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DOES GENOME EDITING HAVE A FUTURE IN EU AGRICULTURE?

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Abstract
Genome Editing, and particularly CRISPR technology, has revolutionized plant breeding approaches. Many countries in the world have decided to use it to create new fields of research and applications in agriculture with appropriate adaptation of the existing regulations on genetic bioengineering facilitating the implementation of the New Genomic Techniques (NGTs).
The work in progress worldwide opens up immense prospects for the plant and animal sectors. The European Union has launched a regulatory review procedure for its use on certain plants. The present review questions the efficacy of the current EU proposals as a response to the European agricultural challenges in question and concludes that based on the precautionary principle repeated over and over again, the challenges of agriculture are only partially taken into account as the regulatory framework remains very restrictive.

Keywords : Gene Editing, European Union, Agriculture, Regulation, Innovation.

INTRODUCTION

Among the new research techniques likely to bring benefits to agriculture are those inducing genetic modifications using the so-called New Genomic Techniques (NGTs) and notably the remarkable CRISPR/Cas Gene Editing technology. The two authors of the first key publication related to the latter, E Charpentier et J Doudna (6) who developed it, won the Nobel Prize in Chemistry in 2020.
Indeed, this technique is a technological breakthrough compared to previous techniques of production of Genetically Modified Organisms (GMOs) such as transgenesis, in that it makes it possible to precisely cut a genome that can be rearranged without «leaving the slightest artificial trace in the rest of the genome» as emphasized by the French Academy of Sciences As a result of this property, it is often referred to as «molecular scissors» (1).
These genomic changes modify the sequence of a gene or allele which result in new properties of the organisms thus edited. The applications are immense both in human health (orphan genetic diseases), in veterinary health and animal welfare, and in agricultural crop production.
The aim of the present review is to focus on plants and report in one first part on the huge potential of this technology in the varietal plant innovation around the whole world and its current progress. In a second part, this paper presents the current EU regulatory environment, its discussion in the EU political and administrative authorities including the latest moves in 2024.
The third part will try to assess the efficacy of the current EU proposals to meet the challenges of its agriculture considering the progress raising from the rest of the world.

1. POTENTIAL OF GENE EDITING FOR VARIETAL INNOVATION WORLDWIDE

The European Commission's Joint Research Centre (EU Commission JRC) published in 2021 two bibliographic reviews on the state of the art of NGT and their applications under development (2, 12, 13). Of the 645 research and development (R&D) projects identified, 66.5% concern plants and fungi, 15% animals and 18.5% the medical field. Nearly two-thirds are at the beginning of the

research and one-third is in a more advanced phase that leaves hope for a market launch in progress or imminent between 2025 and 2030.
Among these applications, two thirds concern agronomic characteristics (yields, cultivation conditions), food quality (human and animal nutrition) of cultivated plants, and one third their tolerance to biotic (pests, diseases) and abiotic stress (drought, heat) and also their industrial uses (15). The most studied species are rice (19), tomato, maize (7), wheat, soybean, and potatoes, as well as model species such as Arabidopsis and tobacco (10). According to Nogué *et al*. (11), of the 145 species mentioned in a set of publications on genome editing (2,415 since 2015), 69 are identified for gene mutations related to specific traits. The authors conclude that not only cultivated plants, but also wild relatives of crop plants would benefit from Genome Editing, notably in the context of the agroecological transition (AET) of agricultural production systems.

In the five continents, many research organizations, universities and private companies have mobilized to develop these varietal improvements. This occurs in the very major economic powers such as the United States or China, but also in Latin American countries (Argentina, Brazil, Uruguay, Chile, Costa Rica). In the Asia-Pacific (Japan, India, Australia) or Mediterranean (Israel, Egypt) zone as well as in Russia or the United Kingdom and Africa (South Africa, Uganda, Kenya, Ethiopia), projects abound. It was identified that 74 countries had published research on genome editing since 2015, led by China with 27% of publications, followed by the United States (21%) (12).
Two first varieties of plants already marketed, were in Japan the “Sicilian Rouge High GABA”, a tomato alicament enriched with GABA (an amino acid that reduces hypertension) by the company Sanatech Seed, start-up of the University of Tsukuba (photo 1), and in the United States a soybean with reduced content of trans fatty acids by Calyxt (now Cibus), a subsidiary of the French company Cellectis (15).

Here Insert photo 1

At the European level, the plants studied are species of field crops (cereals, maize, oilseeds, fodder), vegetable crops, ornamental crops, medicinal crops, but also species of diversification (legumes, hemp, dandelion, stevia, etc.). The projects concern yields and agronomic value (25%), resistance to biotic stress (diseases, pests) for 23% and abiotic stress (climate change) for 15%, the nutritional quality for 18% and the production of metabolites of pharmaceutical interest or alicaments (fibers, fatty acids) for 9% (15).
Several research and trials are underway involving NGT: five in Sweden, four in Belgium, two in Denmark and three in the United Kingdom (18). The European Union’s framework programs FP7 (2007-2014) and H2020 (2014-2020) have funded 78 projects to the level of 271 million euros. Euroseeds, which gathers the European seed companies, conducted a survey in 2020-2021 among 62 member companies representing 92% of European breeders. Its results already underlined the importance of NGT in the R&D sector. The French Seed Union (UFS) echoed this during a public hearing conducted in March 2021 by OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices in the French Parliament): all large companies with a turnover (CA) of more than 450 million euros (M€) use NGT in their R&D programs, medium-sized enterprises (turnover between 50 and 450 million) at 85% while small enterprises use it in 50% of research projects (17).
The number of patents filed involving CRISPR technology is also a good indicator of the vitality of planetary research. Europe, the world’s third largest economy (16.5% of global GDP in 2022 behind the United States 25.2% and China 17.8% (8)) owns 10% of the patents taken on CRISPR when the

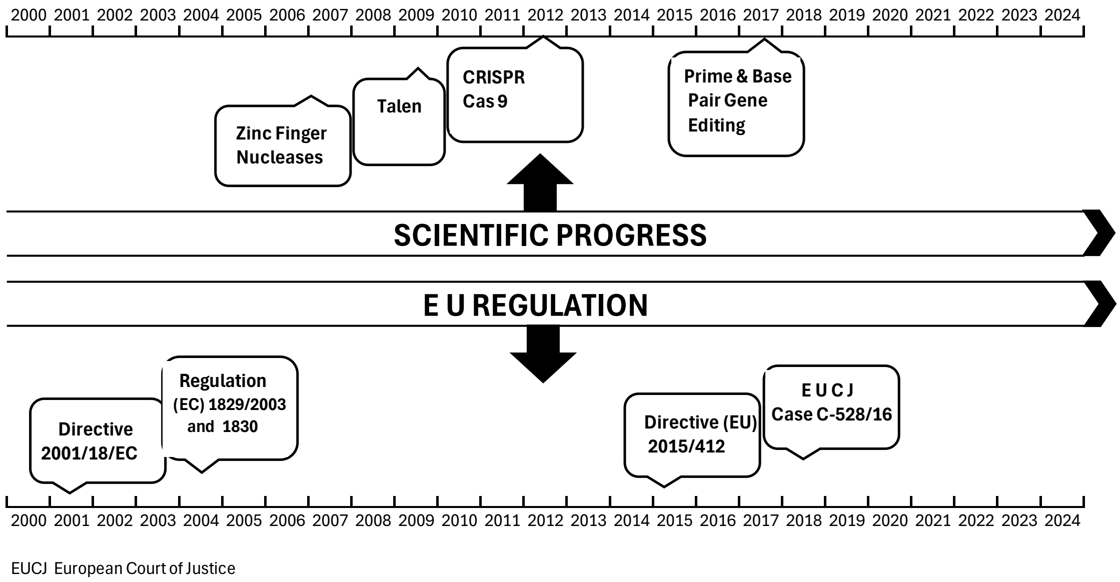
other two countries own 80%! Given that China leads in patents for agricultural applications (14), the European Union (EU) is clearly lagging behind in innovation in this area.

2. EU REGULATORY CONSTRAINTS ON NGT AND CURRENT DEVELOPMENTS

2.1 Regulatory constraints

The current EU regulatory context is a major handicap for European biotechnology innovation. It is largely the result of the regulatory policy applied to the marketing of agricultural products from plant biotechnology in the EU. Since 1989, the various European directives and regulations have been an impediment that has hindered the development of biotechnological innovations in this sector as the regulatory requirements are so onerous to fulfill. Yet today, one can assess that they are disproportionate because of the considerable progress of scientific knowledge over the past 20 years. Figure 1 illustrates the discrepancy between scientific progress in gene editing and the current EU regulation in effect. Up to 2018, the only "new" regulation (2015) to that of 2001 was expanding constraints and increasing barriers throughout these years up to the judgment of the EU Court of Justice (2018 July 25) stating that Organisms obtained by mutagenesis constitute GMOs within the meaning of the provision of Directive 2001/18/EC.

Figure 1 Discrepancy between Scientific Progress in Gene Editing and current EU GMO regulation



It should be of notice that only the large international consortia such as ChemChina-Syngenta, Corteva-Agriscience and Bayer-Cropscience or BASF were financially able to meet these requirements (14). Instead of considering the precautionary principle as a principle of responsibility, the European political authorities and the Member States have interpreted it as a zero-risk instrument. So, when the French Council of State, following an inquiry by several associations hostile to agricultural biotechnologies, sent four questions for a preliminary ruling to the Court of Justice of the European Union (CJEU), the latter rendered a judgment, on 25 July 2018, which considered that any product derived from New Genomic Techniques (NGT) should be regulated as GMOs derived from transgenesis.

While many countries on the American continent and in Asia have decided to soften their national regulations applied to NGT, this CJEU ruling places the European Union in a unique position vis-à-

vis its main trading partners, not only in terms of unbalanced trade by different rules but also by creating a disadvantage to production.
Several bodies, including the SAM (Scientific Advice Mechanism or Group of Chief Advisers to the European Commission), but also the French OPECST, or else the UEAA (The Union of European Academies for Sciences applied to Agriculture, Food and Nature), very early called for a review of the European regulations applied to NGT. Therefore, as early as November 2019, the European Council requested that the European Commission (EC) submits proposals to it in order to change the legislation on NGT.

2.2.<u>Current developments</u>

This is a very lengthy process that has started some five years ago, with several steps. The debates at each step were intense, accompanied not only by exchanges of arguments but also by delaying tactics to slow down the procedure such as a cyber-attack in October 2022 (16). However, the European Commission's proposals were published on 5 July 2023 and were the subject of a public consultation. Parliament's ENVI (environment) committee gave its green light on 24 January 2024 for a submission to a plenary assembly of Parliament. The meeting concluded on 7 February 2024 with a vote on the text entitled "*Plants obtained by certain new genomic techniques and their food and feed"*. This vote was confirmed on 24 April 2024 by the rejection of a final amendment from The Left MEPs to reject the Commission proposal.
The text was adopted by 307 votes in favor (various right and center right: (Identity and Democracy [ID], European People's Party [EPP], European Conservatives and Reformists [ECR], Renew Europe [RE]) and half of the Socialists and Democrats [S&D]), 263 against (mostly left-wing, environmentalists, and the other half of the S&D) and 41 abstentions (3). There are geographical and even geopolitical disparities within the EU: MEPs from the southern EU countries supported the text, while those from the northern EU and some MEPs from the eastern EU countries voted against it.
Many amendments were considered in this plenary, and the adoption of some of them changed the scope of the already limited regulatory review proposed by the Commission.
However, the European legislative procedure must continue with a final planned step concerning trilogue arbitrations. The trilogue brings together representatives of the European Parliament, the Council of the European Union and the European Commission for a final informal inter-institutional negotiation.
The EU Council, composed of the ministers of the Member States, which 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 of the Member States on patents (20). It was therefore decided to postpone the final examination of the case after the European Parliament elections of June 2024.

<u>2.3 New regulatory provisions debated.</u>

• *The European Commission's initial draft* of 5 July 2023 distinguished two categories of plants.

- NGT-1 plants are 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). This dossier would contain very precise information on the permitted genetic rearrangements listed in Annex 1 of the text and which must be minor (for example a substitution and insertion of up to 20 nucleotides). The labelling would concern seeds but not the finished product. The Member States of the Union would not be allowed to prohibit the cultivation and experimental testing in fields or greenhouses of these plants which have received Community approval.

- 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 which must be proportionate to the modified trait. It includes a health and environmental safety risk assessment. The NGT-2 application is much heavier than the NGT-1 application. Must be indicated in particular: (i) the molecular traceability tools or, if this traceability is impossible to achieve, explain the reasons for it; (ii) a labelling that may include positive statements (for example tolerance to drought or disease, improvement of food quality, etc.); (iii) environmental monitoring plans if necessary. Decisions notified by the authorities are recorded in the database mentioned above. The NGT-2 plants are, in fact, subject to very restrictive regulations very close to Directive 2001-18. This requires heavy applications for the approval of GMOs, the evaluation of which involves the many experts from the Member States' commissions and the EFSA (European Food Safety Agency) and is very expensive for the industrial petitioners.

But in fact, it was the first category «NGT-1» that focused the amendments of the MEPs opposed to the regulatory softening.

• *The provisions voted by the European Parliament* have amended several of the Commission's proposals for NGT-1 (3).

✓ Labelling: up to the final product.

The Commission had proposed that NGT-1 plants be subject to traceability with an entry in a public register, but with a simplified labelling procedure to inform the farmer about the seeds he would plant. The final product from the harvest having the same characteristics as plants from a classic selection, would not. Members of the European Parliament (MEPs) voted that all NGT-1 plants, whatever they are, should be labelled up to the final product (amendment 243) "*So as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice"*. In other words, as a result, consumers will have the choice between completely identical products but labeled differently!

✓ Complexity of the administrative authorization - exclusion procedure of herbicide tolerant plants from NGT-1.

MEPs have also made the NGT-1 authorization procedure more complex by requiring that, in addition to confined environment testing, field tests be carried out on "*NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, should be evaluated with the highest level of scrutiny in respect of such plants' impact on nature and the environment"* (Amendment 8). It is further specified in the Annexes that genomic changes (traits) related to yield, including stability and input limitation, must be accompanied by traits relating to tolerance/resistance to biotic and abiotic aggressions or a more efficient use of natural resources such as water and nutrients (amendment 82). Similarly, *"NGT Plants featuring herbicide-tolerant NGT-1 traits"* (to facilitate weeding of plots and control toxic noxious weeds such as ambrosia and datura) *"should not fall within the scope of the category 1 NGT plants"* (Amendment 18).

✓ Prohibitions to take patents on innovations from NGT

While the Commission had not yet ruled on the subject, the patentability of NGT innovations was also rejected by MEPs for various reasons: in order to «preserve the freedom of exploitation as well as the exemption of breeders for varieties» (amendment 23), which is already practiced in the EU with the PVC (plant variety certificate) in the frame of the Community Plant Variety Rights (CPVR) system , but also on the more political ground that " *Allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers'* *access to seeds. In a context where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies. For this reason, patents on these products must be banned* (Amendment 167).

✓ Ban on the use of NGT in organic farming.

MEPs voted for all NGT plants to be excluded from organic production, NGT-2 plants definitively and NGT-1 plants until a compatibility review has been performed

. "*Currently, the compatibility of the use of new genomic techniques with the principles of organic production requires further consideration. The use of category 1 NGT plants should therefore be prohibited in organic production, until such further consideration takes place*" (Amendment 15). This decision runs counter to the position of Jessica Polfjärd, rapporteur of the proposal for a regulation, who considered that NGT should be allowed in organic farming so that "any operator can use these techniques without any discrimination… [and] … to ensure fair competition without imposing a technique to a particular operator" (8).

Still on organic farming, it is recalled in amendment 241 that given the policy of the Green Deal for Europe (Green Deal), this particular organic agriculture was "heralding resilient food supply and sovereignty" and therefore "this Regulation must not compromise the transition of European food systems to 25% organic agriculture by 2030."

3. EFFICACY OF THE CURRENT EU PROPOSALS AS A RESPONSE TO THE EUROPEAN AGRICULTURAL CHALLENGES IN QUESTION.

The stakes of European agriculture are established in several acts.

The major is the Common Agricultural Policy (CAP) which is part of the objectives of the Green Deal for Europe («a peace treaty with nature»). One of its first goals is to lead to a climate neutrality of Europe in 2050. For the period 2023-2027, the CAP has 10 social, environmental and economic objectives, consistent with the National Strategic Plans of the Member States.

The declination of certain objectives, by forced operation, leads to major changes of agricultural practices, without the consequences having been really assessed. The reductions imposed on the use of plant protection products, chemical fertilizers or the extension of organic farming will result in an estimated decline in production of around 16% and an increase in the price of plant products of 18% (4).

Without entering into global economic and trade considerations, it is interesting to identify the contributions of NGT which could support European agriculture?

There are four main topics here involved:

- the maintenance of the level of production considering changes in agronomic and regulatory framework of culture conditions during a concomitant period of climate change,
- the deal with the distortion of competition that already exists, and which will widen with production carried out under other culture conditions (climatic, agronomic, and regulatory) elsewhere in the world,
- the attainment and preservation of European food sovereignty,
- the contribution by the agricultural production to reduce the carbon footprint in Europe,

The climate change that we are facing has numerous consequences, the main one of which is meteorological instability with alternations of violent precipitations, long periods of drought, favoring the appearance and development of diseases and parasites, sometimes new and affecting both animals and plants.

Genetic improvement of crops constitutes an important part of the solutions, as it has already done in the past. However, the speed of change in the production context requires this improvement to be carried out in an accelerated manner. The knowledge accumulated on plant genomes over the past two decades, the description of the genotype-phenotype link and the associated traits, combined with

recent genome editing techniques is a promising path in view of the numerous results and achievements already obtained.
Editing genomes by precisely modifying the sequences of certain genes and alleles has made possible to obtain plants that are resistant to diseases (9, 19), more resilient to water stress (7) or with a composition more appropriate to certain food processes (5). The new varieties thus bred, cultivated in suitable agronomic conditions (direct sowing, soil conservation agriculture, availability of water reserves, etc.) will thus make it possible to stabilize and secure agricultural yields over the years, on the express condition that Europe allows and promotes the development of NGT.

Failing to adopt the necessary tools and in particular NGT's and their products, the distortion of competition will widen the gap with countries which have already adopted genetic advances. Among them are the USA, Canada, Argentina, Brazil and Australia, which have already developed transgenic crops and have approved new edited plant crops (see for example 21, 22).
Taking into account the agronomic conditions but also the more flexible regulatory context of these countries, competition will be tough with imported products, which are cheaper, and which will place the European agriculture in great fragility.
The consequence of the European inaction will be an increased dependence on imports of products which the EU refuses to cultivate (transgenic plants) or imposes strict and cumbersome regulations to follow (edited plants). The cultivation conditions imposed in Europe: reduction-ban on the use of phytosanitary products or chemical fertilizers increase this risk of dependence. Our food sovereignty will be lastingly impacted and the chances of regaining it are likely to disappear completely with serious social consequences (high food prices, resignation of farmers, desertification of the countryside, etc.).

Finally, agriculture contributes very significantly to carbon sequestration mainly through photosynthesis and the sequestration of organic carbon in the soil (crop residues). Cultivation practices have evolved for more sequestration and less soil erosion (plant cover year around, associated crops, direct sowing, etc.) as well as a reduction in fuel requirements (mechanical operations, from plowing to harvesting). Maintaining a good productivity yield contributes to the development of these virtuous practices and the reduction of the carbon impact.

Does the evolution of European regulations on NGT meet such challenges of European agriculture of tomorrow? Based on the precautionary principle repeated over and over again, the challenges of agriculture are only partially taken into account while the regulatory framework remains very restrictive:

a) The simplification of administrative procedures for marketing authorizations for NGT-1 products is minor: it concerns only limited transformations of the genome (less than 20 nucleotides) and nucleotide additions for NGT-1 are only possible in the breeder's gene pool (concerning only crossable species with no addition of genetic material from non-crossable species).
b) The final labelling of these plants NGT-1 until the display will be a factor of confusion for the consumer: why label differently two identical products obtained after laboratory selections on the pretext that different techniques were used when the final characteristics of the result are identical?
c) Exclusions (herbicide tolerant plants, organic farming) are pronounced without scientific basis but on the basis of ideological considerations. Similarly, the ban on patenting NGT innovations will strengthen the development of research outside the EU and Europe's dependence…
d) On the other hand, for the first time one may note a timid opening towards applications of NGT on microorganisms, fungi and animals: "Available knowledge on other organisms, such as microorganisms, fungi and animals, should be reviewed with a view

to future legislative initiatives on them" (Amendment 5). But no deadline is envisaged: is it wishful thinking?

CONCLUSION

Since the development of CRISPR-based genome editing technology in 2012, many countries have not only mitigated the regulations for NGT, but in many cases have exempted from regulation NGT products obtained without the addition of foreign DNA to the species.

For example, the United States of America implemented a regulation called SECURE in 2020, revised in 2023 whose decisions are relying on scientific criteria.

The European Union appears to miss a historic opportunity to overhaul its agricultural biotechnology regulations. It may have made sense in the 1990s, but by 2024 it can be considered obsolete in light of the advances in scientific knowledge over the past twenty years. Moreover, more than 5 years ago in autumn 2018, the SAM (Scientific Advice Mechanism) to the European Commission, had clearly indicated that Directive 2001/18 was inadequate and that it was necessary that the characteristics of the final product be assessed instead of legislating on the basis of the method of production.

The European Commission has again preferred to rely on the precautionary principle as a pillar to its approach and hence fall within the framework of Directive 2001/18 by amending Regulation (EU) 2017/625. It is now well established that there are no adverse health and environmental incidents ever reported caused by biotechnology commercialized products since the development of the first gene modified by genetic engineering fifty years ago. It is high time to move beyond unfounded anxiety-provoking rhetoric. The European Union must look with confidence to an agricultural future based on biotechnological innovation.

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Photo 1. The« Sicilian Rouge High GABA » is a CRISPR/Cas tomato engineered by Tsukuba University and its start-up Sanatech-seed and the first genomic edited product commercialized in Japan in 2021.

SICILIAN ROUGE HIGH GABA

GABA高蓄積トマトの栽培モニター募集（FAQ追加）

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