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TASK FORCE ON SUSTAINABLE AGRICULTURE AND INNOVATION

WHITE PAPER ON THE REGULATION OF GENOME EDITING IN AGRICULTURE

This report is the work of the Task Force on Sustainable Agriculture and Innovation established by Re-Imagine Europa as part of its programme on Narratives, Climate and the Future.

The Task Force consists of more than 70 experts from a wide range of backgrounds and disciplines covering NGOs, academia, CSOs and industry.

Additional information about the Task Force, its ethos and composition, is available here.

N.B. All outputs from the Task Force have been produced by the team at RIE and our knowledge partners. While we have done our utmost to reflect the valuable input provided by the experts and stakeholder representatives who kindly gave up their time, this report should not be taken to represent the position of any individual member of the Steering or Expert Committees nor any organisation with which they may be affiliated.

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EXECUTIVE SUMMARY

This report is the work of the Task Force on Sustainable Agriculture and Innovation which was established by Re-Imagine Europa (RIE) as part of its programme on Narratives, Climate and the Future. The Task Force consists of more than 70 experts from a wide range of backgrounds and disciplines covering NGOs, academia, CSOs and industry.

This report has been prepared in the context of the current discussions on the legislation on genetically modified organisms (GMOs), which should be more resilient, future-proof and uniformly applied. On the 29th of April, the European Commission published a study on new genomic techniques [1] where the Commission indicated that it will initiate a policy action on plants derived from new genomic techniques (NGTs).

Here we present five policy options to be considered in the upcoming debate between the Council, the European Parliament and relevant stakeholders. In an era of climate change and biodiversity loss, the need for innovation in human activity has never been more pressing. The focus of this report is the topic of genome editing as the first innovation, amongst a number, to be considered. The reason for this initial focus is the major developments in the technology over recent years and the legislative ramifications that these developments entail.

There has been much discussion in the European Union in recent years concerning the regulatory status of organisms obtained by novel genomic techniques (NGTs) following a judgment of the Court of Justice of the European Union (CJEU), which "clarified that organisms from new mutagenesis techniques [by implication including those from genome editing] fall within the scope of the EU legislation"[2] . The most significant reaction to the judgment of the CJEU came from the Council of Ministers. The Council requested the Commission to submit, by 30 April 2021, *"a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of* ***novel genomic techniques*** *under Union law* [3]. To better address current needs of an ideal legislation and to develop possible policy options, RIE organized a high-level meeting with the Expert Committee, which has been timed to follow on from the study of the Commission as a contribution to the subsequent debate. It focuses on plant breeding and crops and does not address farm animals or other aspects of genome editing.

Amongst the attributes discussed, it was agreed that an ideal regulatory system should be clear in its scope and implementation, adaptable to advances in scientific understanding, proportional to risks, and it would be enforceable, harmonised as broadly as possible and would be non-discriminatory towards stakeholders. Clarity implies that all active participants in the regulatory system are aware of their rights and obligations. Adaptability implies that a system should be sufficiently capable of remaining compatible with rapid developments in genetics and genome editing. Proportionality implies that a system should not impose measures that are not commensurate with the risks under consideration. Enforceability is self-evident; if legislation is not enforceable, then it is liable to fall into abuse and disrepute. Harmonisation implies that a regulatory system is compatible with equivalent neighbouring systems. Finally, non-discrimination is the notion that legislation should not favour one group of stakeholders over others. It should favour choice and diversity. In terms of policy outcomes, there was a sense within the Task Force that these should be compatible with wider EU policy objectives including the European Green Deal, the Farm to Fork Strategy, the Biodiversity Policy and Sustainable Food Systems. There was a view that genome editing, as one of many innovations in agriculture, could make a positive contribution to these wider aims.

The second element of the report considers policy options which could be pursued in relation to existing Union law on GMOs to address products of genome editing amongst novel genomic techniques. Most of these options focus on Directive 2001/18/EC as has most of the debate following the judgment of the CJEU. These options include the consequences of taking no action; making use of article 7 of Directive 2001/18/EC8, allowing, potentially, for simplified procedures for specific types of GMOs; limited changes to Directive 2001/18/EC such as the amendment of the GMO definition and/ or an expansion of the list of techniques that do not lead to genetic modification; a more thorough revision of the EU GMO legislation; or new legislation which would specifically address genome edited products. It is also clear that there is further discussion to be had on what can be achieved in the short-term as opposed to longer-term solutions. It is also worth noting that there is a view amongst some stakeholders, that there is nothing flawed with current Union GMO law per se. It is the differences of opinion amongst member states as expressed in the Council, for example, that makes any agreement difficult. The discussions that informed this report anticipated many of the issues highlighted in the recently published European Commission study and its conclusions are intended as a point of reference in the continued debate.

Finally, the report includes a section of Conclusions that are relevant to those that attended RIE's Expert Meeting as well as other stakeholders. However, the Conclusions are written especially with the policymaker in mind. They summarise those issues to be addressed when considering the implementation of the policy options discussed at the Expert Meeting.

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BACKGROUND TO THE MEETING

WHY SUSTAINABLE AGRICULTURE AND SUSTAINABLE FOOD SYSTEMS?

There is mounting evidence of our growing impact on the biosphere and the danger to the health of citizens and society posed by severe anthropogenic climate change. The Green Deal is thus at the centre of European policy priorities, with the Farm to Fork strategy occupying a prominent position in recognition of the contributions of the agricultural sector to the issue. Re-Imagine Europa decided to launch a Task Force on Sustainable Agriculture and Innovation to create a forum for real dialogue between different viewpoints on the topic. In particular, the aim is to better understand the emotions and values behind different perspectives and to see if, with ambitious climate goals as a clear priority, it is possible to find positive pathways forward to ensure that Europe can develop a robust and resilient food system that can become a global standard for sustainability.

For the purposes of this discussion, the term "sustainable agriculture" is understood as agricultural practices that do not disrupt the ability of Earth's ecosystems to sustain a diverse range of organisms. Implicit in this understanding is the promotion of biodiversity and thus a limited use of land for agricultural purposes, leaving sufficient areas as natural habitat for other species. Sustainable agricultural practices are thus those that follow agroecological principles.

It is worth noting that there are multiple interpretations in how best to achieve sustainable agriculture, with some arguing for example that the solution lies in the practice of diversity-rich small-holder plots and others advocating intensive agriculture to boost productivity and thereby reduce overall land required for agriculture. A more in-depth discussion on the various interpretations of sustainable agriculture can be found in the companion report 'A European Vision for Sustainable Agriculture and Innovation - Existing Narratives Shaping the Debate and Ways Forward'. More information can also be found in RIE's overview booklet Task Force on Sustainable Agriculture and Innovation as well as on RIE's web site [5, 6].

WHY INNOVATION?

Agriculture represents one of the earliest and most far-reaching milestones of human innovation, stabilising and augmenting the supply of food which in turn has freed ever greater proportions of the global population to further innovate. This positive feedback mechanism has resulted in a major improvement in the material wellbeing of society. Innovation has naturally brought with it new challenges; some of the most recent of these invite us to re-examine the nature of our relationship with each other and our environment.

The aim of the Task Force is to explore the role of innovation in the coming transition towards a new sustainable food system. Although the term "innovation" is generally associated with technological progress, it is important to note that innovation covers any new idea or method. There is a clear need to create stronger alignment on how to reach ambitious climate goals and an awareness of the newly emerging understanding of the relationship between "organic" and innovation as well as of alternative food/protein strategies as a solution to land-use and biodiversity. There is much debate in Europe and elsewhere about the extent to which human biotechnological intervention in agricultural genetics is desirable. Some believe that biotechnological intervention creates unacceptable environmental and human health risks; others that it can help solve challenges including those relating to food insecurity and poor nutrition as well as providing economic and ecological benefits.

For many years, the improvement of crops as well as livestock and animal breeding proceeded through the selection of desirable traits via selective plant and animal breeding; processes known as conventional breeding techniques (CBT). It is well known to those engaged in agriculture, agronomy and plant breeding, but not necessarily to those less familiar with these disciplines, that there is a constant need to develop new plant varieties. There are several reasons for this. The success of plants varieties can be adversely impacted by plant pests and a variety of diseases which can adapt to and impact on new varieties. New varieties are also necessary to adapt to varying climatic and other environmental conditions. There is also a continuing need to improve crop yield and agronomic performance over existing varieties.

Desirable traits are the result of the genetic makeup of an organism. The genetic profile of a population of organisms changes when selection (natural or artificial) takes place over an extended period of time and it always depends on the genetic variability existing within a given population at a given point in time. As can be seen in Figure 1, the ways in which organisms with desirable traits can be selected has become more sophisticated as technology has developed. For example, chemical or physical agents (such as x-rays or other types of ionizing radiation produced in nuclear reactors) have been used to make random changes to plants in a process known as induced or random mutagenesis (third column in Figure 1), in the hope that some changes would result in desirable traits. Many other modern techniques have become available such as embryo rescue, ploidy induction, marker assisted selection amongst others.

Natural selection	**Cross breeding**	**Random mutagenesis**	**Transgenesis**	**Targeted mutagenesis Cisgenesis/ Intragenesis**
Spontaneous mutations occur in nature	Crossing plants and selecting offspring	Introducing of mutations by chemicals or radiation	Insertion of genetic material from other organisms that are sexually incompatible	Edit or rearrangement in same organism or insertion from sexually compatible organinisms

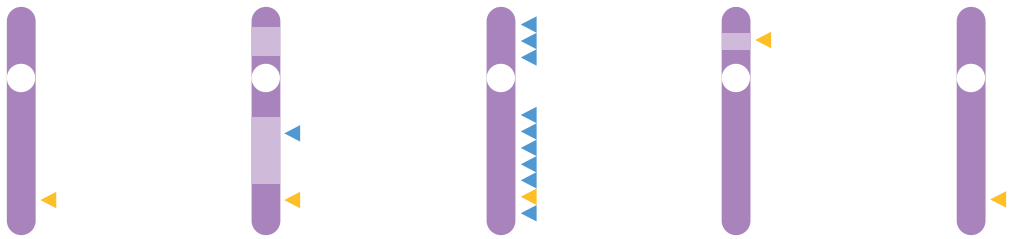


Figure 1. Visual representation of various methods of obtaining genetic changes in crops

More specific modification of the genomes of plants became possible during the 1980s, typically involving the insertion of genetic material into organisms, some of which may be from unrelated species (fourth column in Figure 1). Despite this innovation, it is still necessary to screen many lines to identify those that show desirable characteristics. Organisms resulting from such techniques have since come to be referred to as “genetically modified organisms” (GMOs) or transgenic organisms.

Over the last two decades several new technologies have found their application in agricultural biotechnology, referred to variously as: new breeding techniques (NBTs), genome editing as well as new or novel genomic techniques (NGTs). The most prevalent today are usually referred to as ‘genome editing’. 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. As indicated in the final column of Figure 1, when changes to genetic sequences occur, they are typically made in a much more precise manner, at a chosen location in the genome, in contrast to the random insertions of the established techniques of genetic modification or induced mutagenesis, as described above.

LINKAGES WITH NARRATIVES

This report aims to give a nuanced, evidence-based appraisal of the existing EU regulatory system for products of established (GMO) and novel genomic techniques (NGTs). A recurrent theme in the sections that follow is problems related to ambiguity of terms and lack of clear definitions in legislation compatible with advances in scientific knowledge. A further point of agreement is the need to include all stakeholders (that is, all EU citizens) in the discussion to move beyond oversimplified partisan positions towards a system that better serves the interests of all.

Research in cognitive science suggests that narratives play a primary role in decision-making. Briefly, humans have a limited ability to receive, process, remember, and communicate information that has not been packaged into meaningful structures. Narratives provide such structures and thus tend to guide decision-making. This report is therefore one of two deliverables prepared as a result of the work of the Task Force. The companion report is a discussion on narratives, the analysis of which covers the full spectrum of attitudes toward innovative technologies. It identifies four broad narrative schemata (each with various sub-narratives) which, for convenience, are grouped under the rubric of "precaution-oriented" narratives and likewise four that are loosely grouped as "innovation-oriented" narratives. It is worth emphasising however that narratives are better thought of as lying along a continuum rather than as two oppositely polarised camps. The fact that such a labelling conjures up a binary choice between regulation and innovation in many people's minds is indicative of the power of narratives. The analysis in both reports is intended as a starting point to tackle the present impasse and shift the public debate from a partisan, identity-oriented argument, towards a more open, value- and challenge-oriented discourse.

THE EXPERT COMMITTEE MEETING - POLICY OPTIONS FOR A REGULATORY SYSTEM

THE BACKGROUND

The CJEU judgment, Case C-528/16 (July 2018) [2] was a landmark case, which intensified the debate in the European Union on the regulatory status of organisms obtained by genome editing. Much has been written about the judgment but for the purposes of this discussion, the opinion of the European Commission (EC) is of paramount importance, because the Commission is charged by the EU Council with following up on the CJEU judgment.

The Commission web site states that "*the CJEU clarified that organisms from new mutagenesis techniques fall within the scope of the EU legislation. The Commission is now working with EU countries and stakeholders to implement the Court's ruling.*" [6, 7]

At the request of the Council of the European Union [3], the European Commission has completed "*a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of* ***novel genomic techniques*** *under Union law*" (that is, Directive 2001/18/EC, Regu-lation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC)." The results of this Commission study were not known at the time of the meeting of RIE's Expert Committee; however, this report is intended as a contribution to the discussion following the Commission study.

According to the European Commission, the current EU legal framework related to GMOs aims to:

- *"Protect human and animal health and the environment by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market.*
- *Put in place harmonised procedures for risk assessment and authorisation of GMOs that are efficient, time-limited and transparent.*
- *Ensure clear labelling of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.*
- *Ensure the traceability of GMOs placed on the market".*

The Commission also identifies the following building blocks of GMO legislation:

- "Directive 2001/18/EC on the deliberate release of GMOs into the environment [8].
- Regulation (EC) 1829/2003 on genetically modified food and feed [9].
- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory [10].
- Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms [11].
- Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs" [12].

It is noted that much of the discussion following the CJEU judgment has focussed on the GMO Directive. It should be emphasised that the request from the Council of Ministers to the Commission referred to a more complete set of EU law, including the building blocks identified by the Commission, rather than simply the Directive. It is important to note how EU law in its totality is addressed in the study from the Commission.

In November 2018, the European Commission's Scientific Advice Mechanism (SAM) Group of Chief Scientific Advisors published 'A scientific perspective on the regulatory status of products derived from gene editing, and the implications for the GMO Directive' [13], in which they 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.'

The ALLEA Symposium Report, *Genome Editing for Crop Improvement* [14] reviewed the latest scientific evidence with respect to applications of genome editing in agriculture. The two-day symposium established a dialogue between scientists and other relevant stakeholders and was organised jointly by ALLEA and the Royal Flemish Academy of Belgium (KVAB) in November 2019. The resulting report presents the state of the art of scientific evidence in the field of genome editing and explores what genome editing can deliver for agriculture. In addition, it explores the ethical and societal considerations related to agricultural applications of genome editing, traceability and intellectual property issues, and possible paths to harmonise EU regulation and legislation with recent scientific developments.

The European Group on Ethics in Science and New Technologies (EGE) published an opinion on the Ethics of Genome Editing in March 2021 [15]. Although this report was published between the meeting of RIE's Committee of Experts and publication of this report, it echoed many of the points made in the meeting and is likely to have a significant impact on the debate. It addresses genome editing across a range of sectors including human health, animal livestock breeding and gene drives. It has a chapter dedicated to genome editing in plants. It identifies and discusses a range of ethical questions raised across all sectors in which genome editing is expected to have an impact. It recommends with respect to plants that regulation should be proportionate to the risk. Light touch regulation should be used where the modification achieved by genome editing is through techniques such as gene silencing or where the change in the plant could have been achieved naturally or where the editing involves the introduction of genetic material from sexually compatible plants. Where the modification involves genes from non-sexually compatible organisms or where multiple changes in the genetic material have occurred, there should be a detailed evaluation of the changes including a requirement to test the new variety in the field under different conditions. Similarly, the Commission report states "*As concluded by the European Food Safety Authority (EFSA), plant products with similar risk profiles can be obtained with conventional breeding techniques, targeted mutagenesis and cisgenesis. Thus, a different regulatory oversight for similar products with similar levels of risk would not be justified in these cases. In addition, the current risk assessment procedures, embedded in the existing legislation, are rigid and limit a case-by-case evaluation, preventing risk assessment requirements to adapt to scientific progress.*" [1]

THE EXPERT COMMITTEE MEETING – THE POLICY OPTIONS DISCUSSION

The policy options segment of the meeting of the Expert Committee was supported by a 'Thought-Starter document' to stimulate the discussion. The Expert Committee considered the attributes of an ideal regulatory system as identified and discussed by the experts. It also considered the outcomes expected from a regulatory system. Finally, it went to address policy options, especially concerning genome editing, within the context of existing Union law as well as the regulatory systems in other regions of the globe. Figure 2 illustrates the current (as of February 2021) regulatory approach to crops produced via genome editing techniques in different countries around the globe.

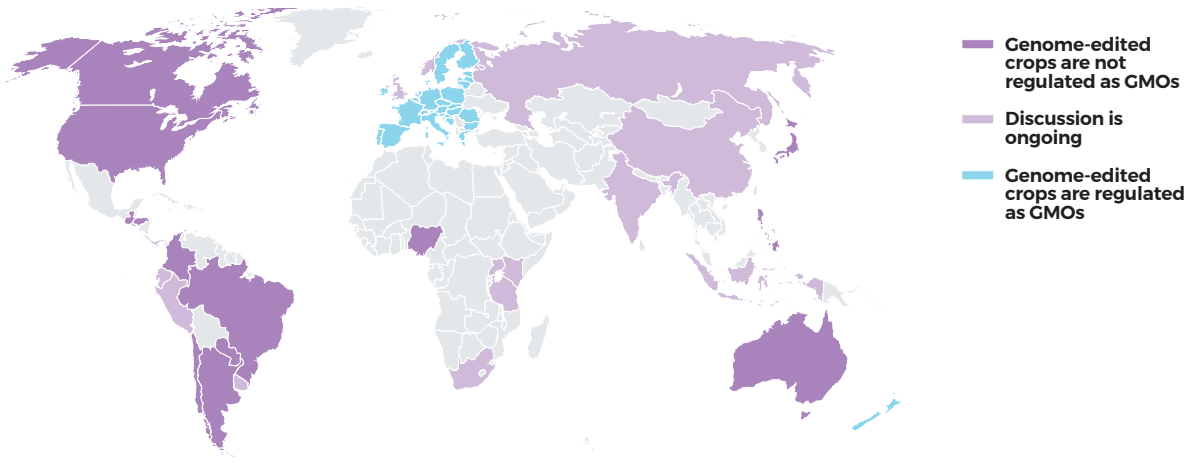


Figure 2: Global overview of regulatory approaches implemented or discussed in different countries for genome-edited crops as of February 2021 [16].

Case Study: The Role of Regulation in Defining a Technology – The Example of Argentina

The discussion was opened with a presentation by Professor Martin Lema (Argentina) on the example of Argentina which has had a long experience with GMOs and has a specific mechanism for establishing the regulatory status of certain products of genome editing. A summary of this presentation is found in the Box. Case Study: The Role of Regulation in Defining a Technology – The Example of Argentina.

The Role of Regulation in Defining a Technology – The Example of Argentina

Argentina's regulatory framework for products of biotechnology has been in place for 30 years. Its Biosafety Commission (CONABIA) has been recognised by FAO as one of its centres of reference for GMO biosafety. Through it, Argentina has established a globally recognised regulatory system for modern biotechnology predating the establishment of the Cartagena Protocol on Biosafety (CBP) to the Convention on Biological Diversity. While Argentina has not ratified the CBP, its domestic policy is aligned with it and the same definition for GMO is used as the CBP definition for Living Modified Organism (LMO) ("'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" [17]) as well as the CBP definition for modern biotechnology.

The first approval of a GM crop in Argentina was 25 years ago. The current period required for the approval of a commercial GMO is 1-4 years not including a prior period of 1-3 years for field-trials. Over 60 GMO products have been approved to date for use in agriculture, mostly consisting of crops as well as some recombinant live vaccines for veterinary use.

Discussions were triggered in Argentina on new breeding techniques (NBTs) in 2011-2012 through international developments and publications including the work of the Joint Research Centre of the EU during this period. The Biosafety Commission began to consider whether and how to regulate NBTs, including products of genome editing, which led to a mechanism to determine the GMO status of an application.

The mechanism is based on a consultative procedure that defines the regulatory status of the product. It is a case-by-case sorting mechanism (product-by-product) procedure that determines whether a product is in the scope of the GMO regulations or not. If a product is a GMO, it will be subject to the provisions of the biotechnology regulations. If the product is not a GMO, it is handled as a conventional new variety. During the consultation procedure, the applicant must present information about the product to al-low the Commission to assess whether there is a novel combination of genetic material (that is, an insertion of recombinant DNA) in the final product and notifies the applicant on the regulatory status. A preliminary determination may also be given during the development stage based on the intended final product. The process must take no longer than 60 days to determine the regulatory status unless additional information is required to complete the process.

The first assessment was performed in 2016. To date there have been 24 cases of NBTs, most of which were gene-edited organisms. Of these, only three products have been determined to be GMOs, and the rest were non-GMOs. After four years, one can already see a greater diversity regarding traits and species in the NBT regulatory applications than in three decades of GMOs. For the same caseload, there is also a dramatic difference in the profile of applicants for NBT products versus those for GMOs. NBTs applications mostly come from local companies as well as overseas SMEs. This contrasts with the 90% of authorisations for GMO products from foreign multinationals. GMO products undergo lengthy and costly regulatory procedures, whereas products obtained via NBTs are regulated under more affordable and less time-consuming processes for conventional new varieties.

By looking at the stories behind these applications, it can be seen that this regulatory approach clearly inspires many local Public-Private partnerships and attracts diversified local investment, which is the opposite of the GMO regulation history worldwide. Seven more Latin American countries have followed the Argentinian approach as of 2021; this includes Brazil, Chile, and Colombia that have already assessed their first cases [18-21].

ATTRIBUTES OF AN IDEAL REGULATORY SYSTEM

For the purposes of this report, the term "regulatory system" refers to the compilation of all relevant EU regulations that together provide the necessary "framework" for regulating GMOs as well as organisms produced using novel genomic techniques (NGTs). The Expert Committee spent time identifying and discussing the attributes of an ideal regulatory system in relation to NGTs, including that it be clear, certain, adaptable (in the sense of being "future-proof"), proportional, enforceable, harmonisation, and non-discriminatory. Existing EU GMO legislation [6-8] does contain elements of some of these attributes. However, the very existence of the current debate on NGTs motivates a discussion on the role of innovation and regulation in adapting to existing and future challenges faced by EU agricultural systems. The following paragraphs discuss each of the attributes in more detail.

Clear and Certain imply that all active participants including technology developers, academia, consumers, farmers, and food and feed chain operators are aware of their rights and obligations with respect to the regulatory system. If rules change frequently or are interpreted in separate ways by different authorities, then stakeholders must regularly adjust to them. Continuous adaptation to changing regulations is a time-consuming and costly process and creates major challenges for stakeholders in making long-term decisions. A lack of legal certainty can also pertain to timelines for approval processes as well as markets for approved products (opt-out directive 2015/412 [10] for example, can be invoked, rendering entire populations outside the market). This can affect the willingness of stakeholders to be active in the EU market, leading to increased prices and reduced freedom of choice for farmers concerning those crops they wish to grow and which seeds to use. It can also impact on consumers concerning which products to buy from which proportional (see below). However, it is worth noting that technologies from other domains such as photonics can securely monitor the entire value chain from farm to fork and certify the origin and content of what is served on our tables [22]. Therefore, while requiring careful thought, multiple strategies may be combined to reduce the regulatory burden and achieve the objective of full transparency and traceability of the complete food chain.

Adaptable or **Future-proof** implies that a system should be sufficiently agile to respond to new developments. To prevent lack of clarity and continuous adaptation (change) of the regulation system, it should be sufficiently flexible to also include developments in genetic techniques and (particularly) the resulting organisms. Technology is moving fast in this sector and, to prevent the need for frequent drafting of new legislation, it should be sufficiently flexible to take into account new technological developments, both present and in the future. In addition to keeping pace with the evolving science, periodic regulatory reviews are encouraged for regulatory frameworks to stay up to date. An ideal regulatory system should also be adaptable to changing needs from technology developers, consumers and farmers, including those dictated by global developments as well as adaptation to climate change. There is considerable knowledge and experience (familiarity) with the procedures for managing applications of crop plants developed by a wide range of breeding techniques. Amongst other things, this 'familiarity' concerns the crop plant species in question, the types of environments in which those crops are cultivated as well as the traits associated with a new variety [23]. Ideally, the accumulation of such knowledge should be taken into account in the regulatory framework, thereby saving time and effort in subsequent risk assessments of similar applications. This notion is thus closely related to that of proportionality (see next).

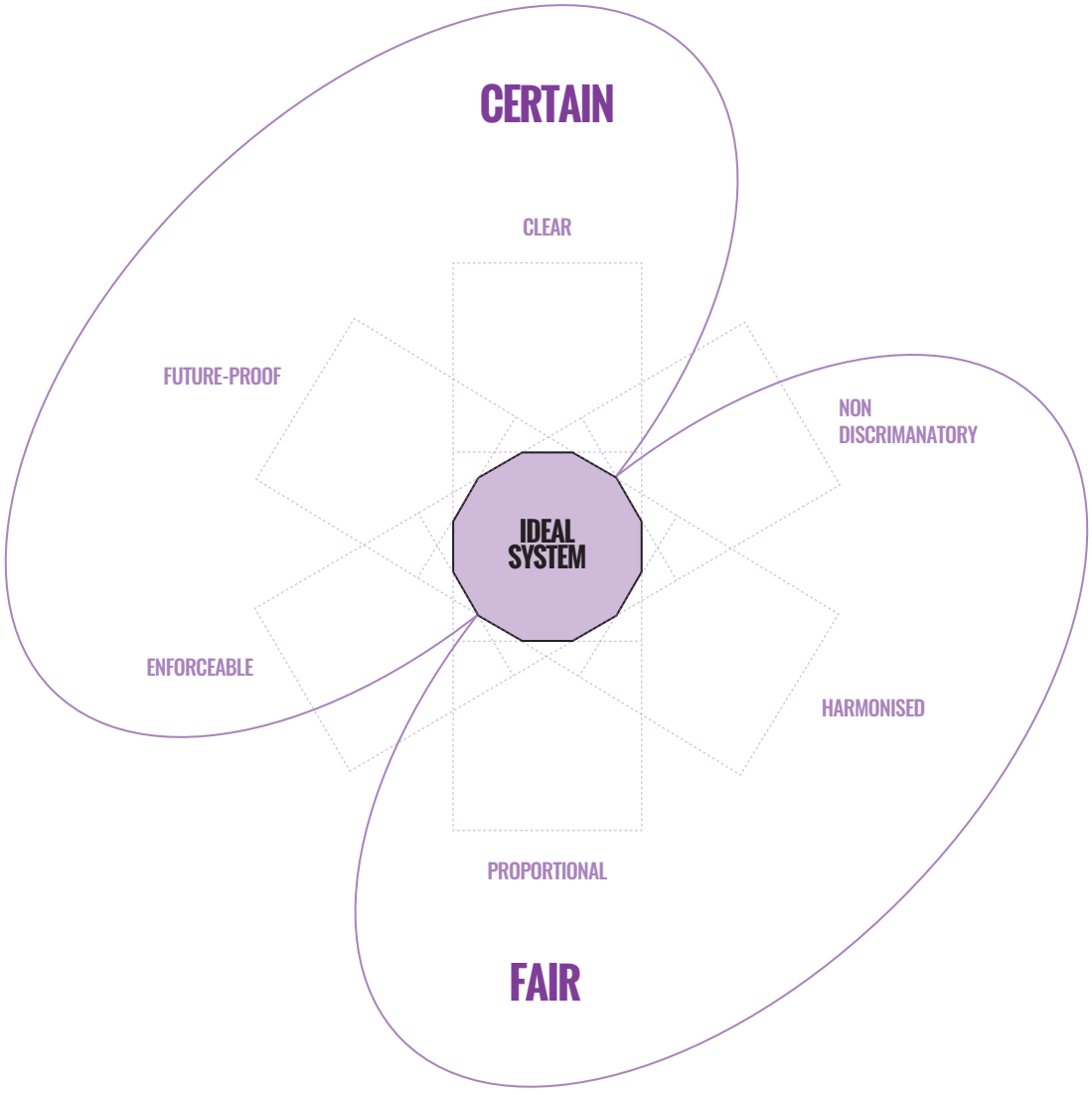
Proportional implies that the regulatory measures are commensurate with the risks of the product from a science-based perspective [13, 15] . If regulatory measures are disproportionate to the risk, then the regulatory burden limits the chance for new products to be developed without any appreciable benefit in return. Much emphasis in the public debate is currently placed on unintended on- and off-target changes that could be introduced through genome editing, although these have been shown to be much less abundant than the number of spontaneous mutations introduced during the normal life cycle of a plant [13, 14, 24]. In contrast, the multitude of unknown and possibly undesirable changes intro-duced through mutational breeding using chemical agents or ionising radiation are regarded as acceptable. This is presumably why EFSA concluded that that the analysis of potential off-targets would be of limited value for the risk assessment [25].

Enforceable implies that infractions of existing or new legislation can in fact be identified and addressed. This is an important consideration when it comes to genome edited crops, some of which are indistinguishable from those generated through conventional breeding. Thus, enforcement of any regulation that discriminates between a product

created by conventional breeding versus the identical product created through genome editing techniques could be extremely difficult. If legislation is not enforceable, then it is liable to fall into abuse and disrepute.

Harmonised refers to the desirability for EU legislation to be as compatible as possible with that of trading partners. The EU exists in an international world in which food and feed chains are often multinational with many products imported from outside of the EU. Ensuring that Union law is as compatible as possible with that of other countries and regions is valuable should the EU wish to be competitive in a global context. Doing so diminishes the risk of trade disruption and enables equal treatment of imported and EU produced products. It should also address harmonisation within the EU itself as, despite the existence of the single market, member states remain non-harmonised.

Finally, **non-discriminatory** implies that legislation should not favour one group of stakeholders (or one group of technologies or one category of products) over others. It should favour equal opportunities regarding choice and diversity for all parties. Diversification in agriculture is important and there is a view amongst many that the current system disadvantages smaller plant breeders, smaller biotech companies and other SMEs due to the costs and complexity of compliance, whereas large multinationals have the financial capability to better absorb the regulatory complexity. It is important to ensure that any benefits of the technology are spread throughout society and accessible to a broad range of stakeholders.



Although not specifically an attribute, there is an international angle that confers responsibility on EU policy and legislation as it influences activity in other regions, particularly in developing countries. Many African countries for example are already experiencing acute pressure on their ecosystems due to climate change and would likely benefit from the adoption of new techniques. Therefore, discussion around policy options should also consider how the EU regulatory system is perceived in other countries and regions.

When asked what attributes an ideal regulatory system on genome editing would have, most participants agreed that the Argentinian regulatory system (see box above [18-21]) possesses many of the ideal merits. Harmonisation, proportionality and adaptability and non-discrimination are four key features of the system, which has been tested in practice since it became effective in 2016.

OUTCOMES EXPECTED FROM AN IDEAL REGULATORY SYSTEM

There was general agreement that a regulatory system based on the attributes described above can have positive impacts. Participants agreed that an ideal regulatory system should be science-based, experience-based, and risk-proportionate; it should balance the need to innovate alongside the precautionary principle. As already noted [21], regulatory systems can have an impact on innovation including the variety of products approved as well as the profile of product developers. Potential outcomes that go beyond the regulation and innovation of techniques will also need to be taken into account. These include market power, access to technologies and innovation by the farming communities here in the EU but also in developing countries, skill requirements, and patents. Finally, a regulatory system would need wide support from those stakeholders involved, including farmers and consumers. A regulatory system enabling the use of genome editing in the context of sustainable agriculture could have the following key outcomes:

Genome editing is one of the many technologies available to innovate in agriculture, other examples including AI or digital-based solutions as well as the growing field of agroecological best practices. The use of genome editing technologies could contribute to the objectives of other EU policies and strategies, such as the Green Growth Strategy, the Farm to Fork and Biodiversity strategies (which is acknowledged in the Farm to Fork Strategy) and the recent EC study on new genomic techniques.

Genome editing could contribute to increased productivity in the agricultural sector and the protection of biodiversity. It could contribute to the reduction of GHG emissions and assist in the adaptation of crops to climate change using traits, such as drought tolerance. It could also lead to a reduction in the use of chemical inputs in agriculture, including pesticides. Genome editing could contribute to ensuring a safe and reliable supply of nutritious and affordable food through increased productivity and the reduction of food waste. It could add value to the development of locally produced food, and in turn, increase diversification and reduce dependency on imported food.

There is no indication that the use of genome editing negatively impacts on agriculture or that its use in plant breeding negatively impacts on current farming practices, such as traditional forms of agriculture or organic farming [26]. Products developed through genome editing should be compatible, able to co-exist, and even considered as tools within those farming practises, as is the case for products developed through mutation breeding by radiation or chemical approaches. In this context, an important theme that emerged was to consider more intensively the needs of farmers and consumers, taking into account the diversity of farming practises in the EU as well as the di-verse environmental conditions and diverse preferences of consumers.

It was recognised that there is an international dimension to this topic. An EU regulatory system should align with those of its global partners in order to avoid, amongst other things, trade disruptions and disputes. It was recognised that measures aimed at international regulatory alignment or harmonisation could be important for smooth international trading relations. It was noted that this should apply to the UK, which despite Brexit, is in close geographical proximity to the EU and remains a major trading partner including in foods and products of agriculture. At the same time, enabling the use of innovative technologies should aid the competitiveness of European industry.

POLICY OPTIONS

The discussion of attributes of an ideal regulatory system made clear that the current regulatory system is far from ideal, if not in its conception, then in its implementation. It could be argued that based on how it has been interpreted to date, the current regulation surrounding NGTs is clear (i.e. that organisms obtained by novel genomic techniques fall under GMO legislation, in the spirit of the Directive). However, the virtual moratorium on products of NGTs in Europe suggests that the system does not respect proportionality to risk nor adaptability to advances in scientific understanding. Additionally, the ability to produce crops through genome editing that are indistinguishable from those generated through conventional breeding presents a challenge to enforceability in the longer term. The EU is neither harmonised internally nor with its trading partners, and the example of the Argentinian regulatory system suggests that current EU legislation risks discriminating against smaller biotech companies and SMEs. The plurality of opinions expressed during the meeting pointed to a lack of clarity as to the meaning of key terms in existing legislation and ambiguity in its interpretation. The Expert Committee considered the potential advantages and disadvantages of the following five policy options as well as other issues arising:

(Option 1) Business as usual
(Option 2) Make do with what we
(Option 3) Harmonisation
(Option 4) A more thorough revision of the EU GMO legislation
(Option 5) A complete overhaul

OPTION 1, BUSINESS AS USUAL:

There was little support for this option as it stands, that is, business as usual. In fact, there is a clear dissatisfaction with the existing EU GMO regulatory system, especially from a longer-term perspective. Although there was a strong consensus amongst the experts that "business as usual" is undesirable, some experts expressed the view that much of the problem with the existing system is linked primarily to the implementation of the legislation and not so much with the actual legal provisions in Directive 2001/18/EC, or any of the other relevant EU legal instruments. In the short-term, it could be preferable to retain the existing system while working to clarify the interpretation. In effect, this is an adjusted option 1. It is known that member states have taken different positions largely for political reasons. Some are sceptical when it comes to the authorisation of GMOs, while others are less so and more supportive of this type of innovation. Notwithstanding the short-term options 2 and 3, in the long term, it is likely that the current regulatory system has to be extensively reviewed.

OPTION 2, MAKE DO WITH WHAT WE HAVE:

This option would involve the use of existing provisions in EU law, notably Article 7, Directive 2001/18/EC, which allows for differentiated procedures for specific categories of GMOs involving simplified procedures while meeting the criteria set out in Annex V. One of the advantages of this procedure is that it might result in a desired outcome without opening the entire Directive. The uncertainty with option 2 is that Article 7 has never been invoked in practice, which is probably linked to difficulties in achieving a qualified majority among Member States [27].

Although the differentiated procedure option may not have been used for the environmental release of GMOs (remit of Directive 2001/18/EC), differentiations made by Member States are commonplace for low-risk GM microorganisms grown in containment (remit of Directive 2009/41/EC), which is under the oversight of national Member State authorities. This does beg the question whether a similar situation might be permitted in practice for plants under the same circumstances.

Another way to apply differentiation is not the procedural pathway but through specific risk assessment guidance. Risk assessment guidance for foods and feed derived from GM plants, for example, was initially drawn up by the EFSA GMO Panel in 2011 and became enshrined into law with only minor modifications, that is, Annex II of Commission Implementing Regulation (EU) 503/2013 [28]. The EFSA GMO Panel has indicated that for modifications using site-directed nucleases (such as CRISPR Cas9, TALENS, zinc-finger nucleases), lesser data requirements may apply. One could envisage that EFSA may be tasked with developing specific guidance for GMOs obtained with these techniques, which then subsequently could become annexed to a new implementing regulation. Hence it does not change the actual framework legislation [8] and GM food and feed Regulation (EU) 1829/2003 [9] but the scientific risk assessment that forms the basis of EFSA's advice to the European Commission.

OPTION 3, HARMONISATION:

There was a good deal of support for option 3, that is, limited changes to Directive 2001/18/EC. For many, it is not plausible to put those products of genome editing, which include no transgenic material, on the same regulatory basis as transgenic GMOs, especially if such changes are similar to those which could have occurred through conventional plant breeding. Such limited changes could include, for example, an amendment of the GMO definition to bring it in line with the LMO definition of the CPB [17]. As the EU and its member states are parties to the CPB, this should not, in principle, pose any difficulties for EU policy, but any changes to the definition would require careful legal and regulatory assessment to ensure a robust and future-proof regulatory framework. In addition, a new interpretation of mutagenesis could be considered, as well as an expansion of the list of techniques under Annex I B that leads to exemption from the Directive, both of which could be achievable. In addition, a description of conventional breeding techniques (including random mutagenesis) that do not lead to the creation of a GMO could be established; the list could be part of an updated list of excluded techniques in Annex I A. In the discussion on harmonisation, there was a reference to the joint proposal of Wissenschaftlerkreis Grüne Gentechnik e.V and the Association Française des Biotechnologies Végétales (AFBV) [29]. Amongst other things, it proposes, that those plants should be exempted from the Directive which have an edited native allele obtained by genome editing which are of the same type as those that can be obtained by spontaneous or induced mutagenesis.

Conversely, some participants cautioned that changing EU law is a very lengthy process and that there is no such thing as a guaranteed 'limited change' of a Directive, as other EU institutions may propose other amendments which would have uncertain outcomes. According to this view, partial/targeted re-opening of the GMO legislation risks serious disruption of the existing regulatory process for GMO import approvals and may result in multiple revisions beyond the definition and regulation of genome editing techniques, with potentially serious repercussions on international trade. Furthermore, such a re-opening may impact products obtained by conventional mutagenesis that are now exempt from the GMO Directive.

OPTION 4, A MORE THOROUGH REVISION

As is the case for option 3, the political reality of pursuing this option is likely to result in political deadlock due to the need for unanimity or a qualified majority among member states. Also, similarly to option 3, the outcome of a more thorough revision of the Directive may prove difficult to predict. For example, it may impact products obtained by conventional mutagenesis that are now exempt from the GMO Directive. An alternative to this option or a companion to it would be to introduce a new piece of legislation or interpretation that considers in general terms the objectives of the use of biotechnologies including desired outcomes and/or undesired impacts. This could take into account other EU objectives related to agriculture such as the Green Growth Strategy, the Farm to Fork Policy and the Biodiversity Strategy.

OPTION 5, A COMPLETE OVERHAUL:

As is the case with option 4, pursuing this option requires a qualified majority among member states but brings the opportunity to specifically address the regulatory oversight of new plant varieties developed using genome editing and other plant breeding innovations. In this case, Directive 2001/18/EC would remain in place for currently and future marketed GMOs, whereas separate legislation would specifically consider products generated using genome editing techniques that could have been produced by conventional breeding. Introducing a separate legislation could allow for a characterization step ahead of a verification of whether a specific product should be assessed under the 2001/18/EC GMO legislation or if it is excluded from it. This would require the establishment of characterisation requirements, and criteria and procedures for verification. This option would be consistent with the current Argentinian approach. However, introduction of new legislation would likely require a change of the current GMO Directive. Given the CJEU ruling that genome editing products are covered by the GMO Directive, a new legislative framework that treats those products differently would require clarification in 2001/18 that at least some of these products are no longer covered there.

Option	Advantages	Disadvantages
1. Business as usual	• No amendments needed	• Interpretation and implementation (enforcement) issues • Domination of multinationals
2. Make do with what we have	• No amendments needed • Opening for SMEs and some genome-edited crops	• Requires qualified majority among member states • implementation (enforcement) issues
3. Harmonisation	• Possibly rapid targeted amendment(s) • Likely more consistent with CPB • Opening for SMEs and some genome-edited crops	• Requires qualified majority among member states • Uncertain outcomes
4. A more thorough revision of the EU GMO legislation	• Could better consider EU objectives like Green Growth Strategy, F2F, etc • Possibly more future-proof	• Requires qualified majority • Uncertain outcomes • More politically difficult (likely longer timeline required)
5. A complete overhaul	• More future-proof	• Requires qualified majority • Very politically difficult (likely longer timeline required)

MULTI-STEP SOLUTIONS:

It was recognised that none of these options are mutually exclusive when taking into account the possibility of long-term versus short-term solutions. The solutions offered by options 4 and 5 entail substantial changes to (or development of) the EU legislative framework, which would involve a more complicated and time-consuming process as compared with option 2 and possibly, option 3. It was pointed out that the complexity of the effort and the associated timelines largely depend on stakeholder and political support for a particular option. Option 3 is perceived as a shorter-term solution but could become lengthy if re-opening of the Directive cannot be limited to targeted amendments only. Option 5 is perceived as a longer-term solution but could be efficient as it focuses the discussion on products generated using genome editing techniques that could have been produced by conventional breeding. Those that favour the need for short-term solutions (such as options 1, 2 or 3) emphasise the need for pragmatism so that scientists and plant breeders have some certainty and can continue to work. This would avoid a loss of competitivity to EU industry. There was some disagreement about what 'short-term' realistically means in an EU legislative context, which could be anything between 2 and 10 years. It was also noted that even if a product is not considered to be a GMO, it will still be subject to regulation concerning new conventional varieties of plants when cultivated in the EU.

CONCLUSIONS

This report and its companion report on Narratives comprise the deliverables of the first meeting of RIE's Task Force on Sustainable Agriculture and Innovation. The report on Narratives shows how attitudes to innovative technologies, including decision-making, depend on the underlying attitudes of stakeholders. Amongst other things, the Narratives report analyses the full spectrum of attitudes toward innovative biotechnologies, especially genome editing. It is important that the concerns and priorities of stakeholders and citizens are considered in a regulatory system in order that there is trust and the narratives analysis aids in this endeavour.

The focus of both reports is on genome editing for crop improvement because it is an innovation of current intense debate in the EU. The scientific and technological aspects of genome editing are evolving at a rapid pace, in turn requiring clarification on the regulatory status of organisms developed using novel techniques. There are merits to the arguments put forward by all parties to the debate, but a legacy of relatively limited stakeholder participation has resulted in a tendency towards oversimplification. As such, this topic is fertile ground for examining the nuances of the regulatory system and the narratives that guide legislation. Other equally significant innovations will be considered at a later stage.

Changes to Union law, for example, Directive 2001/18/EC, are highly likely to lead to even more protracted and polarised discussions involving relevant EU institutions and stakeholder groups, including scientists, industry, NGOs, farmers, and consumers. At the same time, there is a dissatisfaction with the current state of the Union regulatory system on GMOs and a major update to the system seems inevitable in the longer term.

There is a view amongst many that the current difficulties with the Union regulatory system are not necessarily with the law per se, but with the implementation of the law. This arises, among other things, from uncertainty about the scope of the GMO definition and difficulties in obtaining a qualified majority on many issues related to GMOs. This is an issue that EU institutions and policy makers should consider and reflect upon in order to address this impasse.

There are several policy options that can be considered. For example, there is an opinion supported by many that the definition of Living Modified Organism (LMO) from the Cartagena Protocol on Biosafety (CPB) ("any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology") would better serve the EU than the GMO definition in the Directive. The EU and its member states have ratified the CPB and there is no clear incompatibility with EU policy when considering this reform. Although such an approach has clear advantages over the definition used in the Directive, careful legal analysis should be undertaken to ensure that the regulatory framework possesses the attribute of being as future-proof as possible. This is another issue which EU policy makers should consider.

There are other short-term policy options involving the use of Directive 2001/18/EC. Article 7 allows for differentiated procedures for specific categories of GMOs meeting the criteria set out in Annex V. In principle, this could lead to simplified procedures with less onerous requirements for products that contain only a few targeted edits than for transgenic GMOs. One of the advantages of this procedure is that it might provide a solution without the need for a legislative change. The problem with this approach is that Article 7 has never been used in practice. Policy makers may wish to consider why this is the case.

Another possibility is to consider Article 3 and an expansion of the list of techniques of genetic modification under Annex I B, Directive 2001/18/EC, that are exempted from the provisions of the Directive. Currently, this list consists of mutagenesis and cell fusion techniques of plant cells, which can exchange genetic material through conventional breeding methods. This could entail a reconsideration of the meaning of mutagenesis in the context of the Directive. For many, it does not make sense to put those products of genome editing, which include no transgenic material in the final product, under the same level of regulatory scrutiny as transgenic GMOs. Alternatively, a description of breeding techniques that are considered not to lead to the creation of a GMO (such as random mutagenesis) could be established; the list of such techniques could be part of an updated list of excluded techniques in Annex I A.

In the long term, a more thorough revision, or even a complete overhaul, of the system may prove inevitable. The task force acknowledges that the current political reality means that pursuing option 4 or 5 is likely to prove especially difficult due to the need for unanimity or a qualified majority among member states. Short- and long-term solutions are however not mutually exclusive. Some experts believe that more minor changes to the Directive (options 1, 2 or 3) are more pragmatic as they create increased certainty for scientists and plant breeders in the short-term near future, before considering more substantial changes to (or development of) the EU legislative framework (option 4 or 5). However, a belief that targeted regulatory changes are effectively impossible has led other experts to recommend prioritising more substantial changes or drafting of entirely new legislation as the more pragmatic route. Substantial change will require political support and a shift in attitudes in member states. This could happen, but it will ultimately require broad support from EU citizens more generally. In fact, the need for input and support of all stakeholders, including EU citizens, was a point repeatedly stressed by the Task Force.

NEXT STEPS

In addition to an online event to launch the first deliverables of the Task Force on Sustainable Agriculture and Innovation, RIE is planning (depending on Covid restrictions) a face-to-face meeting of the Task Force on Sustainable Agriculture and Innovation to be held in the European Parliament in Brussels in October/ November 2021 (date and time to be announced). This meeting will consider, amongst other things, whether more work should be undertaken on genome-editing and/or whether the time has come to consider other innovations in agriculture. Digital technologies for example, were briefly discussed during the meeting of the Task Force as being well placed to play a significant role in agriculture in the immediate future.

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