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OPEN LETTER

# Detection, identification and quantification of NGTs in EU authorization procedures – No solution without legislative change

[version 1; peer review: 1 approved, 2 approved with reservations]

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## Abstract

For the purposes of GMO authorisation, applicants are required to submit validated methods for the detection, identification and quantification (DIQ). For classical transgenic organisms, this requirement has proven workable. For products derived from New Genomic Techniques (NGTs), specifically those introducing small insertions and deletions (InDels) without foreign genetic material, it has not. NGT-induced genomic changes are frequently indistinguishable from naturally occurring mutations, making identification legally required but technically unachievable with currently available analytical tools. This open letter examines whether recently proposed DIQ methodologies, including genomic fingerprinting approaches based on single nucleotide variant (SNV) profiling, can bridge this gap. We find that while such approaches advance detection capabilities, they fall short of the identification and quantification standards demanded by EU law, for reasons such as the absence of universal pangenome datasets, the complexity of polyploid crop genomes, the loss of fingerprint integrity through elite line crossing, and the dependence of recombination rates on multiple species-specific factors. The mismatch between legal requirements and scientific feasibility has consequences for authorisation procedures, supply chain compliance, organic farming integrity, and international trade. We conclude that no purely technical solution is

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Any reports and responses or comments on the article can be found at the end of the article.

forthcoming and that legislative change is necessary. Aligning the EU's evidentiary standards with technical reality is a precondition for a functional and enforceable GMO authorisation system.

**Keywords**
New Genomic Techniques (NGTs), genome editing, Detection, Identification and Quantification (DIQ), single nucleotide variants (SNVs)




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## Legal requirements

The EU's GMO framework sits among the most demanding regulatory regimes for biotechnology products in the world,[1] making most products manufactured with New Genomic Techniques (NGTs)[2] subject to it.[3] This article addresses NGTs that create mutation(s) without insertion of foreign genetic material, specifically small insertions and deletions (InDels).[4] Under EU GMO law, detection, identification and quantification (DIQ) methods are required to receive an authorisation for the placing on the market (in particular import) and cultivation of GMOs and GM food and feed.[5] Absent reliable DIQ methods, effective enforcement of EU GMO and non-GMO rules cannot be achieved in practice.[6,7] This has significant implications for (1) submission for authorisation for release into the environment and/or for import and processing, (2) international trade with third countries, where not all GMOs are subject to labelling, authorisation or registration requirements, (3) the restriction or prohibition of GMO cultivation to be enforced by Member States under Directive (EU) 2015/412, (4) the exclusion of GMOs by producers in organic production, (5) the provision of freedom of choice for consumers and (6) sustainable agriculture development in the EU.

EU law mandates that the submitted methods must be capable of detecting, identifying and quantifying a specific genetic modification.[8] Detection establishes the presence or absence of a genomic change (also at phenotypic level).[9,10] Identification then attributes that change to a particular modification event, distinguishing between spontaneous mutation and deliberate technical intervention.[11] Quantification assigns a measured mass fraction to a defined GM event, enabling assessment against the labelling thresholds set by EU law.[12] Even with validated methods for detection and quantification, identifying NGT events - in contrast to the identification of classical GMOs - remains challenging, if not impossible.[13,14,15] One could claim that in practice detection methods for classical GMOs may indirectly be used also for identification, as the genetic changes in classical GMOs containing transgenic constructs are unique for the event and generally the result of technical intervention. However, small genomic edits in NGT plants can be identical to modifications that could occur naturally or through classical breeding techniques,[9,13,14] making the establishment of causal links between detection and identification of an NGT-derived line highly challenging or even impossible from a biological point of view. Furthermore, it is questionable if an interpretation of a detection based on likelihoods would serve the legal requirements for establishing causal links. In the EU, DIQ methods are available for products that have been authorized, as they are a legal requirement for receiving authorisation. In contrast, DIQ methods for unauthorised GMOs need to be developed by the public and/or private sector. Food business operators are obliged to do so to operationalise their legal duty to develop control mechanisms in order to verify their compliance with GMO food laws. Existing control mechanisms for unauthorized GMOs are largely designed and developed based on publicly available information. Obtaining positive materials necessary for method validation is often difficult and depends on the readiness of the manufacturer to provide those.

Testing for unauthorized GMOs remains at the discretion of the responsible national control agencies. Traders and processors of food products require, as part of their contractual obligations, declarations regarding the GMO status of the product from downstream market participants. Hence, within the agriculture and food supply chain, these requirements trace back to the producer. In case of crops, GMOs approved for cultivation in a country outside the EU but not within the EU might reduce the production choices of the farmer outside of the EU if the product produced on her/his farm is intended to enter the EU market. They also affect the organisation of international agriculture and food supply chains. They add due to the increased complexity of organising agriculture and food supply chains, which, in the end, have to be paid for by the final consumer through higher food prices.[16]

EU authorisation operates through two parallel tracks[17,18]: deliberate release and market placement fall under Directive 2001/18/EC, while food and feed authorisation is governed by Regulation 1829/2003 and its implementing regulations. This includes GM animals and microorganisms. The majority of applications pertain to GM food and feed of plant origin; hence the GMO Regulation 1829/2003 is more significant in practice.[19] However, product authorisation can be sought simultaneously, and liability has been shown to appear across authorisation paths.[7] Consequently, the individual legal requirements for authorisation should be considered together.

DIQ methods in food and feed are governed by Commission Implementing Regulation (EU) No 503/2013[20] (the GMO Food Authorisation Regulation) and Commission Regulation (EC) No 641/2004.[21] Cultivation and placing on the market is governed by the GMO Directive, read together with national implementing legislation. The "one door one key principle" connects both regimes.

For GM higher plants, the GMO Directive requires a description of the detection and identification techniques.[22] DIQ methods must not be considered confidential (Article 25 of the GMO Directive); only detailed DNA sequence information fulfils this requirement, which in turn requires the use of analytical methods.[7] Implementing Member States cannot and do not deviate from these requirements.[10]

The authorisation procedure outlined in the GMO Regulation concerning food and feed likewise requires the submission of methods. Article 8 of the GMO Food Authorisation Regulation and Commission Regulation (EC) No 641/2004 are framed exclusively around analytical methods,[19] with PCR-based[7] approaches at the core. Critically, unlike other elements of the authorisation dossier, no exemption or derogation is available for DIQ requirements: the legislator treated these as a strict, non-negotiable element of the enforcement regime. Their categorisation as part of the enforcement process also justifies such a strict legal regime.[19] Legal limits to analytical DIQ methods is supported by the practical requirements applicants and laboratories validating the methods face in the authorisation procedure and is shared by the European Network of GMO Laboratories (ENGL).[19]

## Compliance of proposed DIQ methods for NGTs with legal requirements

One publication[23] advertised a basic breakthrough in DIQ methodology. While the proposed methodology is promising for the detection "D" part, major limitations remain for the "I & Q" parts due to the following shortcomings:

- A fundamental prerequisite for the design of fingerprint, i.e. a set of single nucleotide variants (SNVs) which unambiguously identifies a variety line, is the availability of a robust and extensive genomic data set, which includes numerous high-quality reference genomes from a large variety of lines within a species (pangenome). While such data sets may exist for some species, e.g. rice, they are not yet attainable for many other species.

- The chosen example, rice, being a diploid organism, possesses a relatively simple genomic structure, which makes the approach more feasible for this species. However, many other crop species are polyploid and have more complex genomes. Although this complicates the method's application, future advancements in fingerprint development could potentially alleviate this issue to some extent.

- Most importantly, the method does not provide identification. Rather, it creates a fingerprint to trace the origin line and then detects GE-related SNVs within this line. As there is no individual fingerprint for the actual NGT organism, the method does not allow for the differentiation between a NGT-organism and one with the same background where the mutation occurred naturally as there are no links between the fingerprint and the additionally interrogated SNV.

- Moreover, the identification process described in the paper is not a true identification of the origin line but rather an elimination of other well-sequenced lines. Therefore, unless all varieties of a species are used to create the fingerprint, it cannot be considered unambiguous.

- Whereas the approach chosen might be amendable to genetically homogeneous materials, it falls short if mixtures of lines need to be analyzed, which is the most realistic scenario for GMO analyses.

- Another fundamental problem of the analytical strategy arises from the common practice of plant breeders to cross the developed events (modifications) from the developing line into their many different geographically and climatically specific elite lines, resulting in a loss of the fingerprint and a strongly altered SNV profile for each of these lines. Therefore, a new fingerprint would have to be established for each of these elite lines carrying the event, again requiring the supply of the respective positive material. For comparison: there are more than 100 different lines in Europe for the EU-approved MON810 maize event (Bayer Crop Science) alone. It would therefore be necessary for the fingerprint-specific SNVs to be genetically linked to the edited locus, ensuring their preservation in subsequent generations and crossbreeds.[14,15]

However, since the recombination rate depends on various factors, including the total genome size, methylation, the occurrence of recombination hotspots, and imbreeding,[24,25,26,27] it is not feasible to determine a general or species-specific value for a genomic distance or centimorgans in order to establish a generation- and lineage-spanning fingerprint for the event.

- In fact, the proposed method does not provide better "D&I" abilities than a WGS- or even amplicon-sequencing based approach paired with bioinformatic analyses (i.e. determine the variety by means of blast or alignment against references followed by SNV calling). What it does is offer a more targeted approach allowing for the design of PCR based detection methods targeting the fingerprint and the GE SNV, which does have advantages for routine analyses in authorisation settings, but it does not solve any of the D&I issues previously discussed.

## Conclusion

The EU's regulatory architecture for GMOs was built on the premise that every authorised product can be uniquely detected, attributed to a specific modification event and quantified with analytical certainty. For classical transgenic organisms, this premise has largely held. For NGT-derived products producing small, locus-specific alterations, it no longer does. As molecular breeding technologies advance, the gap between what EU law requires and what science can deliver has widened to the point of structural incompatibility.

The central issue is not detection but identification. Although genomic differences can be observed with increasingly sensitive (sequencing) technologies, the legal requirement to identify whether a mutation arose through technical intervention (and to link it to a defined event in the sense of attribution) cannot be met when NGT-induced changes are indistinguishable from naturally occurring variants. No analytical refinement, whether whole-genome sequencing or targeted "fingerprinting," can transcend this biological limitation. These methods may streamline detection within well-characterized species, but they do not provide the unambiguous identification or event-specific quantification that EU law demands.

This mismatch has cascading consequences. Enforcement becomes inconsistent, authorisation dossiers become legally precarious, and supply chains (both within and beyond the EU) must absorb the costs of compliance systems that do not reliably discriminate the products they are designed to police. Farmers, traders and regulators alike are left navigating obligations that cannot be fulfilled with the tools currently available. As international breeding and trade systems continue to integrate genome editing, the EU risks isolating itself behind an evidentiary standard that no longer corresponds to biological reality.

If DIQ requirements are to remain central to the EU's governance of genomic technologies, the legislation itself must evolve. A framework predicated on event-specific traceability is ill-suited for mutation-based NGTs and will only become more strained as these tools proliferate. Aligning regulatory expectations with scientific feasibility (whether through revising definitions, adapting evidentiary standards or developing alternative risk-based approaches) is now essential. Without legislative change, the EU's authorisation system will remain scientifically untenable, practically unenforceable and increasingly disconnected from the innovation landscape it seeks to regulate.

## Disclaimer

The views expressed in this article are those of the author(s). Publication in Open Research Europe does not imply endorsement of the European Commission.

## Ethics and consent

Ethical approval and consent were not required for this study.

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# Open Peer Review

## Current Peer Review Status: ✔ ? ?

**Version 1**

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**Alexios N Polidoros**
Aristotle University of Thessaloniki, Thessaloniki, Greece

The **open letter** manuscript (https://doi.org/10.12688/openreseurope.23629.1) attempts to address the challenges of **detection, identification, and quantification** of plants obtained through New Genomic Techniques (NGTs) within EU authorization procedures. The authors argue, based on experiences with GMOs, that effective traceability and regulatory oversight of NGT-derived products require significant legislative changes to ensure transparency for producers and consumers throughout the product lifecycle.

While the topic is highly relevant to ongoing debates in EU agricultural biotechnology policy, the letter requires **major revisions** before it can be considered suitable for indexing.
Major weaknesses:

1. **Outdated content and failure to reflect current regulatory developments:** The core premise—that "there should be no solution without legislative change" and that NGTs must be treated similarly to GMOs—does not accurately represent the evolving EU framework. The authors overlook the provisional political agreement reached on 3 December 2025 between the European Parliament and Council ( https://ec.europa.eu/commission/presscorner/detail/de/ip_25_2912). This agreement introduces a differentiated, two-tier system:
    - **NGT-1 plants and products** (those indistinguishable from conventional plants) will follow a product-based approach, exempt from GMO regulations.
    - **NGT-2 plants and products** will remain subject to existing GMO rules.

Subsequent steps include the ENVI Committee approval (28 January 2026) (ref), the Council endorsement (21 April 2026) (ref), and the formal adoption by the Council (May 2026) (ref), with publication expected in 2026 and full application around mid-2028 after a transitional period.

1. **Lack of balance and global context:** The letter adopts a process-based regulatory stance for all NGTs, overlooking the EU's partial transition toward product-based regulation for NGT-1, which aligns with approaches taken by countries such as the USA, Canada, the UK, Australia, Japan, and others. Additionally, it downplays the potential benefits of NGTs (ref) for climate resilience, sustainability, and competitiveness, as emphasized in recent

statements from European agri-food organizations. For instance, on May 4, 2026, a coalition of 31 European agri-food value chain organizations issued a joint statement advocating for the prompt adoption of the NGT regulation without further amendments (ref). Furthermore, in a letter dated May 15, 2026, four prominent European plant biotechnology associations urged the members of the ENVI Committee to swiftly approve a pending compromise regulation on NGTs (ref). This letter was endorsed by the French Association of Plant Biotechnologies (AFBV), Forum Grüne Vernunft (FGV), the Society for Plant Biotechnology (GfPB), and the Genomics and Genetic Engineering Research Circle (WGG).

2. **Incomplete discussion of practical implications:** With several NGT products nearing market entry (ref), the letter should better inform stakeholders by presenting the full, up-to-date landscape rather than an outdated, GMO-centric view.

Recommendations for major revision:

1. Update the entire text to incorporate the 2025–2026 legislative timeline and the NGT-1 vs NGT-2 distinction.
2. Revise the central argument to differentiate regulatory requirements between categories.
3. Add a balanced discussion of benefits (e.g., reduced inputs, sustainability) alongside detection challenges for NGT-1 products.
4. Include recent references to industry coalition statements and implementation timelines.
5. Strengthen the letter with clearer structure, updated citations, and acknowledgment of the transitional period toward 2028 applicability.
6. Modify the title accordingly to better reflect the message after the proposed changes.

In its current form, the open letter presents an incomplete and partially obsolete picture of the EU NGT regulatory situation. A **major revision** is necessary to ensure scientific and policy accuracy. After addressing these issues, particularly by incorporating developments post-December 2025, the letter could make a valuable contribution to the discourse on NGT governance in Europe.

**Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)**

Yes

**Does the article adequately reference differing views and opinions?**

No

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Partly

**Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)**
Partly

***Competing Interests:*** No competing interests were disclosed.

***Reviewer Expertise:*** Plant Molecular Biology, Genetics , Biotechnology, Breeding

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Reviewer Report 09 June 2026

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**Federica DeMaria**
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The manuscript addresses a major unresolved conflict between EU agricultural law, supply chain economics, and innovation policy. It examines the EU GMO framework, which requires Detection, Identification, and Quantification (DIQ) for market authorization under Directive 2001/18/EC and Regulation (EC) No 1829/2003. Economically, this requirement aims to reduce information asymmetry and protect consumer choice. While suitable for conventional transgenic products, the paper argues that it becomes problematic for New Genomic Techniques (NGTs), especially simple edits without foreign DNA. These edits are molecularly indistinguishable from natural mutations and therefore cannot be reliably detected by control authorities. The manuscript also critiques a recent proposed technical solution, showing that it fails because breeding processes break the traceable genetic “fingerprint.” As a result, the current framework risks generating market fragmentation, higher compliance and transaction costs, and trade disruption. The authors conclude that no workable technical fix is likely to emerge. Therefore, a legislative revision is necessary to restore regulatory certainty and market efficiency.
**Economic & Policy Critique**: The manuscript clearly highlights the risks this analytical deadlock poses to international trade, supply chain compliance, and the organic food market. However, its rationale is not fully aligned with the institutional and policy context of 2026. The authors state that “legislative change is necessary,” overlooking that EU institutions are already finalizing a major regulatory overhaul through the new NGT Regulation, which classifies NGTs into two categories (NGT1 and NGT2). To strengthen the argument, the paper should emphasize the core regulatory and economic paradox of this transition: the EU plans to exclude NGT1 products from organic farming while also exempting them from mandatory labeling and DIQ testing. This creates an impossible compliance burden and significant negative externalities for the organic

sector, which must ensure the absence of NGTs without having the analytical tools to verify it.
**Economic & Policy Critique**: The paper models the regulatory dilemma as a static technical failure rather than an active conflict between competing regulatory philosophies and economic interests. To be robust, it must reference two opposing viewpoints: a) the Product-Based / Innovation View represented by the agro-biotech industry and seed developers; b) the Process-Based / Precautionary View: Represented by environmental NGOs and the organic food sector.
**Economic & Policy Critique**: The economic and institutional reasoning is highly accurate, but the text lacks the foundational institutional citations required to make its legal-economic arguments, for instance, when stating that NGTs fall under strict GMO law, the authors must cite the landmark CJEU Case C-528/16 (2018 ruling), which is the institutional shock that legally triggered these market frictions; furthermore, when arguing that verification is an impossible standard for enforcement agencies, they should cite the European Network of GMO Laboratories (ENGL) 2019 report, which provides the official institutional baseline proving that laboratory enforcement of unauthorized simple edits is unfeasible.
**Economic & Policy Critique:** While the authors accurately call for a legislative evolution, their recommendations are too abstract for policy implementation. The authors need to move beyond stating *what* is broken and provide concrete, actionable policy pathways regarding how the EU can shift from costly analytical verification to institutional workarounds.
Finally, regarding the **conclusion**, I would suggest expanding them with this economically grounded framework

**Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)**
Partly

**Does the article adequately reference differing views and opinions?**
Partly

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**
Partly

**Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)**
Partly

**Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)**
Partly

***Competing Interests:*** No competing interests were disclosed.

***Reviewer Expertise:*** Applied Economics Agricultural and Food Economics Regulatory Impact AnalysisSupply Chain Economics

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

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The open letter focuses on one of the most legally significant questions in the field of GM crops, food, and feed in the EU, the “detection, identification and quantification[ in the light] of NGTs”. The difficulty of detection is also probably one of the most overused arguments in favour of deregulating NGTs and, despite its technical basis and significant implications, also one of the most controversial (albeit persuasive) arguments. It assumes, from the outset, widespread and systematic non-compliance on the part of breeders, and cunningly presents deregulation as the only possible solution.
The open letter shows that the underlying problems remain unresolved.
In view of potential legislative developments in relation to the key issues raised in the letter, it is suggested that due attention be paid to the wide array of nuances inherent in the overly broad and complex notion of *NGT plants*.

**Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)**
Yes

**Does the article adequately reference differing views and opinions?**
Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**
Yes

**Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)**
Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)**

Yes

***Competing Interests:*** No competing interests were disclosed.

***Reviewer Expertise:*** Intellectual Property and Biosafety Law...

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**