Hollandbio feedback on: Legislation for plants produced by certain new genomic techniques

Biotechnology makes life better. To capitalize on the opportunities of the global biorevolution for health, sustainability, and the economy, a paradigm shift is needed. Instead of amending the current outdated laws and regulations for genetic modification, hollandbio prefers a fresh start with a clean slate. We must put an end to the stigmatization of genetically modified organisms (GMOs) and focus on whether an organism or product is safe for its intended use. Hollandbio advocates for legislation that ensures safety without discriminating based on technology. We call for legislation that encourages the development and use of all innovations contributing to European goals in health, sustainable food production, and the circular economy.

The current proposal aims to modernize legislation for a limited number of techniques in plants. Biotech applications in microorganisms and cell culture, such as biobased materials, cellular agriculture, and medical applications, also face challenges under the inappropriate and outdated European GMO regulations. Therefore, we urge to modernize the GMO regulations for these applications alongside this proposal. We suggest including in the considerations of the current proposal that a proposal for microorganisms and cell culture will be made in the near future.

That being said, hollandbio welcomes the proposal on the application of New Genomic Techniques (NGTs) by the European Commission. This proposal has the potential to develop and cultivate desired NGT applications in plants in Europe, contributing to European goals in sustainability, innovation, and the economy. However, the proposal raises some concerns and ambiguities.

Feasibility of Category 1 and Category 2
The European Commission distinguishes between Category 1 NGT plants and Category 2 NGT plants. If the risk of politicization in the verification procedure is eliminated, we see Category 1 as a feasible route that allows crop breeding with NGTs for plant breeders. However, hollandbio strongly doubts whether this is also the case for Category 2 and whether products will be developed for the European market that must undergo the safety and approval process like 'traditional' GMO plants. Due to the high level of politicization in the approval process under national authorities, no new GMO applications have been submitted in the European Union over the past decades.

Interpretation of Annex I
There is ambiguity regarding the interpretation of Annex I, particularly concerning the number of allowed modifications, which is crucial for the classification (Category 1 or 2) of plants and, therefore, the impact of modernization.

We must not ignore the fact that nature itself is the greatest genetic engineer and does not count modifications. Classification based on the number of base pairs is artificial. Ideally, we would prefer not to have a limit. On the other hand, we understand that specifying a maximum number of modifications facilitates practicality and clarity. Therefore, hollandbio advocates for a clear and consistent interpretation, especially regarding:

- **Polyploidy:** while 20 modifications may be workable for haploid crops, the proposed maximum for polyploid crops is very low, even though the potential and the significant advantage of NGTs over older techniques lie here.
- **Breeder's gene pool:** As the sector continuously advances with their own and each other's starting materials, it seems likely that if your starting material consists of a registered Category 1 NGT plant, you would start counting modifications anew. If not, breeders under Category 1 would quickly lose out to NGTs, as will the sustainability benefits we aim to achieve.

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- **Off-target mutations:** In conventional breeding, which has been ongoing for decades, there are a vast number, sometimes even thousands, of off-target mutations that end up in the DNA. Although NGTs are more precise, there may still be some off-target mutations.

Verification Procedure and Classification
While the current European GMO directive is theoretically feasible on paper, the politicization of the procedure and decision-making has resulted in no GMO crop ever coming to market in Europe since its implementation. The definitions and lack of timelines and terms in Articles 6 and 7 of the NGT proposal, which state that countries can make a 'comment' or 'reasoned objection' make this proposal susceptible to delaying the procedure with undefined timelines and outcomes too, as they leave room for (subjective/political) interpretation.

Organic Sector
Although the organic sector at this point in time explicitly states that they do not wish to use both categories of NGTs, hollandbio urges the commission to limit provisions regarding the use of GMO techniques to the organic legislation, instead of via the NGT proposal. This will make the proposal more future proof, leaving room for a possible changing perspective.

Coexistence Measures
NGT plants are required to comply with coexistence measures. Experience with GMOs shows that coexistence rules can be set in a way that blocks cultivation throughout a member state. Therefore, Europe should at least provide direction and set frameworks for the coexistence measures that member states implement, ensuring they are proportionate and practically feasible and do not obstruct the cultivation of NGT crops.

Detection Requirements
Hollandbio believes that all NGT plants that are indistinguishable or undetectable from conventional plants should be in Category 1, rather than adjusting the detection requirements in specific cases, as proposed by the European Commission. The Commission's proposal is highly inconsistent in this regard.

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