Final Report

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PreSto GMO-ERA-Net lays the groundwork for transnational research on health, environmental and techno-economic impacts of GMOs. The project engages stakeholders throughout all stages of the project to ensure that future research in this area will also be highly relevant and meaningful from a broader societal perspective

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"Preparatory steps towards a GMO research ERA-Net" (PreSto GMO ERA-Net) is a Coordination and Support Action Project of the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities.

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1 Final publishable summary

1.1 Executive Summary

The objective of the PreSto GMO ERA-Net project was to clearly map out the steps needed to create and successfully implement an ERA-Net that will coordinate transnational research on the effects of genetically modified organisms (GMOs) in the areas of human and animal health, the environment, and techno- economics and societies. The varied effects of GMOs could be described, when compared to the status quo, as being negative (i.e. risks are identified and outweigh the potential benefits), neutral/benign, or positive (i.e. benefits are identified which outweigh potential risks). Therefore, research on both risks and benefits was taken into account when developing the future research agenda for the ERA-Net. Putative techno- and socio-economic impacts were factored into the emerging research agenda as part of a comparative approach. Here, techno-economics are defined as a subset of socio-economics with the former focusing on scientific/technological aspects and dimensions, and the latter being broader in scope, looking also at the social fabric of societies and relationships between actors.

PreSto GMO ERA-Net:

- Performed a stock-taking exercise of research performed at national level in the Member States of the European Union and Associated countries, at EU level and internationally.
- Scanned the horizon to identify emerging GMO developments and applications that might reach the regulatory pipeline within the course of the next 10 years.
- Identified research gaps and needs and ranked these based on stakeholders views employing a Delphi survey and a Multi-Criteria-Decision-Analysis model.
- Prepared a Strategic Implementation Plan (SIP) for the ERA-Net, based on the results from the diverse evidence streams and the experiences within other ERA-Nets and nationally funded GMO research programmes and project.

The proposed focus of the ERA-Net will be on GMOs intentionally released into the environment and/or used immediately in feed and food applications and covers environmental, health and socio-economic topics in an inter-disciplinary way, looking at both benefits and risks of GMOs. The ERA-Net should take into account the wider views of a diversity of stakeholders and end-users (e.g. non-governmental organizations, industry, farmers). This will strengthen ownership of the ERA-Net among stakeholders in order to encourage participation of different scientific communities in the future joint transnational calls, to enhance collaboration between actors and to increase the accountability of research trajectories and outcomes.

It is now up to funders from Member States and Associated Countries to assess the usefulness of the SIP and to implement an ERA-Net based on their views, expectations, needs and motivations.

1.2 Summary description of the project context and the main objectives

Progress in science and technology has led to a number of different techniques for the genetic modification of organisms, with different areas of use and varying levels of public acceptance.

GM micro-organisms are used in fermentation processes in confined systems for many different purposes and are the mainstay of industrial biotechnology. Products cover almost every domain of day-to-day life. The use of GM micro-organisms (in industrial "white" or in medical "red" biotechnology) has large realised benefits, has received support from users and appears to be widely accepted by the general public.

Genetic modification can also be used for creating GM plants and animals. Globally, genetically modified plants have been grown on a record 181.5 million hectares in 2014, with an expansion of acreage of 6.3 million hectares from the 175.2 million hectares cultivated in 2013. Since the first introduction of GM crop plants into the marketplace in 1996, the acreage planted has increased every single year, and 28 countries now cultivate these crops mainly in the Americas, Asia and Australia. A bulk of other GM plants with a large variety of traits is being developed by industry and public research institutions all over the world, including a large number of developing countries. Other current developments in genetic modification encompass the release of GM insects to combat vectors of human diseases or to control agricultural pests. GM animals are also developed and tested for a variety of uses, as are GM microorganisms for non-contained use. This means that in up to 10 years' time a large number of different GMOs will potentially reach the regulatory pipeline in the EU (at least for food and feed applications). Indicative numbers point to almost a hundred new GM plants including tree species, 5 five to 10 new commercial GM animals along with eight8 commercial GM arthropods, and a handful of new GM microorganisms including viruses. These developments make it necessary to obtain knowledge and data on the potential impacts of these organisms.

Despite this expansion of the use of GMOs in other world areas, governments in Europe have taken a very precautionary stance on placing GMOs on the market or more precisely on their cultivation in Europe. The EFSA register lists a total of 59 GMOs, mostly plants, which are placed on the market in the EU, predominantly for feed and food uses. Another 29 are listed as pending for feed and food, with many more in various stages of the authorisation process. The EU is heavily dependent upon the import of agricultural products from all over the world, especially soya and derived products as feed for the European livestock sector, but also cotton. Soya and cotton in worldwide production are predominantly GMO, with global levels of adoption of over 80% and 70%, respectively. This stands in contrast to only one GM plant event (Bt-maize MON810) approved for cultivation and the fact that 19 Member States have "opted-out", making use of the possibility to restrict the geographical scope of GMO applications/authorisations.[1]

This hesitation to cultivate GMOs in Europe despite a plethora of research on the risks of GMOs and many other issues (e.g. containment, confinement, technology development) funded over the course of the last 20 years, by the European Union and national institutions has a number of reasons and despite considerable

[1] http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.htm

experiences gained internationally on health, environmental, techno- and socio-economic impacts of the use of GMOs under various conditions. Yet, existing research and experience seem to support the notion that currently cultivated GM crops do not pose unique risks beyond those of conventionally bred plants, and that risks arising from specific traits can be reasonably managed with appropriate measures.

Despite the diverging views of the Member States, a joint ERA-Net on GMO impact research will have great relevance for Europe and will be of benefit for all countries involved. Research performed under such an ERA-Net could aid the European Food Safety Authority (EFSA) and the Joint Research Centre (JRC) in their activities *vis-á-vis* assessments of risks and of socio-economic impacts, respectively. It could increase communication and stakeholder involvement, bringing together the different actors and helping to regain trust between them. The challenge of dealing with all the issues surrounding GMOs and their use is greater than any single Member State could face on its own, making collaboration necessary. However, the way in which the Member States will be ready to work together and the focus of the research need to be discussed by the funders interested in this area. The PreSto GMO ERA-Net project set out to facilitate this discussion, by developing a Strategic Implementation Plan for an ERA-Net, based on various evidence gathering activities.

The objectives of PreSto GMO ERA-Net were four-fold:

First, to start gathering evidence for a comprehensive overview of research in the area of GMO effects at Member States level and internationally, by mapping existing research activities and knowledge regarding the health, environmental and techno-economic effects of GMOs in Europe; to identify and scan emerging applications of GMOs and to ascertain the development of GM technologies worldwide, to identify possible applications, the benefits and effects in an EU context and to subsequently derive potential research needs for the EU on these effects; to start constructing a framework for prioritizing research needs and evidence-based policy requirements that will provide the basis for the research strategy that the ERA-Net will ultimately implement.

Second, to ensure a smooth operation of the PreSto GMO ERA-Net project and a targeted preparation of ERA-Net by networking of national programmes, identifying project management organizations and funding bodies either already active in the field of GMO effects research (on the basis of outputs from the project itself and of the Standing Committee on Agricultural Research Collaborative Working Group “GMO RISK”) or interested to become active; developing a stakeholder involvement policy which will guide the fine-tuning and conduct of all involvement tasks in PreSto GMO ERA-Net and will serve as a reference for evaluating the involvement; designing and implementing a communication strategy including guidelines for communication to relevant stakeholders; establishing an efficient and powerful overall legal, ethical, financial and administrative management structure and an effective and stringent communication between PreSto ERA-Net partners, stakeholders, the EFSA, the JRC and the European Commission.

Third, to collate the information gathered in the stock-taking and horizon scanning activities, to identify future research needs and trajectories from it and to prioritize these based on a broad stakeholder consultation. Results from the stock-taking and horizon scanning activities were brought together, further refined and then used in a

Delphi survey and prioritized by stakeholders. The latter process also yielded a Multi-Criteria-Decision-Analysis-Model to help identify key criteria on which stakeholders base their prioritization.

Fourth, to gather commitments and pool resources for implementing an ERA-Net for research on the effects of GMOs. This was started among the core group of ministries, funding bodies, programme owners and managers, within the PreSto GMO ERA-Net consortium and the Funders Network established by the project. Funding bodies and ministries in Member States and Associated Countries were furthermore informed via the Standing Committee on Agricultural Research (SCAR).

The experiences of the individual funding organisations and the shared lessons learnt from the NETWATCH/ERA-LEARN assessments served as the foundation for good practice principles of implementation for an ERA-Net dedicated to high quality research on the effects of GMOs. These were amended by a strategy for stakeholder involvement for an ERA-Net. The overarching objective of the project was the drafting of a Strategic Implementation Plan (SIP) for an ERA-Net on GMO impact research, based on all activities with the PreSto GMO ERA-Net project.

1.3 Description of the main results

Data on research already performed or currently ongoing, on GMO developments to be anticipated in the near to medium future, as well as stakeholders' views were gathered in the Work Packages WP1, WP2 and WP3.

In WP1, stock was taken on research performed in EU Member States, Associated Countries and internationally on the impacts of GMOs. This was based on the activities of the Collaborative Working Group (CWG) "GMO RISK" of the Standing Committee on Agricultural Research (SCAR) but went beyond what had previously been accomplished. Further data were gathered via literature survey and the all data were analysed and structured to get a clearer picture of the research already performed, key themes and institutions within Europe.

In WP2, the literature as well as application databases worldwide where screened for currently developed GMOs and emerging applications. Additionally, experts were interviewed and expert-elicitation workshops were organized to develop a GMO development pipeline All information were gathered into a horizon-scanning report that draws a coherent picture of the GM applications likely to appear on the market in the next 10 years and their potential effects on health, environment and techno-economic issues.

In WP3, the emerging knowledge gaps and research topics were collated, further refined and then prioritized taking into account stakeholders views via a Delphi survey and through the development of a Multi-Criteria-Decision-Analysis-Model.

These activities and their results are described in the following deliverables:

- D1.3 Report on the analysed database
- D1.4 Report on the workshop – identifying priorities for transnational research needs and sharing of research infrastructures/capacities
- D2.1 Literature review
- D2.3 Horizon scanning report, which contains a EU and worldwide GMO development pipeline of each GM application
- D2.4 List of research needs
- D3.1 Total population of research needs

The Central Access Database for Impact Assessment of Crop Genetic Improvement Technologies (CADIMA; http://www.cadima.info/) developed by the GRACE project (http://www.grace-fp7.eu/) was established as the data repository for PreSto GMO ERA-Net data. The projects collected by the SCAR Collaborative Working Group GMO RISK until year 2010 were categorized by their subject area; by the type of institution that lead the project as well as by the institution which funded the project. Additional data from existing mapping exercises in the area of the risk and benefits assessment of GM organisms was collected and put into the database. A subsequent analysis of the categorized data has been made in order to define the areas in which the research efforts have been made; to identify the key actors – institutions which carried out the research –, and to assess the level of transnational cooperation within the projects. Additionally, literature surveys were performed on three case studies to complement the existing information.

At the time of analysis (D1.3 “Report on the analysed database”), the database comprised a total of 320 projects started between 1989 and 2010 and collected from 3 databases (SCAR Collaborative Working Group ‘GMO RISK’, BiosafeRes, and the compendium ‘A decade of EU –funded GMO research’). The years with the highest number of starting projects were 2001 (44), 2004 (34), 2005 (27), 2006 (28) and 2008 (25). GM plants was the category most widely assessed. Considerably fewer projects studied the effects of other organisms such as GM microorganisms and GM animals.

Not surprisingly, most of the projects were led by research or academic organizations that were usually just collaborating on the national level. Some projects did have international partners, but those were mainly from other European countries. More than 70% of the analyzed projects were financed and managed by different government institutions. The participants in the projects collected in the database were mainly research institutes, universities and governmental organizations. Industry and private companies took part in few studies as project leaders or as partners.

The effects of GMOs on the environment were the predominant subject of study, particularly the preservation of biodiversity and the potential effects of GMOs on non-target organisms. A considerable number of projects were dedicated to the investigation of developing new techniques for GMO development, of tools for GMO detection, analyses of food and feed, of adequate methods for risk assessments, etc. Less studied subjects were the effects on human and animal health. The data furthermore showed a similar ‘pattern of alignment’ of the major research topics per European countries which should facilitate future collaboration.

The performed survey of projects gives an overview on the main sources of funding, main topics of studies and key actors in GMO assessment in Europe as well as the gaps to be filled. The main disadvantage in this analysis was the scarce information for many projects or even the lack of it. Entering the existing data in a complete and correct format presented a considerable challenge for some of the consortium partners. In an attempt to keep continuity with the SCAR CWG, and to accumulate a maximum of current information on the subject, former CWG Member States as well as the SCAR members in general were invited to also contribute to the data gathering effort, but sometimes with only very slow responses.

If the input of relevant project data is maintained in the future, the two major functions of CADIMA, i.e. the production of evidence protocols and synthesis reports, will ensure that new questions and research issues can find some fact-based responses of the current state of research activities, or future funding options.

A workshop to identify and further refine research needs was held on 24 November 2014. It brought together the information available at that time from both WP1 and WP2 and initial thoughts from an expert-elicitation workshop in WP3. The results are published in Deliverable D1.4 “Identifying priorities for transnational research needs and sharing of research infrastructures/capacities”.

The focus of the workshop was on GM crops or other applications (e.g. animals, micro-organisms, etc.) on the marketplace or near to be commercialized, not necessarily in the EU, but that may have effects in the EU. Applications intentionally released into the environment and/or used immediately in feed and food applications were considered. The workshop activities were divided into a morning session, dedicated to share and discuss preliminary project results with the participants, and an afternoon session aiming at defining a list of transnational research needs and requirements for sharing of available research capacities. During this activity, the participants were divided in three working groups based on the area of expertise or interest:

a) Human and animal health,

b) Environment,

c) Techno/socio-economic.

A common process was defined to elicit transnational research needs across the working groups:

- a questionnaire was sent two weeks before the workshop to all the experts and stakeholders to identify the main research needs across GM species/traits and effects;
- based on their replies to the questionnaire, a “long list” of potential topics was populated and integrated with the York’s workshop research needs (held on October 16-17, 2014);
- each working group reviewed this “long list” of potential research needs on its own area discussing their relevance at the European-wide, transnational and national level;
- the capacity and infrastructure needs available to cover these research needs were also discussed by the participants.

The long list of research needs covered a number of 40 issues in the area human and animal health, into the main effects food and feed safety, nutritional value, toxicity and allergenicity. A total of 67 research needs were identified in the area of environment, into the main effects biodiversity, soil, water, plant pest and diseases, air, ecosystem services and climate change. The long list of research needs developed in the area of techno- and socio-economics consisted of 70 items, covering the main effects costs, profitability, segregation / coexistence, legislative framework, socio-economics context (e.g. consumers), macro-economics, and yields. The research needs with relevance for the GMO ERA-Net purpose were then identified during the working groups activities (in contrast to research questions for purely national programmes).

The main requirements for sharing capacities and infrastructures were also identified during the working groups activities:

The “Human and animal health” working group found that there is high level of expertise available in various countries for studying the hypo-allergenicity of GM crops that need to be shared. Harmonization and joint initiatives are possible for sharing experiences about the traceability of specific GM crops. Since applications for RNAi-expressing crops have been mostly developed outside EU (e.g. USA), and limited expertise is available at the EU level, the group concluded that capacities could be organized transnationally. A lot of research has been done on peptide science, e.g. cytotoxic peptides, food peptides with physiological effects (e.g. dairy research, antibiotics): the group found the need to integrate these research capacities available across certain EU countries and sectors, for purpose of assessing potential protein toxicity. Probably only limited capacities are available at the EU level for assessing allergenicity in farm animals, and future research should be organized transnationally. A high level of expertise for GMMs and viral DNA horizontal gene transfer was found in various EU countries; the relative research needs have to be organized transnationally.

The “Environment” working group found the requirements for sharing capacities in terms of protected field sites throughout Europe which should be suitable for GMO field testing and representative of the various European environments. The fields could be used also to avoid several regulation constrains which make it difficult for studying GM for public research. The group discussed about the necessity to have mesocosm facilities for soil-based experiments. The group concluded that technologies/methods for scientific enquiry should be combined basically with calls for multi-/interdisciplinary actions and projects. Finally, it was felt that the GM regulatory/testing/monitoring methods should be harmonised, as much as possible, with other, similar methods and approaches in related areas.

The “Techno-economic” working group discussed the need to develop protocols or guidelines for conducting socio-economic impact assessment, while maintaining some flexibility. Similarly to the “Environment” group, they also found the need to share fields trials to develop more field studies for assessing yields, costs, etc. and to develop multidisciplinary tasks to take into account also qualitative research (e.g. economic/socio-psychology, behavioural economics, etc.). Finally, the group concluded that researchers’ capacities should be shared (training and staff exchange), developing ways to facilitate collaboration among researchers (sharing capacities, Phd programmes, etc.).

A literature survey on the GMO developments in the near future was conducted in Work Package 2. Key-words have been identified to select relevant publications allowing drawing relevant conclusions on emerging GMOs[2] and technologies. Databases such as Web of Science, Scopus, NCBI and others as well as patent databases were subsequently used to select the publications for a first round of screening. As GMOs recently described in scientific publications are mostly in research pipelines, most of them have not been tested in field trials (CBD database). GMOs in regulatory pipelines, approved or deregulated worldwide were identified. International databases (e.g. ISAAA, GMO compass) were retrieved and data were verified using accessible national databases (USA – EPO, USDA, FDA, Canada, Brazil, Argentina, Chile, Australia, China, India, Pakistan, and Philippines). Information provided by companies and country representatives during various conferences and seminars, namely those organized by JRC IPTS Seville were used as independent comparators. An integrated excel file was developed. The full results of this task are described in Deliverable D2.1 “Literature review”.

[2] means those with potential to enter the EC market, GMOs in research pipeline do not fulfil such criteria in EC)

The data obtained yield the following insights:

(1) Any trait may be subjected to genetic manipulation.

However, economically important characters are in the centre of interest of biotechnology companies. These include traits related to various types of herbicide tolerance, pest resistance and their combinations in stacked GM events. Several types of stress tolerant GM plants (drought, salinity) have been developed. Plants better utilizing nutrients (e.g. nitrogen) are considered a valuable contribution to agriculture. Cultivars resistant to biotic stressors (e.g. viruses) are already used. These GMOs address mostly farmers' demands. Further traits associated with end use quality are under development. Apart from oil or starch composition modified crops, biofortified GM species are available. Golden rice is the best known example. Forest trees manipulated to growth faster or have a different wood quality are being developed. GM fish and animals are engineered for faster growth, to become more resistant to certain diseases or to produce pharmaceuticals, nutraceuticals or fibre in milk or eggs. Mosquitos and pest insects are manipulated to supress their populations and to reduce the damages they cause. Microbial hosts with engineered genes that make them more suitable as a part of fertilizers, frost-protectant or type of cell factories producing energy, oils or any type of requested products are also in various stages of development.

(2) Any species can be manipulated.

Again economically important species are preferentially engineered. In addition to the now commonly used GM species GM wheat and rice are about to enter the world market. GM vegetables and fruit species are available outside the EU, and occasionally appear in RASFF (rapid alert system for food and feed – warning against unauthorized agents in food and feed in the EU). Forest tree species are introduced into the environment and GM aspen and eucalyptus are already used in China or Brasil respectively.

GM salmon could enter the market, as could GM cattle, goats and pigs. Various pest insects are modified and open field trials are carried out. The same applies for GM mosquitoes. GM algae are under development and other microorganisms are awaiting open field tests. All these GM organisms may appear on the EU market either in form of their products (import) or they may find environmental uses.

(3) Regionality is an important factor in GM development and uses.

USA and Canada are the most important producers of GM plants that are cultivated across the entire Americas. Currently, development is leaps and bounds in Asia, particularly in China and other countries like the Philippines, Thailand or even Pakistan. These countries develop and test their own GM cultivars of important species for the region, as do many African countries. The EU has not launched programs to develop GM products that meet the specific needs of its agriculture.

(4) GMOs are developed to cover the consumption of food and feed.

It is estimated that biotech cultivars increase productivity by 6 – 8%. They now play an important role in plant breeding.

(5) The role of GM species to ensure demand of industry increases.

GM plants could serve as a source of energy, starches, oils, or lignin; animals may produce various fibres, pharmaceuticals or nutraceuticals in milk or eggs. Possible future uses are manifold.

(6) The impacts of GMOs on health, the environment and techno-economics are important issues in the EC.

The impacts of GMOs upon human and animal health have to be established before the release of the respective GMO into the market. GMOs are risk assessed on a case by case basis. Applicants have to submit the data for each GM event. Independent studies are carried out in the EU. GMOs are widely cultivated and consumed in the world. No negative impact on human health has been reported yet. We assume that the topic is well covered. On the other hand, biofortified products and those with changed end-use quality may be beneficial for human health, at least for some target groups. This issue needs to be investigated in more detail as practical testing has not been carried out. Impacts upon agro-ecosystems are associated mostly with the agricultural practices (e.g. development of resistant weeds due to the wide use of certain herbicides). Impacts on non-target organisms have been widely tested for some types of GMOs, namely pest-resistant crops. Reports from countries cultivating GM crops are available; however they mostly do not cover European areas/environments. Benefits could be expected depending on soil-climatic conditions and the types of economic activities in the landscapes. GM microorganisms are usually kept in enclosed spaces (contained use) and up to now they have found various applications ranging from feed (dry matter), feed and food supplements (derived products), nutra- and pharmaceuticals (derived products) up to remediation. No microorganisms have been released into the environment for agricultural purposes, although several are ready to be used. GM algae for biofuel production have been patented. Situation around GM algae is somehow unclear as the US legislation does not explicitly prevent release of GM algae into the environment. Thousands of algal strains have been redesigned to grow quickly and tolerate extreme conditions. They may spread into the environment and be highly competitive. This is the major fear of risk assessors. No practical experiences are available for microorganisms; however, predictive studies exist.

Work Package 2 also identified data about globally emerging GM applications in the fields of agriculture, aquaculture and forestry (i.e. intentional release), food and feed (i.e. potential for health impacts). Other uses (e.g. medicine and chemistry) were also covered if intentional release into the environment is involved. Members of competent authorities industry and industry bodies and associations, and NGOs in the EU and in relevant third countries and agricultural ministries of EU countries were identified and interviewed. The results of the interviews are described in Deliverable 2.3 “Horizon Scanning report”. Here, the methods used to identify the potential organizations for interviews, the list of identified organizations, and the questionnaire developed and used for the interviews are described. They can also be found in Deliverable D2.2. PreSto partners can access the interview protocols via CADIMA (Services -> Presto Interviews).

A starting point to identify the organisations for interviews was a list of organisations interviewed in earlier EU projects related to GMOs in which PreSto GMO ERA-Net partners participated (e.g. PEGASUS, GRACE). All project partners provided contact details of potential organizations/persons to be interviewed. Next to this an additional internet search was performed using key words such as “emerging GMOs”, “GM plants”, “GM animals”, “GM microbes/microorganism”, “GM insects”, “Biotechnology Company”, “biopharmaceuticals”, “plant/animal genetics”, “GE products”. A database with possible interviewees was created based on the inputs of all project partners, previous projects and above mentioned internet search.

In total 46 organizations (governmental, non-governmental, industrial bodies) were identified as potential candidates for interviews. The total number of organizations to be interviewed was divided among all contributing partners of this task to carry out interviews (2-5 interviews per partner depending on person/month contribution).

An invitation letter to participate in interviews was prepared in cooperation with EuropaBio and was sent to the potential organizations. EuropaBio was involved in the invitation letter in order to especially attract industries and associations to take part in the interviews.

The questionnaire for interviews was developed and discussed with all contributing partners and the coordinator. The questionnaire was sent to the interviewees prior to the interview to get acquainted with the questions. The interviews were carried out by means of Skype, telephone and face to face meetings.

The results of the interviews have shown that the willingness to participate in interviews by organizations involving subject of GMOs in pipeline is very low. From 46 identified organizations only 10 were willing to take part in the interviews. Very strong reluctance to participate in interviews is observed from industrial/commercial organizations. From a total of 10 interviews 8 were carried out with research centres/universities and only 2 interviews involved industry. The reluctance to participate was communicated using various arguments such as:

- ‘The subject is politically sensitive’
- ‘The organization cannot take a part in interviews due to confidentiality of the information’
- ‘The organizations does not operate anymore within EU’
- ‘Not a core business, no current activities in GMOs’
- ‘Not interested’
- No reply at all (after number of reminders)

In another task the results from the literature research and from the interviews were combined with results from expert-elicitation workshops to develop a GMO development pipeline. A workshop protocol was developed and discussed with all partners executing the workshops. The workshops were organized in France (ANSES); Czech Republic (VURV); Bulgaria (ABI); Spain (CRAG), and UK (FERA). The experts covered the following areas: 1) Legal service, development biologist, molecular biologist, climatologists, food security experts, economists, agricultural scientists, 2) Plants, animals, insects and microbes and 3) effects on health, environment and techno-economic issues. In these workshops a coherent picture of the GM applications likely to appear on the market in the next 10 years and the potential effects on health, environment and techno-economic issues was developed. A limitation is the fact that participants were mainly from public research institutes and governmental organizations. Biotech companies (Monsanto Limagrain, BASF, Syngenta) were also invited to some workshops, but refused to participate noting that their activities on GMOs in EU are damped. The workshop reports are available for PreSto partners via CADIMA (Services -> PreSto workshop protocols).

The information gathered in the activities of Work Package 2 were then distilled into a horizon scanning report (Deliverable D2.3 “Horizon scanning report, which contains a EU and worldwide GMO development pipeline of each GM application”). The data from the horizon-scanning report were then translated into research needs for the EU to anticipate the effects of new GM applications in the areas of health, environment and techno-economics based on the research results from the literature review. To do so, a framework was developed that categorized GM products by their potential effects in each of these areas. For each area, subcategories (e.g. direct medicines for “health”, reduced greenhouse gas emissions for “environment”, and increased productivity for “techno-economic”) were identified to which GM applications could be allocated. Allocating all the identified GM applications to the framework and cross tabulating with the on-going or planned research identified gaps in the research as well as research needs for GMOs. Preliminary results were shared with all project participants to comment on.

The full list of over 380 research needs gathered from all sources detailed above and categorised by, source, type of GMO and type of impact is given in Deliverable D3.1 “Total population of research needs” in which all gaps identified in the various activities are listed.

Within WP3, the over 380 research questions resulting from the evidence gathering activities were synthesised and refined, since some needs were duplicates or near duplicates as there was overlap between the participants in several of the sources and inevitably even different sources will provide similar results given the finite number of existing and upcoming GM products and the impacts they can generate. This lead to a total number of 112 refined key research gaps. The process and the results are described in detail in D3.2b “Refining research topics and identifying gaps”.

Following this stock-taking exercise, the views of stakeholders were elicited through the use of two rounds of Delphi survey. The research topics and gaps were then ranked using the input of stakeholders and based on the development of a Multi-Criteria-Decision-Analysis-Model (MCDA). The overall processes of eliciting stakeholder input, developing the MCDA and applying it to rank the research topics and gaps, as well as the end-result are described in the following deliverables:

- D3.2a Delphi Survey
- D3.2b Refining research topics and identifying gaps
- D3.3 A set of criteria on which prioritisation of research needs will be judged
- D3.4 A framework for applying D3.3 criteria to research gaps to enable efficient, transparent and consistent prioritisation of present and future research needs (a MCDA model)
- D3.5 A prioritised list of current research needs

Due to the nature of the tasks of mapping existing research programmes and capacities (WP1) and horizon scanning of emerging GM applications (WP2) there were significant delays in providing these outputs from WP1 and WP2 for the work of WP3, specifically the development of the Delphi and MCDA. Due to the composition of the group in WP3 and following discussion at an internal meeting (held 16 February 2015), it was agreed that in order to provide robust and valuable data for the aim of the project, it was necessary to run the Delphi and MCDA process in parallel. Hence, to ensure that work could be completed in time the two rounds of the Delphi process were run in parallel to the development of the MCDA.

In order to ensure a coherent set of data was produced from WP3, during the development steps for each of these stakeholder engagement methods, the two sub-teams (Delphi – Newcastle and MCDA – Utrecht, Nottingham and APHA) of project partners working on these tasks shared planning and progress details and raw data as responses were being collated. In this task of producing the comprehensive or “long” list of research gaps, this is exemplified by the contribution of the Delphi team to the Schiphol Meeting that was convened to draw out the relevant data from WP1 (Mapping existing research programmes and capacities) and WP2 (Horizon Scanning of Emerging GM applications) that needed to be taken through to MCDA work.

The Multi-criteria Decision Analysis (MCDA) model relies on being able to describe research gaps in terms of a set of criteria. These criteria needed to be easily understandable to people with a range of specialisms and from diverse natural and social science backgrounds. In order to achieve this, development of the criteria was partially based on a survey issued to a wide range of stakeholders (stakeholder contact details were supplied by WP4).

Although WP1 and WP2 had, in conjunction with other methods, used experts to identify research needs, in WP3 it was recognised that the survey presented an opportunity to canvass a much wider set of experts for their views on where there might be research gaps relating to the impacts of GMOs. Furthermore, consideration of criteria on which to judge research gaps is a relatively abstract activity and, although examples were provided to help contextualise thinking on criteria, we believed that this would be further facilitated by allowing experts to consider their own examples of gaps and capturing these examples would bolster our list of research needs. The outputs of the survey relating to the development of the MCDA criteria are presented in D3.3.

The survey was administered online by Survey Sampling International (SSI; https://www.surveysampling.com) and a link to complete the questionnaire was sent to approximately 350 stakeholders. The survey was completed by 32 respondents.

The outcomes from the MCDA criteria survey yielded the addition of 17 new research topics to those already identified in WP1 and WP2, which resulted in.

In order to fully integrate the outcomes of WP1 and WP2 and develop the long list of research topics a meeting was held to bring together lead contributors from each of these work packages. As mentioned above, there had been delays in the outputs from WP1 and WP2 that had a knock on effects for WP3. This was notable as the MCDA work was building, and therefore reliant, on the data from the two mapping work packages (WP1 and WP2). The challenges encountered in the first two work packages highlighted that the tasks of mapping existing and forthcoming GMO technologies was far more complex than originally envisaged. Therefore responding to the delays in finalised outputs, it was important to bring together a representative group to confirm the state of the art at that point in the project and to develop a long list of research gaps as WP3 activities required. The meeting was held at Schiphol, The Netherlands on 20 April 2015.

Given that the overarching aim of WP3 was to prioritise a 'list' of research gaps (that originated from WP1 and WP2) on effects of GMOs on environment, health (animal and human) and techno-economics - these data being complemented by data from the Delphi Survey and other activities in WP3 (e.g. the Criteria Survey, see Deliverable 3.3) – the Schiphol Meeting was attended by WP1, WP2 and WP3 leads as well as the Delphi lead who joined by Skype. The specific objectives of the meeting were to ensure that the relevant data from WP1 (Mapping existing research programmes and capacities) and WP2 (Horizon Scanning of Emerging GM applications) were taken through to MCDA work and the extraction of these relevant data was conducted in a robust and transparent way that can be reviewed so that the outcomes from the MCDA can support the final output of PreSto in a manner that is justifiable.

Members of WP3 first set out the objectives of the meeting and the work to be completed and then discussed what was required in order to synthesise an agreed sub-set of research gaps for the MCDA extracted from WP1 and WP2 data. These data were presented and discussed and the strengths and limitations of the data discussed.

The next part of the meeting discussed the criteria that would be needed to describe these research gaps for prioritisation in the MCDA and criteria were presented from WP1 and WP2 data and the Delphi. Although there was a hope that it might be possible to describe the sub-set of research gaps in terms of the agreed criteria it was recognised that what this process highlighted was the need to ensure that all relevant gaps had been identified and recorded.

As a result of the final session of the meeting a further 33 gaps were identified.

Following this meeting, leads for WP1 and WP2 confirmed that they would supply final versions of the WP1 and WP2 deliverables that set out the justification and details of the research gaps discussed at the meeting.

The full list of over 380 research gaps were gathered from WP1 and WP2, these sources were then complemented by the outputs from the Delphi and the MCDA / WP3 workshop in Schiphol.

Although the task of collating a long list of gaps appears to be more challenging (in the earlier part of the project, i.e. activities of WP1 and WP2) than was predicted, a long list with summary descriptions and categorised by, source, type of GMO and type of impact, was collated and forms the basic dataset for the MCDA and prioritising tasks in this work package.

To develop, or train, the MCDA model required stakeholders to rank scored research gaps. To do this efficiently, gaps with diverse scores needed to be selected in order to fully explore the preferences of the stakeholders doing the ranking. However, there is a limit to how many scores individual participants can properly compare at one time, bearing in mind that each gap was being described by five criteria (i.e. impact uncertainty, susceptibility of the uncertainty to being reduced, social value of addressing the research gap, cost required to reduce the uncertainty, and time this is likely to take). Furthermore, stakeholder fatigue would likely be a serious negative influence on responses if the ranking task was very long and complicated. As anticipated in the Description of Work (DoW), it was therefore necessary to first select a subset of gaps for scoring by the consortium members, before requesting stakeholders to rank them.

The DoW proposed that 20 to 40 research gaps be scored in order to develop the MCDA model, whilst the full list (from Deliverable 3.2b) contained 112 gaps. To ensure sufficient gaps were scored, whilst being mindful that considering all 112 would prove a daunting task for the relatively small group of experts in the consortium, the WP3 team reduced the number of gaps for consideration in a systematic process. First, to make the task more manageable, we grouped research gaps by impact type (animal/human health, environmental, techno-economic) and then, using an on-line random number generator (https://www.random.org/sequences/), selected 20 gaps at random from each impact type to give a possible 60 gaps for scoring. Next, to ensure that at least 20 gaps were scored by multiple experts, we selected seven gaps from each group of twenty on the basis that they represented a diverse range of GMO types (plants, insects, GMMs, etc.) and seemed likely to elicit a wide range of scores. These 21 gaps formed the basis of the scoring exercise, i.e. they would be scored by all participating members of the consortium, with each participant asked to optionally select and score five more out of the remaining 39.

A half-day workshop with consortium members was used to gain consensus on scores and to cross-match expertise (e.g. one expert may have appropriate knowledge to score the capacity available to address a research gap, whilst another may be familiar with the background literature). Prior to the workshop participants were asked to score the gaps using an Excel template. All participants scored a set of 20 gaps, plus a further five gaps of their choice.

Stakeholders’ elicitation was used to train the MCDA models. The elicitation had the form of a multiple ranking exercise whereby stakeholders were asked to rank eleven sets of three research gaps with and without descriptions, one set of three key impact types, and one set of three sub-elements.

The ranking experiment was disseminated in the form of an easy-to-use web-based form (https://www.expertelicitation.com/). An offline MS Word version was available upon request for those who were not able to complete it via the web-based form. In total 8162 stakeholders were invited to complete the questionnaire. These stakeholders had different disciplinary backgrounds and affiliations, i.e. policymakers, people working in the industry, and people working at NGO's. Unfortunately only 53 filled in either the online or the offline elicitation forms and only 28 completed all the forms. As a result no statistically robust conclusions can be drawn from the results.

Stakeholders were asked to rank the research gaps twice: once without their description and once with the description. A stakeholder giving the same rank to the same set of research gaps in both exercises is said to be consistent. On the contrary if a stakeholder gave a different rank to the same set of research gaps is either ranking the gaps at random or the description invoked another criterion on which to rank the research gaps. From the results it appears that the stakeholders are not consistent most of the time, but currently there is little information as to whether they were ranking the gaps at random, they included an unknown criterion when ranking the research gaps with description or, due to their diverse backgrounds/expertise they simply judged gaps on different priorities [from each other].

With probabilistic inversion we were able to find a joint distribution over the weights such that when sampled from and plugged into the MCDA this joint distribution has the same marginal distribution over the rankings as the stakeholders. The scores of the research gaps can be computed with the distribution over the weights. The mean values and order of the research gaps do not change a lot when using either the weights obtained from the rankings blind or with description. The scores obtained from ranking the research gaps blind and ranking the research gaps with description can be found in Deliverable D3.5. With the weights obtained from ranking the research gaps blind we can also compute the scores of other research gaps. It may be noted that the standard deviation (SD) of the additional research gaps is higher than that of the research gaps used to fit the MCDA model. The reason why the SDs are higher for the additional research gaps is because their values were not constrained by the rankings of the stakeholders.

In conclusion, there was little agreement between stakeholders in terms of the rankings they provided. Nonetheless it was possible to fit a distribution to these rankings. These weights did not differ greatly from equal weights but did differ in terms of underlying distribution from equal weights.

Stakeholders who completed both the rankings of research gaps blind and with description were on average not consistent. Only 32% retained their rankings of research gaps blind when they could see the descriptions.

Finally, a distribution over the scores for the research gaps was also obtained from the rankings of the stakeholders. In addition, the remaining 15 gaps were also assessed from the distribution over the weights obtained. For this, only the weights obtained from ranking the research gaps blind were used, because more stakeholders participated in the blind rankings and there was more agreement.

The participation rate of stakeholders was very low; there are several possible reasons for this including:

- stakeholders finding difficulty engaging with what is still a relatively novel elicitation technique;
- technical problems with the web-based ranking exercise (although an MS Word version was available very few respondents requested this option);

- “stakeholder fatigue” - as there is an increasing interest in canvassing stakeholder views and many experts may be approached frequently for input into such exercises;
- timing of the invitation to compete the survey, i.e. mid-summer when many recipients will have been on leave.

The weights obtained seem to suggest that stakeholders as a group are rather indifferent about the criteria to assess the research gaps. Unfortunately, there was not sufficient time to investigate this source of apparent indifference. It may have been an artefact of the (small) number of stakeholders that participated or because of the ranking format. It is recommended to investigate the source of this indifference in the near future before drawing any strong conclusions from the results.

It is recommended to investigate the source of inconsistency of the stakeholders. The inconsistency can either come from stakeholders ranking the research gaps at random or because they have used additional criteria encoded in the description. Future work would benefit from the use of stakeholder workshops to help guide participants through the process and allow exploration of reasons for apparent randomness in gap-ranking decisions.

Applying the MCDA model, the following prioritised list of current research needs (Deliverable D3.5) can be deduced (Table 1).

Table 1: Ranked research needs using the developed multi-criteria decision analysis model. Note: non-bold entries are calculated scores for research gaps used to “train” the model; **entries in bold are ranked according to calculated score**.

Mean score	Standard deviation	Rank	Impact type	GMO type	Research gap description
3.004	0.315	1	Animal/human health	Plants	Herbicide tolerant plants: level of herbicide residues and metabolites in food.
2.988	0.283	2	Techno-economic	General	Acceptability of GMOs
2.936	0.296	3	Animal/human health	Plants	Quantifiable health benefits of bio-fortified gm plants/crops.
2.855	**1.109**	4	**Animal/human health**	**GMMs**	**Effect on food habits if GMMs used in food or feed.**
2.855	**1.109**	5	**Techno-economic**	**Plants**	**Would products of GM crops that were less likely to be infected/infested and had lower levels of toxins than crops managed with conventional pesticides be better accepted by consumers than their non-GM counterparts?**
2.852	0.146	6	Animal/human health	Other animals	Growth-enhanced/altered meat quality in farm animals: effect of compositional changes on certain consumer groups' health due to effect upon food habits.
2.832	0.225	7	Animal/human health	Plants	Herbicide tolerant plants: level of herbicide residues and metabolites in animal feed.
2.756	0.245	8	Techno-economic	Plants	How could the regulatory system be overhauled in order to maximize the public good potentially enabled by GMOs?
2.698	0.373	9	Animal/human health	Plants	What is the impact of herbicides and their metabolites content in herbicide tolerant plants upon human health after long-term exposure of consumers?
2.661	**1.044**	10	**Techno-economic**	**Other animals**	**Development of methods to improve traceability of GM products.**
2.625	**1.003**	11	**Techno-economic**	**Plants**	**What changes in farm management practices are needed to make enhanced [end-use] quality cereals and legumes profitable?**

Mean score	Standard deviation	Rank	Impact type	GMO type	Research gap description
2.618	0.255	12	Animal/human health	Plants	Are pest-resistant plants, e.g. Bt maize, less affected by pests and therefore less susceptible to attack by fungi and bacteria and does this potentially reduced fungal/bacterial-toxin risk have a beneficial effect on the health status of consumers/animals ?
2.615	0.313	13	Animal/human health	Plants	Human health impacts of altered biocide residues and/or altered levels of aflatoxins in food resulting from GM pest/pathogen-resistant crops.
2.564	0.263	14	Techno-economic	Plants	Comparative assessment of crop management options – techno-economic effects.
2.522	0.278	15	Environment	Plants	Impact of GM plants on energy use and greenhouse gas emissions.
2.517	0.198	16	Techno-economic	Insects	Ethical implications of where GMOs are developed and where they are cultivated and/or deployed.
2.437	**0.939**	17	**Animal/human health**	**Other animals**	**Growth-enhanced fish: is the meat equivalent to conventional con-specifics, are changes in composition of fatty acids beneficial?**
2.437	**0.939**	18	**Environment**	**Plants**	**Transfer of non-EU research on impacts [to EU situation].**
2.394	0.412	19	Techno-economic	GMMs	Research into maintaining separation of therapeutics ("pharma" products) produced by GM crops and GM animals from food chain.
2.367	0.185	20	Techno-economic	Plants	Comparative studies on farm-based benefits and effects on decision making from GM plant use
2.34	0.269	21	Techno-economic	Plants	Techno-economic effects of growing poplar trees with modified lignin for biomass production compared to willow.
2.339	0.369	22	Environment	Plants	Environmental effects of altered crop management due to use of GM crops.
2.33	0.313	23	Environment	Plants	Effect of GM crops on

Mean score	Standard deviation	Rank	Impact type	GMO type	Research gap description
					biodiversity.
2.295	**0.956**	24	**Environment**	**Plants**	**Impact of weed suppression (weeds as insect food) on pollination – in natural? And for agricultural production, e.g. orchards.**
2.271	0.313	25	Animal/human health	Plants	Could pest-resistant GM plants have a positive effect on human health through reduced biocide use?
2.253	**0.906**	26	**Animal/human health**	**GMMs**	**Can GM micro-organisms disrupt natural eco-systems and interfere with or destroy their services?**
2.249	**0.896**	27	**Techno-economic**	**Other animals**	**Techno-economic impacts of disease-resistant farm animals.**
2.222	**0.854**	28	**Techno-economic**	**Plants**	**Impacts on forest management practices (silviculture) of trees modified for herbicide tolerance and modified lignin.**
2.216	**0.875**	29	**Environment**	**GMMs**	**Persistence of GMMs in the environment.**
2.203	0.361	30	Animal/human health	Plants	Potential effects on the intestinal flora (e.g. through use of antibiotic resistance genes used as marker genes).
2.177	0.141	31	Techno-economic	Other animals	Effect of altered management practices associated with genetic modification of farm animals on farm animal welfare.
2.164	0.149	32	Animal/human health	GMMs	Potential for pathogenicity of GM oncolytic viruses.
2.163	0.141	33	Techno-economic	Plants	Impact of diversification of approaches in different EU countries on the need for detection methods.
2.156	0.367	34	Environment	Plants	How long does a GM-created resistance last before natural evolutionary processes in pests/fungi/bacteria “catch up” with it?
2.147	0.379	35	Techno-economic	Insects	Economic impact of GM insects to control Dengue fever.
2.111	0.415	36	Environment	Plants	Does pollen-mediated gene transfer in outcrossing species increase the frequency of onset of herbicide-tolerant (HT)

Mean score	Standard deviation	Rank	Impact type	GMO type	Research gap description
					weeds?
2.101	0.265	37	Techno-economic	Plants	Impact of GM biotic stress-tolerant vegetables on integrated pest management practices
2.101	0.3	38	Techno-economic	Plants	Impact of [herbicide-tolerant and pest/disease-resistant] GM crops on agricultural practices.
2.098	0.364	39	Environment	Plants	Will the genes increasing tolerance to herbicide be transmitted via pollen into weedy species and if so will persistence of weeds increase?
2.074	**0.871**	40	**Environment**	**Plants**	**Possible changes upon local ecosystems including plants, invertebrates and vertebrates, when species are dramatically changed.**
2.065	**0.837**	41	**Animal/human health**	**Plants**	**Effects of HT plants and bio-metabolites on human health after long-term exposure.**
2.056	**0.88**	42	**Animal/human health**	**Plants**	**Will consumption of GMOs with enhanced food quality/biofortified (e.g. modified oils, gluten-free, modified/increased vitamin content) improve human health?**
2.044	0.283	43	Environment	Plants	Impact of biofortified GM plants on non-target organisms that might consume them.
1.9	0.42	44	Environment	Insects	Impact on environment through altered insecticide use resulting from use of GM insects to eradicate mosquitoes.
1.788	0.347	45	Animal/human health	Other animals	Animal welfare – impacts of GM techniques on large farm animals.
1.774	0.414	46	Environment	Plants	Effect of GM forests on the forest ecosystem and effect on forest function.
1.725	0.431	47	Animal/human health	Plants	Interactions between the genes and/or their products in the case of stacked events?

Mean score	Standard deviation	Rank	Impact type	GMO type	Research gap description
1.653	**0.694**	48	**Environment**	**Plants**	**Research into what constitutes a healthy soil as a precursor to being able to measure positive [and negative] effects of GM products (such as nitrogen use-efficient wheat, corn and other species).**

The Delphi scoping workshop was the second in a series of 2 workshops held in York over two consecutive days (16th and 17th October, 2014) organized by WP3 partners. The aim of the first workshop was to refine the current knowledge gaps and associated research needs from the outputs of WP1 and WP2. The Delphi scoping workshop began by confirming the research gaps identified in workshop 1, and then aimed to identify the critical issues associated with the research gaps including consideration of the impacts in relation to health, environment and socio- and techno-economics, as well as the ethical issues and governance and capacity building needs associated with the identified gaps. The Delphi scoping workshop led to the identification of five overarching themes that the participants considered important for future GMO research to address applicable to all GMO application areas including plants, insects, other animals and micro-organisms. The five themes were:

1. The focus of current research and the emphasis of the regulatory frameworks is on risks and not benefits; there is a need for better appreciation of the benefits of applications, and consideration of the benefits of the traits offered by GMOs vis-à-vis alternatives approaches to delivering the same benefits through alternative technologies

2. The harmonization of assessment approaches relevant to risks and benefits which occur both in regulatory processes and research

3. The mitigation of impacts of GMOs; there is a need to reduce uncertainty in impact assessment and impact assessment is required to take into consideration the socio-economic and ethical impacts as well those relating to health and the environment. It is important to address uncertainties (and their reduction) in research programs, as well as regulatory measures and communication with stakeholders and society.

4. How can governance frameworks be improved and harmonized globally?

5. Innovation trajectories may be needed which do not assume that different applications of GM technology are equally accepted across all EU member states

These themes provided the basis for the development of the subsequent Delphi questionnaire. Details of the methodologies applied to deliver the workshop; the process, and the outputs the workshop were collated into a workshop report and submitted to the project coordinator and European Commission in November 2014.

The outputs of the scoping workshop were used to inform the design of the first round of the Delphi survey. A draft survey was developed with input from the WP leader (FERA) and partners (UNOTT), WP5 partners (UNI-KLU) and the project coordinator. The survey was developed in English. The draft was circulated for comment and refined, and a final draft version of the survey was piloted using 7 expert participants drawn from academia and research institutions. The survey was adjusted according to feedback received from these participants, and the different sections of the survey are summarized in Table 2. Programming, hosting, and online data processing (i.e., preparing the raw data file) for the survey were performed by a professional survey company (Survey Sampling International http://www.surveysampling.com/).

The survey was introduced with a general introduction to the aims of the PreSto GMO ERA-Net project. The survey content is given full detail in Deliverable D3.2a. The initial questions asked expert opinions regarding the assessment of risks and benefits associated with GMOs, including prioritisation of different research activities.

The extent to which different experts were certain of these views was also assessed. Research and training gaps within the European Research area capacity and capability were identified, and questions focused on specific gaps in research relating to both positive and negative impacts of GMOs on the food chain, the environment and the economy were also asked. Exerts were asked to rate different barriers to GMO impact research. Finally, background information (gender, age group, country of work, type of organization, area of expertise, job experience) was also collected, and a space provided for participants to indicate further comments throughout the questionnaire.

The first round questionnaire was launched in April 2015. Data from Round 1 was then analysed and a second Delphi survey was prepared which incorporated anonymised feedback developed from Round 1 responses. The second Round Delphi survey was launched in June 2015. Data from Round 1 and Round 2 were then analysed and the findings of the Delphi fed into WP3 activities and the PreSto GMO strategic implementation plan (WP4). The full results of the Delphi are described in Deliverable D3.2a.

Based on these results and experiences gained in ERA-Net implementation in general and GMO impact research funding programmes in particular, the Strategic Implementation Plan (SIP) for a future ERA-Net on GMO impact research was drafted (Deliverable D4.2).

The Strategic Implementation Plan makes recommendations for the preparation and implementation of an ERA-Net dealing with research on the impacts of Genetically Modified Organisms on the environment, human and animal health, and techno-economic/socio-economic aspects within the European Union (EU). The SIP also touches upon horizontal and more general issues, as well as on the relevance of such an ERA-Net for Europe and the priorities of the European Commission and various Member States and Associated Countries.

The document is a collection of scientific themes and topics that could be addressed in an ERA-Net. These topics and themes are open and also including questions about the current regulatory system, its fitness for the future in the face of the development of new techniques for genetic engineering, stakeholder engagement and involvement in research agenda setting and research programme implementation, conducive frameworks for research and innovation and many other aspects. The SIP in itself does not call for an overhaul of the regulatory system for GMOs, especially with regard to an analysis or assessment of benefits. While the need to assess benefits has come out clearly from the Delphi survey and from expert inputs, if and how this should be taken into account in the future is a political decision to be taken elsewhere. However, the SIP includes legitimate scientific questions about the impact of the regulatory system on research and application in this, what its current application means for the future development of genetic engineering technologies, and what research questions could be asked to build an evidence base to answer these and similar questions.

Which aspects of the SIP are taken up in an ERA-Net (and indeed if any are taken up at all) remains the sole responsibility and decision of the funding bodies preparing and implementing such an ERA-Net. The SIP is intended to serve as a repository of ideas, as an “options document” and should be viewed as such. It was decided by the drafting team that the SIP should give a number of different options and be as open as transparent as possible, since input from funding bodies and research programme managers was limited to absent throughout the process of preparing the implementation plan. The SIP can also not give full details on the evidence streams and their results. Funders planning to set up and implement an ERA-Net on GMO impact research are encouraged to read the deliverables of the project carefully and assess the relevance of their findings with regard to their priorities and interests. In the SIP, only a brief description of the processes and results of the evidence streams are described in the Annex.

All these deliverables are **public reports** and are available on the website of the project: http://www.presto-gmo-era-net.eu/

1.4 Description of the potential impacts and the main dissemination activities and the exploitation of results.

It is expected that the projects results will consolidate the basis for further coordination efforts between Member States and Associated Countries. Based on the activities from the stock-taking exercise in Work Package 1, it is apparent that a large number of research programmes and project in the area of GMO risk research have been funded, alongside technology development and a more limited number of socio-economic research projects. The data now available in the CADIMA database and analysed in Deliverable D1.3 help funding bodies, programme managers, and policy makers to identify areas for potential future cooperation – either to deepen cooperation where it already exists and strengthen certain scientific fields, or to start up new cooperations and venture into areas where only little research has been performed so far.

Identifying complementarities between national activities and critical gaps is one result from the PreSto GMO ERA-Net activities, which now need to be followed up by a more in depth discussion between funders and programme managers. This discussion could not be achieved by the project, unfortunately, so it needs to be started now on the level of the Programme Committee for Horizon 2020, the Standing Committee on Agricultural Research as well as other similar fora (most notably the PLATFORM 2 project of ERA-Nets, Joint Programming Initiatives).

PreSto GMO ERA-Net also strived to start pooling resources for funding and implementing future research activities in a synergistic manner. However, this was met with little concrete interest from funders. The Standing Committee on Agricultural Research performed an exercise to prioritize the diverse ERA-Net CoFund topics proposed by various sources for the Work Programme 2016/2017 of Horizon 2020. It became evident, that GMO (impact) research was of interest to many, but of importance and urgency only for a limited number of Member States and Associated Countries. This led to the inclusion of an ERA-Net on GMO only for the 2017 part of the Work Programme.

There, the topic is described as follows:

C. GMO research

Scope: The ERA-NET will coordinate transnational research on the effects of genetically modified organisms (GMOs) in the areas of human and animal health, the environment, techno- economics and societies. The focus of the ERA-NET will be on GMOs intentionally released into the environment and/or used immediately in feed and food applications. In addition, the ERA-NET will explicitly take into account the wider views of a range of stakeholders and end-users (e.g. non-governmental organisations, industry, and farmers). This is intended to strengthen ownership of the ERA-NET among stakeholders in order to encourage participation by different scientific communities in future joint transnational calls, to enhance collaboration and to increase the accountability of research trajectories and outcomes. There is a need to better and more openly communicate all societally relevant issues associated with GMOs in order to formulate a more diverse and open view, taking into account both benefits and risks. This will allow people to make an informed choice about whether and how biotechnologies can be used to deliver solutions to current and future challenges in agriculture and other areas. The ERA-NET will build on the results of *the CSA project “Preparatory steps towards a GMO research ERA-NET”. The work is expected to benefit from contribution of social sciences and to apply a 'gender approach'.*

Expected Impact: The overall goal of EU science, development, innovation and agricultural policies is to increase the sustainability and efficiency of agricultural production, leveraging the potential for the implementation of the future bioeconomy, for the greening of agriculture, and for mitigation and adapting to climate change. Therefore, these goals are taken as a benchmark in assessing the nature and magnitude of the possible effects of GMOs and their contribution to these goals and in informing decision-making on how these can be scientifically addressed in a meaningful way. ERA-NET projects will also deliver more meaningful results that can inform both regulatory and political decisions better than the present uncoordinated research structure, in order to protect the environment, human and animal health, and valued socio-economic conditions (e.g. the structure of rural communities, power sharing among different actors in the value chain). The proposed implementation plan will also safeguard the possibility of using GMOs for the benefit of society (e.g. by increasing the sustainability of agricultural systems, protecting biodiversity by replacing current practices that have large negative footprints, and enhancing animal welfare and people's livelihoods in rural communities).

The text is clearly inspired by the results of the PreSto GMO ERA-Net project and the deliverables of the project, foremost the Strategic Implementation Plan, are a good basis for starting a discussion amongst funders on how to structure such an ERA-Net and fill it with research topics and other activities.

This discussion will be had in the course of 2016, depending also on the more general ongoing discussion about ERA-Nets in Horizon 2020 Societal Challenge 2, their governance and the way in which they cooperate.

2 Use and dissemination of foreground

2.1 Dissemination measures

Scientific papers are under preparation by a number of partners. At the time of the preparation of this report, none have been submitted however.

The project's website (http://www.presto-gmo-era-net.eu/) presented the key node for stakeholder interaction and dissemination and supported event preparation (e.g. by announcing stakeholder workshops, promoting online questionnaires of the Delphi surveys and MACDA analysis), implementation and documentation.

The project website (launched in April 2014) recorded about 7.500 visits until the end of the project. The number of visits increased significantly during the project period (on average 440 visits per month over the whole project period, in the last six month about 900 visits per month). The number of pageviews is about 27.000. On average the visit duration was 2 min and more than three visited pages per visit, which indicates a comparatively high attractiveness of the website content for visitors.

The crosslinking with other EU research websites (GMO-Compass and GRACE) resulted in a high number of visits. About 1700 visits of the Presto website came from Presto website links in articles on the GMO-Compass website.

Media contacts to electronic media (PR-online portals, direct mailing) in the event of the availability of final results (including press releases and background paper) were established. Targeted publication resources were:

(1) other relevant EU projects and websites such as GRACE, GMO-Compass and GMO-Safety;

(2) websites of relevant stakeholder groups (e.g. biotech industry/breeder/farmer associations, environmental and consumer NGOs);

(3) EU science and science politics communication resources such as AlphaGalileo, The Parliament and Adjacent Government;

(4) relevant journalists from trade media (e.g., topAgrar, AgraEurope, DLG Mitteilungen).

A list of about 350 such media contacts has been established for dissemination activities of the PreSto GMO ERA-Net project. Information on the project (basic information, project events and final results) were sent to these contacts. Additionally, online PR-portals were used for the dissemination of PreSto GMO ERA-Net related news (newsaktuell/dpa, AlphaGalileo). The dissemination level of such online PR-tools is high because of the use of well-established professional communication networks. Newsaktuell/OTS, for example, are connected with more than 300 media websites and PR portals in Germany alone. Such distribution networks also allow a target-oriented distribution of news releases to relevant media and stakeholder groups, because online PR-channels are directly pushing messages to selected media, journalists and stakeholder groups.

The EU magazines The Parliament Magazine and Adjacent Government are published once every two weeks and about 2,500 copies are distributed directly to all Members of the European Parliament, senior members of the Commission and various EU institutions. Additionally, the Parliament Magazine newsletter digital magazine is distributed to 80,000 contacts including the public affairs contacts from European Public Affairs Directory, bulletin subscribers – from EU officials/Commission staff to project coordinators, university and research specialists, public affairs consultants and journalists worldwide. Presto published project profiles in each of these magazines (January and August 2015).

Most notably, a dissemination and discussion event during the EXPO in Milan was organized on 17 August 2015 in order to present the final project results. About 60 partner, stakeholders and journalists joined this participative event (event title: What do we need to know about GMOs? - Public Discussion on Research Needs to Better Understand Risks and Benefits of Genetically Modified Organisms). The event format is called CaffeeExpo (open space with an expert and a provocateur). The underlying idea is that informal communications offer new opportunities to share ideas, to create new networks and to promote the collaboration and knowledge sharing between general public, professionals and institutions. This event was also used to produce videos summarizing the public debates during the event and presenting interviews with Presto partners and stakeholders on project results and related stakeholder perspectives. The videos were published on the Youtube channel of the Opera Research Centre and on the project website (see: http://agronotizie.imagelinenetwork.com/presto-gmo-era-net/). The videos show interviews with project partner, the presentations given at this event and the CaffeeExpo public discussion. Since this event took place shortly before the end of the project, the number of hits (visitors) is not known.

Finally information material/press releases were sent to several Italian newspapers and agricultural magazines (e.g., La Stampa, Huffington Post, AgroNotizie) and provided to the media centre of EXPO (EU Pavillion, Piazzetta Piacenza). The agricultural journal AgroNotize (the most important agricultural journal in Italy) published a comprehensive project portrait including a video documentation of the Presto EXPO event on its website (see http://agronotizie.imagelinenetwork.com/presto-gmo-era-net/). A 1-pager article on Presto was published in the EXPO magazine CIBIEXPO (an open access online journal with 200 000 copy printed). In total the dissemination activities related to the EXPO event has potentially reached about 0.7 Million readers (according to the number of subscribers).

For full details and examples see Deliverable D5.5 “Report on website and media activities”.

2.1 Exploitable foregroud

All results of the project have been made available as public reports on the project’s webpage: http://www.presto-gmo-era-net.eu/

The foreground can be used by any interested party and mainly consists of the data put into the freely accessible CADIMA database (http://www.presto-gmo-era-net.eu/) as well as the results from the stock-taking exercise, the literature surveys, the workshops, and the Delphi survey.

The key addressee of the PreSto GMO ERA-Net project’s foreground are of course research funders, programme owners and managers active in the area of GMO impacts on health, the environment, and techno-/socio-economics. The final deliverable of the project, the Strategic Implementation Plan for the ERA-Net is aimed at these officials. If and how they will use the information gathered in the various deliverables of the project cannot be known, but will be followed up by the programme owners and managers active in the PreSto GMO ERA-Net consortium given that they have an interest in pursuing the further preparation of an ERA-Net proposal under Horizon 2020.

The potential next steps for the exploitation of the results are described in the Strategic Implementation Plan, and need to be taken in the Programme Committee configuration for Societal Challenge 2 and the Standing Committee on Agricultural Research.