President Jean-Claude Juncker
European Commission
Rue de la Loi / Wetstraat 200
1049 BRUSSELS

Your message from	Your reference	Our reference	Date
		2019-00062	24 January 2019

Genome editing

Dear president Juncker,

On the 25th of July 2018, the Court of Justice of the European Union ruled in the "C-528/16 mutagenesis case". The Court ruled that the products of genome editing using modern systems like CRISPR/Cas are not exempt from the provisions of the EU GMO Directive 2001/18/EC.

As European scientists we are deeply concerned about the consequences of this ruling. Please also see our position statement in annex to this letter. Having to subject genome edited organisms to the same pre-market risk-assessment and authorization processes as for transgenic organisms will push genome editing into the hands of a select number of large multinational corporations. From a societal point of view this is generally considered undesirable.

Scientists consider the exemption of the products of conventional mutagenesis from the provisions of the EU GMO legislation, while **not exempting the products of modern, much more targeted approaches of mutagenesis as scientifically unjustified and discriminatory**. Moreover, scientific evidence shows that the level of uncertainty about the consequences of the mutagenesis process is much higher in conventional mutagenesis than in modern targeted forms of mutagenesis. In plants conventional mutagenesis generally leads to hundreds if not thousands of unintentional genetic alterations.

Regulating genome editing as GMOs also creates serious economic, international trade and enforcement issues. In important other parts of the world genome edited organisms are not regulated as GMOs. In these countries genome edited organisms are developed and placed on the market without having to go over an unsurmountable regulatory threshold. As a result, European farmers, breeders, producers and consumers are faced with a serious competitive disadvantage. On top of that the products of genome editing may enter the EU market unnoticed, as there are no detection and identification methods that provide the necessary legal certainty about the origin of a certain mutation in all possible scenarios.

As scientists we believe this situation should be urgently addressed. Europe should align itself internationally and create a situation in which genome edited organisms that carry genetic alterations that could also have been achieved by means of conventional breeding, are not subject to the provisions of the EU GMO legislation. **If Europe fails to address this issue correctly, more and more companies will delocalize their R&D to countries outside the EU**. These delocalization

decisions are already being taken today. But it would also negatively affect European science and innovation. We as researchers are not only expected to generate relevant scientific knowledge. Your Commissions' innovation policy justly expects us to translate our knowledge into products and services that are beneficial to our society. Blocking this valorization path has a number of negative consequences: (1) it will make European research less innovative, (2) we will miss out on products that are beneficial to our European agriculture and food production, and (3) the research itself will become less interesting leading to a brain drain towards other parts of the world.

Genome editing using methods like CRISPR is not the only answer to the current challenges of agriculture and food production, but if offers a lever that can help translate important genetic knowledge into benefit for our European society in a faster and much more efficient way.

On behalf of 98 European research centers that support the position statement "Regulating genome editing as GMOs will have negative consequences for agriculture, society and economy", we call upon the European Commission to address this situation and create the regulatory environment that will allow the responsible use of genome editing for sustainable agriculture and food production. More specifically, we call upon the European Commission to:

1. Make sure that solving the current problem is **high on the priority list of ongoing dossiers** to be presented to the next European Commission, such that this topic will be addressed immediately after the start of the new European Commission.

2. **Prepare already today, as necessary, a legal or other proposal** that will create the situation that organisms containing small genetic alterations that can also occur naturally and which do not contain foreign genes are not subject to the provisions of the EU GMO Directive but instead fall under the regulatory regime that applies to classically bred varieties. This would bring the EU back in line with the regulatory approaches in major other parts of the world and solve the international trade and enforcement issues.

3. **Pro-actively engage with the member states** to collect the necessary support for the adoption of such a proposal.

Yours sincerely,

Signed by the 98 European research centers that have supported the position statement "Regulating genome editing as GMOs has negative consequences for agriculture, society and economy".

c.c. Commissioner Vytenis Andriukaitis
Commissioner Phil Hogan
Commissioner Carlos Moedas
Commissioner Marianne Thyssen

Annex: -Overview of supporting European research centers
-Position statement


Genome editing, cutting edge technology for a sustainable agriculture

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.

Signatures:

From Austria:	
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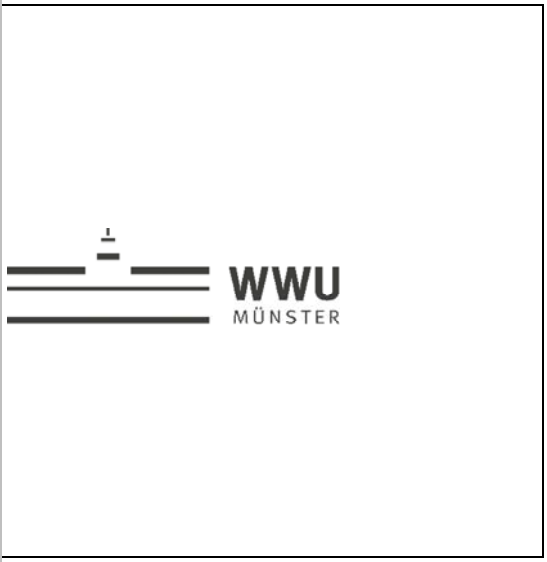
GBM


Fraunhofer
IME


CEPLAS
Cluster of Excellence on Plant Sciences

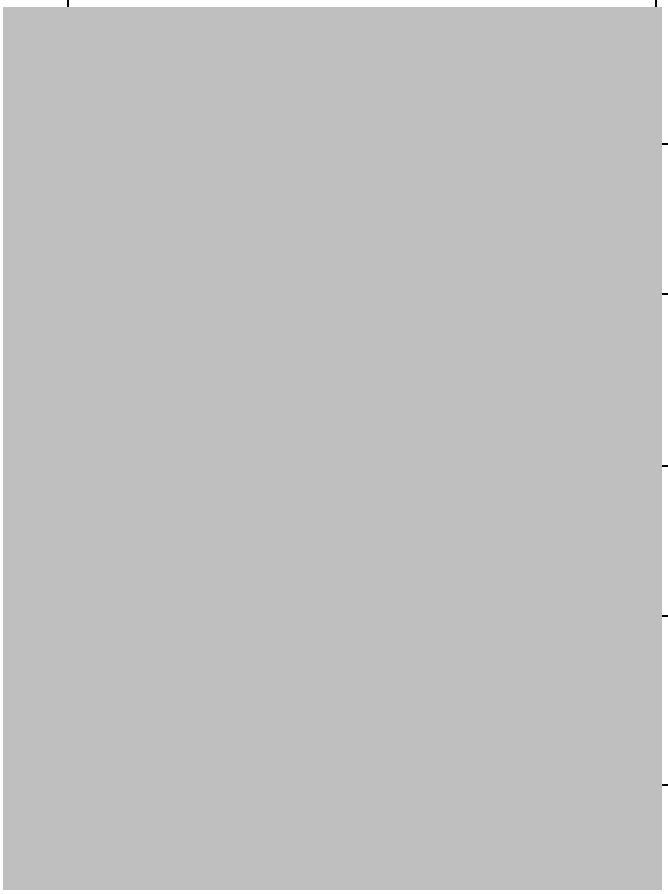

IPK
1943 – 2018


Centre for
Organismal
Studies
Heidelberg



From Hungary:

From Italy:



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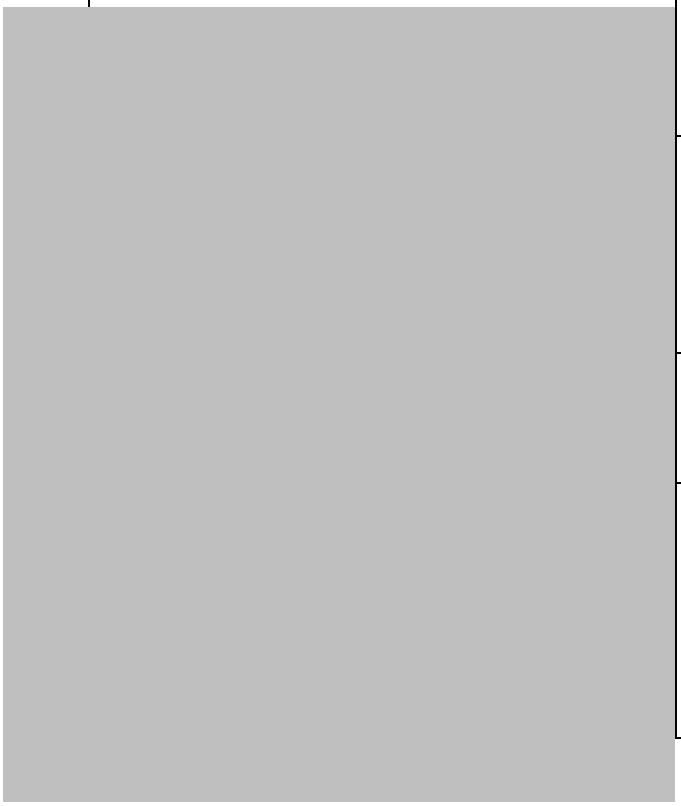
From Slovakia:

From Sweden:



From UK: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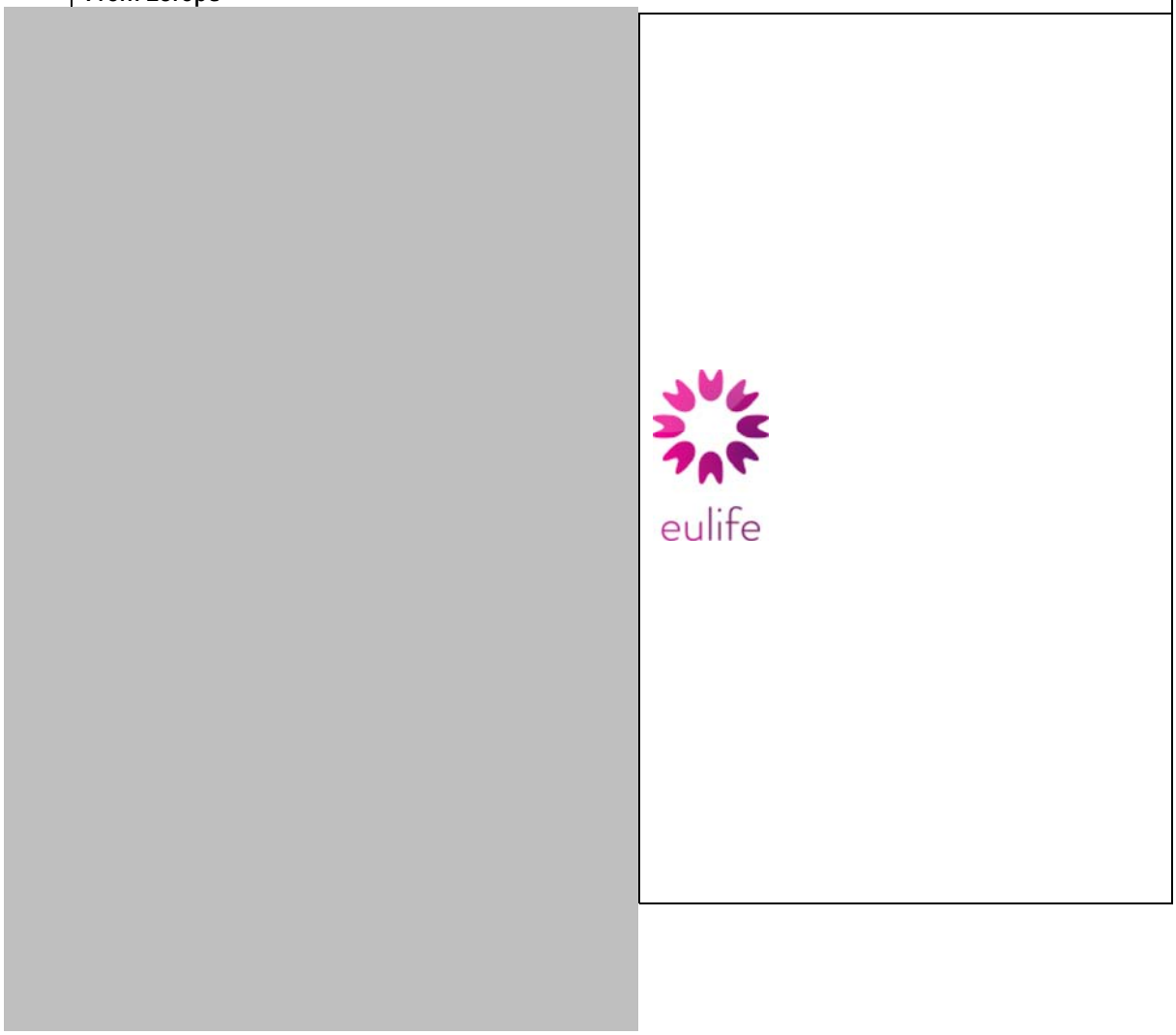
eulife


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The Federation
of European Societies
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