

The **i**NTERPATENT newsletter



THE NEW EU REGULATION ON NEW GENOMIC TECHNIQUES (NGTs): BETWEEN AGRITECH INNOVATION AND THE PATENTABILITY ISSUE

On 17 June 2026, the European Parliament gave its final approval to the new [Regulation](#) (2026/1388) on plants obtained through certain New Genomic Techniques (NGTs)-commonly referred to in Italy as Assisted Evolution Technologies (TEAs)-and their derived products.

This news marks a major turning point for the European agrifood and biotechnology sectors. After more than two decades under a rigid and widely deemed obsolete regulatory framework (the historic 2001 GMO Directive), the European Union is executing a decisive shift. The explicitly strategic objective is to reconcile environmental sustainability and climate change adaptation with the scientific and economic competitiveness of the EU agricultural sector.

Beyond its agronomic and commercial impact, this new framework provides an essential occasion for reflection for companies, research centers, and Intellectual Property professionals. Indeed, the reform not only redefines the authorization process for these plants, but also directly impacts the delicate balance between **patent protection, plant variety rights, and the freedom to use agricultural raw materials**.

An Obsolete Regulatory Context: Why Reform Was Urgent

To appreciate the scope of the new European text, one must recall how NGT regulation had hitherto been stymied by a restrictive judicial interpretation. In 2018, a landmark judgment by the Court of Justice of the European Union (CJEU) ruled that plants obtained through targeted mutagenesis (such as the CRISPR-Cas9 gene-editing technique) had to be fully assimilated to first-generation transgenic GMOs.

This classification entailed the maximum application of the precautionary principle, imposing extremely burdensome authorization procedures, prohibitive compliance costs, and making open-field trials in the EU virtually impossible.

However, scientific reality demonstrates a clear distinction:

- **Traditional GMOs (Transgenesis):** Involve the insertion, into the host genome, of DNA from sexually incompatible species.
- **NGTs / TEAs (Cisgenesis and Targeted**

Mutagenesis): Carry out precise modifications by introducing sequences from the same species or inducing mutations entirely analogous to those that could occur naturally or through traditional breeding methods.

Continuing to treat precision genomic innovation in the same manner as early 1990s genetic manipulations would have condemned Europe to technological backwardness compared to dynamic markets such as the United States, Japan, and the United Kingdom.

Key Aspects of the Regulation: A Two-Tiered Approach

The approved text introduces a fundamental distinction based on the extent and nature of the genetic modification introduced into the plant:

- **Category 1 NGT Plants (NGT-1):** Plants featuring limited modifications (up to a maximum of 20 genetic alterations) that are considered equivalent to those obtainable through conventional methods. **These plants are exempted from the constraints of GMO legislation:** they do not require a complex risk assessment and are not subject to mandatory GMO consumer labeling on the final product (although transparency obligations remain for reproductive material, such as seed bags, along with registration in a public database).
- **Category 2 NGT Plants (NGT-2):** Encompass all other, more complex or extensive modifications. These varieties remain subject to an adapted and streamlined version of the GMO regime, requiring a prior risk assessment and full traceability along the entire supply chain.

An absolute threshold remains: **no NGT plant may be used in organic agriculture**, and plant varieties engineered to be herbicide-tolerant automatically fall under Category 2, regardless of the number of modifications performed.

The Patent Focus: A Complex Balance Between Protection and Accessibility

It is in the realm of Intellectual Property that the regulation sparked the most intense technical and political debate. How can the fundamental right of inventors and biotech companies to recoup substantial R&D investments be balanced against the need for farmers and conventional breeders to access genetic resources?

The European text establishes a compromise based on specific boundaries regarding patentability:

1. Patentability of Technology vs. Exclusivity

over Natural Traits

The regulation clarifies that **technological innovation is patentable** (e.g., a specific sequence modified via CRISPR or a particular editing process), **but genetic sequences or traits already existing in nature or obtainable through traditional breeding methods cannot be patented**. The objective is to prevent the "privatization" of biodiversity and technological lock-in by major seed conglomerates.

2. Relationship with Plant Variety Rights (CPVRs)

Two systems traditionally coexisted in Europe: patents (for biotechnological inventions) and Community Plant Variety Rights (CPVRs)-managed by the Community Plant Variety Office (CPVO)-which guarantee the *breeder's exemption* (the right of third parties to use a protected variety to breed new ones without prior authorization).

The new regulation seeks to prevent legal friction: where an NGT variety incorporates a patent-protected modification or trait, clauses are introduced to safeguard the use of resources for subsequent breeding activities by placing limitations on the scope of product claims.

3. Safeguarding the "Farmer's Privilege"

The right of farmers to save and reuse harvested seed or propagating material on their own holdings is formally protected, preventing overriding patent protection on the genetic modification from nullifying long-standing statutory exceptions for direct farming operations.

Implications for Corporate Patent Portfolio Management

The EU Regulation of 17 June 2026 demonstrates that protecting biotechnology innovations requires a comprehensive strategic perspective.

- **Targeted Filing Strategies:** Agritech companies will need to structure their patent applications with heightened focus on claim drafting. It will be essential to clearly delineate the novel feature introduced via NGTs from pre-existing or natural germplasm characteristics.
- **Integration Between Patents and Plant Variety Rights:** IP strategies can no longer rely solely on patents. Constructing an integrated IP architecture that combines patent protection for technology/gene-editing with plant variety rights will be essential.
- **Transparency Monitoring and Freedom to**

Operate (FTO): The establishment of a central public EU register for NGT-1 products offers dual strategic protection. On the one hand, it mandates the disclosure of existing or pending patents related to the modified genetic trait, enabling companies to conduct significantly faster and more accurate Freedom to Operate (FTO) analyses to avoid inadvertent infringement during breeding. On the other hand, it ensures full transparency across the supply chain, providing breeders and farmers (particularly in the organic and GM-free sectors) with an official tool to verify variety origins and freely plan their commercial choices.

In conclusion, the framework established for NGTs offers extraordinary opportunities for growth, but demands meticulous legal and regulatory planning from the earliest stages of germplasm research. Transparency regarding plant variety rights and patents will be the key determinant for success in the new single market.

Our firm remains at your disposal to discuss your Clients' specific needs and provide tailored advice on protecting their biotechnological inventions.

EPO AND CHINA: A NEW PERMANENT PPH CHANNEL TO ACCELERATE YOUR PATENTS

As you know, the **Patent Prosecution Highway (PPH)** program represents a key mechanism for accelerating patent prosecution before a target Patent Office by leveraging positive examination work performed by partner offices.

Among the European Patent Office's various collaborative agreements of this nature, its partnership with the China National Intellectual Property Administration (CNIPA) has long held strategic importance for many businesses.

In this regard, we would like to highlight an important update: **the EPO and CNIPA have signed a new bilateral PPH agreement**, which will enter into force on **1 August 2026**.

Although a PPH channel between the EPO and CNIPA was already operational under the **IP5** multilateral framework-the cooperative network uniting the world's five major patent offices (the aforementioned EPO and CNIPA, the USPTO in the USA, the JPO in Japan, and the KIPO in South Korea)-the new bilateral agreement introduces a major enhancement: **an indefinite duration**.

Unlike the IP5 multilateral framework, which is subject to periodic renewals and extensions, this direct agreement provides long-term stability and continuity. This guarantees a permanent legal framework of certainty for applicants seeking expedited protection for their inventions in both Europe and the Chinese market, while retaining all the classic advantages of the PPH:

- **Accelerated examination and grant timelines;**
- **No additional official fees for filing the request;**
- **Re-use of search and examination work already conducted by the partner office.**

If your Clients have pending or planned patent applications in Europe and China and wish to explore utilizing the accelerated PPH procedure, our patent attorneys are available to help you determine the most effective strategy.



IMPORTANT CHANGES TO .RU, .PФ, AND .SU DOMAIN REGULATIONS



Beginning **1 September 2026**, mandatory verification through the Unified System of Identification and Authentication (USIA) will take effect for all .RU, .PФ (.xn--p1ai), and .SU domain names. Domain holders must link their domains to an officially verified organization in Russia via an employee holding a verified personal USIA account.

Impact on Foreign Organizations

Because USIA verification requires local Russian identity credentials, **foreign companies without an established branch or representative office in Russia will be unable to set up an account** under current rules.

Key Aspects of the New Regulations

- **Unverified domains** will remain operational until their current term expires, but failure to link them to a verified Russian entity prior to 1 September 2026 **will prevent all future management, renewals, and ownership transfers.**
- To bring a non-compliant domain into compliance after the deadline, it will have to be deleted and re-registered, exposing it to the **risk of being snapped up by third parties.**
- Second-level domains (e.g., .COM.RU) are exempt from this requirement.
- To avoid risking domain loss and jeopardizing the services associated therewith (such as website and email services), **non-resident domain holders should transition their domains to a local trustee prior to 1 September 2026.**
- To initiate the trustee service, standard company registration documents (Certificate of Incorporation, Commercial Register extract, or Articles of Association), in English, Russian, or accompanied by a certified Russian translation, are required.

Our firm can help the holders of Russian domains .RU, .PФ, and .SU in finding a Russian trustee and assist them in all domain-related matters.

FUNDING NOW AVAILABLE FOR CRAFT AND INDUSTRIAL GEOGRAPHICAL INDICATIONS (CIGIS)

As you are aware, under **Regulation (EU) 2023/2411** (adopted on 18 October 2023), effective from December 2025, businesses producing craft or industrial products (such as natural stones, wooden goods, jewelry, textiles, and glass) tied to tradition and geographic origin can register their Geographical Indications through a centralized procedure managed by the **EUIPO** (European Union Intellectual Property

Office). This mechanism ensures enhanced market protection and visibility, establishing a harmonized system for the protection of CIGIs across the European Union.

This new IP right is valid throughout the European Union and extends to craft and industrial products the same protection previously reserved for agricultural geographical

indications, thus enabling the international promotion of local and regional territories and craftsmanship.

The **SME Fund**, managed by the EUIPO and providing vouchers granting partial reimbursement of costs incurred for the protection of IP rights, has therefore expanded its scope to encompass CIGIs as well.

Indeed, alongside the four existing vouchers-Voucher 1 covering IP scan services (not applicable in Italy), Voucher 2 covering trademarks and designs, Voucher 3 covering patents, and Voucher 4 covering plant varieties - **a new grant has been introduced to protect Craft and Industrial Geographical Indications, referred to as "Voucher 5".**

Key Features of "Voucher 5" at a Glance

- **Financial Contribution:** Up to a maximum of **€2,000 per beneficiary** to cover registration costs.
- **Costs Admissible for Reimbursement:**
 - National CIGI filing fees
 - EU-level CIGI filing fees
 - Costs associated with drafting the product specification.

Eligible Applicants

Voucher 5 is aimed at entities involved in the protection of craft and industrial GIs that meet the eligibility criteria, including:

- **Producer groups** established in the EU (provided they include at least one SME)
- **Single producers** qualifying as SMEs
- **Local/regional authorities** and private entities designated by Member States.

Our firm provides comprehensive assistance in securing all of the above-mentioned Vouchers. Please do not hesitate to contact us should you require any further information or clarification on the matter.



SECOND PHASE OF EU DESIGN REFORM BECOMES FULLY OPERATIONAL

On **1 July 2026**, the second and most substantial phase of the European design reform entered into force (**Regulation (EU) 2024/2822** and **Implementing Regulation (EU) 2026/138**), as previously discussed in our newsletters.

Below is a recap of the main updates introduced under the new framework:

- **New Official Terminology:** The concept of "Community Design" has been permanently replaced by "**European Union Design**", aligning standard practice with that of EU Trademarks (EUTMs).
- **Expansion to Digital and Dynamic Products:** Protection has been extended to non-physical products-such as Graphical User Interfaces (GUIs), icons, digital layouts, and virtual environments-with direct protection granted to dynamic elements and animations (e.g., screen transitions, visual movements, and state changes).
- **Removal of the 7-View Limit and Support for New Formats (Video & 3D):** The former cap of seven static views has been abolished, allowing greater visual flexibility to capture complex details. Applicants can now also file

design applications using video files (MP4) to demonstrate animations, as well as 3D files (OBJ or STL).

- **Procedural Simplification and Multiple Applications:** Multiple applications now allow for up to **50 designs in a single filing**, even across different product classes (eliminating the requirement to belong to the same Locarno class).
- **Strengthened Enforcement (3D Printing and Goods in Transit):** Exclusive rights have been expanded to prevent the unauthorized creation or distribution of digital files intended for 3D printing. Also, the EU Design Reform allows registered design holders to block and challenge counterfeit goods in transit through the EU territory, even if the goods are originated outside the EU and not intended for sale within the EU market.

- **Accelerated Procedure for Uncontested Invalidity Actions:** In invalidity applications based on lack of novelty or individual character that are not contested by the proprietor, the EUIPO will apply an expedited, priority examination procedure.

- **New Rules for Recordal of Transfers/Assignments:** Formal documentary evidence is now required when registering transfers/assignments of ownership in the EUIPO Register.

We at Interpatent remain at your disposal for any further details, and we will keep you updated once the third phase concludes (EU Member States are required to transpose the Directive into corresponding national laws by 9 December 2027).



The aim of this newsletter is to keep our Clients and Associates updated about developments in the sector of Intellectual Property in general and our firm in particular. In this way, we wish to provide a broader view of the tools that the field of trade marks, domain names, patents, designs and related rights offers to entrepreneurs to enhance and protect their efforts in researching and developing new solutions and ideas.



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