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Short Version of the Statement

Towards a scientifically justified, differentiated regulation of genome edited plants in the EU

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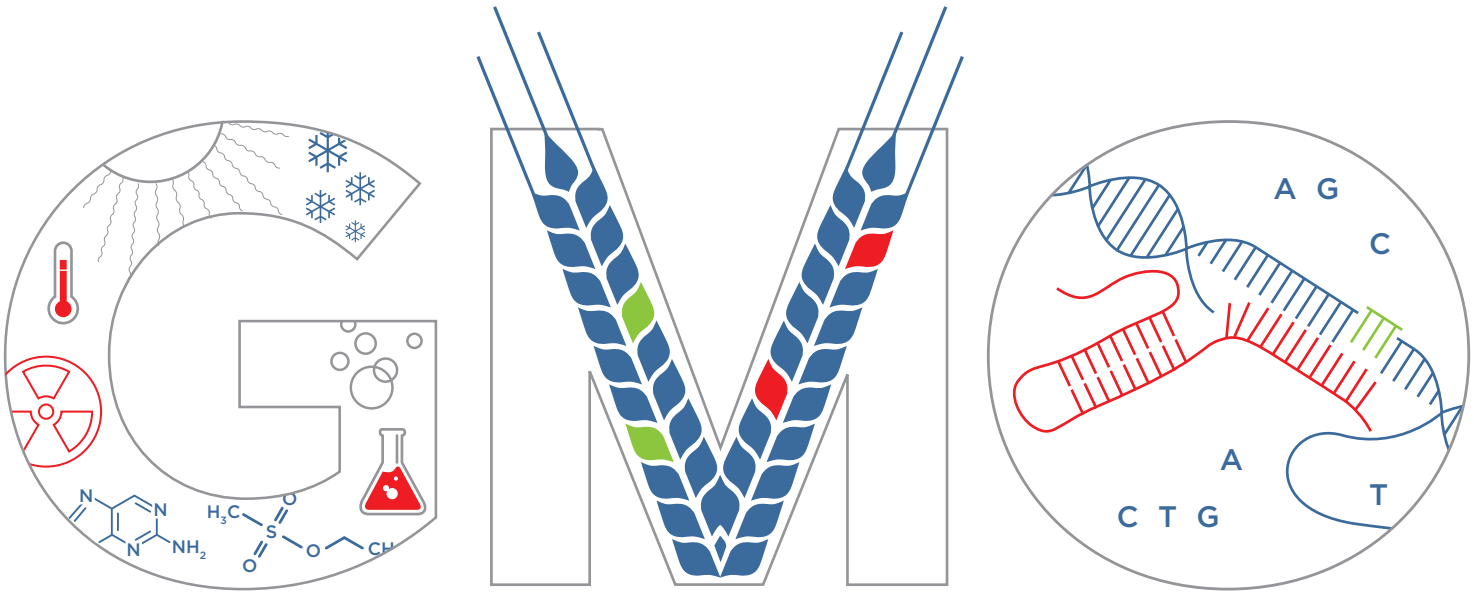
German Research Foundation
Union of the German Academies of Sciences and Humanities



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On 25 July 2018, the European Court of Justice ruled on the interpretation of the definition of the term 'genetically modified organism' (GMO) in the GMO Directive 2001/18/EC. It follows from the ruling that all organisms produced by genome editing are subject to the legal framework applicable to release, placing on the market, labelling, and traceability of GMOs. In contrast to traditional breeding methods, genome editing methods enable directed, cost and time-saving modifications (mutations) of the genome of crops, which are often indistinguishable from naturally occurring mutations. The blanket legal classification as a GMO therefore fails to consider the type of genetic modification present in the genome edited organism and whether this modification could have occurred accidentally or through traditional breeding methods. It also disregards whether the origin of the genetic modification can be identified and attributed to a particular breeding method. The science academies and the German Research Foundation (Deutsche Forschungsgemeinschaft – DFG) therefore conclude that the primarily process-based European regulatory approach is no longer justifiable. After all, potential risks can only emanate from the modified traits of the organism as a product of the breeding process, and not from the process itself.

More than 100 (potentially) marketable genome edited crops are currently known worldwide; these plants have been created through directed point mutations or deletions of a small number of base pairs and are beneficial for nutrition as well as for productive, low-pesticide and resource-conserving agriculture. They include soybeans with healthier fatty acids, gluten-reduced wheat, potato tubers with a longer shelf life, bacteria-resistant rice, fungus-resistant varieties of grapes, wheat and cocoa, and drought-tolerant varieties of corn, wheat, and soybeans. Likewise, it is possible to produce genome edited plants that combine beneficial properties of wild plants with those of high-performance varieties. Some of the new breeding lines have yet to prove these benefits in field trials. Meanwhile, these trials are almost impossible in the European Union (EU) due to frequent vandalism and deliberate destruction of testing fields.

In many countries outside the EU, genome edited plants that could in principle have come about by chance or through traditional breeding are exempted from GMO-related regulations. European genetic engineering legislation, on the other hand, hinders the research, development and application of urgently needed improved crops to support productive, climate-adapted and sustainable agriculture.

The products of random mutagenesis breeding using high-energy radiation or mutagenic chemicals have been classified by the European legislator as 'safe' GMOs for decades and are therefore exempt from GMO regulation. This is in line with the consistent application of the precautionary principle, under due consideration of opportunities as well as risks. Likewise, even after almost 30 years of worldwide utilisation of transgenic crops produced using conventional genetic engineering in agriculture, no risks inherent to the technology could be detected for humans, nature or the environment. Accordingly, the science academies and the DFG see an urgent need to reassess the products of the much more precise and efficient methods of genome editing and to amend European genetic engineering law.

Recommendations

Recommendation 1. Amendment of European genetic engineering legislation: In a first step, the European genetic engineering legislation should be amended. This should include a revision of the GMO definition or the associated exemptions within the current legislative period of the European Parliament in order to exempt genome edited organisms from the scope of genetic engineering legislation if no foreign genetic information is inserted and/or if there is a combination of genetic material that could also result naturally or through traditional breeding methods. An official preliminary examination process should be used in individual cases to provide scientific clarification as to whether a GMO is present within the meaning of the amended regulations. These moderate changes to existing genetic engineering legislation, which can be implemented within a manageable timeframe, would better reflect the current state of scientific knowledge than the existing GMO regulatory framework. This would also align European legislation with the regulation of some of the EU's major trading partners in the agricultural sector.

Recommendation 2. A fundamentally new legal framework: A second step should comprise developing a fundamentally new legal framework that is detached from the previous, process-based regulatory approach to genetic modification. This longer-term action is the logical next step from a scientific point of view. The current process-centric approach cannot be scientifically justified. However, it is also unwarranted for regulation to distinguish between breeding methods with and without transgenic DNA. Risks to humans, nature, and the environment can only arise from the plant (or its new traits) and the way in which it is used, but not from the process on which the genetic modification is based. A new legal framework must therefore link the requirement of authorisation, registration, or declaration to resulting traits. The requirement, nature and scope of a science-based risk assessment should be determined on the basis of the innovative nature of the product or trait concerned. In case of doubt, an upstream assessment process involving the European Food Safety Authority should be established with a national authority. This process should clarify the regulatory status of the plant in question (where appropriate, already early in the development phase). The European Commission should review the new EU regulatory framework on a regular basis, at least every five years, with regard to its adequacy in light of the state of the art in science and technology and against the background of fair market competition. The framework should be revised accordingly where necessary.

Recommendation 3. Facilitating field trials: Genome editing methods are an essential methodological addition to plant and agricultural research, as they allow the genetic make-up of cultivated plants to be modified in a much more precise and time-efficient way than before in order to investigate unknown gene functions in detail. Particularly complex properties such as tolerance to salt, drought or heat are still insufficiently understood at the genetic level. The strict, primarily process-based regulation which covers all genome edited plants indiscriminately, substantially restricts the freedom of research in the EU without substantial justification. The associated bureaucratic effort delays plant research and makes it considerably more expensive. Moreover, it creates a recruitment disadvantage for top researchers and damages the career opportunities of young scientists. Field trials, which are necessary for the transfer of research results from the laboratory to actual cultivation conditions and for approval under current genetic engineering legislation, are virtually non-existent with genome edited

crops in the EU. This is also due to the fact that field trials with GMOs have to be published in a location register and have therefore often been the target of deliberate field destruction. This has resulted in the 'export' of field experiments to non-EU countries, where genome edited plants are regulated in a more differentiated way. However, breeding successes can only be reliably studied in those growing regions in which the varieties are ultimately to be cultivated. Field trials are therefore an essential component of modern plant sciences and breeding research. For this reason, an amendment of genetic engineering legislation is particularly pressing so that field trials in the EU can be made practicable again as quickly as possible. Suitable communication strategies should also be developed in this context to strengthen the voice of science in the societal discourse on genetic engineering.

Recommendation 4. Differentiated discussion of breeding methods: The further development and use of genome edited crops depend not only on regulatory practice but also on consumer acceptance. The sciences should communicate realistic expectations. Critics of genetic engineering should also clearly distinguish between processes and their products as well as between application scenarios, for example in crops and in human medicine. European consumers are under the false impression that most of the food available in Europe, including organic products, is produced 'GMO-free'. However, even ubiquitous products of traditional random mutagenesis breeding are GMOs in the sense of the GMO Directive, but do not have to be labelled as such or in the product. The discussion on the application of new molecular breeding methods should be conducted as part of a constructive dialogue centred on common goals and options for action. New breeding methods and their products can contribute to greater sustainability in agriculture if they are meaningfully combined with other ecologically relevant innovations and practices.

Recommendation 5. Securing freedom of choice: Consumers ought to be informed about genome edited products by way of consistent labelling rules that also reflect the similarity with products of traditionally bred organisms. The challenge for product labelling is that genome editing applications are often not detectable, especially when there is no foreign genetic information in the final product. According to the current legal situation, these products must nevertheless be labelled as 'genetically modified'. This can lead to considerable problems of controllability, particularly in the international trade of goods. Implementation of the regulatory options identified in Recommendation 1 would eliminate the need to label the corresponding genome edited products as 'genetically modified'. In order to nevertheless create freedom of choice for consumers, the following regulation appears appropriate. For products which do not contain any foreign genetic information, the obligation to provide positive labelling specifically for genetic engineering should be waived, while the negative label 'GMO-free' may be used on a voluntary basis. Companies that use this label would have to disclose certificates from along the value chain to ensure that no genetic engineering processes were used.

Recommendation 6. Responsible exploitation of innovation potential: Solving urgent resource problems, which are exacerbated by climate change, requires multi-faceted innovative approaches that minimise losses of food and other biological resources, increase agricultural productivity and preserve valuable agricultural and natural landscapes. In addition to environmentally compatible and more sustainable agricultural practices (e.g. crop rotation), this requires innovative plant breeding methods that increase the diversity and performance of crops and other biological resources. Improved, particularly stress-resistant crops make it possible to increase the productivity and sustainability of value chains for food and biologically produced resources by reducing the use of pesticides, while limiting crop losses and the need to acquire new natural habitats for agricultural use.

Further development of sustainable agriculture in Europe is considerably obstructed by the particularly restrictive, undifferentiated

and time and cost-intensive approval processes for molecular breeding products. The absence of certain innovations also poses costs and risks for humans, nature and the environment. Responsible management of technology-related developments means weighing the positive and negative effects against each other and monitoring them in order to intervene and take control if necessary. The application of the precautionary principle must not be linked to speculative risks. Instead, the precautionary principle should be applied on a scientific basis and, alongside the experience with conventional genetic engineering over the past 30 years, the benefits of new molecular breeding methods and their products must be considered appropriately and in a problem-oriented manner. To this end, research on the consequences for health, ecology, society and the economy of genome edited plants and their use, oriented towards the product and application scenario of new molecular breeding methods, should be publicly funded and strengthened. Research should also focus on the apprehensions and concerns about genetic engineering that are widespread in society.

Recommendation 7. Increasing market competition: The low costs and high efficiency of genome editing methods also make them suitable for use by small and medium-sized enterprises (SMEs) and by public research institutions (including in developing countries). This facilitates molecular breeding of insufficiently cultivated or neglected crops such as legumes or fruit and vegetable varieties of only regional importance. The undifferentiated regulation of genome edited plants prevents SMEs in particular from taking advantage of the opportunities offered by genome editing. A high market share of SMEs can help to counter the process of monopolisation in the already highly concentrated international markets for new plant varieties and seeds. Only large multinational corporations can afford the current costs and delays caused by European approval processes.

Regulatory practice also contributes to a global reduction of applications to a small number of crop species and a handful of traits with high market potential. Targeted regulatory incentives should therefore be created for breeders and seed producers so that improved crops and associated cultivation methods become more productive and at the same time more resource-efficient and environmentally compatible. This could be achieved through the coordinated identification, for instance in the course of dialogue forums, of plant traits that are both agriculturally and socially desirable, and through government support for the development and approval of corresponding new varieties that allow, for example, reduced use of pesticides, water and fertilisers. A science-based GMO regulatory practice can facilitate SMEs' access to the market for new plant varieties and seeds, thereby increasing competition and diversity, e.g. of locally adapted crops. The frequent undetectability of the use of genome editing poses particular challenges for patent and plant variety protection. The legislator should therefore monitor developments in this field and consider legal changes of patent and plant variety protection law where necessary.

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