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GENOME EDITING IN AGRICULTURE IMPLICATIONS FOR SOCIETY REPORT

FIRST EDITION OF
THE BRUSSELS
SCIENCE IN
SOCIETY SALON

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The contents of this booklet should not be interpreted as expressing a position of the European Commission; likewise, only the Group of Chief Scientific Advisors' Statement on Gene Editing and Explanatory Note on New Techniques in Agricultural Biotechnology represent the Advisors' official positions on these subjects at the present time.

GENOME EDITING IN AGRICULTURE IMPLICATIONS FOR SOCIETY REPORT

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FOREWORD

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The current debate surrounding gene editing will have profound impacts on the future of agriculture in Europe and across the world. In this complex, fast moving and emotive area, policy makers need to have a clear understanding of the issues at stake: what is gene editing?; how does it differ from existing genetic modification and traditional plant breeding techniques?; what does this mean for risk assessments and regulatory approvals?; and how can it contribute to Europe maintaining its high standards of food safety and environmental protection?

The European Commission's group of Chief Scientific Advisers have worked intensively on exactly these issues, and it is fitting that this topic was chosen for the first edition of the Brussels Science in Society Salon. Bringing together Parliamentarians, civil society, and other policy makers and stakeholders, this event provided a convivial and respectful setting for a much-needed constructive and open debate.

As society faces rapid advances in science and technology, we will need more of these kinds of debates. And so, I very much look forward to further editions of the Science and Society Salon.



CARLOS MOEDAS
EUROPEAN COMMISSIONER FOR RESEARCH,
SCIENCE AND INNOVATION

INTRODUCTION

Science offers the possibility of far greater well-being for the human race than has ever been known before.

BERTRAND RUSSELL

S

Science and technology have had a major impact on society, and their impact is growing. By drastically changing our means of communication, the way we work, our housing, clothes, and food, our methods of transportation, and, indeed, even the length and quality of life itself, science has not only

altered the way we live, it is also challenging the moral values and traditional way of organising society. In recent years, the need for a stronger nexus between the worlds of science, society and policy has been identified, but there is still much to learn about how to translate effectively between these worlds.

Therefore, Re-Imagine Europa (RIE) together with the Group of Chief Scientific Advisers and the Science Advice Mechanism (SAM) of the European Commission explored the suitability of a regular space to discuss how science and new technologies will impact society and policy. On the 2nd of April 2019, they organised the first edition of the Brussels Science-in-Society Salon on the topic of "Genome Editing in Agriculture – Implications for Society".

The event, hosted at the European Parliament by MEP Paul Rübig (EPP), MEP María Teresa Giménez Barbat (ALDE) and Georgi Pirinski (S&D), brought together fifty leading thinkers from across Europe with different expertise and backgrounds in order to discuss the possible implications on society of genome editing in agriculture.

The event was structured as a high-level salon to allow for real exchange and debate. The full programme and list of participants can be found at the end of this report. In order to allow for an open debate, certain parts of the debates were held under Chatham House Rules.

This aim of this report is to give an overview of the discussions and analyse the need and impact of hosting a Brussels Science-in-Society Salon.



OVERVIEW OF THE ISSUE

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Professor Rolf-Dieter Heuer, Chair of the European Commission's Group of Chief Scientific Advisors (hereafter called 'the Group') and former Director-General of the European Organisation for Nuclear Research (CERN) and Professor Janusz Bujnicki, Member of the Group and Head of the Laboratory of Bioinformatics and Protein Engineering at the International Institute of Molecular and Cell Biology in Warsaw, opened the debate. They gave an overview of the work of the Group in the area of new techniques in agriculture including gene editing and explained the motivation for providing a statement on the regulatory status of products derived from genome editing. The full statement can be found below.

The invention of agriculture around 10,000 years ago gave access to vast new food and energy resources, dramatically transforming the way we lived. Ever since, human beings have endeavoured to impro-

ve their crops and animals. In doing so, we have selected plants, animals and microorganisms that give a greater yield, are more palatable, easier to process, etc. These are known as desirable traits.

For many years, this selection of desirable traits happened when farmers collected and planted seeds from more vigorous plants, or mated specific animals (processes known as conventional breeding techniques, CBT). Because these traits are a result of an organism's genetic makeup, when this kind of selection takes place over an extended period the genetic profile of a population of organisms changes. The offspring of individuals within that population increasingly display the desired characteristics or traits.

The ways in which organisms with desirable traits can be selected has become more sophisticated as technology has developed. At first, chemical or physical agents (such as x-rays) were used to make random changes to plant seeds (in a process known as induced mutagenesis) in the hope that some changes would result in desirable traits. More targeted genetic modification (GM) became possible during the 1980s, typically involving the insertion of genetic material into organisms, some of which may be from other species. This introduced genetic material can sometimes be transferred to offspring, or might only be present in a single generation. While the identity of the inserted genetic material is controlled, the location of its insertion usually cannot be controlled.

More recently, a variety of new breeding techniques (NBT), including gene editing, have found their application in agricultural biotechnology. Some of these techniques

do not lead to the inclusion of genetic material from other species or to changes of genetic sequences, while others do. When changes to genetic sequences are made, they are typically made in a more precise manner than those made with the established techniques of genetic modification (ETGM) described above.

There is debate in Europe and elsewhere about the extent to which human biotechnological intervention in agricultural the genetic make-up of organisms is desirable. Some believe that biotechnological intervention creates unacceptable environmental and human health risks, or that it is unethical to interfere with genetics. Others believe that biotechnological innovation can help to solve challenges including those related to food insecurity and poor nutrition, and can provide economic and ecological benefits.

This has become a very hot topic since the Court of Justice of the European Union (ECJ), in July 2018, decided that organisms obtained by the new techniques of directed mutagenesis are genetically modified organisms (GMOs) within the meaning of the Directive 2001/18/EC. It was stated in Science that this is "the death blow for plant biotech in Europe". Gene-edited plants will have to go through the same regulatory process as genetically modified plants obtained with older techniques. The associated costs of about \$35 million. will be difficult to bear by universities, non-profits, and small companies. Others, such as Greenpeace, welcomed the ECJ's ruling as prioritising 'the protection of human health and the environment'.

This has also reinforced a deeper public discussion to look more in detail at whether



our current regulatory system in the European Union is still fit for purpose in view of recent up-to-date scientific knowledge and technological development. Adapting the law to the current context rises ethical, safety and public health questions since part of the impact of genome editing hasn't been completely assessed. On the other hand more permissive legislative systems allow the exploitation of genome editing techniques to progress at a faster pace.

Recent evidence shows that genome editing technology in agriculture may lead to substantial advantages, for example in terms of lower production costs, improved food safety and quality and resilience of crops to extreme weather conditions. In addition, these techniques are simpler and require fewer resources than techniques of genetic modification that were implemented in the last two decades of the twentieth century.

To discuss in more detail the possible challenges and opportunities of genome editing in agriculture, participants were divided into five groups to look at specific issues. You will find more information about the topics and a summary of the discussions below.

STATEMENT BY THE GROUP OF CHIEF SCIENTIFIC ADVISORS

A SCIENTIFIC PERSPECTIVE ON THE REGULATORY STATUS OF PRODUCTS DERIVED FROM GENE EDITING AND THE IMPLICATIONS FOR THE GMO DIRECTIVE

13 NOVEMBER 2018

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On 25 July 2018, the Court of Justice of the European Union (the Court) decided that organisms obtained by the new techniques of directed mutagenesis are genetically modified organisms (GMOs), within the meaning of the Directive 2001/18/EC on the release of genetically modified organisms into the environment (GMO Directive)¹², and that they are subject to the obligations laid down by the GMO Directive.

New techniques of directed mutagenesis include gene editing such as CRISPR/Cas9 methodologies. The legal status of the

products of such techniques was uncertain, because it was unclear whether they fell within the scope of the GMO Directive.

These techniques enable the development of a wide range of agricultural applications and the ethical, legal, social and economic issues of their use are discussed intensively. The European Commission's Group of Chief Scientific Advisors (the 'Chief Scientific Advisors')³ recognises the complex nature of these debates, which touch upon people's beliefs, values, and concerns, as well as the underpinning science.

The mandate of the Chief Scientific Advisors is to provide scientific advice to the European Commission. Therefore, following our explanatory note on 'New Techniques in Agricultural Biotechnology' (SAM, 2017a), we have examined the GMO Directive taking into account current knowledge and scientific evidence.

1. The Ruling of the Court of Justice

On request by the French Conseil d'État, the Court was asked to determine whether organisms obtained by mutagenesis⁴ should be considered GMOs and which of those organisms are exempt according to the provisions of the GMO Directive. In particular, the Court was asked to determine whether organisms obtained by new directed mutagenesis techniques are exempt from the obligations imposed by the GMO Directive, as are those obtained by conventional, random mutagenesis techniques that existed before the adoption of the Directive, or are regulated like those obtained by established techniques of genetic modification (ETGM).

The Court declared that organisms produced by directed mutagenesis techniques/methods should be considered GMOs

within the meaning of the GMO Directive and subject to the relevant requirements. In this regard, the Court concluded that only organisms obtained by means of techniques/methods of mutagenesis, which have conventionally been used in a number of applications and have a long safety record, are exempt. The Court also considered that 'risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis'⁵ The Court further reasoned that these new techniques 'make it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis'.

New techniques resulting in directed mutagenesis can alter a DNA sequence precisely at one or more targeted positions in the genome. For an overview of different types of gene editing see our explanatory note on 'New Techniques in Agricultural Biotechnology' (SAM, 2017a) including a description of the CRISPR/Cas9 system (Jinek et al., 2012). Random mutagenesis, which has been used extensively in plant breeding since the 1960s (SAM, 2017a), alters an organism's genome at multiple

¹ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0018>

² <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

³ <https://ec.europa.eu/research/sam/index.cfm?pg=hlq>

⁴ Mutagenesis encompasses both random mutagenesis and directed mutagenesis. Random mutagenesis is also often referred to as 'conventional mutagenesis' or 'traditional mutagenesis', whereas 'directed mutagenesis', 'site-directed mutagenesis' or 'precision mutagenesis' are often used as synonyms for 'targeted mutagenesis'. The Court used the term 'directed mutagenesis'

⁵ The term 'transgenesis' is often used to refer to the introduction of a gene or genes from a distinct species into a cell or an organism, but can also be interpreted in a broader sense to refer to the introduction of an exogenous gene or genes into cells or organisms leading to the transmission of the input gene (transgene) to successive generations. This can include the introduction of (a) gene(s) from the same or a sexually compatible species. The present statement collectively refers to these techniques as established techniques of genetic modification (ETGM).

positions in a non-targeted way by treatment with a chemical mutagen or irradiation. ETGM, which have been used in agriculture since the 1980s, can be used to introduce DNA sequences from other organisms.

The background for the Court ruling was an action brought before the French Conseil d'État by the French agricultural union Confédération Paysanne together with eight other associations. This action contested the French legislation according to which organisms obtained by mutagenesis are not, in principle, considered as being the result of genetic modification, and asked for a ban on the cultivation and marketing of herbicide-tolerant oilseed rape varieties obtained by mutagenesis. The claimants argued that such herbicide-resistant seed varieties pose a risk to the environment and health.

2. Issues and questions arising from the ruling and the application of the GMO Directive

The GMO Directive states that 'the regulatory framework for biotechnology should be reviewed so as to identify the feasibility of improving the consistency and efficiency of that framework' (Recital 63). As detailed below, in view of the Court's ruling, it becomes evident that new scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose. Moreover, the GMO Directive gives rise to more general problems, in particular with regard to the definition of GMOs in the context of naturally occurring mutations, safety considerations, as well as detection and identification.

2.1. Definition of GMOs in the context of naturally occurring mutations

The definition of GMOs contained in the GMO Directive dates back to 1990. According to this definition, a GMO is 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.⁶ In the light of current scientific knowledge, it is worth reflecting whether the concept of 'naturalness' is useful when deciding on regulatory requirements for organisms with an altered genome.

Mutations occur naturally without human intervention (SAM 2017a). They arise spontaneously during cell division or are triggered by environmental factors such as ultraviolet light or viral infections, and can be either neutral, harmful or confer a competitive advantage to the organism. This is the underlying mechanism of natural evolution. From the time of the adoption of the GMO Directive until now, owing to progress in analytical methods, extensive scientific evidence has been accumulated on spontaneously occurring genetic alterations. These include point mutations (changes within a single letter in the genomic DNA), insertions, deletions and rearrangements of the genome, as well as the acquisition of exogenous genetic material across species or even kingdoms (e.g. (Kyndt et al., 2015)). Therefore, if referred to in the legislation, the concept of 'naturalness' should be based on current scientific evidence of what indeed occurs naturally, without any human intervention, in organisms and in their DNA.

⁶ https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a84d20-86a80baaf0518d22.0004.02/DOC_1&format=PDF

2.2 Safety considerations

Changes introduced by random mutagenesis are usually more drastic than those resulting from gene editing techniques, and include not only numerous point mutations, but also deletions and major rearrangements of genome fragments. The resulting mutant organisms (in this case plants) require lengthy screening of the organisms' characteristics to identify the few mutants that carry a novel desirable feature and do not present any unwanted features. Despite this lengthy screening process, the ultimately selected end products are likely to carry additional mutations beyond the ones resulting in the desired trait, each of which can be considered to be an 'unintended effect'⁷. Such unintended effects can be harmful, neutral or beneficial with respect to the final product.

In 2001, when the Directive 2001/18/EC was adopted, gene editing technologies were not yet being applied to agricultural organisms. For example, the CRISPR/Cas9 system was first described only in 2012 (Jinek et al., 2012). Gene editing techniques can produce specific alterations at precise locations in the genome ranging from point mutations through to the targeted deletion or insertion of a gene, of parts of a gene or of other functional DNA sequences. Because

of their precision, these gene editing techniques produce fewer unintended effects (Khandagale & Nadaf, 2016; SAM, 2017a) than random mutagenesis techniques. In addition, the end product is better characterised with respect to specific mutation(s) in the targeted position(s).

Because unintended effects will occur less frequently in gene edited products, these products are potentially safer than the products of random mutagenesis⁸. Recently more progress has been made to further increase the efficiency and precision, and thus the safety of the gene-editing techniques (Yin, Gao, & Qiu, 2017).

The Court has argued that new varieties can be produced at a much higher rate and in larger quantities by the directed mutagenesis techniques than by conventional methods of random mutagenesis. Targeted mutagenesis is more efficient than random mutagenesis or other conventional breeding techniques, and can speed up the process of generating desired varieties. However, the greater precision of the directed mutagenesis techniques, which enable better control of the product's characteristics, is a much more important factor to consider in safety deliberations than the rate at which products are generated.

⁷ As explained on page 32 of the Explanatory Note on 'New Techniques in Agricultural Biotechnology' (SAM, 2017a) two different types of unintended effects can occur during breeding: (1) unintended changes and (2) unintended effects of the intended changes. Random mutagenesis results in numerous unintended changes. In the case of gene editing, the unintended changes are often referred to as 'off-target effects'.

⁸ As emphasised in the explanatory note on 'New Techniques in Agricultural Biotechnology' (SAM, 2017a) the frequency of unintended effects does not allow direct conclusions regarding safety to be drawn as unintended effects can be neutral, harmful or beneficial. They therefore need to be assessed case by case. However, the occurrence of unintended effects is often raised in public discussions in relation to concerns about the safety of gene editing products. In general, the precision of the gene editing methods is expected to reduce some sources of unintended effects. Therefore, they have the potential to produce fewer possibly harmful unintended effects at product level.

In addition, gene editing techniques result in fewer intermediate and unwanted 'varieties' compared to random mutagenesis techniques.

The GMO Directive refers to both the process used in genetic engineering and the product resulting from the use of such techniques (Abbott, 2015), but it is often interpreted as being based only on the production technique rather than the characteristics of the resulting product (Sprink, Eriksson, Schiemann, & Hartung, 2016). An example of this is the consideration of the 'long safety record' of random mutagenesis which is introduced by Recital 17 of the GMO Directive as a criterion for deciding whether products generated with different techniques of genetic modification are exempt from its obligations or not. In scientific terms what is more relevant is, whether or not the products have a long safety record, rather than the techniques used to generate them.

In that context, it is important to recognise that the concerns put forward by the Confédération Paysanne about the risk of herbicide resistant seed varieties to the environment and health are not addressed by subjecting organisms produced by directed mutagenesis to the obligations of the GMO Directive. This is because herbicide resistant seed varieties can in principle be produced by all mutagenic procedures including ETGM, new directed mutagenesis techniques, random mutagenesis, as well as other conventional breeding methods. It is not primarily the modified crop that constitutes the potential ecological risk, but rather the use of the herbicide and the overall production system associated with herbicide use (Bioökonomierat, 2018). To answer the question whether herbicide resistant seed varieties constitute a risk to health and

environment, **the features of the final product itself must be examined regardless of the underlying technique used to generate that product.**

As described in our explanatory note (SAM, 2017a), the safety of an organism is determined by multiple factors such as the specific characteristics of the organism, the environment in which it is cultivated, the agricultural practices used, and exposure to human beings and animals rather than by the technique used for its production. Hence, the risks of a product are determined by these factors and therefore logically should be assessed in the same way independently of whether they are produced by conventional breeding techniques, random or directed mutagenesis, or by ETGM. Consequently, the current approach does not properly respect the motivation behind the precautionary principle of ensuring product safety. From the above it follows that the regulatory framework for GMOs should put much more emphasis on the features of the end product, rather than on the production technique. As long as this is not the case, situations can arise where two products are identical, but because of different methods used in their production, they would have to meet completely different regulatory requirements.

2.3 Detection and identification issues

The ability of gene editing techniques to precisely introduce mutations identical to those originating spontaneously or through random mutagenesis has important consequences for the detection of gene edited products, as described in our explanatory note (SAM, 2017a). Depending on the mutation type and the context in which it is used, it will be difficult and sometimes impossible

for applicants to provide a detection method for gene edited products which will meet regulatory requirements (Casacuberta & Puigdomènech, 2018), for instance in the case of point mutations.

Detection becomes even more difficult when there is no prior knowledge concerning the organism under investigation, whether authorised or not, in particular regarding the introduced genetic changes and/ or a suitable detection method (SAM, 2017a). Competent authorities will be faced with such circumstances, for instance, when organisms arrive on the EU market, which have been authorised under regulatory systems outside the EU with differing regulatory requirements. There can be no analytical approach for detecting and quantifying all possible gene edited products. Therefore it cannot be excluded that products obtained by directed mutagenesis will enter the European market undetected. It will be impossible to identify whether the mutations have occurred spontaneously or were introduced by human intervention, or to attribute them to a specific technique such as random mutagenesis or directed mutagenesis, particularly given that in some cases the final product will be identical to that generated by other procedures (Sprink et al., 2016). However, as mentioned before, the safety of a product is determined by its characteristics and not by the way it was generated. **Therefore, the impossibility of distinguishing between spontaneously occurring mutations and different types of human interventions is a major issue from a regulatory point of view.**

A document, currently under prepara-

tion by the European Network of GMO Laboratories together with the European Commission's Joint Research Centre, will look in more detail at the issues related to detection, identification and quantification than we do here.

3. Possible consequences

The ruling of the Court can be expected to have important consequences for European citizens –both consumers and farmers. It may also have impacts on international trade and cooperation with developing countries, and very likely, also on the EU research and innovation landscape. The consequences need to be analysed and discussed elsewhere, as this statement focusses on scientific issues related to the application of the GMO Directive to the new directed mutagenesis techniques, but we make some comments here to inform those discussions.

In legal terms, products of gene editing can be authorised in the EU according to the GMO Directive. However, meeting the obligations of the GMO Directive implies cost- and labour-intensive pre-market evaluations and a long duration of the approval process, which are difficult and onerous to bear, particularly by small and medium enterprises⁹. This may diminish incentives for investment, negatively affect research and innovation in this field, and limit the commercialisation of gene edited products (Bioökonomierat, 2018; Georges & Ray, 2017).

In addition, the obligations, imposed by

⁹ For a description of the length and cost of the regulatory process, see for instance (Bioökonomierat, 2018; Callaway, 2018; Stokstad, 2018).

the GMO Directive, on traceability and labelling of GMOs entering the European market will be very difficult to implement and control due to issues related to the detection, identification and quantification of gene edited products described above (section 2.3). This will become more difficult when exporting countries start to market varieties that they have already decided not to regulate. An example is the case of gene edited mushrooms developed to have a reduced tendency to brown¹⁰ (Georges & Ray, 2017; Waltz, 2016).

Environmental applications of gene editing technologies could enable novel approaches to conservation, bioremediation, the control of invasive species, and the protection of biodiversity (ShuklaJones, Friedrichs, & Winickoff, 2018). Hindering EU progress in this field may prevent the use of gene editing technologies for environmental applications as well as for sustainable food production¹¹, including the reduction of food scarcity in developing countries. Lost opportunities could include producing plants with resistance to pests and diseases, reducing the use of pesticides and fertilizers, generating resilience to harsh weather conditions, or enhancing nutrients in foods (Haque et al., 2018; Georges & Ray, 2017; Palmgren et al., 2015). Several gene edited crops and horticultural plants with novel features, such as healthier nutrient composition, are already in development which have the potential to provide immediate direct benefits to the consumer (for an overview of applications of gene editing in crops, vegetables and fruit

see e.g. Khandagale & Nadaf, 2016; Modrzejewski, Hartung, Sprink, Krause, & Kohl, 2018; Modrzejewski, Hartung, Sprink, Krause, Kohl, et al., 2018).

It is a concern that countries in the developing world exporting feed and food to the EU might not benefit from gene edited crops if they follow the EU authorisation practices, as some of them currently do. No single breeding technique alone can provide a magic bullet for solving the problem of unsustainable food production and food scarcity in the world. However, gene- editing has the potential to contribute to food security, which is particularly relevant given the growing world population and climate change (Haque et al., 2018; Jones, 2015). In view of the above, we make some proposals regarding the way forward in the following section.

4. Further reflections and proposals

There is danger that unless the EU improves the regulatory environment for products of gene-editing, it will be left behind in this field, which could also diminish EU influence on ongoing debates at the international level with respect to specific applications and regulatory processes. Further research and innovation in this area will help better understanding of possible risks and benefits for society, the environment, agriculture and the economy. There is a need to improve EU GMO legislation to be clear, evidence-based, implementable, proportionate and flexible enough to cope

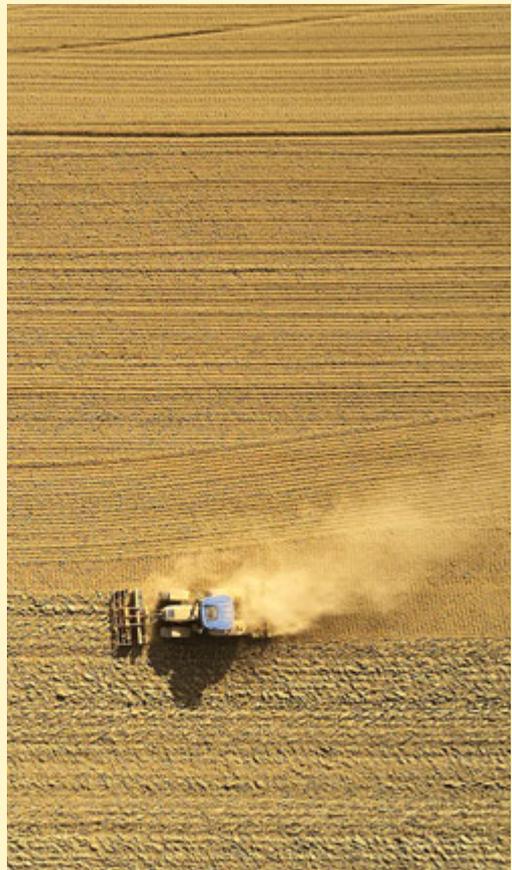
¹⁰ USDA. Reply to Request for Confirmation that Transgene-Free, CRISPR-Edited Mushroom Is Not a Regulated Article 2016. https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-32101_air_response_signed.pdf

¹¹ One of the Sustainable Development Goals (SDGs) to which the EU has subscribed

with future advances in science and technology in this area. To achieve this, we recommend revising the existing GMO Directive to reflect current knowledge and scientific evidence, in particular on gene editing and established techniques of genetic modification. This should be done with reference to other legislation relevant to food safety and environmental protection.

We acknowledge that there are strongly held views in the debate regarding the regulation of GMOs, based on a range of differing underlying values, ethical, legal and social issues, and that may lead to other options being preferred. In this context, it should be noted that the European Commission has requested further guidance by the European Group on Ethics in Science and New Technologies (EGE) on ethical issues raised by such technologies.

Moreover, it is essential to promote a broad dialogue with relevant stakeholders, and the public at large. Indeed, we have already urged that a more general inclusive discussion should be initiated on how we want our food to be produced in Europe (SAM, 2017b, 2018). Any change to the existing GMO legislation should make use of new, participatory forms of social dialogue (Bioökonomierat, 2018). In doing so, it is important to take account of the highest possible protection of health and environment and the creation of a favourable regulatory environment for innovation, so that society can benefit from new science and technology. In addition, we conclude that there is a need for robust and independent evidence to be provided in a systematic and transparent way to the Court when dealing with complex scientific issues. Factors other than scientific evidence are and should be considered in policy-making as well as in



jurisdiction. However, when reasons other than scientific evidence inform decision making, such as those based on ethical, legal, social and economic considerations, these should be clearly identified and communicated as such in a transparent way. At the same time, relevant and robust scientific evidence should be provided to inform decisionmaking and good regulation. This is essential to generate good policy and regulation, to maintain public trust in science, and to reduce the potential reputational risk to the EU, if it appears that the EU is not employing the best scientific evidence to generate good public policy. We stand ready to provide further scientific advice to the European Commission on the subjects outlined above should the College of Commissioners wish to have such advice.

GENERAL DISCUSSION

During the lunch, the participants were divided into five tables each discussing a separate issue relating to the impact of genome editing in agriculture. Debate touched on a variety of issues, from the potential risks and benefits of the use of new breeding techniques in agriculture to the ethical and societal implications of their use and non-use. Regulatory issues, the use of science to inform decision making and the international context were also discussed.

New applications of gene editing technologies in the pipeline that may enable novel approaches in agriculture beyond herbicide and insecticide tolerance in plants or more productive crops were described, including plants with advantageous features for the environment regarding e.g. conservation, bioremediation and more efficient nutrient use, and for consumers, e.g. improved nutrient content, less allergens, improved quality in terms of taste and shelf life. It was emphasised that the added value of such plants should be made more obvious to consumers, in particular through new ways of communication.

The implications of altering genetic code in a very targeted way raised questions about how gene editing technology should be

developed, regulated and applied. The low cost of equipment, the accessibility of the technology and possible harm to the environment raises concerns over how to ensure responsible use of this technology. At the same time, the non-use of the technology may also present ethical concerns.

Following the ruling of the European Court of Justice that products of gene editing fall under the GMO Directive (2001/18/EC), participants discussed consequences for regulating gene edited products and, more generally speaking, NBTs. The implications for detection, identification and quantification, as well as the consequences for traceability and labelling requirements, and consumers' choice were all discussed.

The role that scientists and science bodies may play in supporting a balanced debate on the future of NBTs was examined. This included the use of new forms of communication (e.g. social media) as well as methods of close cooperation with and participation of stakeholders as integral part of the societal debate.

Finally, participants also examined the distinct approaches of different countries and what they will imply for international trade and cooperation, for Europe as well as for third countries. NBTs have an international dimension in view of the large quantities of crops from third countries, which are imported in the EU and the distinct policy and regulatory approaches already established in several countries worldwide to deal with products obtained with gene editing.

Below you will find a more detailed overview of each topic.

NEW BREEDING TECHNIQUES - AGRICULTURAL APPLICATIONS - WHAT SCIENCE CAN DELIVER

FACILITATOR

PROFESSOR DIRK INZÉ, FULL PROFESSOR AT GHEENT UNIVERSITY AND SCIENTIFIC DIRECTOR OF THE VIB, DEPARTMENT OF PLANT SYSTEMS BIOLOGY, MEMBER OF KVAB

RAPPORTEUR

PROFESSOR JANUSZ BUJNICKI, MEMBER OF THE EUROPEAN COMMISSION'S GROUP OF CHIEF SCIENTIFIC ADVISORS

New applications of gene editing technologies in agriculture could enable novel approaches beyond herbicide and insecticide tolerance in plants or more productive crops. This includes advances in improving nutrient content, improved nutrient use efficiency, resilience to drought and heat, higher yield, bioenergy crops, the control of invasive species and the protection of biodiversity. Research for example is underway that is trying to build more efficient means of CO₂ or nitrogen fixation or better drought tolerance in plants with a potentially significant impact on future agricultural practices.

The session examined how the Court ruling will affect public and private research in NBTs and how the use of NBTs could help to meet a variety of societal demands and challenges linked to more sustainable food production and climate change.

- Can NBT's* help solve the big challenges of our time (e.g., climate change)?
- Will they be able to provide healthier, more nutritious, safer, and cheaper food?
- All false promises? Can the NBTs actually deliver on their promises?
- What lessons have we learned from the established techniques of genetic modification?
- Can gene editing contribute to sustainable and/ or organic agriculture (as random mutagenesis)?

**The 'new breeding techniques' as described in the explanatory note on 'New Techniques in Agricultural Biotech' comprise a variety of different techniques including gene editing (e.g. with CRISPR-Cas systems); the main focus of the discussions will be on gene editing.*

ETHICAL/ SOCIETAL CONSIDERATIONS RELATED TO AGRICULTURAL APPLICATIONS OF NBTS

FACILITATOR

PROFESSOR PERE PUIGDOMENECH, ALLEA BOARD MEMBER / CENTER FOR RESEARCH IN AGRICULTURAL GENOMICS, BARCELONA

RAPPORTEUR

PROFESSOR EUGENIJUS GEFENAS, MEMBER OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EGE), PROFESSOR AND DIRECTOR OF THE DEPARTMENT OF MEDICAL HISTORY AND ETHICS AT THE MEDICAL FACULTY OF VILNIUS UNIVERSITY; DIRECTOR OF THE LITHUANIAN BIOETHICS COMMITTEE.

The enormous implications of altering the genetic code of all organisms from microorganisms to animals and plants in a very targeted way has raised important questions about how the gene editing technology should be developed, regulated and applied.

Further, the low cost of the equipment and the accessibility of the technology raises concerns over the possibility of ensuring responsible use of this technology. Possible harm to the environment, business models used for the marketing of genetically modified products and related agricultural practices and the risk of mistakes which could result in irrevocable damage are all issues that play an important role in the ongoing

debate about the use of gene editing in agriculture.

Moreover ethical factors such as concerns about the 'interference with nature' and 'playing God' also play an important role.

At the same time, NBTS have the potential to be safer and more effective than other technologies currently in use and could be a big part of the solution to many of our most pressing problems related to climate change and sustainable food production.

- What are ethical concerns related to the use (or non-use) of gene editing in agriculture?
- What type of agriculture do we want in Europe?
- Do we need new business models for gene editing?
- Can a participatory public debate help? What is the role of scientists/ regulators/ politicians/ media?
- What lessons have we learned from the established techniques of genetic modification?
- What could be the impact of the ECJ decision on consumers' choice?

REGULATORY ISSUES

FACILITATOR

DR PETER KEARNS, PRINCIPAL ADMINISTRATOR
- ENVIRONMENT DIRECTORATE, ENVIRONMENT,
HEALTH AND SAFETY DIVISION, OECD

RAPPORTEUR

BERND HALLING, HEAD OF CORPORATE POLICY
AND STRATEGY OF BAYER

Following the ruling of the European Court of Justice that products of gene editing fall under the GMO Directive (2001/18/EC) the session discussed what the consequences are for regulating gene edited products and, more generally speaking, NBTs and if the current legislation still reflects the original motivation behind its establishment and the precautionary principle.

The session addressed the question, if the end product should be in the centre of the regulatory approach rather than the production process. What are the implications of detection, identification and quantification issues? What are the consequences for traceability and labelling requirements, and consumers' choice and how can they be addressed.

Finally, the group looked into the chances and challenges to reopen the respective

legislation and discuss potential options to propose new regulation that is clear, evidence-based, proportionate, flexible and adequate to the novel features of the new technology.

- Does the EU GMO legislation still achieve what it was intended for?
- Could we think of a different approach for dealing with/ regulating organisms of which the genome has been modified by using different techniques?
- How to deal with identification and detection issues related to gene-edited products?
- Is the concept of 'naturalness' still helpful in the definition of GMOs and what does this imply in view of recent evidence?
- What exactly do we want to regulate in the European law?
- How to consider the safety of an end product in the broader context (features, use, agricultural practices, environmental impact)?
- What does 'long safety record' mean?
- How to deal with questions left unanswered by the ECJ decision?

SCIENCE QUALITY AND SCIENCE INFORMED DECISION MAKING

FACILITATOR

PROFESSOR ROLF-DIETER HEUER, CHAIR OF THE EUROPEAN COMMISSION'S GROUP OF CHIEF SCIENTIFIC ADVISORS AND FORMER DIRECTOR-GENERAL OF THE EUROPEAN ORGANIZATION FOR NUCLEAR RESEARCH (CERN)

RAPPORTEUR

MEP PAUL RÜBIG, MEMBER OF THE EUROPEAN PARLIAMENT, VICE-CHAIR OF STOA, PRESIDENT OF SME CONNECT

Given the often controversial discussion on the future of genome editing in Europe, the session looked into the role scientists and science bodies can play in supporting a balanced debate on the basis of scientific facts on the future of NBTs in Europe. This should include the use of new forms of communication (e.g. social media) as well as methods of close cooperation with and participation of stakeholders as integral part of the societal debate.

The session further addressed the role of science quality and science informed decision making in the European Union in the Development of future policies on genome editing.

The session also looked into what role the European Union should play in Life Science research on NBTs and how well the EU is positioned to compete with other world regions in research on the global level as

well as how to advance research on the role of Life Sciences in sustainable agriculture.

- How should scientific evidence be provided to the Court?
- The Gordian knot: How to disentangle scientific facts from other aspects in the public debate?
- What additional scientific evidence is needed to answer questions and concerns of the public/ the regulators?
- How to increase public trust in evidence provided by experts in this highly politicised, controversial, value-loaded area?
- How to improve communication with the public: what is the role of scientists/ regulators/ politicians/ media?

NBTS - INTERNATIONAL COMPARISON (USA, ARGENTINA, BRASIL, CHINA)

FACILITATOR

JENNIFER LAPPIN, U.S. MISSION TO THE
EUROPEAN UNION

RAPPORTEUR

MEP MARÍA TERESA GIMÉNEZ BARBAT,
MEMBER OF THE EUROPEAN PARLIAMENT,
MEMBER OF STOA

When biotech crosses borders

NBT is an issue that has an international dimension in view of the large quantities of crops from third countries, which are imported in the EU and the distinct policy and regulatory approaches already established in several countries worldwide to deal with products obtained with gene editing. Moreover, in today's connected world organisms are not geographically contained.

This session looked at the distinct approaches of different countries and what they will imply for international trade and cooperation, for Europe as well as for third countries. How can the EU deal with the related challenges?

- What could the possible impact of the ECJ decision be on:

- a. the competitiveness of European agriculture, biotech, seed companies?

- b. international trade and cooperation (in particular in view of identification and detection issues related to gene-edited products)?

- c. research using gene editing?

- Do we 'impose' our values/ preferences/ regulations on third countries?

- What will be the role of the EU in the discussions on NBT/ gene editing at international level?



SCIENCE-IN-SOCIETY SALON EVALUATION OF METHODOLOGY

T

Truth, trust and expertise matter in every walk of life. Yet, recent political trends as well as polling data show that the trust between science and society has been tarnished. This is particularly troubling as the pace of scientific development and the advancement of new technologies is speeding-up and will be crucial in finding solutions to some of the biggest challenges of our time.

However, it is important to note, as pointed out in the ALLEA Discussion Paper on "Loss of Trust? Loss of Trustworthiness? Truth and Expertise Today", "science, research and expertise are always debated, argued over and contested. This is the normal state of affairs that we aim to encourage and support in order to advance our understanding and knowledge. Contestation is therefore not a bad thing and is often necessary to lead to consensus".

In fact, a key outcome of that report concluded that:

"Science, politics, policy-making and publics are all connected in many direct and

¹ ALLEA (2018). Loss of Trust? Loss of Trustworthiness? Truth and Expertise Today, (ALLEA)

indirect, and visible and less visible ways. Good trustworthy expertise from scientists is important but it can also be disruptive and often can be unwelcome, especially in the short term. This raises the old chestnut of how to speak truth to power but also how do we speak truth to power and publics whilst nourishing a culture that welcomes expertise and can be tolerant of the odd disruption this brings? In addition, if expertise and science are to engage effectively in the public and policy arenas how can such knowledge be brought to bear, manifested and conceptualised, in widely differing contexts, to draw together and deliver good trustworthy advice?"

To bridge the growing gap that exists today between, science, citizens and policy, there is a need for a stronger dialogue and exchange of ideas. To provide a forum where different perspectives and experiences can be discussed with the aim of trying to understand each other and finding compromises. This is what the Brussels Science-in-Society Salon hopes to contribute at a European level.

In a time where science, evidence and expertise are being questioned and policy decisions are sometimes taken against scientific advice, Re-Imagine Europa feels that it is ever more important to create a space for constructive and open deliberation between different stakeholders in order to re-establish trust and find ways for positive compromise and deliberation.

One of the aims of the first edition of the Brussels Science-in-Society Salon was to

test the proposed format, to see whether there is an interest from the different stakeholders to engage in such a project and to explore how this can be transformed into a more regular sequence of events with the new European cycle 2019-2024.

The below evaluation is based both on qualitative and quantitative data with key partners providing feedback after the event and on an anonymous online survey carried out with all . So, what are the main takeaways?

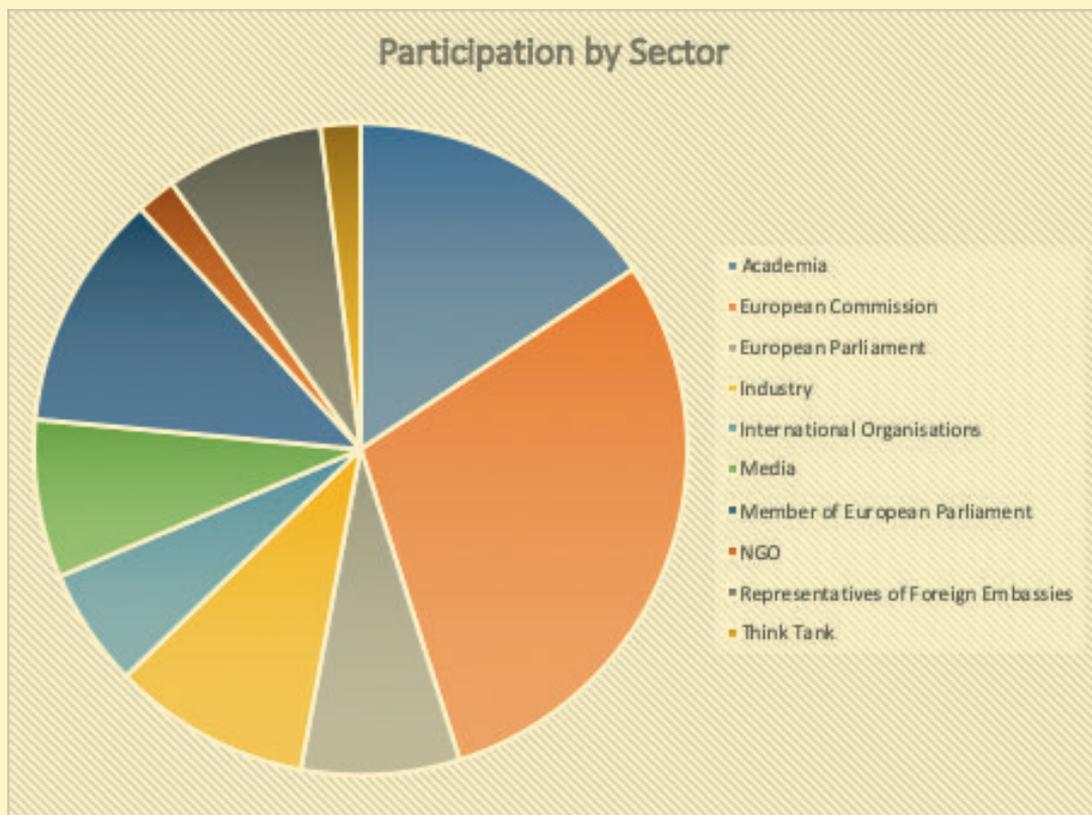
The need for a space for open debate, like that provided by the Science-in-Society Salon was clear from the high interest in participation in the event. Even though the event was organized with short-notice and during the last weeks of activity of the European Parliament ahead of the European elections, we had a full house and over twenty Members of the European Parliament expressed an interest in supporting the event and being informed of it's conclusions.

With a maximum capacity of fifty participants the overall break-up of expertise can be summarized as follows: 10% Members of the European Parliament, 16% Academia, 29% European Commission, 8% European Parliament (not including MEPs), 10% Industry (including SMEs, large corporations and industry organisations), 6% International Organisations, 8% Media, 2% NGOs, 8% Representatives from foreign embassies and 2% from think tanks.

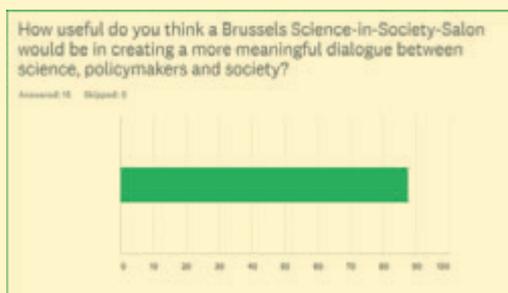
Overall the participation represented different perspectives, areas of expertise

² Susan Owens (2015), Knowledge, Policy, and Expertise: The UK Royal Commission on Environmental Pollution 1970-2011, (Oxford: Oxford University Press), p.1

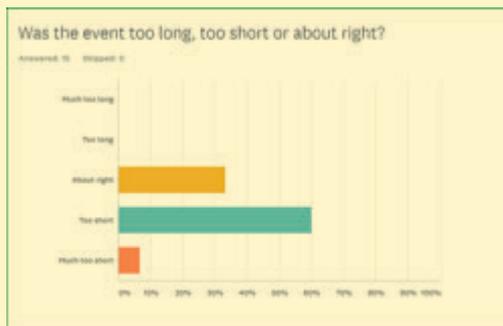
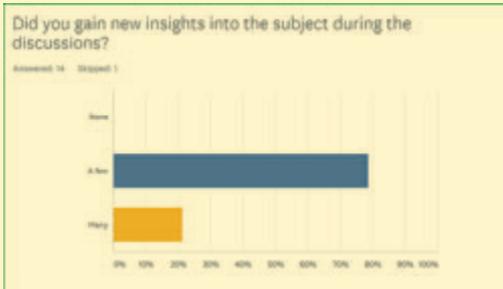
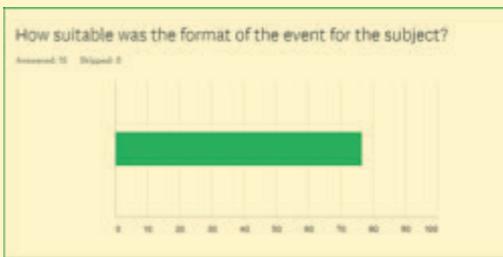
and gave rise to lively debates during the day. The organization of the event was structured so as to try to ensure that all major stakeholders were present around the table and joined in the discussion. The low participation of NGOs was noted by the organizers already ahead of the meeting and several NGOs were invited to join but unfortunately were unable to do so due to conflicting agendas. This is something that will have to be more balanced for the coming editions.



The timeliness and interest in continuing organizing Science-in-Society Salons was underlined by the fact that participants rated the event very high (over 80% satisfaction rate) Its utility in creating a more meaningful dialogue between science, policymakers and society, to support evidence-informed policymaking and in increasing trust between the different to nearly 90%.



Participants felt that the format was very good in order to allow both for evidence and expertise to be presented as well as to discuss the possible opportunities and challenges for society in broad groups with different perspectives and expertise. Most participants felt they did gain insights from the debate. However, most participants



expressed that they would have wanted more time to discuss and exchange ideas.

The success of the event is further supported by the fact that participants have requested that Re-Imagine Europa organize a second edition of the Salon in autumn with the new European Parliament on the same topic.



In conclusion, it is clear that there is a need for strengthening the dialogue between science, evidence and policy-makers at the European level. The Science-in-Society Salon can be a first step to do so and to explore novel ways to strengthening these deliberations and explore new ways to approach this challenge at a European level.

Despite certain organizational challenges, the first edition was very appreciated by participants and there was an overall feeling that such a format can be very useful in creating a more robust conversation and debate about the real challenges and opportunities of science and new technologies.

CONCLUSIONS

Don't be afraid of science'

MR CARLOS MOEDAS
EUROPEAN COMMISSIONER FOR RESEARCH, SCIENCE
AND INNOVATION

In a digital world where unverified information is being exchanged at the speed of light, getting trusted scientific evidence has become paramount for politicians and the general public, said Carlos Moedas, EU Commissioner in charge of Research, Science and Innovation.

Around the world, scientists have also increasingly come under attack from politicians. In the US, President Donald Trump described evidence on global warming as "bullshit", despite overwhelming consensus in the scientific community that climate change is real and largely caused by human activity.

The infamous quote from Michael Gove stating that Britons had "had enough of experts" sparked an outrage as well as significant concern about the status of "the truth"

in today's world. This assault on evidence, facts and science underline the need for a more systemic approach on how to bridge the gap between science and society, between scientists and policy makers.

This is a deeply worrying trend and Re-Imagine Europa feels that it is ever more important to create a space for constructive and open deliberation between different stakeholders in order to re-establish trust and find ways for positive compromise and deliberation.

This is becoming even more difficult as new technologies are changing alliances and making the classical debate around new technologies more complex. With most new technologies, whether in life sciences or in digital, the traditional positions seem outdated and in need of rethinking based on new evidence and possibilities.

The first edition of the Brussels Science in Society Salon on "Genome Editing in Agriculture – Implications for Society" showed that there is a need for such a space at a European level.

The public reactions to the Court of Justice of the European Union's judgement of 25 July 2018 concerning the regulatory status of organisms obtained using new techniques of directed mutagenesis, including 'gene editing techniques' showed the importance to start a more evidence-informed debate on this issue. Something that was further highlighted by the Group of Chief Scientific Advisors' own-initiative statement, published 13 November 2018.

Genome editing techniques enable the development of a wide range of agricultural applications and the ethical, legal, social and economic issues of their use are discussed

intensively. The debates touch upon people's beliefs, values, and concerns, as well as the underpinning science.

Although the discussions of the 2nd of April were not conclusive on what should be done at a European level to address this question, it was clear that the application of the EU legislation on genetically modified organisms to products of genome editing is challenging and comes with many open questions.

In the light of the need for further debate, Re-Imagine Europa, the Group of Chief Scientific Advisors and the Science Advice Mechanism of the European Commission will organize further editions of the Science-in-Society Salon.

ABOUT RE-IMAGINE EUROPA



Launched in 2018, Re-Imagine Europa is the first incubator for new political ideas to reinforce Europe's role as a global economic power in the 21st century able to safeguard a prosperous future of peace, freedom and social justice for all its citizens

Re-Imagine Europa was founded by President Giscard d'Estaing to honour his life-long friendship and collaboration with Chancellor Helmut Schmidt and building on the spirit of pragmatism and solidarity that was foundational in the creation of the European project.

ABOUT GROUP OF CHIEF SCIENTIFIC ADVISORS IN THE EUROPEAN COMMISSION'S SCIENTIFIC ADVICE MECHANISM

N

The Group of Chief Scientific Advisors (formerly known as the Scientific Advice Mechanism/High Level Group) has been providing scientific advice to the College of European Commissioners (the College) since shortly after it was established at the end of 2015.

Advice is requested by the College and helps them to act by making sure they know what science has to say about a particular subject. The Group can also suggest that the College requests its advice on a subject, and can make recommendations to improve the interaction between European Commission (EC) policy making and scientific advice.

The Group is unique in its dialogue with, and provision of advice directly to, the College; the Group also works with other science advice structures supporting decision making within the EC such as the Joint Research Centre (JRC); the various decentralised agencies of the Commission; and the Scientific Committees, etc. This cooperation and coordination enables expertise to be shared and overlap to be avoided.

The Group has up to 7 members, who are distinguished scientists reflecting the breadth of scientific expertise across Europe. They work closely with the scientific community, mainly through the Horizon 2020 funded 'SAPEA' (Scientific Advice to

Policy by European Academies) project consisting of 5 European academy networks (Academia Europaea, ALLEA, EASAC, Euro-CASE, and FEAM). The expertise brought together by SAPEA from more than 100 European academies and over 40 countries enables the production of comprehensive, unbiased and high-quality evidence reviews. These reviews may contain policy options, which inform the Group's scientific opinions and policy recommendations.

The Group is supported by a secretariat in the ECs Directorate General (DG) for Research and Innovation, to which staff from the JRC and national experts are seconded. The secretariat also enables links between the Group, SAPEA, other DGs, services and agencies of the EC; and with other science advisory bodies in Europe and worldwide. Collectively, the Group, SAPEA and the secretariat are known as the Scientific Advice Mechanism.

To date, the Group has provided five scientific opinions: Closing the gap between light-duty vehicle CO₂ emissions and laboratory testing (CO₂); Cybersecurity in the European Digital Single Market (Cyber); Food from the Oceans (FFO); Novel Carbon Capture and Utilisation Technologies (CCU); and EU Authorisation Processes of Plant Protection Products (PPP). These scientific opinions were well received and show impact in their corresponding policy areas: 'CO₂' forming part of the evidence base for the regulation of post-2020 CO₂ vehicular emissions measurement standards; 'Cyber' for the review of the Commission's cybersecurity strategy and related elements; FFO for the development of future maritime, fisheries and aquaculture policy development and implementation. Having only recently been published, evidence of

impact for 'CCU' and 'PPP' is expected later in the year.

The Group has also provided two explanatory notes: Scientific advice for the regulatory assessment of glyphosate in plant protection products, and New techniques in agricultural biotechnology. The first explanatory note is of direct relevance to the Group's scientific opinion on PPP. The second supports a broad debate among stakeholders concerning the use in agriculture of organisms produced with these techniques.

The Group is presently working on scientific advice in three further areas: Making Sense of Science under Conditions of Complexity and Uncertainty (for June 2019); Transforming the Future of Ageing (for April 2019) and Microplastic Pollution – Scientific perspectives and its impacts (Statement, July 2018; Explanatory Note end 2018; Scientific Opinion, early 2019).

The Group and SAPEA work together so that the Group can provide high quality, independent and timely input to policy, based on different forms of evidence reviews, ranging from literature review to expert elicitation. The principles of excellence, transparency and independence are of paramount importance and are underpinned, among others by:

- The use only of literature which is publicly accessible as evidence, which must also be clearly cited. The methods used to obtain and analyse literature are also clearly explained.
- The clear identification of experts consulted in workshops or other meetings.

HOW SAM WORKS

Request for Advice



Evidence Review and Analysis

Working closely with SA^{TE}PEA



Impact



- Scientific advice to ensure that the Commission's proposals for policy or legislation are well-informed.
- Process designed to be transparent and as free of bias as possible.
- Complementing an extensive and diverse scientific advisory system underpinning EU policies, including the Joint Research Centre and European agencies, etc.

ANNEX 1

PROGRAMME

11:30-12:00 ● REGISTRATION AND WELCOME

Please note that it takes around 30 minutes to get through security of the European Parliament. If you have requested a badge, someone will be waiting for you at the entrance to escort you to the room. Coffee and tea will be served

12:15-12:30 ● INTRODUCTORY REMARKS

Erika Widegren, Re-Imagine Europa

12:30-12:40 ● WELCOME ADDRESS

Paul Rübige MEP
María Teresa Giménez Barbat MEP

12:40-13:10 ● KEYNOTE ADDRESS

Professor Rolf-Dieter Heuer, Chair of the European Commission's Group of Chief Scientific Advisors and Former Director-General of the European Organization for Nuclear Research (CERN)

Professor Janusz Bujnicki, Member of the European Commission's Group of Chief Scientific Advisors. Head of the Laboratory of Bioinformatics and Protein Engineering, International Institute of Molecular and Cell Biology, Warsaw

Q&A

Moderated by: **Erika Widegren**, Re-Imagine Europa

13:15-14:15 ● LUNCH AND SALON DISCUSSIONS

Participants will be divided into 5 tables, each table addressing a different sub-topic. Each table has one facilitator and one rapporteur. Tables are:

- New Breeding Techniques (NBT) - agricultural applications - what can the science deliver?
- Ethical/ societal considerations related to agricultural applications of NBT
- Regulatory issues (particularly post-Court of Justice of the European Union decision);
- Science quality and science informed decision making ;
- NBTs - International comparison (USA, Argentina, Brazil, China).

14:15 - 15:00 ● PLENARY, CONCLUSIONS AND NEXT STEPS

Luca De Biase, Founder and Editor of Nova24

ANNEX 2

LIST OF PARTICIPANTS

WE WOULD LIKE TO THANK ALL THE PARTICIPANTS WHO TOOK THEIR TIME TO JOIN US AT THE EUROPEAN PARLIAMENT ON THE 2ND OF APRIL FOR THE FIRST EDITION OF THE BRUSSELS SCIENCE-IN-SOCIETY SALON ON THE TOPIC OF "GENOME EDITING IN AGRICULTURE - IMPLICATIONS FOR SOCIETY".
IN ALPHABETICAL ORDER

Hubert Bocken, ALLEA Vice President / Honorary President of Royal Flemish Academy of Belgium for Science and the Arts (KVAB)

Jeremy Bray, Deputy Head of Unit - DG Research and Innovation, Unit 0.2 Scientific Advice Mechanism - European Commission

Wim Broothaerts, Joint Research Council - European Commission

Chantal Bruetschy, Head of Unit - DG SANTE - unit E3 - European Commission

Maria Teresa Bucu, Public Affairs Manager at Novozymes

Janusz Bujnicki, Chief Scientific Advisor - European Commission Group of Chief Scientific Advisors, Head of the Laboratory of Bioinformatics and Protein Engineering, International Institute of Molecular and Cell Biology, Warsaw

Maria Da Graça Carvalho, DG Research and Innovation, Unit 0.2 Scientific Advice Mechanism - European Commission

Sierd Cloetingh, President of Academia Europaea and Chair of Science Advice for Policy by European Academies Board

Roger Corcho, European Parliament

Luca De Biase, Journalist, Founder and Editor of Nòva24 - Sole 24Ore - Media Director at Re-Imagine Europa

Jens Degett, President of the European Union of Science Journalists' Association (EUSJA)

Joanna Dupont, Secretary General of EuropaBio

Robin Fears, Bioscience Programme Director of European Academies Science Advisory Council

Steffi Friedrichs, Director of AcumenIST

Gaston Funes, Attaché for Agriculture - Mission of Argentina to the EU

Elisabetta Gardini, Member of the European Parliament

Eugenijus Gefenas, Member of the European Group on Ethics in Science and New Technologies (EGE), Professor and Director of the Department of Medical History

and Ethics at the Medical Faculty of Vilnius University; Director of the Lithuanian Bioethics Committee.

Maria Theresa Gimenez Barbat, Member of the European Parliament, STOA Panel Member

Cesar Gonzalez, Manager Public Affairs of Euroseeds

Harald Hartung, DG Research and Innovation - Head of Unit B.6 Inclusive Societies - European Commission

Rolf Heuer, Chair of the European Commission's Group of Chief Scientific Advisors, Former Director-General of the European Organization for Nuclear Research (CERN)

Dirk Hudig, Secretary General of the European Risk Forum

Dirk Inze, Full Professor at Ghent University and Scientific Director of the VIB, Department of Plant Systems Biology, member of KVAB

Sabine Juelicher, DG Health and Food Safety - Director E Food and Feed Safety, Innovation - European Commission

Louiza Kalokairinou, DG Research and Innovation - Unit 0.2 Scientific Advice Mechanism - Ethics and Research Integrity Sector - European Commission

Theodoros Karapiperis, Head of Unit for Scientific Foresight Unit of EPRS - European Parliament

Peter Kearns, Principal Administrator - Environment Directorate, Environment, Health and Safety Division at the OECD

Johannes Klumpers, Head of Unit 0.2 Scientific Advice Mechanism - DG Research and Innovation - European Commission

Mihalis Kritikos, STOA Policy Advisor - European Parliament

Jennifer Lappin, Attache for Agriculture - US Mission to the EU

René L'Her, DG Agriculture and Rural Development - Policy officer, G2 Unit - Wine, spirits and horticultural products

Majja Locane, DG Research and Innovation, Scientific Advice Mechanism Unit 0.2 - EGE Team - European Commission

Bo Lyu, Counsellor of the Chinese Mission to the EU - Mission of the P.R. China to the E.U.

Michael Matlosz, President of Euroscience

Anthea McIntyre, Member of the European Parliament, STOA Panel Member

Andrea Mertens, Seeds Market Acceptance Manager EU of Bayer

Matteo Nicolosi, Science writer

Justin Nogarede, Digital Policy Advisor at the Foundation for European Progressive Studies

Georgi Pirinski, Member of the European Parliament, STOA Panel Member

Pere Puigdomenech Rosell, ALLEA Board Member / Center for Research in Agricultural Genomics, Barcelona

Paul Rübige, Member of the European Parliament, STOA Vice Chair and President of SME CONNECT

Michael Scannell, DG Agriculture and Rural Development - Director G Markets and Observatories - European Commission

Keith Sequeira, Member of the Cabinet Commissioner Moedas, DG Research and Innovation

Cathy Trinckle, Head of Innovation & Technology Policy at BASF

Guy Van den Eede, Joint Research Center - Head of Unit F.7 - European Commission

Lambert van Nistelrooij, Member of the European Parliament

Lieve van Woensel, European Parliamentary Research Service - Scientific Foresight

Barend Verachtert, DG Research and Innovation - Unit F.3 - European Commission

Sigrid Weiland, Manager of the EC's Group of Chief Scientific Advisors, DG Research and Innovation, Unit 0.2 Scientific Advice Mechanism - European Commission

Erika Widegren, Chief Executive of Re-Imagine Europa

Lin Yang, Third Secretary - Economic & Commercial Counsellor's Office Mission of the P.R. China to the E.U.

REFERENCES

- Abbott, A. (2015). Europe's genetically edited plants stuck in legal limbo. *Nature*.
<https://doi.org/10.1038/528319a>
- ALLEA (2018), Loss of Trust? Loss of Trustworthiness? Truth and Expertise Today, (ALLEA)
https://www.allea.org/wp-content/uploads/2018/05/ALLEA_Discussion_Paper_1_Truth_and_Expertise_Today-digital.pdf
- Bioökonomierat. (2018). Genome editing : Europe needs new genetic engineering legislation. Berlin. Retrieved from http://biooekonomierat.de/fileadmin/Publikationen/berichte/BOER-Memo_Genome-Editing_ENG.pdf
- Callaway, E. (2018). CRISPR plants now subject to tough GM laws in European Union. *Nature*, 2016.
<https://doi.org/10.1038/d41586-018-05814-6>
- Casacuberta, J. M., & Puigdomènech, P. (2018). Proportionate and scientifically sound risk assessment of gene-edited plants. *EMBO Reports*, 19(10), e46907.
<https://doi.org/10.15252/embr.201846907>
- Georges, F., & Ray, H. (2017). Genome editing of crops: A renewed opportunity for food security. *GM Crops and Food*, 8(1), 1–12. <https://doi.org/10.1080/21645698.2016.1270489>
- Haque, E., Taniguchi, H., Hassan, M. M., Bhowmik, P., Karim, M. R., Śmiech, M., ... Islam, T. (2018). Application of CRISPR/Cas9 Genome Editing Technology for the Improvement of Crops Cultivated in Tropical Climates: Recent Progress, Prospects, and Challenges. *Frontiers in Plant Science*, 9(May), 1–12. <https://doi.org/10.3389/fpls.2018.00617>
- Jinek, M., Chylinski, K., Fonfara, I., Hauer, M., Doudna, J. A., & Charpentier, E. (2012). A Programmable Dual-RNA – Guided DNA Endonuclease in Adaptice Bacterial Immunity. *Science (New York, N.Y.)*, 337(August), 816– 822. <https://doi.org/10.1126/science.1225829>
- Jones, H. D. (2015). Regulatory uncertainty over genome editing. *NATURE PLANTS*, 1(January), 2014–2016. <https://doi.org/10.1038/NPLANTS.2014.11>
- Khandagale, K., & Nadaf, A. (2016). Genome editing for targeted improvement of plants. *Plant Biotechnology Reports*, 1–17. <https://doi.org/10.1007/s11816-016-0417-4>
- Kyndt, T., Quispe, D., Zhai, H., Jarret, R., Ghislain, M., Liu, Q., ...Kreuze, J. F. (2015). The genome of cultivated sweet potato contains *Agrobacterium* T-DNAs with expressed genes: An example of a naturally transgenic food crop. *Proceedings of the National Academy of Sciences (Vol. 112)*. <https://doi.org/10.1073/pnas.1419685112>
- Modrzejewski, D., Hartung, F., Sprink, T., Krause, D., & Kohl, C. (2018). Übersicht über

Nutz- und Zierpflanzen , die mittels neuer molekular- biologischer Techniken für die Bereiche Ernährung , Landwirtschaft und Gartenbau erzeugt wurden Julius Kühn-Institut Institut für die Sicherheit Biotechnologischer Verfahren bei Pflanzen, 1–33.

Modrzejewski, D., Hartung, F., Sprink, T., Krause, D., Kohl, C., Schiemann, J., & Wilhelm, R. (2018). What is the available evidence for the application of genome editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: A systematic map protocol. *Environmental Evidence*, 7(1), 1–8. <https://doi.org/10.1186/s13750-018-0130-6>

Owens, S., (2015). *Knowledge, Policy, and Expertise: The UK Royal Commission on Environmental Pollution 1970-2011*, (Oxford: Oxford University Press)

Palmgren, M. G., Edenbrandt, A. K., Vedel, S. E., Andersen, M., Landes, X., Østerberg, J. T., ... Pagh, P. (2015). Are we ready for back-to-nature crop breeding? *Trends in Plant Science*, 20(3), 155–164. <https://doi.org/10.1016/j.tplants.2014.11.003>

SAM. (2017a). *New Techniques in Agricultural Biotechnology*. <https://doi.org/10.2777/17902>

SAM. (2017b). *Food from the Oceans*. <https://doi.org/10.2777/067256> <https://doi.org/doi.10.26356/foodfromtheoceans>

SAM. (2018). *Plant Protection Products*. <https://doi.org/10.2777/71851> <https://doi.org/10.26356/plantprotectionproducts>

Shukla-Jones, A., Friedrichs, S., & Winickoff, D. (2018). *Gene editing in an international context: Scientific, economic and social issues across sectors*. (OECD Publishing, Ed.) (OECD). Paris. <https://doi.org/http://dx.doi.org/10.1787/38a54acb-en>

Sprink, T., Eriksson, D., Schiemann, J., & Hartung, F. (2016). Regulatory hurdles for genome editing: process- vs. product-based approaches in different regulatory contexts. *Plant Cell Reports*, 35(7), 1493–1506. <https://doi.org/10.1007/s00299-016-1990-2>

Stokstad, E. (2018, July 25). *European court ruling raises hurdles for CRISPR crops*. <https://doi.org/10.1126/science.aau8986>

Waltz, E. (2016). Gene-edited CRISPR mushroom escapes US regulation. *Nature*, 532(September), 293. <https://doi.org/10.1038/nature.2016.19754>

Yin, K., Gao, C., & Qiu, J.-L. (2017). Progress and prospects in plant genome editing. *Nature Plants*, 3(8), 17107. <https://doi.org/10.1038/nplants.2017.107>



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