



Brussels, 18 October 2024
(OR. en)

**Interinstitutional File:
2023/0226(COD)**

12514/24
ADD 2

LIMITE

AGRI 584
AGRILEG 351
ENV 809
CODEC 1693
PI 130

CONTRIBUTION

From: General Secretariat of the Council
To: Delegations
Subject: Regulation on new genomic techniques (NGT) – comments from Slovenia

Delegations will find in annex a submission from Slovenia on the above subject, put forward after the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 19 July 2024.

SLOVENIA**Slovenian Statement to the Presidency non-paper****Overall Statement:**

Slovenia expresses its concerns regarding the adoption of the proposal for a Regulation of the European Parliament and of the Council on plants produced by certain new genomic techniques and food and feed products derived therefrom and amending Regulation (EU) 2017/625, which treats organisms of the NGT1 category as equivalent to conventionally produced ones and for which no environmental risk assessment is proposed. Slovenia proposes a simplified risk assessment, which would ensure safety in an appropriate framework, for NGT1 plants and products.

Of particular importance for Slovenia is the regulation of NGT1 plants and products at EU level. In this respect, Slovenia highlights in particular the following important elements:

- respect of the precautionary principle in relation to NGT1 plants and products, both in terms of the benefits and the potential risks they entail;
- comprehensive addressing and establishment of harmonised rules and measures to prevent possible negative impacts of new techniques on human, animal and environmental health, as well as on other production methods;
- preserving the existence of conventional and organic farming (prohibition of the use of NGT seeds and plants in organic farming) and thus preserving sustainable production, food and nutritional safety and the environment, biodiversity;
- ensuring transparency through mandatory labelling of the presence of plants and ensuring traceability for NGT plants and products, thus preserving the basic right of consumers to information and choice;
- clarifying the patentability of the processes of new genomic techniques used to obtain NGT1 plants;
- the scope of implementing acts adopted by the Commission and compliance with international treaties (e.g. Cartagena Protocol on Biosafety to the Convention on Biological Diversity).

Detailed Statements of Slovenia according to the points of the non-paper:

1. Annex I. - Criteria of equivalence of NGT plants to conventional plants

Slovenian position:

An analysis of the type, size and number of mutations is not a reliable and sufficient basis for an equivalence assessment that would allow effective detection and risk management. All available research and the precautionary principle should be taken into account in the development of the criteria.

We consider that equivalence does not imply safety and therefore a simplified risk assessment in the context of the NGT1 verification process also in terms of molecular analysis would be appropriate.

2. Risk assessment for category 1 NGT plants and products

Slovenian position:

We agree that a simplified risk assessment should also be used as part of the verification process and which must cover all possible risks.

Slovenia proposes a compromise to establish an expert body at EU level to monitor NGT applications and to warn of risks if they arise. Particular attention should be paid to NGT 1 plants that may have "weedy" or "invasive" characteristics. For the latter, an environmental part of the risk assessment might be required, as foreseen for NGT 2.

Simplifications could only be accepted if they are based on sound scientific grounds and do not have negative safety implications. It is also acceptable to establish a risk assessment following the ANSES proposal of February 2024 and the molecular characterisation and proteomics proposal.

Please note that systematic monitoring of the implementation of the regulation cannot replace risk assessment, especially in the absence of appropriate analysis methods - if we do not request them at the time of application, we will not have them. It will not be possible to remove plants that are found to be harmful or dangerous post festum. It is an irreversible process, and systemic risks therefore ensuring safety is possible only by prior consideration of the precautionary principle and risk assessment - this applies to the entire NGT1 group, not only to wild plants. The risks of NGT have already been identified in recent research, which must be taken into account.

2.1. Scope of the regulation - wild plant species

Slovenian position:

All plant species, including wild ones, are currently subject to the Regulation. Indeed, the greatest benefit of using NGT technology is seen in agricultural plants. If the Regulation were limited to agricultural plants, Slovenia proposes to include also wild relatives of agricultural plants. Care should be taken that the definition is broad enough to include wild relatives (gene pool) and the possibility of using old varieties/traditional varieties. We suggest that further consideration be given to the use of this technology in invasive plant control measures.

In the light of the above, we further stress the precautionary principle and the need for at least a simplified risk assessment also in relation to interference with natural eco-systems.

Slovenia also wants the proposal to clarify the meaning of wild plants and check their equivalence. Additionally, the issue of patenting wild plants is raised.

3. Labelling of category 1 NGT food and feed products

Slovenian position:

Slovenia is in favour of a ban on the use of NGT in organic production and absolutely supports the labelling of all NGT crops and products throughout the chain, as in addition to ensuring the consumer's right to free and informed choice, such an approach allows for traceability, in particular in relation to the ban on NGT 1 in organic farming.

4. Detection and identification of NGT plants and products

Slovenian position:

Slovenia considers that it is essential to have scientific methods that can be used to detect and identify NGT plants with certainty or certainty before releasing them into the environment. In the absence or unavailability of such a method, Slovenia considers that the release cannot be controlled, which means that traceability, transparency and informed consumer choice cannot be ensured. In case general methods are not known or available to us, it is appropriate to insist on the use of individual methods for all known mutation events. The administrative burden should not and cannot outweigh human health and the protection of the environment and biodiversity.

5. Sustainability

Slovenian position:

Slovenia considers that this issue should be addressed in a broader horizontal approach, e.g. in the announced "Legislative Framework for Sustainable Food Systems".

6. Exports to third countries - equivalence criteria with conventional seeds regarding third countries

Slovenian position:

At this moment, we are still reviewing this data and will provide our opinion later on.

7. The verification procedure (increased administrative burden on Member States and possible effects on operators)

Slovenian position:

Assessment will impose a significant burden on competent national authorities, especially in smaller EU member states. We support the possibility of transferring the verification process to the EU level, also considering time constraints but above all from the point of view of a uniform approach in processing applications.

8. Empowerment of the Commission for adopting delegated acts

Slovenian position:

Slovenia agrees with the Presidency that this issue has not yet been resolved and remains unclear from a legislative perspective. Slovenia believes that essential substantive elements, such as Annex 1, should not be modified through delegated acts.

9. Compliance with the Cartagena Protocol on Biosafety

Slovenian position:

Slovenia expresses its concerns regarding the adoption of the proposal for a Regulation on New Genomic Techniques (NGT), which treats organisms of the NGT1 category as equivalent to conventionally grown ones and there is no proposed environmental risk assessment. NGT 1 organisms could represent a potential conflict with requirements under the Cartagena Protocol, as this compliance has not yet been precisely defined. This could also lead to non-compliance with the international obligations of the EU and the Member States. Slovenia therefore welcomes the evaluation of potential contradictions between Cartagena Protocol and the proposal for a Regulation on NGT. That is why Slovenia supports the preparation of an assessment of the impact of the proposed regulation on the international obligations of the EU and Member States.

10. HR initiative to invite the experts who prepared the studies (notably ANSES, EFSA) to attend the Council's WG meeting.

Slovenian position:

Slovenia supports the Croatian initiative.