Regulating genome-edited organisms as GMOs has negative consequences for agriculture, society and economy

On July 25th, 2018, the Court of Justice of the European Union (ECJ) ruled that organisms obtained by modern forms of mutagenesis such as CRISPR are not exempt from the EU GMO legislation. Consequently, genome-edited organisms must comply with the strict conditions of the EU GMO legislation. This is in stark contrast with the opinion of the Advocate-General of the Court, which was published in January 2018 and advised ruling otherwise. We regret the purely process-based interpretation of the legislation by the Court and conclude that the EU GMO legislation does not correctly reflect the current state of scientific knowledge. Organisms that have undergone simple and targeted genome edits by means of precision breeding and which do not contain foreign genes are at least as safe as if they were derived from classical breeding techniques. Therefore, we call upon all European authorities to quickly respond to this ruling and alter the legislation such that organisms containing such edits are not subject to the provisions of the GMO Directive but instead fall under the regulatory regime that applies to classically bred varieties. In the longer term, the GMO Directive should be thoroughly revised to correctly reflect scientific progress in biotechnology.

There are many reasons why agriculture in Europe and around the globe must become more sustainable. Agricultural practices put pressure on our environment, we are faced with a growing population (mounting to an estimated 10 billion mouths to feed by 2050), and climate change poses increasing challenges for crops – climate measurements from the summer of 2018 underline the urgency of this message.

Time is a luxury we don't have. Reducing the environmental footprint of agriculture and adapting farming to a changing climate are imperative. For example, crops that are more tolerant to rapidly changing and harsher environments will be crucial for the success of tomorrow's food production approaches. To address challenges like this and to efficiently meet food production goals, we will need to use all knowledge and technical means available and thus also new technologies, specifically biotechnology. One of the latest breakthroughs in this field is precision breeding, an innovative crop breeding method based on genome editing. Crops developed with precision breeding could help the farmer to minimize inputs such as fertilizers and pesticides. Precision breeding can also contribute to tailoring crops to a specific area, taking into account the environmental factors of a certain region. E.g. having plants that are drought resistant could mean higher crop yields without increasing arable land.

Taking traditional breeding to the next level

The search to introduce additional genetic variation in crops is anything but new. Plant breeding started around 8,000 BC, when farmers selected seeds from crops with the best characteristics obtained through spontaneous genetic mutations and crossbred them to produce new crop varieties with desirable properties. In more recent times, chemicals and radiation are applied to incite these mutations. This type of conventional mutagenesis is exempt from the provisions of the GMO legislation because of its long safety record. Nevertheless, this method incites hundreds or even thousands of random mutations with unknown effects and consequences. Mutations leading to non-intended changes then must be removed during the further breeding process, which is very time-consuming and not always successful.

New genome editing technologies follow the same principle, but with a higher efficiency and precision, as they apply only one or a few targeted mutations – the type of changes that can also occur naturally or through traditional mutagenic approaches. Recent breakthroughs in plant research allow breeders to know exactly where the change will occur and to better predict the effects of the changes. That is why these techniques are called **precision breeding**. In addition, no DNA from non-related species is present in the final crop, in contrast to GMOs.

What the ECJ ruling means

It is generally concluded that the ECJ ruling means that the crops obtained through this type of precision breeding must comply with the strict GMO directive. In practice, the implications are far-reaching. European agricultural innovation based on precision breeding will come to a halt because of the high threshold that this EU GMO legislation presents. This will hinder progress in sustainable agriculture and will give a competitive disadvantage to plant breeding industries in Europe. The impact on our society and economy will be enormous.

From a scientific point of view, the ruling makes no sense. Crops containing small genome edits are at least as safe as crops obtained through classical mutagenesis or conventional breeding. But more importantly, we find the ruling irresponsible in the face of the world's current far-reaching agricultural challenges.

The ruling proves that current EU GMO legislation is outdated and not in line with recent scientific evidence. As a result, it is crucial that the legislation is adapted such that organisms containing small edits are not subject to the provisions of the GMO legislation, but instead fall under the regime that applies to conventionally bred varieties. Additionally, a more thorough revision of the legislation is necessary for GMOs and new breeding techniques to correctly reflect scientific progress in biotechnology.

Agricultural innovation will miss an important opportunity

Let's make these consequences a bit more tangible. The strict legislation will make precision breeding very expensive and, by consequence, a privilege of just a few large multinational companies. As such, European farmers will miss out on a new generation of hardier and more nutritious crop varieties that are urgently needed to respond to the results of climate change.

For example, diseases and pests from southern areas are rapidly spreading due to increasing temperatures. Switching off certain genes could make crops resistant to these diseases without the use of new pesticides. This applies particularly to crops that reproduce asexually, like potatoes, bananas and strawberries. These crops are more susceptible to diseases because offspring are genetically identical to their parent plants, leading to a lack of diversity. The same principle applies to drought: a significant problem many regions in the world are facing right now. On top of that, precision breeding is also ideal to improve food quality and safety, such as the breeding of new crop varieties with fewer allergens.

Societal and economic impacts

Europe is in a leading position in terms of innovative agricultural research. This has led to the formation of dynamic biotech clusters consisting of numerous innovative start-ups and corporate partnerships. Many of these (small) European seed-breeding companies embrace the new technologies, as they can be implemented relatively cheaply and quickly, and because they can democratize the research and development of new agricultural products.

However, the ruling of the ECJ forces companies to go through a very long and expensive regulatory process. For entrepreneurs engaged in start-up projects involving precision breeding and their potential investors, this creates a low probability of market admission for products developed through precision breeding. Due to this significant uncertainty and additional risk, smaller biotech companies will seek refuge elsewhere. Small- and medium-sized enterprises and investors might consider it too great a risk to develop activities in this hostile environment, ultimately leading to job losses in the sector. Additionally, we risk a brain drain effect when plant researchers leave Europe for better job opportunities abroad.

This also means that in Europe, developing genome-edited crops is only financially feasible for large (multinational) companies and for application in large, broad-acre crops such as maize and soy. In other words, Europe is pushing technology back into the hands of the big market players. This is in huge contrast with countries that have adopted more flexible regulations. In such countries, universities, government institutions and small companies are poised to lead the precision-breeding revolution in agriculture. For example, US regulators have taken the view that genome-edited crops are not a problem as long as they do not contain any foreign genes and are therefore not genetically different from crops developed through traditional breeding processes. As a result, genome-edited crops will soon appear on the American market. Meanwhile, relative lower production costs in non-European areas will lead to more food and feed imports in the EU.

Summary

Subjecting crops obtained through modern genome editing to GMO regulations will deny European consumers, producers, researchers and entrepreneurs important opportunities in sustainable agriculture. Therefore, an urgent review and amendment of the European legislation on new breeding technologies is needed. In the short term, the legislation should be altered such that crops with small DNA adaptations obtained through genome editing are **not subject to the provisions of the GMO Directive but instead fall under the regulatory regime that applies to classically bred varieties.** In the long term, new regulations for GMOs should be developed that are adapted to modern breeding techniques. This new directive should provide more legal certainty and evaluate new crop varieties on a scientific basis.

We therefore urge European policy makers to act to safeguard Europe's competitiveness on all levels.

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