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Open Letter

from the associations of the agricultural and food sector regarding the judgment of the European Court of Justice on new breeding methods

Dear Madam or Sir,

The judgment of the European Court of Justice (ECJ) in case C-528/16 of 25 July 2018 on the application of targeted mutagenesis using new breeding methods causes great concern in the entire agricultural and food sector. In a sweeping approach, the court decision classifies, inter alia, all plants obtained with targeted mutagenesis methods such as CRISPR/Cas9 as genetically modified organisms (GMOs) and also their products become subject to labelling according to the GMO legislation. This judgement has a huge impact and practically blocks the implementation of new breeding methods in Germany and the EU, and hampers a beneficial use of these methods for biodiversity, sustainability and agriculture.

The ECJ judgment is highly problematic for the following reasons:

The judgment is based on legislation that dates back to the year 2001 and relies on scientific findings from the 1980s. Up until now, this legislation has exclusively served

to regulate classical genetic engineering (i.e. introducing foreign DNA into organisms). On this basis, the ECJ ruled on modern new breeding methods without taking current scienctific progress into account.

• Genetically modified transgenic plants (i.e. plants with foreign DNA) and products derived from them are easily detectable. This ensures the legally required traceability and labelling. In the vast majority of cases, no foreign DNA is introduced when using new breeding methods. Instead, targeted point mutations are induced in existing genetic information, such as they can also occur in nature without human intervention. It is, therefore, not possible to distinguish or prove whether a given mutation occurred spontaneously in nature, is the result of conventional mutagenesis (using radiation or chemicals) or of targeted mutagenesis (i.e. new breeding methods). This fact is also scientifically substantiated in the report of the European Network of GMO Laboratories / ENGL of 26 March 2019.¹

The new breeding methods offer opportunities to reduce the impact of climate change and to promote sustainability and biodiversity in agriculture:

- In order to minimise yield losses due to climate change and to make agricultural systems less vulnerable to increasingly variable cultivation conditions, crops need to be more resistant to water shortage or flooding, salinisation, heat/cold, diseases and pests. Moreover, crops should have improved nutrient efficiency. These challenges call for innovations in plant breeding. The new breeding methods have the realistic potential to help address such challenges in a relatively short time.
- It is also worth noting that the new breeding methods can enhance the existing natural genetic diversity, with this variation becoming available for an even larger diversity of crops.
- This also opens up the chance for a more sustainable land management and a reduced need for fertilisers and plant protection products.
- Furthermore, the new breeding methods offer the possibility to provide varieties for an
 even better choice of renewable plant raw materials, thus producing bio-based
 resources for industrial production in a bio-economy. This supports the transition from
 a largely fossil-based economy to one which is based more strongly on renewables,
 contributing to the UN climate goals.

With the ECJ ruling, the potential of the new breeding methods remains largely unutilised – and further undesirable consequences must be expected:

- Qualified scientists will relocate to countries where they can contribute actively to innovations. In consequence, the European Union and Germany will more and more fall behind in international developments, so that the competitiveness of the EU and Germany as a location of science and the (agricultural) industry is at stake.
- In most third countries, plants from targeted mutagenesis using new breeding methods are not regulated as genetically modified organisms (GMOs). For the continued functioning of international trade flows and to avoid risks to supply markets, the rules on agricultural raw materials in the different regions of the world must be compatible

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¹ The report can be accessed at this link: http://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

with each other. In trade and logistics with commodities such as wheat, rapeseed, maize and soya, the goods from many different fields are mixed as early as in their countries of origin. Therefore, it is impossible already today to determine for which products in and from third countries the new breeding methods have been used. This situation will become even more difficult in the coming years.

• Neither trade nor the monitoring authorities can comply with the requirements of the existing GMO legislation: Firstly, a legally reliable identification of the cause of mutation is not possible (see above explanation) and, secondly, the described commodities logistics preclude traceability and labelling per se. This means that the ECJ ruling cannot be implemented in practice. There is an urgent need for political action. Otherwise, imports of agricultural raw materials and their processing products into the European Union and Germany and, consequently, food and feed supplies in the EU and in this country are at risk as a whole.

For the above reasons, at the Agriculture and Fisheries Council on 14 May 2019, a majority of EU Member States took the position that the new European Commission should review the outdated and non-implementable GMO legislation and adapt it to the current state of science and technology. Against the outlined background, we are calling upon politicians in Europe and in Germany:

- The European GMO legislation should be adapted soon to the current state of scientific findings, and needs to be open for future developments. The expert knowledge of many independent German and European public agencies² should be included in this exercise. Even before the ECJ judgment, they arrived at the conclusion that the existing European GMO definition does not apply to most plants from targeted mutagenesis using new breeding methods and that the majority of such plants should be legally treated as those obtained with conventional breeding methods.
- The future European legislative framework must safeguard with legal certainty the global trade in agricultural raw materials and processing products.
- A fact-based and unbiased political and societal debate on the application or non-application of the new breeding methods should be actively encouraged. Together with scientists and politicians, we are ready to engage in an objective and matter-of-fact societal discourse.

As delegates of industry, we intensively observe and analyse the proposals from science and society for an adaptation of the European GMO legislation. We would very much appreciate an opportunity to engage in an exchange with you and to discuss in more detail our appraisal regarding the steps that are necessary to modernise this legislation in the light of new technical and scientific findings.

Yours sincerely

² German Federal Office of Consumer Protection and Food Safety / BVL (2012), expert agencies of the German Federal Ministry of Food and Agriculture / BMEL (2017), Scientific Advice Mechanism (SAM), European Food Safety Authority (EFSA), Joint Research Centre (the EU Commission's science and knowledge service), expert group of the Member States (2012), Advocate General Michal Bobek (18 January 2018).

Separational

Stephanie Franck Chairwoman

German Plant Breeders Association (BDP)

L. Co

Dr. Holger Bingmann

President

Federation of German Wholesale, Foreign Trade and Services (BGA)

Peter Sun

Dr. Peter Heinrich

CEO

German Biotechnology Industry Organization (BIO)

Konrad Linkenheil

Chairman

German Association of the Fruit, Vegetable and Potatoe Proceccing Industry (BOGK)

Illulo.

Rainer Schuler President

Federal Association of Agricultural Traders

Dr. Wolfgang Ingold

Chairman

Federation of German Food and Drink Industries (BVE)

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(BVA)

Christoph Hövelkamp

Chairman

German Association of Producer Organizations

Fruit and Vegetable (BVEO)

Andreas Kientzler

Chairman

CIOPORA Germany

S. Cetho

Dr. Matthias Braun

Chairman

German Association of Biotechnology Industries within the German Chemical

Industry Association (DIB)

Bernhard Krüsken Secretary General

German Farmers Association (DBV)



Dieter Krauß President

German Fruit Trade Association (DFHV)

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Franz-Josef Holzenkamp

President

German Raiffeisen Federation (DRV)

Jan Lahde President

German Feed Association (DVT)

Patrick Knüppel

CEO

German Association of Wholesale Traders in Oils, Fats and Oil Raw Materials (GROFOR)

Dr. Manfred Hudetz

President

Plant Care Industries Association (IVA)

Jaana Kleinschmit v. Lengefeld

President

OVID Association of the oil crushing and oil refining industry

Wolfen Opp.

Wolfgang Vogel

Chairman

The Union for the Promotion of Oil and Protein Plants (UFOP)

Olaf Feuerborn Chairman

Union of the German Potato Industry (UNIKA)

Klaus-Jürgen Philipp

President

Association of the German Fruit Juice

Industry (VdF)

Thorsten Tiedemann

Chairman

Grain Traders Association of the Hamburg

Exchange (VdG)

M. Gulling

Michael Gutting Speaker of the Presidency German Cereal Processing, Milling and Starch Industries' Association (VGMS)

Climal

Dr. Hans-Jörg Gebhard Chairman German Economic Association of Sugar (WVZ)

Axel Aumüller Chairman German Association of Sugar Industry (VdZ)