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First Considerations and talking points on the NGT proposal

NGT Proposal – principle considerations, what we need to keep, what we want to change

Euroseeds welcomes that the Commission proposal finally recognizes the need for a differentiated regulatory approach to certain “conventional-like” NGT-derived plants and products from the GMO legislation.

The proposal establishes a verification process to verify if an NGT plant is meeting the equivalence criteria to be grouped as Category 1 (conventional-like). Consequently, those Cat 1 plants should also be subject to the same regulatory framework as conventional breeding products. Any additional requirements would be discriminatory and unjustified.

Euroseeds supports transparency and consumer choice by making information about the use of NGTs publicly available (public databases). The additional seed bag labelling provisions and the prohibition for organic production create a third category of plant products between conventional and GMOs. This is inconsistent and not in line with the approaches taken in other countries and will create trade issues.

We reiterate that any GMO-light approach (Category 2) is considered unworkable for Europe, specifically for SMEs. Despite the lighter risk assessment procedure, it keeps the plants in under the GMO legislation which proved itself to be dysfunctional.

Principle Considerations:

- The proposal establishes a verification process to verify if an NGT plant is meeting the equivalence criteria to be grouped as Category 1 (conventional-like). Consequently, those Cat 1 plants should also be subject to the same regulatory framework as conventional breeding products. Any additional requirements would be discriminatory and unjustified. Instead, the Commission proposal creates a distinct category and foresees specific requirements for verified conventional-like NGT plants different from conventional plants and from exempted GMOs like random mutagenesis. This creates confusion and legal complexity. It would be much more consistent to **include verified conventional like Cat 1 NGT plants under Annex IB of Dir. 2001/18** (could be addressed in Art 5 (1))
- The Commission study highlighted that *“there are implementation and enforcement challenges, in particular related to the detection and differentiation of NGT products that do not contain any foreign genetic material”*. This is a problem for enforcement authorities, operators and applicants. The current criteria are complex and only partly solve this problem. **Logically, Annex I should focus on those criteria that solve the enforcement and detection and identification problems as identified by the Commission study¹ for NGT products that do not contain any foreign genetic material.**

¹ https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en

- Already today certain private standards in the organic sector exclude seeds derived from certain conventional breeding methods (e.g. cms) based on transparent information from the breeding sector. The prohibition for organic farmers to use conventional-like NGTs (Category 1) in their production is neither science-based nor politically justifiable. It is also inconsistent to regulate this in the NGT regulation. **It should therefore be left to the organic operators to decide which seeds to use in their production (private certification standards) and all references to organics should be deleted from the NGT proposal** (could be addressed in Art 5 (2)).
- The proposal suggests that for certain Category 2 NGT plants no or only an adapted identification method can be developed. Although regulated GMOs these plants will not be fully identifiable or distinguishable from conventional plants. This is a specific challenge for imports. If for imports, it is not possible to identify unauthorized NGTs with Category 2 changes, it is discriminatory to require GM traceability and labelling of such products in the EU. **Consequently, Cat 2 plants for which no or only an adapted identification method can be developed –should logically be treated as Cat 1 NGT plants (conventional-like)** (Art 14 (1) f).

What do we need to keep?

- **A differentiation between conventional-like NGT plants and regulated GMOs**
- **No traceability and labelling for products from conventional-like Cat 1 NGT plants** – conventional-like have been verified as such and are with this indistinguishable from conventional products. Any traceability and labelling requirements would reintroduce enforcement issues as already identified by the EC study. (Art. 10)
- **No coexistence measures for conventional-like Cat 1 NGT plants** - Conventional plant varieties and varieties used in organic agriculture are genetically identical and have coexisted without specific coexistence rules. Creating new barriers would result in numerous measures to be taken by farmers and increased complexity and costs across the agri-food value chains.
- **No opt-out for Cat 1 NGT plants.** Conventional-like Cat 1 NGT plants have been verified as such and are with this indistinguishable from conventional plants and like conventional plants suitable for cultivation in all member states. Breeding and seed production as well as marketing of seed often takes place in different member states. Any opt-out would disrupt seed value chains and undermine the EU internal market for seeds and be contradictory to the ambition of the Commission to harmonize the seed marketing legislation.
- **Verification of NGT plants by member states authorities-** this lowers access hurdles specifically for SMEs (Art 6).
- **Possibility of future proofing of Annex I by delegated acts to consider technical developments and scientific knowledge.** Science is advancing rapidly, and we welcome the Commission approach to future proofing the regulatory framework by delegated acts which allows keeping up regulations with scientific progress. (Art 26)
- **The progeny of NGT1 (cross with NGT1 or conventional variety) should stay NGT1 (Art 4)** – Any restrictions for crosses between two verified conventional-like NGT 1 plants would restrict the access to germplasm for further breeding and the breeder's exemption as foreseen in the PVP law.

- **Transparency via the variety catalogue** - Euroseeds supports transparency and consumer choice by making information about the use of NGTs publicly available (public databases). This allows farmers and value chains to choose or avoid NGT derived plant varieties. (Art 9)

What do we want to change?

- **The verification procedure should be science based and not allow for unjustified political consideration.** Any intervention of the Commission or another member state should be scientifically justified and based on correct application of the equivalence criteria (Annex I). Breeding companies invest up to 20% of their turnover in research & development and rely on legal certainty for their investments. The verification process should therefore be effective and predictable (within a reasonable timeframe) based on clear criteria and the scientific expertise of member states CAs. (Art 6)
- **Equivalence Criteria, Annex I**
 - **The equivalence criteria must be clear without ambiguity of interpretation by MS** to provide legal certainty for companies in view of R&D investments.
 - The Criteria to establish equivalence with conventional plants **should allow crops with complex genomes (polyploids like e.g. wheat) to benefit from NGTs in the same way as diploid crops** – the 20 genetic changes should be based on the haploid genome.
 - **Off-target changes should not be taken into account.** EFSA² concluded that off-target changes would be the same types (and fewer) as those produced by conventional breeding techniques. There is a risk that a requirement for the identification of these off-targets might discriminate crops (specifically smaller crops) for which no whole genome sequence is available.
 - **Regarding cisgenesis (type 3): We would like to point to the fact that there are multiple examples of cisgenesis being used to introduce beneficial traits. As long as the insertion does not result in the creation of an intragenic plant which would express a chimeric protein neither random introductions nor interruptions of endogenous genes by cisgenes should be excluded from Category 1.** Excluding these applications from Annex I means less opportunities for developing beneficial traits by cisgene(s) in Category 1 (e.g. introduction of multiple disease resistant cisgenes to ensure durable resistance). (Annex I (3)).
- **We consider seed bag labelling for verified conventional-like NGT plants as discriminatory.** In line with our principal position that conventional-like NGT plants should be treated conventionally, this extra requirement is creating unjustified distinctions and administrative burden. Euroseeds supports transparency and consumer choice by making information about the use of NGTs publicly available (public databases). But the additional seed bag labelling provisions and the prohibition for organic production create a third category of plant products between conventional and GMOs. This is not in line with the approaches taken in other countries and will create trade issues. (Art 10)
- **The sustainability criteria (Annex 3, Part 1) should be aligned between different policy proposals (e.g. PRM)** in order to avoid inconsistencies and legal uncertainty. The sustainability criteria as currently drafted in Annex 3, Part 1 are not fully aligned with those in the PRM proposal (Art 52 (1)).

² doi: 10.2903/j.efsa.2020.6299