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Date: 25.09.2026
Your ref: Ares(2026)8283054

Plants obtained by new genomic techniques: information requirements and verification of category 1 status

This initiative supplements Regulation (EU) 2026/1388 on plants produced by certain new genomic techniques (NGTs). It specifies the information required from operators to demonstrate that a plant is an NGT plant and the information needed to verify plants and products equivalent to conventional ones (category 1).

The purpose is to provide clarity and predictability for operators on how to prepare verification requests and how to submit information on patents. It will also support Member States and EFSA in implementing Regulation (EU) 2026/1388.

Draft act feedback period 31 August 2026 - 28 September 2026.

The Norwegian Institute of Bioeconomy Research (NIBIO) is a public research institute with expertise in plant genetics, molecular biology, genome editing, plant breeding, plant pathology and the molecular detection and characterization of genetically modified organisms. NIBIO serves as Norway's National Reference Laboratory for genetically modified organisms and contributes scientific expertise to European cooperation on GMO detection and analysis. This response draws on NIBIO's research and regulatory experience with new genomic techniques in crop plants.

NIBIO acknowledges the need for a proportionate, science-based verification procedure for category 1 new genomic technique (NGT-1) plants. The information required should be limited to what is necessary to demonstrate compliance with the NGT definition and the equivalence criteria set out in Annex I.

Verification should focus on the final product rather than on intermediate steps in the development process. It should be limited to two key elements: (i) confirmation that the intended genetic modification(s) have been successfully introduced using new genomic techniques, demonstrated by

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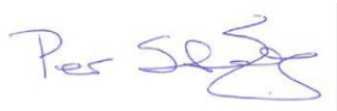
PCR amplification and targeted sequencing of the edited locus or loci, or of the inserted cisgene; and (ii) PCR-based confirmation that the T-DNA construct temporarily introduced to induce the mutation is no longer present. Whole-genome sequencing should not be required as a mandatory part of NGT-1 verification, whether to confirm the intended modification, verify the absence of foreign DNA, or assess potential off-target mutations. Where suitable reference genome information is available, guide RNAs should be designed to minimize the likelihood of off-target effects. Beyond this, off-target screening should not be required for NGT-1 verification. Current scientific evidence indicates that genome-wide analyses cannot reliably distinguish mutations caused by genome editing from naturally occurring mutations, from variation between individual genomes within a species, as illustrated by pan-genome studies, or from mutations induced by tissue culture. The latter is a background source of variation that is already present and accepted in conventional plant breeding. A potential off-target mutation identified by PCR screening and targeted sequencing of bioinformatically predicted sites is therefore not necessarily a hazard simply because it arose during the editing process. A more meaningful indicator of the absence of unintended off-target effects is the demonstration of a consistent phenotype across independent editing events during product development. These are data that developers will normally already have available when submitting a verification application, and their use would avoid additional time-consuming and resource-intensive trials.

Kind regards



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