

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

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Introduction



1. A MAJOR TECHNOLOGICAL BREAKTHROUGH

New Genomic Technologies (NGTs), and particularly Genome Editing, have developed rapidly over the past two decades.

They enable genetic improvement with unprecedented precision, speed, and accessibility.



2. WELL SUITED TO RESEARCH AND SUSTAINABLE AGRICULTURE

These technologies are especially well suited to research and sustainable agricultural development,

helping to address the major challenges now facing agriculture, notably those related to climate change.



3. THE CENTRAL QUESTION

In an increasingly globalized world, how is the **European Union** seeking to reconcile **scientific progress** with a regulatory framework that is both **effective** and **democratically acceptable**?



4. OBJECTIVE OF THIS PRESENTATION

This presentation will highlight the recent and significant—although still limited—progress achieved in the European Union's regulatory framework for New Genomic Technologies.



TAKE-HOME MESSAGE

NGTs offer unique opportunities for sustainable agriculture. The challenge for the European Union is to build a regulatory framework that supports innovation while ensuring safety, transparency and societal trust.



1. A GROWING PORTFOLIO OF GENOME-EDITED VARIETIES IN PLANTS



GLOBAL RESEARCH AND DEPLOYMENT OF NGTs IN PLANTS: A RAPIDLY EXPANDING LANDSCAPE



CRISPR/Cas: THE MOST WIDELY USED TECHNOLOGY



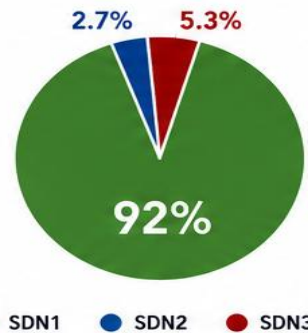
924 reported applications



The vast majority involve small, targeted changes, predominantly **SDN1-type edits (92%)**



These modifications are generally **indistinguishable from natural mutations** when conventional detection methods are used.



A LARGE AND DIVERSE RESEARCH PORTFOLIO

According to the EU-SAGE database, **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:



324

TOLERANCE TO
BIOTIC & ABIOTIC
STRESSES



59

HERBICIDE
TOLERANCE



216

YIELD
IMPROVEMENT



28

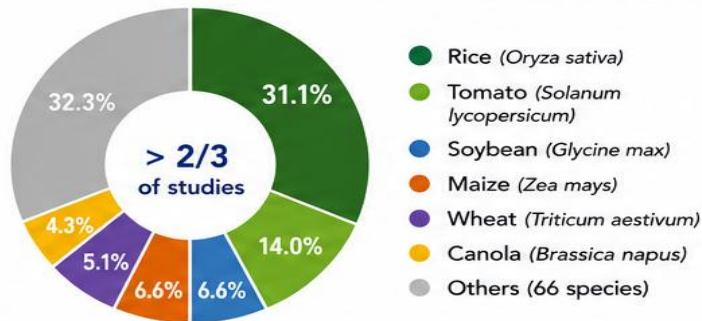
POST-HARVEST
RESILIENCE



RESEARCH FOCUSED ON A FEW MAJOR CROPS

Research activity is concentrated on a limited number of major crops.

Six species account for more than two-thirds of all studies, with rice alone representing **over 30%**.



A GLOBAL MOVEMENT

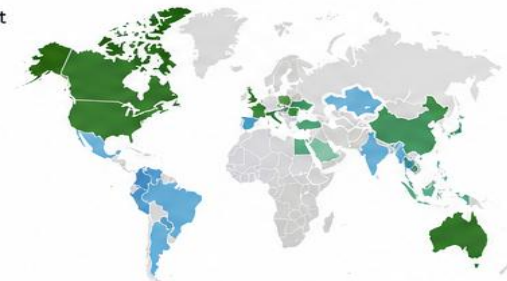
Overall, research on varietal improvement using NGTs is now underway in

more than 35 countries,

with field trials being conducted

in more than 15 countries.

This reflects the rapid global deployment of these technologies.



■ Field trials ongoing ■ Research ongoing ■ Research initiated



Sicilian Rouge High-GABA Tomato

Photo source Sanatech seeds

First CRISPR edited tomato approved for marketing in September 2021 in Japan

Italy tests first gene-edited vines for winemaking

Europe's first field trial of gene-edited vines began in northern Italy on 30 September 2024. Developed by EdiVite, a spinoff from the University of Verona, these Chardonnay vines have undergone gene inactivation to enable them to better defend themselves against downy mildew, a major fungal disease. The trial is being conducted on university land, with plans to expand to another site in the Veneto region. Researchers aim to gather initial data by 2025, with the potential for experimental winemaking in 2026.

By Anna Meldolesi

A CRISPR-Cas9 complex was introduced into naked cells (protoplasts) to target a gene from the *Downy* family, encoding a protein that typically suppresses the plant's immune defense by limiting salicylic acid production. "Editing is the easy part; however, regenerating the vines is challenging and requires variety-specific tricks," said Mario Pezzotti, a geneticist and co-founder of EdiVite. If the proposed new EU regulation on new Genomic Techniques (NGTs) is approved in Brussels, these vines should be exempt from GMO restrictions because they do not contain any foreign DNA.

Viticulture urgently needs innovation to become more sustainable, as vineyards account for just 2% of Europe's cultivated area but use 48% of its fungicides. Cross-breeding with resistant wild vines could help, but at the expense of the genetic identity of grape varieties, which is the cornerstone of their commercial value. Gene editing circumvents this issue by leaving the genome intact except for the desired mutation. Knocking out a single susceptibility gene, however, may offer only partial protection against downy mildew, according to lab tests. "The field trial



Chardonnay is a renowned grape that is easy to grow but suffers from fungal diseases.

should clarify whether this translates into a reduced need for fungicides in the real world," explained geneticist Sara Zenoni, co-founder of the spinoff, which also involves some local wine producers.

Other Italian groups are nearly ready to follow with further advancements. The Edmund Mach Foundation (FEM) in San Michele all'Adige has developed a Chardonnay grape with both *Downy* genes knocked out, aiming to achieve higher protection. "We are applying to field-test the single and double mutants to compare the results," said Umberto Salvagnin, a researcher at FEM. Meanwhile, a collaboration between the Research Centre for Viticulture and Enology (CREA-VE), operating under the supervision of the Ministry of Agriculture, and a team from the national research Council in Turin is also progressing. "We have several gene-edited varieties undergoing final checks before applying for field trial authorization. The first to be tested could be a Chardonnay resistant to powdery mildew," said Riccardo Velasco, director of CREA-VE.

It's a promising sign that Agriculture Minister Francesco Lollobrigida backs these efforts, marking a turning point from opposing GMOs to embracing NGTs. It's also notable that Ettore Prandini, president of the Coldiretti farmers' association and a longtime critic of GMOs, went to Verona to underscore the shift by planting an edited vine with his own hands.

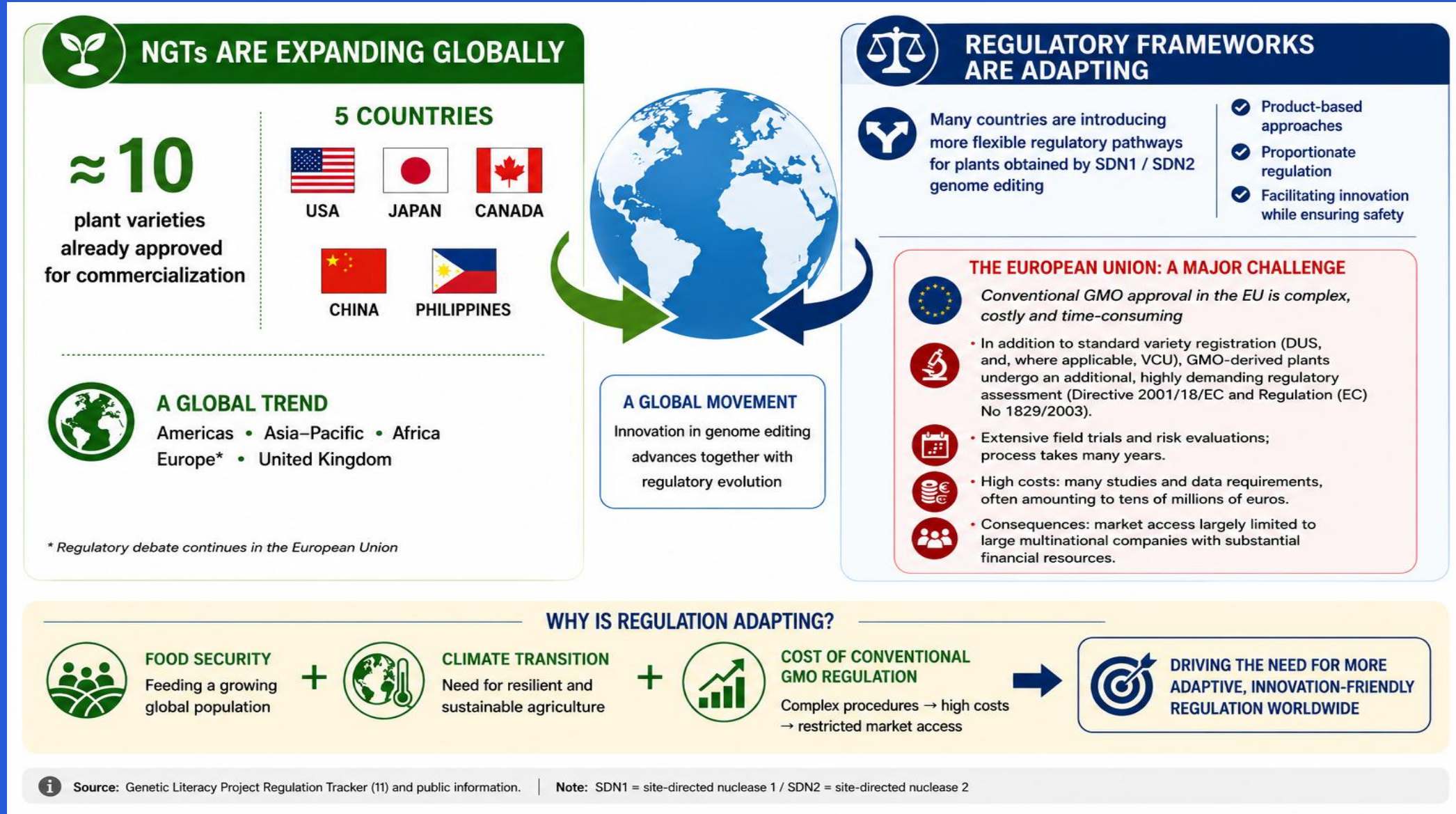
Earlier this year, Italy gave the green light to the experimental release of a rice variety edited for fungal resistance by the University of Milan, ending a 20-year deadlock due to opposition to GMOs. This first field was vandalized in June, a month after it began. Still, no one has claimed responsibility for the act, and geneticist Vittoria Brambilla, who leads the project, remains undeterred: "We received a great deal of support from institutions and the public, so we look forward to continuing the trial in 2025."

Anna Meldolesi
Bologna, Italy

Field trial initiated on September 30th, 2024



2. NGTS EXPANDING GLOBALLY ALONGSIDE REGULATORY ADAPTATION



3. IN THE EUROPEAN UNION, A LONG PROCESS TO UPDATE REGULATION



A REGULATORY JOURNEY LEADING TO CHANGE



2018

The Court of Justice of the EU rules that organisms obtained through genome editing fall under the EU GMO framework and are therefore subject to Directive 2001/18/EC.



2019

In response to this decision, widely contested by scientific and economic stakeholders, the European Commission, at the request of the Council of the European Union, launches a regulatory review.



5 JULY 2023

The European Commission submits its proposal for a regulation on plants obtained by certain NGTs and their food and feed.



DECEMBER 2025

After examination by the European Parliament and the Council, trilogue negotiations are concluded.



APRIL 2026

The Council adopts the new rules.



17 JUNE 2026

The European Parliament gives its final approval.



A REFORM TO SUPPORT INNOVATION AND EUROPEAN AGRICULTURE

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**.



4. KEY ELEMENTS OF THE REGULATORY FRAMEWORK

HOW THE NEW RULES WORK IN PRACTICE

Two categories, two regulatory pathways

NGT-1 PLANTS

SIMPLIFIED PROCESS – LIGHTER OBLIGATIONS

- 

Declaration 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**.
 - 

No new verification for subsequent progeny
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.
 - 

No labeling at consumer level
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**.
-  **NGT-1 plants benefit from a lighter regulatory framework while ensuring transparency and traceability.**

NGT-2 PLANTS

EXISTING GMO FRAMEWORK CONTINUES TO APPLY

- 

Subject to the existing GMO framework
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.
 - 

Flexibility for Member States
Member States may restrict or prohibit the cultivation of NGT-2 plants on their territory. They may also implement **coexistence measures** to avoid unintended presence in other production systems, including conventional and organic agriculture.
-  **NGT-2 plants remain under the current GMO regime ensuring safety, control and the right to choose.**



KEY TAKE-HOME MESSAGE

The new rules establish a balanced approach: simplification and innovation for NGT-1 plants, while maintaining robust safeguards and national flexibility for NGT-2 plants.



5. ANIMALS REMAIN OUTSIDE THE NEW EU FRAMEWORK



GENOME EDITING IN ANIMALS: HIGH POTENTIAL, MAJOR CHALLENGES IN EUROPE

1 HIGH POTENTIAL AND KEY APPLICATIONS

Genome editing in livestock offers considerable potential and is likely to develop in the coming decades, including in Europe.

Main expected applications:

-  **Control of contagious animal diseases** by generating disease-resistant, disease-insensitive or resilient populations
-  **Reduction of disease outbreaks**
-  **Mitigation of zoonotic risks**

“ Genomic editing will constitute a major tool for the prophylaxis of contagious animal diseases in the 21st century (17)

2 A DUAL CONSTRAINT IN EUROPE



Low public acceptance of animal-derived products obtained through genomic modification (5)



Societal resistance discourages economic stakeholders and livestock organizations from promoting these technologies



Fear that adoption could further depress consumption of meat and other animal products

3 RESEARCH PRIORITIES



Priority should be given to research targeting diseases that:

- can cause **major economic losses** (e.g., foot-and-mouth disease)
- pose **significant societal risks** in the context of zoonoses



These research priorities are actively pursued in countries such as **China** and the **United States**.



4 A PARADOXICAL SITUATION IN THE EU



In 2021, the then Vice-President of the European Commission, Maroš Šefčovič, indicated in a letter to the Portuguese Presidency of the Council of the EU 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.

5 UEAA RECOMMENDATIONS – A FIRST STEP NOT YET TAKEN INTO ACCOUNT



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 is a major step for plants, but it leaves unresolved the broader question of NGT applications in animals and microorganisms.



TAKE-HOME MESSAGE

Genome editing in animals holds major promise for animal health, public health and the economy.

For Europe, the challenge is to enable responsible research and innovation while addressing societal concerns and regulatory barriers.



(5) Public acceptance of GM animal-derived products remains low. (17) Quote on genome editing and prophylaxis of contagious animal diseases in the 21st century.

(18) UEAA Electronic Working Group (2022) – Recommendations for revising the regulatory framework for genome editing in plants and animals.

6. CONCLUSION



A MILESTONE FOR EUROPEAN AGRICULTURE: A NEW ERA, WITH CHALLENGES AHEAD



- 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.



- 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.



- The adoption of the Regulation represents a **historic milestone**: it aligns policy more closely with scientific progress, however with regrettable limits such as **excluding livestock**.



**Will Europe fully capitalize
on the opportunities offered by NGTs ?**



6. CONCLUSION

THANK YOU

FALEMINDERIT



Figure 2
**Maïs génétiquement
édité pour une
floraison précoce et
une tolérance au sel**
*Travaux de l'Université
d'agriculture du
Henan (Chine)*