ÖFFENTLICHE STELLUNGNAHME

Europäische Wissenschaftlerinnen und Wissenschaftler appellieren an das neu gewählte Europäische Parlament und die Europäische Kommission, die Nutzung neuer Präzisionsmethoden für die züchterische Verbesserung von Kulturpflanzen zu vereinfachen, um die Entwicklung einer nachhaltigen Landwirtschaft und Nahrungsmittelproduktion in Europa zu ermöglichen.

Die Agenda 2030 der Vereinten Nationen definiert **Ziele für eine nachhaltige Entwicklung** unseres Planeten. Auch die europäische Landwirtschaft ist aufgefordert, dazu ihren Beitrag zu leisten.

Neue, innovative Werkzeuge der molekularen Pflanzenforschung, wie etwa die Präzisionszüchtung mit Hilfe der Genomeditierung (z.B. mit Hilfe der sogenannten Genschere CRISPR/Cas), haben ein enormes Potential, diese Ziele schneller und effizienter zu erreichen.

Die derzeitige Auslegung der Europäischen Gesetzgebung (case C-528/16) verhindert jedoch den Einsatz von Genomeditierungstechnologien zur Entwicklung verbesserter Nutzpflanzen für eine nachhaltigere Landwirtschaft und Nahrungsmittelproduktion in der Europäischen Union. **Bereits eine geringfügige Änderung des existierenden Regelwerks** würde es erlauben, die Europäische Gesetzgebung mit den Regelwerken anderer Länder zu vereinheitlichen. Dies würde es europäischen Wissenschaftlern, Pflanzenzüchtern, Landwirten und Produzenten ermöglichen, Genomeditierung als Werkzeug zu nutzen, um Beiträge für die Bewältigung der zukünftigen Herausforderungen für eine nachhaltige Entwicklung zu leisten.

Auf Grund der ständig wachsenden Weltbevölkerung, der globalen Erderwärmung und dem kontinuierlichen Verlust an biologischer Vielfalt steht die Menschheit nie da gewesenen Herausforderungen gegenüber. Um diese meistern zu können, müssen wir bereit sein, unsere Lebensweise grundlegend zu ändern und Investitionen in Forschung und innovative, ressourcenschonende Technologien zu erhöhen.

Landwirtschaft und Lebensmittelproduktion müssen nachhaltiger und umweltverträglicher werden. Zugleich muss der Pflanzenanbau an den sich beschleunigenden Klimawandel

angepasst werden. Zum Beispiel bedroht Trockenheit zunehmend die Ernteerträge, wie wir es dieses Jahr wieder in Europa erleben. Um die Nahrungsmittelproduktion langfristig zu sichern, müssen alle zur Verfügung stehenden Technologien verantwortungsvoll genutzt werden. Die Pflanzenzüchtung kann mit der Einwicklung neuer Sorten, die weniger anfällig gegen Krankheiten oder widerstandsfähiger gegen Trockenheit sind, dazu einen entscheidenden Beitrag leisten.

Angesichts der großen globalen Herausforderungen müssen Wissenschaftler und Züchter das Potenzial aller zur Verfügung stehenden Technologien nutzen können. Die konventionelle Kreuzungszüchtung ist limitiert durch die langen Generationszeiten, die für die Kombination günstiger Eigenschaften in einer neuen Sorte notwendig sind. Präzisionszüchtung mit Genscheren kann den Züchtungsprozess deutlich beschleunigen. Sie ermöglicht es Wissenschaftlern und Züchtern, einfacher, schneller und preiswerter als bisher neue Sorten mit verbesserten Eigenschaften zu erhalten. Deshalb sollte es Wissenschaftlern und Züchtern in der Europäischen Union ermöglicht werden, diese neuen Technologien für eine nachhaltige Landwirtschaft und Nahrungsmittelproduktion ohne unangemessene Einschränkungen anwenden zu können.

So könnte man zum Beispiel den Einsatz von chemischen Mitteln zur Bekämpfung von Pilzkrankheiten im Weizenanbau deutlich verringern, indem man die sogenannten *MLO*-Gene, die für die Resistenz gegen den Mehltaupilz verantwortlich sind, mit der Genschere minimal verändert. Diese Art von Veränderung existiert bereits in der Natur, aber es wäre extrem schwierig und würde Jahre bis Jahrzehnte dauern, diese Veränderungen mit konventioneller Züchtung in moderne, ertragreiche Weizensorten einzubringen.

Vor genau einem Jahr, am 25. Juli 2018, entschied der Europäische Gerichtshof, dass Pflanzen, die mit der Genschere erzeugt wurden, genau wie transgene Pflanzen, als genetisch veränderte Organismen (GVOs) eingestuft werden müssen. Gleichzeitig sind Pflanzen, die mit den weit weniger präzisen konventionellen Methoden der Genveränderung (Mutagenese) hergestellt wurden, von der Regulierung ausgenommen. Die Folge ist, dass Pflanzen mit einer einzigen von einer Genschere erzeugten Mutation als gentechnisch veränderte Organismen (GVO) klassifiziert werden, während konventionell erhaltene Mutanten mit hunderten oder tausenden Mutationen nicht der strengen GVO-Regulation unterliegen.

Die europäische GVO-Gesetzgebung von 2001 ist nicht mehr zeitgemäß und berücksichtigt nicht den aktuellen Stand der Wissenschaft. Es gibt keine wissenschaftlichen Gründe, identische Veränderungen im Genom abhängig von der Methode der Erzeugung zu machen und völlig unterschiedlich zu regulieren. Pflanzen, die einfache, gezielt mit Genscheren erzeugte Veränderungen enthalten und in die keine fremden Gene eingefügt wurden, sind von Pflanzen konventioneller Züchtung nicht zu unterscheiden und genauso sicher.

Die aktuelle Regelung ist wissenschaftlich nicht zu rechtfertigen und stellt eine unverhältnismäßige Einschränkung dar, die insbesondere den öffentlich finanzierten Forschungsinstitutionen und kleineren Züchtungsunternehmen schadet. Für diese ist es zu teuer und zu aufwendig, die für die Freisetzung von GVOs vorgeschriebenen langwierigen Verfahren zu absolvieren. Als Konsequenz des EuGH-Urteils wird die Nutzung der neuen Präzisionszüchtungstechnologien das Privileg einer kleinen Gruppe finanzstarker multinationaler Konzerne werden. Das macht Investitionen in Forschung und Entwicklung in Europa unattraktiv und wird dazu führen, dass Europa im internationalen Wettbewerb um die Entwicklung neuer Sorten mit verbesserten Eigenschaften zurückfällt.

Die Europäische Union soll ihre hohen Standards für Nahrungsmittelsicherheit und Umweltschutz bewahren. Auch jede nicht als GVO eingestufte Pflanze und deren Produkte werden sorgfältig geprüft. Hierfür wird, in jedem Fall, ein umfangreiches Gesetzeswerk zur Nahrungsmittelsicherheit, zum Sortenrecht sowie zum Schutze der Umwelt und der Artenvielfalt herangezogen.

Die GVO-Gesetzgebung der EU unterscheidet sich von der vieler anderer Länder. Diese klassifizieren Pflanzen nicht als GVOs, wenn sie lediglich Veränderungen aufweisen, die sich von natürlichen Mutanten oder konventionellen Züchtungen nicht unterscheiden lassen. Diese Regelung entspricht dem aktuellen Stand der Wissenschaft und vereinfacht die Nutzung der Genomeditierungstechnologien für die Züchtung verbesserter Nutzpflanzensorten.
Die veraltete GVO-Gesetzgebung der EU wird absehbar zu Störungen des internationalen Handels führen und Konsequenzen für die Nahrungsmittelsicherheit in Europa haben. Da das Ergebnis der durch Genomeditierung erzeugten Veränderungen oft identisch ist mit Mutationen, die spontan in der Natur entstehen, ist es im Normalfall unmöglich von der Anwesenheit einer solchen Veränderung auf die Art ihrer Entstehung zu schließen. Dies

bedeutet, dass die aktuelle restriktive GVO-Gesetzgebung der EU bei importierter Ware durch Kontrollen nicht einmal mehr durchgesetzt werden kann.

Es ist deshalb geboten, **zeitnah durch eine Modernisierung der europäischen Gesetzgebung** eine Angleichung an internationale Standards herbeizuführen. Die europäischen Wissenschaftler und Züchter müssen ihren Beitrag zu einer nachhaltigen Entwicklung unseres Planeten leisten können. Dazu müssen sie in der Lage sein, moderne Präzisionstechnologien wie die Genomeditierung ohne unangemessene Einschränkungen und bürokratische Hindernisse einsetzen zu können.

Die Unterzeichner dieser öffentlichen Erklärung fordern die Europäischen Institutionen einschließlich des Europäischen Rats, des neuen Europäischen Parlaments und der zukünftigen Europäischen Kommission auf, die notwendigen Schritte einzuleiten, um das veraltete europäische Gentechnikrecht zu modernisieren und an internationale Standards anzupassen. Nur wenn die massiven Hindernisse bei der Nutzung der Genomeditierung in der Landwirtschaft beseitigt werden, wird es den europäischen Wissenschaftlern und Züchtern möglich sein, international konkurrenzfähig zu bleiben und nachhaltig zum Wohl und zur Gesundheit der Bürger Europas beizutragen.


Give CRISPR a chance!

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

On July 25th, 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 of this year 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 meet food production goals efficiently, 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 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 impacts 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 be 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 hyper-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. SMEs 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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Susan Gasser, Director of the Friedrich Miescher Institute for Biomedical Research (FMI)	FMI Friedrich Miescher Institute for Biomedical Research

From the Netherlands	
Sjef Smeekens, Professor at Utrecht University **Rens Voesenek,** Professor at Utrecht University **Corné Pieterse,** Professor at Utrecht University **George Kowalchuk,** Professor at Utrecht University **Ronald Pirsik,** Professor at Utrecht University **Guido van den Ackerveken,** Professor at Utrecht University	Utrecht University
Rene Medema, Director of The Netherlands Cancer Institute	NETHERLANDS CANCER INSTITUTE ANTONI VAN LEEUWENHOEK

From UK:	
Achim Dobermann, Director Rothamsted Research	ROTHAMSTED RESEARCH
Dale Sanders, Director John Innes Centre	John Innes Centre Unlocking Nature's Diversity
David Baulcombe, Professor at University of Cambridge	UNIVERSITY OF CAMBRIDGE

Jane Langdale, Professor at University of Oxford	
Julian Ma, Director, Institute for Infection and Immunity, St. George's Hospital Medical School	
Nicholas J. Talbot, Executive Director of the Sainsbury Laboratory (Norwich) **Jonathan Jones,** Group Leader at the Sainsbury Laboratory (Norwich)	
Jeff Cole, EFB Vice-President on behalf of the European Federation of Biotechnology Executive Board	
Michael Wakelam, Director of the Babraham Institute	

From Europe	
Marta Agostinho, EU-Life Director EU-Life: - Austria: Research Center for Molecular Medicine of the Austrian Academy of Sciences (Ce-M-M) - Belgium: Flanders Institute for Biotechnology (VIB) - Czech Republic: Central European Institute of Technology (CEITEC) - Denmark: Biotech Research and Innovation Centre (BRIC) - Finland: Institute for Molecular Medicine Finland (FIMM) - France: Institute Curie - Germany: Max Delbrück Center for Molecular Medicine in the Hemholtz Association - Italy: European Institute of Oncology (IEO) - Portugal: Gulbankian Institute for Science (IGC)	

- Spain: Centre for Genomic Regulation (CRG) - Switzerland: Friedrich Miescher Institute for Biomedical Research (FMI) - The Netherlands: The Netherlands Cancer Institute - UK: Babraham Institute	
FESPB is an umbrella organization for the European Societies of Plant Biology that encompasses 5000 plant scientists. Andrea Schubert, President of the Federation of European Societies of Plant Biology (FESPB) Christine Foyer, Secretary General of the Federation of European Societies of Plant Biology (FESPB)	FESPB The Federation of European Societies of Plant Biology