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CONFIDENTIAL

FOCUS ON THE MAIN PROBLEMS AFFECTING COMMISSION'S PROPOSAL FOR A REGULATION ON PLANTS OBTAINED BY CERTAIN NEW GENOMIC TECHNIQUES, THEIR PRODUCTS, AND THEIR FOOD AND FEED

The proposal, submitted by the Commission on July 5th, intends to set out new rules specifically for plants obtained by targeted mutagenesis and cisgenesis (including intragenesis), their progeny, food and feed, and products they might be contained in.

This proposal leads to the deregulation of certain genetic modifications, meaning the latter will not be submitted to the exiting GMO legislation.

Beyond the very object of this proposal, which may be questioned, the proposal also includes various other problematic aspects that should be presented.

I. Objective pursued by the proposal

According to the Commission, the proposal is based, among others, on **Article 114 TFEU**, which gives competence to the European executive for preparing legislative proposals "*concerning health, safety, **environmental protection and consumer protection***" that will "*take as a base **a high level of protection**, taking account in particular of **any new development based on scientific facts***". EP and Council, according to this article, "*will also seek to achieve these objectives*".

- As it stands, Commission's proposal might be 'violating' Article 114 TFEU by **not ensuring a high level of consumers' protection** considering they would not be informed in any manner on cat 1 NGTs.

- In addition, the **criteria of equivalence** of NGT plants to conventional plants, set out in Annex I of the proposal, doesn't seem to be "based on scientific facts". Indeed, **no justification whatsoever is provided for the determination of these criteria** (20 genetic modifications / 20 nucleotides…), which therefore appear arbitrary.

II. Definitions

1. General definition of NGT

According to Article 3 (2) of the proposal, an NGT is:

- "*a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof*
- *on the condition that it does not contain any genetic material originating from outside the breeders' gene pool*"

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Thus, the content of the genetic material originating from the breeders' gene pool is essential, since the presence of genetic material originating from outside the breeders' gene pool excludes the plant from being qualified as NGT, which will then subject it to GMO Regulation.

- Yet, the definition of the "breeders' gene pool", laid down in Article 3 of the proposal, is very large and includes the possibility of going way beyond the total genetic information available in one species. Indeed, according to Article 3, the "'*breeders' gene pool' means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses*;". The "advanced techniques" listed here make interspecific and intergeneric crosses possible. As a consequence, the proposed notion of "breeders' gene pool" **allows for the introduction of a wide range of foreign genes into NGT plants**.

2. Definition of Category 1 NGT plants

According to Article 3 of the proposal, a 'category 1 NGT plant' is the one:
- that fulfils the **criteria of equivalence** to conventional plants set out in Annex I, or
- is a **progeny of that NGT plant, including progeny derived by crossing of such plants**, on the condition that there are no further modifications that would make it subject to the GMO legislation.

- The technical and scientific basis of the criteria laid down in Annex I are not provided in the proposal. The quotas proposed (20 genetic modifications / 20 nucleotides) appear completely arbitrary. No rational explanation is provided whatsoever for such numbers.
- In some cases (Annex I, (2) (3) (4)), the Proposal provides no maximum number of nucleotides at all, which makes possible for the breeder to modify enormous parts of the genome, if desired.
- "sequence similarity with the targeted site", in Annex I, excludes the examination of any unintended mutations/modifications on other sites of the genome.

Concerning the progeny of Cat 1 NGT plants:
- The respect of the equivalence's criteria set out in Annex I does not have to be demonstrated.
- The crossing of several Category 1 NGT plants could lead to a violation of Annex I by the progenies. The only reservation that "*there are no further modifications that would make it subject to the GMO legislation*" might not be sufficient to ensure these progenies are equivalent to conventional plants. It would be preferable to exclude the crossing of NGT plants from the scope of Category 1, and submit it to Category 2.

- Note also that herbicide-tolerant crops are not excluded from the regulatory route for Cat 1 NGT plants.

- Finally, the right for the Commission to adopt delegated acts amending the criteria of equivalence laid down in Annex I "*in order to adapt them to scientific and technological profess*" seems to violate article 290 TFEU, which provides that "*A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application*

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to supplement or amend ***certain non- essential elements of the legislative act****."* However, the criterion of equivalence seem to be **the most essential element of this legislative proposal**, as both definitions of cat 1 NGT and cat 2 NGT are based on this criterion.

III. PROBLEMS CONCERNING THE CATEGORY 1 NGT REGIME

A. General issues

Category 1 NGT plants derogated from the GMO legislation rules. As such they are subject to a simple **verification procedure**. No ground for refusal or withdrawal are foreseen in the Proposal.

Category 1 NGT plants will therefore **not require authorization, risk assessment, traceability and labelling** as GMOs (except in this regard for plant reproductive material (PRM), as labelling is foreseen for PRM). For these plants, only a **transparency register** would be established.

- Neither farmers nor consumers will be informed about Cat 1 NGT plants and products in their fields or in their plates.
- Ensuring NGT-free-farming, especially in organic agriculture - where NGTs are banned - will be impossible, as information on the ground and detection methods are not foreseen in the proposal. Contamination with genetic modifications seems therefore unavoidable.
- The absence of a risk assessment and of traceability rules for Cat 1 NGT makes it impossible to know the risks and to monitor the effects of these plants.
- As other European or national registers, the "transparency register" will probably remain unknown and useless.
- The proposal remains blurry about the kind of information that will be displayed in this register. Most probably, it will bring information on what kind of NGTs have been "verified" and are on the market (as the varieties register), but no precise information on the genetic modifications they hold or information on where they are cultivated.

Finally, Member States are not allowed to ban the use and cultivation of NGT plants on their territory.

B. Specific issues depending on the purpose of the NGT

i. For other purpose than placing on the market (Article 6)

When the NGT plant is not aimed to be placed on the marked (e.g. field trials), it is the 'competent authority' of the Member State where the release is going to take place - or of the Commission in a subsidiary capacity – who will determine if NGT plants belong to category 1.

Deadlines for the Member State to analyze the request (**30 days**), and for other Member States to submit comments (**20 days**), are very short.

- This raises doubts about the **quality of the checks** that will be carried out.

In case the Commission or a Member State makes a comment, the competent national authority shall forward the file to the Commission.

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- If **the Commission wants the lead on the decision-making, she only has to make a comment.** The Member State's prerogatives will then consist solely of making comments.

- **At no point, the verification request is made public** (contrary to the leaked draft version).

- Finally, going through the Article 6 procedure will **exempt the applicant from going through the placing on the market procedure** (Article 7), even if he intends to place the plant on the market. As a consequence, going through Article 6's procedure would **prevent the public from having access to the verification request** submitted and to all the relevant information on the plant supplied by the requester.

ii. For placing on the market (Article 7)

The Commission is competent for adopting the verification decision and the EFSA shall be consulted. After the EFSA's statement, the verification request and all relevant information supplied by the requester shall be made **public**. Commission decision is submitted to comitology.

- The delay for the EFSA to render its statement is rather short (30 days).

Cat. 1 NGT plants that have obtained a positive decision are listed in a **database**, publicly available. Cat. 1 NGT **seeds** (PRM) will bear a label indicating the words 'cat 1 NGT'.

- The catalog of plant varieties will not provide information on NGT status.
- The proposal does not detail what kind of information will be published in the database.

IV. PROBLEMS CONCERNING THE CATEGORY 2 NGT REGIME

A. General issues

EU legislation on GMOs, insofar as it is not derogated from by the Proposal, shall apply to category 2 NGT plants and category 2 NGT products (Art 12). Therefore, category 2 NGT plants and products remain subject to the GMO labelling requirements.

However, the possibility for Member States to restrict or prohibit cultivation pursuant to Directive 2001/18 does not apply to category 2 NGT plants.

- This prohibition potentially goes against article 114 §4 et §5 TFEU (possibility for Member States to maintain or introduce national provisions on grounds of "major needs", as "the protection of health and life of humans, animals or plants" or a problem specific to that MS and for "the protection of the environment")

Regarding the **environmental risk assessment**, and unlike regular GMOs, the type and amount of information shall be **adapted to the risk profile** of the Cat 2 NGT presented. Furthermore, in the risk assessment, specific information on **hazard identification and characterization**, is required "*only if the specific characteristics and the intended use of the category 2 NGT plant or category 2 NGT food or feed give rise to a **plausible risk hypothesis***".

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- "plausible risk hypothesis" is not defined anywhere. **EFSA** shall deliver pre-submission advice on "plausible risk hypothesis", but only when Cat.2 NGT is intended to be placed on the market.

B. Specific issues depending on the purpose of Cat 2 NGT

i. Release for any other purpose than for placing on the market

A **notification procedure** applies. The notification procedure is roughly the same as for standard notification procedure for GMOs set out in article 6 of directive 2001/18/EC.

- No ground for refusal or withdrawal is foreseen in the Proposal.
- Safety assessment is not required.

ii. Release for the purpose of placing on the market NGT products other than food and feed

A **notification procedure** applies. The content of the notification slightly varies as compared to GMOs. The notification dossier shall contain an environmental risk assessment and a proposal for labelling.

A "**written consent**" is given by the national competent authority for a maximum period of 10 years and shall specify monitoring requirements (or state that monitoring is not required) and labelling requirements.
After being renewed once, the consent of the national competent authority shall be valid for an **unlimited period**.

- The validity of administrative decisions should not be unlimited, especially because the proposal does not contain any provision that would permit the withdrawal of the decision.
- Safety assessment is not required.

iii. Release for the purpose of placing on the market NGT products for food and feed

An **authorization procedure** applies. EFSA is consulted upon the authorization decision (6 months delay), but its opinion is only advisory. Authorizations are renewable. Once renewed, "*the authorization shall be valid for an unlimited period*".

- The validity of administrative decisions should not be unlimited, especially because the proposal does not contain any provision that would permit the withdrawal of the decision.

The application shall contain a **safety assessment**. However, specific information concerning **hazard identification and characterization, is only to be provided in the 'plausible risk hypothesis'**.

- "plausible risk hypothesis" is not defined anywhere.