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Invitation to a high-level conference on the regulation of Genome edited plants in Brussels

5 February 2020

Dear Dr. Jülicher,

The German National Academy of Sciences Leopoldina and the German Research Foundation will hold an international conference on the amendment of the European Genetic Engineering Legislation in Brussels in autumn 2020. The background are the new molecular breeding methods and corresponding regulatory models in non-European countries. The conference will also present the statement "Towards a scientifically justified, differentiated regulation of genome edited plants in the EU" published in December 2019 and discuss its recommendations with Members of the European Parliament and the German Federal Minister of Food and Agriculture, Julia Klöckner. A copy of this statement is enclosed.

This event is planned to be held on 1-2 October 2020 as a side event of the German Presidency of the Council at the Permanent Representation of Germany in Brussels. We would like to invite you to participate in a panel discussion on the first day (1:30 - 3:00 p.m.) entitled "Competitiveness of EU's R&D in Plant Breeding and Seed Industry" with representatives of academic research, the European Parliament and industry.

Vereinsregisternr.: 20649 Steuernr.: 110/142/41061 Please find enclosed the outline of the conference programme.

We would be grateful if you could let us know by 20 February 2020 whether you could arrange to attend this panel discussion. Dr. [+49] (+49]

eopoldina.org) and Dr.

Pleopoldina.org) are available to provide more detailed information and answer any questions you may have.

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We look forward to hearing from you.

Yours sincerely,



German Research Foundation



National Academy of Sciences Leopoldina





International conference on scientific advice to policy-makers and society Under the auspices of the German Presidency of the European Union Council

Genome Editing in Europe: New Agenda or New Disputes? Sharing Knowledge in Designing EU's Future GMO Regulation

1-2 October 2020

Target audience: 150 to 200 speakers and attendees: outstanding scientists on GMO related issues, European policy-makers from the EC, EP and EUCO, national and regional policy-makers, MEPs and MS legislators, stakeholders from civil society, farmers' associations, plant breeding associations, business etc.

Rationale: In light of the ECJ Judgment in Case C-528/16 of 25 July 2018 on GMOs, the EUCO asked the EC on 8 November 2019 to submit by April 2021 a study on the "status of novel genome editing techniques under Union law". If regarded recommendable, the study shall include a "proposal" that might transcend into a legislative proposal amending existing EU regulation. This study should be informed by a comprehensive review of foreign regulatory frameworks.

Against the background of diverse reactions to the ECJ Judgement from local to Union-level and from business to consumers, the German Academies of Science and the German Research Foundation (DFG) decided to bring light to the debate through facts based on scientific evidence. Subsequently, they released a report drawn up by an interdisciplinary group of experts in the field. The report calls for a more differentiated approach to regulation of GMOs in Europe, stressing the need to develop a foresighted new regulatory framework, and to insert scientific facts into the design of policy and regulation.

The meeting intends to be an agora for discussing the latest aspects of GMOs in Europe and the world, focussing on prospective EU regulation and on the optimal use of scientific findings in policy design and consumer protection. Additionally, the report commissioned by the German Science Academies and the German Research Foundation will be presented and explained to the audience.

Preliminary programme:

Day 1 11:00 – 11:30 Opening

Julia Klöckner, German Federal Ministry of Food and Agriculture, Germany German National Academy of Sciences Leopoldina German Research Foundation

11:30 – 12:30 Session 1: Rethinking the EU's Regulatory Framework for GMOs (baseline presentations)

Genome editing methods enable directed, cost- and timesaving modifications of the genome of crops, often indistinguishable from naturally occurring mutations and the results of traditional breeding methods. More than 100 (potentially) marketable genome-edited crops are known as nutrition-beneficial, having higher productivity, requiring less use of pesticide and enabling a more sustainable and resource-saving agriculture. The shortcomings of regulating genome-edited organisms (GEOs) in the same way as "genetically modified organisms" (GMOs) call for a general overhaul of the EU's regulatory framework in this area.

The session intends to discuss the state of affairs and prospects for such an undertaking (25 min. presentation each + 10 min. discussion).

- Urgency to Overhaul EU's GMO Regulation in the Context of Climate Change, Sustainable Agriculture and Economic Pressure
- Scientific Recommendations by the German Science Academies and the German Research Foundation

12:30 – 13:30 Buffet lunch

13:30 – 15:00 Session 2: Role and Competitiveness of EU's R&D (high-level panel discussion)

The EU's regulatory framework imposes undue pressure on both researchers and plant breeders. Field trials of GMOs require an authorisation and have to be publicly registered. In the past, these circumstances led to an extensive destruction of test fields, thus triggering a chilling effect on open-field research in the EU. Further, it leads to a relocation of plant breeding research to countries with a more favourable regulatory climate, such as the USA. The GMO authorisation procedure is time-consuming, costly as well as highly unpredictable because of over-politicisation of the matter in public debates.

Therefore, the amendments or a completely new EU GMO regulation should reinforce Europe's global top role in GMO and GEO R&D, plant breeding and agriculture. The session intends to search for ways and means to fulfil this strategic aim (5 min. introductory statement each + 60 min. discussion).

- Dacian Cioloş, MEP
- María Angeles Benítez Salas, Acting Director-General, European Commission Directorate-General for Agriculture and Rural Development
- Sabine Jülicher, Director, European Commission Directorate-General for Health and Food Safety
- European Seed Association
- Copa & Cogeca European Farmers' Associations
 - /IB-U Gent Center for Plant Systems Biology

15:00 – 15:30 Coffee break

15:30 – 17:15 Session 3: Socio-economic and Environmental Concerns (presentations + panel discussion)

A new EU GMO regulatory framework should take into consideration legitimate societal, economic and environmental concerns as voiced by different actors, such as end consumers, farmers, environmental activists or SMEs. Equally, the regulation in case must accommodate the fundamental objectives of environmental protection, nature conservation and sustainable agriculture. According to the precautionary principle, the benefits of new molecular breeding methods and their products need appropriate consideration in a problem-oriented manner, building upon the experience with conventional genetic engineering over the past three decades.

The session intends to bring current debates onto a more objective level, through rational analysis and inclusive dialogue (20 min. presentations each + 45 min. panel discussion)

- Socio-economic and Environmental Concerns in Light of the Sustainable Development Goals
- The Potential of Molecular Breeding for a Sustainable Agriculture and a Plant-based Bioeconomy
- Application of the Precautionary Principle the European vs. the Anglo-American Approach
- Panel Discussion

18:00 - 20:00 Buffet dinner

Day 2: 9:00 – 10:30 Session 4: Regulation of GEOs in the EU and Worldwide (Presentations + Panel discussion)

According to the ECJ Judgment in Case C-528/16 of 25 July 2018, GEOs are generally GMOs in the terms set by the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001. Therefore, GEOs are subject to the legal framework applicable to release, market placing, labelling and GMO traceability. Having in mind the EU's major international trading partners and competitors, there is a tendency to exempt certain GEOs from the rules applicable to GMOs. This applies, in particular, to Argentina, Australia, Japan, and the United States. In Canada, genome-edited seeds may be subject to a product-based authorisation process if it causes "novel traits" of the respective seeds. Therefore, the EU has to deal with asymmetric regulatory approaches worldwide. This can set up unjustifiable trade barriers, which can lead to so-called "trade wars".

The session intends to explore similarities and differences on the global level concerning GMO regulation, having in mind the international competition and trade relations (15 min. presentations each + 45 min. panel discussion).

- GEO Regulation in the EU
- GEO Regulation in Argentina
- GEO Regulation in Australia
- Panel Discussion

10:30 – 11:00 Coffee break and snacks

11:00 – 12:30 Session 4 continuation

- GEO Regulation in Canada
- GEO Regulation in the US
- GEO Regulation in Japan
- Panel Discussion

12:30 End of conference