Brussels, 13 November 2018

COST 092/18

DECISION

Subject: **Memorandum of Understanding for the implementation of the COST Action "Genome editing in plants - a technology with transformative potential" (PlantEd) CA18111**

The COST Member Countries and/or the COST Cooperating State will find attached the Memorandum of Understanding for the COST Action Genome editing in plants - a technology with transformative potential approved by the Committee of Senior Officials through written procedure on 13 November 2018.

MEMORANDUM OF UNDERSTANDING

For the implementation of a COST Action designated as

COST Action CA18111
GENOME EDITING IN PLANTS - A TECHNOLOGY WITH TRANSFORMATIVE POTENTIAL (PlantEd)

The COST Member Countries and/or the COST Cooperating State, accepting the present Memorandum of Understanding (MoU) wish to undertake joint activities of mutual interest and declare their common intention to participate in the COST Action (the Action), referred to above and described in the Technical Annex of this MoU.

The Action will be carried out in accordance with the set of COST Implementation Rules approved by the Committee of Senior Officials (CSO), or any new document amending or replacing them:

a. “Rules for Participation in and Implementation of COST Activities” (COST 132/14 REV2);
b. “COST Action Proposal Submission, Evaluation, Selection and Approval” (COST 133/14 REV);
c. “COST Action Management, Monitoring and Final Assessment” (COST 134/14 REV2);
d. “COST International Cooperation and Specific Organisations Participation” (COST 135/14 REV).

The main aim and objective of the Action is to assess the full innovation potential and impact of plant genome editing; to set the future direction of research priorities, to promote the link between research and innovation in a socially responsible manner, and to examine the synergistic interactions with closely related fields. This will be achieved through the specific objectives detailed in the Technical Annex.

The economic dimension of the activities carried out under the Action has been estimated, on the basis of information available during the planning of the Action, at EUR 80 million in 2018.

The MoU will enter into force once at least seven (7) COST Member Countries and/or COST Cooperating State have accepted it, and the corresponding Management Committee Members have been appointed, as described in the CSO Decision COST 134/14 REV2.

The COST Action will start from the date of the first Management Committee meeting and shall be implemented for a period of four (4) years, unless an extension is approved by the CSO following the procedure described in the CSO Decision COST 134/14 REV2.

OVERVIEW

Summary

A great challenge of this century is to provide adequate nutrition for an increasing global population while developing a more socially, economically and environmentally sustainable agriculture that counters climate change, biodiversity loss and degradation of arable land. Plant research and breeding are very important in meeting this challenge. Building on scientific progress, a number of genome editing techniques have been developed over the past two decades allowing an unprecedented level of precision in our control over genetic material and its corresponding traits.

This COST Action will bring together expertise from a range of disciplines to evaluate plant genome editing techniques and their resulting products from various perspectives. The findings will serve to design a roadmap for directing and facilitating applications of genome editing in plant research and breeding, which in turn will help setting R&D priorities and stimulating further cross-national and cross-disciplinary collaborations.

Areas of Expertise Relevant for the Action	**Keywords**
● Agricultural biotechnology: Genetic engineering, transgenic organisms, recombinant proteins, biosensors for agricultural biotechnology, animal biotechnology ● Biological sciences: DNA synthesis, modification, repair, recombination and degradation ● Agriculture, Forestry, and Fisheries: Sustainable Agriculture ● Biological sciences: Ethics of biological sciences ● Industrial biotechnology: Genetic engineering, transgenic organisms, recombinant proteins, biosensors for industrial biotechnology	● Genome editing ● Plants ● Research and breeding ● Innovation ● Sustainability

Specific Objectives

To achieve the main objective described in this MoU, the following specific objectives shall be accomplished:

Research Coordination

● Evaluate improvements required for future crop plants for sustainable agricultural production and improved consumer health in Europe and beyond and the extent to which genome editing can be utilized to achieve these improvements.
● Examine genome editing techniques and their comparative advantages and disadvantages in various plant research and breeding applications.
● Establish synergies, whenever possible, between the research needs and priorities for genome editing platforms with those of sequencing, genomics, phenomics, “big data” and systems biology platforms.
● Collect and analyse, where available, information on the potential socio-economic, environmental and human health impact of genome editing in plant breeding and commercial development.
● Contribute to the ongoing discourse on the regulatory frameworks in the EU and other relevant countries and their potential applicability for plant genome editing, and provide future-oriented solutions if necessary.
● Contribute to the emerging intellectual property policy discussions related to genome editing and the resulting products and assess their implications for the plant research and breeding sector and for farmers.
● Provide clarity in terminology and give input towards workable definitions.
● Map the perceptions of various stakeholders of plant genome editing, identify where input from key actors could be gathered according to responsible research and innovation principles, and contribute to an enhanced public awareness.
● Coordinate outreach activities based on the output from all of the above.

Capacity Building

● Enhance existing, as well as form novel, research consortia, building further on existing national and/or international research programmes involving plant genome editing through meetings, Teaching Schools

(TSs), Short Term Scientific Missions (STSMs) and other events, as well as further joint research proposals.

● Promote mutually beneficial interactions between the public research sector and the private R&D sector related to plant genome editing, as well as with policy makers, farmer organisations, consumer interest organisations, environmental organisations and other stakeholders, through active participation in various events

● Provide opportunities for interdisciplinary training and career development of Early Career Investigators through their involvement in organisation of Action activities and participation in training events (TS and STSM).

● Promote new ERASMUS agreements between partner universities.

● Contribute to the body of scientific literature in the field of plant genome editing.

● Promote gender equality and female leadership in this new field of research

● Encourage the participation of Inclusiveness Target Countries (ITCs) and Near Neighbour Countries (NNCs) in Action activities and for key Action management positions

● Disseminate knowledge obtained in the Action through various teaching material, notably interactive Massive Open Online Courses (MOOCs) targeting undergraduate and/or graduate students, video interviews and making information and/or education material available in several of the languages spoken in Europe.

1. S&T EXCELLENCE

1.1. CHALLENGE

1.1.1. DESCRIPTION OF THE CHALLENGE (MAIN AIM)

Plant research and breeding play vital roles in the delivery of a sustainable and sufficient supply of nutritious food and feed, while at the same time contributing towards lowering the environmental footprint of agriculture. Energy, fuel and industrial raw material production are also becoming increasingly dependent on agricultural output in the transition to a more sustainable, bio-based society. Building on scientific progress, a multitude of chemical, physical, and molecular biology techniques have been utilised since the early 20th century to increase the genetic variation in plants and to manage the diversity of traits available for plant breeding, as well as enabling plant researchers to elucidate new levels of molecular and genetic interactions. More recently, genome editing has shown great potential as an emerging set of technologies allowing rapid genetic alterations at a level of precision not seen before. The corresponding capacity for improved plant research and crop trait management has the potential to provide important economic and environmental benefits for our society (e.g. higher yielding crops, crops with improved nutrient profiles, reduced greenhouse gas emissions, more effective and less disruptive (toxic) pest control). Many research groups in Europe have been proactive in applying emerging techniques, such as the clustered regularly interspaced palindromic repeats (CRISPR)/Cas system, transcription activator-like effector nucleases (TALEN), and zinc finger nucleases (ZFNs). For example, Europe is second only to China, and on par with USA, in terms of the number of peer reviewed publications relating to the use of these techniques for agricultural applications in the last three years. **There is huge potential for the European public and private plant research and development (R&D) community to apply genome editing for the benefit of a sustainable European agriculture and society.**

Considering the rapid development and uptake of plant genome editing in the research and innovation community, it is important to set the future direction of research priorities and examine the synergistic interactions with closely related fields such as genomics, sequencing technology, phenomics, big data and systems biology. To foster responsible adoption of these techniques and to harness their potential, it is vital that relevant stakeholder, including the public, have access to information early on and opportunities to contribute to the discussions in order to shape the future of these technologies as per responsible innovation principles. In this way, future policy and regulation is more likely to meet the needs of stakeholders and society. However, few innovative plant gene technologies have been commercially developed in Europe due to uncertainties at the regulatory level and its related costs and whether the market will cover the costs of development, with most successful innovations being applied and potentially commercialised elsewhere. To close this gap between research, innovation and application and let the potential societal benefits of genome editing come to fruition in Europe and elsewhere, **it is vital that regulations of these new techniques and their resulting products facilitate application of these innovations, whilst providing citizens with assurances relating to safety and environmental impact.**

A coherent, inclusive and objective expert assessment of genome editing and its actual and potential application in plants is now required. This researcher-driven and multidisciplinary Action will bring together world-leading expertise from both within Europe and outside to identify the full innovation potential and societal impacts of plant genome editing and contribute to more efficient transfer from research to innovation and application. The Action will coordinate efforts to meet this challenge by identifying impacts, benefits and risks of plant genome editing on a

case by case (technique, product and species basis) as well as analysing and advising on appropriate regulatory mechanisms.

1.1.2. RELEVANCE AND TIMELINESS

Genome editing technology is being utilised in research and developed in a range of plant applications, and proceeding towards commercial application and use in some countries. The need for innovative and efficient approaches to plant production is great in relation to future food strategies and sustainable development goals. Sustainable agricultural pest and disease control, highly nutritious food supply, production of more vegetable protein sources, reduced land impact from livestock, conservation of fish stocks, and a supply of renewable industrial raw material all represent important consumer, public interest and societal pull factors for using novel technologies. It is therefore important that all aspects of plant genome editing are now comprehensively scrutinised through an independent and research-driven approach. This Action is timely and relevant as there is an inherent need to adapt and improve plant research and breeding techniques as an essential part of the response to rapid climate changes, population increase, affordability in relation to nutritional value, and public health issues. These challenges require a multidisciplinary approach combining various fields of expertise that are represented here.

It is important that the scientific state-of-the-art on these techniques is discussed with policy makers, risk assessors, researchers and funding agencies so that 1) the appropriate risk assessment procedures and levels are discussed, 2) informed decisions can be made, and 3) strategic priorities for research funding and innovation support are set. These challenges require a multidisciplinary approach combining various fields of expertise that are represented here.

The priorities for the EU framework programme for research and innovation (R&I) must reflect the societal challenges and the potential impacts of certain technologies. **The priorities for the next EU R&I framework programme, FP9, are currently being negotiated, and it is therefore timely to engage the scientific community to provide balanced and thoroughly researched input relating to plant genome editing. The deliverables from this Action can make valuable contributions.**

Genome editing and its application in plant research and breeding is currently high on the agenda of EU authorities and bodies. On 28 September 2017, the European Commission (EC) hosted the high-level conference Modern biotechnologies in agriculture – paving the way for responsible innovation, where multiple stakeholders discussed emerging techniques. The Scientific Advice Mechanism to the EC also delivered in April 2017 an explanatory note on New techniques in agricultural biotechnology, including a thorough description of genome editing, and in June 2016 a European Parliament (EP) report was adopted, calling for “open and transparent dialogue among all stakeholders and the public on the responsible development of high-precision, innovative solutions for breeding programmes, including on its risks and benefits; notes that this will require efforts to raise awareness and understanding of new techniques..”. A case on mutagenesis at the Court of Justice of the European Union (CJEU) may also deliver regulatory clarity to a subset of genome editing techniques later in 2018.

Regulatory authorities in EU member states, including Finland, Germany, Sweden and the UK have already unilaterally adopted interim positions on specific genome-edited plant events, triggered by requests from companies or public research groups. Some non-EU countries, such as Argentina and Brazil have adopted normative legislation on innovative techniques of precision breeding (including genome editing). The US have treated some genome-edited crops (such as CRISPR/Cas-modified waxy corn and oligonucleotide-directed mutagenesis (ODM)-modified herbicide-tolerant rapeseed) as conventionally bred crops. US Department of Agriculture (USDA), though only regulating on the basis of plant health/pathogens, also recently declared that they do not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques, while the Food and Drug Agency (FDA) and the Environmental Protection Agency (EPA) are currently doing a review of their respective regulations. The Norwegian Biotechnology Advisory Board (BAB) has also initiated a public discussion on the future regulation of gene technologies, and has presented a model for level-based approval system based on the type and extent of genetic change. Other criteria are also relevant, including altered traits, the intended use of the organism, the risk to health or the environment, sustainability, societal benefits and ethics. The Norwegian BAB will deliver a report before the end of 2018. In the context of international and intra-EU trade and for providing a stable and predictable market environment in which businesses can operate, it is essential that scientists and regulators from Europe

and beyond analyse the current regulatory framework for novel genome-edited crops first and then prepare a harmonized decision about the need to develop additional regulatory oversight.

1.2. OBJECTIVES

1.2.1. RESEARCH COORDINATION OBJECTIVES

This Action aims to establish an international consortium of scientists and other stakeholders in Europe and other relevant countries, to share knowledge of the national research programmes that involve plant genome editing for a mutually beneficial exchange of knowledge and experiences on plant genome editing and wider dissemination of results and novel ideas. This researcher-driven, multidisciplinary and multi-stakeholder Action will assemble, synthesize and disseminate available information on plant genome editing through organised Working Groups (WGs) with detailed distribution of tasks presented in section 3.1. The scope of this Action covers all plants, including research model plants, agri- and horticultural crops, aquatic plants (micro- and macro-algae) and trees. It will also cover applications ranging from food and feed, biomaterials, pharmaceutical products and bioenergy.

The most important Research Coordination Objective are to:

- Evaluate improvements required for future crop plants for sustainable agricultural production and improved consumer health in Europe and the technology requirements to achieve these improvements (WG1, WG2),
- Examine genome editing techniques, including their utility in various plant research and breeding applications as compared with conventional and other techniques as well as their actions in relation to naturally occurring genetic variation (WG1),
- Compare, and whenever possible integrate, the research needs and priorities for genome editing platforms with those of sequencing, genomics, phenomics, “big data” and systems biology platforms (WG1),
- Collect, where available, information on the potential socio-economic, environmental and human health impact of genome editing in plant breeding and commercial development (WG2),
- Evaluate existing regulatory frameworks in the EU and other relevant countries and their potential applicability for genome editing and provide future-oriented solutions if necessary (WG3),
- Contribute to the emerging intellectual property policy discussions related to genome editing techniques and their resulting products and assess their implications for the plant research and breeding sector and for farmers (WG3),
- Provide clarity in terminology and input towards workable definitions (WG1, WG3),
- Improve our understanding of the perceptions of various stakeholders of plant genome editing technologies and their applications and identify where input from key actors could be gathered according to responsible research and innovation principles (WG4).

As a major outcome; develop and deliver an integrative roadmap for future R&D priorities, strategic collaborations, investments and societal acceptance of genome editing applied in plant research and breeding (all WGs).

1.2.2. CAPACITY-BUILDING OBJECTIVES

The Action will aim to improve capacity building relating to plant genome editing and its scope for delivering innovative products for the benefit of citizens in Europe and beyond. The key capacity-building objectives and initiatives of this Action are to:

- Form novel research consortia, building further on existing national and/or international research programmes involving plant genome editing (all WGs) and promote sustainable interactions between industrial and public research, as well as policy makers, related to novel breeding techniques through Training Schools (TS), meetings, Short Term Scientific Missions (STSM) and round-table discussions,
- Encourage the participation of new Inclusiveness Target Countries (ITCs) and Near Neighbour Countries (NNCs) in Action activities,
- Promote gender equality and women leadership in this new field of research,

- Improve opportunities for interdisciplinary training and career development of Early Career Investigators (ECIs) through their involvement in organisation of Action activities and participation in training events (TS & STSM),
- Promote new ERASMUS agreements between partner universities,
- Disseminate knowledge obtained in the Action through interactive Massive Open Online Courses (MOOCs) targeting undergraduate and/or graduate students, video interviews and making information and/or education material available in several of the languages spoken within the EU (all WGs).
- Develop tools that enhance and improve understanding of innovation[1] with regard to plant genome editing technologies among citizens, policy makers and regulators. This will include constructing, where appropriate, new information tools and establishing links with existing publicly available tools (e.g. websites), as well as building a publicly available roster of experts listing each participant's specific core competence and serving as an easily accessible source of information (WG5).

1.3. PROGRESS BEYOND THE STATE-OF-THE-ART AND INNOVATION POTENTIAL

1.3.1. DESCRIPTION OF THE STATE-OF-THE-ART

The field of genome editing has exploded in the last few years, with several enzymatic and/or nucleic acid-based systems now available and optimised, and many more expected to be discovered. The central aim of the Action is to assess the full innovation potential and societal impacts of plant genome editing. Genome editing spans both directed mutagenesis and recombinant nucleic acid technology, homologous recombination-mediated precise knock-in of genes, gene conversion, and novel applications such as targeted crossovers during meiosis and modulation of the epigenome. A number of systems with reprogrammable site-directed nucleases (SDNs) that introduce double-strand breaks (DSBs) at preselected positions have been developed. Early but limited success has been achieved with protein-directed SDNs such as ZFNs, TALENs and meganucleases, but the field has expanded rapidly with the development of RNA-directed SDNs based on the bacterial CRISPR system and CRISPR-associated (Cas, Cpf1) nucleases. The advent of CRISPR-derived systems has facilitated access to plant genome editing by smaller laboratories all over the world. Also, unlike earlier technologies that focused first on model species and made the transition to more diverse plants later, SDNs have been applied to a wide range of crops from the very beginning.

Relevant to the development of genome editing technology is also the development of sequencing technology and a wide range of –omics, especially genomics, epigenomics and transcriptomics. The accumulation of sequence data coupled with drives to characterize selected parts of all our major crops provide plenty of opportunities for targeted approaches for trait management using genome editing. It is therefore important to assess common research priorities and develop joint strategies for future research and applications.

This rapid technical progress and wide uptake in research and breeding has spurred plenty of discussions regarding their impact on society and the way policy makers and regulators should approach these techniques and their resulting products. Earlier progress with recombinant nucleic acid technology and transgenesis led to the development of a specific subset of regulations on genetically modified organisms (GMOs) in the EU and many other countries, but the issue of whether these regulations are applicable also to genome editing, and under which conditions, is far from settled in most countries however with a few exceptions. Given the recent discussions on the regulatory handling of genome edited crops, it is likely the many of such crops do fall under other regulations such as the general food law or regulations concerning plant propagation materials. A current case at the European Court of Justice (ECJ), for which a ruling is expected by the summer of 2018, analyses, among other issues, whether organisms resulting from (new forms of) mutagenesis techniques should be subject to the GMO legislation or whether member states can set up additional regulatory oversight for plants resulting from mutagenesis. This ruling will most likely have important consequences for the policy and regulatory approaches in the EU to many, if not all, genome editing techniques and their applications.

[1] In the EU, the Innovation Principle means ensuring that whenever policy is developed, the impact on innovation is fully assessed. The principle should provide guidance to ensure that the choice, design and regulatory tools foster innovation, rather than hamper it (https://ec.europa.eu/epsc/publications/strategic-notes/towards-innovation-principle-endorsed-better-regulation_en).

Plants can be subject to patents according to Directive 98/44/EC. Plants (or animals) obtained by an essentially biological process are excluded from patentability though, while plant breeder´s rights may apply to all new varieties. In the context of the new breeding techniques aspects like the effect of IP on innovation, access to technology and biological material for further research and breeding and impacts for farmers are of concern. In this context also concepts of open innovation, the establishment of licensing platforms or compulsory licensing are of major interest.

Understanding of the perceptions relating to genome editing techniques among policy-makers, regulators, citizens and a wide range of stakeholder is limited, although if based on the limited information in the public domain and presented in mainstream media and on social media, they tend to be negative on gene technologies in general. This Action will respond to this timely challenge.

1.3.2. PROGRESS BEYOND THE STATE-OF-THE-ART

Genome editing and its application in plants has considerable potential, improving the ways we produce food, industrial raw materials and bioenergy for a sustainable and bio-based society and providing opportunities for novel value chains such as ornamental or pharmaceutical plants. **This Action represents a forward-looking approach combining experts from several disciplines and from various stakeholders to provide the research community, policy makers and the public with information about this rapidly growing field of bioscience.** As this Action will provide resources for numerous meetings, workshops and symposia, this will stimulate interactions and collaborations both within Europe and globally among research teams. These interactions will promote exchange of knowledge and experiences in an open and mutually beneficial manner and help set the direction for research projects.

The progress in genome editing technology is closely linked with progress in other technologies such as nucleic acid sequencing, phenotyping/ phenomics, "big data" handling and systems biology. The available genomes provide blueprints for controlled and directed genome editing and the resulting phenotypes can be more readily screened and evaluated, and systems biology (at an organism level) provide holistic approaches to integrate multiple platforms. This Action will help to coordinate international activities in genome editing with other linked technologies and so aim to optimise their utilisation. It will establish common research needs with the goal of increasing our knowledge of plants and delivering improved traits for innovative and sustainable production.

A synergistic value of this Action is also the joining of experts from various disciplines to develop a roadmap for future applications of this technology. It will also provide a valuable source of information for policy makers to inform the development of a proportional, appropriate and fit for the future regulatory framework to handle genome editing technologies and their derived products.

1.3.3. INNOVATION IN TACKLING THE CHALLENGE

The application of genome editing in plant research and breeding has the potential to benefit society while properly addressing the global challenges ahead. Genome editing should be used in line with both the Precautionary and Innovation Principles. However, accurate, independent and objective information and analysis relating to the potential benefits of the technology is currently in short supply. **This is to our knowledge the first COST Action that is specifically focusing on plant genome editing. It will study the science, development, application, biosafety and societal adoption of a wide range of these technologies.**

Although there is a considerable body of literature on individual research relating to specific techniques and/or applied in a specific plants, there are also important gaps. The role of science in the risk assessment of this technology needs to be better elucidated, the connections between various related technological platforms, including genetic and phenotypic data, need to be reinforced, and all relevant information should be made available to the public in an appropriate, non-technical format to promote scientifically sound perceptions of the technology.

The Action will tackle these challenges through the collaborative efforts of experts from a wide range of disciplines covering genetics, plant breeding, molecular biology, ecology, economics, law, social sciences and ethics. Their combined knowledge, expertise and analysis will provide a unique resource for decision makers tasked with developing appropriate regulation and for engagement with many stakeholder groups and the public through seminars, discussions, public debates and social media.

Online tools will be extensively used in this Action, besides the dedicated website showcasing its outputs such as events, research, practical applications and much more. Video interviews will be developed and promoted. In addition to social media channels targeted to different audiences, the development of MOOCs covering the topics of WG1-4 (see section 3.1.1) to inform and engage a large audience into the discussion.

1.4. ADDED VALUE OF NETWORKING

1.4.1. IN RELATION TO THE CHALLENGE

To address the key challenges presented in section 1.2, the Action will build a multidisciplinary, international consortium including teachers, researchers, companies and public officials in the areas of molecular biology and genetics, ecology, law, sociology, economics, ethics and communication, who will work synergistically to reach the Action objectives. Early career researchers will benefit from access to a wide range of expert contacts within this field, together with the opportunity to interact with and work in institutes and laboratories with different expertise. Stakeholders such as the commercial sector, the farming sector, policy makers and regulators, non-governmental organisations and the public, will benefit from facilitated access to a pool of knowledge. Accordingly, five main fields of competence are targeted in relation to the challenge:

Technical platforms (WG1): The Action will 1) map and assess the actual and potential output within existing technical platforms applying genome editing in plant research and plant breeding in both the European public as well as, whenever possible, private research and development (R&D) community, and 2) map and assess potential synergistic interactions with technical platforms related to sequencing technology and –omics technologies.

Impact assessment (WG2): The Action will map the current and potential near-future impact on plant R&D, in terms of 1) utility of this technology and novel opportunities for discoveries, elucidation of pathways, and global cellular knowledge, 2) utility as a facilitator for trait management in breeding, and 3) identify and evaluate the data requirements for rigorous socio-economic, environmental and health impacts.

Regulation and policies (WG3): The Action will 1) evaluate the applicability of the existing wider EU regulatory frameworks and policies for plant-based production and consumer information on genome editing techniques and their resulting products, and 2) evaluate and compare the regulatory approaches to genome editing in the EU and all other relevant countries.

Perceptions and opinions (WG4): The Action will collect and analyse surveys performed among various stakeholder groups as well as the public in many EU and non-EU countries, in order to assess the perceived potential, risks, knowledge about, and attitudes to the application of genome editing in plant breeding. The Action will also facilitate an improved understanding widely of genome editing and its use in research and breeding, taking advantage of the wide international coverage of the network of participants.

Integration and communication (WG5): The Action will integrate all data provided in WG1-4 and develop a number of communication tools and initiatives to reach all relevant stakeholders including the public, as well as facilitate widely the access to accumulated knowledge and experience.

1.4.2. IN RELATION TO EXISTING EFFORTS AT EUROPEAN AND/OR INTERNATIONAL LEVEL

As most of the participants in this Action are involved in national and/or international research activities including plant genome editing, the Action will promote a number of synergistic interactions among these activities, not only within Europe but also with other countries. Many national and international projects and initiatives have already been launched to address certain aspects of genome editing. International organisations, such as the European Plant Science Organisation (EPSO), the Public Research and Regulations Initiative (PRRI), and the Global Plant Council (GPC) regularly provide information and advice on these technologies that is made available to policy makers and arrange public outreach activities. Collaborative research projects in several of the countries represented in this Action have also contributed. However, these initiatives have, to date, been limited in scope. This Action offers a comprehensive plan to tackle the important challenges relating to plant genome editing and aims for substantial and international impact on the setting of research priorities and optimisation of resource utilisation.

Recently, a “cooperative governance network” model was proposed by a team of scientists in the USA for conducting genome editing technology research under a framework of acceptable sustainability criteria and institutional capacity for adaptive governance and enforcement. This type of model has been successfully implemented in a number of cases and appears to be compatible with the Responsible Research and Innovation (RRI) concept developed in the EU. This Action will explore the potential of a cooperative governance network and develop a set of recommendations for plant genome editing, not least by including the experience from projects carried out by participants from International Partner Countries (IPC). The Action will also take inspiration from the recently launched initiative Association for Responsible Research and Innovation in Genome Editing (ARRIGE). The aim of ARRIGE is to provide a comprehensive setting for all stakeholders to allow the development of genome editing for human and animal research in a safe and socially acceptable environment. Though the scope of ARRIGE is different from this Action (which focuses on plants), there is potential for synergistic interactions between the two initiatives. Also the ORION EU project that puts RRI into practice for open science will be liaised with to benefit from best practice and make efficient use of EU research.

2. IMPACT

2.1. EXPECTED IMPACT

2.1.1. SHORT-TERM AND LONG-TERM SCIENTIFIC, TECHNOLOGICAL, AND/OR SOCIOECONOMIC IMPACTS

The short-term impact of this Action is to create a sustainable, international, multidisciplinary and intersectoral collaboration between communities working on different aspects of plant genome editing. The Action will improve the scientific knowledge base for researchers on plant genome editing by providing networking opportunities, sharing of information and experiences and stimulating novel research ideas. This will in turn enable new collaborative research programmes and initiatives to be developed at national and EU levels, targeting areas of bio-economy, environmental and human health, utility of sequence data, and technology optimisation. Connecting researchers with plant breeders will promote faster transmission of research results into practical applications including plant genome editing, provided that a more proportionate and adaptive regulatory system is simultaneously developed. A crucial factor here is that the Action will develop a platform for dissemination and outreach activities, which will raise the awareness and knowledge level among stakeholders, policy makers and the public in order to gain acceptance for sound applications of these technologies. The plant breeding industry is currently hesitating to make investments in genome editing-based breeding in the EU due to the lack of legal certainty for many of these techniques. As a short-term impact, the Action will strengthen the necessary trust into a fact-based and innovative regulation based on excellent scientific research that fulfils the needs of all stakeholders.

2.1.2. LONG-TERM SCIENTIFIC, TECHNOLOGICAL, AND/OR SOCIOECONOMIC IMPACTS

A first long term effect of this Action will be the maintenance of competitiveness of scientific research and plant breeding industry R&D activities in the EU since no more unnecessary delays in development of products are expected to occur. For GM plants, several companies have already moved much of their R&D activities to other parts of the world for the same reasons. A risk- and innovation-based interpretation of the legal framework that is *de facto* and *de jure* fit for purpose and provides predictability and certainty for plant breeders is likely to have important positive innovation and economic impacts in Europe and beyond, for which this Action can provide important inputs.

A second long-term impact of the Action will be enhanced and sustainable communication with the public and other stakeholders to promote an improved understanding of the benefits and risks of the technology aiming at improving acceptance of the products derived from the technology. This will be facilitated by establishing a number of dedicated tools such as a website, social media, educative material including fact sheets, video interviews and other items that are easily disseminated to a large audience. In the longer term the knowledge and novel initiatives generated by this Action will aim to impact on basic plant research, applied research and pre-breeding, crop production and quality, food security and food quality, as well as on sustainable practices for plant-based production in agriculture and other systems.

2.2. MEASURES TO MAXIMISE IMPACT

2.2.1. PLAN FOR INVOLVING THE MOST RELEVANT STAKEHOLDERS

The consortium directly brings together relevant stakeholders including research institutes, universities, business/ enterprise partners, and public officials. There are many stakeholders affected by the progress and outcome of this Action. This Action has a wide international dimension that meets the Inclusiveness Policy of COST and extends beyond Europe.

The scientific community: Many of the participants in this Action are scientific leaders in their field and have large networks of colleagues, ensuring that the progress of the activities in the Action will be well anchored within the wider scientific community as well as enabling the outcomes to be widely distributed and discussed.

Local, national and EU-level policy makers, national Competent Authorities: This Action will address many issues relevant to national and EU-level policy makers dealing with potential regulations of genome editing. Many of the participants of this Action have experience in policy development and in consultations with relevant national Ministries and Competent Authorities. The experiences and contact network gained over the years will equip the Action with opportunities to fulfill one of the goals of COST which is to provide input to policy makers and regulatory bodies via a two-way communication strategy.

The commercial plant breeding sector: The economic potential of genome editing techniques is high to the commercial seed sector, including small and medium-sized enterprises (SMEs). The inclusion of industry representatives in this Action will ensure that these perspectives are taken into account.

The agricultural and food sector: Directly affected by the outcome of this Action, the farming sector will be actively engaged through contact with local/national and European farmer, trader and food industry organizations.

Civil society: Genome editing technologies and their potential impact on plant research, breeding and innovation have far-reaching implications for society; therefore it is important to involve the public when developing the activities of this Action. Online surveys targeting specific groups will be designed to obtain the opinions of the public, including consumer organizations and other stakeholders, obtaining data that is not hitherto captured by the Eurobarometer. Social media will be developed for a two-way open communication, and much of the information and dissemination material produced will target the general audience and be written in a laymen style. Public engagement will be measured through metrics such as views on and downloads from the website, social media and published video interviews.

Non-governmental organizations (NGOs): Several NGOs have expressed concern about certain novel gene technologies for research and breeding, as well as a willingness to participate in the discussions on the future strategies including their governance. It is therefore important to establish and maintain a transparent and efficient two-way communication, and relevant NGOs will for this purpose be invited to meetings and workshops.

International scientific organisations: Many relevant international organisations are participating in this Action. In addition many of the participating researchers have contact with other organisations such as the Food and Agriculture Organization (FAO), Consultative Group of International Agricultural Research (CGIAR), European Food Safety Authority (EFSA), Global Plant Council (GPC), Public Research and Regulations Initiative (PRRI), European Plant Science Organisation (EPSO), European Molecular Biology Organisation (EMBO) and EuropaBio. There will be many opportunities for joint workshops and conferences, as well as potential for communication and exchange about the objectives and outcome of the Action.

2.2.2. DISSEMINATION AND/OR EXPLOITATION PLAN

The results from the Action will be distributed widely through open-access scientific publications, books/book chapters, popularized summaries in press and media, presentations at workshops and conferences, social media and published video interviews. The target audience includes researchers, students, biotech and plant breeding companies, small and medium-sized biotech enterprises (SMEs), national and international research funding agencies and policy makers, as well as the wider public.

The dissemination plan includes:

1. Setting up a dedicated website as the main platform for dissemination activities and material. All results and output, including publications and video interviews, will be made available on this website and via relevant social media platforms. Several of the research programmes associated with this Action also have active webpages and newsletters (in English and various other languages). These programmes have already indicated a willingness to help in the dissemination of the outcomes from this Action.

2. Linking meetings and workshops, whenever possible, to other major conferences on topics related to plant genome editing, such as those organized by FESPB/EPSO, PRRI, GPC, SEB, EFSA, ISBGMO, EUCARPIA, EurSafe, IPMB and FAO. This will also be an opportunity for the Action participants to further promote the activities of the Action.

3. Developing learning materials of various levels of understanding. Higher level students will be targeted through the organization of MOOCs on specific topics linked to the Action WGs, and will be regularly offered. The wider, public audience will be approached through popular science fact sheets as well as participation in public events and via media.

2.3. POTENTIAL FOR INNOVATION VERSUS RISK LEVEL

2.3.1. POTENTIAL FOR SCIENTIFIC, TECHNOLOGICAL AND/OR SOCIOECONOMIC INNOVATION BREAKTHROUGHS

The conditions for plant research and breeding have changed continuously and dramatically over the past two decades with the introduction of new technologies such as genome editing. These technologies have great potential to move beyond the state-of-the-art and enable novel biological questions to be inquired, improved traits to be developed, and may provide tools for progressing towards bio-based economies in Europe and beyond. **This Action will bring together many of the key actors involved in researching and developing these technologies, which will enhance the likelihood of both scientific innovation and new breakthroughs.**

Plant research groups and commercial entities all over the world have adopted genome editing at an unprecedented rate and it is a matter of time before we will see a multitude of products on the market. It is therefore not surprising that the regulatory issues of these technologies are currently high up on the agenda of many national and international authorities, including in the EU. In this process, it is crucial to aim for **scientifically sound conclusions and developments**. This is one area where this Action will play an important role. The concerted efforts of the experts from various fields that come together in this Action give the best possible chance to elucidate the opportunities and drawbacks of plant genome editing in regard to scientific, political, economic, environmental and social aspects.

A potential risk factor for the progress and applications of genome-edited plant products is that a high level of **public acceptance is not to be taken for granted**. A parallel can here be made to the way genetically modified organisms, GMOs, and their derived products have been received over the past two decades. Certain genome editing techniques involve transgenics and their resulting organisms and their derived products are thus regulated as GMOs. This may have consequences for public and stakeholder acceptance of the entire category of genome editing, some of which does not involve transgenics. Many of the participants of this Action have considerable experience of science communication and outreach activities including those related to GMOs. Important lessons have been learned from these activities and it is hoped that this will contribute to improved dissemination of sound science and informative, accurate and objective information about genome editing technology.

There is concern that public and private funding of R&D and the application of these useful technologies will suffer if there is public and/or stakeholder antagonism towards plant genome editing. This Action will identify the **actual and potential impacts of these technologies on bio-economy, the environment, sustainable agriculture and food safety and quality, and follow up by increasing the awareness of the importance of R&D investments through communication with national and EU funding agencies and authorities.**

3. IMPLEMENTATION

3.1. DESCRIPTION OF THE WORK PLAN

3.1.1. DESCRIPTION OF WORKING GROUPS

The activities of this Action will be carried out within five Working Groups (WGs), each with the main responsibility for particular tasks of the Action. Participants will join the WGs according to their specific field of expertise, although it is expected that there will be opportunities for cross-WG and cross-disciplinary interactions and collaborations. This is a strength of the large network included in the Action. Here follows a brief description of the WGs:

WG1. Technical platforms

Objectives:

- WG1 will map and assess the actual and potential output within existing technical platforms applying genome editing in plant research and plant breeding in the European public sector research and development (R&D) community. Where possible, and dependent of data availability, this will be extended to include the private R&D community and research programmes in third countries (e.g. USA and China) as well. This will provide background information to discuss and design common research agendas and priorities.
- WG1 will analyse the relations between technical platforms for genome editing and other interlinked technical platforms (see 1.3.2) to evaluate if synergy may be achieved by coordinating their respective strategic research priorities.
- WG1 will examine how to set common research priorities and enhance the joint development of mutually beneficial collaborations between genome editing technologies.
- WG1 will compare genome editing to other plant breeding techniques, such as randomly induced mutagenesis and transgenesis by random insertion, from various perspectives such as efficiency and impact on breeding programmes, ease of use and potential for trait management, relation to natural genetic variation etc.

Deliverables:

1. An online atlas, regularly updated, covering existing genome editing technical platforms in Europe and elsewhere and their applications in plant research and breeding;
2. Identification of gaps and needs for further research in plant genome editing and presentation of conclusions in a peer-reviewed publication;
3. An online report on mutually beneficial collaborations with other interlinked technical platforms and their common research priorities along with a peer-reviewed publication;
4. An interactive, web-based platform for discussing future research needs and priorities;
5. Publicly available guidelines on terminology along with a peer-reviewed publication;
6. A dedicated MOOC.

WG2. Impact assessment (research, breeding, socio-economic, environmental, health)

Objectives:

- WG2 will map and assess the current and potential near-future impact on plant research, in terms of utility of this technology and novel opportunities for discoveries, elucidation of pathways, and global cellular knowledge. For this, exchange and collaboration particularly with WG1 is essential.
- WG2 will map the extent to which commercial breeding applications using genome editing tools are being developed world-wide.
- WG2 will evaluate/assess the extent to which genome editing tools have had an impact on plant breeding in terms of facilitated trait management, efficiency and speed.
- Socio-economic, environmental and health impacts will be considered in relation to whether there are specific data gaps and data requirements for the evaluation of the applications and products of genome editing.
- Strategies for the communication of the results of biosafety and socio-economic information to stakeholders and consumers will be developed.

Deliverables:

1. Report on the impact of genome editing on plant research based on surveys carried out among the international plant research community; a peer-reviewed publication;
2. Report on the applications of genome editing in plant research and breeding based on collecting and analyzing all available peer-reviewed and grey literature; (a) peer-reviewed publication(s);
3. An online report, to be updated regularly, listing public and private research applications that are already commercialized or in the pipeline for commercialization;
4. A report on data gaps and requirements for socio-economic, environmental and health impacts of plant genome editing applications;
5. A communication strategy for the biosafety and socio-economic information to stakeholders and consumers;
6. A dedicated MOOC.

WG3. Regulations and policies

Objectives:

- WG3 will evaluate the applicability of the existing wider EU regulatory frameworks (such as the EU Food Law or Variety Registration) and policies for plant-based production and consumer information on genome editing techniques and their resulting products. For this overall purpose, input from all the other WGs is essential.
- WG3 will scrutinize policies for labelling, post-market monitoring, and general enforceability of potential regulatory details in relation to genome editing, with input specifically from WG1.
- WG3 will assess perspectives from regulatory frameworks in other countries and regions and compare them with the EU situation, taking full advantage of the inclusion of participants from International Partner Countries (IPC) in this Action, as this will have an important impact on our future competitiveness of EU research, breeding and agriculture as well as international trade and food security.
- A survey of existing or planned registers hosted by regulatory authorities will provide useful information regarding international developments and trade impacts.
- WG3 will monitor the development within the intellectual property landscape of these techniques and their derived products and provide easily accessible information on this topic for the R&D community.

Deliverables:

1. Peer-reviewed publications discussing various regulatory aspects of plant genome editing;
2. Report on how other countries and regions develop their legislation on genome editing and make comparisons with the situation in the EU;
3. Workshop-, publication-, and discussion- outcomes communicated to and between Regulatory Authorities and relevant policy makers at a national and EU level;
4. A report on regulatory approaches to genome editing and recommendations for harmonization and integration of EU regulations with those in other countries;
5. Up-to-date publicly available database on the IP context for all relevant genome editing systems;
6. A dedicated MOOC.

WG4. Perceptions and opinions

Objectives:

- WG4 will collect and analyze surveys performed among various stakeholder groups as well as the public in a number of EU and non-EU countries, in order to assess the perceived potential, risk, knowledge about, and attitudes to the application of genome editing in plant breeding.
- Closely linked with the other WGs, WG4 will address these issues taking full advantage of the multidisciplinary structure of the participating experts.

Deliverables:

1. Reviews on the collected material/surveys on perceptions of genome editing, and/or whenever relevant similar technologies for comparison; (a) publication(s);

2. Multidisciplinary analyses, published in peer-reviewed literature, on the scientific-ethical consequences of our increased capacity for control over the genetic material and its corresponding traits; (a) publication(s);
3. Development of a publicly available body of literature, including layman-style popularized material, to promote public learning;
4. A dedicated MOOC.

WG5. Data integration and communication

Objectives:

- WG5 will establish efficient two-way/ multiple-way communication as well as wide distribution of our findings. The results will be widely distributed to a broader range of EU and national policy makers and Competent Authorities, EU policy makers and authorities, and also main contact points in other countries outside of the EU.
- Results will also be used to produce a number of fact sheets on plant breeding, breeding techniques, biosafety assessment, EU and other legislation on plant breeding techniques, written in a laymen style and published on the website.
- WG5 will set up a dedicated website that will be the main instrument for sharing the results and linking to social media.
- WG5 will actively work on public engagement early on through social media.
- WG5 will prepare and organize meetings with representatives of EU-level and national governmental bodies and competent authorities. These would aim to occur regularly during the course of the Action, to provide input based on the results of the Action and to facilitate two-way communication and follow up on any potential policy change.
- WG5 will be responsible for the production and launch of a number of video interviews on specific topics and in connection with the synthesis workshops, as part of the outreach activities. This is unique in a COST Action context and has high potential for reaching a large audience.
- WG5 will coordinate engagement of students through the development of MOOCs, one from each of the WGs 1-4.
- WG5 will work on integration of the results from all the other WGs to design a Roadmap for the future potential inclusion and impact of genome editing technical platforms in European plant research and breeding. This Roadmap will help designing future R&D priorities as well as facilitate and stimulate cross-national and cross-disciplinary collaborations within the area of plant genome editing. WG5 will assemble and synthesize output from the other WGs, as well as engage in two-way communication with all stakeholders listed in section 2.2.1. and use this to develop the Roadmap.

Deliverables:

1. A dedicated website targeting a high number of visitors, and a strategically selected and well-resourced number of social media (Twitter, Facebook, YouTube, LinkedIn) interactions;
2. A large set of fact sheets on plant genome editing available for public, wide dissemination including to primary and secondary schools;
3. A series (at least ten) of video interviews from all WGs (1-4), published via the website as well as via a public channel such as YouTube;
4. Assist the other WGs to develop a series of MOOCs on the specific WG topics;
5. By the end of the Action, an extensive and integrative R&D Roadmap for plant genome editing, disseminated widely to all stakeholders but in particular to relevant national and EU-level risk assessors, risk managers and funding agencies.

Overall milestones:

Year 1: Start of the Action. First meeting of the MC. Recruitment of Action and WG Leaders and Vice-Leaders. First joint meeting for all of the WGs – kick-off meeting.
Year 2: Meeting of the MC and separate WGs to plan collaborative actions. Parallel meetings of the WGs and of the MC.
Year 3: Meeting of MC and separate WGs to evaluate progress and plan further collaborative actions. Meeting of MC and separate WGs to evaluate activities.
Year 4: Final evaluation meeting on with invited speakers and presentation of the Action results and MOOCs prepared.

Meetings

The Management Committee (MC), composed of one or two representatives of each COST Member Country participating in this Action, will meet once per year to summarise the achievements reached so far and, if necessary, adjust the Work Plan for the coming year.

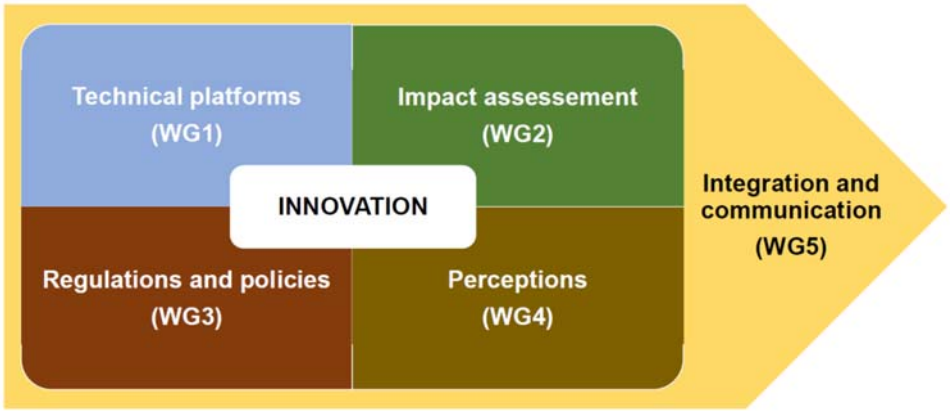
Two types of workshops will be organized, both which will emphasize active participation rather than passive listening. Training Schools will focus on internal work within the Action, with invited selected experts on particular topics, and may be organized if possible as satellite meetings to other conferences or relevant meetings. Synthesis workshops will target a wider audience and multiple stakeholders, providing an update on the progress within a particular field and discuss major outlines for further progress. In the final year, an international open conference with all stakeholders and Action participants will audit all perspectives of plant genome editing and deliver contributions to a future integrative roadmap.

3.1.2. GANTT DIAGRAM

GANTT diagram with milestones for each WG indicated.

	Year 1				Year 2				Year 3				Year 4			
	q1	q2	q3	q4	q1	q2	q3	q4	q1	q2	q3	q4	q1	q2	q3	q4
WG1. Technical platforms																
Meetings; training workshops																
Gaps and needs in research identified, review article submitted																
Online library of current plant genome editing research																
Data exchange completed, new collaborations established																
Recommendations on future directions and legislative actions																
Synthesis workshop																
Training through MOOC																
WG2. Impact assessment																
Meetings; training workshops																
Impact on plant research assessed, review article submitted																
Impact on plant breeding assessed, review article submitted																
Requirements for socio-economic, environmental and health impacts assessed, report finished																
Synthesis workshop																
Training through MOOC																
WG3. Regulations and policies																
Meetings; training workshops																
Review articles on regulatory aspects of plant genome editing																
Comparative report on genome editing legislation in EU and non-EU countries																
Online reporting on intellectual property landscape in relation to genome editing																
Communication of outcomes to policy makers																
Synthesis workshop																
Training through MOOC																
WG4. Perceptions and opinions																
Meetings; training workshops																
Review on existing data on perceptions of plant gene technologies																
Surveys on perceptions of plant genome editing; articles submitted																
Article on scientific-ethical consequences of plant genome editing																
Compilation of relevant literature completed																
Synthesis workshop																
Training through MOOC																
WG5. Data integration and communication																
Website established																
Fact sheet compilation and dissemination																
Production of video interviews; dissemination																
Establishment of MOOCs in cooperation with all WGs																
Publication and dissemination of Roadmap on plant genome editing																
Conference: Integrative Roadmap for plant genome editing																

3.1.3. PERT CHART (OPTIONAL)



3.1.4. RISK AND CONTINGENCY PLANS

RISK	CONTINGENCY MEASURES
Limited outreach of the Action	70 researchers from 24 countries participate in the Action thus guaranteeing high impact of the Action.
Limited access to information about plant genome editing from the private commercial sector, particularly in relation to the activities in WG2	The Action already involves partners from private seed companies. The cooperation will be offered to more partners from the private sector.
Failure to demonstrate that the information provided is credible and objective	All dissemination material will be based on scientific evidence and where new data will be gathered these will be collected, analysed and presented on the basis of scientific rigour and best practice for each of the disciplines involved in the Action. All participants are qualified professionals in their field. Action participants are highly experienced and able to handle situations of this sort that may appear.
Slow exchange of data between the participants leading to databases that are not complete or up-to-date	Collection of each data set will be assigned to one person, who will collect data from all the participants and send updated files back to them. Internet tools, such as clouds, will be used to facilitate data exchange and their safe storage.
Uncertainty regarding the future regulatory situation for genome editing in the EU and many other countries	The Action will follow closely the regulatory and political development on this issue, in order to adjust the work accordingly. The Action is well prepared for this, with many participants having followed closely, and been involved with, the political development in the EU for many years.

3.2. MANAGEMENT STRUCTURES AND PROCEDURES

The activities of this Action are organised within five Working Groups (WGs). They vary in time span and intensity and will therefore involve a varying number of participants. Each WG will have a Leader and an Executive Management team, organized according to the COST rules, responsible for implementing the activities and/or delegating the work among the WG members. The WG members including Leader and Executive Management team may be elected at the annual meetings of the Management Committee, in a dynamic structure that allows for yearly reorganisation depending on work load of each WG and expansion of the Action. This will help reaching the milestones of each WG. A Steering Committee (SC) consisting of the Chair, Vice Chair, WG Leaders will be established, that will monitor the overall progress and develop and revise the overall vision of the Action. Each WG has a set of activities, which will formally be adopted at the first MC meeting (kick-off). However, the annual MC meetings allows for a dynamic structure also when it comes to specific activities in a WG.

3.3. NETWORK AS A WHOLE

The Action will bring together researchers and experts from various scientific disciplines, lawyers, plant breeders, organization representatives and other stakeholders from most European and many other countries. This Action contains many of the world-leading experts on biosafety assessment, biotech policy development, and the technical aspects of plant genome editing as well as application in the public and private sector. The network covers many disciplines that are highly relevant for the topic, including natural sciences, applied ethics, environmental philosophy, environmental, public and commercial law, and agricultural economics. This is one of the great strengths with the network, enabling us to cover all necessary aspects of this potentially transformative technology. The Action will also be open to newcomers to join the Action whenever relevant, and also to participate in workshops and in other ways take part in the work.

Given the current diverging political context among the European countries, it is a strength of this network to include representatives from 20 COST countries. This will enable the Action to have a two-way communication with policy makers and competent authorities of these countries. The Action also meets the Inclusiveness Policy of COST as it extends to several of the ITC countries. Similarly, it is beneficial to include participants from Near-Neighbour Countries (NNC) as well as International Partner Countries (IPC). Some of these countries have already deregulated some genome-edited plants, thus have experience with commercialization, marketing, consumer responses etc., and some countries also have legislative frameworks for plant research and breeding techniques that may in certain aspects differ from the EU and other COST countries, particularly for the risk management processes, All of this will provide the Action with further valuable perspectives.