



30 October 2023

## Joint COCERAL- FEDIOL - FEFAC Position Paper Legislation for plants produced by certain New Genomic Techniques (NGTs)

COCERAL, FEDIOL, and FEFAC welcome a rather well-balanced proposal that acknowledges the potential of NGTs to contribute to the transition to more sustainable food systems. Nevertheless, attention should be paid to avoid trade disruption and preserve farmers and other operators of the feed and food chain from misuse of certain provisions (labelling, co-existence) in a way that would make production, use, and trade of NGT products hardly possible.

### Welcoming the positives

We support several aspects of the European Commission proposal:

- The **predictability and transparency** of the regulatory framework.
- The **clear approval timelines for verification - authorisation** outlined in the proposal including the application/exclusion of the GMO legislation provisions.
- The introduction of **different categories of NGTs based on scientific and technical arguments**. The open definition of conventional-like traits and the establishment of evaluation methods are appreciated steps, promoting a comprehensive understanding of NGTs' potential benefits.
- The risk assessment and **verification-authorization process, which the proposal establishes, is to be conducted by the European Commission with the support of EFSA**, while still allowing for engagement with the Member States as needed.
- The **forward-looking approach** embedded in the legislation, aligning with the future evolution of technology and scientific understanding. Both the criteria proposed are considered open to updates, in what constitutes a “future-proofing” context.
- The **ban of “opt-out”** clauses for the cultivation of NGTs, ensuring a harmonised vision of the role of NGTs in the EU.

### **Aspects for improvement**

At the same time, there are points for improvement for the legislation to meet its goals and stand the test of time.

- **Category 1 NGT plants and their derived products** are considered conventional-like in the proposal and **should therefore not fall under the scope of the EU GM regulations** for any given aspect.
- The proposal should provide **clear rules on ‘negative labelling’** and avoid misuse of information.
- The new regulation should provide clear requirements regarding how the traceability of **Category 2 products for which no detection method is available** can be ensured.
- More clarity should be provided on the scope of measures Member States can take to avoid the unintended presence of NGT plants in conventional products (**co-existence rules<sup>1</sup>**). We are indeed concerned that certain Member States may decide to instate a *de facto* cultivation ban without naming it, by setting the co-existence rules at an unworkable level. This would be in contrast with Art. 25, and incoherent with the legislative proposal, that allows free cultivation of NGTs in the Single Market.
- Alignment with the broader GMO legislation for **technical uses**, which would require Category 2 NGTs for technical uses to be excluded from the provisions for labelling, traceability, and segregation.
- We further call for more clarity on **NGTs in international trade**. Traders need provisions to ensure smooth trade operations in case third export countries adopt a different regulatory framework for NGTs. Flexibility and contingency plans should form an integral part of the proposal.
- Finally, **excluding considerations** for the sole scope of the **organic production**. We agree on the Draft Report by the Rapporteur’s amendment. In addition, **delivering clarity on GMO-related concepts** and definitions, would improve the understanding, and hence the implementation of the law.

Please note that we remain committed to engaging constructively during the legislative process to achieve the goals outlined above and welcome suggestions for improvement.

Attached is an Annex that provides an explanation of the aspects we have outlined for improvement.

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<sup>1</sup> **Art. 24. Measures to avoid the unintended presence of category 2 NGT plants**

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

## **ANNEX**

### **Exclusion of Category 1 from GMO considerations**

Category 1 NGT varieties and Category 1 NGT products must be regulated and perceived as conventional-like ones. Hence, there is a need for the deletion of any reference to GMOs. This would ensure predictability and legal certainty for all different actors across the supply chain. Category 1 NGT plants and their derived products should not be considered GMO within the scope of the GMO Directive and thus, subject to any obligation for labelling and traceability.

### **Transparency and risk of negative labelling**

Our associations support provisions intended to enhance transparency in the regulatory process and along the supply chain. However, transparency should relate to relevant and factual information that is in line with EU-wide harmonised provisions on food labelling and information to consumer.

Category 1 NGT varieties and Category 1 NGT products are proposed to be considered as conventional-like in the current proposed regulation legislation. Hence, the rules for labelling of food and feed products should comply with EU legislation on Food Information to Consumer. Food information shall not be misleading, including about the presence or absence of specific attributes when all similar products possess such characteristics.

### **Considerations for Category 2 varieties with no detection methods available**

If, for some Category 2 NGT varieties, detection methods are not available, Food & Feed Business Operators (FBOs) could face potentially adverse consequences for both EU and international trade. Unintentional presence in conventional supply chains with Category 2 NGT varieties at low levels may happen. The resulting presence of what is legally and technically considered a GMO, but with no detectability in place, would leave the traders and the middle-of-the-food chain operators bearing the risk of potential compliance issues and the authorities with no tools for enforcing the regulation.

### **Coexistence plans should ensure real freedom of cultivation**

In contrast with the GMO legislation, where the Member States can lawfully impede GMO cultivation on their territory, in the current draft law Category 2 NGT cultivation cannot be restricted to any possible extent (art. 25).

However, a *de facto* ban could arise from the implementation of 27 different coexistence plans, impeding in practice the cultivation. While it is important to implement measures guaranteeing the freedom of cultivation (art. 24), hence avoiding the unintended presence of Category 2 NGTs, any indiscriminate restrictions should not be possible. This could lead to internal market disruption and disturbance to Food Business Operators' activities. Specific provisions should be in place to prevent it. Furthermore, Category 2 NGTs are considered non-GMO for the opt-out ban (art. 25), but GMO for coexistence purposes (art. 24). This contradiction must be fixed to have rules easily implementable and deliver certainty of the law for all the Food Business Operators.

### **Regulatory Consistency for technical uses (non-food/non-feed products)**

For Category 2 NGT plants and products, the Regulation sets requirements for both food and feed and for products other than food and feed. This is inconsistent with the GMO regulation

that does not include requirements for the marketing of products other than food and feed derived from GMO. It is unclear why such a deviation has been proposed, which could cause an additional burden for the imports and use of such products.

### **Clarity on NGTs dimension of international trade**

With the proposal, NGTs could formally still be considered GMOs in Europe and conventional in third countries. This seems a delicate, asymmetric situation not playing in the interest of continued and uninterrupted supply of food and feed. This regulatory gap must be addressed with contingency measures to avoid trade disruption. Flexibility should become an inbuilt feature of the EU legislation, to stabilise the markets and guarantee safe food and feed delivery. International databases or public-private registers to monitor NGTs market release could be an option, bearing in mind that if NGTs are considered conventional in third countries, they will not be reflected in the register.

### **Considerations for Organic Production**

Organic production considerations should be left outside the scope of the current legislation as a matter of clarity for operators and of consistency with existing legislation. Indeed, this is in line with the current organic legislation, where it is the specific organic regulation that determines the methods and techniques that are allowed for use (for example which pesticides or which feed & food additives may be used)

### **Regulatory consistency with existing legislation**

**GMO definition:** The combination of the existing GMO legislation, with a new *lex specialis*, makes the framework difficult to understand and implement. The Commission Study (2021) stressed the need to better define some concepts referring to the GMO definition, including mutagenesis, long safety history, the role of use, the role of the process vs. the end-product, and how to frame emerging breeding techniques. We regret that this has not been done and, quoting the Commission Study (2021), “*developments in biotechnology, combined with a lack of definitions (or clarity as to the meaning) of key terms, are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty.*”

**COCERAL is the European association of trade in cereals, oilseeds, pulses, olive oil, oils and fats, animal feed and agrosupply.** It represents the interest of the European collectors, traders, importers, exporters and port silo storekeepers of the above-mentioned agricultural products. COCERAL's direct members are located in 14 EU countries, with one European association, Unistock representing the professional portside storekeepers for agribulk commodities within the EU and one associated member in Switzerland. With about 3,000 companies as part of COCERAL national members, the sector trades agricultural raw materials destined to the supply of the food and feed chains, as well as for technical and energy uses. Gafta is an extraordinary member of COCERAL.

**FEDIOL, the EU vegetable oil and protein meal industry association,** represents the interests of the European oilseed crushers, vegetable oil refiners and bottlers. FEDIOL members are 10 national associations and associated company members in 7 other EU countries. With about 180 facilities in Europe, the sector provides 20,000 direct employments. Its members process approximately 55 million tonnes of basic products a year, both of EU origin and imported from third country markets. The sector processes notably rapeseed, sunflower seed, soybeans and linseed into oils and meals for food, feed, technical and energy uses essentially on the European market.

**FEFAC, the European Compound Feed Manufacturers' Federation,** represents 21 national Associations in 21 EU Member States as well as Associate members in Norway, Switzerland, Turkey and United Kingdom. The European compound feed industry employs over 100,000 persons on app. 3,500 production sites often in rural areas, which offer few employment opportunities.