

STOA online workshop

The challenges of genome editing in plants, with a focus on crops

Participants' booklet

The challenges of genome editing in plants, with a focus on crops

STOA workshop Thursday 15 April 2021, 10:30 - 13:00

Online by WeBex

Participants' booklet

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1. Programme

Co-chaired by Herbert Dorfmann, MEP and STOA Panel Member, and Andrius Kubilius (MEP)

10.30-10.40 Welcome Andrius Kubilius, MEP

10.40-11.00 Keynote: **'CRISPR**-Cas technology**: science and applications'** Virginijus **Šikšnys, Chief** Scientist and Head of the Department of Protein-DNA Interactions at Vilnius University, Institute of Biotechnology

11.00-11.10 **'Genome editing in plants and crops** - Towards a modern biotechnology policy**'** Michelle Habets, Rathenau Instituut

11.10-11.20 **'The status under EU law of organisms developed through novel genomic techniques'** Piet van der Meer, Ghent University and Vrije Universiteit Brussel

11.20-11.30 **'A presentation of the opinion by the EGE on the Ethics of Gene Editing'** Julian Kinderlerer, European Group on Ethics in Science and New Technologies (EGE)

11.30-11.45 **'Deregulation is not an option – a food sector perspective on genome edited crops'** Heike Moldenhauer, Secretary General, European Non-GMO Industry Association (ENGA)

11.45-11.55 **'Foresight and stakeholder engagement on possible futures, wi**shes and concerns' Bjørn Bedsted, Deputy Director of the Danish Board of Technology Foundation

11.55-12.10 'A presentation on citizens' perception of GMO'

Mahiel Reinders, Wageningen University and Research

12.10-12.50 Discussion and Public Q&A

12.50-13.00 Closing Remarks Herbert Dorfmann, MEP and STOA Panel Member

2. Introduction

Novel applications of genome editing, in particular of CRISPR-Cas9, have reinvigorated debate concerning these technologies. This event will seek to identify those issues and challenges arising from the application of genome engineering to crops that are in need of particular attention. It will include a presentation of the science behind genome editing and its applications, and will consider the possible benefits, as well as societal concerns, expected from genetic engineering applications. Moreover, it will discuss ways current EU legislation can address these issues and challenges to better prepare for the widespread use of these novel technologies, and ensure that it is beneficial to society and their risks are addressed properly.

This coincides with an ongoing study by the European Commission on new genomic techniques. In this study, the European Commission carried out a consultation of EU Member States through a specific survey, which ended on 30 April 2020. At the same time, it conducted a targeted stakeholder consultation through a survey involving EU-level stakeholder organisations, which ended on 15 May 2020. The results of this study will be delivered by 30 April 2021.

Following the opening remarks of <u>Andrius Kubilius</u>, MEP, <u>Virginijus Šikšnys</u>, Head of the Department of Protein-DNA Interactions at the Vilnius University Institute of Biotechnology, will deliver the keynote lecture. Professor Šikšnys received multiple awards for his work, including the Kavli Prize for Nanoscience in 2018 and the Warren Alpert Foundation Prize for his contributions to the understanding of CRIPSR and its adaptation to genome editing in 2016.

The keynote speech will be followed by a presentation of the Rathenau Instituut study '<u>Genome</u> editing in plants and crops - Towards a modern biotechnology policy focused on differences in risks and broader considerations' by Michelle Habets, senior researcher and author of the study. Piet van der Meer, associate professor at Ghent University and Vrije Universiteit Brussel, will be outlining the state of the current EU legislation on genome editing. Julian Kinderlerer, who is representing the European Group of Ethics in Science and New Technologies (EGE; European Commission), will present the recently published EGE opinion on the 'Ethics of Gene Editing'.

Heike Moldenhauer, Secretary General, European Non-GMO Industry Association (<u>ENGA</u>), will provide a food-sector perspective of genome-edited crops to further enrich the debate.

Bjørn Bedsted, Deputy Director of the Danish Board of Technology Foundation, will present the stakeholder engagement exercise that preceded this event and was conducted for collecting views from diverse stakeholders on the future of plant genome editing. Lastly, Machiel Reinders, behavioural scientist at Wageningen University and Research, will give a presentation of a consumer and citizen perspective on genome editing. The presentations will be followed by a public Q&A session. The event will conclude with the closing remarks of <u>Herbert Dorfmann</u>, MEP and STOA Panel member.

3. Chairs

3.1. Herbert Dorfmann, MEP and STOA Panel member

Herbert Dorfmann is South Tyrolean and in the European Parliament he is representing the people of the Euroregion Tirol-South Tyrol-Trentino and of the Belluno and Friuli areas. He was born in 1969 in Brixen/Bressanone and studied Agrarian Sciences in Piacenza.

His professional career started as a professor at the Agricultural College in Auer/Ora before he became the director of the agriculture department at the Bozen/Bolzano Chamber of Commerce. Later on, he directed for pearly 10 years the South Tyrelean Farmer



directed for nearly 10 years the South Tyrolean Farmers' Federation.

He started his political career in 2005, with the South Tyrolean People's Party, as mayor of his hometown. In 2009, he was elected for his first mandate at the European Parliament and was reelected in 2014 and 2019 for a second and a third mandate.

3.2. Andrius Kubilius, MEP

Andrius Kubilius is Member of the European Parliament, member of the AFET & ITRE Committees, Co-President of the Euronest Parliamentary Assembly and Head of the EPP Lithuanian delegation. He is former Prime Minister of Lithuania.

Born on 8 December 1956 in Vilnius (Lithuania), he graduated from Vilnius State University, Faculty of Physics. Previously, he held the post of Secretary-in-Charge of the Lithuanian Proindependence Reform **Movement Sajūdis in 1990**-1992 and was chairman of



the Homeland Union – Lithuanian Christian Democrats (2003-2015). From 1992 to 2019, he was a Member of the Seimas of the Republic of Lithuania. He was elected twice as Prime Minister of Lithuania (1999-2000 and 2008-2012).

In this term of the European Parliament (2019-2024), he is member of the Committee on Foreign Affairs (AFET), the Committee on Industry, Research and Energy (ITRE), Chair of the European Parliament Delegation to the European Parliamentary Assembly, as well as member of other EP bodies: the Conference of Delegation Chairs, and the Delegation to the EU-Ukraine Parliamentary Association Committee.

Andrius Kubilius is Head of the EPP Lithuanian delegation, and Chairman of various intraparliamentary groups in the European Parliament: Lithuania Caucus in the EP, Baltic Caucus in the EP, EU Neighbourhood East Forum, and Friends of European Russia Forum. He is also author of international initiatives such as 'Marshall Plan for Ukraine' (later - 'European Plan for Ukraine'), 'Trio Strategy For the Future of Eastern Partnership', and 'Western Strategy Towards Russia'.

4. Speakers

4.1. Keynote: CRISPR-Cas technology: science and applications - Virginijus Šikšnys, Chief Scientist and Head of the Department of Protein-DNA Interactions at Vilnius University, Institute of Biotechnology

Dr Virginijus **Šikšnys** holds the position of Distinguished Professor of Vilnius University and is Chief scientist/Department Head at the Institute of Biotechnology of Vilnius University. He also serves as Chairman of the Board of Life Science Center of Vilnius University. His research on the CRISPR system for antiviral defence has had a major impact on the field. His studies of the Cas9 protein paved the way for the development of novel tools for genome-editing applications. He is a member of the Lithuania Academy of Sciences, Norwegian Academy of Sciences and Letters, Academia Europaea and European Molecular Biology Organization (EMBO). His work has been recognized with several awards and prizes.



Key message

CRISPR-Cas systems transformed biological research by providing the tools that enable robust genome manipulation in living organisms. These tools can be reprogrammed to target any desired site in the genome, creating a wide range of applications from basic biology to biotechnology and medicine. In plants, genome-editing technologies enable precise changes of plant genomes to improve traits without integrating foreign DNA. Precise plant breeding empowered by genome-editing technology is set to change agriculture and could help secure the global food supply.

4.2. Presentations on ethical, legal, societal, and policy-related aspects of genome editing in crops

4.2.1. 'Genome editing in plants and crops - Towards a modern biotechnology policy' - Michelle Habets, Senior Researcher at Rathenau Instituut

Michelle Habets is a senior researcher at the Rathenau Instituut, where she studies societal aspects of emerging biotechnologies. She is involved in projects on gene editing, gene therapy, risk governance, and synthetic life.

Michelle studied biology and philosophy at the Radboud University Nijmegen. After completing her PhD at the Lab of Genetics at Wageningen University, she studied the risks of using antimicrobial peptides in healthcare settings at the University of Liverpool. Subsequently, she obtained an MA in Healthcare Ethics and Law at the University of Manchester. In 2016, she finished her PhD at the University Medical Center Utrecht on the ethics of translational pluripotent stem cell research. At the Erasmus University Rotterdam, she worked on a project combining empirical research and expertise in health care and law to better understand and regulate end-of-life policies.



Key message

The debate in Europe over how to govern novel techniques of gene editing in plants is fast developing into an impasse with actors rapidly consolidating positions on either side of the debate. Such polemic is not good for science nor for public policy.

Two policy options for the EU dominate the debate on gene editing in plants and crops. One option is to uphold the GMO Directive, the other is to exempt genome-editing techniques from the GMO Directive if and only if there is no foreign DNA present in the end product. Both policy options come with societal consequences and challenges. A third, less prominent policy option in the debate attempts to unify the benefits of both options. This third option requires new legislation. Applications will be assessed individually for safety at different assessment levels. In addition, and importantly, applications will be assessed for their anticipated societal value.

Taking into account the differences of opinion of various stakeholders, as well as the ruling of the European Court of Justice, the Rathenau Instituut offers a way forward to modernise the current biotechnology policy, based on a Norwegian proposal: a level-based policy, focused on differences in risks while simultaneously taking account of ethical and societal aspects. The history of the GMO debate illustrates how important these cultural and ethical issues are. Views on how we should feed ourselves involve much more than just questions of safety. They are related to particular sociopolitical beliefs and socio-ecological systems. It is therefore essential that these broader issues are taken into account when drawing up new regulation for biotechnology.

4.2.2. 'The status under EU law of organisms developed through novel genomic techniques' - Piet van der Meer, Ghent University and Vrije Universiteit Brussel

Piet van der Meer trained as a biologist and a lawyer at the University of Leiden, the Netherlands. From 1988 to 1999, he was in charge of biosafety/GMO regulation in the Netherlands, during which he was also actively involved in many international and EU fora. From 1999 to 2002, he managed the project 'Implementation of National Biosafety Frameworks of the pre-accession countries in Central and Eastern Europe'. From December 2002 to May 2004 he managed the UNEP-GEF projects on Implementation of National Biosafety Frameworks.



Since August 2004, Piet van der Meer operates as an independent consultant, offering consulting and management services in the fields of international and national environmental policies and regulations, specialising in biotechnology regulation. His main clients are governments and international organisations. Over the years, Piet van der Meer has provided scientific and regulatory support for biotechnology regulation in over 50 countries and to many national and international organisations. Since 2006 he teaches biotechnology regulation as a guest professor at the University of Ghent, Belgium, and as of 2014 also at the Free University of Brussels (VUB). Piet van der Meer also coordinates the VUB Multi-disciplinary Program on Sustainable Food and Biomass Systems.

Key message

In a ruling on 25 July 2018, the Court of Justice of the European Union (CJEU) concluded that organisms obtained by means of techniques/methods of mutagenesis constitute GMOs in the sense of Directive 2001/18, and that organisms obtained by means of techniques/methods of directed mutagenesis are not excluded from the scope of the Directive. Following the ruling, there has been much debate about its possible wider implications. In October 2019, the Council of the European

Union requested the European Commission to submit, in light of the ruling, a study regarding the status of novel genomic techniques under Union Law. The presentation will summarise an article published in January 2020 in the European Journal for Risk Regulation that aims to contribute to the discussion on the legal status of organisms developed through novel genomic techniques. The **article presents a detailed analysis of the EU GMO definition, following the CJEU's standard methods** of interpretation, by considering the wording, the general scheme and the spirit of the EU GMO Directive. The analysis concludes that for an organism to be a GMO in the sense of the Directive, the technique used, as well as the genetic alterations of the resulting organism, must be considered. The article further details that the 2018 CJEU ruling did not alter this interpretation.

4.2.3. 'A presentation of the opinion by the EGE on the Ethics of Gene Editing'Julian Kinderlerer, European Group on Ethics in Science and New Technologies

Julian Kinderlerer is a visiting Professor, School of Law, University of KwaZulu-Natal. He is the immediate past President of the European Group on Ethics in Science and New Technologies (EGE); Emeritus Professor of Intellectual Property Law, University of Cape Town, former Professor of Biotechnology and Society at the Delft University of Technology, and former Professor of Biotechnological Law and Ethics at the University of Sheffield. In addition, he is a former Director in charge of Biosafety at the United Nations Environment Programme.

At the request of the Director General of the European Commission's DG RTD he was one of the two co-authors of a report on the working of the ethics review system for EU-funded scientific projects. He was first involved



in the regulation of modern biotechnology as a founding member of the Advisory Committee on Genetic Modification (UK) in the early 1980's and has acted as the specialist adviser to the House of Lords Agriculture Committee when examining the regulation of modern biotechnology. He has never been employed by or received any funding from industry.

Key message

It was over 3 years ago that the European Commission requested an opinion from EGE on the ethics of genome editing. The opinion addresses the profound ethical questions that very obviously arise where it is possible to modify the genetic make-up of living organisms in a precise manner. It questions the meaning of naturalness, humanness and diversity. Should modification of the genetic material of life be allowed at all? If it is, how do we judge whether it is safe or acceptable? What are the responsibilities accepted when profound changes are made? What is the likely impact on society (including psychological, social and environmental dimensions) when technology is available that modifies living systems (including the whole ecosystem)?

The section on animals considers the impact of the technology in research as well as commercial use. There is a need for a careful monitoring of the impact of the new technologies on the implementation of the 3Rs. The possible humanisation of animals for research or for clinical purposes needs reflection and constraints. The well-being of genome-edited livestock must be **assured during all stages of the animal's life. Reflection around sustainable food production is** necessary.

There is a need to balance the potential and risks of genome-edited plants. Use could have positive or negative impacts on product availability (food, feed, fibre and fuel), human and animal health, and the agricultural and natural environment. There is a need for a holistic approach to implementation of these new techniques on agricultural practice to include impacts on ecosystems,

agricultural and natural biodiversity, land use, economic impact, and food or feed security. The regulatory system should be proportional to the risks (in particular) that might be posed. Concern that the regulatory regime should not simply benefit large companies is expressed, and public concern at the introduction of new products must be taken fully into account.

4.2.4. **'Deregulation is not an option** – a food sector perspective on genome **edited crops'** - Heike Moldenhauer, Secretary General, European Non-GMO Industry Association (ENGA)

Heike Moldenhauer has been Secretary General of ENGA (European Non-GMO Industry Association) since January 2021. Previously, she served as an EU Policy Advisor for VLOG (German Association Food without Genetic Engineering). She was Head of Section for GMO policy at Friends of the Earth Germany for 17 years and was active as a member of the GMO steering group of Friends of the Earth Europe. She received her degree in philosophy and in German language and literature from the Free University in Berlin. She has been promoting non-GMO food and agriculture in Europe for nearly 30 years.



Key message

Deregulation would mean that products made using the new genetic engineering techniques would come on the market untested and unlabelled. EU political and societal key achievements would be abolished: the precautionary principle, risk assessment, transparency requirements (labelling and traceability), as well as the possibility of product recalls if a GMO should show negative effects after market authorisation.

It is the food sector that would be most affected should it come to a deregulation of genome-edited crops. Farmers, seed, food and feed producers and retailers would lose control over their value chains. Food retailers would run the risk of selling unwittingly and unintentionally GMO products to their customers. The food sector, rather than developers and marketers of GM seeds, would be exposed to critical inquiries and anger of consumers.

The current EU GMO legislation is balanced: GMOs receive EU market authorisation, and it allows business operators to keep GMOs out of the food-and-feed-production value chains and thus enables consumers to consciously avoid GMOs in their food.

Genome-edtied crops do not have a long history of safe use, their alleged safety is a mere claim and not substantiated by any systematic scientific studies.

Whether genome-edited crops will ever contribute to a sustainable agriculture and mitigate the consequences of climate change and biodiversity loss is an open question. Attempts to soften a functioning legislation and the CJEU ruling for mere promises is irresponsible and cannot be communicated to an EU public that is critical of GMOs.

4.2.5. 'Foresight and stakeholder engagement on possible futures, wishes and concerns' - Bjørn Bedsted, Deputy Director of the Danish Board of Technology Foundation

Bjørn Bedsted (M) is the Deputy Director of the Danish Board of Technology (DBT) Foundation and has led numerous technology assessment and public engagement projects in various technology and policy fields. He is an expert in stakeholder and citizen participation and responsible research and innovation.

Key message

Bjørn will present the foresight and stakeholder engagement process for the exploration of possible futures, wishes and concerns relating to the governance of plant genome editing.



4.2.6. **'A presentation on citizens' perception of GMO'** - Mahiel Reinders, Wageningen University and Research

Machiel J. Reinders (PhD) is a Senior Researcher in Consumer Behaviour at Wageningen University and Research, The Netherlands. He coordinates and conducts (international) consumer research projects and has the role of senior scientist within the organisation. His research topics focus on consumer behaviour related to sustainable and healthy food products, consumer response to new food products and technologies and behavioural change.

Machiel holds a PhD in Marketing from Vrije Universiteit Amsterdam. His PhD research focused on consumer response to product

innovations, resulting in a dissertation **on** 'Managing consumer resistance to innovations'. He has published his work in international peer-reviewed journals such as *Food Quality and Preference* and *Trends in Food Science and Technology*.

Key message

The future of genome editing in plants also depends on whether this development will be accepted by society. Over the past years, extensive research has been conducted related to citizen/consumer perceptions of genetically modified organisms utilised in agrifood systems and food production. In his presentation Machiel Reinders will provide an introduction to the most important insights from this research. His presentation will **show that not only rational arguments play a role in consumers'** evaluation of gene technologies, but due to a lack of knowledge also automatic and irrational responses play an important role. Moreover, because there is no such thing as an overall consumers' opinion, the societal debate could be advanced by making a more nuanced distinction between different applications of gene technologies and different types of consumers. The presentation will end with some policy recommendations.



5. About STOA

5.1. Mission

The Panel for the Future of Science and Technology (STOA) forms an integral part of the structure of the European Parliament. Launched in 1987, STOA is tasked with identifying and independently assessing the impact of new and emerging science and technologies.

The goal of its work is to assist, with independent information, the Members of the European Parliament (MEPs) in developing options for long-term, strategic policy-making.

The STOA Panel

The STOA Panel consists of 27 MEPs nominated from eleven permanent parliamentary committees: AGRI (Agriculture & Rural Development), CULT (Culture & Education), EMPL (Employment & Social Affairs), ENVI (Environment, Public Health & Food Safety), IMCO (Internal Market & Consumer Protection), INTA (International Trade), ITRE (Industry, Research & Energy), JURI (Legal Affairs), LIBE (Civil Liberties, Justice and Home Affairs), REGI (Regional Development) and TRAN (Transport & Tourism).

Ewa KOPACZ is the European Parliament Vice-President responsible for STOA for the first half of the 9th parliamentary term. The STOA Chair for the first half of the 9th parliamentary term is Eva KAILI with Christian EHLER and Ivars IJABS elected as 1st and 2nd Vice-Chairs respectively.

The STOA approach

STOA fulfils its mission primarily by carrying out science-based projects. Whilst undertaking these projects, STOA assesses the widest possible range of options to support evidence-based policy decisions. A typical project investigates the impacts of both existing and emerging technology options and presents these in the form of studies and options briefs. These are publicly available for download via the STOA website: www.europarl.europa.eu/stoa/.

Some of STOA's projects explore the long-term impacts of future techno-scientific trends, with the aim to support MEPs in anticipating the consequences of developments in science. Alongside its production of 'hard information', STOA communicates its findings to the European Parliament by organising public events throughout the year. STOA also runs the MEP-Scientist Pairing Scheme aimed at promoting mutual understanding and facilitating the establishment of lasting links between the scientific and policy-making communities.

Focus areas

STOA activities and products are varied and are designed to cover as wide a range of scientific and technological topics as possible, such as artificial intelligence, blockchain, 5G, genetic engineering, antibiotics resistance, internet addiction, face recognition, pollution, sustainable agriculture, COVID-19 and health in general.

These activities are clustered within three main thematic areas: Artificial intelligence & other disruptive technologies; The new Green Deal; and Quality of life. In addition, STOA's work addresses four cross-cutting policy areas: Science, technology and innovation; Societal and ethical challenges; Economic challenges; and Legal challenges.

ESMH

The European Science-Media Hub (ESMH), operating under the political responsibility of the STOA Panel, is a platform to promote networking, training and knowledge sharing between the European Parliament, the scientific community and the media. The ESMH creates a network among policy-makers, scientists and media involving science, academia, educational and research entities, and professional associations of journalists and scientists. The ESMH aims at promoting information based on evidence and making it available to journalists, other media and citizens, about new scientific developments, as well as about scientific topics that attract media attention.

For journalists and media representatives, the ESMH organises training sessions and workshops on current technological developments, both as subjects of their reporting and as means of facilitating their work. Via media monitoring and media intelligence tools, the ESMH also follows the most popular topics in the field of science and technology on different platforms including journals, newspapers and social media.

5.2. STOA Panel members

Panel Member	Committee		Panel Member	Committee
Ewa KOPACZ (EPP, PL) EP Vice-President STOA Bureau member			Herbert DORFMANN (EPP, IT)	AGRI
Eva KAILI (S&D, EL) STOA Chair STOA Bureau member	ITRE		Lina GALVEZ MUÑOZ (S&D, ES)	EMPL
Christian EHLER (EPP, DE) 1st STOA Vice- Chair - STOA Bureau member	ITRE		Alexandra GEESE (Greens/EFA, DE)	ІМСО
Ivars IJABS (Renew Europe, LV) 2nd STOA Vice- Chair - STOA Bureau member	ITRE		Alexis GEORGOULIS (GUE/NGL, EL)	CULT
Anna-Michelle ASIMAKOPOULOU (EPP, EL)	INTA		Maria GRAPINI (S&D, RO)	TRAN
Rosa D'AMATO (NI, IT)	REGI	B	Ivo HRISTOV (S&D, BG)	AGRI
Francesca DONATO (ID, IT)	AGRI		Marina KALJURAND (S&D, ET)	LIBE

 Panel Member	Committee		Panel Member	Committee
Othmar KARAS (EPP, AT)	ITRE	B	Hermann TERTSCH (ECR, ES)	ENVI
Maria Manuel LEITÃO MARQUES (S&D, PT)			Barbara THALER (EPP, AT)	TRAN
Karen MELCHIOR (Renew Europe, DK)	ІМСО		Patrizia TOIA (S&D, IT)	ITRE
Caroline NAGTEGAAL (Renew Europe, NL)	TRAN		Yana TOOM (Renew Europe, ET)	EMPL
Dennis RADTKE (EPP, DE)	EMPL		Viola VON CRAMON- TAUBADEL (Greens/EFA, DE)	ITRE
Michèle RIVASI (Greens/EFA, FR)	ENVI	Bib	Tiemo WÖLKEN (S&D, DE)	JURI
Susana SOLÍS PÉREZ (Renew Europe, ES)	ENVI	AGRI:Agriculture and Rural DevelopmentCULT:Culture and EducationEMPL:Employment and Social AffairsENVI:Environment, Public Health and Food SafetyIMCO:Internal Market and Consumer ProtectionINTA:International TradeITRE:Industry, Research and EnergyJURI:Legal AffairsLIBE:Civil Liberties, Justice and Home AffairsREGI:Regional DevelopmentTRAN:Transport and Tourism		

5.3. STOA administration

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