# Response of AFBV and WGG to the Inf'OGM article dated August 5, 2025

On August 5, 2025, Inf'OGM published an article by Denis Meshaka commenting on the joint AFBV-WGG note dated July 4, entitled: "The scientific lobby invites itself into the trilogue discussions on the deregulation of GMOs/NTGs".

We appreciate the interest shown by Inf'OGM in our joint note. Its article presents us with an opportunity to react to some of their perceptions and to clarify our own previous remarks.

1. **Inf'OGM describes AFBV and WGG as a "scientific lobby".**

As a reminder, ***Association Française des Biotechnologies Végétales*** (French Plant Biotechnology Association - AFBV) is a strictly independent NGO established under French law. It brings together individuals from diverse backgrounds who are convinced of the benefits of plant biotechnology for France, in particular to develop sustainable agriculture.
***Wissenschaftskreis Genomik und Gentechnik e.V.*** **(WGG)** is also an NGO established in Germany, organized independently and for the same goals AFBV, for Germany, Austria and Switzerland. The two organizations have been working closely together for eight years.

Our members are mostly scientists or people with scientific training or culture. As we do not represent any economic sector, the use of the term "scientific lobby" to describe us seems inappropriate.

2. **Inf'OGM believes that AFBV and WGG defend "an agricultural model centred on biotechnologies and the industrial interests that go with it" and that this "sectoral position on NGTs relegates the precautionary principle, food sovereignty and transparency to the background".**

Our July 4 note and our recent communications do not propose or defend any agricultural model. Our comments are directed to the Commission's regulatory proposal on NGTs, which is currently under discussion in the Trilogue.

As for the subjects that Inf'OGM considers to be "relegated to the background", the Commission has nevertheless taken them into account in the text of its regulatory proposal:

a. Regarding the **Precautionary principle**, the Commission has referred to it three times, at page 4 (under “general objectives” and under “consistency with existing provisions”, and page 13 (fundamental rights)), emphasizing that its initiative was **in line** with the precautionary principle and contributes to achieving a high level of human health protection. https://eur-lex.europa.eu/resource.html?uri=cellar:c88fe9ac-1c06-11ee-806b-01aa75ed71a1.0001.02/DOC_1&format=PDF

b. Regarding **food sovereignty**, the Commission does not specifically use this term (it mentions the "concept of Open Strategic Autonomy"), but on pages 2-3 of its proposal it describes the challenges facing the European agri-food system that NTG plants could help solve:

> "There is significant demand in the Union and globally for NGT plants, because of their potential to contribute to addressing current challenges in the agri-food system. Climate change and biodiversity loss have put the focus on long-term resilience of the food chain and the need to transition to more sustainable agriculture and food systems. The European Green Deal's Farm to Fork Strategy7 specifically identifies new techniques, including biotechnology, that are safe for consumers and the environment and bring benefits to society as a whole, as a possible tool to increase sustainability of agri-food systems and contribute to guaranteeing food security[8]."
>
> " The Covid-19 pandemic and Russia's war of aggression against Ukraine have also revealed the Union's external dependencies. In its Trade Policy Review Communication[9], the Commission stressed the role of trade openness within the concept of "Open Strategic Autonomy", recalling the importance of an open and fair trade with well-functioning, diversified and sustainable global value chains. NGTs are applied to a far larger range of crop species than established genomic techniques and can contribute, for example, to decreasing the Union's dependence on imports of plant proteins. They can also support the special needs in the Outermost Regions. NGTs are more technically accessible than established genomic techniques as they have low entry and operating costs. This could mean that the developers and users of these techniques are more diversified if access to and affordability of the technologies is maintained. NGTs could be also relevant in low- and middle income countries, which would benefit from adapting traditional, local crop species so that they can withstand changing conditions. An enabling framework in the EU could also support use in those countries." https://eur-lex.europa.eu/resource.html?uri=cellar:c88fe9ac-1c06-11ee-806b-01aa75ed71a1.0001.02/DOC_1&format=PDF

c. Finally, in terms of **transparency**, recitals 16, 21, 24 and 32 of the proposal inform us that the need for transparency has been taken into account in several concrete ways:

i. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.

ii. Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database and for the purpose of labelling of plant reproductive material derived from them.

iii. To ensure traceability, transparency and choice of operators (including to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard

consumer trusts , during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT. In addition, NGT plants that have obtained a category 1 NGT plant status declaration should be listed in a publicly available database.

iv. Finally, in the case of Category 2 NGT plants, to increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products as GMO with information on the trait conferred by the genetic modification. https://eur-lex.europa.eu/legal-content/FR/TXT/DOC/?uri=CELEX:52023PC0411

These provisions to ensure transparency are to be compared with the absence of similar provisions for products resulting from random mutagenesis and cell fusion (GMOs exempted under Regulation 90/220/EC and Directive 2001/18/EC), for which since 1990 there has never been any labelling, either on products sold to the consumer or on seed bags.

3. **According to Inf'OGM, "the Council has not yet finalised its position at first reading, although it has already given the Presidency a negotiating mandate".**

To be factual, on 14 March 2025, the Permanent Representatives Committee [COREPER] approved the text presented by the Polish Presidency, which will serve as a negotiating mandate with the European Parliament. The Polish Presidency informed Parliament of the Council's willingness to start interinstitutional negotiations.
https://data.consilium.europa.eu/doc/document/ST-9879-2025-INIT/en/pdf

4. **According to Inf'OGM, AFBV and WGG "plead for an 'acceptable compromise', which consists of integrating the sustainability assessment into other texts concerning varieties, in this case the proposal for a regulation on plant reproductive material (PRM) (or "seed regulation") currently under debate", which "would make it possible to remove the issue from this debate without ensuring that it is addressed in the other texts".**

Our proposal was not designed to remove the issue from the current debate. Sustainability cannot be evaluated on an edited plant because it is not a variety. When the edited plant, after several rounds of breeding crosses, reaches the stage where it is a candidate for variety registration, it should be evaluated for its sustainability in comparison with other candidate varieties. We believe that sustainability should be an important evaluation criterion for all varieties, regardless of how they are obtained.

5. **According to Inf'OGM, the position defended by AFBV-WGG (which support the Council's text) according to which NTG-1 plants should not be subject to specific labelling because their modifications cannot be distinguished from natural mutations is based on "semantic confusions dressed up in scientific language".**

There is no semantic confusion. Not only are "the genetic modifications generated by NGT-1" indistinguishable from natural mutations", but they also cannot be distinguished from mutations resulting from random mutagenesis (*in vivo* or *in vitro*) of chemical origin or obtained by irradiation. In AFBV's datasheet on mutations, we previously explained:

"The use of mutagenic treatments significantly increases the frequency of mutations compared to spontaneous mutations, commonly by a factor of 1,000, which reduces in the same proportion the number of individuals needed to select the desired mutation. These mutagens cause "damage" to DNA, causing in a second phase further mutations if such “damage” is not perfectly repaired. The mutation is the result of an interaction between the inducer (the mutagenic agent), the target DNA sequence, and the reaction of the cell's DNA repair systems. We can thus clearly see the intrinsically random nature of mutations that occur within the genome, random by the modifications of the sequence and random by their position on it. During a mutagenic treatment, spontaneous mutations are added to the induced mutations, in a very small proportion. As the DNA alterations caused in both cases can be the same, there is no signature on the origin of a mutation, spontaneous or induced. There is only a greater probability that it was caused by the treatment rather than spontaneously. A mutation "occurs", it is not "manufactured", unlike a transgene that is "constructed".
https://www.biotechnologies-vegetales.com/wp-content/uploads/2020/10/Fiche-Information-Comprendre-linteret-des-mutations-dans-la-selection-des-plantes-FR-1.pdf

6. **According to Inf'OGM, regarding the impact of patents on new technologies, "unsurprisingly, AFBV and WGG strongly defend patent protection, which they believe is essential for start-ups in the sector".**

Our associations defend the two types of intellectual property protection for plants (PBRs for a variety and patents for a trait) and believe that they should coexist harmoniously.

As a reminder we have previously made four proposals designed to address the concerns currently raised by intellectual property protection systems:

i. **Make it mandatory to publish the patent status** covering a variety in the EU Catalogue of Species and Varieties and in the CPVO database,
ii. **Interpret the Unified Patent Court Agreement** so that the breeder's exemption covers genetic material, the tools used to improve and modify it, all regulatory steps prior to sales and seed production prior to launch,
iii. **In all cases where a compulsory licence** is required (due to dependence on a patent or a variety protected by a PBR), (A) **interpret the criteria of "considerable economic interest" or "public interest"** as being met by the listing of a variety with a trait with a known and measurable economic advantage (such as disease resistance) or increased tolerance to measurable environmental factors (such as resistance to drought) and (B) **apply FRAND (** fair, reasonable and non-discriminatory) **terms** to the licence.
iv. Reassure small breeders by asking the European Patent Office (EPO) to **formally confirm that the so-called "disclaimer" clause (§28 (2)) covers both the plant containing a gene or a native trait and the corresponding gene and trait.**

7. **According to Inf'OGM, the two associations support the Council's position to maintain the criterion of less than 20 genetic modifications by adding the terms "per monoploid genome" (one copy of each chromosome) ... "to usefully take into account the need for a certain flexibility for polyploid plants".**

Since the publication of our note, the following article has been published: Schulman, A.H. et al. (2025) Proposed EU NGT legislation in light of plant genetic variation. *Plant Biotechnol. J.*, https://doi.org/10.1111/pbi.70228

This paper finds that current genomic data indicate that the natural variation in the genetic material used by breeders is much greater than previously thought, and that conventional selection and mutagenesis can introduce larger and more frequent genomic changes than would be possible under the NGT-1 limit of "20 insertions of no more than 20 bps." In addition, natural variation also evolves with genome size and complexity, a factor not taken into account in the European Commission's proposal. The authors conclude that the proposed thresholds below which an NGT plant is considered equivalent to conventional plants do not correspond to what is observed in nature, conventional breeding and mutagenesis. Updating the "20/20" rule to broader limits would facilitate breeding for climate resilience, agricultural sustainability, and nutritional security, while ensuring that NGT-1 plants are equivalent to conventional plants. The authors are part of EPSO and their contribution has led EPSO to propose new ceilings for Appendix I that better reflect the latest scientific observations on the size and frequency of mutations found in nature and in conventional breeding:

> "1. The number of insertions regarded as NGT-1 shall be a maximum of 10 insertions per Gbp of the monoploid genome, with a floor of at least 20 permitted in total for monoploid genomes under 1 Gbp; deletions may be of any number.
> 2. The number of insertions also shall be scaled by ploidy (hence, 40 in a diploid, 80 in a tetraploid, 120 in a hexaploid, as the floor for genomes ≤ 1 Gbp).
> 3. If a limit is set to the number of insertions permitted per protein coding sequence as NGT-1, the limit shall refer discretely to each round of edits that results in a released cultivar.
> 4. The size of insertions regarded as NGT-1 shall be a maximum of 150 bp, with deletions being of any size.
> 5. Crosses or further rounds of edits of NGT-1 cultivars on the market to produce improved plant lines also shall be regarded as NGT-1. If two or more NGT-1 lines with different edits are conventionally crossed (as in the current EC proposal), or an NGT-1 cultivar is edited again, the offspring shall continue to be regarded as NGT-1, providing that the number of changes added in each round leading to a new cultivar does not exceed the limits specified in points 1—4."
> https://epsoweb.org/wp-content/uploads/2025/07/25_07_08_EPSO-Recommendation_Legal-proposal-NGTs-plant-genetic-variation-1.pdf

8. **According to Inf'OGM, "the recommendations of AFBV and WGG are in fact lobbying objectives. The clear support of these two associations for the proposals of the Parliament or the Council in favor of the deregulation of GMOs/NGTs shows unconditional support for these techniques. »**

Neither AFBV, nor WGG, nor EPSO are lobbies. (For information, EPSO, the European Plant Science Organisation, is an independent academic organisation currently representing 70 institutional members bringing together more than 200 research institutes, departments and universities from 31 countries in Europe and beyond. EPSO's mission is to improve the impact and visibility of plant science in Europe. Its top priorities are to provide advice on science policy towards a strategic approach and critical mass funding for basic and applied research in Europe,

to coordinate research activities at national and European levels – and beyond, and to facilitate understanding of plant science.)

AFBV and WGG are regularly following and supporting the ongoing legislative process, based on the Commission's proposal of 5 July 2023, with adjustments proposed by the Parliament and the Council, to the same extent as stakeholders or many other interested persons or institutions, such as EPSO for example.

Like EPSO and other stakeholders, we have produced notes and issued recommendations to inform the debates. The Commission's proposal for a regulation of NGTs is indeed a new regulatory framework. It is therefore not a question of deregulation.

9. **According to Inf'OGM, the arguments of AFVB and WGG put them at odds with certain opinions of official institutions in their respective countries: the March 2024 opinion of ANSES and the "April 2025 report of the German government" on the compatibility of this deregulation proposal with the Cartagena Protocol on biosafety**.

ANSES's opinion, relating to the scientific analysis of Annex I, was the subject of a critical analysis by EFSA and explanations before the European Parliament. The opinion itself does not call into question the Commission's proposal for the regulation of NGTs, which is supported by the French Government. In its opinion, ANSES has made many comments on the definitions of technical terms which present legitimate questions to be taken into account. We do not consider ourselves at odds with the ANSES opinion.

Regarding Silja Vöneky's article on the compatibility of the Commission's proposal with the Cartagena Protocol, it is not a report by the German government but an academic article whose positions are those of Professor Vöneky and her co-authors. It does not reflect the position of an EU member state. As far as we are concerned, we believe that the authors did not get sufficiently close to the lawyers and regulatory experts who worked in the context of the drafting of the Protocol and Directive 2001/18/EC. Professor Vöneky, however, acknowledges that many countries interpret today the Protocol in such a way as to exclude many NGT-derived products from the scope of the Protocol. Our position is that products that meet Annex I equivalency requirements are not GMOs under Directive 2001/18 because they are do not present novel combinations of genetic material and have not been altered in a way that does not occur naturally by mating and/or natural recombination; or, to use the wording of the Protocol, the application of modern biotechnology to create these NGT-1 plants does not overcome "natural physiological reproductive or recombination barriers".

To put it more simply, if the result of the application of biotechnology is a **mutation** of the types described in Annex I, without the insertion of exogenous genetic material, it is neither a GMO nor a LMO. As explained in point 5, a mutation "occurs", it is not "manufactured". The natural phenomenon by which a mutation occurs is cell repair, which, in the case of a double-strand break, takes the form of non-homologous end joining (NHEJ) or homologous recombination.

Today, countries that follow this line of reasoning and have amended their legislation accordingly include Argentina, Australia, Bangladesh, Brazil, Canada, Chile, Colombia, Costa Rica, Ghana, Guatemala, Honduras, India, Indonesia, Israel, Japan, Kenya, Malawi, New Zealand, Nigeria, Pakistan, Paraguay, the Philippines, Thailand, Singapore and Uruguay.

Regarding our interpretations of the Directive and the Protocol, we particularly recommend three texts:

1. Van Der Meer P., *et al*. The Status under EU Law of Organisms Developed through Novel Genomic Techniques, published online by Cambridge University Press: 06 January 2021 https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/status-under-eu-law-of-organisms-developed-through-novel-genomic-techniques/4812A77647B94B3BB789D3532379C081

2. Callebaut, S., New developments in modern biotechnology: A survey and analysis of the regulatory status of plants produced through New Breeding Techniques Master thesis submitted in fulfillment of the degree of 'Master in Law' https://libstore.ugent.be/fulltxt/RUG01/002/213/647/RUG01-002213647_2015_0001_AC.pdf

3. Makenzie R. *et al.*, An Explanatory Guide to the Cartagena Protocol on Biosafety (2003), https://portals.iucn.org/library/efiles/documents/eplp-046.pdf

**10. Inf'OGM states that AFBV and WGG have consistently "supported an approach that is favourable to the sector's industrialists... who seek to restrict the access of small and medium-sized farmers and seed companies to plant traits".**

In all of our submissions on NGTs, our two associations have expressed the wish that NGTs be accessible to all who wish to use them, including SMEs, and in particular the poorest countries. Several of the countries mentioned in point 9 above are poor countries. When AFBV invited companies developing NTG plants to speak at its workshop organized on March 12, 2025 in Lyon, all presenters were small or medium-sized companies (Healthycrop (DK), Rainbow Crops (BE), Tropic BioSciences (United Kingdom) and Edivite (IT)). None of them was a seed company.

**11. For Inf'OGM, the joint AFBV-WGG note reflects "above all a sectoral position carried by actors in favour of agriculture based on technical developments that are incompatible with organic farming".**

We do not reflect a sectoral position.

The interests of the actors in the organic sector have been taken into account by the Commission which explained at page 11 of its proposal:

> "As regards the treatment in organic production of NGT plants and derived products that meet the criteria to be considered equivalent to conventional breeding, two possible sub-options were considered in the Impact Assessment: to treat them as GMOs or as conventional products. The use of new genomic techniques is currently incompatible with the concept of organic production in the Regulation (EC) 2018/848 and current consumers' perception of organic products. This was reflected in the concerns of the majority of the organic sector in the impact assessment. Therefore, the former scenario has been chosen. As a consequence, these NGT plants will remain prohibited in organic production. To allow choice at the beginning of the supply chain to support maintaining organic production free from NGTs and preserve consumer trust, in addition to the information in public registries considered in the

impact assessment, an additional measure is proposed: the indication of the use of NGTs in the labelling of seeds. » https://eur-lex.europa.eu/resource.html?uri=cellar:c88fe9ac-1c06-11ee-806b-01aa75ed71a1.0001.02/DOC_1&format=PDF

We recall that the labelling of plant reproductive material does not exist for plants that result from random mutagenesis or cell fusion (GMOs exempted under Directive 2001/18/EC).

12. **Inf'OGM concludes that by "advocating permissive criteria and minimal or even no regulation of GMOs/NGTs, AFBV and WGG relegate to the background .... the precautionary principle, food sovereignty, transparency and easier access to genetic resources, which are fundamental for a fair European construction that protects all".**

To remain factual, our two associations support the proposal for the NTG Regulation proposed by the European Commission, with reasonable adjustments proposed by the Council of the EU and the European Parliament. We have great hope that this proposal will soon be adopted in the Trilogue.

In conclusion, AFBV and WGG are grateful to Inf'OGM for the interest it has shown in our work. Its criticisms have provided us with an opportunity to better explain the reasons for our recommendations.

Philippe Dumont for AFBV and WGG Karlsruhe and Paris, 22 August 2025