

**Comments on amendments voted by**

**the European Parliament on 7 February 2024**

**regarding theEU Commission’s draft NGT Regulation**

**While we believe that the European Parliament's positive vote on the EU Commission’s proposed regulation**

**on plants and products obtained by certain new genomic techniques(NGT) represents a positive step towards the adoption of a regulation allowing the development and marketing of these plants and products, we note that amendments to the draft, if retained in the final text, could lead touncertainties regarding the real possibilities to market such plants and products in the EU. Our close analysis of the amendments voted by the EU Parliament1 lead us to make the following comments regarding those amendments we believe call into question the basic principles of the draft presented by the Commission.**

1. **Prohibition of patentability of NGT plants and products (amendments N°292, 167, 23, 33, 253, 66 and 69)**

Through several amendments, the Parliament voted to ban the patentability of NGT-1 plants and products (aban also extended to plants and products currently exempted from the scope of GMO legislation). In addition, Parliament calls on the Commission, by June 2025 at the latest, to present a report on "the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and, in particular, on opportunities for SMEs ". While AFBV recognizes that industrial property (IP) can lead to difficulties, it is necessary to provide essential innovation protection for inventors while providing access to plant genetic resources for breeders and farmers, even if some actors find that these modalities do not provide all the freedom they want. We believe that a decision on the patentability, or not, of NGT plants and products at EU level should follow the modalities in force in the EU under the Interinstitutional Agreement on Better Law-Making of 12 May 20162. It provides that any proposed legislation requires an impact assessment, stakeholder and public consultation, feedback, and an ex-post evaluation of existing legislation under Section III. It seems to us that the request for a report on the role and impact of these patents is justified and that this report and any proposals it may make should be awaited before any decisions are taken. Thedeadline of June 2025 proposed by the European Parliament or "no later than 31 December 2025" by the Spanish Presidency, could be compatible with the entry into force of the regulation that could take place after June 2026, as the trilogue does not appear to be feasible before the end of the current mandate.

We believe that the above-mentioned amendments should be re-examined taking into account the compromise text prepared by the Spanish Presidency.

1. **Introduction of labelling at NGT product level (amendments N°243, 264 and 265)**

While the Commission's draft provided for labelling of 'plant reproductive material', the Parliament introduced 'New Genomic Techniques' labelling for 'Category 1 NGT plants, products containing or consisting of category 1 NGT plant(s) and plant reproductive material, including for breeding and scientific purposes that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge’. The stated objective is to "ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner". This labelling, based on the technique used, can be considered discriminatory with regard to plants and products with the same traits but obtained by different methods. It does not give any information about the plant or the product itself, only information **about one of the many techniques** that have been used to produce it.

Under the terms of theCommission’s draft proposal, operators and consumers who do not wish to use or consume NGT-1 plants or their products will be able to use plants and products from organic production since the use of NGT-1 plants and their products will not be authorisedwithin the framework of this production. In order to facilitate the activity of those involved in organic production, it is foreseen, in the case of NGT-1 varieties, to label plant reproductive material as ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from. This labeling will allow those involved in organic production to choose the appropriate reproductive material (seeds or seedlings). In addition, information on NGT-1 plants, which have been validated for compliance by the competent authorities, will be available in a publicly accessible database. We believe that these two sources of information -- seed labelling and an accessible database -- provide necessary and sufficient information to all players involved in agricultural productionin addition to consumers.

1. **Annex I criteria (amendments 10, 12, 71, 72, 73, 74, 75, 76 and 78)**

In order to enable a confirmation response to the classification of plants in Category 1, we believe that the criteria in Annex I should be simple, clear and precise and should not lead to the possibility of interpretation by the authorities in charge of such confirmation. Several of the proposed amendments modify the Commission’s initially proposed criteria making them more complex and different, as shown in our comments below.

The Commission’s proposed text for Annex I introduced a limitation to 20 genetic modifications, with each modification meeting one of five proposed criteria. The amendments adopted need to be clarified in order tospecify their scope and avoid any ambiguities. In particular, we have difficulty understanding the following:

* *Amendments Nos 10 and 12* state that reference should be made to the concept of ploidy in order to take account of modifications made by NGTs. We understand that this explanation was added in order to specify that insofar as we would like to limit the number of modifications obtained by NGTs, this number should be calculated for each haploid genome.
* *Amendment No. 71:* In view of the above remark, we do not understand why the reference to the “20 genetic modifications” (per haploid genome) has been removed in this amendment. In addition, criteria 1 to 5 of the original proposal that applied to the 20 modifications (one criterion per modification) have been replaced by conditions 1 and 1a (1 and 1bis in the French translation). Does this mean that the plant must meet all of these conditions to be classified as a category 1? This would be very difficult to achieve technically and unnecessary to obtain the desired traits for an NGT-1 plant.
* *Amendment N°72:* we understand point 1 as allowing for up to three modifications of the coding part of a gene for a given protein. Does this mean that you can modify several proteins in a plant, without limitation, provided that there are no more than three modifications per protein? Does linking with (a) and (b) mean that each change can be made according to (a) or (b)? Note that a deletion of any number of nucleotides can result in more than three changes in the coding part. In the original proposal, (a) and (b) corresponded to criteria 1 and 2.
* *Amendments Nos. 73 and 75:* We understand that Amendment No. 73 (1a(a) and (b)) is intended to replace the text deleted by Amendment 75. Why is it linked to the three modifications of Amendment No. 72? 1a (a) and (b) may relate to sequences broader than the three modifications mentioned in 1. Why limit paragraph (c) tothe1acriteria? In the original proposal, this was an independent criterion (criterion 4). This independence should be maintained.
* *Amendment N°77:* We propose that former criterion 5 of the original proposal be retained as an independent criterion. We understood that this criterion could correspond, for example, to the reproduction of an allele in the NGT plant, which allele has previously been identified in another plant in the breeder's gene pool (for breeding purposes). For us, it corresponds to the ordinary and principal work of the breeder in conventional breeding: the introduction into a plant of a sequence of another plant from the same gene pool.

1. **Sustainability (amendments N°37, 40 and 81) and Annex III criteria (amendments N°81, 82 and 83)**

According to amendments Nos. 37, 40 and 81, in order to be classified in category 1, NGT plants will have to meet sustainability criteria. We recognize that sustainability is an important parameter. This is also one of the pillars of the new proposed PRM regulation3 (see Article 52 of this proposed Regulation). As foreseen in the Commission’s proposal, NGT-1 plants will be treated as conventional varieties which, in order to be included in the variety catalogue, and as such, will have to meet the species-specific sustainability criteria as set out in Article 52 of theproposed PRM Regulation. In addition, the evaluation of sustainability characteristics can only be carried out on varieties tested in the conditions of cultivation and value for agricultural and food use of the species in question. It cannot be done on an NGT-1 plant that does not necessarily have the characteristics of a variety. Finally, the sustainability of a variety or trait of that variety depends on the expression of that trait in its environment and not on the technology used to achieve that trait.

*Amendment No. 82:* Yield is an important parameter for global agriculture. In a context of strong growth in the world population, it will have to increase because the available areas of cultivated land are increasingly limited.One can obtain an increase in yield without necessarily knowing the biological causes for such increase. Associating a yield criterion with one of the other three criteria (2, 3 or 4) creates an additional constraint in that improving one of these other criteria does not always result in a significant increase in yield. This parameter, if deemed necessary for the species in question, must be taken into account when listing a variety, independently of the technology(ies) used to obtain it.

*Amendment No. 83:* We do not understand this amendment. Indeed, Category 7 aims to address traits susceptible of reducing the use of both fertilisers and plant protection products, which constitute an EU target. There can be no contradiction with Part 2 of Annex III because a herbicide tolerance trait will not, in the majority of cases, lead to a reduction in the use of plant protection products. Part 2 deals with the topic of herbicide tolerance regardless of the impact on the reduction or not of the utilization of these products.

1. **Denomination of the variety (amendments Nos. 41, 48 and 52)**

The requirement to provide the denomination of the variety in Articles 6, 7 and 9 will in most cases be impossible to fulfill. Indeed, we understand that the procedures referring to these articles would be carried out, **in the majority of cases**, with an NGT-1 plantand not an NGT-1 *variety*. It is essential to obtain the classification of an NGT plant in Category 1 as soon as the plant has been produced and the data to obtain the classification confirmation will be made available. This NGT-1 plant will then be used to produce NGT-1 varieties through conventional breeding. In addition, the attribution of a varietaldenomination is subject to a legal procedure lasting several months before the acceptance of the denomination between the variety testing authority and the CPVO (Community Plant Variety Office), which gives its approval to the denomination in comparison with denominations already granted, not to mention oppositions that may come from third parties. Such a request would slow down the procedure for the acceptance of the NGT-1 plant. It is also expected that the confirmed NGT-1 plant will receive an identification number that will allow it to be found in the database foreseen under the proposal.

1. **Environmental Effects Monitoring Plan (Amendments Nos. 8 and 260)**

As NGT-1 plants are plants that could occur in the wild or be obtained through conventional breeding, AFBV does not understand why an environmental effects monitoring plan should be put in place systematically. Such a plan, if deemed necessary, should be adapted to the trait(s) introduced, not to the technology used. Where warranted, this monitoring plan should be proposed at the time of variety registration, as is already the case for certain conventionally bred varieties.

1. **Herbicide tolerance (Amendment 18)**

A herbicide tolerance trait is not a unique consequence resulting from the use of NGTs, as this trait can be obtained by other means such as spontaneous mutagenesis, induced mutagenesis or other conventional breeding techniques. This trait should be addressed in the Commission’s proposed PRM regulation3.

1. **Impact on the organic sector (amendment N°241)**

This amendment appears to have been introduced out of concern that NGT-1 plants would limit the development of organic farming. If this were to be the case, Amendments Nos 15 and 34 provide in any event for a review to assess the compatibility of the use of new genomic techniques with the principles of organic production within seven years from the entry into force of the Regulation. It will therefore be possible to review and amend the ban on the use of NGT-1 plants in organic farming.

1. **Definition of the Breeder's gene pool (Amendments 25, 27 and 39)**

We understand that Amendment No 27 changes the original terminology and definition. If this is the case, why has the terminology "Breeder's gene pool" been retained in the majority of cases throughout the text? What is itspurpose? The terminology and definition of Breeder's gene pool used by EFSA in its study dated 30 September 2022 ("Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis") seems to us to be adequate. (EFSA GMO Panel, 2012a, 2022a) - DOI: 10.2903/J.EFSA.2022.7618, p.5.

1. **Disclosure of patent application (amendment 253):**

This information does not appear to us to be necessary to respond to the request for verification of an NGT-1 plant, unless one wishes to use the presence or absence of a patent as a criterion for the qualification of this plant, which does not appear to be relevant, since it is absent from Annex 1.

**Independently of the amendments voted by Parliament on February 7, 2024, AFBV has carefully read the two ANSES reports4 relating to the Commission's NGT proposal and does not see any element or argument in these two documents which is likely to call into question the scientific foundations of the Commission's NGT proposal, drafted on the basis of numerous EFSA opinions. Other European regulatory agencies, notably Belgian5, Dutch6, and German7, also confirm the scientific merits of the Commission's proposal.**

1<https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.html>

2<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016Q0512(01)>

3<https://food.ec.europa.eu/plants/plant-reproductive-material/legislation/future-eu-rules-plant-and-forest-reproductive-material_en>

4<https://www.anses.fr/en/content/ntg-en>

5<https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/20240314_shc-9801_ngt_vweb.pdf>

6<https://cogem.net/app/uploads/2023/11/231124-01-Advice-to-amend-Annex-1-EC-NGT-proposal_ENG.pdf>

7<https://www.zkbs-online.de/ZKBS/SharedDocs/Downloads/Kommentare%20als%20PDF/Stell%20zu%20NGT,%20EU%20Vorschlag_EN.html?nn=14677668>

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