proposal

Plants obtained by targeted mutagenesis, cisgenesis and intragenesis (hereinafter, 'NGT **plants**', therefore not animals), but not by other new genomic techniques. Such NGT plants do not carry genetic material from a non-crossable species. The use of new genomic techniques introducing genetic material from a non- crossable species (transgenesis) should remain subject to the current GMO legislation

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2 CATEGORIES OF NGTs

- Plants obtained through targeted mutagenesis or cisgenesis, which could also *occur naturally or be produced through conventional breeding* ('**category 1 NGT plants**') would be treated similarly to conventional plants – no foreign material.
- All plants from NGTs that do not fall under the first case are called **category 2 NGT plants'** and **would fall under GMO legislation and therefore undergo an authorisation process**.

Criteria in Annexe 1 which can be modified by delegated acts

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Category 1, NGT plants – equivalent to conventional

If notification takes place prior to field testing, **verification** of the criteria takes place at Member State level and the national decision has EU-wide effect and also applies to placing on the market.

For placing on the market where no field trials have been carried out in the EU, including imports, the decision is taken by the Commission, following verification of the criteria by EFSA. The competent authority has 30 days to declare the notification inadmissible.

Another Member State and the Commission may comment or present reasoned objections within 30 days.

The final decision will be made within a **short period of time** also because decisions on whether an NGT plant meets the criteria of equivalence with conventional plant are of a **technical nature and do not involve any risk assessment or risk management considerations**.

A transparency register would be established.

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Category 2, NGT plants: not equivalent to conventional

Authorisation process with some derogation from GMO regulation. The risk assessment would be adapted to take into account their different risk profiles and measures would be introduced to incentivise plant products that could contribute to a sustainable agri-food system.

There will be **regulatory incentives** for (potential) applicants of category 2 NGT plants containing traits with the potential to **contribute to a sustainable agri-food system**, e.g. an accelerated procedure, or where the applicant is an **SME**, (e.g. it shall be exempted from the payment of the financial contributions to the Union Reference Laboratory and to the European Network of GMO Laboratories).

Traceability would be maintained as well as **labelling as GMOs**. On a voluntary basis, GMO labelling can be supplemented with **information on the purpose of genetic modification**, e.g. to increase the sustainability of the plant.

Unlike for GMOs, for these plants it will not be possible for Member States to restrict their cultivation or circulation on the market.

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Organic production

- **Both NGT Category 1 and NGT Category 2 will be banned in organic production;**

- to enable this, **it will be mandatory to indicate the use of NGT in seed and reproductive materials labelling for both categories**.

- Member States will take implementing measures for coexistence.

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Open questions

- Excluding innovation from **organic production** : is it a wise choice for the development of the sector? What will be the issues with coexistence?
- Category 2 NGT: despite a faster authorisation process than GMOs, **will the incentives for SMEs and sustainability criteria be enough** to foster innovation ?
- What will be the **interactions between the seeds and the NGT regulations** as both regulation will be discussed together ?

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