In support of a timely and state-of-the-art regulation of the products of new breeding techniques as a contribution to tackling multiple crises in the 21st century

Position paper of the Permanent Senate Commission on Genetic Research of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation)

Background

The process-based regulatory approach of European and German law on genetically modified organisms (GMOs) dates back to the 1990s. It was based on the initial assumption that genetic engineering techniques might cause new environmental and health risks. After several decades of worldwide use of the technology, these hypothesised risks have not materialised. By contrast, the world currently faces very real, existential threats, in particular the **climate, biodiversity, and food crises.**

These multiple global threats require a wide range of solutions, including concerted efforts to make agriculture more sustainable and resilient to climate change. In combination with a series of other approaches, such as improved agricultural practices, plant breeding can and must make an important contribution to an overall strategy for securing food production. In this regard, new breeding techniques using CRISPR/Cas and other methods of so-called genome editing offer particularly promising potential [1, 2, 3]. According to the European Commission's assessment, these new techniques in plant breeding can contribute substantially to achieving more sustainable food production, to implementing the Green Deal and the Farm-to-Fork Strategy of the EU, and to realising the United Nations' Sustainable Development Goals [4]. In order to give these new breeding techniques based on CRISPR/Cas a chance in Europe and Germany, it will be necessary that the outdated legal framework they are subject to is modernised and adjusted in line with the current state of science and technology.

The scientific facts

The products of new breeding techniques are **indistinguishable from those of conventional breeding,** provided they do not contain any foreign genetic material. However, in light of German and EU **GMO legislation**, they are regulated just as strictly

as classic GMOs. The European Parliamentary Research Service has meanwhile stipulated that the risks associated with genome editing are lower than those of conventional mutagenesis using chemicals or radioactivity [5]. Nevertheless, these traditional forms of mutagenesis have always been exempt from the European and German legal framework on GMOs. Several other countries, including many of the largest agricultural nations (e.g., Argentina, Australia, Brazil, China, Canada, India, and the USA), therefore decided that new **plants resulting from genome editing** should not be regulated in the same way as conventional GMOs. Despite the fact that national regulatory approaches vary to a great extent, the compelling justification for **simplified regulation or de-regulation** is that no foreign DNA is permanently integrated into the genome and/or the genetic modification could also have arisen naturally or by means of conventional breeding.

The problems

A restrictive legal framework treating products resulting from genome editing unvaryingly as GMOs results in **serious obstacles to research in Europe and Germany in particular**, as well as in delays in developing **urgently needed new technologies for global food security** [2, 3, 5].

As a result of the restrictions, field experiments are being relocated to non-European countries, and making use of the new methods becomes virtually impossible for breeders. This has a strong deterrent effect on companies as well as on early-career researchers, who leave Europe or opt for entirely different professional careers outside academia.

The fact that the origin of mutations caused through genome editing cannot be verified exacerbates the regulation of the respective organisms as GMOs considerably, since such regulation **cannot be reliably enforced in practice**. In addition, there are serious concerns regarding **adverse impacts on world trade**. Furthermore, especially small- and medium-sized plant breeders located in Germany and Europe will face **significant competitive disadvantages**.

In 2021, a study by the European Commission concluded that **European GMO legislation is no longer fit for purpose** [4]. It is entirely unsuitable for the new genome editing technologies and must be revised urgently.

The way forward

An **amendment to European GMO legislation** should ensure that organisms altered through genome editing techniques are exempted from the scope of GMO law, provided that their genome

does not contain any foreign genetic material, and/or the alteration to their genetic material could also occur naturally or be the result of conventional breeding methods (e.g., conventional mutagenesis techniques). Generally, a **safety assessment of new plants** should not depend on the underlying technology but should be carried out according to a product-based, case-by-case approach that focuses on the properties of the final product in question. The DFG, the Leopoldina and other research organisations have been calling for such a regulatory approach for many years [1, 6].

These recommendations do not affect the issue of **labelling** of products resulting from new breeding techniques. Safeguarding consumers' freedom of choice is a key concern, which can be addressed appropriately even if the products that result from genome editing are no longer subject to risk regulation under current GMO legislation.

Literature

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