

# Genetic engineering in the food and feed industry

## **New legal framework: EU Commission dares to take a big step in the right direction**

*The EU Commission wants to deregulate certain genetically modified plants in the future. For low-risk varieties, the complex approval procedure and mandatory labeling are to be eliminated. Criticism has been voiced by some politicians and consumer associations. But the project is long over-due.*

A guest article by Dr. Wolfgang Schönig, LL.M.<sup>1</sup>

According to United Nations estimates, the world's population is set to grow from the current eight billion to around 10 billion by 2050. At the same time, climate change is threatening harvests worldwide due to extreme weather events. To respond to this, agriculture must become more efficient and sustainable. Accordingly, the “farm to fork” strategy is intended as part of the EU Green Deal to make the European Union climate-neutral by 2050—an ambitious goal.

As part of this effort, the Commission is focusing on the use of genetic engineering techniques in plant breeding. Such techniques can modify the genetic material of plants in such a way that they grow faster, require less fertilizer, pesticides, and water, or are more resistant to extreme weather.

For decades, seeds have been exposed to radioactive radiation for this purpose (so-called conventional mutagenesis). Among thousands of mutations in the genome provoked in this way, a random positive mutation can then be found by means of a screening process, which brings about the desired improvement in the plant's properties, a lengthy and inefficient process.

But science has developed a solution. Through the use of the 2020 Nobel Prize-winning CRISPR/Cas9 gene scissors, plant genes need no longer be altered randomly, but can be specifically modified to achieve the desired improvement in properties. Targeted mutagenesis (also known as genome editing) is a real game-changer and an opportunity to achieve the ambitious climate targets in the remaining time.

## **How the current legal situation suppresses progress**

However, the use of genetically modified organisms (GMOs) is governed by the strict GMO Directive of 2001, which includes an elaborate approval procedure and labeling requirements. The European Court of Justice has expressly ruled that targeted mutagenesis is also subject to these rules, but that conventional mutagenesis is excluded from the scope of the directive because it has long been considered safe.

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Above all, the strict approval procedure has virtually prevented the development of a market for gene-edited plants in the EU, which could make agriculture more sustainable without any loss of productivity. The procedure is very cost-intensive and takes several years. It is an effort that is only worthwhile—if at all—for large international players. For startups, it is actually impossible.

## Why a change in the legal framework must take place

In 2001, strict regulation was justified by the precautionary principle. The concern about unknown risks of GMOs for humans, animals, and nature was too great. However, more than 30 years of risk research show that targeted genetically engineered plants are no more dangerous than those from conventional breeding. There is no justification for differentiating so strictly according to the methods of genetic modification, rather than according to the properties and risks of the plant itself. This is also the view of the German Academy of Sciences Leopoldina, which called for a corresponding change in the legal situation in 2019.

The voices of the scientific community have now been heard by the EU Commission. On July 5, 2023, the Commission presented a proposal for a “regulation on plants obtained by certain new genomic techniques and their food and feed.” It completes the long-awaited move away from the approval requirement for gene-edited plants to a risk-based approach.

Accordingly, category 1 plants are those whose characteristics also occur naturally or as a result of conventional breeding methods. These are plants with up to 20 genetic modifications in their genome. The plants would not be treated differently than if their modifications had occurred naturally or they had been bred conventionally. This means: no approval, but registration and entry in a database, with no labeling obligation.

All other gene-edited plants remain subject to approval and labeling requirements as category 2 plants. The simplified regulations do not apply to organic agriculture either. The same applies to plants in which genes of another species have been introduced (so-called transgenesis).

## What happens next

There is hardly any other topic in Europe where science and public opinion are so far apart. Nature and consumer protection associations spoke out against the proposal. Politicians, e.g., from the German Green Party, also voiced their disapproval. Criticism is levelled at the alleged lack of re-search into GMO risks and the lack of a labeling obligation.

The scientific community and the German government, including German Federal Research Minister Bettina Stark-Watzinger (Liberals), are in favor. If we want to continue to feed the rapidly growing world population in the future and at the same time combat climate change, supporters of the proposal believe that we must also rely on GMOs and regulate them in a risk-appropriate manner.

Unfortunately, the proposal threatens to be instrumentalized by GMO-opponents in the European elections in the summer of 2024. It remains to be seen whether the voice of reason will prevail and the Commission’s proposal will successfully pass through the legislative process in Parliament and the Council.

*This is a translation of an article originally published in German by Börsen-Zeitung, available at: [Neuer Rechtsrahmen für Gentechnik | Börsen-Zeitung \(boersen-zeitung.de\)](https://www.boersen-zeitung.de/Neuer-Rechtsrahmen-fuer-Gentechnik)*