

Briefing 47 A New European Regulation on Plants Derived From New Genomic Techniques (NGT)

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Summary

- “NGT plants” are plants obtained using new genomic techniques (NGTs). The most well-known of these involves targeted genome editing using Crispr-Cas9. Since 2018, NGTs have fallen under Directive 2001/18/EC on genetically modified organisms (GMOs) and are prohibited in France, as are the latter.
- The proposed European regulation creates exemptions for varieties obtained after a limited number of modifications, based on the premise that these plants could have occurred naturally and are equivalent to conventional varieties. Several parts of the text are still contentious, including questions of labelling and patentability.
- Scientific opinion is divided over NGTs: while these techniques could offer useful solutions in the context of climate change and pressure from diseases, objections have been raised over the very principle of direct genome editing and the risk of seeing agribusiness evolve into an oligopoly that would ultimately reduce crop diversity.

Pierre Henriët, Member of the National Assembly

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In the summer of 2023, the European Commission proposed a European regulation on plant varieties obtained by new genomic techniques. The text will soon enter the trilogue phase. Plants obtained using new genomic techniques, the foremost of which involves targeted genome editing using Crispr-Cas9, have been subject to GMO regulation (2001/18) since a ruling by the Court of Justice of the European Union in 2018.¹ However, this regulation could allow them to enter the European market through a simplified procedure that is only a little different to the one that applies to so-called conventional varieties.

NGT varieties inspire both enthusiasm and rejection: enthusiasm from part of the scientific community, industrial stakeholders and some farmers, who see them as a tool for the agroecological transition and improved disease resistance, but rejection from the long-standing opponents of GMOs, including some scientists, who are concerned for the environment and want consumers to be duly informed.

The divide harks back to the GMO debate, and the arguments of both sides often draw on it. The absence of feedback data on the cultivation and commercialisation of NGT varieties leaves no choice but to refer to scenarios. The concentration of the OGM agribusiness sector and its focus on just a few traits² call for caution. The regulation

will be decisive in shaping the future of the European market.

While GMOs are now familiar to consumers, this is less true of NGTs. Hence why we have not (yet) seen large-scale opposition to them. Since the regulation would be directly applicable and therefore would not be examined by the French parliament,³ OPECST wishes to fulfil its duty to inform members of Parliament by presenting the scientific and regulatory context of NGTs, the different points of the text that are sources of contention and the speculations they rouse.

■ The use of targeted genome modification in crops: context and legal framework

➤ The role of NGTs in plant breeding

- *Plant breeding, pressure by humans on the plant genome*

Plant breeding carried out by humans to meet their needs has endowed plants with traits that were not favoured by natural selection.⁴ For a long time, this activity was uniquely phenotypical, i.e. based on plants’ observable characteristics, but the understanding of heredity made it possible to control the transmission of characteristics. From the 1950s, mutagens⁵ were used to alter plant genomes and produce new variants, which were then selected based on phenotypical criteria – a process called random mutagenesis.⁶ It was only with the dawn of

genetic engineering that humans were able to directly edit the genome. Transgenesis, which emerged in the 1980s, allowed scientists to transfer a desirable gene into a plant, which was called a GMO.⁷

The seed industry is a highly dynamic sector in France, with €4 billion in turnover and €1.3 billion in trade surplus, despite its focus on conventional varieties. The sector continues to innovate to improve the diversity and resilience of crops.⁸

- *Targeted genome editing made possible by new genomic techniques*

New genomic techniques⁹ are techniques that allow targeted genome editing and have emerged in the last 30 years. Today, the most widely used one is Crispr-Cas9, which uses an enzyme capable of cleaving DNA – Cas9 nuclease – and synthetic DNA that guides Cas9 and targets a region of the DNA.

These tools allow several types of targeted genome editing, from the isolated modification of a few DNA bases to the insertion of a foreign gene. The objective of the operation can be to turn off a gene and its function, modify the corresponding protein with varying degrees of consequences on its function, or add a function.¹⁰

- *Open perspectives*

Several dozen NGT varieties have already been brought to the market worldwide.¹¹ Breeders aim to endow crops with new traits such as drought tolerance, later or earlier flowering, different nutritional composition or disease resistance. These advances stem from improved knowledge of the plants' genomes. However, it is important to note that some functions are controlled by several and sometimes many genes, which makes modulating them a complex task.¹²

Inrae stresses that NGTs are tools for the agroecological transition just like any other and are not miraculous techniques capable of resolving all of today's challenges.¹³ For their advocates, NGTs also help accelerate varietal innovation. Field-crop selection programmes take between seven and ten years; with international monitoring, varieties with resistance to emerging pathogens could be launched more quickly.

- *Questions that remain*

Beyond opposition for ethical reasons to the principle of humans directly editing the genome of crop species, some highlight uncertainties linked to the techniques themselves¹⁴ and their unknown or unwitting consequences.¹⁵ Jérôme Enjalbert also argues that we have insufficient hindsight on the modification of genes that have been preserved through the evolutionary process and which play an essential role in the plant.¹⁶

While the successive backcrossing habitually carried out in the breeding process allows errors introduced into the rest of the genome to be gradually erased, Yves Bertheau asserts that only 92 to 96% of the genome is "cleansed". However, the same is true for random mutagenesis.¹⁷

The case of the winegrowing sector

Due to the extended duration of breeding programmes (25 years), the winegrowing sector hopes that NGTs will enable innovation to advance at a faster rate and provide solutions to the challenges it faces sooner.

The main challenge lies in the sector's substantial use of phytosanitary products (30% of volumes used in France, for 2% of agricultural land) to prevent the development of fungi such as mildews and insect pests.

However, the industry can only adopt this technology if wine appellation criteria are broadened to include the new varieties, or if conventional grape varieties endowed with a desired trait can simply be considered clones.

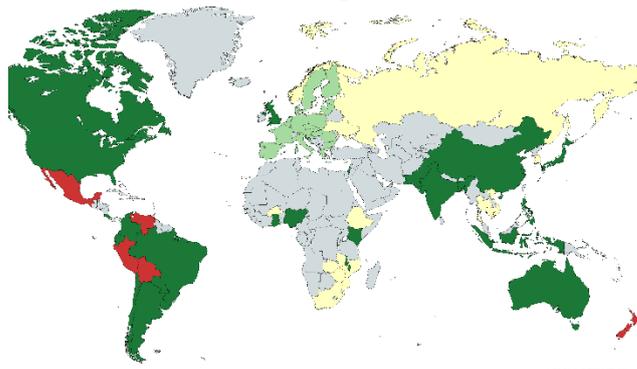
- *The judicial and regulatory context, origin of the current text*

- *The status of NGTs referred to the Court of Justice of the European Union*

In 2015, nine associations lodged an appeal with the Conseil d'État to call for greater precision in the legal status of varieties, known as NBTs at the time.¹⁸ The Conseil d'État applied to the Court of Justice of the European Union the same year. In its judgement,¹⁹ handed down in 2018, the Court ruled that NGTs could not be classified with the exempted techniques of Directive 2001/18,²⁰ because they could not be considered as "techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record".

- *The need for new regulation*

The current state of NGT regulation across the world



Dark green: liberal; light green: liberal development in progress; yellow: restrictive with perspectives of development; red: restrictive²¹

The Court's ruling was welcomed by some and criticised by others, including the chief scientific advisors of the European Commission.²² In 2021, the Commission published a study in which it concluded that the regulation needed reviewing.²³ A new text was therefore awaited with anticipation by those who criticised Europe for being backward compared with many countries who had already adopted a very favourable position towards NGTs and the brain drain and investment cuts it had

caused (only 10% of patents on NGT characteristics are European).

■ Regulatory exemption for NGTs

The proposed regulation in a few points – the Commission's version of summer 2023

Building on Directive 2001/18, the regulation introduces a two-tier categorisation, with exemptions for certain varieties from the requirements of the GMO directive:

- NGT1 varieties would simply require to be registered with verification that NGT1 criteria are met – the list of NGT1 plants is publicly available;
- NGT2 varieties would be subject to the GMO directive, which requires a risk assessment.

The distinction between NGT1 and NGT2 is based on a threshold of 20 modifications (including insertions of up to 20 nucleotides, or deletions of any number of nucleotides).

Labelling of plant reproduction material (seeds and plants) is required for NGT1 varieties. For NGT2 varieties, the labelling requirement is extended to products, as in the GMO directive.

NGT2 plants are subject to the environmental monitoring requirements of the same directive.

As the regulation is directly applicable, no opt-out is possible.

While Ms Regnault-Roger and Ms Ricroch expressed their regret that the GMO directive was not reviewed, which they consider obsolete, the French Association for Plant Biotechnologies (AFBV) considers that it is more agile to change the legal framework applicable to NGTs in this way.

➤ Substantial modifications by the Parliament

The European Parliament adopted the text in the spring of 2024 but put a cap on the broader framework scope desired by the Commission, refusing NGT1 status for varieties that produced a chimera protein²⁴ or did not present at least one sustainability criterion.²⁵ The Parliament added that all varieties produced by the hybridisation of NGT1 varieties must meet the same criteria in order to be included in this category. It set the threshold for distinction between NGT1 and NGT2 status at three modifications per gene,²⁶ introducing a requirement for proportionality with regards to the size of the genome that was missing from the original text.

Members of the European Parliament wanted to include a ban on patenting NGT plants²⁷ and limit the scope of all plant patents.²⁸ The labelling requirement was extended to products, and it was stipulated that the registration of an NGT1 variety must be accompanied by a plan for monitoring effects on the environment, provided by the applicant.²⁹

➤ A consensus obtained with difficulty by the Council

The Council negotiations led to a consensus in March 2025. The adopted text is similar to the Commission's

version but, unlike the latter, the NGT1/NGT2 distinction is based on the total number of modifications relative to the number of sets of chromosomes.³⁰ While it removed the sustainability criterion requirement for the NGT1 category, the Council also excluded herbicide-tolerant varieties from this same category. In addition, all member states are able to ban NGT2 plants from their territory.

The Council maintained the requirement to publish all the patented characteristics of NGT1 varieties in a database and to offer the same conditions of access to licences in all European countries. It also provided for the creation of a group of experts to monitor the effect of patents on access to innovation. The Commission will deliver a report on this subject one year after the regulation comes into force.

■ Points that are still strongly debated

The trilogue phase should settle the disagreements between the three European institutions. Once the text has been adopted, the European Food Safety Authority (EFSA) and competent national authorities will be responsible for proposing homogenous conditions of application across Europe.

➤ The binary nature of the regulation and the NGT1/NGT2 distinction

Some scientists feel that the equivalence on principle between NGT1 and conventional varieties, upon which the regulation is based, is true in the case of minor modifications, as these mutations could have occurred naturally. This argument is based on the fact that mutations occur naturally during DNA replication every time a cell is divided into two.

Other scientists, including the *ad hoc* committee of experts brought together by Anses, argue that not all mutations are equivalent: on the one hand, it is not the size of the mutation that counts, but where it takes place in the genome; on the other, modifications, and especially combinations of modifications, are not all equally likely to occur naturally.³¹ The advocates of this argument call for a regulation based on the characteristics of varieties with a proportionate risk assessment, as proposed by EFSA.³² Furthermore, according to Jérôme Enjalbert, the Council's exclusion of herbicide-tolerant varieties from the NGT1 category due to their anti-agroecological nature,³³ reflects the view that priority should be given to the function of the characteristics conferred.

Although the regulation's binary nature and the 20-modification threshold seem little justified scientifically,³⁴ they reflect the Commission's desire to operate by categorisation of risk, which is more convenient to manage. Christian Lannou agrees that it is important not to repeat the mistake made with the overly strict biocontrol regulation.³⁵ Lastly, the stakeholders all agree on the fact that the introduction of a foreign gene must remain subject to a risk assessment.

➤ Intellectual property

Closely linked to economic interests, the question of intellectual property is a focal point of tensions.

• PVR and the request to patent traits

The Community Plant Variety Rights (PVR) system is designed to protect plant varieties but facilitates incremental innovation thanks to a breeders' exemption that authorises breeders to freely use protected varieties for the creation of new ones. Most French institutional and industrial actors are satisfied with this system, although the latter would prefer to protect their innovation with a patent, which would cover not only the plant, but also new traits obtained by NGTs. NGT opponents consider that patenting is unacceptable because it would inevitably lead to the emergence of an agribusiness oligopoly dominated by a handful of giants. On the other hand, the *Union Française des Semenciers* (French Seed Association) argues that patents would allow innovations to be protected and disseminated through licensing, which would be a fair way to receive a return on investment.³⁶

• Legal and economic perspectives

Market concentration³⁷ could lead to the homogenisation of the agricultural landscape, while the fragmentation of intellectual property could hinder the dissemination of innovation.³⁸ Certain precautions such as the ban on patenting native traits³⁹ and transparency requirements⁴⁰ - which are already provided for -, the breeder's exemption⁴¹ and compulsory licence attribution,⁴² may ensure the freedom to innovate.

➤ Traceability and labelling

The traceability of NGT characters is strictly document-based. With no prior information, it is impossible for most scientists to prove the NGT nature of a variety.⁴³ For Yves Bertheau, a matrix-based approach that searches for a number of markers would give an indication of the probability of whether the allele has been modified using NGTs. Two major research projects dedicated to this question have recently been financed.⁴⁴

Stakeholders who consider that NGT1 varieties are not equivalent to conventional plants call for labelling on the products concerned, based on the consumer right to information.⁴⁵ Others hold that such labelling is unnecessary and would generate significant costs linked to the segregation of business lines and would put consumers off. In addition, it seems illusory to require traceability for products from NGT plants that have come from countries where such varieties are assimilated with conventional plants, although this is conversely possible for seeds.

➤ Post-authorisation monitoring to be defined

Based on current knowledge, the problem of NGT diffusion depends on each new allele created and its capacity to integrate into a genome from a different variety. In any case, Anses recommends carrying out

environmental monitoring to detect any problems arising from the use of NGT varieties in France.⁴⁶ Some stakeholders deem it necessary to define buffer zones to protect crops that do not use NGTs, such as organic crops.

■ Conclusions and recommendations

The rapporteurs duly record the opening of the European market to NGT varieties and express their regret that the European Union took so long to draw up a legal framework for this tool. They welcome the Commission's decision to regularly reassess the adequacy of the regulation in the light of scientific developments.⁴⁷ They note that certain organic farmers would like to be able to use NGT varieties that require fewer inputs.⁴⁸

They deplore that the approach adopted by the Commission is centred on genome editing and not on the modification of the function, but they understand the management requirements that motivated this decision.

The rapporteurs call for sustainable NGT varieties to be developed as a priority, particularly through public funding. The regulation should be accompanied by communication to inform citizens of the issues surrounding targeted genome modification, especially since a text on the use of NGTs in animals should follow within a few years.

The rapporteurs recommend:

- that particular attention be paid to the resumption of tests in the field of NGT varieties,⁴⁹ which are essential for the development of new varieties. It is important to engage in uncontentious dialogue on the issues surrounding NGTs, perhaps through local consultations;
- that a multidisciplinary assessment committee be tasked with examining the systemic impacts of NGT varieties on the French agricultural system, to avoid falling into the same traps observed in the case of GMO cultivation;⁵⁰
- that the precautions provided for by the European Parliament to withdraw any variety that poses health or environmental problems after being placed on the market be maintained in the final text;
- that concerted action be taken at European level to clarify the intellectual property rules that are unclear with the European Patent Office, to prevent the sector from veering towards an oligopoly.

The OPECST's websites:

<http://www.assemblee-nationale.fr/commissions/opepst-index.asp>

<http://www.senat.fr/opepst>

People consulted

- A delegation from the French Agency for Food, Environmental and Occupational Health & Safety (Anses):
 - Mr. Matthieu Schuler, Managing Director General in charge of the Science for Expertise Division
 - Ms. Céline Druet, Deputy Director of the Risk Assessment Department
 - Mr. Youssef El-Ouadrhiri, Head of the Biotechnology Risk Assessment Unit
 - Mr. Brice Laurent, Director of the Social Sciences, Economics and Society Department
- A delegation from the French National Research Institute for Agriculture, Food and the Environment (Inrae):
 - Ms. Carole Caranta, Deputy Director General for Science and Innovation
 - Ms. Isabelle Litrico, Research Director at Inrae, Head of the Biology and Plant Improvement Department and Coordinator of the "Plant Breeding" priority research programme
 - Mr. Fabien Nogué, Research Director at Inrae, Member of the GMO panel of the European Food Safety Authority (EFSA)
- Academics:
 - Mr. Yves Bertheau, Research Director at Inrae and Honorary Scientist at the Muséum national d'histoire naturelle (French Natural History Museum)
 - Mr. Jérôme Enjalbert, Research Director at Inrae in the Quantitative Genetics and Evolution – Le Moulon laboratory and member of the Scientific Council of the Permanent Technical Committee for Crop Breeding
 - Pr. Fabien Girard, Faculty Member in the Law Department at Université Grenoble-Alpes (Legal Research Centre) and Junior Member of the French University Institute
 - Mr. Stéphane Lemarié, Research Director at Inrae in the Grenoble Applied Economics Laboratory
 - Pr. Catherine Regnault-Roger, Emeritus Professor at the University of Pau and the Pays de l'Adour, Full Member of the French Academy of Agriculture
 - Ms. Agnès Ricroch, Faculty Member at AgroParisTech, Corresponding Member of the French Academy of Agriculture
- Industrial stakeholders in the seeds and plant sector:
 - Mr. Rémi Bastien, Vice-President of the Board of Directors of the Union Française des Semenciers (UFS), Specialist Member of the Vegetables and Ornamentals Department, Director of the Vegetable Seeds Division of Limagrain
 - Mr. Guillaume Mercier, President of Mercier Group, French vine nursery leader
 - Mr. Pierre Pagès, President of Semae, French Interprofessional Organisation for Seeds and Plants
 - Mr. Olivier Zekri, Deputy Director and Director of R&D of Mercier Group
- Association stakeholders:
 - Mr. Thierry Langin, Research Director at CNRS, President of the French Association for Plant Biotechnologies (AFBV)
 - Ms. Yvette Dattée, Full Member of the French Academy of Agriculture and Secretary General at AFBV
 - Mr. Philippe Dumont, former lawyer, Head of International Relations at AFBV
- Members of the OPECST's Scientific Advisory Board:
 - Ms. Virginie Courtier-Orgogozo, Research Director at CNRS, Member of the OPECST's Scientific Advisory Board
 - Ms. Christine Noiville, Research Director at CNRS, Member of the OPECST's Scientific Advisory Board
 - M. Christian Lannou, Research Director at Inrae, Member of the OPECST's Scientific Advisory Board
- Parliamentarians:
 - Mr. Jean-Yves Le Déaut, Honorary Deputy, former President of OPECST, co-author of a report on targeted genome modification, published in 2017, Full Member of the French Academy of Agriculture
 - Mrs. Catherine Procaccia, Honorary Senator, former member of OPECST and co-author of reports on targeted genome modification in 2017 and 2021
 - Mr. Loïc Prud'homme, Deputy, former member of OPECST and co-author of a report on targeted genome modification in 2021

Contributions

- Written contribution by Phyteis,
- Joint written contribution by the Union Française des Semenciers, Semae and Mercier Group

References

- ¹ Ruling of the Court of Justice of the European Union of 25 July 2018, Case C-528/16.
- ² Most of the GMO crops grown today contain a glyphosate-tolerant gene or the Bt gene that makes them toxic for insects. The diversity of GMO crops is extremely limited.
- ³ However, both chambers were able to express their positions during the examination of two proposed European resolutions. While the National Assembly rejected the one presented by deputies Lisa Belluco and Stéphane Delautrette, the Senate adopted the one presented by Senators Jean-Michel Arnaud, Karine Daniel and Daniel Gremillet; https://www.assemblee-nationale.fr/dyn/16/textes/116b2232_proposition-resolution-europeenne and <https://www.senat.fr/leg/ppr23-452.html>.
- ⁴ On this subject, *Les clés du champs – Comment domestiquer les plantes* (Keys to the Field – How to Domesticate Plants) by François Percy, published by humenSciences / Humensis in 2024, explains how humans have indirectly modified plant genomes through selection processes, using several examples.
- ⁵ The mutagens used are ionising radiation or chemical agents.
- ⁶ Mutagenesis is not concerned by the regulation on techniques that produce genetically modified organisms (GMOs). It is included in the list of exceptions in Annex IB of Directive 2001/18/EC (Directive 2001/18/EC of the European Parliament and Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0018>)
- ⁷ Directive 2001/18 defines the term GMO (genetically modified organism) as “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”. However, evidence from the hearings shows that this term is reserved for organisms modified by transgenesis, while the term NGT is more readily used to refer specifically to organisms produced by targeted genome editing.
- ⁸ According to Jérôme Enjalbert, it is scientifically proven that there is a direct correlation between the diversity and stability of an agricultural system. See also the conclusions of the Inrae collective expert appraisal: “Protect crops by increasing plant diversity in agricultural areas”, December 2023; https://www.inrae.fr/sites/default/files/pdf/RegulNat-synth%C3%A8se_12-12-23_V3.pdf. Tests such as those carried out during the MoBiDiv project have shown that using a mixture of crops can reduce the use of phytosanitary products by up to 70%; Elodie Yan, Nicolas Munier-Jolain, Philippe Martin and Marco Carozzi. “Intercropping on French farms: Reducing pesticide and N fertiliser use while maintaining gross margins”. *European Journal of Agronomy* 152 (1 January 2024): 127036. <https://doi.org/10.1016/j.eja.2023.127036>
- ⁹ Meganucleases, zinc-finger nucleases, TALEN and Crispr-Cas9. The common feature of these techniques is that they all use (at least in part) an enzyme capable of cleaving DNA (nuclease). Using different biochemical mechanisms, they can perform a targeted scission in the DNA, which causes the gene in question to mutate if the repair is defective.
- ¹⁰ For more information on this technique, see the *Report on the Economic, Environmental, Health and Ethical Issues of Biotechnologies in Light of the New Research Avenues* by Deputy Jean-Yves le Déaut and Senator Catherine Procaccia (Opecst, 2017). The types of modifications carried out are often categorised as follows:
- Silencing genes using targeted cleaving and defective repair (Site-Directed Nuclease 1 or SDN1),
 - Targeted modification of a few nucleotides in a target gene (SDN2),
 - Targeted insertion of a foreign DNA sequence at a given site (SDN3).
- Cisgenesis involves the insertion of a DNA sequence taken from the breeders’ gene pool, which is taken to mean “genetic material from all the genomes of the plants with which the plant in question can be cross-bred”, according to the Anses *Opinion* on the analysis of Annex I of the proposed regulation of the European Commission on NGT plants.
- ¹¹ In her personal register which she made available to the rapporteurs, Ms Agnès Ricroch counted 60 varieties that have been granted a market authorisation. The two most commonly cited examples are the Calyxt soybean, which is low in saturated fatty acid, and the Sanatech tomato, which is high in GABA. Other examples include certain varieties of potatoes, avocados and salads that do not brown. In its collective expert appraisal report on the health and environmental risks and socioeconomic challenges linked to plants obtained by new genomic techniques, Anses observed that the modifications carried out aim mainly to modify the plant’s composition, then to modify its architecture or yield, and finally to make it resistant to biotic stress (disease, pests) or create a breeding tool. Herbicide-tolerant varieties only accounted for 5% of modified varieties, which is far below the share of this trait in GMO plants (p. 42). <https://www.anses.fr/system/files/BIORISK2021SA0019Ra.pdf>
- ¹² This is particularly true of drought tolerance, which has been criticised several times in hearings as being a mirage by opponents to the use of this technology, who recall the “promise economy” touted with the emergence of GMOs. However, recent Chinese research, cited by Mr. Fabien Nogué, shows that this characteristic can be modified by targeting the WUSCHEL transcription factor: Li, Hui, Wanying Ma, Xiao Wang, Hongling Hu, Lina Cao, Hui Ma, Jingwei Lin, and Ming Zhong. “A WUSCHEL-Related Homeobox Transcription Factor, SIWOX4, Negatively Regulates Drought Tolerance in Tomato”. *Plant Cell Reports* 43, n° 11 (6 October 2024): 253. <https://doi.org/10.1007/s00299-024-03333-5>.
- ¹³ To illustrate this key point, Christian Lannou provided the example of plant varieties that had been made insect-resistant through toxin generation. In fact, insects adapt and can develop avoidance strategies – a phenomenon already observed with GMOs. To prevent such varietal obsolescence, insecticide must be used to control the insects and protect the plants’ resistance. It therefore cannot be affirmed that insect-resistant NGT varieties will make insecticides unnecessary. The use of phytosanitary products for varieties that are promoted as not needing them seems misleading if this principle is not first explained to users and the general public.
- ¹⁴ Examples include: unintended DNA editing, remnants of the genetic sequences used in the process, chromosomal rearrangement and consequences on the epigenome.

¹⁵ These modifications can have functional consequences when they concern a protein-coding gene, but this may also be true when they concern non-coding DNA, because the latter also contains regions that regulate gene expression. Chromosomal rearrangements occur when long strands of DNA are displaced. The epigenome is the collection of epigenetic variations of a cell's gene expression (without altering the DNA sequence itself).

¹⁶ Based on several years of hindsight, conventional breeding methods allow varieties to be cultivated in different contexts with different selection pressures. This type of test must be carried out for NGT varieties as well – something that Phyteis stressed in its written contribution. Even so, Jérôme Enjalbert argues that by editing genes that have undergone very little evolutionary change, plants could become vulnerable to unforeseen sensitivity to external factors (weather, parasites, etc.).

¹⁷ In addition, with random mutagenesis, no search is carried out for new mutations; selection is based on the phenotype. Mutations located outside of the genes associated with the target characteristics are therefore likely to remain present after backcrossing. Chromosomal rearrangement events are also likely to occur with this technique.

¹⁸ The appeal also called for a ban on herbicide-tolerant varieties produced by random mutagenesis. https://www.confederationpaysanne.fr/sites/1/communiqués_de_presse/documents/Tribune%20recours%20VTH.pdf, <https://www.legifrance.gouv.fr/ceta/id/CETATEXT000033191647/>

¹⁹ Judgement of the Court of Justice of the European Union of 25 July 2018, Case C-528/16. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62016CJ0528>

²⁰ The list of exempted techniques is included in Annex IB of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62016CJ0528>

²¹ Map created using mapchart.net and based on available maps:

- Clark, Lisa F., and Jill E. Hobbs. "How Are Gene Editing Technologies Regulated in the Agrifood System?" In *International Regulation of Gene Editing Technologies in Crops: Current Status and Future Trends*; Edited by Lisa F. Clark and Jill E. Hobbs, 31-59. Cham: Springer Nature Switzerland, 2024. https://doi.org/10.1007/978-3-031-63917-3_3.

- <https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/>

²² In a declaration, the Group of Chief Scientific Advisors of the European Commission's Science Advice Mechanism expressed the opinion that the GMO regulation was obsolete and ill-adapted to new genomic techniques, based on its 2017 paper titled "New techniques in agricultural biotechnology".

Declaration of 2018: <https://op.europa.eu/en/publication-detail/-/publication/a9100d3c-4930-11e9-a8ed-01aa75ed71a1/language-en>

Report of 2017: <https://scientificadvice.eu/advice/new-techniques-in-agricultural-biotechnology/>

²³ Study by the European Commission on the status of new genomic techniques under Union law and in light of the ruling by the Court of Justice in Case C-528/16 (2021): https://food.ec.europa.eu/document/download/5135278b-3098-4011-a286-a316209c01cd_en?filename=gmo_mod-bio_ngt_eu-study.pdf

²⁴ By "chimeric proteins", the European Parliament means "proteins created through the joining of two or more genes or parts of genes that originally coded for separate proteins" and which did not previously exist in the breeders' gene pool. The term "breeders' gene pool" in the text refers to "genetic material from all the genomes of the plants with which the plant in question can be cross-bred", according to Anses in its *Opinion* on the scientific analysis of Annex I of the European Commission's proposal for a regulation on NGT plants.

²⁵ Article 6, paragraph 3, point d, sub-point ii: "the NGT plant meets the criteria set out in Annex I, at least one of the traits in Annex III, Part 1, and the exclusion criteria of Annex III, Part 2". The sustainability criteria are the following:

- improved yield,
- tolerance and resistance to biotic stress,
- tolerance and resistance to abiotic stress, including adaptation to climate change,
- more efficient use of natural resources (water, nutrients, etc.),
- reduced dependence on inputs (fertilisers and plant protection products),
- improved nutritional characteristics,
- bioremediation varieties (e.g. using plants to eradicate soil pollutants).

²⁶ More precisely, per coding sequence, i.e. per sequence of nucleotides directly used for protein synthesis. Therefore, regulatory sequences and introns can undergo limitless modifications.

²⁷ Article 4a: "NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable".

²⁸ These restrictions were introduced by the modification of Directive 98/44/EC. The Parliament wanted patents to be inapplicable to plants containing a trait that was already patented elsewhere, if it had been obtained by an essentially biological process. In connection with the vote by the Parliament, the European Patent Office adjusted its regulation to include a disclaimer in all patent applications to ensure they only applied to characteristics that had been obtained by non-mainly-biological means, in order to avoid situations of conflict between the producer of an NGT variety and a conventional seed producer who had obtained the same trait. The Parliament also wanted to exclude the possibility of extending patents to plants containing a patented trait if it was indistinguishable from plants with the same characteristic obtained by mainly biological means.

²⁹ The Parliament also included a provision for withdrawal from the market in the event of an environmental or health problem arising after placing on the market.

³⁰ Depending on the species, chromosomes can be present in sets of two (diploid organisms, like humans) or three or sometimes more. Each copy contains a gene to be modified, hence the need for the modification threshold to be proportional to the ploidy.

³¹ Anses *Opinion* on the scientific analysis of Annex I of the European Commission's Proposal for a Regulation of 5 July 2023 on New Genomic Techniques (NGT) – Review of the proposed equivalence criteria for defining category 1 NGT plants, November 2023; <https://www.anses.fr/system/files/BIOT2023AUTO0189EN.pdf>

³² EFSA Panel on Genetically Modified Organisms (GMO), Ewen Mullins, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank, et al. "Criteria for Risk Assessment of Plants Produced by Targeted Mutagenesis, Cisgenesis and Intragenesis". *EFSA Journal* 20, no. 10 (2022): e07618. <https://doi.org/10.2903/j.efsa.2022.7618>.

³³ According to the researcher, herbicide-tolerant varieties (HTV) are the very archetype of that which should be avoided. HTVs lead to a dependence on phytosanitary products and contribute to damaging the environment for commercial interests.

³⁴ The Commission delivered a technical paper made publicly available in which it justified the 20-modification threshold by comparison with the number of genetic modifications obtained using conventional means (random mutagenesis produces between 30 and 100 modifications), based on scientific analysis by the Joint Research Centre (JRC). It is important to note that this absolute number does not take account of the significant variability in the size of crop genomes. For example, the rice genome contains 400 million base pairs, whereas the wheat genome has 16 billion (<https://www.semae-pedagogie.org/sujet/genomique/>). "Technical paper on the rationale for the equivalence criteria in Annex I" https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_14204_2023_INIT

³⁵ In the case of molecules, biocontrol solutions in France are regulated in the same way as phytosanitary products. Their promoters – companies and research institutes – are therefore subject to the same administrative and financial requirements. On this subject, see the grievance expressed by Ms Ené Leppik during the public hearing organised by deputy Pierre Henriet and senator Daniel Salmon on Agriculture and the Challenges of Climate Change and Biodiversity Loss: the Role of Science (April 2025); https://www.senat.fr/fileadmin/cru-1758178896/Office_et_delegations/OPECST/Synthese_en_anglais/Synthese_Agriculture_Climat_EN_VF.pdf

³⁶ Industrial stakeholders feel that it would be too easy to copy the genetic modifications that have produced the trait obtained because the technology is so easily accessible. Although the cost of research and development is lower than for the development of GMO species, a return on investment is still required. For Fabien Girard and Stéphane Lemarié, the need to patent in order to obtain such a return, as claimed by the sector, can be justifiably questioned. In their view, the commercial payoff from a variety that the Community PVR system already allows may be sufficient.

³⁷ Research to date is reassuring: the market is not yet concentrated. The regular discovery of new versions of tools for targeted genome modification contributes to the diversity of economic stakeholders, but stakeholder concentration could become a problem, particularly as regards the property rights to the fundamental technology patents (patents held by the University of Berkeley, the University of Vienna, Jennifer Doudna and Emmanuelle Charpentier on the one hand, and the Broad Institute of MIT and Feng Zhang on the other hand). The holders are generally willing to share their innovation. The Commission has also proposed a system to help preserve a balance between small organisations and agribusiness giants, which offers a simplified application process for NGT2 varieties that present characteristics that meet sustainability criteria.

³⁸ Breeders must be able to pay for several licences in order to use the technology and bring the resulting product to the market. Varieties may include several patented traits and therefore be dependent on multiple licences. This fragmentation may contribute to a freeze in innovation or its effective dissemination if certain stakeholders refuse to grant licences.

³⁹ Native genes are existing genes that have been preserved during evolutionary changes or obtained using conventional selection methods. See note 28.

⁴⁰ The version of the draft regulation adopted by the European Council in early 2025 requires that all category 1 NGT patents be registered in a public database.

⁴¹ The breeder's exemption regarding patents is allowed for by the Unified Patent Court. However, AFBV considers that an interpretative opinion from the European Commission is necessary in order to guarantee breeders' access to genetic material, tools to improve or modify it, the necessary regulatory processes for placing on the market and the production of seeds before market launch.

⁴² Researchers have warned that such a measure is inapplicable in the current state of international agreements (TRIPS by the WTO). Nevertheless, united European action in this direction would allow changes to the European Patent Office regulation. Initiatives such as exchange platforms for ACLP field crop patents or ILP vegetable patents may create the necessary conditions for much broader licensing. According to Phyteis, ACLP holder members commit to guaranteeing other members:

- breeder's exemption, even in countries where it is not included in legislative framework (unlike France),
- a compulsory non-exclusive commercial licence,
- reasonable royalty conditions, guaranteed by an independent arbitration committee composed of experts,
- an annual fee set according to the size of the company.

⁴³ I.e. the information provided on the modified genes can be verified by DNA sequencing. Without such information, it is impossible to tell whether a variety has been obtained by conventional selection methods or NGTs.

⁴⁴ DARWIN and DETECTIVE, financed by the Horizon Europe programme: <https://darwin-ngt.eu/>, <https://detective-ngt.eu/>.

⁴⁵ It is to be noted that Directive 2001/18 does not require labelling for products produced using exempted techniques such as random mutagenesis.

⁴⁶ Industrial stakeholders should contribute to this effort, as stipulated in Article 251-1 of the French Rural Code: "IV. – *Those responsible for the voluntary dissemination of genetically modified organisms, the distributor and the user of these organisms must participate in the biological monitoring system of the territory, in particular by communicating to the officers in charge of plant protection all the information necessary for this monitoring.*"

⁴⁷ Besides, the Commission included a clause allowing it to update equivalence criteria based on available scientific knowledge. Article 5 of the proposed regulation reads: *"The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding."*

⁴⁸ The ban on the use of targeted genome editing in the organic farming sector was effective from the start at its own request. However, some organic farmers have expressed interest in the technology. This clause could be part of the elements that the Commission could reconsider in the future, by decree, if the sector were to make such a request.

⁴⁹ The last crop trials of genetically modified varieties (GMO) were carried out by Inrae in 2010 (vines uprooted by protesters in 2009 and 2010 in Colmar) and 2013 (poplars, destroyed by Inrae after the request to renew its authorisation, which was made late, was denied).

⁵⁰ These may include socioeconomic but also health and environmental impacts. The committee must therefore be composed of at least agronomists, geneticists, plant pathologists, sociologists and economists, as proposed by Jérôme Enjalbert.