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FINAL

APPRAISAL
EU Commission Proposal for a New Regulation on New Genomic Techniques

On 5 July, the EU Commission adopted the text of the new legislative proposal to regulate the release into the environment of plants obtained by NGTs and their use as food and feed.

The main proposed changes are likely to strongly affect the way Euro Coop members deal with GMOs.
The Regulation proposes to split NGTs into **two categories:**

- **NGT-1,** obtained through cisgenesis and site mutations and leading to results allegedly reachable through conventional breeding and/or classic mutation techniques or by natural mutations.
- **NGT-2** which is referred to other kinds of genetic alteration leading to results which are not expected to occur in natural or through natural processes.

NGT-1 Category

NGT-1 plants will be considered just like any other **conventional** variety and can be released into the environment and used including their products, as food and feed or other uses **without** any ex-ante risk assessment. The plants will be **scrutinized** by a simple notification procedure whose aim is not to ascertain whether they are safe but just whether they fulfil the criteria to be deemed as NGT-1 as defined in Annex 1. ***NGT-1 products will not be subject to any monitoring or labelling.***

Herbicide resistance (HR) is **not allowed** under NGT-1 in consideration of the risk of intensifying resistant weeds, like it already happened with HR GMOs. Those NGT-1 plants whose release – but not use – will be published in the publicly accessible dedicated database within the EU plant varieties catalogue. **NGT-1** reproductive materials (i.e. seeds) shall be **labelled** as NGT-1 when they are given to third parties in exchange for money but not only. This provision is designed to make farmers aware of the nature of the seeds they buy and represents the only measure that would eventually help primary food producers to trace them, and if of interest, to avoid them. This aspect is of particular importance considering that **NGT-1** plants and products will be considered as **GMOs for organic products** where they won't be allowed.

Although the EU Commission text does not include any measures for **ex-post traceability** after the introduction of NGT-1 plants/products into the environment/market, the EU Commission proposes to **monitor** and **evaluate** their **economic, environmental** and **social** impacts. However, data on those aspects are expected to be reported no sooner than **3 years** after the first products have been notified and/or authorized, while an evaluation should be carried out no sooner than 2 years after the first monitoring report has been published (hence, 5 years after the notification).

The **monitoring report** should contain the following information:

1. NGT **plants** that are as **safe** as their conventional counterparts:
   - Number of **products** authorized or notified to be placed on the **market;**
   - Reported **cases** demonstrating **risk** to human / animal **health** and the **environment** due to the genetic modification in authorized/notified product and any regulatory action taken.
2. NGT **plants** featuring a **wide range** of plant species / traits by various developers:
   - Number of **crop-trait combinations** in notification / authorization applications;
   - Number and proportion of SMEs / public institutions applying for field, trail / notification / authorization **applications**.

3. NGT **plants** featuring traits that can **contribute to a sustainable agri-food system:**
   - **Impact of NGT plants in the EU on economic, environmental and social sustainability,** i.e., through pesticide / fertilizer use, biodiversity, greenhouse gas emissions, yield, yield stability, health benefits.

NGT-2 Category

NGT plants obtained through different techniques and/or that **do not** satisfy the requirements for the NGT-1 category will be treated as **NGT-2 plants** and they will be regulated through the **existing GMOs legislation** with some changes.

In particular, because of the high theoretical number of possible outcomes, **the requirements** for the disclosure of identification techniques of the genetic modification(s) and **ex-post** monitoring plans for marketed NGT-2 and their products, including for food and feed, could be **waived** in case the proponent can demonstrate that the identification is technically **impossible** and that **no environmental or health risks** are supposed to arise from their use. This waiver is not allowed when NGT-2 are deemed to be released in the environment. For NGT-2 carrying modifications aimed at improving **food production sustainability**, incentives are granted in the form of reduced time for authorization, technical assistance to identify critical aspects of the authorization request and reduced fee for if the proponent is a SME. ***NGT-2 and their products will be considered GMOs and subject to the same rules regarding labelling.***

In recognition of the potential positive role that some NGT-2 plants can provide for the greening of food production, there will be the possibility to integrate the normal **labelling with complementary information** about the type of the genetic modification and/or the expected benefits.

Once NGT-1 or NGT-2 and their products are granted the permit to be released into the environment and or used in food and feed, EU Member-States are **no longer allowed to ban them** on their territory. That means that Article 26.b of Regulation 2001/18 on the deliberate release of GMOs that allowed Member-States to ban the cultivation of authorized GMOs **won't apply any longer.** Furthermore, Member-States will be asked to adopt **coexistence plans** for NGT-2 to avoid cross contamination.

Euro Coop Appraisal of the Proposal

The proposal reflects the initial intention of the EU Commission to **deregulate certain GMOs** as defined by European Court of Justice, but it does so more on a **political basis, rather than a scientific basis.**

Ignoring science

Practically, **certain genetic techniques** can be used to generate plants that will be deemed **safe** *assuming* their genome could be the result of natural mutation or traditional mutation or breeding with compatible species. This assumption is **scientifically baseless** especially when considering that while insertion or substitution of new DNA should be contained to 20 nucleotides (i.e. the single brick molecules of the DNA), the **deletion** of part of the DNA can involve *any* number of nucleotides. This approach is a mechanistic one and **ignores** altogether the complexity and interconnection amongst different DNA regions and genes and possible unexpected effects.

Risk for organic production

Although **NGT-1** remain **banned** from **organic** products**,** the lack of basic information and **ex-post traceability** and **monitoring** makes it quite difficult to apply. Organic farmers will never know whether their neighbours use NGT plants and contamination is quite unavoidable adding technical and administrative burdens to organic food producers. *If an organic product is found to be or to contain an NGT-1, it is subject to market withdrawal regardless of whether it is intentional or accidental.*

Policy contradiction

The **lack** of any **traceability** and **monitoring** will make it almost **impossible** for the EU Commission to gather the necessary information from proponents / Member-States in view of preparing the **monitoring report** expected after the first 5 years. Particularly, in the absence of strict pre-established criteria, it would be **impossible to demonstrate risks** to human / animal health and the environment due to the genetic modification in authorized / notified product(s).

While **NGT-2** will be subject to stricter conditions, as the text stands currently, it would be **impossible to verify possible unexpected / side effects**, because of the lack of requirement for food / feed actors to present any detection and quantification methods nor ex-post monitoring**.**

Compromising freedom of choice

The new rules would **reduce the freedom of choice of food producers and consumers** and **increase the uncontrolled proliferation** of plants and products whose safety is merely conceptual and lacks scientific ground; disregarding the techniques, some of which are identical to GMOs, used to create new varieties.

No right to ban

Member-States would lose the right to ban cultivation on their territory for any **NGT plants** notified or authorized at EU level. This would be destructive **in those areas where particular (i.e. organic) food production occurs** that could be challenged by the release of genetically modified varieties.

Pertinent Articles

- **Article 5** - Status of category 1 NGT plants.
- **Article 6** - Verification procedure of category 1 NGT plant status prior to the deliberate release for any purpose other than placing on the market.
- **Article 7** - Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products.
- **Article 9** - Database referencing decisions declaring the category 1 NGT plant status.
- **Article 10** - Labelling of category 1 NGT plant reproductive material, including breeding material.
- **Article 14** - Content of the notification referred to in Article 13 of Directive 2001/18/EC (§1.h).
- **Article 15** - Specific provisions on monitoring.
- **Article 16** - Labelling in accordance with Article 23.
- **Article 19** - Specific provisions on the application for authorization referred to in Articles 5 and 17 of Regulation (EC) No 1829/2003 (§ 3.b).

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