



Council of the
European Union

Brussels, 22 July 2024
(OR. en)

12514/24

LIMITE

AGRI 584
AGRILEG 351
ENV 809
CODEC 1693
PI 130

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

CONTRIBUTION

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

Delegations will find in annex submissions from delegations 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.

REGULATION ON NEW GENOMIC TECHNIQUES (NGT)-Presidency non-paper on the main issues (doc. 11820/24)***-Written comments from Croatian delegation-***

The Republic of Croatia recognizes the efforts made by the previous Presidencies in the organization of discussions on the proposal for the Regulation on New Genomic Techniques with the aim to achieve the Council General Approach. However, the legitimate interests of certain Member States have not been fully respected. Consequently, adequate answers on key open issues are still not found and thus not appropriately addressed in the last compromised legal text. In order to protect public interest, our solutions must be of high quality, transparent and science-based, covering agricultural, environmental and health aspects of the Regulation.

Therefore, we welcome the intention of the Hungarian Presidency for different and more comprehensive approach. Presidency non-paper 11820/24 reflects the current situation regarding remaining open issues.

Croatia already emphasized the need to respect and apply the precautionary principle, ensuring fundamental rights in terms of health and environmental protection.

We also reiterate the Member States' right to decide on a possible restriction or ban of the cultivation of NGT plants on their territory. Croatia is declared as GMO-free country. There is a consensus of all relevant national authorities, including Parliament, to remain as such.

Another key issue is related to the consumer's right for free choice as well as to the right to be fully informed about the product they are buying. In this respect, we must ensure adequate labelling and traceability of both categories of NGT products throughout the entire production chain.

The important political question of NGT patent rights is also unsolved yet. Indeed, we have to clarify the compliance of NGT Regulation with international and EU principles of limitations of legal protection and effect of patents in respect of biotechnological inventions. Reinforced restriction of patent protection and effect of patents for certain industrial sub-branch or separate sub-group of products within that branch is not *a priori* foreseen in current framework. In addition, proposed solution is too far complicated, demanding an extensive administrative procedure for farmers and SMEs. It is currently unclear on which scientific studies and EU patent legislation this solution was based upon and what could be the possible impact on investments in the field of biotechnological research of NGT plants in the EU. Commission should prepare an adequate impact study and present all relevant evidence and information related to the NGT patents at the Council Working Party for Intellectual Property.

We agree with the Presidency that the interests and concerns of organic producers have not been adequately addressed. In order to protect the European concept of organic farming, the possibility of Category 1 NGT products being labelled as organic farming should be ruled out. We are in favour of a complete ban on both categories of NGT plants in organic agriculture.

Presidency emphasized several other open questions that we have not discussed at all until now, at least not in a satisfactory manner. For example, they address the problem of available NGT laboratory detection methods, NGT products export to the third countries or possible violation of the provisions of the Cartagena Protocol, on which a written opinion of the Council's Legal Service must be obtained.

Finally, the Republic of Croatia considers that wild plants should be excluded from the scope of this Regulation. Otherwise, due to possible irreversible consequences for ecosystems, a comprehensive risk assessment should be provided, which would be very difficult to implement in the practice.