

- Agriculture -

# “It is time to review the EU’s outdated rules on GMOs” (Interview)

By European Scientist - 12.11.2024



*Curious about where the EU currently stands on regulating green biotechnology? For a comprehensive overview, dive into our exclusive three-way interview with Catherine Regnault-Roger\*, Michel Thibier\*\*, and Alain Toppan\*\*\*, all esteemed members of the French Academy of Agriculture. They have generously shared their insights, providing in-depth responses on this hotly debated subject.*

**The European Scientist :** You’ve recently published “Does Genome Editing Have a Future in EU Agriculture?” What prompted this inquiry? Could you provide more context on your paper’s background?

**Michel Thibier :** This paper has been presented at the UEAA (Union of the Academies of Agriculture) Scientific Symposium “New Research

Techniques And The Agricultural Progress” in Bucharest, 10-11 October 2024.

It appeared to us that it was quite timely and also appropriate as the UEAA has often dealt with the Genomics Edition issue in its publications and has been quite active in stressing the need to adapt new EU regulations on NGT's (1).

Therefore the 12th General Assembly of the UEAA, debated and adopted unanimously, in Bucharest, at 10 October 2024, the following motion :

*Genome Editing, and particularly CRISPR technology, has revolutionized plant breeding approaches and has immense benefits as a response to the European Agricultural Challenges and in full agreement with the objectives of the Green Deal for Europe. The European Union must look with confidence to an agricultural future based on biotechnological innovation.*

***UEAA recommends the adoption of relevant regulatory rules on Gene Editing that reinforce an EU agriculture more productive, environmentally friendly and economically competitive in a globalized world.***

Indeed, the current EU regulatory context on GMO's is a major handicap for European biotechnology innovation. Since 1989, the various European directives and regulations have been an impediment. However, in November 2019, the European Council requested from the European Commission (EC) to submit its proposals to it in order to change the regulation on NGT. Such a proposal was published on 5 July 2023 and then subject to a public consultation. Ultimately, The EU Council, composed of the ministers of the Member States, who met a few hours after the European Parliament's vote to reach an agreement on a negotiating mandate for the trilogue, failed because there would be differences of position between the Member States on patents. It was therefore decided to postpone the final examination of the case after the European Parliament elections of June 2024. So, the new regulation project is still on hold and should be revisited by the EU governance.



**TES :** Could you introduce to us the most recent developments in genetic engineering? What is New Genomic Techniques (NGT) in simple terms, and how does it differ from traditional GMOs? What are the implications for the agricultural sector?

**Catherine Regnault Roger :** Considering the scientific advances of these last decades, one can distinguish two generations of genetic modifications. The first one generated in the 20<sup>th</sup> century involved random mutations and later, in the 1980s, transgenesis. These techniques are difficult to carry out and require a laborious sorting process to select the desired genetic transformations from among the many obtained transformations. The second generation, the New Genomic Techniques (NGT's), have been developed since the beginning of the 21<sup>st</sup> century. It includes the CRISPR/Cas technique first described in 2012 in the renowned scientific journal "Science". This is considered a real technological breakthrough as it simplifies the implementation of genetic modifications in the laboratory. You've probably heard of molecular scissors! This is it.

Indeed, Gene Editing techniques can produce specific alterations at precise locations in the genome thanks to the association of nucleic acid with some specific proteins (nucleases). The DNA to be modified is cut in a very precise place and no longer randomly as with the previous generation of techniques. One is now talking about rewriting or editing the genome.



Hence, these NGT's are more accurate, easier to perform and cheaper! They are a huge success: between 2013 and October 2024, the PubMed database lists 34,123 scientific publications dedicated to CRISPR!

Agronomic applications are numerous such as the development of new varieties able to better resist drought but also floods, therefore referring to climate change, and dealing with bio- aggressors (pathogens and pests) or improving the nutritional composition of plant products. As an example, an Alicament tomato with enhanced levels of gamma-amino-butyric acid (which has relaxing and blood pressure reducing effects), the *Sicilian Rouge High GABA*, was marketed in Japan in 2022.

**TES.: A global trend in agricultural innovation, particularly with tools like CRISPR, is evident across all continents for developing new plant varieties. Could you summarize these advancements? How does Europe position itself within this global innovation landscape?**

**Alain Toppan :** Varietal creation is a process that provides the farmer with plant varieties best suited to local growing conditions (soil, pests, etc.) and food or industrial outlets. The current climate change requires an acceleration in the creation of new varieties. The breeder's job is to group in a single plant the traits (genes) that will give it the expected qualities.

These traits were derived from the known variability of the species and sometimes created by random, chemical or physical mutagenesis. The knowledge acquired these last 20 years or so has also led to improving these genes, which are absent in the species, by copying known sequences from related or wild species. It is then a directed, very targeted, quick and easy mutagenesis process that several tools, such as CRISPR, can achieve to create the improved genes that agriculture needs.

Every day, optimizations of these tools are published and patented: speed of implementation, possibility to modify several genes simultaneously, application to new plant species, are the most frequent. Innovation comes from the west (North America) or east (Asia), where there are a lot of

patent applications. Many states (USA, Argentina, Japan, Brazil, etc.) have exempted products containing mutations created by genomic editing techniques such as CRISPR, thus promoting their development and acceptance.

Europe is far behind, definitely lagging behind. This is probably due to the consequences of anti-GMO battles that led researchers to a more or less marked censorship, more or less violent. The destruction of field trials has discouraged scientists who have also lost funding for their research projects. The very strict testing regulations have also been a factor in the decline of research in Europe. As history goes on, a genomically-enhanced rice trial by a laboratory at the University of Milan was destroyed last June. It was created to resist disease ...

**TES. : Your work appears critical of EU regulations, suggesting they hinder agro-technological progress through the application of the precautionary principle. Could you expand on this critique?**

**C.R.R.:** Indeed, the European regulation applied to plant genetic modifications is now inadequate if not obsolete! Actually, this is not only my opinion, but that of the European Commission's Senior Scientific Advisors (SAM) Mechanism.

In response to the judgment of the Court of Justice of the European Union (CJEU) on 25 July 2018 that products obtained by techniques subsequent to Directive 2001/18/EC which regulates GMOs in the European Union must be subject to the GMO regulations, SAM issued a statement in November 2018, which stressed that:

*"it becomes evident that new scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose."*

This statement refers to the developments reported since 2001 and points out that there are difficulties in establishing controls and achieving traceability of products obtained by NGTs in trade, as some modifications

made by Genome Editing are *a posteriori* undetectable. Consequently, the SAM calls for the evaluation of the characteristics of the final product instead of legislating based on the method of production. It stresses the need to create a regulatory environment conducive to innovation so that the public at large can benefit from new science and technology.

The foundation of the EU's regulation on GMOs is Directive 2001/18, which is based on current knowledge dating from the last decade of the 20<sup>th</sup> century and the precautionary principle. This principle, such as considered by this Court, puts the brakes on innovation. If at some point there are legitimate concerns about an innovation, it is indeed necessary to propose a regulation that considers the risks incurred after having evaluated them. But when scientific doubts are removed, the regulations must evolve and become more flexible.

For more than 25 years that GMO crops have been grown yearly on over 180 million hectares worldwide on five continents, it has been found that no health damage has occurred. The three U.S. Academies, The National Academies of Science, Engineering and Medicine, published a report in 2016 entitled Genetically Engineered Crops: Experiences and Prospects [3] which was over 600 pages long. After considering agronomic and environmental effects, public health effects and social and economic consequences over a period of 20 years, the three academies concluded that these biotech plants grown in accordance with good agricultural practices do not present more toxicity and ecotoxicity or environmental risks than conventional plants.

All this shows that it is high time to review the EU's outdated rules on GMOs.

**TES.: Since around 2019, there's been a noticeable shift with efforts to introduce new legislation on gene editing. What was the underlying rationale for these legislative efforts? Why was the final amendment not adopted? What new regulatory discussions are currently on the table?**

**A.T.:** The European Commission had already begun to consider products resulting from new techniques for modifying gene sequences in 2007. The analysis of these techniques has progressed very slowly. The main issue was whether the directives and regulations governing the marketing of GMOs were appropriate for products produced by these techniques. Economic studies, EFSA opinions have been published, without translation in the regulatory package. More recently, the arrival of such easy-to-use techniques as CRISPR and the presence on the US markets of varieties enhanced by CRISPR, not subject to GMO regulation, have forced the European Union to move a bit faster on this issue.

Based on the GMO regulations, and without going into a total overhaul that would have required some ten years of work, the Commission considered plants as exempted, when obtained using the NGT's but which could have been obtained by conventional selection. In jargon, these plants are called NGT1, minor modifications, without the addition of exogenous DNA and whose mutation could have occurred in nature.

There has been a long history of getting there to make it short. Let us retain the essential points.

- A desire of the Commission to conclude before the end of the 2019-2024 mandate which could not be implemented on time.
- A proposal by the Commission in July 2023 differentiating NGT products to apply different rules to NGT1 plants but introducing the ban on their use in organic farming.

Following the positive vote of Parliament in February and April 2024 on the proposal for exemption of NGT1 plants, the file was brought before the Council but was blocked by the positions of several countries. Issues of labelling, accidental presence, detection tools, patentability have been re-introduced and have made any compromise impossible.

In addition, the NGT issue is not supported by some EU presidencies, currently Hungary and Poland in the first semester of 2025, both opposed

to a relaxed regulatory evolution on NGT.

In short, **over and over again, ideological positions prevent the major innovation** that agriculture is waiting for to face the challenges occurring; there is an urgency because elsewhere in the world, the products of this innovation are already cultivated.

**TES. : You argue that climate neutrality, food sovereignty, international competition, and agricultural practice improvements are crucial for supporting new laws on NGT. What are the current chances of such legislation passing? How do you envision a resolution to this legislative deadlock?**

**CRR.:** The bill under consideration proposes considering a regulatory amendment for two categories of plant products:

- NGT-1 plants: considered equivalent to conventional plants and whose minor genetic modifications, produced in the laboratory by NGT techniques, could have occurred spontaneously in nature or as a result of a conventional selection process without the addition of foreign DNA to the gene pool. These NGT-1s would be exempt from the GMO regulations. Plants in this category would receive a positive notification from the authorities, in a database open to all, following the submission of a dossier and opinion from the European Food Safety Agency (EFSA).
- NGT-2 plants include those that have been modified by NGT but whose modifications do not fall within the criteria of category NGT-1. These NGT-2 plants are subject to GMO-type regulations despite the wishful thinking that it “must be proportionate to the modified character”. The NGT-2 are, in fact, subject to a more restrictive regulation similar to Directive 2001/18 which, it should be recalled, is a regulation requiring heavy files, expensive for the industrialists who have applied for approval, and which are evaluated by numerous



committees of experts from the Member States and the EFSA (European Food Safety Agency).

It is clear that the proposed simplification of administrative procedures for marketing authorizations for NGT-1 products is minor and limited

The many amendments voted by the European Parliament also contribute to darkening the picture

Is this law, which has been passed but not yet ratified, likely to give confidence to the biotechnology industries applied to agriculture? While many countries around the world have waived (or eased) regulation of NGT products, the European Union is missing an historic opportunity to re-examine its agricultural biotechnology regulations. It may have made sense in the years 1990-2000, but by 2024 it is clearly obsolete, as indicated earlier, in light of the advances in scientific knowledge over the past twenty years or so. It is high time to move beyond baseless anxiety-provoking rhetoric.

The European Union and its members must look with confidence to an agricultural future that should be based on biotechnology innovation! Competitiveness and our sustainable agriculture are at stake!

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**\*Catherine Regnault Roger** : Professor Emeritus of the E2S University of Pau and the Adour countries, member of the French Academy of Agriculture and the National Academy of Pharmacy

**\*\*Michel Thibier** : past President of the UEAA (Union Européenne des Académies d'Agriculture), member of the Académie d'Agriculture de France, Académie Vétérinaire de France

**\*\*\*Alain Toppan** : Research scientist at the CNRS, he later joined private companies where he worked in R&D functions placing on the market

biotechnological plant varieties. Member of the French Academy of Agriculture.

(1) [www.ueaa.info](http://www.ueaa.info)

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