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DG SANTE, Unit E3 Biotechnology
Danish Chamber of Commerce

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The Danish Chamber of Commerce's response to DG SANTE - Legislation for plants produced by certain new genomic techniques

The Danish Chamber of Commerce (Dansk Erhverv) believe that the Commission is right in considering the current legislative framework unfit for purpose considering the European Court of Justice's ruling (C-528/18) due to the significant advances in gene-editing technologies since the entry into force of directive 2001/18/EC (the GMO Directive). These developments mean that consumers who want to avoid GMO products cannot currently be guaranteed this, as the detecting technologies are not in place. Furthermore, the legal restrictions imposed on the biotechnology sector will be detrimental to the sectors prospects in Europe, while only lead to a leakage of the sector to other parts of the world. Furthermore, biotechnology is identified as a key enabling technology by the Commission in the EU Green Deal and Farm to Fork. Therefore, a modernization and update og the regulatory framework is urgent.

Data requirements for micro-organisms

The Commission has put forward a limited and targeted review of the GMO directive, with a view to only consider plants due to a lack of data on microorganisms. The Commission and the JRC should specify the type and amount of data needed by the industry in order for the Commission and JRC to conduct a thorough evaluation so the Commission can come with a legislative proposal for micro-organisms as well. Without any policy action on microorganisms, these will remain subject to the current GMO legal framework while development and application in other parts of the world will continue rapidly.

Risk assessment

The current legal framework treats all gene-editing treatments developed after 2001 collectively, without reference to the potential risks (or benefits) such changes may cause to an organism. At the same time, exceptions for legacy methods are allowed, although these may cause greater changes to an organism's genome. This approach is neither appropriate nor proportional to the actual changes or risk assessment of an organism. Risk assessment should be based on a scale of risk and be proportionate to the changes of characteristics of organism, rather than only on the process used, as is currently the case.

Innovation

The current risk assessments are process-based, we believe they should be product-based. A process-based risk assessment is neither conducive to research and development in the field, nor to

the protection of humans or nature. It furthermore limits the potential for start-ups and SMEs to enter the field with innovations.

It is crucial that EU regulation does not put undue burdens on innovation in the biotech sector, which as a key enabling sector has enormous potential in providing solutions in diverse fields such as human health and medicines development (including covid-19 vaccines), biological alternatives to chemical pesticides, alternative proteins, plants resistant to effects of climate change and industrial uses.

Fair Competition
Diverging global approaches to NGT technologies, which can modify genomes in a way that is indistinguishable from the processes occurring in nature, will put Europe at a disadvantage. European food companies could be forced to label one product as GMO while a similar product from a 3rd country might not be subject to such a requirement – despite them being similar. Due to the lack of testing methodologies, it can be very hard to find out, whether a product from a 3rd country is GMO.

For the biotech industry, the differing regulatory regimes mean that a high-value sector which can help achieve many of the EU's high goals in the Green Deal, the Farm to Fork and Biodiversity strategy, are likely to relocate to areas with more favourable regulatory regimes, thus leading to a brain-drain and a technology-leakage.

Proper and trustworthy labelling
Consumers have the right to choose the products they want.
Verifiable, correct, meaningful, and trustworthy labelling is an imperative for consumer choices and trust in NGT technologies. We therefor believe that the existing rules and criteria for GMO-labelling should be maintained.

In the case of imports into the EU, we believe as is the case in the food supply chain in general, that it is the importer who bears responsibility that the products comply with EU-rules, and therefore must verify the veracity of GMO/non-GMO claims on food products.

Best regards

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