

Recommendations on information requirements and verification of Category 1 NGT plants under Regulation (EU) 2026/1388

Executive Summary

The successful implementation of the Regulation (EU) 2026/1388 will depend on secondary legislation that provides legal certainty, scientific robustness, proportionality and practical applicability across the diversity of crop species, breeding approaches and operators in the European Union. The delegated act should establish a predictable, harmonised and future-proof framework that supports research, innovation and the development of crop varieties better adapted to climate change, emerging environmental challenges, evolving societal and consumer expectations, and the transition towards more sustainable agricultural systems.

Implementation should remain firmly aligned with the core principles of the Regulation, in particular the distinction between Category 1 and Category 2 NGT plants. Category 1 NGT plants should be considered equivalent to conventionally bred plants once the verification procedure has been completed, and the verification process should focus on demonstrating compliance with the criteria set out in the Annex 1 of Regulation, rather than evolving into a de facto risk assessment process. Once a plant has been verified as a Category 1 NGT plant, it should be treated as equivalent to a conventionally bred plant throughout the Union, without additional regulatory burdens that could undermine the effectiveness and objectives of the Regulation.

The implementation framework should be benchmarked against conventional breeding practices, ensuring that verification requirements remain proportionate to the objective of demonstrating compliance with the Annex I criteria. It should provide legal certainty, accommodate scientific and technological developments, and remain practical and accessible for operators of all sizes, including small and medium enterprises (SMEs) and public research organisations.

1. Verification of Category 1 NGT Plants

The verification procedure for Category 1 NGT plants should be designed as a scientific and administrative verification exercise aimed at establishing whether a plant or batch of plants fulfil the criteria set out in Annex I and, where relevant, does not contain genetic material from outside the gene pool for conventional breeding purposes. The focus should remain on the characteristics of the final plant rather than on the breeding technique or intermediate products used to obtain it, in agreement with recital 17 “*Any genetic modifications temporarily introduced during the development of the NGT plant and removed from the plant that is to be deliberately released or placed on the market should not be relevant for the verification of the criteria of equivalence*”¹. At the same time, verification requirements should be limited to demonstrating compliance with the criteria set out in Annex I of the Regulation and should remain aligned with scientific and technical progress. The verification procedure should follow the following principles:

- Science-based and evidence-driven.
- Proportionate to the objectives of the Regulation.
- Harmonised across Member States.
- Predictable and accessible for all developers, including SMEs and public research organisations.
- Compatible with practical plant breeding realities.
- Future-proof and adaptable to technological progress.

Once a plant has been verified as a Category 1 NGT plant, it should be treated as a conventionally bred plant throughout the Union. We wish to reiterate that Member States are not allowed to implement additional national measures targeted specifically at Category 1 NGT plants. The introduction of national requirements beyond those foreseen in the Regulation would risk undermining legal certainty, creating divergent implementation across Member States, and disrupting the proper functioning of the EU internal market.

The legislation should be sufficiently flexible to allow the applicant to propose, and justify on a scientific basis, the most appropriate comparator(s) for assessing the changes introduced, information that sequences are from the conventional breeding gene pool, the type of change induced or intended, the boundaries within which that change falls, etc.

2. Interpretation of Annex I

The delegated act should provide clear and workable interpretations of the concepts contained in Annex I to ensure consistent implementation throughout the Union. Attention should be given to:

2.1) Interpretation of the 20-Modification Limit

2.2) The interpretation of “*a combination of genetic sequences already occurring in the gene pool for conventional breeding purposes*”

¹ [Regulation \(EU\) 2026/1388](#) on Plants Obtained by Certain New Genomic Techniques and Their Products (2026).

2.3) The interpretation of "*interruption of endogenous genes*"

2.4) The treatment of cisgenic modifications

2.5) Status of NGT1 Progeny

2.6) The meaning and scope of "*reasoned objection*"

2.1) Interpretation of the 20-Modification Limit: the current limit of 20 genetic modifications may become increasingly restrictive as plant breeding and research programmes move towards the stacking and combination of multiple beneficial traits to address agricultural, environmental, societal and consumer-related challenges. This is particularly relevant for the development of complex polygenic characteristics and the combination of traits contributing to sustainability, resilience, productivity and quality. Annex I, point (3), of the Regulation is clear that the maximum number of modifications permitted under criterion 1 is 20 per monoploid genome. Consequently, the allowable number of modifications should be calculated according to the number of monoploid genomes sets present in the species. For example, a tetraploid species would be permitted up to 80 modifications (4×20). The delegated act should confirm this interpretation and ensure its consistent application across species with different ploidy levels, without requiring separate assessments of individual homologous chromosome copies or haplotypes.

2.2) The interpretation of "*a combination of genetic sequences already occurring in the gene pool for conventional breeding purposes*": The delegated act should take into account the scientific considerations on the breeders' gene pool set out in *EFSA's Scientific Opinion Addressing the Safety Assessment of Plants Developed through Cisgenesis and Intragenesis*². In particular, the interpretation should be consistent with the understanding that functional copies of genetic elements originating from sexually compatible species may be transferred as such within the gene pool for conventional breeding purposes, and therefore by the use of NGTs. Evidence relating to the gene pool for conventional breeding purposes should rely on scientific literature, breeding knowledge and established breeding practice, without requiring unnecessary experimental demonstration *sensu lato* of sexual compatibility on a case-by-case basis or limited to a pre-existing documented sequence in a database. In addition, for cisgenesis purposes, the introduction of a cisgene with its endogenous transcriptional regulatory sequences originating from the gene pool for conventional breeding purposes should be considered meeting the criterium that *it results in a combination of DNA sequences that occur in the gene pool for conventional breeding purposes* even where the integration site is located within an endogenous gene, provided that no chimeric proteins are created. Such an interpretation should allow condition (i) to be applied independently of condition (ii), in accordance with the Regulation's requirement that cisgenic modifications fulfil *one or both* of those conditions. Otherwise, the practical applicability of condition (i) for cisgenic modifications could be unduly restricted.

2.3) The interpretation of "*interruption of endogenous genes*": for the purposes of applying Annex I condition in cisgenesis applications, *gene* should be understood as the protein coding regions, and not extending to surrounding regulatory elements such as promoters, enhancers or other non-

² [Scientific Opinion](#) on Cisgenesis and Intragenesis (EFSA 2012).

transcribed regulatory regions. Therefore, *interruption of an endogenous* gene should be understood as structural and functional.

2.4) The treatment of cisgenic modifications: The delegated act should ensure a flexible and scientifically justified interpretation of cisgenic modifications that remains consistent with the objectives of Regulation (EU) 2026/1388 and existing EFSA scientific opinions. Compliance with Annex I should be assessed on the basis of the final genomic configuration of the plant rather than the technical process used to generate it and without the transformation process itself constituting grounds for categorisation. Therefore, where multiple cisgenic modifications are introduced simultaneously³, they should be assessed as individual modifications for the purposes of Annex I. Furthermore, plants obtained through non-targeted cisgenesis, including *Agrobacterium*-mediated transformation, should remain eligible for Category 1 status where the resulting genetic modifications fulfil one of the both conditions set out in the Annex I (Criteria 2-b) criteria. Residual technical sequences, such as T-DNA border sequences and fillers, should not, in themselves, result in a plant being considered to contain foreign DNA². Consistency with existing EFSA considerations on cisgenesis, and the breeders' gene pool should be maintained.

2.5) Status of NGT1 Progeny: In accordance with Article 3(13)(b) and Recital 21 of the Regulation, the progeny of a verified Category 1 NGT plant obtained through conventional breeding techniques, including, *inter alia*, crossings with conventionally bred plants or with other verified Category 1 NGT plants, continues to be considered a Category 1 NGT plant and remains equivalent to a conventionally bred plant without the need for a new verification procedure. Recital 21 and Article 3(13)(b) clearly confirm that conventional crosses involving one or more verified Category 1 NGT plants do not give rise to a new verification requirement. Once verified, Category 1 NGT plants should thereafter be considered part of the gene pool available for conventional breeding purposes and should remain accessible for further breeding activities under the same conditions as conventionally bred material. Where additional genetic modifications are subsequently introduced to a previously verified line through targeted mutagenesis or cisgenesis, the newly introduced modifications should be subject to a new verification procedure against the Annex I criteria⁴; the threshold therefore applies on a per-generation basis and is not to be understood as a cumulative ceiling across successive verified generations.

2.6) The meaning and scope of "reasoned objection": reasoned objections should be limited to scientifically substantiated concerns demonstrating that one or more of the criteria set out in Annex I have not been fulfilled. The verification procedure is intended to verify compliance with the conditions for Category 1 status and should not be delayed by objections that are not supported by evidence or that fall outside the scope of the Annex I assessment. To ensure legal certainty, efficiency and harmonised implementation across the Union, objections should be based on clear scientific

³ [Report on the Economic and Environmental Impacts of Disease-Resistant Crops Developed with Cisgenesis](#) (JRC 2023).

⁴ [Council General Approach](#) on the Proposal for a Regulation on Plants Obtained by Certain New Genomic Techniques (Council of the European Union 2023)

reasoning and identified deficiencies in the verification dossier. Furthermore, once a particular reasoned objection has been assessed and determined to be incorrect, objections relying on the same interpretation should not be allowed to repeatedly be raised in subsequent procedures.

3. Interpretation of Annex II

The implementing legislation should provide a scientifically robust and proportionate interpretation of the trait-based exclusions set out in Annex II, particularly regarding herbicide tolerance and traits related to the production of a "substance with a known insecticidal action". In line with Recital 19, plants in which herbicide tolerance has been introduced as a selection marker^{5,6}, and not for cultivation in combination with the use of the relevant herbicide, should not be considered to fall under the herbicide-tolerance exclusion. The assessment should therefore focus on the intended function of the trait and the purpose for which it was introduced.

The implementation framework should also ensure that concepts such as *substance with a known insecticidal action* are interpreted in a clear, predictable and scientifically consistent manner, and are restricted to substances whose known function is to kill insects. The diversity of plant defense mechanisms and naturally occurring plant traits that have a direct or indirect role in defending plants against insects should not be treated as substances with a known insecticidal action.

4. Data requirements

The delegated act should establish outcome-oriented data requirements while allowing developers sufficient flexibility to choose appropriate methodologies for demonstrating compliance with the Regulation, and the framework should focus on the intended genetic modifications relevant for demonstrating compliance with Annex I.

Consideration should be given to the dynamic nature of plant genomes and the verification process should remain centred on demonstrating fulfilment of the regulatory criteria rather than on identifying incidental variation that may be indistinguishable from naturally occurring genetic changes.

Whole genome sequencing should not be a requirement for Category 1 verification. Such an approach would be technically challenging across many crop species and difficult to implement at the scale required by practical breeding programmes⁷.

Instead, developers should be allowed to use scientifically justified methodologies that are fit for purpose for demonstrating:

- The nature of the intended modifications.

⁵ [Transgene-Free Genome Editing](#) of Vegetatively Propagated and Perennial Plant Species in the T0 Generation (Nature Plants, 2023)

⁶ [Transgene-Free Edited](#) Banana Generated Through Agrobacterium-Mediated Base Editing (New Phytologist 2025)

⁷ [Haplotype-Resolved Genomics](#) in Horticultural Crops: Advances, Challenges and Perspectives (Horticulture Research 2026)

- Compliance with Annex I criteria.
- The absence of genetic material originating from outside the gene pool for conventional breeding purposes, only in cases where such genetic material was used in the process of NGT1 product generation.

Targeted sequencing approaches and other scientifically appropriate methods would be able to provide sufficient information to demonstrate compliance with the relevant criteria, and common evidence standards should be targeted towards ensuring reliability while maintaining technical flexibility which would support harmonised implementation cross the Union. Evidence requirements should remain limited to the essential, proportionate and technology-neutral; and the delegated act should avoid the request of specific technologies that may be prescriptive or rapidly become outdated as scientific methodologies continue to evolve.

5. Natural Genetic Diversity and Crop Diversity

The implementation framework should recognise the extensive natural genetic diversity that exists within crop species and relatives, and that naturally occurring genetic variants and DNA sequences present within the gene pool for conventional breeding purposes are not fully represented in currently available genomic databases or reference assemblies^{8,9}. The absence of a particular sequence or variant from (publicly) available resources should not be taken as evidence that it does not occur within the relevant breeding gene pool. Implementation should therefore avoid interpretations that rely exclusively on existing genomic databases and should take into account the inherent limitations of current knowledge and documentation of crop genetic diversity. The delegated act should allow sufficient flexibility to accommodate differences in the availability of genomic information across crop species and relatives. The framework should also be applicable across the full diversity of agricultural crops, including species with complex genomes, polyploid crops, orphan crops and crop species whose genomes have not yet been fully sequenced or for which available reference genome assemblies remain incomplete or of limited quality.

6. Verification procedures compatible with R&I and breeding practices

The delegated act should recognise the realities and scale of plant breeding research and innovation and those of current breeding programmes. Plant breeding activities involve the evaluation of large numbers of lines generated from the same modification strategy, or plants intended to have a common traits/characteristics obtained through multiple strategies. Requiring entirely separate submissions for every individual breeding line could create substantial and unnecessary administrative burdens, disproportionately affecting SMEs, public research organisations and other smaller actors across the plant breeding value chain. Individual, line by line assessments are also not sustainable. The implementation framework should allow for batch submissions, so that multiple

⁸ [Plant Pangenomes for Crop Improvement](#), Biodiversity and Evolution (Nature Reviews Genetics 2024).

⁹ [Plant Pan-Genomics](#) and Its Applications (Molecular Plant 2024)

plants can be verified together. This is essential to enable established breeding practices, which routinely advance many lines in parallel, to be applied to NGT plants. Where the manner in which plants are developed ensures that the Annex 1 criteria are met by design, this should be sufficient grounds to streamline the review of batch submissions.

The verification framework should also take account of the fact that genome editing is used not only to obtain final commercial traits-crop combination but also as a research and breeding tool to generate genetic variation that is subsequently incorporated into breeding pipelines^{10,11,12}, and supporting the identification, selection and combination of desirable traits within breeding programmes¹³. While scientific evidence supporting the intended relationship between genetic modifications and the traits intended to be conveyed by those modifications may be derived from scientific literature, previous experience with similar modifications, breeding data and other relevant sources, the implementation framework must recognise that NGTs are frequently used to generate and evaluate novel genetic variation whose phenotypic effects and breeding value are progressively assessed throughout the breeding process and under field conditions¹⁴. In addition, the relationship between genetic modifications and intended traits may be established once the breeding programme advance and knowledge of the developed material increases. The assessment framework should therefore reflect the role of NGTs as both research and a breeding tool to create genetic variability, and as an integral component of current plant breeding practices. In line with the previous, verification procedures should support efficient field testing and selection for variety development, while maintaining compliance with the requirements established by the Regulation.

7. Confidentiality and Protection of Commercially Sensitive Information

The delegated act should provide a balanced approach between transparency and protection of confidential business information. Verification dossiers may contain commercially sensitive information relating to breeding strategies, proprietary germplasm, genetic sequence information, unpublished research results, and intellectual property. The disclosure of such information could compromise competitive advantages, diminish incentives for research and innovation, and affect future investments in research and innovation ecosystem as well as the development of improved plant varieties.

Transparency measures should therefore be targeted to information necessary to ensure public confidence and effective implementation of the Regulation while safeguarding legitimate commercial

¹⁰ [Enhancing Grain Yield](#)-Related Traits Through CRISPR-Cas9 Promoter Editing of Maize CLE Genes (Nature Plants 2021).

¹¹ [Engineering Quantitative Trait](#) Variation for Crop Improvement by Genome Editing (Cell 2017)

¹² [Targeting a Gene Regulatory Element](#) to Enhance Rice Grain Yield (Nature Biotechnology 2022)

¹³ [Bohanec et al. \(2023\)](#), BREEDIT: a multiplex genome editing strategy to improve complex quantitative traits in maize

¹⁴ [Cryptic variation](#) fuels plant phenotypic change through hierarchical epistasis (Nature 2025)

interests. The disclosure of information should not undermine innovation incentives or negatively affect the competitiveness of European research institutions, breeders and developers.

8. Conclusions

The implementation of Regulation (EU) 2026/1388 represents an important opportunity to establish a regulatory framework that enables the effective integration of New Genomic Techniques into European plant breeding and research activities. A science-based, proportionate and workable implementation will be essential to ensure that the Regulation supports continued innovation, facilitates the development of improved crop varieties, and contributes to maintaining Europe's scientific and breeding capacity in an increasingly competitive and changing global environment.

The delegated act should provide sufficient legal certainty and flexibility to accommodate scientific progress, technological developments and the diversity and scale of breeding systems and crop species developed and produced across the Union and beyond. Achieving these objectives will be critical to ensuring that researchers, breeders, public institutions and companies of all sizes can fully contribute to developing varieties capable of addressing future agricultural, environmental, societal, and climate-related challenges.

Plants for the Future ETP remains available to provide further scientific, technical and practical input to support the development and implementation of the delegated act.

[Plants for the Future ETP](#) (Plant ETP) is a multi-stakeholder European Technology Platform representing the plant sector, from the seed and breeding sector, the farming community and academia. Plant ETP brings stakeholders from the plant sector together to consider the challenges and opportunities of agricultural value chains in a systemic way, while developing a vision for future systems spanning food, feed, and biobased raw materials. In this way, Plant ETP provides strategic direction, recommendations of essential research and innovation, and science-based advice for the benefit of policymakers, research funding providers, practitioners, and innovators throughout agricultural value chains.