



Dear Commissioner Kyriakides, Dear Commissioner Wojciechowski,

IFOAM Organics Europe and the European Non-GMO Industry Association (ENGA) call on you to ensure that the upcoming impact assessment on potential future legislation on "New Genomic Techniques" (NGTs) fully takes into account the impact of changes in the legal framework on the non-GMO farming and food sectors, and the impact of the enforcement of patents on products derived from these new technologies. Any new legal framework needs to ensure the co-existence for breeders, farmers, feed and food producers, and the retail sector. Mandatory traceability and GMO labelling all along the production chain is an indispensable requirement for this, to ensure transparency and freedom of choice both for all business operators and for consumers, as well as to ensure that breeders, farmers, and the European model of innovation in breeding, are not threatened by abuses of the patent system by the owners of intellectual property rights on NGTs.

We appreciate the commitment of DG SANTE to enter into dialogue with a broad spectrum of voices and include the range of concerns that were raised during the inception impact assessment, the public consultation as well as the targeted survey as stated in the <u>Public Consultation Factual Summary Report</u>. Among other things, the summary report names diverse points that were raised regarding issues of co-existence and states that "co-existence measures should benefit all levels of agriculture, especially for organic farming; measures safeguarding co-existence should be strengthened at the EU level, e.g. labelling, traceability, seed purity, and protection against contamination".

We are concerned that the new legislative proposal potentially creates a tremendous conflict of goals with the Farm to Fork strategy goal to expand GMO-free, organic farming to 25% by 2030, as it may abolish the basis for GMO-free agriculture in the EU. In addition, this would have impacts far beyond the organic and non-GMO production chains, as the whole conventional EU food sector would be affected. In Germany alone, for example, the explicit non-GMO producing food and feed sectors have an annual turnover of nearly 30 billion euros: While the organic market represents a 15 billion euros turnover, sales of conventional GMO-free food products reach more than 14 billion euros. And hundred of thousands of farmers across Europe want to be able to use seeds that have not been modified through NGTs. The question of co-existence is essential for the entire future EU agriculture and food and feed production and must be a focal point in the impact assessment and legal proposal.

This is crucial since the economic impacts of a lighter regulatory framework that does not fully guarantee co-existence will be significant. While difficult to quantify, we foresee substantial economic losses in a variety of aspects. First, consumers' trust in organic and conventional GMO-free products of course depends on the ability of producers to fully guarantee that no GMOs have been used in the production process.

The organic and conventional non-GM supply chains have to live up to thorough and complex quality standards and clearly stated consumer expectations. A loss of consumer trust would undoubtedly threaten sales of such products, which are already impacted by the context of inflation. Secondly, a lack of regulatory safeguards is likely to lead to frequent cases of contamination of both organic and conventional products, which can occur at various stages of the supply chain from breeding to processing. The contaminated products then will loose their premium or have to be discarded, both of which can have high costs for non-GMO supply chain actors.

Thirdly, in case of a lack of sufficient co-existence provisions, the burden of proof and measures for GM-free production would fall on the organic and GMO-free sectors, making it very costly for operators and threatening the competitiveness of these products on the market.

With 20 years of experience, a traceability system for products of genetic engineering is a well-established legal and operational standard and a basic requirement of European consumers for food production in the XXIst century. In case analytical detection methods for NGTs might not available, traceability alone will suffice for a transparent labelling of NGT products. On the other hand, exempting some NGTs from traceability and labelling would thoroughly undermine consumers' trust. It would also have negative economic impacts on a whole range of farmers and business operators in the food market.

Another matter that should be thoroughly considered in the impact assessment is the impact of the NGT regulation on the issue of patents. The mandatory traceability system established by the current legislation on GMOs allows for clear identification and information on whether a given genetic material or product falls within the scope of a patent claim. This allows breeders and farmers to avoid using such material, and therefore be protected from legal threats related to patent infringements, or from paying royalties to patent owners.

Reports show that exempting plant or animal genetic material protected by a patent from traceability would expose all actors in the food supply chain, to significant legal uncertainty as to what they can or cannot do with the plants and animals they work with on a daily basis, and access to plant breeding material might be significantly restricted. This is a threat to the European model of innovation in the breeding sector, which relies on lighter forms of intellectual property rights that allow the circulation of genetic material, and this will lead to a harmful concentration in the seed sector.

Lastly, we would like to point out that there were repeated and multiple criticisms about how the inception impact assessment, targeted survey, and public consultations were led, among other things due to their inadequate standards and intransparency (see the critique in more detail in the-joint letter, signed by 40 national and European organizations in October 2022, and this letter that was sent by the European Non-GMO Industry Association to DG Sante in August 2022).

In this context, we therefore urgently ask the Commission to reassess the impact assessment and make sure that it is based on comprehensive economic and scientifically sound analyses as well as transparency. The impact assessment must take into account essential topics like co-existence and traceability, in view of the tremendous economic impact that a lighter regulatory framework would have especially on organic and conventional GMO-free production, as well as on food and breeding sovereignty.

We would be grateful to discuss these issues in a meeting with you before the publication of the impact assessment.

The organic food and farming movement and the conventional non-GMO sector count on your support.

Yours sincerely,

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