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D6.6 Policy brief intermediate

(Version 0.3, 27/02/2026)

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Deliverable description

DELIVERABLE: D6.6 – Policy brief intermediate
WORK PACKAGE: WP6 - Environmental, economic and political assessment
AUTHOR(S): Federica Binello, Consorzio Italbiotec (ITB)
DUE DATE: 28/02/2026
ACTUAL SUBMISSION DATE: 27/02/2026
DISSEMINATION LEVEL Select the proper one and delete the remaining PU: Public (must be available on the website)
GRANT AGREEMENT No: 101082091
PROJECT STARTING DATE: 01/07/2023
PROJECT DURATION: 60 months

REVISION HISTORY			
Version	Date	Modified by	Comments
0.1	18/02/2026	ITB	First drafts shared with the consortium
0.2	20/02/2026	UMIL, HHU, UP	Small text changes
0.3	24/02/2026	ITB	Small changes in the formatting of the policy brief

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Glossary of terms

AIPPI	International Association for the Protection of Intellectual Property
ECVC	European Coordination Via Campesina
EPSO	European Plant Science Organisation
EU	European Union
GMOs	Genetically Modified Organisms
IP	Intellectual Property
MS	Member State
NGTs	New Genomic Techniques
PBOs	Precision Bred Organisms
PVRs	Plant variety rights
R&D	Research and Development
SME	Small and Medium enterprises

1. Introduction

This deliverable, **D6.6 – Policy brief intermediate**, has been produced within Work Package 6 (Environmental, economic and political assessment) of the BEST-CROP project. It documents the activities carried out for the preparation of the intermediate policy brief, due at Month 32, entitled: *"Unlocking the Potential of New Genomic Techniques (NGTs): Overcoming Regulatory and Intellectual Property Barriers in the EU"*.

The purpose of this deliverable is to describe the rationale, objectives, methodological approach, and development process of the policy brief, rather than to reproduce its full substantive content. As the first policy-oriented output of the project, this policy brief aims to position BEST-CROP within the ongoing EU debate on the regulation of NGTs by highlighting regulatory, intellectual property, and implementation challenges that may affect the translation of genome editing research into concrete agricultural innovation.

The policy brief builds on both internal project activities and external engagement efforts carried out in the previous months. In particular, discussions held within the consortium, stakeholder exchanges, and a policy forum organised in the framework of BEST-CROP have provided important background insights that informed the identification of key regulatory challenges and policy priorities. These activities can be considered preparatory steps that support the analytical work underlying the policy brief.

The methodological approach combines desk-based analysis of EU legislation (including Directive 2001/18/EC, the 2023 Commission proposal on NGTs, and the 2025 Trilogue Provisional Agreement), policy communications, scientific literature, and position papers from relevant stakeholders. This analytical work was complemented by insights emerging from BEST-CROP research activities, particularly the case study on next-generation barley.

2. Structure and content development

The policy brief is structured to guide the reader progressively from the broader strategic and technological context to the identification of regulatory bottlenecks and corresponding policy recommendations. It opens with key messages for policymakers and an executive summary that frames the relevance of New Genomic Techniques (NGTs) in light of climate change, food security, and the objectives of the European Green Deal, Farm to Fork Strategy, and Bioeconomy Strategy.

The document then places NGTs within the evolution of plant breeding, clarifying the distinction between traditional GMOs and newer genome-editing techniques. This technological clarification provides the foundation for a discussion of the potential contribution of NGTs to sustainable agriculture, including climate resilience, reduced reliance on chemical inputs, improved nutritional quality, and enhanced competitiveness of the EU agri-food sector. Particular attention is given to staple crops that are strategically important for European food systems.

A substantial part of the brief is dedicated to the EU policy debate. It examines the current GMO framework, the implications of the 2018 Court of Justice ruling, and the proposed reform introduced by the 2023 Commission proposal and the 2025 Trilogue Provisional Agreement. This regulatory analysis is complemented by an overview of Member State positions and by a comparative perspective on international regulatory approaches, notably in the United Kingdom, North and South America, Japan, and Australia.

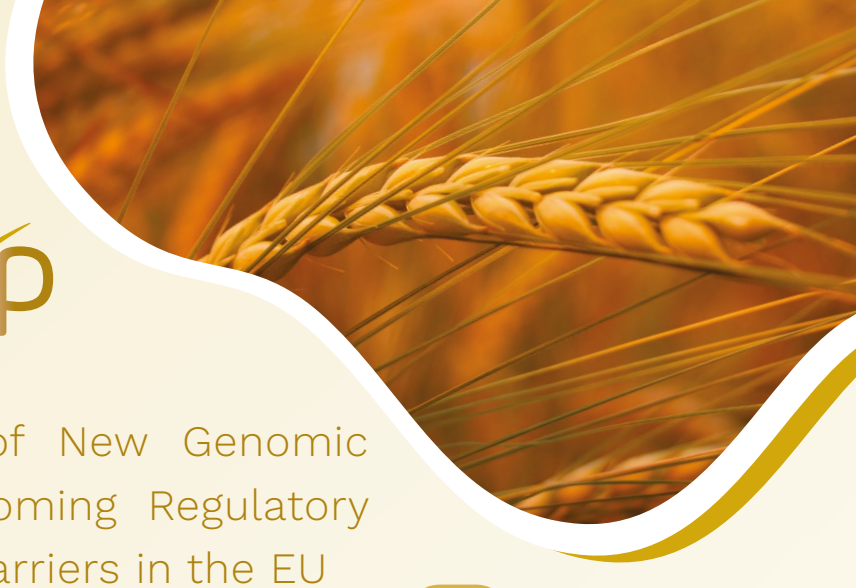
The policy brief further **identifies the main barriers** to the effective uptake of NGTs in the EU, including research and innovation limitations, consumer perception and coexistence concerns, and intellectual property challenges. These issues are analysed not only from a legal perspective but also in terms of their impact on investment decisions, market structure, and access to innovation for SMEs and public research organisations.

A dedicated section focuses on **next-generation barley**, linking the regulatory discussion directly to BEST-CROP's research activities. This case study illustrates how regulatory design and implementation can influence the translation of scientific results into field-level applications and socio-economic benefits.

The document concludes with a set of **preliminary policy recommendations** aimed at promoting harmonised implementation, addressing intellectual property bottlenecks, strengthening transparency and coexistence mechanisms, encouraging a more outcome-based regulatory approach, and supporting farmer adoption through advisory and training measures.

3. Conclusions

This deliverable is a first step in the activities related to the preparation of the intermediate policy brief under BEST-CROP. The resulting document provides a structured and policy-relevant contribution to the debate on the regulation of New Genomic Techniques in the European Union. The work carried out under D6.6 establishes the analytical foundation for continued policy engagement within the project and will inform the preparation of the final policy brief foreseen at Month 56, which will further analyse BEST-CROP's contribution to EU agricultural and bioeconomy policy discussions.



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Unlocking the Potential of New Genomic Techniques (NGTs): Overcoming Regulatory and Intellectual Property Barriers in the EU

Key messages for policymakers

Intellectual property must balance access and incentives

Transparent and fair IP arrangements are crucial for enabling SMEs, public research organisations, and plant breeders to innovate, while still protecting long-term R&D investments.

Regulatory clarity is essential for innovation

Consistent and science-based implementation of the NGT framework across Member States is needed to reduce legal uncertainty and support investment in plant breeding.

Coexistence and consumer trust must be safeguarded

Effective transparency and coexistence measures are necessary to safeguard organic and GMO-free supply chains, preserve consumer choice, and maintain trust.

Support farmers in adoption and integration

Develop advisory services and training programs to help farmers understand and adopt NGT-derived crops by integrating them into the conventional agroecological strategies.

NGTs should deliver measurable sustainability benefits

Policy implementation should clearly link NGT deployment to Green Deal, Farm to Fork, and Bioeconomy objectives, shifting the focus from breeding techniques to verified environmental, economic, and societal impacts.

Executive Summary

European agriculture faces extensive pressure from climate change, resource constraints, and increasingly ambitious environmental targets, where farmers are expected to sustain productivity while reducing chemical inputs, emissions, and biodiversity impacts. In this context, **New Genomic Techniques (NGTs)** have emerged as a promising tool to support sustainable agriculture, food security, and competitiveness, but also triggering intense political and societal debate.

NGTs enable precise genetic changes, without introducing foreign DNA, and can deliver tangible benefits such as *improved climate resilience, reduced pesticide use, enhanced yield potential, improved nutritional quality, and more efficient agri-food value chains*. These advantages are particularly relevant for staple crops such as wheat, barley, rice, maize and potatoes, which are central to Europe's food systems but increasingly exposed to climate and pest pressures.

Despite this potential, EU uptake of NGTs has been limited by an outdated GMO framework and regulatory uncertainty. The European Commission's 2023 proposal and the 2025 Trilogue Provisional Agreement, which introduced NGT-1 and NGT-2 categories, represent a major step toward regulatory change. However, their success will depend on consistent implementation across Member States and on addressing concerns about consumer acceptance, coexistence with organic farming, and intellectual property.

This policy brief, created within the **BEST CROP project**, analyses the current regulatory landscape, stakeholder positions, and remaining barriers to NGTs adoption. It concludes with policy recommendations aimed at fostering innovation, protecting farmer and consumer choice, and ensuring that NGTs can contribute effectively to the EU's sustainability, competitiveness, and food security objectives.

Introduction

The EU's agricultural system is facing numerous challenges, including climate variability, soil degradation, water scarcity, and increasing pest pressure, which are already affecting yields and farm profits across Member States. At the same time, farmers are expected to reduce chemical inputs, lower greenhouse gas emissions, and contribute to biodiversity protection, while maintaining high and steadily increasing levels of agricultural productivity to meet growing food demand and ensure the economic viability of the sector.

In response to these challenges, the EU Green Deal, Farm to Fork, and Bioeconomy objectives have given a boost to plant biotechnology as an emerging key area for scientific research. However, while it offers immense potential for agricultural innovation and sustainability, it has deep-seated socio-economic concerns regarding patents, farmer autonomy, and consumer choice, which are consequently affecting the EU policy debate.
To fully understand the complexities of this discussion, it is essential to first define the technologies in question and place them within the broader strategic context of the European Union's green transition and food security objectives.

From traditional GM to NGTs

Plant breeding evolved significantly over the last century. While conventional breeding relies on techniques such as *hybridization and random mutagenesis*, the late 20th century saw the rise of Genetically Modified Organisms (GMOs). Since 2001, a new group of more precise tools has emerged and been developed, collectively known as **New Genomic Techniques (NGTs)**[1].

TABLE 1: Comparison of the three key NGTs central to the current legislative scene with the traditional transgenesis.

Technique	Description	Key Characteristic
Targeted Mutagenesis	Induces mutations in precise and predictable regions of the genome.	No foreign genetic material is inserted.
Cisgenesis	Involves the insertion of new genetic material from a sexually compatible (crossable) species.	The new genetic sequence is from the breeders' existing gene pool.
Intragenesis	Induces modification of the genetic material with combination of different sequences from the same species	The new sequence is a rearranged copy of the sequences already present in the starting gene pool.
Transgenesis	Involves the insertion of a desirable gene from a non-crossable species.	Introduces genetic material from a non-crossable species.

Compared to traditional genetic modification, NGTs allow for highly accurate and targeted changes to an organism's genome, combining precision with speed. Among gene editing tools, **CRISPR/Cas9** is the most well-known and is commonly used to achieve targeted mutagenesis. It functions as "molecular scissors", enabling precise cuts at specific DNA locations without introducing foreign genetic material[2]. For this reason, in many cases, the resulting plants are impossible to differentiate from those produced through conventional breeding or naturally induced mutations.

Relevance for Sustainable Agriculture

NGTs developed crops can offer significant benefits that align and contribute directly to EU sustainability and climate goals[3]. Between the key potential advantages could be found:

- **Climate Resilience:** Developing crop varieties that can help farmers maintain yields in the future by improving drought, heat, and disease tolerance.
- **Disease and Pest Resistance:** Creating plants that are naturally resistant to common diseases and pests, reducing the reliance on pesticides and fungicides.
- **Improved Nutrition and Food Safety:** Enhancing the nutritional profile of food products.

1 Authority (EFSA) EFS, Paraskevopoulos K, Federici S. Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques. EFSA Journal. 2021;19(4):e06314.

2 Bortesi L, Fischer R. The CRISPR/Cas9 system for plant genome editing and beyond. Biotechnology Advances. 2015 Jan 1;33(1):41–52.

3 Wang Y, Zafar N, Ali Q, Manghwar H, Wang G, Yu L, et al. CRISPR/Cas Genome Editing Technologies for Plant Improvement against Biotic and Abiotic Stresses: Advances, Limitations, and Future Perspectives. Cells [Internet]. 2022 Dec 5 [cited 2026 Jan 29];11(23). Available from: https://www.mdpi.com/2073-4409/11/23/3928.

- **Enhance yield potential:** Developing new plant ideotypes more adapted to current agricultural conditions or plants with improved photosynthetic performance.
- **Improved Agricultural Waste's Properties:** Boosting the physical and chemical properties of agricultural wastes to improve their usage for bio-based materials of economic interest.
- **Strengthening Competitiveness:** Boosting the innovation capacity of the European agricultural sector, including for SMEs and research institutes, by accelerating breeding programs and enabling the development of more resilient crop varieties.

The Case of Staple Crops: Strategic Relevance for The European Food System

The strategic relevance of NGTs is most evident when applied to staple crops such as **barley**, **wheat**, **rice**, **maize**, and **potatoes**, which form the foundation of Europe's food systems, rural economies, and agri-food value chains. These crops are central to food security and farm income, yet they are increasingly exposed to climate stress, resource constraints, and evolving pest and disease pressures. NGTs offer targeted and efficient solutions to these challenges, enabling the development of crop varieties with increased abiotic stress tolerance[4], exhibit enhanced resistance to major diseases such as late blight in potatoes[5], or display improved photosynthetic efficiency and greenhouse gas assimilation in cereals[6]. In doing so, NGTs translate an abstract policy debate into tangible innovations that can directly support farm environmental sustainability and long-term food security.

EU Policy Debate

The strategic importance of NGTs is reflected in the intense legislative debate currently underway. This section dissects the European Commission's policy framework and its proposed solution to the regulatory impasse and examines the sharply divided reactions from key stakeholders and institutions.

2001 — EU Directive 2001/18/EC – first regulation for GMOs

2018 — Court of Justice ruling on targeted mutagenesis organisms

2023 — Submission of an EU legislative proposal for a new regulation on plants produced by NGTs and their derived food/feed

2025 — *European Commission, the Council of the European Union and the European Parliament* reached a provisional political agreement on the Regulation on plants obtained by certain NGTs

4 Zhang S, Zhang R, Gao J, Gu T, Song G, Li W, et al. Highly Efficient and Heritable Targeted Mutagenesis in Wheat via the Agrobacterium tumefaciens-Mediated CRISPR/Cas9 System. Int J Mol Sci. 2019 Aug 30;20(17):4257.

5 Resjö S, Iqra, Kieu NP, Zahid MA, Lenman M, Andersson B, et al. Late blight field resistance in potatoes carrying Solanum americanum resistance genes (Rpi-amr3 and Rpi-amr1). GM Crops Food. 16(1):263–71.

6 Pesaresi P, Bono P, Corn S, Crosatti C, Daniotti S, Jensen JD, et al. Boosting photosynthesis opens new opportunities for agriculture sustainability and circular economy: The BEST-CROP research and innovation action. The Plant Journal. 2025;121(3):e17264.

The Recent EU GMOs Framework

Despite their clear potential, the development and distribution of NGT-derived crops in the EU remain severely limited by regulatory uncertainty and an outdated legal framework. Today, EU legislation groups a wide range of techniques under the umbrella of *"genetically modified organisms"* (GMOs). This includes traditional transgenesis, where genes from non-crossable species are introduced, as well as the newer genome-editing approaches that do not introduce foreign genetic material.

The EU legislation on Genetically Modified Organisms is based on the **Directive 2001/18/EC**[7], which establishes a process-based regulatory system for GMOs and is among the strictest in the world. It mandates a rigorous safety assessment, authorisation, traceability, and labelling regime for any organism defined as a GMO. While appropriate at the time of adoption in 2001, this framework was not designed to accommodate NGTs technologies.

In **2018**, the Court of Justice of the European Union provides more clarity concerning NGTs, ruling that organisms created through targeted mutagenesis are legally classified as GMOs and therefore subjected of GMOs regulation[8]. This legal interpretation effectively subjected most NGT-derived plants to the same regulatory process as transgenic GMOs, regardless of risk profile, and for this reason has been widely perceived as one of the primary policy barriers to innovation. In particular, many stakeholders argue that the existing framework is not fit for purpose for NGT plants that are scientifically indistinguishable from conventionally bred varieties and do not carry foreign DNA.

The Possibility of a New Regulatory Landscape

In **July 2023**, the European Commission submitted a legislative proposal for a new regulation on plants produced by NGTs and their derived food/feed[9]. The 2023 proposal's central feature is the creation of two distinct regulatory pathways based on a plant's risk profile:

- **NGT Category 1:** includes plants obtained by targeted mutagenesis or cisgenesis that could also occur naturally or be produced through conventional breeding. These plants are subject to a prior verification procedure to confirm that they meet the criteria laid down in the Regulation. Once verified, they are considered equivalent to conventional plants and are exempt from the requirements of Directive 2001/18/EC, but they remain subject to specific transparency measures, including

7 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration [Internet]. OJ L Mar 12, 2001. Available from: http://data.europa.eu/eli/dir/2001/18/oj

8 Sands P, Galizzi P, editors. Court of Justice of the European Union PRESS RELEASE No 111/18. In: Documents in European Community Environmental Law [Internet]. 2nd edn Cambridge University Press; 2018 [cited 2026 Jan 29]. p. 787–836. Available from: https://www.cambridge.org/core/product/identifier/CBO9780511610851A064/type/book_part

9 REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625.

notification, listing in a publicly accessible database, mandatory labelling of seeds and exclusion from use in organic production.

- **NGT Category 2:** Covers plants that do not fulfil the criteria for Category 1. These remain subject to the existing GMO framework, including mandatory risk assessment, authorisation, traceability, and labelling requirements under EU GMO legislation.

In **December 2025**, following interinstitutional negotiations, the European Commission, the Council of the European Union and the European Parliament reached a provisional political agreement on the Regulation on plants obtained by certain NGTs. The agreement confirms the two-category system proposed in 2023 but introduces **more precise eligibility criteria for Category 1 plants**, including an explicit exclusion list of traits (such as herbicide tolerance and certain insecticidal traits) that automatically fall under Category 2. It also adds **new patent transparency requirements**, including the obligation to declare existing or pending patents for Category 1 plants and their inclusion in a public database.

In addition, the proposed agreement provides **greater flexibility for Member States**, notably the possibility to restrict or prohibit the cultivation of Category 2 plants and to adopt coexistence measures, particularly to protect organic farming. **Category 1 plants remain exempt from GMO risk assessment and food/feed labelling**, while seed labelling and a strengthened verification procedure are maintained.

Although politically agreed, **the Regulation is not yet in force**, as it still requires formal adoption by both the Council and the European Parliament. Once adopted, it is expected to be published in the Official Journal in 2026 and to apply after a transitional period. Its implementation will include monitoring of economic, environmental and social impacts, with particular attention to sustainability and safety standards.

Member States (MS): A divided Landscape

Although EU legislation is aiming for harmonisation, national implementation and political positions vary widely across Europe, revealing a split between some MS that actively support NGTs as tools for competitiveness, sustainability, and strategic autonomy; however, others emphasise precaution, coexistence with organic farming, and consumer concerns.

For example, among the MS that actively support the exploitation of NGTs, several have played a prominent role. **Sweden** has been a strong proponent of NGTs categorization and actively pushed for the simplified NGT-1 category, viewing it as essential for the competitiveness of EU[10]. **France** has supported NGTs as part

10 Dionglay C. EU's Proposal on NGTs: Updates and Recent Developments [Internet]. Science Speaks. [cited 2026 Jan 29]. Available from: https://www.isaaa.org/blog/entry/default.asp?BlogDate=2/12/2025

11 Gabrielczyk T. EU trilogue sets clear path for new genomic techniques [Internet]. European Biotechnology Magazine. 2025 [cited 2026 Jan 29]. Available from: https://european-biotechnology.com/latest-news/eu-trilogue-sets-clear-path-for-new-genomic-techniques/

12 Statement-EU-MS-approve-deregulation-of-GMOs-obtained-by-NGTs-EN.

of its strategy to enhance EU autonomy and food sovereignty, aligning NGT development with the European Competitiveness Fund and aiming to re-industrialize its biotech sector[10]. **Estonia** & **Czech Republic** have both emphasized the need to finalize NGTs discussions to support the EU agri-food sector. **Denmark** has also strongly supported the new EU framework for NGTs during its Council Presidency (July-December 2025), in which the NGTs regulation file was made a priority[11].

Other MS were more cautious: **Italy**, although generally supportive of NGTs to aid the agricultural value chain, emphasizes caution, ensuring NGTs benefit the "Made in Italy" brand without compromising quality standards. While Germany has many industries (e.g., KWS, Bayer) that are global leaders in Agri-patents, the domestic political landscape remains divided, with strong opposition from environmental factions concerned about coexistence with organic farming. For this reason, the German government abstained in the critical trial vote in December 2025[12].

This divergence risks creating regulatory fragmentation, legal uncertainty for innovators, and unequal access to NGTs technology across Europe.

The External Benchmark: United Kingdom

The **United Kingdom** represented a clear external benchmark for the European Union due to its deliberately divergent regulatory approach to genome editing. Through the Genetic Technology (Precision Breeding) Act 2023[13] and the subsequent 2025 Regulations[14], England has established a distinct legal category for Precision Bred Organisms (PBOs), organisms obtained by Genetic technologies, separating certain genome-edited plants from the traditional GMO framework[15]. Unlike the EU's emerging New Genomic Techniques management, the UK does not mandate consumer labelling for PBOs and does not impose patent transparency obligations, significantly reducing administrative and compliance burdens for developers. This lighter regulatory environment is widely perceived as more favourable to innovation and has increased the UK's appeal as an R&D hub, particularly for startups and small technology developers.

This regulatory divergence also creates strategic risks for the EU. Stricter verification, labelling, and traceability requirements may act as trade barriers and incentivise EU-based companies to relocate research activities to the UK in order to avoid EU procedures, including NGT-1 status verification and associated labelling obligations. In this respect, the UK approach not only illustrates alternative regulatory pathways but also exposes the competitive pressures facing the EU's agri-biotech innovation ecosystem.

13 Participation E. Genetic Technology (Precision Breeding) Act 2023 [Internet]. Statute Law Database; [cited 2026 Jan 29]. Available from: https://www.legislation.gov.uk/ukpga/2023/6/contents.

14 The Genetic Technology (Precision Breeding) Regulations 2025 [Internet]. King's Printer of Acts of Parliament; [cited 2026 Jan 29]. Available from: https://www.legislation.gov.uk/ukdsi/2025/9780348269123.

15 What are precision bred organisms? | Food Standards Agency [Internet]. [cited 2026 Jan 29]. Available from: https://www.food.gov.uk/business-guidance/what-are-precision-bred-organisms.

The External Benchmark: Rest Of the World

At a global level, several Western countries have already adopted more enabling regulatory approaches to NGT crops, resulting in concrete commercial and field-level applications[16]. In the **United States**[16], **Argentina**[17], **Brazil** and other **Latin American countries**, gene-edited plants that do not contain foreign DNA are generally regulated outside GMO legislation, following case-by-case assessments. This has facilitated the commercialization of products such as high-oleic soybean, non-browning mushrooms, improved canola, and drought-tolerant maize.

Similarly, **Japan** and **Australia** have clarified that certain genome-edited crops (particularly the CRISPR-Cas9 type modifications) are not subject to full GMO requirements, allowing the market entry of products such as gene-edited tomatoes with enhanced nutritional profiles in Japan.

Overall, across North and South America, Japan, and Australia, regulatory clarity and proportionate supervision have accelerated field trials, investment, and commercialization, providing a broader perspective on how NGTs are already contributing to agricultural innovation outside the EU and shaping global competitiveness in plant breeding.

16 Gene-Edited Plants: Regulation and Issues for Congress [Internet]. [cited 2026 Feb 12]. Available from: https://www.congress.gov/crs-product/IF12618

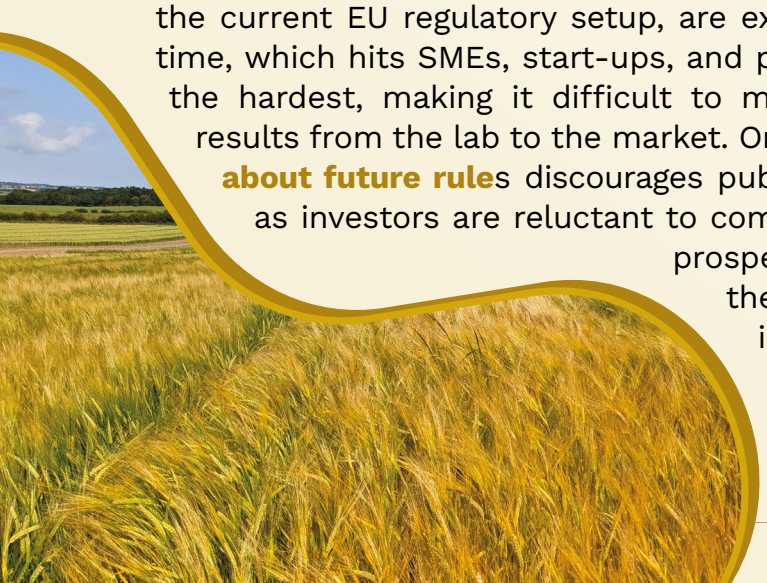
17 Regulatory framework for CRISPR-edited crops in Argentina. In: Global Regulatory Outlook for CRISPRized Plants [Internet]. Academic Press; 2024 [cited 2026 Feb 12]. p. 213–30. Available from: https://www.sciencedirect.com/science/chapter/edited-volume/abs/pii/B9780443184444000090.

Barriers to the adoption of NGTs

Despite the recent legislative progress, the EU continues to face significant obstacles that constrain the effective uptake of NGTs. In particular, **three structural barriers** continue to limit the EU's ability to fully exploit the potential benefits of NGTs and contribute to fostering the increasingly polarised debate.

A | Research and Innovation Barriers

Field trials and **approval procedures** to use NGT plants, with the current EU regulatory setup, are expensive and take a long time, which hits SMEs, start-ups, and public research institutes the hardest, making it difficult to move promising scientific results from the lab to the market. On top of that, **uncertainty about future rule**s discourages public–private partnerships, as investors are reluctant to commit when the regulatory prospect is unclear. Together, these issues reduce incentives to innovate and slow down the development of NGT crops, even when they



could clearly deliver agronomic or environmental benefits.

These challenges are made worse by **uncertainty regarding the definition of NGT-1 plants**. The current proposal relies on a simple numerical rule, no more than 20 genetic modifications, to decide whether a plant qualifies for lighter regulation. However, scientific organisations (EPSO) have warned that fixed numerical limits can quickly become outdated as technology evolves, and in the future innovations could end up in the more restrictive NGT-2 category simply because they exceed this numeric threshold[18].

B | Consumer Acceptance and Organic Concerns

Consumer perception remains one of the most significant barriers to the wider adoption of NGTs, despite the scientific consensus that NGT-1 plants are as safe as conventionally bred varieties. In fact, for most consumers, NGT's perception is associated with GMOs rather than with an informed understanding of breeding techniques or regulatory distinctions; for this reason, it is crucial to focus on communicating the differences and the benefits correctly.

At the same time, the current regulatory proposal maintains mandatory labelling and traceability requirements for NGT-1 plants, which, although intended to enhance transparency, may increase costs along the value chain and risk reinforcing existing negative perceptions for consumers.

By contrast, more complex concerns related to coexistence, such as the risk of unintentional mixing between NGT crops and conventional or organic production, are primarily raised by specific stakeholders within the agricultural sector. These actors express concern about potential impacts on organic and GMO-free supply chains, which could further reduce trust and market differentiation[19,20].

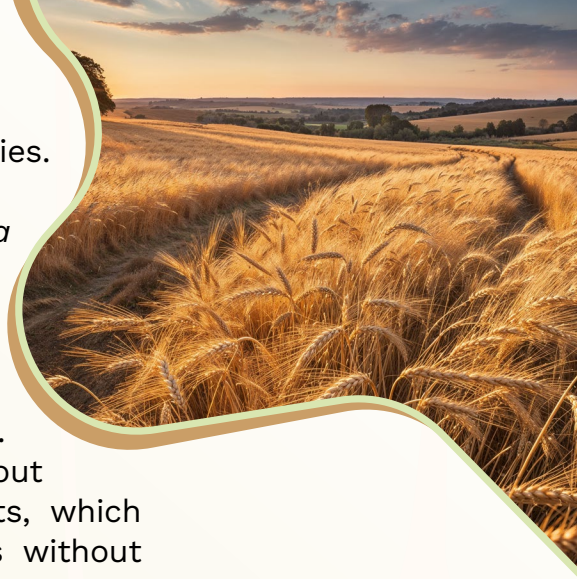
C | Intellectual Property, Investment Risk, and Access to Innovation

Intellectual property (IP) remains one of the most questioned aspects of the NGT legislative debate, reflecting the pressure between incentivising innovation and ensuring fair access to genetic resources. The International Association for the *Protection of Intellectual Property (AIPPI)* argues that banning patents on NGT plants would weaken motivations for R&D, particularly for SMEs, start-ups, and public research organisations that rely on patent protection to attract investment and secure returns on long-term research. In this view, patents are also seen as a transparency

18 Schulman AH, Hartung F, Smulders MJM, Sundström JF, Wilhelm R, Rognli OA, et al. Proposed EU NGT legislation in light of plant genetic variation. Plant Biotechnology Journal. 2025 Oct;23(10):4261–70.

19 Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops.

20 NGT vote a step backward for biosafety [Internet]. IFOAM Organics Europe. [cited 2026 Jan 28]. Available from: https://www.organicseurope.bio/news/ngt-vote-a-step-backward-for-biosafety-that-nonetheless-safeguards-the-possibility-for-traceability-and-national-coexistence-measures/.



tool, as they require public disclosure of new technologies.

By contrast, *European Coordination Via Campesina (ECVC)*, which represents small and medium-scale European peasant farmers, warns that patents on NGT plants could undermine farmers' rights to save, use, and exchange seeds, while accelerating concentration in the seed market and the privatisation of genetic resources[21]. These risks are intensified by farmers' concerns about reduced traceability and seed detection requirements, which could expose farmers to patent infringement claims without effective means to demonstrate whether patented traits arise from natural processes or unintended contamination.

Moreover, the interaction between patents and plant variety rights (PVRs)[22] creates an additional challenge. While PVRs include a breeder's exemption that facilitates access to genetic material, patents on NGT-derived traits may restrict this access, particularly where NGT-1 plants are indistinguishable from conventionally bred varieties. The new Parliament–Council compromise introducing patent transparency obligations improves information availability but does not address licensing costs or cumulative IP obligations. As a result, smaller breeders may continue to face "patent thickets", potentially reinforcing the market position of market the main players.

21 Patents-on-NGTS Briefing-note.

22 Plant variety property rights - Food Safety - European Commission [Internet]. [cited 2026 Jan 28]. Available from: https://food.ec.europa.eu/plants/plant-variety-property-rights_en.

Case Focus: Next Generation Barley

Barley is a strategic crop for Europe, supporting food, feed, malting, brewing, and emerging bio-based industries. For this reason, **the BEST-CROP project** has decided to focus on demonstrating how targeted genetic modification in barley organisms can lead to significant increases in carbon assimilation and yield, O3 uptake, and straw composition. The BEST CROP's studies provide strong evidence in support of further investment and clearer regulation for the production of Next Generation Barley Plants derived primarily by natural and induced genetic variability (NGT-1). Under the current and transitional regulatory framework, however, many of the innovations explored by BEST-CROP face significant barriers, such as prohibitive costs and delays, limiting their translation from research to market.

The project, therefore, serves as a concrete case study illustrating genome editing as a key enabling technology for the genetic improvement of barley as a model staple crop, while highlighting how regulatory design and implementation directly shape the return on European research investments. Ultimately, unlocking the full societal and economic benefits of these advances will depend on the establishment of a coherent, science-based, and

innovation-friendly regulatory framework capable of translating NGT-driven research into tangible gains for European food security, agricultural sustainability, and competitiveness.

Preliminary Policy Recommendations

To transform the 2025 **EU Trilogue Provisional Agreement on New Genomic Techniques** into a functioning innovation ecosystem, policymaker should consider the following actions:

- **Harmonise implementation of the NGT framework**
  The Commission should ensure a uniform interpretation of NGT-1 criteria and guarantee mutual recognition across all Member States to prevent regulatory fragmentation and market distortions, including the consistent application of the threshold for genetic modifications.
- **Address intellectual property bottlenecks**
  Patent transparency and fair licensing mechanisms should be strengthened to lower entry barriers for SMEs, public research institutions, and breeders, while preserving incentives for innovation.
- **Reinforce transparency and coexistence mechanisms**
  Public access to information on approved NGT plants and coordinated EU-level oversight of national coexistence measures are essential to protect organic and GMO-free markets, helping to build trust among farmers, consumers, and value-chain actors.
- **Move towards an outcome-based regulatory approach**
  In the longer term, EU regulation should increasingly focus on the traits and sustainability impacts of new plant varieties rather than the breeding techniques used to produce them. This also prevents new technologies, currently not yet known, from overrunning the EU legislation.
- **Strengthen public communication and engagement**
  Communication strategies on NGTs should shift from technical classifications to clear societal and environmental benefits, supported by transparency and evidence.
- **Supporting Farmer Adoption of NGTs**
  The European Union should strengthen advisory services and training programs to ensure that farmers have access to clear, science-based information on NGT-derived crops, their agronomic performance, and their role in sustainable farming systems, enabling informed decisions tailored to local conditions and production systems.

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Funded by the European Union
Grant Agreement No 101082091

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