



# **New Genomic Techniques (NGT): issues and agri-food sovereignty**

# Table des matières

<b>About the Author</b>	<b>3</b>
<b>About Institut Sapiens</b>	<b>4</b>
<b>Introduction</b>	<b>5</b>
NGT regulations: a geostrategic factor	<b>6</b>
European public debate for a revision of the regulations applied to NGT	<b>7</b>
A process by the European Commission in progress	<b>9</b>
A strategic initiative focused on plants	<b>10</b>
A strategic initiative under high tension	<b>11</b>
European locks. And yet...	<b>14</b>
NGTs, tools of agro-food sovereignty	<b>16</b>

# About the Author

## Catherine Regnault-Roger



Catherine Regnault-Roger is a professor emeritus at the University of Pau and Pays de l'Adour (E2S UPPA). Part of the High Counsel of Biotechnology (Haut Conseil des biotechnologies) Scientific Committee throughout her mandate from 2009 to its dissolution in December 2021, as an expert in ecotoxicology and regulatory issues on the post-marketing surveillance of transgenic crops, she is also a full member of the French Academy of Agriculture (plant production section) and the National Academy of Pharmacy (environmental health section).

Author of several reference books (French, Spanish and English) and numerous scientific publications on the bioprotection of agrosystems and of the environment through a chemical ecology approach and the sanitary quality of crops, but also on transdisciplinary research in the biotechnology and biocontrol fields, she has received several distinctions: medal of excellence from the French Association for Plant Protection (2015), Knight of the Legion of Honor and Officer of Agricultural Merit.



# About Institut Sapiens

The Institut Sapiens is an independent, non-partisan *think tank* that explores new conditions for shared prosperity in the digital age. Humanism is its fundamental value. Its objective is to enlighten the French and European economic and social debate by spreading its ideas.

It federates an extensive network of experts from all fields, academics, lawyers, business leaders, entrepreneurs, and senior civil servants, around members interested in the current primary debates. Sapiens is committed to relaying the most cutting-edge academic research.

Sapiens' work is structured around **seven thematic observatories**: sustainable development; AI and ethics; science and society; health and innovation; work, training, and skills; policies, territory, and social cohesion; and economic and social innovation.

Its vocation is threefold:

**Decipher** — Sapiens helps people step back from current events to understand the significant issues they raise. The Institute is a leading think tank on major contemporary economic topics.

**Decomartmentalize and promote dialogue** — Sapiens brings together professional worlds that are too often separated: academics, members of the public sphere, business practitioners, and ordinary citizens. The Institute is a crossroads where they can meet to reflect and dialogue.

**Training** — The 21st century is the century of information; it must become the century of knowledge for the individual. The immense power of technology calls for a new effort to step back and analyze. Sapiens aims to be a place of personal growth for those who want to participate through its publications, events, and meetings.

To learn more, visit our website : [institutsapiens.fr](https://institutsapiens.fr)



# Introduction

The evolution of techniques for modifying the genome by genetic engineering was accompanied by a technological breakthrough with the invention of the CRISPR technique published in the journal *Science* in 2012 by the “European”<sup>1</sup> Emmanuelle Charpentier and the American Jennifer Doudna, who received the 2020 Nobel Prize in Chemistry for this scientific breakthrough.

Today, alongside the 20<sup>th</sup> century’s first-generation biotechnologies, whose products derived from transgenesis are defined as genetically modified organisms (GMOs) and are subject to each country’s specific regulations, we now distinguish the current second-generation biotechnologies, NGT (*New Genomic Techniques*), which are developing several techniques including those for genome editing with targeted mutagenesis such as CRISPR.

The geopolitical situation in recent months, the Covid-19 pandemic, but also the war in Ukraine, have demonstrated how important it is for a country to be able to care for and feed its population in complete autonomy. Among the levers available, NGTs provide innovative solutions to better human and animal health as well as agriculture. It is also necessary that the regulations applied to them do not slow down their development.

Where do we stand in Europe?

We will examine the situation through two prisms:

1. That of existing regulations and current developments;
2. The existing barriers in the European Union (EU) to the development of innovative biotechnological solutions which are nevertheless being deployed elsewhere in the world.

---

<sup>1</sup> Thesis in France but has had her career in various European countries; today she directs the prestigious Max Planck Research Center for Pathogen Science (*Max-Planck- Forschungsstelle for the Wissenschaft der Pathogene*)

# NGT regulations: a geostrategic factor

On April 29, 2021, the European Commission (EC) opened a debate on the regulatory status of new genomic techniques (NGT<sup>2</sup>) in the Union by publishing a position document<sup>3</sup>.

This opening is in response to the European Court of Justice (CJEU) judgment of July 25, 2018, which indicates that all products resulting from new genome modification techniques after 2001 must be considered and regulated as GMOs. However, this legal decision is part of an administrative and not a scientific logic. It places the EU at odds with a world where a large number of countries on the American, Asian and Pacific continents have opened up, to varying degrees, to new genomic techniques (NGT) by adopting regulations adapted to their specificities. In this context, can the European Union position itself on the margins of the world market?

Today, there is a divide in the agricultural world between the 28 probiotech countries which grow and import/export GMO crops and the 42 countries, including France, which import GMO crops but refuse to grow them: on the one hand, American and Asian continents, the Pacific-Oceania zone, on the other, the Middle East, Russia, a majority of African countries and European countries (with the exception of Spain and Portugal which grow transgenic corn). This cleavage on GMOs can be found in the reception given to products originating from NGT.

This acceptability of new biotechnologies is measured by the regulations applied to them in each country. Today, the probiotech countries have decided to exempt more than 95% of the products obtained by NGT from the regulations applied to GMOs because of their final properties, while many other countries are conducting discussions to determine the level of exemption to grant them according to the modification of the genome carried out.

---

<sup>2</sup> Previously, NGTs were called NBT, *New Breeding Techniques, when applied to plants*.

<sup>3</sup> European Commission (2021) *EC study on new genomics techniques* Brussels, 29.4.2021 SWD(2021) 92 final, [https://ec.europa.eu/food/plant/gmo/modern\\_biotech/new-genomic-techniques\\_en](https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en)

European regulations on GMOs, which have been in force for more than 20 years, have become obsolete due to scientific advances made in the field in the last two decades. It is in fact based on Directive 2001/18, which imposes the constitution of heavy files whose justification, after more than 25 years of scientific research, is called into question. The costs of European marketing authorization files and post-marketing monitoring of approved GMOs have favored the large international consortia (Corteva, ChemChina-Syngenta, Bayer or BASF) which alone can assume them. This regulation has hindered the development of agricultural GMOs in the Union.

## European public debate for a revision of the regulations applied to NGT

As soon as the judgment of the CJEU of 25 July 2018 was published, several European institutions and bodies in the scientific and academic sphere, but also in civil society, were concerned about the obstacle to technological progress and development in the EU, and as a corollary, to the circulation of goods in a globalized market.

Among the voices that have been raised to request this revision, that of SAM (*Scientific Advice Mechanism*), the Principal Scientific Advisers to the European Commission group's name, intervened very quickly. He published as early as November 2018 a statement entitled "*A scientific perspective on the regulatory status of products derived from gene editing and its implications for the GMO directive*" in which he points out that "*due to new scientific knowledge and recent technical progress, the GMO directive is now unsuitable*".

This text specifies the difficulties of operating the traceability of genome editing products since the same minor genetic modification can be the result either of a natural phenomenon (spontaneous mutation) or of classic genetic selection techniques or genome editing. It is difficult, under these conditions, to distinguish in the batches marketed, the products derived from NGT (regulated as GMO in the EU) and those obtained by non-regulated methods or produced naturally. Consequently, the SAM requires that the final product's characteristics be evaluated and not the production method. It emphasizes the need to take into account current knowledge to create a regulatory environment conducive to innovation so that "*society can benefit from new science and technology*".

The European Union of Agricultural Academies (UEAA), supported by several member state academies, in turn calls for “ a regulatory framework with the aim of facilitating the use of genome editing safely in R&D European ”. She argues about the “ critical need for the development of research programs which are also carried out everywhere in other parts of the world ”. It calls for the development of research concerning plant and animal genome editing products<sup>4</sup> .

A *European Citizens' Initiative* of European students of eight different nationalities from Wageningen University (Netherlands) was initiated in the summer of 2019 and concluded in July 2021. Entitled *Grow scientific progress: crops matter!*<sup>5</sup> , it called for a change in current legislation to assess “ the end product rather than the technique, so that safety is guaranteed without the valuable benefits of new techniques being lost through absurd regulatory hurdles ”.

French and German political actors also spoke:

- A platform of elected politicians from the *Grünen* Green party, - among them MEP Viola von Cramon-Taubadel, Katharina Fegebank, member of the Scholtz II Senate who leads the city of Hamburg, Anna Christmann and Kai Gehring, Members of the Bundestag -, was published in June 2020 under the title “ *Neue Zeiten, neue Antworten: Gentechnikrecht zeitgemäß regulieren (new times, new answers: regulating genetic engineering law in a modern way)* ”<sup>6</sup> . It insists on the need for new rules so that NGT can be used by public institutions and medium-sized companies to innovate and meet future challenges;
- In France, the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST), which brings together deputies and senators in a common and collegial reflection, is not to be outdone. Extending the report entitled “ *The economic, environmental, health and ethical issues of biotechnology in the light of new avenues of research* ”<sup>7</sup> that it published in 2017 with Jean-Yves Le Déaut, then president of the OPECST and a Socialist Party deputy, the Senator Catherine Procaccia (LR) has joined forces with LFI MP

---

4 <https://ueaa.info/2022/01/03/the-ueaa-recommendations-for-an-eu-regulation-frame-concerning-genome-editing-research-and-development-for-crop-plants-and-farm-animals/>

5 European citizens' initiative: sign the petition for Green Biotech, C.Regnault- Roger, European scientist 17.02.2020, <https://www.europeanscientist.com/fr/agriculture-fr/initiative-citoyenne-europeenne-signez-la-petition-pour-les-biotech-vertes/>

6 An initiative of the German Green Party in favor of new green biotechnologies, C.Regnault -Roger, EUropean Scientist 15.06.2020, <https://www.europeanscientist.com/fr/opinion/une-initiative-de-verts-allemands-en-faveur-des-nouvelles-biotechnologies-vertes/>

7 Report n° 4818 of the National Assembly (AN) and n° 505 of the Senate, of April 13, 2017,

Loïc Prudhomme to produce a new OPECST report on “ *New plant breeding techniques in 2021: advantages, limits, acceptability* ”<sup>8</sup>. This report follows a public hearing held on March 18, 2021 under the direction of the two parliamentarians. It insists on the need to revise Directive 2001/18/EC and recommends that risk assessments of new products be based on their final characteristics and not on the technique used to obtain them. It suggests that regulations regular revisions take place in order to take into account scientific and technological advances as well as societal debate;

- It is also the French Minister of Agriculture (2020-2022), Julien Denormandie, who insists, as the 2021 Annual Meetings of the French Seeds Union (UFS), on the strategic interest of implementing the varietal improvements by NGT to “ *reclaim our food sovereignty* ”<sup>9</sup> ;

Following these various positions, European officials spoke at the Forum organized by the European Commission on November 29, 2021 about “ *New genomic techniques - the way forward for safe and sustainable innovation in the agri-food sector* ”<sup>10</sup>. The European Commission Vice-President, Frans Timmermans explained that “ *gene editing is part the agro-food sector’s sustainable development strategy* ”, and the European Commissioner for Health and Food Safety, Stella Kyriakides, stressed for his part that the NGT could make it possible “ *to better our objectives’ achievement within the European Green Deal framework and the strategy ‘from farm to fork’* ”<sup>11</sup> .

## A process by the European Commission in progress

Very quickly, in November 2019, the Council of the EU invited the European Commission to open a procedure to change the status of NGTs in EU law. This comprises several stages, organized around a scientific study, an impact analysis, then the implementation of a strategic initiative intended to propose a new European regulation.

The first phase was carried out between 2019 and 2021. The European Commission (EC) commissioned the Joint Research Center (or JRC *Joint Research Center* which is the scientific and technical research

---

8 Report n°4220 AN and n° 671 Senate of June 3, 2021

9 The UFS meetings of May 6, 2021. <https://www.youtube.com/watch?v=O-36rFNLMy8>

10 [https://ec.europa.eu/info/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-nov-29\\_fr](https://ec.europa.eu/info/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-nov-29_fr)

11 For Frans Timmermans, gene editing is part of the sustainable development strategy of the agri-food sector, Natasha Foote, Euractiv 8 Dec. 2021

laboratory of the European Union) to draw up a state of the art on NGT and the progress of R&D projects. Two reports were thus made public in the spring of 2021<sup>12</sup>, following which the EC published an open letter on April 29, 2021 addressed to Portugal (country that presided over the EU that semester) asking it to make proposals for regulatory framework changes and to organize a debate on the subject in order to start the strategic initiative phase.

## A strategic initiative focused on plants

The initiative entitled “ *Legislation applicable to plants produced using certain new genomic techniques* ” was therefore launched in autumn of 2021. Its aim is to lead a reflection on the European legal framework which could be applied to plants obtained by targeted mutagenesis and by cisgenesis, as well as to the products derived therefrom and intended for human and animal consumption. The genome modified by these techniques can also be obtained by natural mutations or conventional selection techniques.

Organisms which do not belong to the plant kingdom, ie micro-organisms and animals, are therefore not concerned. Nor are genetic modification techniques concerned, which are neither cisgenesis (which uses genetic engineering to transfer genes belonging to the same species) nor targeted mutations. The European Commission has therefore restricted the scope of the upcoming revision of the regulations. For this, it bases itself on the conclusions of the European Food Safety Authority (EFSA), which indicate that plants obtained by targeted mutagenesis and by cisgenesis have a risk profile comparable to that of plants coming from conventional selection. On the other hand, it considers that the work of the EFSA on the harmlessness of these techniques applied to animals and micro-organisms is not, to date, sufficiently substantiated.

This decision to exclude the animal kingdom from the scope of the review is contested by the French Veterinary Academy. In an open letter to the President of the European Commission dated February 28, 2021<sup>13</sup>, the academy stresses that research on gene editing

---

12 - First report: Broothaerts W, Jacchia S, Angers A, Petrillo M, Querci M, Savini C, Van den Eede G, Emons H (2021) New Genomic Techniques: State-of-the-Art Review EUR 30430 EN, Publications Office of the European Union, Luxembourg ISBN 978-92-76-24696-1 doi:10.2760/710056 JRC121847; - Second report: Parisi C, Rodríguez- Cerezo E (2021) Current and future market applications of new genomic techniques EUR 30589 EN, Publications Office of the European Union, Luxembourg ISBN 978-92-76-30206-3 doi:10.2760/02472 JRC123830

13 <https://academie-veterinaire-defrance.org/publications/avis-rapports-prises-de-position/genome-des-animaux-domestiques-modifications-ciblees>

of production animals contributes " to improving animal health or even public health in the case of zoonoses " and " offers new means to eventually control the prophylaxis of these major panzootic diseases ". As proof of this, it points to the success of the work of American and Chinese teams who have produced pigs insensitive to classical swine fever and to the PRRS virus (porcine reproductive and respiratory syndrome), a disease whose cost of economic losses in the pig farming is estimated at 2.5 billion per year. And it insists on the fact that genome editing techniques induce modifications to the genome " most often indistinguishable from natural genetic variants " and that the experiments carried out on mammals, domestic production animals, are carried out in a confined environment, therefore controlled by man. This position is fully shared by the European Union of Academies of Agriculture (UEAA) which has sent recommendations to the European Commission expressing <sup>14</sup> concern that in these times of zoonoses (monkey pox, Covid-19), the work of European genome editing research on animals are hampered by regulatory uncertainties related to the exclusion of animal NGT from the current review process.

## A strategic initiative under high tension

The controversy over GMOs in Europe and the poor opinion of a significant part of the European public owe much to campaigns by militant NGOs, well known for their political views in favor of economic negative growth under the guise of protecting the environment, and their struggles against technological progress in general and biotechnologies in particular. After GMOs and " *hidden GMOs* " <sup>15</sup>, the activists of this political movement are now attacking the strategic initiative to revise the regulations in order to invalidate the current procedure.

The first maneuver was observed during the start of the process stage, that of the impact analysis during which the public is consulted for a month (from September 24, 2021 to October 22, 2021); 70,879 responses were received. A large majority came from citizens of the Union (more than 96% or 68,183 contributions), university research institutes (113 contributions), professional bodies and

---

<sup>14</sup> The UEAA Recommendations for an EU regulation frame concerning Genome Editing Research and Development for Crop Plants and Farm Animals <https://ueaa.info/2022/01/03/the-ueaa-recommendations-for-an-eu-regulation-frame-concerning-genome-editing-research-and-development-for-crop-plants-and-farm-animals/> (3.01.22)

<sup>15</sup> Biotechnological challenges, from GMOs to genome editing, Catherine Regnault-Roger, 2022, Presses des Mines, collection Académie d'agriculture de France, pp 205

associations (190 contributions), environmental and consumer NGOs and associations, trade unions (93). Among the nationalities, the Germans came first (46%) ahead of the French (36%) or 92% of the responses, far ahead of Belgium, the Netherlands and Austria (3%) and Italy (2 %), the other countries contributing less than 1% each.

However, the abnormally high number of responses received (more than 70,000 instead of the usual 2,000 to 3,000) alerted the European Commission, which launched an investigation to find out the reasons. A cyber attack supported by MEPs from the Green EFA (European Free Alliance) political group who are leading the campaign “ *Let’s keep GMOs out of our fields and our plates* ”<sup>16</sup> has been highlighted to obstruct the revision of the regulations. With the help of an Estonia-based communications agency reportedly financed from funds allocated by the European Parliament to political parties, the European consultation was inundated with more than 69,000 spam messages: an action that the German Federal Minister of agriculture, Julia Klöckner, qualified in her time (November 2021) as sabotage of a legislative process<sup>17</sup>. The format of the spams having been spotted, they were deleted with the following message posted on the website: “ *This review has been removed as it did not comply with the European Commission’s rules for reviews and suggestions.* ”

After the positive conclusions of the impact analysis stage, the actual consultation was held from April 29 to July 22, 2022. It questioned the public on various points: the interest of carrying out a risk assessment for products resulting from targeted mutagenesis or cisgenesis when the products obtained cannot be distinguished from a product harvested in nature or obtained by conventional selection techniques, taking into account the durability of these products, the information to be communicated to operators and consumers in full transparency and the technological access that this new regulation would give to European SMEs.

It should be noted that an association of opponents of GMOs and the ongoing regulatory review, the European Coordination Via Campesina (ECVC), a network of professional organizations of “ *small and medium-sized farmers* ”<sup>18</sup>, boycotted the consultation, explaining in an open letter dated June 9, 2022, thus respecting the democratic

---

16 Martin Häusling (DE), Benoit Biteau (FR), Eleonora Evi (IT), Tilly Metz (LU), Michèle Rivasi (FR), Thomas Waitz (AT), Sarah Wiener (AT) <https://act.greens-efa.eu/fr/gardons-les-ogm-hors-de-nos-as-siettes>

17 “A scandalous procedure” about the European Commission consultation Spamming on “GMOs” and “NGT” Schillipaepa <https://seppi.over-blog.com/2021/11/un-procede-scandaleux.html> and CheckNews. Has the Green party at the European Parliament organized a “spamming” campaign against a consultation on GMOs? <https://www.liberation.fr/checknews/le-groupe-des-verts-au-parlement-europeen-a-t-il-organise-une-campagne-de-spams-contre-une-consultation-sur-les-ogm>

18 European Coordination Via Campesina Open letter: ECVC refuses to respond to the European Commission’s biased consultation on new genomic techniques, <https://www.eurovia.org/>

framework. They dispute the terms of the consultation and refuse “ *the possibility of abandoning the current GMO regulations* ”. The EELV-ALE MEPs, those who had supported the cyberattack against the impact study stage, for their part, sent a letter to the European Commission on February 8, 2022 to request, this time, funding to “*develop methods for assessing and detecting the risks*”<sup>19</sup> of the products resulting from the targeted mutations. An opinion from the French High Counsel for Biotechnologies dated June 29, 2020 has already responded to this concern by indicating “ *that it does not identify biochemical differences between mutations, whether they are obtained by random mutagenesis in vitro, in vivo, or spontaneously, on isolated cells or multicellular entities. There are also no differences between the phenotypes induced by these techniques* ”<sup>20</sup>. The request of these MEPs is therefore scientifically unfounded.

The conclusions of the public consultation were published on September 16, 2022<sup>21</sup> . A total of 2,300 opinions were validated, three quarters of which were expressed by EU citizens: the Germans (27.3%) followed by the Italians (23.5%) then the French and the Spaniards (15.3 and 8.8%) represent 71% of the responses. More than 79%, almost four fifths, of participants (research and academic institutions, players in the agricultural, seed, biotechnology and bioindustry sectors as well as those in marketing and distribution) approve of the revision of European regulations, while 17% want the status quo (mainly NGOs and environmental and consumer associations). These contrasting positions are reflected in the various issues addressed. Thus, the essential point of the risk assessment involves the following opinions: the majority (61%) would like the assessment of the risks associated with plants resulting from targeted mutagenesis and cisgenesis to be adapted to the characteristics of the genetically edited plant by the techniques indicated, while 22% ask for the maintenance of the current regulations and, on the *contrary*, 13% are in favor of the abolition of this evaluation, considering it, taking into account the genetic modifications made by the techniques considered, as useless. In the end, this consultation is largely in favor of the evolution of European regulations for site-directed mutagenesis and cisgenesis NGTs applied to plants.

On the very day of the publication of the results of the public consultation, the Ministers of Agriculture and Fisheries of the 27 EU countries, gathered from September 14 to 16 in Prague by the

---

19 MEPs call for EU funding for research on publishing oversight, Natasha Foote | Eurativ.com 31.03 2022

20 Haut Conseil des Biotechnologies (2021) Synthesis on the detection of products resulting from new genomic technologies (NGT) applied to plants, Scientific Committee Report (26 November 2021), <http://www.hautconseildesbiotechnologies.fr/fr/article/publications-hcb>

21 [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/F\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/F_en)

Czech Presidency within the framework of an “ informal meeting ”, expressed their support for the current European initiative. This is therefore continuing and will therefore conclude in the spring of 2023.

We hope that the new European regulations that will be proposed will facilitate the use of NGTs in the plant sector where they can bring essential innovations for the competitiveness and sovereignty of European agriculture, but also soon in the animal sector where they are just as promising (animal welfare, fight against epizootics, improvement of farm production performance).

## European locks. And yet...

My latest book “ Enjeux biotechnologiques ” (Biotechnology issues) published in the spring of 2022 emphasizes that “ *agricultural biotechnologies in France and Europe are in decline. It is a descent into Hell that has lasted for several* <sup>22</sup> *decades.* ” To illustrate this statement, it was not difficult for me to enumerate a long list of turpitudes ranging from orchestrated media campaigns and political agreements, to particularly effective activism by NGOs despising biotechnologies. Their lobbying after European authorities aims to promote the objective of a economic negative growth future to save a sacred nature to which man should submit. Added to this is organized vandalism by activists of experimental field trials of new varieties, the ransacking of seed storage facilities and invasions of public and private research laboratories to intimidate researchers. On a less violent mode, the marketing messages of certain retail chains that surf on “ GMO-free ” claims as if GMOs were toxic, or even the procrastination of magistrates with limited scientific knowledge, and often themselves lost in the contradictory information of the scientific controversy, has reinforced the feeling of insecurity vis-a-vis GMOs. It is not surprising that public opinion in France and in Europe expresses, under these conditions, its distrust of biotechnologies.

The consequences are that today there are no longer any experimental GMO trials in the field in France, whereas twenty years ago there were nearly 800. Faced with the judicial impunity enjoyed by the militant raids of destruction in the field or intimidation in laboratories and companies, and the poor prospects for return on investment due to administrative obstacles linked to regulations as well as the gloomy societal context, several international companies

---

22 Biotechnological challenges from GMOs to genome editing, Catherine Regnault-Roger, *op.cit* p 49

have relocated their research activities outside the European Union, on the American continent and also, since Brexit, in Great Britain which opens its arms wide to them.

In these countries, biotech varieties have therefore been developed to meet the requirements, not only of growing conditions, but also of the expectations of consumers and international trade: for example, Brazilian transgenic soybeans are 80% exported to China. NGTs, which are indeed more precise, faster and less expensive genetic modification tools than transgenesis, constitute an effective and more diligent response to the immediate concerns of countries.

The needs of European countries for new varieties to better resist the pests and diseases that plague them are not a priority for biotech companies that use transgenesis and NGT, because the products obtained by these techniques are regulated by GMOs. In Europe, the development of new varieties adapted to changes in biotic stress (harmful insects, pathogenic fungi) and abiotic stress (drought) is carried out by conventional breeding techniques so that they escape the qualifier of GMO and that they can be cultivated in Member States which refuse the cultivation of transgenic plants. Obtaining a new variety is longer and more laborious and does not allow rapid solutions to the vagaries of environmental changes (bad weather and drought linked to global warming, invasive insect species, fungal or viral epidemics).

Thus the French sugar beet sector was faced with a major crisis of declining yields with 280 million euros in losses in 2020 due to an invasion of aphids carrying the jaundice virus. These, in the absence of phytopharmaceutical control solutions, have proliferated: neonicotinoid insecticides had been banned in France since September 2018. A temporary derogation from their use had to be granted for the 2021 campaign in order to deal with this scourge. But just as well, a response can be provided by selecting genetically edited varieties made resistant to pests and drought and adapted to the local conditions of Hauts de France, with the added bonus of other environmental advantages. Thomas Nuytten, beet director at Saint Louis Sucre (sugar), points out: "*Targeted mutagenesis and cisgenesis have proven to be tools that open up the possibility of making plant breeding more precise and efficient so that breeders can create more resistant to pests and diseases, less susceptible to abiotic stress (such as drought), more productive and more beneficial to the environment*". He adds: "*To date, there is no good alternative insecticide available in the coating... The use of NBTs, on the other hand, could reduce the use of pesticides, and not just neonicotinoids*"<sup>23</sup>.

---

23 Thomas Nuytten (2021) answer F2744930 dated October 22, 2021 to the European initiative "Legislation applicable to plants produced using certain new genomic techniques"

More than 400 R&D projects concerning plants are currently carried out around the world using NGT techniques. Almost all cultivated plants are the subject of varietal improvement research by NGT. Food crops are concerned (tomato, wheat, corn, soy, potato) but especially rice (which is not surprising when we know that the Asian continent alone has piloted more than 50% of these research publications), but also ornamental plants, fruit trees, or sugar plants (beet and cane) and oil plants, tubers, fodder plants, etc. The purpose of these genomic modifications primarily concerns agronomic traits (technical itineraries, growth, yield), food quality (human and animal nutrition), tolerance to biotic (insect pests, diseases, viruses, etc.) and abiotic stresses. (drought, nitrogen deficiency, UV radiation, etc.), tolerance to herbicides (weeding) and industrial recovery<sup>24</sup>. Thus, research teams compete around the world to develop wheat tolerant to drought (Egypt, China) or to excess water (Japan) or to rust disease (Australia). As we can see, R&D projects are numerous, and many countries have adapted their regulations in order to benefit from technological advances for the development of sustainable agriculture.

The large seed companies of the European Union, very international and very exporting, have also joined forces. According to the French Union of Seed Companies (UFS), all large companies (that are international) with a turnover of more than €450 million use NGT for their varietal improvement programs. This percentage drops to 85% in medium-sized companies (turnover between €50 and 450 million) and to 50% in small companies (turnover less than €50 million)<sup>25</sup>. A change in EU regulations would be likely to encourage European SMEs to use these new, more efficient tools that are new biotechnologies, a remark that politicians from the *Grünen party* had issued in their opinion piece published in 2020.

## NGTs, tools of agro-food sovereignty

A relaxation of European regulations on plant NGTs would be a strong signal that the European Union once again trusts the scientific and technological approach to widen the range of available technologies in order to propose varietal improvements adapted to environmental conditions and ecosystems of member states. This development could only give confidence to biotechnology companies, which should no longer neglect the European market.

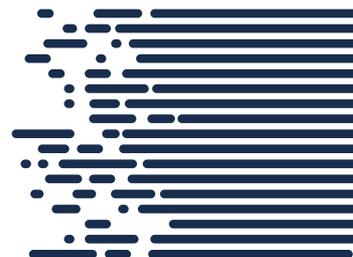
---

<sup>24</sup> Biotechnological challenges, *op.cit.* p.172

<sup>25</sup> UFS (2021) New plant breeding techniques in 2021: advantages, limits, acceptability, Written contribution OPECST public hearing - March 18, 2021, <https://www.vie-publique.fr/rapport/281292-rapport-sur-les-nouvelles-techniques-de-selection-vegetale-en-2021>

New biotechnologies (NGT) have experienced rapid growth since 2012 and today 80% of worldwide patents filed on applications of the CRISPR technique are American or Chinese (and less than 10% European), with a hegemony of China for plant biotechnology applications<sup>26</sup> : for 2020 alone, China filed 10,624 patents compared to 8,800 for the United States, 1,027 for France and 2,048 for Germany, according to the World Intellectual Property Organization (WIPO). Gone are the days when the journal *Biofutur*, which defines itself as “ *the European monthly review for Biotechnology* ”, could headline “ *When European authorities lead the way* ” pointing out that in 1972 the R&D expenditures of European and American companies were competing and that the number of European patents (203) exceeded that of the United States (178)<sup>27</sup> .

The European Union cannot and must not ignore the issues of agro-food sovereignty linked to the rise of NGT in this globalized world. Let's hope that the new position of the European Commission on the revision of the regulations to be applied to NGT in the plant sector will allow the Union to face the challenges of the future with appropriate biotechnological tools, and that the current reflection will soon broaden to farm animals.



---

26 Biotechnological challenges, *op.cit*, p 151

27 Hoeveler A, Magnien E (1997) When European authorities lead the way, *Biofutur* 172: 12-15