

**Submission of Claire Robinson, Co-Director, GMWatch and Michael Antoniou, PhD, Professor Emeritus of Molecular Genetics and Toxicology, King's College London, on the implementation of Regulation (EU) 2026/1388 of the European Parliament and of the Council of 17 June 2026 on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625 (Text with EEA relevance)**

23 September 2026

## **Introduction**

This submission is in response to the European Commission's consultation regarding Regulation (EU) 2026/1388 (hereafter called "the Regulation"), on 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)".<sup>1</sup>

Article 1 states: "This Regulation aims to ensure a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle, and the effective functioning of the internal market in relation to plants obtained by certain new genomic techniques, to food and feed containing, consisting of or produced from such plants, and to products, other than food and feed, containing or consisting of such plants, while enhancing innovation, sustainability and competitiveness."

In its Implementation Strategy for Regulation (EU) 2026/1388, the Commission announced the following steps to implement the new law: "To support the regulatory procedures concerning both category 1 and category 2 NGT plants, the guidance will assist operators by providing the scientific and technical details on how to demonstrate that a plant is an NGT plant. This may include, for example, molecular methods and data requirements to demonstrate the absence of genetic material originating from outside the gene pool for conventional breeding purposes used during breeding.

"For category 1 NGT plants, guidance will, amongst other things and in alignment with the delegated act, assist operators by providing details on the information required from verification requesters to demonstrate compliance with the conditions for category 1 NGT plants. This will include, in particular, the scientific and technical details to demonstrate compliance with the criteria of equivalence, such as the genetic information, methodologies and quality standards."<sup>2</sup>

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<sup>1</sup> European Commission (2026). Plants obtained by new genomic techniques: information requirements and verification of category 1 status. [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/18805-Plants-obtained-by-new-genomic-techniques-information-requirements-and-verification-of-category-1-status\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/18805-Plants-obtained-by-new-genomic-techniques-information-requirements-and-verification-of-category-1-status_en)

<sup>2</sup> European Commission (2026). Implementation Strategy for Regulation (EU) 2026/1388 on plants obtained by certain new genomic techniques and their products. [https://food.ec.europa.eu/document/download/4c13763b-bed7-40f1-8009-56fc4b7c7a57\\_en?filename=ngt\\_leg\\_implementation-strategy\\_reg-2026-1388.pdf](https://food.ec.europa.eu/document/download/4c13763b-bed7-40f1-8009-56fc4b7c7a57_en?filename=ngt_leg_implementation-strategy_reg-2026-1388.pdf)

## Definition of NGT1 status

NGT1 plants (Recital 16 of the Regulation) are defined as plants “that could also occur naturally or be produced by conventional breeding techniques”. However, the criteria set out in Annex I are not by themselves adequate to evaluate equivalence between NGT and conventionally bred/naturally occurring plants. These criteria must therefore be supplemented, either by amending Annex I or by mandating EFSA to set data requirements.

## Requirements for verification of NGT1 status

We agree with the submission of Testbiotech that:

- “The data requirements for verification of NGT1 status should include data for an assessment of the plausibility that such an NGT plant may be obtained by conventional breeding or natural processes. If sufficient plausibility is lacking, the plants fall under category NGT2.
- “For decisions on the applicability of the Novel Food Regulation, peer reviewed publications including data on all intended and unintended changes caused by the application of NGTs should be requested from the producer;
- “For the public database, peer reviewed publications should be requested from the applicant including data on results of field trials. In addition, to avoid confusion with similar plants, relevant details should be provided, as well as information about the regions in which the plants are cultivated. These data should be updated continuously.
- “The structure and the content of the data requirements (including peer reviewed publications) should be guided by EFSA.”<sup>3</sup>

To verify the NGT1 status of a plant, molecular characterisation (including “omics” analyses) of the candidate plant as compared with the non-genetically modified (GM) parent plant should be required to be performed. The objective is to reveal the full extent, type, and effects of both the intended and unintended changes brought about by the gene editing tool and the processes associated with gene editing (e.g. tissue culture; GM transformation process involving *Agrobacterium* infection or biolistics). The following comparative analyses should be performed on the NGT1 candidate plant and its non-GM parent:

- Whole genome sequencing (long-read) to reveal the full spectrum of DNA changes. Note: standard short-read whole genome sequencing can frequently miss unintended outcomes such as large DNA deletions and rearrangements including chromothripsis, which can occur at both off-target and on-target genome edit sites. Thus, short-read whole genome sequencing cannot be relied upon to provide comprehensive information of the full range of genetic alterations arising from NGT processes.
- Transcriptomics, to reveal changes in global patterns of gene expression

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<sup>3</sup> TESTBIOTECH Background 09 - 09 – 2026. [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/18805-Plants-obtained-by-new-genomic-techniques-information-requirements-and-verification-of-category-1-status/F33569183\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/18805-Plants-obtained-by-new-genomic-techniques-information-requirements-and-verification-of-category-1-status/F33569183_en)

- Proteomics, to reveal changes in the protein profile
- Metabolomics, to reveal changes in the metabolite profile.

Several scientific papers recommend molecular characterisation and/or “omics” analysis in the evaluation of NGT plants, including Koller and Cieslak (2023);<sup>4</sup> Eckerstorfer et al (2023);<sup>5</sup> Eckerstorfer et al (2019);<sup>6</sup> Kawall et al (2020);<sup>7</sup> Agapito-Tenfen SZ et al (2018);<sup>8</sup> and Biswas S et al (2020).<sup>9</sup>

These analyses are especially important given the exceptionally loose criteria for equivalence specified in Recital 18 of the Regulation: “targeted substitutions and insertions of limited size, deletions of any size, larger substitutions with, and insertions of, continuous sequences of genetic material from the gene pool for conventional breeding purposes, as well as inversions and translocations of continuous endogenous DNA sequences, should be included in the criteria of equivalence”. The Regulation fails to explicitly ask the question: “What effects will these genomic alterations, both intended and unintended, have on the organism’s biochemistry and composition with downstream impacts on the consumer, and the environment?”, despite the fact that answers to this question are necessary to ensure a “high level of protection of human and animal health and of the environment”.

In order to fulfil the aim of the Regulation, therefore, either Annex I will need to be amended, or EFSA will need to be tasked with establishing robust data requirements, to ensure that such analyses are performed and that their findings can inform the accurate categorisation of claimed NGT1 plants.

## The “foreign DNA” question

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<sup>4</sup> Koller F, Cieslak M (2023). A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment. *Front. Bioeng. Biotechnol.* (11–2023), 27 October 2023. Sec. Biosafety and Biosecurity. <https://doi.org/10.3389/fbioe.2023.1276226>. <https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2023.1276226/full>

<sup>5</sup> Eckerstorfer MF et al (2023). Recommendations for the assessment of potential environmental effects of genome-editing applications in plants in the EU. *Plants* 2023, 12, 1764. <https://doi.org/10.3390/plants12091764>

<sup>6</sup> Eckerstorfer MF et al (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). *Front. Bioeng. Biotechnol.* 7:31. doi: 10.3389/fbioe.2019.00031. <https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full>

<sup>7</sup> Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environ Sci Eur* (2020) 32:106 <https://doi.org/10.1186/s12302-020-00361-2>

<sup>8</sup> Agapito-Tenfen SZ et al (2018). Revisiting risk governance of GM plants: The need to consider new and emerging gene-editing techniques. *Front. Plant Sci.* 9:1874. doi: 10.3389/fpls.2018.01874. <https://www.frontiersin.org/articles/10.3389/fpls.2018.01874/full>

<sup>9</sup> Biswas S et al (2020). Investigation of CRISPR/Cas9-induced SD1 rice mutants highlights the importance of molecular characterization in plant molecular breeding. *Journal of Genetics and Genomics*. May 21. doi:10.1016/j.jgg.2020.04.004. <https://www.sciencedirect.com/science/article/pii/S1673852720300916?via%3Dihub>

An NGT plant is not allowed to contain “any genetic material originating from outside the gene pool” (Article 3.9). We understand this as meaning it must not contain any foreign DNA.

At present, the standard method to gene edit a plant is to introduce plasmids (circular DNA molecules) encoding the gene editing tool into plant cells grown in tissue culture. Kim and Kim (2016) used this plasmid transformation method to gene edit the model plant *Arabidopsis thaliana*. Using a DNA sequencing screening method targeted to the edit site (not whole genome sequencing), the researchers found that plasmid-derived DNA sequences had inserted into the genome of the plants.<sup>10</sup> These sequences would also have been revealed using long-read whole genome sequencing.

Kim and Kim (2016) pointed out that the standard screening methods commonly used by developers of gene-edited organisms are likely to miss the inadvertent presence of foreign DNA and thus these organisms may be deregulated on the false pretence that they do not contain it. For example, in the US, a gene-edited mushroom was exempted from regulatory oversight by the USDA on the basis of claims by the developer that it was “transgene-free” and had “no foreign DNA” integrated into its genome. However, Kim and Kim wrote that based on their research findings, the deregulated mushroom “may still contain tiny fragments of foreign DNA in its genome”.<sup>11</sup>

Within the EU this mushroom, which was created with a theoretically small and simple gene knockout (so-called SDN1), would almost certainly have been claimed by the developer to be NGT1. A thorough analysis, such as we propose should be mandated, would have established whether it genuinely qualified for NGT1 status.

While a mushroom is a fungus, which would not fall under Regulation (EU) 2026/1388 because it only relates to plants, Kim and Kim’s experiment with *Arabidopsis* used the same plasmid method used by the non-browning mushroom developer – so the results of this experiment are directly relevant to the Regulation.

Whole genome sequencing (long-read), transcriptomics, proteomics, and metabolomics data should be performed as a prerequisite to ascertaining whether a plant qualifies as NGT1. Such analyses would fulfil the aim of the Regulation to correctly classify plants as NGT1.

Whole genome sequencing (long-read), transcriptomics, proteomics, and metabolomics data would also be needed to decide whether an NGT1 plant has “significantly changed composition or structure that affects the nutritional value,

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<sup>10</sup> Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* 34, 1014–1015 (2016). <https://www.nature.com/articles/nbt.3680>. A summary of the findings of this research and their implications, as well as links to the regulatory correspondence, are in: Robinson C (2022). “Transgene-free” GMOs may be exempted from GMO regulations under false pretences. *GMWatch*, 9 Apr. <https://www.gmwatch.org/en/latest-news/20013>

<sup>11</sup> Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* 34, 1014–1015 (2016). <https://www.nature.com/articles/nbt.3680>

metabolism or level of undesirable substances of the food” (Recital 31) and therefore falls under the Novel Food Regulation.

Based on these analyses, comparison of the NGT1 candidate plant with existing non-GM plants should also be performed, using reference databases and/or reference samples, to establish the degree of similarity between them.

## Hypermorphing

Recent research describes a strategy for making “compact deletions and motif insertions that strongly increase protein production (>30-fold relative to wild type), outperforming transgenic enhancer elements”.<sup>12</sup> The Regulation provides that NGT plants with fewer than 20 genetic modifications will be authorised without a risk assessment. However, strategies such as hypermorphing may well have fewer than 20 intended genetic modifications, while still causing extreme and potentially risky changes.

Recital 53 states: “In order to reflect the rapid evolution of scientific and technical knowledge in the areas of plant science and plant breeding, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of adapting the criteria of equivalence to scientific and technical progress as regards the types and extent of genetic modifications which can occur naturally or through conventional breeding.”

Article 5.3 states: “The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt those criteria to scientific and technological progress, to the extent justified by advances in scientific knowledge as regards the types and extent of genetic modification which can occur naturally or through conventional breeding.”

Based on these texts, the Commission should use its powers under Recital 53 and Article 5 of the Regulation to proactively require that applicants provide the technical data to enable EFSA to accurately and verifiably assign the NGT status of a plant based on scientific evidence of the level of risk.

## Conclusion

The analyses described above should form part of the plausibility test to ascertain whether a plant qualifies as NGT1. Such analyses are the minimum required to “ensure a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle”, as required by the

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<sup>12</sup> Groover ED et al (2026). Mapping cis-regulatory mutations at scale in sorghum enables modulation of gene expression. Nature Biotechnology (2026). <https://www.nature.com/articles/s41587-026-03046-y>

Regulation. They would also provide legal and technical certainty for developers, thereby enabling “the effective functioning of the internal market”.