UPDATE ON GENE EDITING IN AGRICULTURE IN THE EU
- A REVIEW

Catherine Regnault-Roger[1], **Michel Thibier**[2] and **Mario Pezzotti**[3]

1 Académie d'Agriculture de France - Université de Pau et des Pays de l'Adour (E2S-UPPA-CNRS UMR 5254 - IPREM), 18 Rue de Bellechasse, 75007 Paris, France. Phone : +33147051037 ; Fax : +33145550978 catherine.regnault-roger@univ-pau.fr

2 Académie d'Agriculture de France, 18 Rue de Bellechasse, 75007 Paris, France. Phone : +33147051037 ; Fax : +33145550978 michel.thibier@outlook.fr

3 Università di Verona, Department of Biotechnology, Strada Le Grazie 15, 37134 Verona, Italy. Phone :393476920082 Fax : +39045 8027929 mario.pezzotti@univr.it

Corresponding author: catherine.regnault-roger@univ-pau.fr

ABSTRACT

The long and complex process of revising the European regulatory framework for plants obtained by New Genomic Techniques (NGTs) has now culminated in the adoption of Regulation (EU) 2026/1388 by the European Parliament and the Council on 17 June 2026. The new rules introduce a dedicated framework for NGT plants and distinguish between two categories: category 1 (NGT-1) plants, which meet criteria of equivalence to conventional plants and will follow a simplified pathway, and category 2 (NGT-2) plants, which remain subject to the existing GMO regulatory framework, as adapted by the new Regulation. This review summarizes the scientific basis of genome editing, the global development of genome-edited crops, the evolution of regulatory approaches, and the main provisions of the new EU framework. It also discusses the remaining limitations of the reform, including exclusions from NGT-1 status, organic production, patent-related concerns, and the continued absence of an EU pathway for genome editing in farm animals and microorganisms.

Keywords: *Plant breeding; New Genomic Techniques (NGTs); EU regulation; sustainable agriculture.*

UPDATE ON GENE EDITING IN AGRICULTURE IN THE EU
- A REVIEW

INTRODUCTION

The discovery of the structure of DNA in the mid-20th century laid the foundation for genetic engineering and enabled the targeted modification of the genomes of living organisms. These biotechnologies have delivered major advances across multiple sectors, including therapeutic solutions for human diseases, applications in veterinary medicine, improvement of plant varieties, and the development of food-processing technologies such as fermentation.

Building on these scientific advances, laboratory-based approaches have made it possible to move beyond the randomness of natural mutations and to introduce specific genetic changes to address defined challenges. Two principal strategies have historically been used: mutagenesis and transgenesis. A well-known example is the production of human insulin for diabetes treatment, obtained from genetically modified microorganisms carrying human genetic sequences introduced through transgenesis.

Since the early 2000s, a new generation of tools, collectively referred to as New Genomic Techniques (NGTs), has emerged. These tools are characterized by greater precision, speed, and accessibility.

The most prominent is CRISPR/Cas (Clustered Regularly Interspaced Short Palindromic Repeats), described in 2012 by Emmanuelle Charpentier and Jennifer Doudna, who were awarded the Nobel Prize in Chemistry in 2020. Often referred to as "molecular scissors", this technology enables highly targeted genome modification; Doudna has also compared it to a "surgical scalpel", in contrast to earlier transgenesis approaches, which have been likened to a "blacksmith's hammer".

Genome editing now encompasses a broader set of techniques. Earlier methods, such as TALEN (Transcription Activator-Like Effector Nucleases), ZFN (Zinc Finger Nucleases), and ODM (Oligonucleotide-Directed Mutagenesis), developed between the 1990s and 2010s, are increasingly being displaced because of their higher cost and lower efficiency. More recent approaches, including base editing (2017) and prime editing (2019), can introduce precise nucleotide changes without necessarily inducing double-strand DNA breaks. As emphasized by David Liu and colleagues, these technologies function more like a "pencil" that rewrites specific bases, producing minimal genetic changes. They are more precise, easier to implement, and faster to deploy, accelerating applications in plant and animal health, human medicine, and agriculture more broadly (14).

A GROWING PORTFOLIO OF GENOME-EDITED VARIETIES

Advances in plant breeding based on genome editing were rapidly recognized by breeders, who identified early the potential of these approaches, then often referred to as New Breeding Techniques (NBTs), to develop crops better adapted to consumer expectations and to increasing climatic variability, including the rise in global temperatures observed in recent decades.

NGT applications are commonly classified according to the type of DNA modification generated by site-directed systems: SDN1, involving gene inactivation through small insertions, deletions, or base substitutions; SDN2, involving precise sequence replacement without stable insertion of recombinant DNA; and SDN3, involving the insertion of exogenous DNA at a defined genomic location, typically considered equivalent to transgenesis and detectable with standard methods.

CRISPR/Cas is by far the most widely used technology, with 924 reported applications, followed by TALEN in 30 and base editing in 27; together, these approaches account for more than 98% of all reported modifications. The vast majority involve small, targeted changes, predominantly SDN1-type edits (92%) and, to a lesser extent, SDN2 (2.7%). These modifications are generally indistinguishable from natural mutations when conventional detection methods are used.

According to the EU-SAGE database (10), more than 1,000 studies covering a similar number of traits have been conducted across 72 plant species. The targeted traits primarily relate to plant health and performance, including tolerance to biotic and abiotic stresses (324 studies), herbicide tolerance (59 studies), yield improvement (216 studies), and post-harvest resilience (28 studies). Additional modifications concern quality attributes such as color and flavor (56 studies), as well as industrial applications (117 studies) (2).

Research activity is concentrated on a limited number of major crops. Six species - rice (*Oryza sativa*), tomato (*Solanum lycopersicum*), soybean (*Glycine max*), maize (*Zea mays*), wheat (*Triticum aestivum*), and canola (*Brassica napus*) - account for more than two-thirds of all studies, with rice alone representing over 30%. A second group includes potato (*Solanum tuberosum*), tobacco (*Nicotiana tabacum*), and barley (*Hordeum vulgare*), followed by a broader set of species studied at lower frequency, including cucumber, cotton, cassava, watermelon, grapevine, poplar, and banana.

Looking ahead, genome editing is expected to expand to additional crops between 2027 and 2029, including almond (*Prunus amygdalus*), camelina (*Camelina sativa*), turnip rape (*Brassica rapa*

subsp. oleifera), and avocado (*Persea americana*), targeting improved agronomic performance, enhanced oil composition, and increased resistance to drought and diseases (2).

Overall, research on varietal improvement using NGTs is now underway in more than 35 countries, with field trials being conducted in more than fifteen, reflecting the rapid global deployment of these technologies.

NGTS EXPANDING GLOBALLY ALONGSIDE REGULATORY ADAPTATION

According to the Genetic Literacy Project regulation tracker (11), approximately ten genome-edited plant varieties have already received commercialization approval in five countries: the United States, Japan, Canada, China, and the Philippines. Among the earliest examples are a functional tomato developed in Japan to support blood-pressure regulation and a soybean with an improved nutritional profile commercialized in the United States. In China, which accounts for a large share of global genome-editing research, several varieties have been authorized, including wheat tolerant to powdery mildew, soybean varieties, and rice with enhanced agronomic or nutritional traits (2).

Recognizing both the economic implications of the climate transition and the need to ensure food security for a growing global population, many countries have adapted their regulatory frameworks. In particular, they have introduced more flexible pathways for products derived from SDN1- and SDN2-type genome editing by revising existing GMO legislation or by interpreting it in a product-based manner.

The rationale for these adaptations lies in the complexity and cost of conventional GMO approval procedures. In the European Union, for example, in addition to the standard requirements for registering a new plant variety - namely demonstrating distinctness, uniformity and stability (DUS), and, where applicable, value for cultivation and use - GMO-derived products must undergo an additional, highly demanding regulatory assessment. This process includes extensive field trials and risk evaluations and typically requires many years to complete. This additional regulatory layer is defined principally by Directive 2001/18/EC and Regulation (EC) No 1829/2003 governing GMO products intended for food and feed. Compliance entails a substantial number of studies and data requirements, often resulting in development costs of several tens of millions of euros. Such costs effectively limit market access to large multinational companies with significant financial resources.

By contrast, regulatory simplification applied in several jurisdictions to NGT-derived plants, particularly those lacking foreign DNA and indistinguishable from conventionally bred varieties, enables faster and more cost-effective market access. This shift is especially relevant for small and medium-sized enterprises (SMEs), which are often nationally based and can play a key role in plant-breeding innovation.

This trend toward regulatory adaptation is global in scope. It encompasses countries across North and South America, the Asia-Pacific region, and parts of Africa. In Europe, the United Kingdom has also moved in this direction following Brexit, having regained the authority to define its regulatory framework independently.

IN THE EUROPEAN UNION, A LONG PROCESS TO UPDATE REGULATION

In the European Union, the regulatory framework for genome editing has now changed. The process was triggered by the 2018 ruling of the Court of Justice of the European Union, which established that organisms obtained through genome editing fall under the EU GMO framework and are therefore subject to Directive 2001/18/EC.

In response to this decision, which scientific and economic stakeholders widely contested, the European Commission, at the request of the Council of the European Union, launched a regulatory review in 2019. This process focused specifically on plants and on a defined subset of genomic modifications. It was extensive and complex because it involved scientific assessments, impact analyses, and numerous public consultations intended to include economic and social stakeholders at successive stages of the decision-making process (3,6).

The review began with scientific assessment work conducted by the Joint Research Centre (JRC) between 2019 and 2021, which produced reports establishing the state of knowledge and the potential implications of NGTs. It was followed by consultations aimed at assessing societal and stakeholder perspectives: an initial public consultation linked to the impact assessment in September-October 2021, a consultation on the regulatory roadmap between April and July 2022, and a final consultation in 2023 on the proposed legislative text.

On 5 July 2023, the European Commission submitted its proposal for a regulation on plants obtained by certain NGTs and their food and feed. After examination by the European Parliament and the Council, trilogue negotiations were concluded in December 2025 (15). The Council adopted the new rules in April 2026, and the European Parliament gave its final approval on 17 June 2026. The new framework is now Regulation (EU) 2026/1388, which enters into force on the twentieth day following publication in the Official Journal of the European Union and will apply two years after entry into force, with specific provisions on patents applying earlier (7,8).

The Regulation creates a new pathway from research and field experimentation through to commercialization, providing greater legal certainty for developers. More broadly, the reform is expected to create conditions more conducive to innovation, enabling European research and breeding systems to develop solutions tailored to the agronomic, environmental, and socio-economic challenges faced by EU agriculture, while contributing to the strengthening of European food sovereignty and strategic autonomy.

A LIMITED REGULATORY EASING: THE DISTINCTION BETWEEN NGT-1 AND NGT-2 PLANTS

The regulatory easing introduced by the Regulation is significant but limited. It establishes a two-tier classification system, distinguishing between NGT-1 and NGT-2 plants, and it applies only to plants obtained by targeted mutagenesis and cisgenesis, including intragenesis, as well as their food and feed products. Microorganisms and animals remain outside the scope of the new rules.

NGT-1 plants are those that fulfill the equivalence criteria set out in Annex I of the Regulation and do not include any trait listed in Annex II as intended to be conveyed by the genetic modifications (3). For targeted mutagenesis, Annex I allows substitutions or insertions of no more than 20 nucleotides and deletions of any number of nucleotides. The number of these genetic modifications must not exceed three per protein-coding sequence, while modifications in introns and regulatory sequences are not subject to that specific limit. For cisgenesis, the permitted modifications concern DNA sequences within the gene pool for conventional breeding, including insertion, substitution, inversion, or translocation under defined conditions. Overall, the combined number of eligible genetic modifications must not exceed 20 per monoploid genome (7).

Once verified as NGT-1, these plants will be treated similarly to conventional plants and will not be subject to the EU GMO rules. Importantly, NGT-1 status is not based on a mandatory sustainability trait. Rather, eligibility depends on equivalence criteria and on the absence of excluded traits. The Commission and Member States will monitor sustainability impacts, and the Regulation separately

identifies traits that may justify incentives, such as yield stability, resistance to biotic or abiotic stresses, more efficient use of resources, reduced need for external inputs, and improved quality or nutritional characteristics.

By contrast, NGT-2 plants include NGT plants that fall outside the NGT-1 criteria due to the type, number, or complexity of the genomic alteration, or because the intended trait is excluded from category 1 status. They remain subject to the existing GMO regulatory framework, including authorization, risk assessment, traceability, and labeling requirements adapted to the specific profile of NGT-2 plants.

Significant exclusions remain. At the request of the European Parliament, plants engineered for herbicide tolerance or for the production of a known insecticidal substance cannot be classified as NGT-1, even if the underlying genetic modification would otherwise meet the equivalence criteria. These plants are therefore treated as NGT-2 and remain subject to GMO authorization, traceability, and monitoring requirements. Bt maize MON 810, currently the only GMO crop cultivated in parts of the EU, illustrates the type of insecticidal trait that remains within the GMO/NGT-2 logic.

Finally, NGT-derived plants are excluded from organic production under the new rules. However, the Regulation also requires the Commission to assess whether the framework imposes administrative, economic, or practical burdens on organic operators, including burdens arising from operators' and consumers' perceptions.

KEY ELEMENTS OF THE REGULATORY FRAMEWORK

Before field trials or market access, developers must obtain a declaration that the plant qualifies as NGT-1. For field trials, the verification procedure is conducted by the competent national authority, with a Union-level decision required only if the Commission or another Member State raises a reasoned objection. For market access, where no previous NGT-1 declaration exists, the procedure is conducted at the Union level to ensure consistency.

Once a plant has been declared NGT-1, subsequent progeny obtained through conventional breeding, including crosses involving NGT-1 plants, do not require a new verification, provided no further NGT modification is introduced. NGT-1 plants and products will not be labeled at the consumer level. However, plant reproductive material, including seed bags, must be labeled as NGT-1, and the relevant information must be made available in a public EU database. This is intended to ensure transparency and to allow operators to maintain NGT-free production chains where desired.

All other plants, classified as NGT-2, remain subject to the existing GMO framework. In this case, authorization, risk assessment, traceability, and mandatory labeling continue to apply. Member States may restrict or prohibit the cultivation of NGT-2 plants on their territory and may implement coexistence measures to avoid unintended presence in other production systems, including conventional and organic agriculture.

PATENTABILITY OF NGT PLANTS AND TRANSITIONAL MONITORING

The protection of intellectual property has been one of the most debated aspects of the Regulation. During the legislative process, amendments were introduced in the European Parliament aiming to exclude the patentability of innovations derived from NGTs. However, the final compromise did not create a general patent ban. Patentability remains governed by the existing EU Biotechnology Directive and the broader European patent framework. The Regulation nevertheless introduces transparency and monitoring mechanisms intended to address concerns from breeders and farmers.

For category 1 NGT plants and products, applicants must provide information, to the best of their knowledge, on existing and pending patents. This information will be included in a public database. Patent holders may also voluntarily indicate their willingness to license patented NGT-1 plants or products under fair and reasonable conditions.

The Regulation also provides for a Union-level code of conduct on patent transparency and fair access, and for an expert group on the effects of patenting NGT plants. This group will include Member State experts as well as representatives from the European Patent Office and the Community Plant Variety Office. The Commission is required to assess the impact of patenting on innovation, access to genetic material, farmers' access to reproductive material, market concentration, and the competitiveness of the EU breeding sector. If significant barriers emerge, legislative follow-up may be proposed.

ANIMALS REMAIN OUTSIDE THE NEW EU FRAMEWORK

The application of genome editing in domestic animals, particularly livestock species, offers considerable potential and is likely to develop in the coming decades, including in Europe. Its primary applications are expected to include the control of contagious animal diseases (13, 16), notably by generating disease-resistant, disease-insensitive, or resilient livestock populations. In this context, it has been suggested that "genomic editing will constitute a major tool for the prophylaxis of contagious animal diseases in the 21st century" (17), thereby contributing to the reduction of disease outbreaks and the mitigation of zoonotic risks.

However, the use of NGTs in animals faces a dual constraint in the European socio-economic environment. On the one hand, public acceptance of animal-derived products obtained through genomic modification remains low (5). On the other hand, this societal resistance discourages economic stakeholders and livestock organizations within the European Union from openly promoting these technologies, due to concerns that their adoption could further depress consumption of meat and other animal products.

Consequently, research efforts in this field within the European Union remain limited, largely because the restrictive regulatory framework governing genetically modified organisms constrains scientific investigation. Nonetheless, some contributions can be noted, including work conducted by INRAE researchers in France on prion diseases in Alpine goats (1).

Priority should therefore be given to research targeting viral diseases with the potential to generate major economic losses, such as foot-and-mouth disease, as well as diseases posing significant societal risks in the context of zoonoses. These research priorities are being actively pursued in countries such as China and the United States. Recent examples of diseases that are difficult to eradicate or for which no effective vaccines exist, such as African swine fever, highlight the urgent need for sustained research funding, particularly as these diseases continue to spread.

A striking paradox lies in the position expressed by Maroš Šefčovič, then Vice-President of the European Commission, to the Portuguese Presidency of the Council of the European Union in 2021. The letter stated that no modification of existing regulations on GMOs and NGTs for animals should be considered until more research has been conducted and published. Under current conditions, however, such research is difficult to carry out within the European Union to say the least.

A compelling illustration of this limitation has recently been provided. Following the United Kingdom's departure from the European Union, a research team at the Roslin Institute in Edinburgh published an important study reporting the successful production, through gene editing, of pigs fully

resistant to classical swine fever virus (CSFV). Using CRISPR/Cas9 technology, the authors generated pigs carrying modifications in the host protein DNAJC14. In vivo challenge experiments demonstrated complete resistance to infection (4).

In 2022, the Electronic Working Group of the UEAA issued recommendations for revising the regulatory framework governing genome editing, not only for plants but also for animals, marking a first in terms of formal proposals concerning livestock (18). These recommendations have not yet been taken into account. The new Regulation therefore represents a major step for plants, but it leaves unresolved the broader question of NGT applications in animals and microorganisms.

CONCLUSION

1. The adoption of Regulation (EU) 2026/1388 on New Genomic Techniques by the European Parliament and the Council on 17 June 2026 marks a turning point in the governance of plant-breeding innovation in Europe. Policymakers have acknowledged that genome-editing technologies did not exist when the current GMO framework was established in 2001 and that the existing legislation was not designed to address these scientific developments.

2. The new Regulation introduces a dedicated framework for plants obtained through NGTs. In particular, NGT-1 plants that meet defined equivalence criteria and do not carry excluded traits will follow a simplified pathway and will be treated similarly to conventional plants. By contrast, NGT-2 plants will continue to be subject to the regulatory requirements applicable to GMOs, including authorization and risk assessment adapted to their specific profile.

3. Uncertainty nevertheless persists as to whether the framework will be sufficient for the European Union to harness the opportunities offered by NGTs fully. This question is particularly relevant in a context where the EU has historically taken a cautious stance toward transgenic crops, while other regions are advancing more rapidly. The ability of the EU to respond to global agricultural challenges - from climate change and emerging pathogens to food security and competitiveness - will depend on its capacity to align regulatory approaches with scientific progress, not only for plants and crops but eventually also for farm animals and microorganisms.

4. Stakeholders have broadly welcomed this development. Euroseeds, representing the European seed sector, described the agreement as a long-awaited signal for both breeders and farmers, while also noting that additional requirements and restrictions remain and that their practical implications will need careful evaluation (9).

5. At the international level, the International Seed Federation has similarly stressed the need for regulatory systems to keep pace with scientific progress. As its Secretary General, Michael Keller, recently stated, “policies need to evolve as science evolves”, calling for breeders to have access to the full range of available technologies rather than being constrained by “a patchwork of conflicting rules” (12).

6. The adoption of the Regulation comes at a time when agriculture faces unprecedented challenges, including climate change, emerging pests and diseases, resource constraints, and increasing demands for sustainability. In this context, genome editing provides breeders with a powerful tool to accelerate the development of improved crop varieties while preserving valuable genetic backgrounds and varietal identities.

7. Whether Europe fully capitalizes on the opportunities offered by NGTs will depend not only on the new regulatory framework but also on continued investment in research, breeding, and technology transfer. Nevertheless, the adoption of the Regulation represents a historic milestone: it aligns policy

more closely with scientific progress. It creates the conditions for a new generation of crop innovations capable of supporting more sustainable, resilient, and competitive agri-food systems.

REFERENCES

1. Allais-Bonnet et al. (2025). CRISPR/Cas9-editing of PRNP in Alpine goats. Veterinary Research, 56:11. https://doi.org/10.1186/s13567-024-01444-1
2. Biotechnologies végétales Info (2026). Dossier Intégration des NGT dans les choix stratégiques, n°38, 4.
3. Council of the EU (2025). New genomic techniques: Council and Parliament strike deal to boost the competitiveness and sustainability of our food systems. https://www.consilium.europa.eu/en/press/press-releases/2025/12/04/new-genomic-techniques-council-and-parliament-strike-deal-to-boost-the-competitiveness-and-sustainability-of-our-food-systems/
4. Crooke H. R., Schwindt S., Fletcher S., Isken O., Harding S., Berkley N., Tait-Burkard C., Warren C., Whitelaw B., Tautz N. and Lillico S. (2026). DNAJC14 gene-edited pigs are resistant to classical pestiviruses. Trends in Biotechnology, 44(2), 570-586. https://doi.org/10.1016/j.tibtech.2025.09.008
5. Duclos R., Delanoue E., Dockès A. C., Journaux L., Sourdioux and Bidanel J. P. (2022). Les modifications ciblées du génome appliquées aux animaux d'élevage : à la croisée des controverses. INRAE Productions Animales, 35(1), 61-72.
6. Council of the EU (2025). New genomic techniques for plant breeding - Consilium. https://www.consilium.europa.eu/en/policies/new-genomic-techniques-for-plant-breeding/
7. European Commission (2026). EU legislation on new genomic techniques for plants; Regulation (EU) 2026/1388 of the European Parliament and of the Council. https://food.ec.europa.eu/plants/new-genomic-techniques/legislation-plants_en
8. European Parliament (2026). New genomic techniques for plants to boost innovation in sustainable agriculture. Press release, 17 June 2026. https://www.europarl.europa.eu/news/en/press-room/20260611IPR45215/new-genomic-techniques-for-plants-to-boost-innovation-in-sustainable-agriculture
9. Euroseeds (2025). Europe's seed sector welcomes conclusion of NGT trilogue. https://euroseeds.eu/app/uploads/2025/12/25.0869.1-Europes-seed-sector-welcomes-the-positive-conclusion-of-trilogue-negotiations-on-NGTs.pdf
10. EU-SAGE (2026). Europe Sustainable Agriculture Through Genome Editing. https://www.eu-sage.eu/genome-search
11. Genetic Literacy Project (2026). Regulation Tracker: Agriculture. https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/#jet-tabs-control-1401
12. Morrison O. (2026). "A map that's green everywhere": ISF chief pushes for global alignment on gene-edited seeds. AgTechNavigator, 18 February 2026. https://www.agtechnavigator.com/Article/2026/02/18/isf-chief-pushes-for-global-alignment-on-geneedited-seeds/
13. Pailhoux E. and Vilotte J.-L. (2023). Modifications ciblées du génome ("genome editing") chez les animaux d'élevage : où en est-on en France et en Europe? Bulletin de l'Académie Vétérinaire de France, 176. https://doi.org/10.3406/bavf.2023.71031
14. Regnault-Roger C. (2023). Biotech Challenges. Springer Nature, 157 p.
15. Regnault-Roger C. (2025). NGT: the new EU regulations for plant editing in the midst of parliamentary turbulences. The European Scientist, 5 July 2025. https://www.europeanscientist.com/en/features/ngt-the-new-eu-regulations-for-plant-editing-in-the-midst-of-parlementary-turbulences/
16. Söllner J. H., Mettenleiter T. C. and Petersen B. (2021). Genome editing strategies to protect livestock from viral infections. Viruses, 13, 1996. https://doi.org/10.3390/v13101996
17. Thibier M. (2021). Communication orale. Séminaire GIS/Elevage: Regards croisés sur les modifications ciblées du génome appliquées aux animaux d'élevage. Paris, 16 November 2021.
18. Union Européenne des Académies d'Agriculture (UEAA) (2022). The UEAA recommendations for an EU regulation frame concerning genome editing research and development for crop plants and farm animals.

https://ueaa.info/2022/01/03/the-ueaa-recommendations-for-an-eu-regulation-frame-concerning-genome-editing-research-and-development-for-crop-plants-and-farm-animals/ (accessed 25 March 2026).