NGT Regulation Trilogue Policy Brief by UEAA

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Executive Summary

As trilogue negotiations on the Regulation for New Genomic Techniques (NGTs) approach their conclusion, aligning the positions of the Commission, Parliament and Council remains essential. The Regulation must reconcile innovation in plant breeding with transparency, consumer trust and equitable access to technology, ensuring a science-based and globally competitive framework for sustainable European agriculture. This brief highlights four priority areas that require convergence on: genetic equivalence criteria, traceability and labelling, cultivation and coexistence and access to intellectual property. It proposes pragmatic solutions designed to uphold scientific coherence, economic viability and the EU's global leadership in sustainable agriculture

Key messages:

- **Maintain** a broad interpretation of genetic equivalence for NGT Category 1, consistent with Annex III**.**
- **Avoid** over-regulation of traceability and labelling that contradicts the 'equivalence to conventional varieties' principle.
- **Ensure** flexibility rather than obligation in Member-State coexistence measures
- **Support** realistic and transparent patent provisions that safeguard access for breeders and researchers.

1. Genetic Equivalence Criteria (NGT Category1)

The Parliament's stance on sustainability and the 'positive list' of traits, if declared before environmental release (Art. 6) and specified upon market placement (Art. 7), is acceptable provided the list remains broadly interpreted. The Council's amendments on equivalence align well with the Commission's draft, notably by including ploidy, a scientifically necessary parameter. While excluding intragenesis from admissible techniques is not ideal, its impact appears limited.

Recommendation: Maintain broad interpretability of Annex III; endorse the Council's inclusion of ploidy; reconsider the complete exclusion of herbicide-tolerance traits by replacing it with specific biosafety provisions to prevent unintended spread.

2. Traceability and Labelling

Labelling of reproductive material is feasible, but mandatory labelling of all NGT1-derived products (including food and feed) would impose disproportionate costs without additional safety or traceability benefits. It would also contradict the Regulation's own definition of NGT1 varieties as equivalent to conventional ones.

Recommendation: Restrict labelling obligations to reproductive material; rely on existing traceability mechanisms within production chains to ensure consumer protection and product recall capability.

3. Cultivation and Coexistence Measures

The opt-out clause for NGT2 cultivation proposed by the Council may satisfy anti-GMO Member States but risks replicating the GMO scenario, widespread non-cultivation across the EU with subsequent reliance on imports. Parliament favours mandatory coexistence measures, while the Council allows them at national discretion.
Recommendation: Prefer possibility over obligation for coexistence measures, ensuring flexibility for Member States while maintaining science-based safeguards (e.g. isolation distances for organic crops).

4. Patents and Access to Genetic Material

Patents on CRISPR/Cas systems, vectors or genes are already governed by international law and remain valid independently of this Regulation. The Parliament's proposal to exclude patents from NGT recognition is technically unworkable, as NGTs inherently rely on patented components. Likewise, revising global patent law solely within the EU would isolate European innovation. The Council's approach that ensures transparency, accessibility and fairness through open databases and equitable licensing is balanced and feasible. However, the timing of the disclosure obligation should be clarified.

Recommendation: Require declaration of relevant patents before market placement (Art. 7), not before environmental release (Art. 6), to avoid unnecessary burdens during field-testing. Include an explicit EU-wide harmonisation of breeders' and research exemptions to guarantee open access for innovation and public research.