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European Commission
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Open Letter to Commission President Juncker, Commissioner for Health Andriukaitis, Commissioner for Agriculture Hogan, Commissioner for Research, Science and Innovation Moedas, and Commissioner for Jobs, Growth, Investment and Competitiveness Katainen

Proposals for (1) a coherent interpretation of the GMO definition of EU Directive 2001/18/EC, (2) designation of an EU authority for GMO status determination and (3) engagement in discussions with agricultural exporters and importers to harmonize the regulatory status of plants derived from genome-editing technologies

Dear President Juncker, Dear Commissioners,

A case before the European Court of Justice numbered C-528/16, resulting from a court initiative in France by several non-governmental organisations to determine the regulatory status of plants derived from techniques of mutagenesis, has put on hold all European initiatives ongoing since 2008 to determine the regulatory status of plants derived from so called "new breeding techniques". While the decision of the European Court due July 25 should clarify the status of certain plants obtained using techniques that cause genome editing, it will not provide answers to other long outstanding questions (because not raised before the court) of the research and development community in Europe involved in plant breeding.

In 2018 countries such as the United States (USDA) and Brazil (CTNBio) made regulatory decisions and provided guidance regarding specific categories of plants derived from genome-editing technologies. The first plant product derived from genome-editing technologies, high oleic soybean oil, is expected to be launched in the United States this year by Calyxt, Inc., the U.S. affiliate of Cellectis S.A., a *French* life sciences company which has pioneered genome-editing technologies.

By this letter, **we suggest that three actions could be quickly taken to enable Europe through its public and private sectors to place itself again at the forefront of plant breeding innovation**, in the interest of consumers, farmers, the environment and industry. This is particularly important because it is estimated that the combination of genome-editing technologies and artificial intelligence will boost innovation in biology in all areas, providing significant growth and economic advantage to countries willing to invest. Europe has the capabilities to be engaged and should not be denied such opportunity through collective inaction.

<u>First Proposed Action</u>: in as far as the ECJ will in its ruling not provide a further interpretation of the GMO definition under Article 2, paragraph 2 of EU Directive EC 2001/18, adopt a coherent and concise interpretation as follows[1]:

"genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" *obtained at least through a technique listed in Annex IA, Part I, involving the incorporation in the resulting organism of a new combination of genetic material that cannot occur naturally*." The words in italics qualify the language of Article 2, paragraph 2 of the Directive in accordance with the current written wording of the Directive.

Moreover, it would appear possible and in conformity with the powers of the Commission to adopt this interpretation, without the necessity to seek an amendment. As part of adopting our proposed interpretation, the Commission could clarify the following determinations[2] regarding plants obtained by modern genetic engineering, but which either cannot be considered as GMOs because they do not contain a new combination of genetic material that cannot occur naturally, or because they fall under the exemption of part 1B of the Directive:

(i) Null segregants – these are progeny of genetically engineered plants from which the GMO feature has been eliminated by crossing;

(ii) Organisms which have undergone deletions of any size

(iii) Organisms which have undergone a substitution of a single pair of nucleotides (i.e. a mutation) or an insertion of less than 20 base pairs

(iv) Cisgenic organisms (incorporating a native gene or a gene from a sexually compatible species, in each case with the gene in its natural orientation)

As is the case of a similar interpretation by USDA on 28 March 2018 and announced through a press release, such an interpretation by the Commission could be accompanied by explanatory and educational communications targeting all interested stakeholders, including researchers, growers, consumers and industry.

[1] This concise interpretation would also be consistent with the Cartagena protocol definition of Living Modified Organism ("LMO"): "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology"; "Modern biotechnology" means the application of "a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."

[2] Our recommendation is in conformity with that of EASAC which in July 2015 asked "EU regulators confirm that the products of New Breeding Techniques, when they do not contain foreign DNA, do not fall within the scope of GMO legislation, consistent with the advice of the "New Techniques" expert working group (Podevin et al 2012) and other expert groups (for example ACRE 2013)".

<u>Second Proposed Action</u>: identify, similar to the approach taken elsewhere in the world, which authority would be capable of verifying individual cases for conformity with exclusions or exemptions under the terms of the directive, with respect to the categories of plants referred to above, at what stage of research or development, and on the basis of which criteria.

Currently, applicants for a field trial under EU Directive 2001/18/EC address their questions to the competent authority of the Member State in which a field trial is intended to occur. However, as the determination that needs to be made (exclusion, exemption or inclusion under the 'GMO' definition) has impact throughout Europe, we suggest a European authority be identified to address determination requests, it being understood that it would need resources to be able to make determinations expediently (e.g., within 90 days). Data requirements for status determinations should be proportionate and reasonable, consistent with those requested by other countries, so as not to inhibit public sector and small private companies from engaging in this field.

<u>Third Proposed Action</u>: begin discussions with the competent authorities of agricultural export and import countries in order to harmonize the regulatory status of genome-edited plants to facilitate inter-country movements.

In conclusion, the signatories of this letter believe that Europe must not forego the opportunities offered by genome-editing technologies in plants for the following reasons:

- to enable European researchers and growers to benefit from multiple innovations that will be derived from these technologies;

- to avoid competitive distortions with major agricultural countries already in the process of adopting these technologies;

- to develop competitiveness and sustainability of all forms of European agriculture;

- to bring a significant contribution from European agriculture to the commitments required under the Paris Climate Agreement; and

- to implement an essential leverage for the development of the bio-economy, a priority of the EU.

It is by permitting European public and private research to become a major player in plant genome editing technologies that the EU will regain its rank in the next wave of biotechnologies.

The signatories of this letter are prepared to answer any questions or otherwise be engaged with the Commission to follow up the above-mentioned proposals.

Respectfully, on behalf of the Initiative

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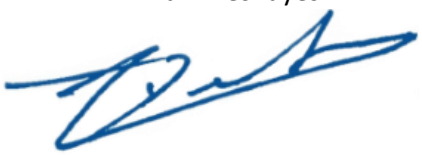
Wissenschaftlerkreis Grüne Gentechnik e.V (WGG)

Alain Deshayes



Association Française des Biotechnologies Végétales (AFBV)

European initiative for genome editing in plants

First signatory organizations and associations

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