

Beyond GMO: Europe's New Regulatory Architecture for New Genomic Techniques and the Coming Transformation of Food Innovation

How Regulation (EU) 2026/1388 changes the legal meaning of genome-edited plants, redraws the boundary between biotechnology and conventional breeding, and creates a new competitive landscape for European food, agriculture and biotechnology

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Abstract

Regulation (EU) 2026/1388 establishes the first dedicated European Union regulatory architecture for plants obtained through certain New Genomic Techniques (NGTs), principally targeted mutagenesis and cisgenesis. Adopted on 17 June 2026, entering into force on 16 July 2026 and becoming generally applicable on 17 July 2028, the Regulation represents substantially more than a procedural simplification of existing genetically modified organism (GMO) legislation. It creates a new legal taxonomy based partly on the molecular characteristics of genetic modifications and partly on the traits that those modifications convey.

The central innovation is the distinction between Category 1 NGT plants, which after verification are largely released from the EU GMO regulatory framework, and Category 2 plants, which remain within that framework but under modified requirements for risk assessment, analytical detection, monitoring and authorisation. The result is neither conventional deregulation nor continuation of the classical GMO model. It is a hybrid system in which regulatory status depends on technique, genomic outcome, biological trait and the interaction of the NGT Regulation with horizontal legislation governing food safety, novel foods, seed marketing, organic production and intellectual property.

This article examines the scientific basis and limitations of that architecture; its consequences for plant breeding, food formulation, ingredient manufacturing, analytical control, international trade and innovation; and the unresolved issues that must be addressed before July 2028. Particular attention is given to the distinction between regulatory equivalence and biological risk, the analytical limits of determining whether a small sequence variation originated through genome editing, the continuing role of the Novel Food Regulation, patent access and freedom-to-operate, organic supply chains, international regulatory divergence, and the emergence of new research opportunities in crop resilience, food composition, processing performance and regulatory science.

The principal conclusion is that Regulation (EU) 2026/1388 does not merely create a faster route to market. It changes the object of European biotechnology regulation itself. For a substantial class of genome-edited plants, the decisive question will increasingly cease to be “Was genetic engineering used?” and become “What genomic change was created, what phenotype does it produce, how is that change documented, and which horizontal rules apply to the resulting product?” That transition is likely to alter European plant biotechnology, food-product innovation and the competitive structure of agricultural R&D well beyond the formal field of GMO law.

Keywords

New Genomic Techniques; NGT; genome editing; CRISPR; targeted mutagenesis; cisgenesis; Regulation (EU) 2026/1388; GMO regulation; plant breeding; food biotechnology; novel foods; traceability; patents; intellectual property; food innovation; agricultural biotechnology; EFSA; regulatory science; precision breeding; European Union.

Key Points

- Regulation (EU) 2026/1388 does not abolish GMO regulation for genome-edited plants. It creates a lex specialis with two regulatory pathways.
- Category 1 is based on defined genetic-equivalence criteria and exclusion of two specified traits; verification is expressly not a risk assessment.
- Category 2 remains within the GMO architecture, but with proportionate adaptations to risk assessment, detection, environmental monitoring and authorisation.
- Category 1 status does not remove all regulatory scrutiny. Food with significantly altered composition or structure may still enter the EU Novel Food regime.
- Category 1 reproductive material will be identified as “NGT-1”, while derived food is not subject to the classical GMO labelling regime.
- Analytical detection and regulatory traceability are no longer synonymous: a nucleotide change may be detectable without the method by which it arose being scientifically identifiable.
- NGT-1 therefore creates an increasingly information-based traceability architecture relying on regulatory identifiers, databases, variety catalogues, documentation and supply-chain identity.
- Both NGT-1 and NGT-2 are excluded from EU organic production, although adventitious or technically unavoidable NGT-1 presence does not automatically constitute organic non-compliance.
- Patent access may become proportionally more important as a commercial barrier once regulatory authorisation ceases to be the dominant barrier for Category 1 plants.
- The framework could materially accelerate innovation in disease resistance, climate resilience, nutrient efficiency, food composition, post-harvest stability and processing performance—but regulatory simplification does not itself demonstrate sustainability or safety of an individual product.
- Important operational questions remain unresolved and must be addressed through Commission delegated and implementing acts, EFSA guidance, analytical guidance and the emerging patent code of conduct before July 2028.

1. Europe has not deregulated gene editing. It has changed the regulatory question.

For more than two decades, European biotechnology law was organised around a relatively clear conceptual divide. Organisms produced through techniques falling within the legal definition of genetic modification entered a dedicated GMO system built principally around Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. Deliberate release, environmental risk assessment, food and feed authorisation, traceability and labelling were consequently attached to the regulatory identity of the organism as a GMO.

The Court of Justice of the European Union reinforced that architecture in its 2018 *Confédération paysanne* judgment, holding that organisms obtained by newer mutagenesis techniques fall, in principle, within Directive 2001/18/EC rather than benefiting automatically from the historical mutagenesis exemption reserved for techniques conventionally used in a number of applications with a long safety record. That decision made a crucial technological problem visible: small genomic changes that could in principle have arisen naturally or through conventional breeding could nevertheless receive a substantially different legal treatment merely because a newer targeted technique had been used to produce them.

The European Commission's 2021 study subsequently concluded that the existing legislation was not fully adapted to certain NGT applications and that scientific and technological development had generated both implementation problems and legal uncertainty. That did not establish that all NGT applications were

equivalent or risk-free. It established a different proposition: that a single regulatory architecture designed around earlier generations of genetic engineering no longer mapped efficiently onto the diversity of possible genomic outcomes.

Regulation (EU) 2026/1388 is the Union's answer.

Its conceptual importance is easily underestimated. The Regulation does not simply reduce the documentation required for selected GMOs. Instead, it creates a legal mechanism through which certain genetically modified plants produced using targeted mutagenesis or cisgenesis can, after verification, cease to be subject to the rules that Union legislation applies to GMOs. That is a change in regulatory architecture.

Established fact: Article 5 provides that Union rules applying to GMOs do not apply to qualifying Category 1 NGT plants and products. Category 2 NGT plants, by contrast, remain subject to GMO rules except where the new Regulation expressly derogates from them.

Interpretation: Europe is moving from a predominantly process-centred biotechnology framework toward a hybrid model combining process, molecular outcome and phenotype.

This distinction will shape much of European food biotechnology after 2028.

2. Scope: important technologies remain outside the new system

The Regulation is narrower than the expression “new genomic techniques” may suggest.

It applies to plants obtained using targeted mutagenesis, cisgenesis, or a combination of those approaches, provided that genetic material originating outside the gene pool available for conventional breeding does not remain in the resulting plant. Transgenic plants containing material from non-crossable species therefore remain within the existing GMO framework.

The Regulation likewise does not create a corresponding system for genome-edited animals or microorganisms. Those areas remain subject to their existing legal frameworks and future policy development.

This limitation matters for the food industry. The legal transformation analysed here concerns primarily the plant-derived food and ingredient economy: cereals, oilseeds, vegetables, fruit, pulses, starch crops, protein crops, speciality crops and plant-derived ingredients.

It is therefore incorrect to describe Regulation 2026/1388 as an EU-wide regulatory settlement for CRISPR or gene editing generally. It is a plant-specific regulatory architecture for defined NGTs.

3. The central architecture: NGT-1 versus NGT-2

3.1 Category 1: regulatory equivalence to conventional plants

A Category 1 NGT plant must satisfy two independent conditions:

1. its genetic modifications must satisfy the equivalence criteria contained in Annex I; and
2. it must not contain a trait excluded by Annex II.

The distinction is fundamental because verification of Category 1 status is expressly technical and declaratory. The Regulation's recital 58 states that verification does not involve either risk assessment or risk-management considerations.

Annex I: the molecular boundary

For targeted mutagenesis, Annex I permits:

- substitutions or insertions of no more than 20 nucleotides;
- deletions of any number of nucleotides;
- a maximum of three genetic modifications per protein-coding sequence, with modifications in introns and regulatory sequences not subject to that per-coding-sequence limit; and
- no more than 20 relevant modifications per monoploid genome overall.

For cisgenesis, Category 1 can encompass defined insertions or substitutions using continuous DNA sequences from the conventional breeding gene pool, as well as specified inversions or translocations of endogenous DNA, provided the conditions laid down in Annex I are met. The aggregate maximum of 20 modifications per monoploid genome also applies.

Annex II: phenotype can override molecular equivalence

Even where those molecular criteria are satisfied, two intended traits exclude a plant from Category 1:

- tolerance to herbicides;
- production of a known insecticidal substance.

Such plants fall into Category 2.

That produces an unusual but intellectually important regulatory structure.

A plant is not classified solely by technique. It is not classified solely by sequence change. And it is not classified solely by phenotype.

The legal result emerges from all three.

3.2 Why the Category 1 criteria should not be mistaken for a safety threshold

This distinction is essential.

The Annex I limits do not mean that 20 modifications are scientifically “safe” while 21 are “unsafe”. EFSA itself made this clear when examining the proposed equivalence criteria in 2024.

ANSES had questioned, among other issues, whether the size and number of mutations adequately reflected their possible functional consequences. EFSA agreed that mutation size alone does not determine biological consequence, while noting that the same limitation applies to mutations arising naturally or from conventional breeding. EFSA characterised the numerical limit as a risk-management decision, while considering the chosen threshold scientifically conservative in light of the mutational variation possible through spontaneous and conventional processes.

This distinction has significant consequences.

Annex I allows deletion of an unrestricted number of nucleotides while restricting an insertion to 20 nucleotides. A large deletion can obviously have substantial biological consequences. The legal criterion is therefore not a linear measure of biological effect.

Established fact: Annex I defines equivalence to the types and extent of genetic change that can occur naturally or through conventional breeding.

Interpretation: Category 1 status is best understood as a regulatory equivalence class, not as a direct quantitative measurement of biological risk.

That interpretation is consistent with EFSA’s own explanation of the scientific basis of the framework.

4. The scientific foundation—and what it does not prove

4.1 Targeted mutagenesis does not create a completely new category of molecular hazard

EFSA’s 2020 assessment of plants produced using SDN-1, SDN-2 and oligonucleotide-directed mutagenesis did not identify hazards specifically associated with those genomic modifications that were different in kind from hazards considered for conventional breeding or other genomic techniques. EFSA also concluded that parts of the existing GMO assessment guidance connected specifically with exogenous DNA were unnecessary where such DNA was absent from the final plant.

For cisgenesis and intragenesis, EFSA’s 2022 reassessment similarly concluded that no new risks had been identified compared with those previously considered. Site-directed insertion can reduce some unintended host-genome alterations associated with random insertion, potentially allowing reduced data requirements on a case-by-case basis.

This evidence forms an important part of the scientific foundation underlying the differentiated framework.

It should nevertheless be interpreted accurately.

EFSA did not conclude that every NGT-derived phenotype is safe. Rather, it concluded that targeted mutagenesis does not in itself introduce a unique class of hazard requiring an automatically distinct assessment simply because the technique was used.

The phenotype, composition and biological function still matter.

4.2 Off-target effects: real analytical question, frequently overstated regulatory distinction

CRISPR and related systems can produce unintended alterations. This is scientifically established.

The relevant regulatory question, however, is not whether unintended changes are possible—the same is true of conventional crossing, spontaneous mutation, tissue culture and classical mutagenesis—but whether their nature or frequency creates a distinct risk profile.

EFSA has concluded that unintended modifications following targeted mutagenesis are generally of types also observed through conventional breeding, and can occur at lower frequencies than with random mutagenesis. Modern whole-genome sequencing, high-quality reference genomes and improved bioinformatics nevertheless make increasingly detailed characterisation possible where biologically justified.

The critical scientific issue is therefore shifting from the simplistic question “Are there off-target mutations?” toward more useful questions:

- Does an unintended change alter a biologically significant gene or regulatory element?
- Does it materially affect composition or phenotype?
- Is it inherited?
- Can the relevant change be distinguished from background variation?
- What comparator is scientifically appropriate?
- At what point does additional molecular characterisation improve safety assurance rather than merely generate more genomic data?

These are questions of regulatory science, not merely sequencing capability.

5. The first major transformation: genome editing becomes a plant-breeding platform rather than a regulatory identity

Genome editing has already progressed beyond simple CRISPR-induced gene knockout. Modern plant genome engineering includes base editing, prime editing, precise sequence substitutions, targeted insertions, multiplex editing and increasingly sophisticated manipulation of genomic regions. These technologies make it possible to modify alleles with a level of targeting that conventional recombination generally cannot reproduce on the same timescale.

Regulation 2026/1388 therefore arrives at a technologically consequential moment.

Under the previous European architecture, reducing the time required to create a desirable genotype could be partially offset by the regulatory burden attached to the method used to create it. For Category 1 plants, that relationship changes.

Interpretation: The commercial value of precision breeding in Europe may increasingly derive not simply from creating traits that were previously impossible, but from creating breeding outcomes that were technically possible but economically or temporally impractical.

Examples include:

- modification of an elite variety without repeated backcrossing;
- introduction of disease-resistance alleles while reducing linkage drag;
- modification of quality traits without replacing the remainder of an established genotype;
- rapid adaptation of cultivars to geographically specific climatic stress;
- targeted modification of complex food-quality genes;
- accelerated improvement of perennial species in which conventional breeding cycles are intrinsically slow.

The strategic implication is significant: the Regulation can alter the economics of incremental biological innovation, not only enable spectacular new phenotypes.

6. Food innovation becomes one of the most important downstream beneficiaries

Much public discussion of NGTs focuses on farm productivity. That captures only part of the opportunity.

Modern genome editing can modify characteristics directly relevant to food manufacturing, nutrition and ingredient functionality: lipid composition, protein composition, starch architecture, antinutritional factors, taste, bitterness, texture, colour, post-harvest browning and storage behaviour. Reviews of current genome-editing research document applications across biofortification, macronutrient engineering, flavour, post-harvest losses and nutritional quality.

This shifts NGTs from being merely an agricultural technology toward becoming a potential food-design technology.

Lipid architecture

Editing fatty-acid biosynthetic pathways can alter ratios of oleic, linoleic and other fatty acids, potentially affecting oxidative stability, processing performance and nutritional composition.

Protein composition

Targeted changes can modify specific storage proteins, antinutritional proteins or immunoreactive fractions.

A useful illustration is wheat. CRISPR research has produced experimental lines showing substantial reductions in gliadin immunoreactivity. An early study reported reductions of approximately 85% in immunoreactivity in selected lines, while subsequent work targeting ω - and γ -gliadin gene clusters demonstrated large reductions in those proteins and approximately 47-fold lower immunoreactivity without detectable deterioration of the evaluated dough-quality parameters.

These findings must not be overinterpreted. Reduced immunoreactivity is not equivalent to demonstrated clinical safety for people with coeliac disease, and current experimental results do not justify presenting gene-edited wheat generally as “coeliac-safe”.

The example is nevertheless important because it demonstrates the possibility of editing complex multigene food-quality traits that are difficult to address through conventional breeding alone.

Processing performance

Other potential targets include:

- starch composition and gelatinisation behaviour;
- reducing precursors of processing contaminants;
- enzymatic browning;
- milling properties;
- grain hardness;
- texture;
- fruit softening;
- oxidation susceptibility;
- storage longevity;
- processing yield.

These traits create an important new research frontier: breeding for the processing plant rather than only for the field.

7. Category 1 is not a regulatory vacuum: the Novel Food “second gate”

One of the most consequential provisions has received considerably less attention than the NGT-1/NGT-2 distinction itself.

Regulation 2026/1388 makes clear that Category 1 food with a significantly changed composition or structure affecting nutritional value, metabolism or the level of undesirable substances may still qualify as novel food under Regulation (EU) 2015/2283 and therefore require assessment under that framework.

This creates what can usefully be described as a second regulatory gate.

A plant may be:

3. Category 1 for purposes of the NGT Regulation;
4. exempt from GMO authorisation;
5. but still subject to Novel Food authorisation because of what has been changed in the resulting food.

That is legally and commercially important.

A disease-resistant plant whose edible composition remains materially conventional may have a very different downstream regulatory pathway from an NGT-1 plant deliberately engineered to produce an unusual nutrient profile or materially altered metabolic composition.

Interpretation: The future European food-innovation strategy cannot consist merely of “designing for NGT-1”. Developers must simultaneously design for:

- NGT classification;
- food safety;
- Novel Food status;
- nutrition and health claims;
- allergen considerations;
- seed and variety law;
- intellectual property;
- commercial specification;
- and, where relevant, export-market rules.

The regulatory object has become multidimensional.

8. Category 2 remains GMO—but the GMO architecture itself becomes more proportionate

Category 2 contains NGT plants that do not satisfy Category 1 requirements, including plants with more extensive modifications and plants intentionally conveying Annex II traits.

The essential GMO principles remain:

- pre-market authorisation;
- risk assessment;
- GMO traceability;
- GMO labelling;
- environmental controls.

However, Regulation 2026/1388 introduces adaptations that permit requirements to reflect the characteristics of the modification rather than mechanically reproducing every element of a conventional transgenic GMO dossier. Environmental monitoring can in defined circumstances be waived following adequate justification, and analytical-method requirements may be adapted where conventional identification or quantification is technically impracticable.

The Regulation also creates incentives for Category 2 plants conveying specified sustainability-relevant traits, including:

- yield and yield stability;
- resistance to biotic stresses;
- tolerance to abiotic stresses;
- improved water or nutrient efficiency;
- reduced need for external inputs;
- improved sustainability of storage, processing or distribution;
- improved quality or nutritional characteristics;
- bioremediation.

Herbicide tolerance is specifically excluded from those incentives.

This is a second conceptual innovation.

The legal framework does not simply classify risk. It also attempts to differentiate the regulatory treatment of innovation according to intended agronomic or food-system function.

Whether those incentives materially influence investment will depend on their practical implementation, dossier costs, EFSA workload, IP constraints and expected commercial market.

9. Traceability after NGT-1: from analytical identity to informational identity

This may become one of the most difficult aspects of the entire system.

Traditional GMO control works particularly well when an analytical laboratory can detect a transformation-event-specific sequence or another distinctive molecular signature.

That assumption becomes problematic when the relevant NGT modification is a small deletion or single-nucleotide change identical to a sequence that could have arisen through spontaneous mutation, conventional breeding or tissue culture.

The sequence may be detectable.

Its history may not be.

The European Network of GMO Laboratories concluded in 2023 that analytical testing cannot support traceability for all plants produced by targeted mutagenesis or cisgenesis because of both technical and implementation limitations.

The problem has been demonstrated experimentally. A PCR method proposed as specific for genome-edited oilseed rape could detect the relevant single-nucleotide mutation, but subsequent evaluation found that the same mutation also occurred in material arising through somaclonal variation. The assay could therefore detect the genotype but could not uniquely establish the technological origin of that genotype.

This distinction is fundamental:

Detection of a sequence is not necessarily identification of the process that produced it.

9.1 The NGT-1 system therefore creates documentary traceability

For Category 1, the Regulation relies on:

- prior verification;
- unique identification numbers;
- a public database;
- identification in plant-variety catalogues;
- mandatory “NGT-1” labelling of plant reproductive material made available to third parties.

Derived Category 1 food and feed are not subject to classical GMO labelling merely because they originate from an NGT-1 plant.

The practical consequence is a transition from exclusively analytical traceability toward regulatory and documentary identity.

Proposed conceptual model

Genomic identity: Known sequence and varietal information.

Regulatory identity: NGT verification decision and unique identification number.

Commercial identity: Seed lot, variety, breeder and supply-chain records.

Digital identity: Machine-readable documentation connecting source material, regulatory status and downstream batches.

Analytical verification: Used where a sufficiently discriminatory molecular marker exists, but not assumed capable of determining technological origin in every case.

This is not currently mandated as a single integrated technical system. It is a logical direction for future regulatory and industrial research.

10. The organic sector creates a deliberate parallel supply chain

Both Category 1 and Category 2 NGT plants are excluded from EU organic production.

For Category 1, however, adventitious or technically unavoidable presence is not automatically treated as non-compliance with Regulation (EU) 2018/848. The Regulation explicitly seeks to avoid imposing disproportionate burdens on organic operators while maintaining their ability to exclude NGT material deliberately.

This solution is legally pragmatic but operationally complex.

Organic and NGT-free supply chains will increasingly depend on:

- seed purchasing controls;
- varietal identification;
- supplier declarations;
- chain-of-custody records;
- contractual specifications;
- audit systems;
- and, where technically useful, analytical testing.

The difficulty is obvious: contractual or voluntary “NGT-free” specifications may demand information that cannot always be established retrospectively by laboratory analysis.

Interpretation: NGT-1 may consequently increase rather than eliminate the commercial value of high-quality identity-preserved supply chains.

11. Intellectual property may become the next principal bottleneck

The reduction of a regulatory barrier does not mean the disappearance of barriers to innovation.

It can change which barrier matters most.

Plant-related inventions remain subject to the wider European framework for patents, plant variety rights and biotechnology inventions. Regulation 2026/1388 does not create a general patent exclusion for NGT-1 plants.

The Commission’s 2025 study on intellectual-property protection in agricultural biotechnology found that an increasingly complex patent environment can create particular freedom-to-operate and licensing challenges for smaller breeders, while also recognising the investment and disclosure functions performed by patent protection.

This is precisely why patent provisions became a significant component of the final Regulation.

11.1 What the Regulation actually does about patents

Among other measures, the framework establishes:

- patent-information elements associated with Category 1 verification;
- a dedicated expert group examining the effects of NGT plant patenting;
- Commission monitoring of patent practices and their effects on breeders, farmers, innovation, competition and access to biological material;
- patent-related guidance;
- development of an EU-level voluntary code of conduct.

The code of conduct is to be ready by 17 January 2028 and is intended to address patent transparency, licensing on fair and reasonable terms and amicable mechanisms for certain disputes. Its functioning must subsequently be evaluated, with the possibility of legislative proposals if voluntary mechanisms prove insufficient.

Patent information supplied through the NGT system is not equivalent to a definitive legal freedom-to-operate opinion. Patent scope, validity, territorial effect and infringement remain legal questions requiring dedicated analysis.

11.2 Why IP becomes relatively more important after regulatory simplification

Interpretation: Under the classical GMO model, the high cost and duration of regulatory approval itself acted as an important barrier to entry. If Category 1 substantially reduces that barrier, then other constraints become relatively more important:

- access to CRISPR and other enabling technologies;
- trait patents;
- sequence or allele-related patent claims;
- transformation and regeneration technologies;
- licensing conditions;
- access to germplasm;
- plant variety rights;
- freedom-to-operate analysis.

This produces a paradox.

A regulatory reform intended partly to broaden innovation could produce its strongest effect only if the resulting intellectual-property environment remains sufficiently navigable for universities, start-ups, SMEs and specialist breeders.

The success of the Regulation should therefore not be measured only by the number of NGT-1 verifications. Market diversity, applicant diversity, licensing accessibility and concentration of ownership will be equally informative.

12. Market access: one plant, multiple legal identities

The global regulatory landscape for genome-edited crops remains heterogeneous.

Direct comparison requires caution because different jurisdictions regulate different questions through different institutions. Nevertheless, a broad pattern is visible.

Jurisdiction	Principal regulatory approach	Practical consequence
European Union	Hybrid technique/outcome/trait model. NGT-1 requires verification against statutory equivalence criteria; NGT-2 remains largely within GMO law.	Formal EU regulatory identity remains necessary even for conventionally equivalent NGT plants.
United States	USDA APHIS exemptions focus substantially on whether a modified plant could otherwise have been developed through conventional breeding and whether plant-pest regulation is required. FDA applies its risk-based new-plant-variety food policy to genome-edited food and provides voluntary pre-market engagement routes.	Regulatory treatment is distributed among agencies and focuses more heavily on product characteristics than on a dedicated NGT category.
Canada	Product-based Novel Food system; final characteristics rather than the use of gene editing itself determine novelty. Non-novel gene-edited plant products can enter a voluntary transparency process.	Some edited plants do not undergo pre-market novel-food assessment when the resulting product is non-novel.
England	Precision-bred organisms must contain changes achievable through traditional processes. Food/feed use requires authorisation, with Tier 1 and Tier 2 routes reflecting the nature of potential food-safety concerns.	A separate precision-breeding system operates outside the classical GMO regime for qualifying products.
Australia / New Zealand food system	Food definitions were modernised in 2025 around the presence of novel DNA; genome-edited food without novel DNA is not classified as GM food under the revised definition. Australia's environmental Gene Technology framework separately excludes qualifying SDN-1 organisms from the GMO definition.	Food and environmental regulatory classification must be considered separately.

No jurisdictional model is simply interchangeable with another.

The important commercial consequence is regulatory translation.

A cultivar considered exempt by USDA APHIS, non-novel in Canada or non-GM under an Australian food definition does not automatically acquire NGT-1 status in Europe.

Exporters and importers will therefore need product-specific regulatory maps rather than relying on the regulatory decision of the country of origin.

13. International trade meets the detectability paradox

This is where international regulatory divergence and analytical limitations intersect.

Suppose a small edited allele is commercialised in a country where no full pre-market authorisation is required. The same allele could also exist in conventionally bred material. The product subsequently enters an EU supply chain.

Two separate questions arise:

6. What is its legal status under EU law?
7. Can an enforcement laboratory independently establish how that allele originated?

Those questions may not always have the same answer.

Interpretation: For some NGT products, border and market control will depend increasingly on reliable upstream information rather than exclusively on retrospective laboratory determination.

This increases the strategic importance of:

- international regulatory databases;

- unique identifiers;
- reliable developer declarations;
- customs documentation;
- seed and variety records;
- interoperability between regulatory systems;
- methods for associating genomic information with verified provenance.

It also creates a significant field for future regulatory technology.

14. What becomes newly possible for the European food and biotechnology sectors?

The most important effect of Regulation 2026/1388 is not that every genome-edited plant becomes commercially attractive. It is that a much larger number of research hypotheses may now be economically rational to test.

14.1 Disease resistance without introducing foreign genes

Targeted disruption of plant susceptibility genes, modification of receptors, or cisgenic transfer of resistance alleles could generate resistance without introducing genetic material outside the conventional breeding gene pool.

JRC case studies of cisgenic late-blight-resistant potato and scab-resistant apple illustrate the agronomic and economic interest of such approaches.

For long-cycle crops or crops in which conventional introgression introduces undesirable linked traits, the time advantage could be particularly important.

14.2 Climate resilience

Genome editing can target pathways involved in:

- drought response;
- salinity;
- heat tolerance;
- flooding;
- nutrient-use efficiency;
- root architecture;
- stomatal regulation;
- yield stability under stress.

The existence of an NGT pathway does not establish that any particular edited genotype will be agronomically superior. Those outcomes require field validation across environments.

Nevertheless, Annex IV expressly recognises abiotic stress resistance and resource efficiency as traits relevant to the sustainability objectives of the Regulation.

14.3 Lower-input production

Disease resistance and improved nutrient efficiency could reduce external inputs in specific production systems.

This possibility should not be converted into a generic sustainability claim.

A plant is not sustainable because it was genome edited.

Sustainability is an outcome requiring measurement.

Relevant metrics may include:

- pesticide use per tonne of crop;
- fertiliser requirements;
- water use;
- yield stability;
- land-use efficiency;
- greenhouse-gas intensity;
- storage losses;
- processing losses;
- biodiversity effects;
- resistance evolution.

The Regulation itself recognises this distinction by requiring monitoring of positive and negative economic, environmental and social sustainability impacts.

14.4 Foods designed around composition rather than merely agricultural performance

Genome editing could enable raw materials with:

- modified fatty-acid profiles;
- altered starch functionality;
- modified protein fractions;
- reduced antinutrients;
- modified flavour precursors;
- improved micronutrient profiles;
- reduced browning;
- enhanced shelf life.

This opens a direct bridge between plant genomics and formulation science.

For the food industry, the relevant research question may increasingly become:

Can functionality currently obtained through processing, additives, fractionation or formulation instead be partly encoded in the agricultural raw material?

That question could generate a new class of collaborations between breeders, food technologists, ingredient manufacturers and processing engineers.

14.5 Minor crops become more scientifically and economically interesting

The economics of conventional GMO authorisation strongly favoured high-value traits in globally important crops because regulatory expenditure needed to be recovered across a sufficiently large market.

A substantially lighter Category 1 pathway could change that calculation.

Research hypothesis: Regulatory simplification may improve the economic feasibility of genomic innovation in:

- regional crops;
- speciality vegetables;

- horticultural varieties;
- traditional varieties;
- orphan crops;
- crops adapted to specific European agroclimatic niches.

Whether this occurs will depend heavily on regeneration systems, breeding economics, access to editing technologies, seed-market size and intellectual property.

The Regulation removes one barrier. It does not remove all of them.

15. The hidden technological bottleneck: editing is not the same as recovering a commercial plant

The sophistication of CRISPR sometimes obscures a practical fact.

Designing an edit computationally is only one part of plant genome engineering.

Commercial development may require:

- delivery of editing reagents;
- transformation or transfection;
- tissue culture;
- regeneration;
- removal of editing constructs where used;
- genotyping;
- segregation;
- phenotyping;
- seed multiplication;
- stability testing;
- variety registration.

Many important crops remain difficult to transform or regenerate, and these processes can be genotype-dependent. Current research therefore increasingly focuses not only on improved editing enzymes but on delivery methods, regeneration, haploid induction and transformation-independent editing.

Interpretation: In an NGT-1 world, the principal technical bottleneck may migrate from the nuclease itself toward the plant-development platform.

This makes regeneration biology, delivery technology and genotype-independent transformation strategically important R&D fields.

16. The July 2028 deadline is not administrative detail

Although Regulation 2026/1388 entered into force on 16 July 2026, its principal regulatory pathways do not become applicable until 17 July 2028. Until then, targeted-mutagenesis and cisgenic plants remain subject to the existing GMO rules.

Articles concerning guidance, the patent code of conduct and the patent expert mechanism already apply.

The two-year period is therefore an implementation phase rather than a commercial Category 1 route.

As of the evidence cut-off for this article, the Commission had opened a call for evidence on the delegated and implementing acts needed to make the system operational; that consultation runs until 28 September 2026.

EFSA must meanwhile develop administrative and scientific guidance for Category 1 verification and Category 2 applications and risk assessment. EFSA is also scheduled to support preparation of the Commission's delegated act by 30 September 2027 and implementing act by 30 November 2027, with its own guidance due by the Regulation's application date.

The period from 2026 to 2028 will therefore determine much of the Regulation's real economic effect.

17. Ten implementation questions that remain material

17.1 How will modifications be counted in complex genomes?

The statutory limit is expressed per monoploid genome. Operational application to polyploid crops, homoeologous genes, multiple edited alleles and complex structural changes will require scientifically reproducible conventions.

17.2 Which genome annotation determines whether an edit affects a protein-coding sequence?

Genome annotations change. Alternative transcripts, uncertain gene boundaries and improved assemblies can alter the classification of a sequence as coding, regulatory, intronic or intergenic. The delegated and implementing framework will therefore need sufficiently robust conventions to prevent regulatory classification from becoming dependent on arbitrary bioinformatic choices. Research opportunity: develop validated reference-genome and annotation standards specifically for regulatory NGT verification.

17.3 How should large deletions be characterised?

Annex I does not impose a nucleotide-length ceiling on deletions. That makes scientifically robust characterisation of deletion boundaries, affected functions and possible structural consequences important even where the formal Category 1 criterion is satisfied.

17.4 What evidence is sufficient to demonstrate that no relevant exogenous DNA remains?

Different editing workflows leave different molecular histories. Clear validation standards will be necessary for transient delivery, segregated constructs and other development pathways.

17.5 How will Category 2 analytical methods be adapted when event-specific identification is impossible?

The Regulation recognises that conventional analytical expectations may sometimes be technically inappropriate. The implementing framework must determine what an acceptable alternative looks like without confusing “detecting an allele” with “proving its technological origin”.

17.6 How will third-country products demonstrate EU status?

A globally commercialised edited variety may enter Europe after being regulated under a very different legal model. The EU will need workable verification and information routes that do not assume identical foreign regulatory documentation.

17.7 Will the patent code of conduct work?

A voluntary system can improve transparency only if relevant right-holders participate and the information produced is useful. Participation, licensing behaviour, dispute resolution and SME accessibility should therefore be treated as measurable outcomes rather than formal achievements.

17.8 Can the Novel Food boundary be predicted early enough?

Where the commercial purpose of an edit is precisely to alter food composition, developers will need an early strategy for determining whether the resulting food falls within Regulation 2015/2283. This determination should occur at the target-product-profile stage, not after breeding is complete.

17.9 How will private “NGT-free” standards interact with the legal framework?

EU law does not require GMO-style consumer labelling of NGT-1 food. Private certification, retailer specifications or export customers may nevertheless impose additional provenance requirements. Those requirements could become commercially significant even where no equivalent statutory obligation exists.

17.10 How should sustainability claims be demonstrated?

The legislation identifies potentially beneficial traits but does not transform potential benefit into demonstrated environmental performance. Comparative agronomy, lifecycle assessment and appropriate counterfactuals will remain necessary.

18. Research & Innovation Opportunity Platform

R&I Opportunity 1 — Regulatory-by-design genome editing

Develop bioinformatic systems capable of evaluating proposed edits against Annex I modification limits, protein-coding regions, regulatory regions, trait exclusions, exogenous-DNA requirements, Novel Food risk indicators and known patents. The result could be a regulatory design layer integrated directly into genome-editing pipelines.

R&I Opportunity 2 — NGT regulatory bioinformatics

Europe will require reproducible methods for sequence alignment, reference-genome selection, variant attribution, modification counting, polyploid genome interpretation, structural-variant characterisation and cisgenic-sequence verification. This is likely to become a specialised field combining genomics, regulatory science and computational biology.

R&I Opportunity 3 — Genotype-to-food-function prediction

A major industrial opportunity lies in connecting genomic edit → metabolic effect → ingredient composition → processing behaviour → finished-food performance. AI-assisted predictive models could integrate genomic, transcriptomic, proteomic, metabolomic and process-engineering data to identify edits with direct food-industry value. This would move precision breeding toward precision ingredient design.

R&I Opportunity 4 — Processing-oriented crops

Potential programmes include crops designed for improved extraction yield, lower oxidation, modified rheology, improved protein functionality, altered emulsification, modified starch behaviour, reduced processing contaminants, improved colour stability and reduced post-harvest loss. The most valuable traits may not necessarily be visible to consumers in the field. They may manifest inside the factory.

R&I Opportunity 5 — Resistance without classical insecticidal traits

Because production of a known insecticidal substance excludes Category 1 status, alternative biological strategies could become particularly interesting. These may include editing susceptibility genes, modifying pathogen-entry factors, strengthening endogenous defence pathways and cisgenic transfer of disease-resistance alleles. Regulatory classification would still depend on the precise molecular outcome and intended trait.

R&I Opportunity 6 — Precision breeding for European speciality agriculture

Lower regulatory barriers could support innovation in smaller European crops that historically lacked the market scale necessary to justify full GMO development programmes. This may be particularly relevant for fruit, vines, vegetables, Mediterranean crops, speciality grains, pulses and regional cultivars.

R&I Opportunity 7 — NGT identity and traceability systems

The detection problem creates an opportunity for a new generation of traceability technology combining regulatory IDs, variety records, genomic fingerprints, authenticated breeder data, seed-lot documentation, supply-chain records and interoperable digital certificates. The objective should not be technological complexity for its own sake. It should be evidentiary continuity.

R&I Opportunity 8 — Automated patent-to-genome mapping

Current patent searching is predominantly document-centric. Plant genome editing increasingly demands sequence-centric freedom-to-operate analysis. Future systems could map genomic locus → allele → trait → patent family → claim scope → territory → licence availability. Such tools would have particular value for SMEs and public research organisations.

R&I Opportunity 9 — Evidence-based sustainability verification

NGT sustainability should become measurable rather than rhetorical. Research programmes should establish pre-defined indicators comparing NGT plants with appropriate conventional alternatives across yield, input intensity, pesticide use, water, nutrient efficiency, energy, food loss, processing efficiency, greenhouse emissions, biodiversity effects and economics. Such evidence could become commercially valuable independently of regulatory compliance.

R&I Opportunity 10 — Cross-jurisdiction regulatory intelligence

A single edited crop may face five or more regulatory classifications across global markets. There is therefore an opportunity to develop regulatory digital twins describing the legal status of a specific genotype across jurisdictions and automatically identifying notification requirements, authorisations, documentary obligations, labelling, food-safety assessments, environmental approvals, import requirements and patent constraints. For internationally traded plant ingredients, this could become an important component of market-access infrastructure.

19. Critical analysis: what the Regulation solves—and what it merely relocates

19.1 It solves a genuine regulatory mismatch

Treating a precisely introduced nucleotide change as automatically equivalent, for regulatory purposes, to a conventional transgenic event because both technically satisfied the GMO definition created a mismatch between legal categories and contemporary molecular breeding. The new Regulation directly addresses that mismatch.

19.2 It does not prove equivalence of every phenotype

Genetic equivalence criteria define access to a regulatory category. They do not establish that every resulting biological phenotype is harmless or desirable. This is why horizontal food law, Novel Food law and general safety obligations remain necessary.

19.3 It reduces one innovation barrier but exposes others

If Category 1 works as intended, regulatory cost should fall substantially for qualifying plants. That will reveal the relative importance of transformation technology, germplasm access, intellectual property, field-testing capacity, seed multiplication, market acceptance, retailer requirements and export regulation. This is not a weakness of the Regulation. It is a predictable consequence of removing one dominant bottleneck.

19.4 Its most difficult control problem may be epistemic rather than analytical

European regulators are accustomed to asking laboratories to determine what is present in a sample. NGT-1 sometimes requires a different question: What evidence establishes how this sequence came to exist? Those are not equivalent questions. The first may be solved with molecular analysis. The second may require records. That distinction is likely to influence official control, customs, litigation and supply-chain certification for years.

19.5 The architecture may reward precision itself

Because Category 1 depends on the nature and number of genetic changes, plant-engineering strategies capable of achieving a phenotype through minimal, highly targeted alterations may acquire a regulatory advantage. Hypothesis: The Regulation may therefore influence the direction of technology development, favouring base editing, precise allelic substitution and other molecular strategies capable of reaching useful phenotypes within Category 1 boundaries. This would represent a rare case in which statutory molecular criteria directly influence engineering optimisation. It should be studied empirically after implementation rather than assumed.

20. Strategic implications for the European food industry

Food companies should not regard NGT regulation as a problem belonging exclusively to seed companies.

The technology could eventually change the specifications of raw materials themselves.

Procurement, R&D, quality, regulatory affairs and innovation teams may therefore need to evaluate additional questions when sourcing future crop ingredients:

Regulatory identity: Is the variety conventional, NGT-1, NGT-2 or GMO under EU law?

Food status: Does the resulting ingredient enter Novel Food legislation?

Composition: Has the nutritional, allergenic, toxicological or technological profile changed?

Traceability: Which records establish variety and NGT status?

Intellectual property: Are downstream uses or propagation subject to relevant patent or licensing restrictions?

Organic and private standards: Is the material compatible with intended certification or customer specifications?

Exportability: How is the same ingredient classified in destination markets?

Claims: Can sustainability, nutritional or functional benefits actually be substantiated?

The most advanced companies will integrate those questions before raw-material selection rather than after commercial development.

21. Implications for European SMEs

The possible effect on SMEs deserves particular attention.

Lowering formal regulatory burden can expand participation, but regulatory simplification alone does not guarantee democratisation of biotechnology.

A small developer may still face:

- expensive plant transformation;
- patent searches;
- licence negotiations;
- greenhouse and field-trial costs;
- genomic characterisation;
- varietal testing;
- seed production;
- commercial distribution;
- litigation risk.

The Regulation acknowledges part of this problem through SME support, reduced analytical-method costs in relevant Category 2 procedures, pre-submission advice and the patent-access provisions.

The ultimate test will be empirical:

Does the number and diversity of European organisations capable of commercialising advanced plant biotechnology actually increase after 2028?

That is a more meaningful innovation metric than the number of edited varieties alone.

22. A new discipline may emerge: NGT regulatory engineering

The interaction between molecular design and legal classification suggests the emergence of a new professional field.

Traditional regulatory affairs typically begins after a product has been designed.

NGT regulation creates an incentive for regulatory analysis to become part of the design process itself.

A multidisciplinary NGT development team may require:

- plant geneticists;
- molecular biologists;
- bioinformaticians;
- breeders;
- food technologists;
- toxicologists;
- environmental scientists;
- regulatory lawyers;
- patent specialists;
- analytical chemists;
- data engineers.

The central task becomes optimisation across multiple dimensions:

biological performance × regulatory classification × food safety × analytical verification × IP freedom × manufacturing value × market access

This is qualitatively different from conventional post-development regulatory compliance.

23. Outlook to 2028 and beyond

Europe has spent much of the past twenty-five years debating whether emerging genomic techniques belong inside or outside the category “GMO”.

Regulation 2026/1388 does not make that historical debate irrelevant.

It makes it less useful as the sole organising principle.

The new framework asks more granular questions:

- Which technology was used?
- What DNA remains?
- How many changes were made?
- Where are they located?
- What trait is produced?
- Could the genetic outcome exist through conventional breeding?
- Does food composition change significantly?
- Can the product be analytically identified?
- Can its technological origin be established?
- Who owns the relevant technology or allele?
- Can breeders access it?
- Can farmers and food companies trace it?
- How is it classified outside Europe?
- Does the claimed sustainability benefit survive real-world measurement?

Those questions are more difficult than asking whether something is “GMO”.

They are also scientifically more informative.

24. Conclusions

Regulation (EU) 2026/1388 constitutes one of the most consequential changes to European plant-biotechnology regulation since the GMO framework was constructed at the beginning of the century.

Its importance lies not merely in providing a faster route for selected genome-edited plants, but in redefining the relationship between biological technique and regulatory status.

For Category 1 plants, the European Union has accepted a principle with far-reaching implications: certain genomic changes produced intentionally by modern biotechnology can be regulated substantially like changes achievable through conventional breeding when they satisfy defined equivalence and trait criteria.

Category 2 preserves the GMO architecture for more complex or specifically excluded applications while allowing greater proportionality.

The system is therefore neither blanket deregulation nor continuation of the previous model.

It is a stratified regulatory architecture.

Its greatest opportunities are likely to arise where precision genomic modification can solve biologically important problems without introducing unnecessary genetic complexity: disease resistance, resource efficiency, climate resilience, food composition, post-harvest performance and processing functionality.

Its greatest unresolved challenges lie elsewhere: patent access, regulatory bioinformatics, analytical provenance, supply-chain traceability, international divergence, organic coexistence and the translation of potential sustainability into measurable outcome.

The most important technological consequence may ultimately be conceptual.

Genome editing allows breeders to intervene at nucleotide resolution.

Regulation 2026/1388 begins to regulate some of those interventions at a correspondingly finer resolution.

That alignment between molecular precision and regulatory precision could substantially change the economics of European agricultural biotechnology.

But regulation alone cannot create innovation.

The framework must still be translated into reliable guidance, scientifically defensible verification, workable analytical rules, transparent intellectual-property systems and commercially credible supply chains before 17 July 2028.

If that implementation succeeds, Europe's next generation of plant biotechnology may no longer be organised principally around the binary distinction between “GMO” and “non-GMO”.

It may instead be organised around a more sophisticated question:

What biological change has been made, what evidence supports its consequences, and how intelligently can that change be converted into safer, more resilient and more useful food systems?

That is the deeper transformation initiated by Regulation (EU) 2026/1388.

Evidence Status and Limitations

This publication distinguishes four evidentiary categories:

Established fact — statements directly supported by legislation, regulatory authorities or replicated scientific evidence.

Interpretation — analytical consequences inferred from established facts but not themselves statutory conclusions.

Emerging evidence — scientifically credible findings whose commercial, agronomic or clinical significance remains under development.

Research opportunity / hypothesis — prospective applications proposed for investigation and not presented as demonstrated commercial outcomes.

The regulatory framework remains under implementation. Delegated acts, implementing acts, EFSA guidance, analytical guidance, patent-related guidance and practical enforcement approaches may materially refine some conclusions before Regulation 2026/1388 becomes generally applicable on 17 July 2028.

Internal Tags

NGT · New Genomic Techniques · Regulation EU 2026/1388 · CRISPR · Genome Editing · Targeted Mutagenesis · Cisgenesis · NGT-1 · NGT-2 · GMO Regulation · EFSA · Plant Biotechnology · Food Biotechnology · Precision Breeding · Novel Foods · Food Law · Traceability · Genome Analytics · Intellectual Property · Plant Patents · Food Innovation · Sustainability · Agricultural Biotechnology · Regulatory Science · Market Access

Related INTABIOTECH Knowledge Areas

- Food Biotechnology & Genomics
- European Food & Feed Regulation
- Food Safety & Regulatory Science
- Novel Foods
- Plant Breeding & Agricultural Biotechnology
- Intellectual Property & Biotechnology
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- Food Traceability & Supply-Chain Integrity
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- Ingredient Innovation & Food Processing
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Declaration of Scope and Editorial Independence

This publication is a technical, scientific and regulatory analysis intended for professional and academic information. It does not constitute individual legal advice, regulatory authorisation advice or a safety assessment of any particular NGT plant.

Scientific potential, regulatory eligibility and sustainability benefit are treated as separate concepts throughout the article. References to possible future applications should not be interpreted as claims that any individual NGT-derived food or plant has been demonstrated to be safe, sustainable, nutritionally superior or commercially viable without product-specific evidence.

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