

Statement: As EU court ruling risks blocking innovation, the European biotech industry calls for science-based political decision making on genome edited products

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The European biotechnology industry acknowledges with grave concern the EU Court ruling of 25 July 2018. This ruling interpreted the Annexes of the EU's Directive 2001/18 in such a way that organisms resulting from modern mutagenesis techniques are uniformly to be treated like genetically modified organisms¹.

Together with Europe's world leading scientific community in this field, we regret that implementation of this ruling could cause European life science innovation effectively to come to a halt². If fast mitigation is not done, the ruling will cause a halt to EU sustainability and competitiveness ambitions by hindering the delivery of innovative bio-based products to the market, sustainable innovative food-solutions and certain healthcare solutions to patients. We, therefore, call on the EU Commission to thoroughly assess the consequences of the ruling, clarify the status of products made using other innovative approaches, and secure that Europe can benefit from modern precision editing methods.

EuropaBio firmly believes that, in order to advance the UN Sustainable Development Goals by 2030, a proportionate, fit-for-purpose and science-based approach to modern technologies, such as innovative biotechnology and life sciences, is essential. As a case in point, we regret that the lack of such an approach has already resulted in profound consequences for the adoption of environmentally and socially beneficial crops in Europe.

The EU's approval system for GMOs has prevented farmers from accessing products that have been used safely for decades in other parts of the globe and is so slow and expensive that even import authorisations represent an insurmountable hurdle for small and medium-sized companies and public institutions. Yet it is exactly these SMEs and publicly funded innovators who have the biggest share of genome-

¹ Court of Justice of the EU [Ruling on Case C-528/16](#) and associated [Press Release](#). EuropaBio [Press Release](#).

² [Position paper from 85 European plant and life sciences research centers and institutes](#), "Regulating genome edited organisms as GMOs has negative consequences for agriculture, society and economy", 24 October 2018. Statement of EU Commission's Scientific Advice Mechanism: "[A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing...](#)", 13 November 2018. For additional statements and context, see also [EuropaBio website news item](#) and EuropaBio's [Green Biotech rEvolutions newsletter](#).

edited organisms ready to offer to the market and will now likely be unable to do so in the EU. The result is that they will instead focus their research on other parts of the world, where these organisms are usually not treated like genetically modified organisms³. As such, the EU consistently undercuts its potential to compete in a global market and to reap the benefits of its own innovation in this field.

To prevent further attrition of biotech's potential to other regions and to boost EU's competitiveness and innovation, and reach the environmental and climate commitments, we call for a constructive change. Our goal is to obtain science-based, predictable and proportionate rules that reflect technical progress and that seek to ensure that organisms developed with more sustainable, precise, modern mutagenesis techniques are not subject to disproportionate regulatory requirements, when the very same products could also be obtained through earlier breeding or classical mutagenesis methods or could simply result from spontaneous processes in nature.

As the EU has already fallen far behind the rest of the world in this essential area of research and commercialisation, we hope that decision-makers in the Member States and at EU level will promote progress and innovation as a matter of urgency. Such an approach would be appropriately in line with President Juncker's plea not to "stifle innovation and competitiveness with too prescriptive and too detailed regulations"⁴, as well as holding true to the European Council's demands for a future-proof and technology-neutral better regulation approach⁵.

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents 78 corporate and associate members and bio regions, and 15 national biotechnology associations in turn representing over 1800 biotech SMEs. Read more about our work at www.europabio.org.

³ As of August 2018, in the USA alone, 15 gene-edited plants and 1 gene-edited mushroom were considered as non-regulated. Of these 16 products which are non-regulated in the USA: 7 are from medium to large private companies not including the four multinational companies which hold most GMO authorisations; 6 are from public research institutions; 3 are from multinational companies. Source: Julius Kühn-Institut: 1. Aktualisierung der [Übersicht über Nutz- und Zierpflanzen](#), die mittels neuer molekularbiologischer Techniken für die Bereiche Ernährung, Landwirtschaft und Gartenbau erzeugt wurden (Version 20.09.2018)

⁴ "A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change Political Guidelines for the next European Commission" (2014)

⁵ Research and Innovation friendly regulation - Council conclusions (adopted on 27/05/2016): <http://data.consilium.europa.eu/doc/document/ST-9510-2016-INIT/en/pdf>