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Ms Stella Kyriakides, Commissioner for Health and Food Safety

Copy to: Mr Frans Timmermans, European Commission Executive Vice-President for the European Green Deal, Mr Janusz Wojciechowski, Commissioner for Agriculture, Mr Virginijus Sinkevicius, Commissioner for Environment, Oceans and Fisheries

*By electronic email*

Brussels, 9 September 2021

**Your letter of 29 June 2021 regarding the Retailers´ Resolution Against Deregulating New GMOs**

Dear Commissioner Kyriakides,

I would like to thank you for your letter of 29 June 2021, providing answers to many critical issues and severe worries expressed in the Retailers' Resolution from 25 May 2021 that is being supported by a large and still growing number of major representatives of the European retail sector.

Unfortunately, your letter does not help dispel the concerns on our side (i.e. ENGA – as the representative and joint voice of the dynamically expanding European Non-GMO industry), nor on the side of many players from the European food sector.

Having carefully read your response, the EC study on NGTs and its accompanying documents, we are very concerned that the only conclusion seems to be that the Commission will aim to lower existing safety and transparency standards for new GMOs. For us, this leaves no other interpretation than that the Commission is set on a course of exempting new GMOs to a large extent from the current EU GMO legislation. The term deregulation seems appropriate to us after assessing all written and oral explanations by the Commission.

We therefore want to outline once more in full clarity that the European food sector, above all the retail sector, is responsible and liable for all products it produces and sells – towards the full value chain as well as towards consumers. Therefore, European food producers and retailers are reliant on a thorough and credible food safety risk assessment for *all* GMOs (new GMOs as well as old GMOs), without any gaps and any exemptions.

Full transparency and freedom of choice are indispensable to be able to fulfill the commitment retailers and food producers have towards consumers. This is especially valid for old and new GMOs! As you are fully aware from many opinion polls, a vast majority of European consumers clearly reject GMOs in food products and demand for GMO labelling.[1] Transparency, labelling and traceability of any GMO therefore are a clear obligation towards customers.

[1] https://www.greens-efa.eu/en/article/news/opinion-poll-on-the-labelling-of-gm-crops

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**1. There is clear evidence in EC documents of a planned lowering of existing GMO safety standards for new GMOs.**

In your response to the Retailers' Resolution you outline that the European Commission is envisaging policy action on plants derived from targeted mutagenesis and cisgenesis, and that the policy action will aim at a proportionate regulatory oversight. In its letter to the Portuguese presidency the Commission explains what this means: adapting the risk assessment and authorisation procedures and the requirements for labelling and traceability.

The letter to the Portuguese presidency also states: „As concluded by the European Food Safety Agency (EFSA), plant products with similar risk profiles can be obtained with conventional breeding techniques, targeted mutagenesis and cisgenesis. Thus, a different regulatory oversight for similar products would not be justified in these cases."

In our understanding this is a clear confirmation that the Commission in fact suggests that products derived from targeted mutagenesis and cisgenesis shall be treated like those derived from conventional breeding techniques. As a logical consequence in a future GMO legislation, the precautionary principle would not be applied any more for plants produced with targeted mutagenesis and cisgenesis techniques. Thus, risk assessment and authorisation procedures would not be seen as compulsory, nor would labelling and traceability requirements.

In our perspective this is a clear proof that a large-scale deregulation of new GMOs is the key target of the Commission.

In your response to the Retailers' Resolution you mention that NGTs are a diverse group of techniques that can achieve different results; therefore it is stated that a case-by-case risk assessment and more flexibility in the legal framework would be needed. However, for ENGA and many of our partners in retail and food production it remains unclear what the Commission concretely means with a case-by-case risk assessment.

- Does this mean that a risk assessment has to be carried out for each individual NGT plant?
- Or – following the EFSA opinion on similar risk profiles of targeted mutagenesis, cisgenesis and conventional breeding – does this mean that whole groups of plants (those produced with mutagenesis and cisgenesis techniques) can be excluded from a risk assessment?
- It also remains unclear how the concrete starting point for a case-by-case risk assessment will be defined. The terms mentioned in your letter are „results" and „outcomes" – does this suggest that a case-by-case risk assessment will be triggered by NGT products and their properties and not by the process applied to produce them, i.e. the NGT technique used?

What is needed from our perspective is a thorough and transparent risk assessment specific to *all* NGT products. NGT products do not have a long history of safe use (or not even a history of use, with currently three products on the market). There is hardly any practical experience in day-to-day business with new GMOs, that is under real-life conditions - neither concerning environmental aspects, nor impacts on the food value chain.

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Up to now the safety of NGT products primarily is a mere claim, not substantiated through systematic studies.

However, already at this very early stage of analysing the safety aspects of NGTs, there are numerous studies showing unwanted changes both at the target site and on off-target sites. To maintain the high level of protection for human and animal health and the environment, as envisaged by the Commission, we propose to thoroughly assess the findings in a recently published study from experts of various national safety authorities. Their „Considerations for a Focused Case-Specific Risk Assessment in the EU" paint a very differentiated picture for a method as well as trait related risk assessment for NGTs.[2] In our opinion it is indispensable that this study receives very close attention before any further steps taken on this matter.

**2. When assessing the documents provided by the EC until now, we miss any statement supporting the need of GMO labelling and comprehensive information to consumers. Furthermore, there is no indication that and how coexistence between an agriculture and a food system with and without GMOs will be ensured in the future.**

The only mentions of these highly relevant issues we managed to detect in the Commission's documents including your letter read „The impact assessment will look at (…) coexistence with non GMO and organic sectors and information to consumers (…)." This is far from being a reliable commitment that coexistence and labelling requirements will be considered and maintained. Please understand that this is highly worrying for all players within the Non-GMO value chain (from breeders to farmers to food producers to retail), as well as for consumers who want to have freedom of choice for GMO-free food. Without strict and comprehensive coexistence and labelling rules a Non-GMO agriculture and food system is impossible.

From our perspective there are two clear commitments expected from the Commission:

- labelling and traceability for *all* new GMOs have to be mandatory;
- coexistence between agriculture and food production with and without GMOs have to remain guaranteed, for the conventional as well as for the organic sector.

**3. In the EC documents we witness a consideration of hypothetical plants which serve as a justification for the intention of lowering or even abolishing the current GMO safety and transparency standards for new GMOs.**

The Commission stresses the potential of new GMOs to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and the Farm to Fork Strategy.

We would like to remind the Commission that with only three NGT crops[3] worldwide on the market until now new GMOs are rather promises than a reality. Whether their potential will ever materialize is an open question.

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[2] https://www.mdpi.com/2673-6284/10/3/10

[3] A herbicide resistant canola, developed by the US company Cibus and cultivated in Canada and the US; a soybean with an altered fatty acid profile, developed by the US company Calyxt and cultivated in the US; Sanatech Seeds' (Japan) Crispr/Cas GABA tomato, provided to about 5.000 Japanese home-gardeners free-of-charge.

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As you are aware the first ever cultivated NGT crop, a canola, developed by the Cibus company and grown in the US and in Canada, is herbicide-resistant (oddly enough not listed in the EC study, despite the fact that EFSA confirms its GMO status) and the first EU authorisation application for a NGT crop is Corteva's herbicide resistant, insecticides producing Crispr/Cas maize. In both cases a NGT has been used to produce a plant with exactly the same traits which constitute old GMOs.

We do not believe that the EC considers a crop tolerating sulfonylurea and imidazolinone herbicides (Cibus´canola) and a glufosinate resistent crop that is producing an insecticide in each cell (Corteva´s maize) as a contribution to a sustainable agriculture in line with the objectives of the European Green deal and its aim to reduce the use of chemical pesticides by 50 percent till 2030.

What is needed from our perspective is a holistic approach: the resilience and diversity of agricultural systems, not the fixation on plant genomes. A good condition of the entire agricultural ecosystem is far more important for long-term stable harvests than isolated, genetically engineered DNA segments. The preservation of biodiversity is far better served by moving away from monocultures and maintaining healthy soils than by new and highly controversial high-tech experiments such as NGTs and NGT products.

**4. In the EC documents we see an overemphasis of implementation challenges, i.e. the current lack of detection methods and traceability for new GMOs.**

We agree that there are significant implementation challenges. But we also see that they can be overcome, assuming the necessary political will.

In recent years hardly any research has been done in the fields of detection, identification and quantification of NGT crops. The EC study reports that national funding for detection methods, risk assessment and monitoring has amounted to 1.6% of the total research funding for NGTs.

We at ENGA, but also significant parts of the European retail and food production business, have the clear expectation that the Commission takes its responsibility of overcoming implementation challenges. We therefore call upon the Commission:

- To support EU member states to protect their markets against non-authorized GMOs. Instead of leaving it to individual member states to develop detection methods for NGT plants we are convinced that the EC needs to act as a coordinating body and takes full responsibility for progress in this highly relevant matter. This includes the responsibility for providing necessary budgets and research capacities at EU level, and to coordinate all relevant endeavors in an efficient manner.
- To award a contract to the European Network of GMO Laboratories (ENGL) to develop testing methods for each of the NGT plants already on the market and/or to initiate calls for tender in suitable research programs. An essential part of this

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research needs to focus on detection of the individual technology used to create a NGT product, for example CRISPR/Cas, TALENs, ODM.

- To advocate at international level for a global transparency register that includes all GMOs worldwide, both old and new.

Should detection for some of the NGT products or technologies not be feasible, we want to remind the Commission that several highly successful global product segments completely rely on traceability through documentation. Among others, this applies for products from fair trade, from organic farming or from free-range egg production. In these production areas, traceability systems guarantee full transparency and freedom of choice for consumers as well as for all participants within the full value chain.

In conclusion, we would like to state with all sobriety: Hypothetical crops – products that do not exist, have not yet proven their safety and have not yet contributed to a healthy, climate-friendly, sustainable agri-food system – definitely do not justify an attempt of lowering existing GMO food safety standards and labelling and traceability requirements. From our point of view, it is not justified to overrule a legislation that has been working well for more than 15 years and to ignore the very precise ruling of the European Court of Justice of 25 July 2018.

We would be pleased to discuss these issues in a meeting with you.

Yours sincerely,