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## Academies issue statement on progress in molecular breeding and on the possible national ban on cultivation of genetically modified plants

### Summary

Since the mid-1990s, cultivation of genetically modified plants has been increasing steadily. These plants differ from the original cultivars in that genes are deliberately introduced into the plants, or existing genes are deliberately modified. This intervention may lead, for example, to increased resistance to pests or adaptations in the composition of vitamins and storage compounds such as starch and fatty acids. In 2014, *genetically modified organisms* (GMOs) were grown on 13 percent of the world's farmland. Science-based data show that the use of GMOs can result in increased yields, higher incomes for farmers, and reduced use of insecticides. The international trend towards increased GMO cultivation is clearly visible; however, it conflicts with the political and legal situation in Germany, where field tests and commercial cultivation of genetically modified plants are no longer taking place.

It is questionable whether the regulations under the German Genetic Engineering Act, which are linked to specific types of genetic modification, are still practicable and appropriate. The breeding products of some new molecular genetic methods can hardly be distinguished, or cannot be distinguished at all, from the products of non-regulated techniques that are considered *conventional* breeding. Moreover, similar plants can be produced using traditional breeding methods, but those methods are less efficient and take much longer.

The German National Academy of Sciences Leopoldina, acatech – the National Academy of Science and Engineering, and the Union of the German Academies of Sciences and Humanities strongly recommend that future risk assessment should be based primarily on the specific characteristics of new plant cultivars and not on the process by which they are produced. The Academies argue against a general ban on GMO cultivation, which is not scientifically justified. The Academies consider such prohibitions in Germany an acute threat to freedom of research and professional freedom, to property protection and general freedom of action, and thus to opportunities for studying, developing and commercially utilising genetically engineered crop plants. Therefore, the German academies emphatically recommend a science-based evaluation on a case-by-case basis. Moreover, field trials are indispensable for risk assessment of GMOs, especially following a deregulation procedure.

## **Background**

In recent years, novel breeding methods have been developed that allow the genetic material of crops to be adapted to particular growing conditions and to demand in a targeted manner that saves time. Often, the resulting plant cultivars cannot be distinguished from plants obtained through conventional breeding, which may be placed on the market without prior authorisation. It is clear that the current regulation under the German Genetic Engineering Act (GenTG) is inconsistent, because plants that have been produced by novel molecular genetic approaches could be regarded as *genetically modified organisms* (GMOs) whereas conventionally bred plants, although indistinguishable from their GMO counterparts, are classified as non-GMOs.

After the enactment of the “opt-out-clause” in Directive 2001/18/EC by the legislative bodies of the European Union, the member states of the EU are free, as of April 2015, to adopt national prohibitions or restrictions on the cultivation of GMOs. There is an on-going discussion in Germany as to whether a general nationwide ban on the cultivation of GMOs should apply or whether opt-out measures should be left up to the individual states.

## **Current definition of genetically modified organisms**

Plant genetic engineering refers to a number of very diverse molecular genetic methods for which no specific risks relating to the particular technique have been demonstrated in any of the numerous safety studies. According to the GenTG (Section 3(3)), an organism is considered genetically modified if its genetic material has been altered in a way that does not occur naturally by mating or natural recombination. In particular, the techniques of genetic modification include, according to the GenTG (Section 3(3a)), techniques that introduce nucleic acid molecules produced outside an organism into a host organism in which they do not naturally occur. This means that the breeding technique, and not the resulting characteristic, is the criterion that triggers necessity for legal regulation.

In the European Union, the legislature has introduced an exception according to which organisms whose genetic material has been modified using irradiation or chemical mutagenesis are not considered to be genetically modified. With these time-consuming techniques, which have been practiced for years and are classified as *conventional* or even as *natural* breeding, thousands of random mutations are induced across the genome while only a tiny minority of them will ultimately result in a favourable phenotype. Many cultivars that are widely cultivated today, such as barley, wheat and grapefruit, were modified in this way, meaning that every day consumers ingest grain, fruit and vegetables that have been extensively genetically altered – yet these products are not considered genetically modified in the sense of the GenTG.

## **Modern molecular breeding techniques**

TILLING (targeted induced local lesions in genomes) has been frequently used in conventional breeding in which random mutations within a particular gene can be identified using a high-throughput method. In marker-assisted breeding (precision breeding), plants are selected for their marker genotype, using sequence-based methods, and are bred further in a targeted way. Because no genes have been altered by genetic modification, the plants produced by the aforementioned techniques are not considered GMOs. Likewise, techniques, in which genetic material from an organism is introduced into the same or a closely related species that can also exchange genetic material by means of natural processes, are not considered genetically modified if no genetic engineering techniques are involved.

Commonly used genetic engineering breeding methods generally used to leave easily detectable traces in the genome of the plant, which helped to classify a crop as *genetically modified*. Frequently, these traces were segments of genetic material from bacteria or viruses that are used as molecular genetic tools and that also naturally introduce their genes into plants. Modern molecular techniques, like *TALEN* or *CRISPR-Cas*, often referred to as *genome editing* or *gene surgery*, now enable gene modification in a targeted and controlled manner. This occurs, for example, by means of targeted inactivation or modification of individual genes using enzymes that recognise well-defined DNA sequences. These can achieve results in a very short period of time that are comparable to the results of lengthy conventional breeding techniques.

The plants obtained by means of the new breeding methods can hardly be distinguished, e.g. using gene tests, from conventionally bred plants – for example, if no foreign DNA has been introduced. This lack of differentiation illustrates that the GenTG's process-specific approach to regulation is inappropriate and that regulations that seek above all to ensure health and environmental safety must be based on an organism's characteristics, regardless of the (breeding) techniques on which these characteristics are based.

### **Consequences and recommendations**

1. Concerning the risk assessment of new plant cultivars, the focus should be on the specific characteristics of the breeding products rather than on the methods used to produce them. This would contribute to increased objectivity in public debate on novel molecular genetic breeding techniques and on plant genetic engineering in general, and would do justice to science-based insights.
2. Plant cultivars that are created in a targeted and time-saving manner using novel molecular breeding techniques cannot always be distinguished, neither genetically nor on the basis of the characteristics obtained, from crops produced through conventional breeding. If cultivars obtained in this way fall under the GenTG on the sole basis of the specific breeding technique used, the regulatory approaches of both the GenTG and the EU, which focus specifically on the genetic engineering breeding technique, are misguided. German and European law-makers should do justice to this fact in the future by rejecting the process-specific approach. The law should instead focus on risks generated by the characteristics of the plants that the breeding process creates.
3. Freedom of research, which is protected by Article 5(3) of the German Constitution, must be preserved. Non-method-specific support for research into new plant breeding techniques is legitimate and, with respect to both climate change and global food security, desirable. Such breeding methods can contribute significantly to increasing the nutritional value of plant products, to increasing yields through resistance to pests, and to strengthening tolerance to unfavourable growing conditions like drought and soil salinity. It must, however, be ensured that laboratory experiments and field tests with approved GMOs, which are indispensable for yield and risk assessments, remain possible and are, in particular, effectively protected from vandalism and damage.
4. The global trend in plant breeding cannot be stopped. In our globalised market, a 100-percent GMO-free supply of food and feed is already unrealistic. General bans on the cultivation of plants obtained using novel molecular genetic breeding methods will result in this area of research becoming unattractive for scientists in Germany. As a consequence, they will emigrate to other countries and we will lose a research sector that is important for our country's industrial development. In addition, research efforts in Germany will be excluded from international research

programmes related to this area. We should consider, critically and without prejudice, whether Germany might thereby lose the opportunity to help ensure these technologies are handled responsibly in the future.

5. The possible ecological and health-related risks of newly bred plants should still be tested in each individual case. Only evidence-based scientific risk assessment should be used to make decisions. Germany is already a world leader in biological safety research. Field trials, especially those with approved GMOs, are indispensable for these tasks as well as for careful examination of plant cultivars and for analyses in the context of scientific experiments. Such trials become impossible, however, when sweeping bans are imposed.
6. Because most of our food is imported, and Germany is a favourable agricultural location, no acute need for increased yields is perceived here. However, yields in those countries that plant the crops to produce our food often fall short due to unfavourable environmental conditions. In a globalised world with limited natural resources and growing demand, Germany and Europe bear an international responsibility to continue increasing agricultural productivity, including by means of sustainable new breeding methods. In addition, the political message that a complete ban on GMO cultivation in Germany sends to other (e.g. African) countries, where increases in production are urgently needed in order to fight hunger, should not be underestimated.
7. The successes of molecular breeding make it possible to breed plants that can help us achieve ecologically oriented, sustainable agriculture, environmental protection and preservation of species diversity. These advances can support sustainable farming methods that prevent further soil erosion, water shortages and water pollution.

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