AISR
Alianța Industriei Semințelor din România

European Commission
Directorate General for Health and Food Safety (DG SANTE)
TO : Director Ms Sabine Juelicher
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Ref:ECJ ruling C-528/16 and consequences for the seed sector; request for change of Directive 2001/18

Dear Ms Juelicher

We would like to come back to the ruling of the European Court of Justice in Case C-528/16 on the regulatory status of plants resulting from mutagenesis. This ruling has major implications for innovations in plant breeding and with that agriculture and food production in view of our major challenges like climate change and sustainability of our production systems.

Plant breeding is dependent on natural or induced genetic diversity as the basis for the adaptation of our crops and vegetables to changing environmental conditions and agricultural as well as societal needs. Random mutagenesis techniques with chemicals or radiation are used to increase genetic diversity since almost 80 years. The latest innovations can induce the exact same genetic changes by a more targeted and efficient approach. These innovations comprise methods like Crispr or TALEN, also summarized by the term genome editing. The plants resulting from these techniques are in most cases indistinguishable from those resulting from random mutagenesis. In view of the regulatory status of these plants, the breeding sector developed the following position that reflects the genetic modification introduced in the plants and its distinguishability from natural occurring genetic changes.

We believe that **those plant varieties developed through the latest breeding methods should not be subject to different or additional regulations if they could also have been produced through earlier breeding methods or by natural processes without human intervention. We underline that this position is not only broadly shared by scientists and experts but also increasingly adopted as principle regulatory approach by countries around the world.**

In contrast to the opinion of Advocate General Bobek in the above-mentioned case, the ECJ comprised all plants resulting from mutagenesis techniques to falling under the GMO definition of Directive 2001/18 and excluded only those from the obligations of the Directive and related regulatory framework that have conventionally been used in a number of applications and have a long safety record.

This has led to the situation **that two genetically identical plants**, one resulting from conventional mutagenesis, the other from new forms of targeted mutagenesis **might fall under different regulatory regimes and requirements**. In our view this raises several fundamental questions and concerns as follows:

1) EU Compliance with the living modified organism definition in the Cartagena Protocol:

a) The inclusion of classical mutagenesis in the GMO definition of Directive 2001/18 is inconsistent with related EU law that was implemented after the EU has ratified the Cartagena Protocol on 27 August 2002 and transposed into European law by Regulation 1946/2003 / EC dated 15 July 2003. In the context of this transposition, the Commission adopted Regulation 1829/2003/EC dated 22 September 2003 on genetically modified food and feed, and on the same day, Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. In the case of these three Regulations, the Commission considered it necessary, following the ratification of the Protocol, to define a GMO in the following way:

'Genetically modified organism' or 'GMO' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;

In the definition of a "living modified organism" (LMO) under the Cartagena Protocol, "techniques used in traditional breeding and selection" are not part of "modern biotechnology" and as such organisms obtained by mutagenesis techniques using chemical agents or irradiation are not GMOs, which logically would explain why mutagenic organisms were deliberately excluded from the definition of a GMO in the three Regulations mentioned above. By putting the respective organisms under the GMO definition of Directive 2001/18 the ECJ seems to ignore the obligations of the **EU as contracting partner of the Cartagena protocol.**

b) In Paragraph 2 of Article 2 of the Cartagena Act, a "Living Modified Organism" (LMO) is defined as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

With that the LMO definition clearly considers the process (modern biotechnology) and the outcome/product "possesses a novel combination of genetic material". Both requirements need to be fulfilled to subject an organism to biotechnology regulations. This was also the approach Advocate General Bobek considered in its opinion. In contrast to that the ECJ interprets the GMO definition of Directive 2001/18 in a purely process oriented manner. The ECJ therefore concludes that organisms obtained by new means of targeted mutagenesis must considered to be GMOs as defined in article 2(2) of the GMO Directive.

With that Dir 2001/18 seems to conflict with the LMO definition of the Cartagena protocol that requires besides the application of modern biotechnology also the **presence of a novel combination of genetic material in a living organism**. This is not the case for targeted mutagenesis applications where the only genetic change constitutes a mutation in the organism's intrinsic nucleic acid (no novel combination of genetic material). Countries like Argentina, Chile, Brazil and Colombia as well as Japan clearly regard the LMO definition in the Cartagena protocol as a basis for excluding products resulting from targeted mutagenesis from their biotechnology regulation and with that come to the conclusion that respective products are not covered by their respective biotechnology regulations.

As already stated by the JRC in its report from 2012 and as confirmed by the Scientific Advice Mechanism (SAM) in its Explanatory Note from 2017 as well as the recent Statement of the SAM, putting organisms resulting from latest forms of mutagenesis methods that are genetically identical to organisms resulting from conventional mutagenesis results in problems regarding their detectability and distinguishability. Without prior knowledge a detection of similar genetic changes is difficult and their distinguishability by breeding method impossible.

Also, subjecting genetically identical organisms to different regulatory requirements seems to infringe the principle of proportionality and non-discrimination.

These fundamental legal and technical problems regarding enforcement of the Directive 2001/18 and related law make it impossible for regulators and developers to comply with requirements regarding the prevention of adventitious presence and respective thresholds in view of international trade, but also cultivation in the field and possible outcrossing. Also, if it would come to applications for approval of these kinds of organisms as GMOs, the developer would not be able to provide a unique identifier that allows a doubtless distinguishability of the product in view of its breeding methods.

Since these fundamental problems cannot be solved by technology development, but instead make the regulatory system unworkable for the latest plant breeding innovations, we ask Commission to urgently work together with member states to provide a science based and workable regulatory framework that is compliant with international regulatory requirements and obligations and takes into account the above-mentioned considerations.

We are of the opinion that this change can most efficiently and effectively be achieved by a targeted amendment of Directive 2001/18 that excludes products of old and new mutagenesis breeding from its definition and adapts Annex IB accordingly. This will align the EU's policy and rules with those established and being developed in the rest of the world; it will also create legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis.

We also already addressed the issue also with the responsible representatives of our national authorities: Agricultural Ministry, Sub state secretary [redacted] General director [redacted] General Direction of Agricultural Politics, [redacted] National Inspection for Seed Quality.

Kind regards,

[redacted]

Romanian Seed Industry Alliance

ALIANTA INDUSTRIEI SEMINTELOR DIN ROMANIA (AISR)

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