



Resolution
of the conference-discussion
“Genome editing: challenges and possibilities”

Organized by the Lithuanian Academy of Sciences, Vilnius University
and the Lithuanian Research Centre for Agriculture and Forestry
April 25, 2019

**REGARDING THE LEGAL REGULATION
OF THE GENOME EDITING TECHNOLOGY**

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.

The Lithuanian Academy of Sciences, Vilnius University, Lithuanian Research Centre for Agriculture and Forestry, as representatives of the Lithuanian scientific community, are deeply concerned about the consequences of this ruling. 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 technologically advanced countries, such as USA and Japan, 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.

Lithuanian scientists are one of the pioneers of genome editing system discovery, and continue to improve this technology to make its practical application as safe as possible. 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, but also to translate our knowledge into products and services that are beneficial to our society. Blocking this valorisation 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.

The position statement “Regulating genome editing as GMOs will have negative consequences for agriculture, society and economy” is supported by 114 European research centers. We join this initiative and call to support our position and help create the regulatory environment that will allow the responsible use of genome editing for sustainable agriculture and food production.

Yours sincerely,

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