Open Letter to Member States on the EU Court Ruling on Mutagenesis

23 April 2019

Dear Madam, dear Sir,

We, the undersigned European organisations, are writing to reiterate our concern about the European Court of Justice ruling on case C-528/16 (25 July 2018), by which the Court interpreted the provisions of the EU GMO Directive 2001/18 in such a way that products resulting from innovative, targeted mutagenesis methods are regulated under the provisions of the GMO-Directive.

The introduction of targeted genetic variation in crops and other organisms can help to achieve important sustainable development goals and to contribute to a cleaner environment, to healthy diets, and the protection of biodiversity. It can also contribute to making crops more resilient and better withstand climate change.

The costly and lengthy EU approval process for the products resulting from targeted mutagenesis, combined with potential national cultivation opt-outs under Directive 2001/18, will effectively deprive European farmers & consumers from the benefits of these products. Furthermore, the ruling is hindering the delivery to the market of innovative bio-based products and sustainable industrial, agricultural and healthcare solutions that involve gene-edited microorganisms. Some of the EUs most innovative sectors will effectively be cut off from scientific progress and be put at a competitive disadvantage compared to a rapidly growing group of countries with more enabling regulations.

The ruling is also difficult to implement and virtually impossible to enforce, given that many gene-edited products may be indistinguishable from products changed by natural processes or with conventional breeding techniques, as reconfirmed by the report of the Joint research Centre “Detection of food and feed plant products obtained by new mutagenesis techniques”, published on 26 March 2019.

The report highlights two aspects that are of major importance

1) “*For non-unique DNA alterations affecting one or a few DNA base pairs, **an applicant may not be able to develop** an event-specific method.*”
2) “*Plant products obtained by genome editing may **enter the market undetected**. Moreover, if a suspicious product with an unknown or non-unique DNA alteration would be detected on the EU market, it would be difficult or even impossible to provide court-proof evidence that the modified sequence originated from genome editing.* “

We are in full agreement with scientists, stakeholders and EU trade partners, that it has become urgent for the EU to adapt its legislation to reflect and welcome technical progress and align it with legislation in other parts of the world. We are committed to engaging with policy makers, stakeholders and all interested parties to work for a constructive, targeted change. Our goal is to obtain practical and science-based rules for products resulting from the latest mutagenesis methods that foster public confidence and trust. This would unlock great potential for a high-performing, innovative and diversified European bio-

based solutions in sectors such as plant and animal breeding, agriculture, animal feed, food, healthcare and energy thereby contributing to Europe's resilience to climate change, and to benefits for consumers, patients and the environment.

Products should not be subject to Directive 2001/18 requirements and related regulations if they could also have been obtained through conventional methods or result from spontaneous processes in nature. We wish to emphasize that this position is also increasingly adopted as a principal regulatory approach in a growing number of countries around the world. It should also create legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis. It will furthermore prevent that two otherwise indistinguishable products or organisms are regulated in two different ways, which would open the door to unfair competition with imports from non-EU countries.

We therefore call upon member states and the EU Commission to initiate a legislative change that provides innovation-friendly rules.

Yours sincerely,

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Association of Manufacturers and Formulators of Enzyme Products

Marc Vermeulen, Executive Director of Specialty Chemicals, The European Chemical Industry Council

Marie-Christine Ribera, Director General, European Association of Sugar Manufacturers

Jérôme Bandry, Secretary General, CEMA - European Agricultural Machinery

Elisabeth Lacoste, Director
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Ana Granados Chapatte, Director, European Forum of Farm Animal Breeders

Jean-Philippe Azoulay, Director General, European Crop Protection Association

Bernard Valluis, President, European Flour Milling Association

Patrick FOX, Secretary General, EFFCA - European Food and Feed Cultures Association

Thierry de l'ESCAILLE, Secretary General – CEO, European Landowners' Organization

Raquel Izquierdo, Secretary General, European Potato Trade Association

Susanne Meyer, Secretary General, EUVEPRO - European Vegetable Protein Association

Garlich von Essen, Secretary General, ESA - European Seed Association

Joana DuPont Inglis, Secretary General, EuropaBio – The European Association for Bioindustries

Nick Major, President, European Feed Manufacturers' Federation

Joerg Seifert, Secretary General, FEFANA Asbl - EU Association of Specialty Feed Ingredients and their Mixtures

Ernesto Morgado, President, Federation of European Rice Millers

Nathalie Lecocq, Director General, FEDIOL - EU Vegetable Oil and Protein Meal Industry Association

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