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UEAA Position Paper on Parliament and Council Proposals on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed

Introduction

The regulation of plants obtained through certain new genomic techniques (NGTs) remains a key issue in the European Union's legislative process. The European Parliament and the Council have proposed distinct approaches regarding genetic modifications, cisgenesis, patents, environmental risks, labeling, the precautionary principle, and regulatory monitoring. This paper examines the differences between the two proposals and explores potential mediation strategies that align with the fundamental principles of the regulation.

1. Key Differences Between the Parliament's and the Council's Proposals

1.1. Scope of Genetic Modifications

The European Parliament's proposal does not limit the number of genes that can be modified in each event, thereby avoiding constraints related to multigenic families. However, it restricts the number of mutations per gene to three. In contrast, the Council's proposal maintains a limit of 20 modifications per haploid genome.

Scientifically, neither approach is fully justified, but the Parliament's proposal offers greater flexibility and feasibility for plant breeding.

1.2. Cisgenesis and Gene Editing

The Council's proposal restricts targeted inversions through gene editing by limiting the scope of modifications. In contrast, the Parliament's proposal takes a clearer and more consistent approach by not differentiating between cisgenesis and gene editing.

This Parliament’s proposal allows for the inversion or translocation of continuous endogenous DNA sequences within the breeders' gene pool, thereby broadening the applicability of NGTs for plant breeding.

1.3 Compromise Proposed by UEAA on Genetic Modifications, Cisgenesis, and Gene Editing

The Parliament’s proposal allows unrestricted modifications of types not already in the breeders’ gene pool. This could be controversial, as it may be perceived as altering the genome beyond what could naturally occur. A balanced approach is necessary to address this concern—one that aligns with the regulation’s primary objective: permitting the use of NGTs to deactivate genes or introduce favorable alleles that already exist in the gene pool.

The UEAA's proposed compromise integrates aspects of the Parliament’s and the Council’s proposals to ensure scientific robustness and regulatory coherence. This mediation establishes practical regulatory limits while accommodating technological advancements and aligning with conventional breeding principles.

1.4. Criteria for Equivalence of NGT Plants to Conventional Plants

An NGT plant is considered equivalent to conventional plants if either of the following conditions is met:

1. The plant differs from the recipient/parental plant by no more than 20 genetic modifications per monoploid genome, involving any of the following types of changes in DNA sequences that share sequence similarity with the targeted site, as predicted by bioinformatic tools:
   a) Substitution or insertion of no more than 20 nucleotides.
   b) Deletion of any number of nucleotides.
   c) Insertion of continuous DNA sequences existing in the gene pool for breeding purposes (the traits from Annex III, Part 1, and the exclusion criteria of Annex III, Part 2).
2. The plant differs from the recipient/parental plant by the following genetic modifications, which may be combined, provided that the modification does not interrupt an endogenous gene and that the resulting combination of DNA sequences already occurs in a species from the breeders’ gene pool:
   a) Substitute endogenous DNA sequences with continuous DNA sequences existing in the gene pool for breeding purposes, the traits from Annex III, Part 1, and Annex III, Part 2, and the exclusion criteria.
   b) Inversion or translocation of endogenous DNA sequences.

This compromise ensures a regulatory framework that is both scientifically robust and adaptable to technological advancements. By integrating elements of the Parliament’s and the Council’s proposals, the UEAA supports an approach that enables innovation while maintaining coherence with conventional breeding principles.

2. Other Key Aspects of the Proposals

2.1. Patents

The Council's proposal presents a more rational and realistic approach. While the Parliament's proposal excludes patents for NGT plants cultivated for non-commercial release, the Council acknowledges the potential presence of patents. Applicants must provide relevant information "to the best of their knowledge." Additionally, Article 30bis introduces a structured framework for monitoring the impact of patents on NGT plants, making the Council's approach more pragmatic and enforceable.

UEAA recommendation: The Council's proposal

2.2. Environmental Risk Assessment and Food and Feed Safety

The Council's approach is preferable, as it mandates a case-by-case adaptation of environmental risk assessments for category 2 NGT plants and the safety assessment of category 2 NGT food and feed. This is aligned with Annex III of Directive 2001/18/EC, ensuring a flexible and scientifically sound framework that accounts for varying levels of risk.

UEAA recommendation: The Council's proposal

2.3. Labeling

The Parliament's proposal requires broad labeling for all category 1 NGT plants and products containing them. In contrast, the Council's proposal limits labeling requirements to plant reproductive material, which aligns with the European Commission's initial position.

The Council's approach is more practical. It avoids excessive regulatory burdens while ensuring traceability for breeding and research purposes.

2.4. Precautionary Principle

The Parliament's proposal explicitly references the precautionary principle, which has historically been misapplied to restrict biotechnological advancements. The Council's proposal omits such references, making it a more scientifically sound and regulatory-friendly approach. Given the extensive safety assessments already in place for NGT plants, avoiding unnecessary precautionary restrictions ensures a more balanced and innovation-supportive policy.

UEAA recommendation: The Council's proposal

2.5. Monitoring

The Parliament's text (P9_TA (2024)0325) includes a provision requiring the Commission to reassess equivalence criteria every four years and update them if

necessary. The Council's version does not include this provision. However, given continuous advancements in science and technology, maintaining this monitoring mechanism would be beneficial for ensuring an adaptive and evidence-based regulatory framework. Periodic reviews ensure that regulations align with emerging scientific insights and technological developments.

UEAA recommendation: The Parliament's proposal

Conclusion

The European Parliament and the Council have proposed frameworks to effectively regulate NGT plants. The Council's approach offers a more structured and scientifically justified framework, while the Parliament's proposal provides greater flexibility and clarity in certain areas.

A well-balanced compromise integrating key elements from both proposals would ensure the most effective and scientifically robust regulation for NGT plants and their derived food and feed products.

The UEAA recommends adopting a mediation approach that incorporates the strengths of both proposals so that the European Union can establish a forward-looking regulatory framework that supports innovation while ensuring safety, transparency, and public trust.