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IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

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Abbreviations

Term or acronym	Meaning or definition
CJEU	Court of Justice of the European Union
CD	Celiac Disease
DG SANTE	Directorate-General for Health and Food Safety
DUS	Distinctness, Uniformity and Stability
EASAC	European Academies' Science Advisory Council
EFSA	European Food Safety Authority
ENGL	European Network of GMO (Genetically Modified Organisms) Laboratories
ENSSER	European Network of Scientists for Social and Environmental Responsibility
ERA	Environmental Risk Assessment
EU	European Union
EURL	European Union Reference Laboratory
EU-SAGE	European Sustainable Agriculture Through Genome Editing
FAO	Food and Agriculture Organization of the United Nations
F2F	Farm to Fork Strategy
FRM	Forest reproductive material
FSFS	Framework for a sustainable food system
FTE	Full Time Equivalent
GHG	Greenhouse gas
GMO	Genetically Modified Organism
GM	Genetically modified
HRI	Harmonised Risk Indicator
HT	Herbicide-tolerant
IIA	Inception impact assessment
IPR	Intellectual property rights
ISAA	International Service for the Acquisition of Agri-biotech Applications
JRC	European Commission's Directorate-General Joint Research Center
LCA	Life-cycle assessment
MRIO	Multi-regional input-output modelling
NCWS	Non-celiac wheat sensitivity
NGT	New genomic techniques
OECD	Organization for Economic Co-operation and Development
PLB	Potato Late Blight
PRM	Plant reproductive material
QALY	Quality-adjusted life year
R&D	Research and development
RNQP	Regulated non-quarantine pest

SAM HLG	Scientific Advice Mechanism High-Level Group
SDG	Sustainable Development Goal
SME	Small and medium-sized enterprise
SPS	Sanitary and phytosanitary measures
SUR	Sustainable use of plant protection products regulation
TFEU	Treaty on the Functioning of the European Union
UAA	Utilised Agricultural Area
UN	United Nations
UPOV	Union for the Protection of New Varieties of Plants
VCU	Value for Cultivation and Use
WTO	World Trade Organization

Glossary of scientific terms

Term or acronym	Meaning or definition*
Agrobiodiversity	A measure of the number and relative abundance of species and varieties in cultivation; it also takes into account the genetic diversity within varieties
Breeders' gene pool	The total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses.
Cisgenesis / intragenesis	Insertion of genetic material (e.g. a gene) into a recipient organism from a donor that is sexually compatible (crossable). The exogenous genetic material can be introduced without (cisgenesis) or with modifications/rearrangements (intragenesis).
Clustered regularly interspaced short palindromic repeat associated nucleases/CRISPR associated protein (CRISPR/Cas)	A family of SDNs (see definition below) that recognise a precise position in the DNA where a cut will be effected.
Cover crop/cash cover crop	Plants planted to cover the soil. These crops are used to manage, among others, soil erosion, soil fertility, soil quality and weeds. Cash cover crops also fulfil this function but also supply harvestable and marketable products.
Desoxyribonucleic acid (DNA)	The genetic material carrying the information for the development, functioning, growth and reproduction of all known organisms and many viruses.

Established genomic techniques	Genetic modification techniques developed prior to 2001, when the existing GMO legislation was adopted. In the context of this impact assessment, the term does not include random mutagenesis techniques, which are exempted from the requirements of the GMO legislation.
Event-specific detection method	A detection method that is capable to detect and identify a specific transformation event. In the context of this impact assessment, this means a method that is able to differentiate a specific NGT product from conventional ones that contain the same modification(s).
Exogenous DNA	DNA produced by whatever means outside a recipient organism from a donor organism that can be sexually compatible or not.
Foreign DNA	DNA produced by whatever means outside a recipient organism from a donor organism that is sexually incompatible (non-crossable).
Genetically Modified Organism (GMO)	An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Genome	The entire genetic material present in a cell of an organism.
Genome editing (gene editing) techniques	A subset of NGTs that allow precise modification of the DNA in targeted positions in the genome. Genome editing encompasses a variety of techniques, which may be applied in mutagenesis, cisgenesis or transgenesis.
Mutagenesis	Creation of mutation(s) in an organism without insertion of foreign genetic material.
New Genomic Techniques (NGTs)	An umbrella term used to describe a variety of techniques that can alter the genetic material of an organism and that have emerged or have been developed since 2001, when the existing legislation on the deliberate release of GMOs into the environment was adopted.
Niche crops	Either neglected and underutilized crops cultivated in previous centuries for food, feed and fibre uses, but which have in recent times been reduced in importance and value and for which hardly any breeding activity is ongoing, or high value crops produced on relatively small volumes.

Off-target effects	Unintended mutations that are introduced in locations of the genome other than the intended one.
Oligonucleotide directed mutagenesis (ODM)	A targeted mutagenesis technique by which oligonucleotides (short pieces of DNA) are used to introduce small, precise mutations in a genome.
Plant Reproductive Material	Any plant material (for example seeds, tubers, cuttings, rootstocks, seedlings, young plants, fully grown trees) that is used for the production of other plants.
Random mutagenesis	An umbrella term used to describe conventional breeding techniques based on mutagenesis that have been used since the 1950s; they involve irradiation or treatment with chemicals in order to produce random mutations in a genome, and typically involve screening of a large number of mutants to select one with desirable properties.
Site-directed nucleases (SDN)	Enzymes that cut DNA at precise and selected target locations. SDNs use a guiding molecule to target the site to be cut. Various SDNs exist, depending on the nature of the guiding molecule and the type of enzyme, e.g. ZFNs, TALENs, CRISPR/Cas. Depending on their type and application, SDNs can be used for mutagenesis, cisgenesis and transgenesis.
Site-directed nuclease type 1 (SDN-1)	A targeted mutagenesis technique using SDNs to introduce small mutations in a specific location of the genome. In SDN-1, no DNA template is provided, so the type of mutation is random.
Site-directed nuclease type 2 (SDN-2)	A targeted mutagenesis technique using SDNs to introduce small, precise mutations in a specific location of the genome. In SDN-2, a DNA template is used to obtain a pre-determined mutation.
Site-directed nuclease type 3 (SDN-3)	An application of SDNs that allows the introduction of exogenous genetic material in a specific location of the genome. If the inserted material comes from a donor organism that is sexually compatible with the host organism, the result is cisgenesis; if the inserted material comes from a donor organism that is sexually incompatible with the host organism, the result is transgenesis.
Sustainability	The long-term ability of food systems to provide food security in a way that does not compromise the economic, social, and environmental bases that generate food security

	for future generation (HLPE 2020).
Targeted Mutagenesis	An umbrella term used to describe newer techniques of mutagenesis that induce mutation(s) in selected target locations of the genome without insertion of foreign genetic material.
Transformation event	A genetically modified plant that has exogenous DNA inserted in (a) certain location(s) of the genome
Transgenesis	Insertion of foreign genetic material (e.g. a gene) into a recipient organism from a donor organism that is sexually incompatible (non-crossable).
Unique alteration/ modification	An alteration/modification that is not present or unlikely to be present in other GMOs or conventional/natural varieties.

* For the purpose of this document

1. Introduction: Scientific, Political, and Legal Context

This impact assessment explores economic, environmental, social (including health) impacts, as well as impacts on fundamental rights and administrative burden, of options for a legal framework for the deliberate release, including placing on the market, of plants and their food and feed products developed using certain new genomic techniques (NGTs), namely targeted mutagenesis and cisgenesis[1].

The term 'new genomic techniques' is specific to the EU regulatory environment and encompasses genetic modification techniques that have emerged or have been developed since 2001, when the centrepiece of the current EU legislation on genetically modified organisms (GMOs) was adopted[2] (see section 1.1. below and Annex 5).

Plant breeding, the practice of changing and/or selecting the traits of plants in order to produce desired characteristics, is a constantly evolving field. Humans have made use of natural variation (i.e. mutations) since first cultivating land and breeding livestock around 13 000 years ago, selecting and retaining organisms suitable for agricultural use. For centuries, breeders have used new scientific findings to increase the effectiveness and efficiency of their efforts constantly adding new plant breeding techniques to their toolbox. During the 20th century a gradual shift took place from breeding being conducted mostly in public institutions toward the private sector, mainly due to the introduction of hybrids. This led to consolidation in the industry and the dominance of several key companies in the major field crops. The emergence of biotechnology in agriculture in the 1980s led to a further reorganisation of the sector moving plant breeding to a high-tech industry involving more and more trans-national companies.

Today, the EU market for plant reproductive material (PRM) (agriculture and forestry) has an estimated annual value of EUR 15 billion[3]. The EU seed market is the third largest after the USA and China and accounts for around 20% of the global market. Its value is estimated at EUR 7-10 billion[4] and it comprises about 7 000 companies (most small and medium sized enterprises, SMEs) with about 52.000 employees. EU companies are highly diverse as regards size, portfolio of crops, geographical area and activities (plant breeding, maintenance of varieties, multiplication, trade). The EU breeding sector is highly innovative and spends around 15% of its annual turnover on R&D.

1.1. Scientific context

Development of the techniques

The advent of NGTs in the past two decades, associated to advances in the understanding of how genes function and in genome sequencing techniques, provides new opportunities to alter the genetic material of an organism allowing the rapid development of plant varieties with specific characteristics. NGTs, as any breeding technique applicable in agriculture, make use of genetic diversity either naturally occurring or resulting from human intervention, in order to select or generate plants that feature desirable characteristics. NGTs constitute a diverse group of techniques, each of which can be used in various ways to achieve different results and products. NGT products may or may not contain foreign DNA; when they do, they may result from the introduction into an organism of genetic material derived from the same species or from other species, either crossable or non-crossable. In this respect, NGTs may

[1] Unless specified, the term cisgenesis in this document encompasses also intragenesis.
[2] Directive 2001/18/EC
[3] Eurostat, see European Commission, 2023b. Annex 4.
[4] Ragonnaud (2013)

produce modifications that could or could not be obtained in nature or by conventional breeding. In most cases, these new techniques can lead to more targeted and precise changes than conventional breeding or established genomic techniques.

Targeted mutagenesis and cisgenesis are considered NGTs and differentiated from established genomic techniques because they have introduced novel features (e.g. higher precision and speed, introduction of genetic material from a crossable species). They do not introduce genetic material from a non-crossable species (transgenesis), which is the case with established genomic techniques. In certain cases, genetic modifications introduced by NGTs cannot be identified by analytical methods, while this is always possible for established genomic techniques.

Targeted mutagenesis induces mutation(s) in selected target locations of the genome without insertion of foreign genetic material and, in certain cases, can produce alterations of the genetic material that can also occur naturally or that can be obtained by conventional breeding. Cisgenesis includes the insertion of genetic material, by random or targeted technologies[5], into a recipient organism from a donor that is sexually compatible (i.e. crossable) and produces alterations that in some cases can also be obtained by natural crossing or conventional breeding. Both targeted mutagenesis and cisgenesis can also produce alterations of the genome that are more complex and challenging to obtain through conventional breeding.

Opinions of scientific bodies

Over the last decade, there have been numerous scientific opinions on NGTs (including on targeted mutagenesis and cisgenesis) in the EU, e.g. by the Commission's Scientific Advice Mechanism High-Level Group (SAM HLG)[6], the European Academies' Science Advisory Council (EASAC)[7], the Commission's Joint Research Centre (JRC)[8], and the European Food Safety Authority (EFSA)[9] (see Annex 6). These reflect the majority positions on the relevant scientific issues.

The above-mentioned bodies report on the increasing precision of certain NGTs compared to conventional breeding approaches. Changes introduced with conventional breeding techniques occur randomly, while certain NGTs can produce precisely located alterations to DNA sequences. In view of their increased precision, such NGTs do not require the extensive screening of large plant populations, necessary for conventionally bred plants, to select the organism with the desired characteristics.

In addition, when changes are small and known in other organisms, the resulting products are expected to display more predictable characteristics. For these reasons and for their increased precision, many NGTs shorten the development time to obtain organisms with desired traits. Since NGTs allow to target modifications, they generally result in fewer unintended genetic modifications compared to conventional breeding techniques.

The European Group on Ethics in Science and New Technologies (EGE) published in 2021 an opinion on the ethics of genome editing, which focuses on applications in the human, animal

[5] Since the first discussions in the EU in 2007, cisgenesis and intragenesis have been included among the new genomic techniques, regardless of the technology (random or targeted) used to produce them.
[6] European Commission (2017)
[7] EASAC (2017)
[8] European Commission (2021a)
[9] EFSA (2012, 2020, 2022a, 2022b, 2022c)

and plant domains[10]. Among its conclusions on plants, EGE recommends a systems approach to evaluate costs and benefits in any future use and regulation proportional to the risk.

The European Union Reference Laboratory for GM food and feed (EURL GMFF) and the European Network of GMO Laboratories (ENGL) issued in 2019 a report on the detection of food and feed plant products obtained by new mutagenesis techniques[11]. They concluded that it is not feasible to differentiate a specific NGT product from conventional ones that contain the same modification(s). An updated report by the EURL-ENGL is expected in 2023[12].

Overall, the above-mentioned opinions and reports recognise the variety of NGTs techniques, and of the different products with different risk profiles they can generate. They note that similar products obtained by different techniques are not expected to present significantly different risks. Also, when the introduced changes are limited and not novel, the assessment of potential risks might be facilitated.

Regarding targeted mutagenesis and cisgenesis techniques, EFSA and other scientific bodies concluded that there are no new hazards specifically linked to the genomic modification produced via these techniques as compared with conventional breeding or established genomic techniques.

EFSA also considered that on a case-by-case basis, a lesser amount of data might be needed for the risk assessment of plants produced by targeted mutagenesis and cisgenesis and therefore there is a need for flexibility in the data requirements for risk assessments. EFSA and other scientific bodies also concluded that, in targeted mutagenesis, off-target modifications are fewer than those occurring with most mutagenesis techniques and, where such changes occur, they are of the same types as those produced by conventional breeding.

The considerations above are shared by other major scientific bodies outside the EU, including the US National Academies of Sciences, Engineering, and Medicine[13], Health Canada[14], the UK Advisory Committee on Releases to the Environment[15] and the Norwegian Biotechnology Advisory Board[16]. FAO acknowledges that issues of safety must be considered[17]. FAO also considers that priorities can be established for regulatory interventions including a food safety assessment while also recognizing that some of the food products produced from gene editing could have food safety characteristics similar to foods with a long history of safe use[18].

However, some scientific organisations and agencies, such as the German Federal Agency of Nature Conservation, the European Network of scientists for social and environmental responsibility (ENSSER) and TestBiotech, disagree with the above opinions[19]. They raise the concern that NGTs pose new and specific risks to the environment and human health compared to previous applications of genetic engineering[20]. They consider that NGTs can be used to achieve genomic changes beyond what is known from conventional breeding and can

[10] https://ec.europa.eu/info/files/ethics-genome-editing_en
[11] European Network of GMO Laboratories (ENGL) (2019)
[12] European Network of GMO Laboratories (ENGL) (2023)
[13] National Academies of Sciences, Engineering, and Medicine (2016)
[14] Government of Canada (2022)
[15] ACRE (2021)
[16] Norwegian Biotechnology Advisory Board (2018)
[17] FAO (2022)
[18] FAO (2023)
[19] Bundesamt für Naturschutz (2021); ENSSER (2021); Testbiotech (2022)
[20] Kawall (2021)

alter the genome to a much greater extent with multiple modifications than with any previous breeding method. Furthermore, they refer to unintended genetic changes that, according to them, would be specific to the processes of NGTs and unlikely to occur via random processes or conventional breeding. Furthermore, these organisations question that NGTs are precise, controllable and predictable.

EFSA has evaluated the scientific literature provided by these organisations in the public consultations conducted in the preparation of its opinions and considered that it does not provide new evidence which would alter the validity of its scientific opinions. While acknowledging that the application of NGTs can lead to a complexity of scenarios and that a case-by-case approach is applicable to NGT plants, EFSA has confirmed that NGTs are more precise, controllable and predictable than conventional methods and their precision is continually increasing with technological progress. In addition, there are no unintended modifications that would be specific for NGTs. EFSA has noted that introducing multiple modifications is also not specific to NGT approaches; this can also be achieved by conventional breeding approaches and established genomic techniques.

Research and development

Globally, the majority of the research on crops using NGTs is conducted in China (43%), followed with some distance by the US (18%), with 14% of this research taking place in the EU[21]. Research in the EU, also funded through the Horizon programme[22], is mainly conducted in France, Germany, Italy, Belgium and the Netherlands.

The type of plant applications that feature prominently in the research and development pipeline, coupled with the fairly easy and speedy applicability of these new techniques, could deliver benefits to farmers, consumers and to the environment. JRC[23] as well as a database of available literature on the use of genome editing in crop plants maintained by the EU-SAGE network[24] and a recent report from the Food and Agriculture Organization of the United Nations (FAO)[25], show that research using these techniques concerns a wider variety of crops and traits compared to the transgenic organisms authorised in the EU or globally so far. Examples include plants with improved tolerance or resistance to biotic stress (plant diseases and pests), plants with improved tolerance or resistance to climate change effects in general and abiotic stresses (environmental, e.g., temperature, drought), improved nutrient and water-use efficiency in plants, and plants with improved agronomic (e.g., higher yield/input ratio and improved resilience) and quality characteristics (e.g., taste, shelf-life). NGTs can contribute to the development of new and improved plants and can further support the use of underutilised, neglected and local crop species – this can also support the special needs in the Outermost Regions. The research pipeline also includes applications of NGTs to develop the type of traits that have been the most common in the GMOs authorised so far in the EU or in other countries, such as herbicide-tolerance (see Annex 7).

[21] https://www.eu-sage.eu/index.php/genome-search
[22] E.g. GeneBEcon – (https://cordis.europa.eu/project/id/101061015). In addition, Horizon Europe includes a forthcoming call HORIZON-CL6-2023-FARM2FORK-01-11: New detection methods on products derived from new genomic techniques for traceability, transparency and innovation in the food system.
[23] Parisi & Rodriguez Cerezo (2021)
[24] https://www.eu-sage.eu/index.php/genome-search
[25] FAO (2022)

NGTs have the potential to support the implementation of the UN 2030 Agenda for Sustainable Development and the relevant Sustainable Development Goals (SDG)[26], in particular (see Annex 3.3):

- SDG2 (End hunger, achieve food security and improved nutrition and promote sustainable agriculture), by facilitating plant breeding applied to a wide variety of crops and beneficial traits, thus contributing to three of the four components of food security (food availability, stability and utilisation).
- SDG3 (Good Health and Well-being), by facilitating the breeding of diverse nutritious and healthy foods.
- SDG9 (Industry, Innovation and Infrastructure), by promoting research in plant breeding, strengthening the research capacity in plant biotechnology and facilitating the development of innovative and sustainable products.
- SDG12 (Responsible consumption and production), by contributing to the sustainable management and efficient use of natural resources (e.g. nutrients and water).
- SDG13 (Take urgent action to combat climate change and its impacts) by contributing to resilience adaptive capacity to climate change, supporting sustainable farming practices (no tilling), the development of crops not requiring land use change and land saving.

1.2. Political context

GMOs today

GMOs have been a controversial topic in the EU since the adoption of the EU GMO legislation. Since the entry into force of Regulation (EC) No 1829/2003[27], no draft Commission decision proposing the authorisation of GM food and feed has obtained a favourable opinion by qualified majority of the Member State in the relevant Regulatory Committee, notwithstanding favourable EFSA opinions. The Commission has authorised 284[28] GMOs for food and feed and 6 GMOs for non-food uses[29], based on favourable EFSA opinions. 20 of these have been renewed following a favourable EFSA opinion. All these GMOs have been judged by EFSA as safe as their conventional counterparts. No regulatory measures (to withdraw, suspend or amend an existing authorisation) have been taken based on evidence of risks to human or animal health or to the environment.

In the EU, the only GMO authorised for cultivation is maize MON810. It is commercially grown in Spain since 1995 and to lesser extent in Portugal. Since 2015, when a "cultivation opt-out"[30] was introduced in the legislation, 18[31] of the 27 EU Member States restricted/prohibited the cultivation of this GMO in all or part of their territories.

The number of field trials in the EU has decreased from 387 (between 2008 and 2014) to 63 (between 2015 and 2022)[32].

[26] https://www.un.org/sustainabledevelopment/sustainable-development-goals/
[27] Regulation (EC) No 1829/2003
[28] This number includes single events and stacked events including their sub-combinations authorised to be placed on the market
[29] Cut flowers (carnations)
[30] Directive (EU) 2015/412
[31] Austria, Belgium (Wallonia), Bulgaria, Cyprus, Croatia, Denmark, Germany, France, Greece, Hungary, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Slovenia
[32] Parisi & Rodriguez Cerezo (2021)

While the market for genetically modified (GM) food products in the EU is small, a substantial market exists for GM feed. The EU is a major importer of high-protein content agricultural commodities for feed use[33], mainly from countries where cultivation is dominated by GMOs. According to 2016 figures[34], out of the 36 million tonnes of soybean equivalent imported per year into the EU, around 30 million (i.e. 85%) was GM.

Whereas cultivation of GMOs in the EU is very limited, globally there is now experience of more than 25 years since the first commercialisation of GM crops. Beyond the EU, in 2019, 27 countries grew around 190 million hectares of biotech crops. An additional 17 countries imported biotech crops for food, feed, and processing. Thus, including the EU, a total of 71 countries have adopted biotech crops so far[35]. An extensive study by the US National Academies of Sciences, Engineering and Medicine published in 2016 on GM crops reported no observed adverse effects on health and the environment, while recognising the difficulty to assess long-term environmental impacts[36].

NGTs in the context of key EU strategies

The debate on NGTs is polarised in the EU, along similar lines as the debate on GMOs. However, it takes place in a context that has changed significantly.

The double crisis of climate change and biodiversity loss have put the focus on long-term resilience and the need for a transition to more sustainable agriculture and food systems. In this context, the European Green Deal's Farm to Fork Strategy presents the Commission's plan for a transition to a sustainable food system[37]. It specifically refers to biotechnology as a possible tool for increasing sustainability, provided they are safe for consumers and the environment while bringing benefits for society as a whole. The Biodiversity Strategy[38] aims to support and incentivise the transition to fully sustainable agricultural practices, improving the condition and diversity of agroecosystems.

In its 2022 Communication[39] "Safeguarding food security and reinforcing the resilience of food systems", the Commission has identified NGTs as potentially contributing to food security. In this context, according to the FAO[40], although the extent of the impact is still speculative, the introduction of gene-editing technologies will have far-reaching implications for agri-food and social systems in terms of their potential for improving and securing production of food.

The Covid-19 pandemic and Russia's war of aggression against Ukraine have also revealed the EU's external dependencies. While EU food security has not been at stake, a global spike in prices of inputs needed for agri-food production, in particular energy, animal feed and feed additives, and fertilisers has shown the EU's vulnerability to price shocks. In its Trade Policy Review Communication[41], the Commission has stressed the role of trade openness within the concept of "Open Strategic Autonomy", notably recalling the importance of an open and fair trade with well-functioning, diversified and sustainable global value chains.

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[33] EU Feed Protein Balance Sheet (November 2022), https://agriculture.ec.europa.eu/data-and-analysis/markets/overviews/balance-sheets-sector/oilseeds-and-protein-crops_en
[34] European Commission (2016)
[35] ISAAA (2019)
[36] National Academies of Sciences, Engineering, and Medicine (2016)
[37] European Commission (2020a)
[38] European Commission (2020b)
[39] European Commission (2022a)
[40] FAO (2022)
[41] European Commission (2021b)

Strategic autonomy and resilience also depend on the diversification of the food system. NGTs are applied to a far larger range of crop species than established techniques and can thereby contribute, for example, to decreasing the EU's dependence on imports of plant proteins. NGTs and their technical accessibility could also support the diversification of developers and users in the food systems, if access to and affordability of the technologies is assured.

Under the European Climate Law[42], the EU must continuously progress in enhancing adaptive capacity, strengthening resilience and reducing vulnerability to climate change. In its Communication 'Forging a climate-resilient Europe - the new EU Strategy on Adaptation to Climate Change', the Commission acknowledged that making better use of genetic diversity and non-harmful plant genetic resources for adaptation based on the latest science is among the urgently needed solutions to help farmers and land managers tackle climate risks[43].

The EU Bioeconomy Strategy[44] supports innovation at the service of the Green Deal objectives, in particular the deployment of a circular bio-based industry contributing to the replacement of fossil resources by sustainably generated bio-based materials and chemicals. It recognises the potential of biotechnology and life sciences to achieve such objectives. The Council's conclusions on the opportunities of the bioeconomy from March 2023[45] specifically mentioned the importance of seizing the opportunities presented by the bioeconomy and called on the Commission to enhance the integration of the bioeconomy into all policies and ensure coherence among policies.

The European Parliament has adopted several resolutions[46] where it refers to new plant breeding techniques and recognises the importance to develop and use such techniques which respond to societal and agricultural demands and enhance the competitiveness of the agriculture and horticulture sectors. In 2021 on a resolution[47] on Farm to Fork Strategy, the European Parliament also referred to the Commission's plans to initiate a regulatory policy action plants derived from certain new genomic techniques highlighting the precautionary principle and the need to ensure transparency and freedom of choice to farmers, processors and consumers. Against this background, there is currently a strong demand by a range of stakeholders including breeders, farmers and academia, to adapt the regulatory framework to enable the development, marketing and use of NGTs as tools contributing to address current challenges. Other stakeholders, however, consider that the benefits of NGTs are hypothetical and achievable by means other than biotechnology. Some are concerned about safety (e.g., environmental organisations) and/or possible negative impacts on their business (organic and GM-free sectors).

Other factors affecting the development and marketing of NGTs

There is widespread recognition that the development and marketing of NGTs, and the realisation of their potential, depends on various factors. An appropriate regulatory framework is important, but patents, access of farmers, public organisations and SMEs to the

[42] Regulation (EU) 2021/1119
[43] European Commission (2021d)
[44] European Commission (2018)
[45] Council of the European Union (2023)
[46] https://www.europarl.europa.eu/doceo/document/TA-7-2014-0131_EN.html; https://www.europarl.europa.eu/doceo/document/TA-8-2016-0251_EN.html; https://www.europarl.europa.eu/doceo/document/TA-8-2016-0252_EN.html;
[47] https://www.europarl.europa.eu/doceo/document/TA-9-2021-0425_EN.html

technologies and the market, and factors affecting consumer acceptance, will also have an impact.

The intellectual property landscape regarding NGT plants is complex and rapidly evolving[48]. Patents and access to affordable patent licenses for NGT technologies and for genetic material obtained by these techniques will play a role in breeders' (especially SMEs') ability to develop and market new plant varieties based on these techniques. Some plant breeders are concerned that the cost of licences to access the technology can be prohibitive, notably for small crops[49]. In addition, there are calls from some stakeholders that patentability should not negatively impact the ability of farmers to choose, afford and propagate harvested NGT plant seeds on their farms.

Consumer acceptance of NGTs has been the subject of several social research studies and national/international surveys conducted across the EU (EU-wide and in Sweden, Norway, Italy, the Netherlands, Belgium, Austria, Germany), as well as in other countries (such as the UK, Switzerland, Canada, US, Australia, Japan, Korea and China), in the last 5 years.

Research so far is limited, and some studies involve limited participation. However, they provide emerging evidence of factors that may drive consumer acceptance of NGTs. General research on consumer perceptions and attitudes to food and food safety has also provided insights into expected consumer views on NGTs.

Regarding citizens' current perception of NGTs, there are studies reporting on the one hand negative attitudes and on the other hand an increased acceptance of NGT food compared to current perception of GMOs. Attitudes on GMOs in general and NGTs in particular are closely connected to levels of knowledge and the perceived safety levels[50]. Several studies indicate that the majority (60-64%) of Europeans have not heard of NGTs and that consumers' knowledge on NGT organisms and GMOs is limited[51]. However, comparatively, at this stage they appear to be more knowledgeable about GMOs generally than about NGTs[52]. The level of awareness on NGTs varies among different countries but is generally low[53].

EFSA has recently conducted research into food safety in general as well as on NGTs concretely. Food safety is considered important by the majority (70%) of the EU population. In terms of the most important concerns, 26% expressed concern about GM ingredients and 8% about NGT ingredients. Regarding NGTs, citizens are interested in possible risks (69%), who benefits and who bears the risks (42%), regulation (40%), what benefits NGTs bring (38%), consumers' choice (38%), and the scientific process and techniques (31%). As regards information on food risks, this research also showed high trust in scientists in all Member States and in EU institutions in several Member States[54].

Research conducted globally suggests that the majority of the respondents are receptive to the use of NGT products, particularly in the agricultural sector, as long as they bring societal

[48] Kock (2021)
[49] See Annex 5, section 2.3.3. in Technopolis *et al*. (2023)
[50] Strobbe *et al.* (2023), FSA. (2021), Sprink *et al* (2022), Son & Lim (2021), Bundesinstitut für Risikobewertung (BfR) (2017), GENEinnovate. (2020), Beghin & Gustafson (2021)
[51] European Commission (2021c), section 4.10.2, EFSA (November 2021). FSA (2021), Swedish Gene Technology Advisory Board, Department of Plant biology (SLU), Novus. (December 2021), GENEinnovate. (April 2020), The Greens/EFA (2021)
[52] Hu *et al*. (2022)
[53] Strobbe *et al.*(2023), Busch *et al* (2022), Kato-Nitta *et al* (2021), Beghin & Gustafson (2021)
[54] EFSA. (November 2021), EFSA. (September 2022)

benefits and promote sustainability[55], for example through traits adapted to climate change, reduced pesticide use and improved nutritional content. A recent Eurobarometer on citizens expectations on sustainability indicated that for consumers the most important characteristic of sustainability are the health and nutritional aspects (41%), the absence of pesticides (32%) and affordability (29%). 18% of the respondents correlated organic food with sustainability[56].

The majority of respondents in research studies believe that labelling of NGT products is necessary[57]. In some cases, there is also a preference for distinct labelling of GM and NGT products. Research indicates that consumers may also desire information on the specific trait that has been modified and which genetic technology has been used, to be provided on product labels[58].

In the context of this initiative, consumer trust is relevant not only as regards acceptance of NGTs but also in relation to organic production. Research shows different results on the importance of the absence of GMOs in the decision to purchase organic food. This decision seems to depend on different factors, such as health awareness, food safety concerns, environmentally friendly production practices, consumer knowledge of organic foods, animal welfare, avoidance of chemical substances, perceived or subjective social norms and availability of organic food options[59].

In its 2021 opinion, EGE acknowledges the prevalence of public concern in relation to GMOs, including the lack of public dialogue and informed debate, which in its view accompanied the introduction of GMO products, and calls for more attention to public dialogue on NGT plants[60].

1.3. Legal context

In the EU, regulatory requirements for GMOs are enshrined in five main legislative acts[61] and have two main objectives: to protect human and animal health and the environment and to ensure the effective functioning of the internal market. They establish harmonised procedures requiring an authorisation for the deliberate release of GMOs into the environment for experimental purposes as well as for the placing on the market and cultivation of GMOs and GM food and feed. This authorisation system is based on an assessment of the risks to human and animal health and the environment, and includes requirements for post-authorisation monitoring, labelling and traceability.

In the context of the Cartagena Protocol on Biosafety, the EU has made a number of international commitments with respect to the safe transfer, handling and use of living modified organisms resulting from modern biotechnology[62].

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[55] Swedish Gene Technology Advisory Board (2021), GENEinnovate. (April 2020), Kato-Nitta *et al*. (2021), Baum *et al* (2023), Sikkema (2021), Grain Club (2023), Rathenau Instituut (2023), Saleh *et al.* (2021)., Beghin & Gustafson (2021)

[56] Special Eurobarometer 505 – Wave EB93.2 – Kantar (December 2020)

[57] YouGov (2022), Lindberg *et al.* (2023), The Greens/EFA (2021), Rathenau Instituut (2023)

[58] GENEinnovate. (April 2020), Swedish Gene Technology Advisory Board (2021), YouGov (2022), Lindberg *et al.* (2023), The Greens/EFA (2021)

[59] Gundala *et al*. (2021), Singh & Verma (2017), Paul & Rana (2012), Michaelidou & Hasan (2008), Padel *et al*. (2015), Torjusen *et al*. (2004), Pew Research Centre (2016), IFOAM, BEUC, Special Eurobarometer 520 – Kantar (2022)

[60] European Group on Ethics (EGE) (2021)

[61] Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC.

[62] https://bch.cbd.int/protocol/text/

In 2018, the Court of Justice of the EU (CJEU) ruled[63] that new mutagenesis techniques are not exempted from to the requirements of the EU GMO legislation (as is the case of old mutagenesis techniques) (Annex 8).

In November 2019, the Council noted that, while the Court ruling clarified the scope of the GMO legislation, concerns remained about the application of the EU legal framework when products obtained with new mutagenesis techniques are not distinguishable from those resulting from natural mutations or from conventional breeding. The Council therefore requested[64] the Commission to prepare a study on the status of NGTs under EU law (hereinafter referred to as 'Commission NGT study').

The Commission 2021 NGT study[65] concluded that, based on the reasoning followed by the Court, the EU GMO legislation also applies to organisms produced by other NGTs, including cisgenesis. On the basis of the products in the research and development pipeline, it considered that NGTs can contribute to the achievement of the Green Deal and Farm to Fork objectives, as well as to a more competitive economy. The study considered that the current EU GMO legislation needs adaptation to scientific and technological progress to be suited to certain NGTs and the diversity of products they can deliver. It also reported on the concerns expressed by certain stakeholders and concluded that the application of NGTs in agriculture should not undermine other aspects of food production, e.g., organic agriculture.

In a recent judgment, the Court clarified that organisms obtained by i*n vitro* random mutagenesis techniques/methods are exempted from the GMO legislation (judgment of 7 February 2023, Case C-688/21 Confédération paysanne and Others)[66]. *In vitro* random mutagenesis techniques are not concerned by this policy initiative since they are exempted from the application of the GMO legislation and are not NGTs.

1.4. International dimension

Globally, NGT organisms[67] and their products are either considered as GMOs or novel foods, or as conventional products[68]; some countries require a case-by-case consideration of each product in order to establish the applicable regulatory framework. Various non-EU countries have adapted, or are in the process of adapting, their legislation in order to specifically address NGTs; this includes important EU trade partners such as the US, Japan, Argentina, India and the UK. A recent report by the FAO provides a detailed overview of current regulatory approaches across the world[69]. China, leading country on research, does not have a specific regulatory framework on genome edited crops, but has released guidelines for the safety evaluation of genome edited plants[70] that are intended to provide a more streamlined approval process than for GMOs. The African Union Agenda 2063[71] aims at utilising genome editing to improve agricultural productivity and crop resistance. Kenya and Nigeria have already implemented regulations for a case-by-case review of genome-edited crops[72]. NGTs could be relevant in low- and middle income countries, which would benefit from adapting

[63] Judgment of 25.6.2018 in Case C-528/16 Confédération paysanne and Others. ECLI:EU:C:2018:583
[64] Council Decision (EU) 2019/1904
[65] European Commission (2021c)
[66] ECLI:EU:C:2023:75
[67] The term NGT is only used in the EU. Other jurisdictions use other terms such as "genome editing", "gene-editing", "precision breeding" or other variants. These terms may cover different techniques.
[68] European Commission (2021c)
[69] FAO (2022)
[70] USDA (2022)
[71] https://au.int/en/agenda2063/overview
[72] Buchholzer & Frommer (2023)

traditional, local crop species so that they can withstand changing conditions. An enabling framework in the EU could also support use in those countries.

Switzerland is considering a new authorisation regime[73] for plants that have been obtained using new breeding technologies and are not transgenic. Canada has a product-based legislation; products with novel traits are subject to risk assessment, regardless of the technique used. Other countries, such as New Zealand[74] and South Africa[75], continue applying their GMO legislation to NGT organisms.

Actions taken by these third countries thus consist in partial or (most frequently) full exemption of certain NGT products from GMO authorisation requirements, including specific GMO labelling and traceability obligations. These exemptions are often linked to the absence of foreign genetic material and whether a specific product could also have been obtained naturally or by conventional breeding.

The determination of the status of these products ranges from self-determination by the developer, voluntary consultation of the competent authority, to compulsory notification or consultation and decision by a national authority. The evidence to be provided ranges from a simple documentary declaration to analytical evidence that the product complies with the exemption criteria.

Third countries that have made adjustments to their regulatory oversight to take into account the specificities of NGTs are expected to see NGT products increasingly arrive on the market in the years to come (as shown for example by the 30 NGT plants that have already cleared a regulatory procedure in the Argentina from 2015 to mid-2022). Emerging evidence from Argentina and Japan shows that a change in legislation has contributed to the shift in developers from international to national companies and from multinationals to public institutions and SMEs.

Currently regulatory developments on NGTs across the world differ to various extents and the resulting alignment or divergence will impact trade in plants, food and feed, and may lead to trade frictions as illustrated by the experience with GMOs.

In the context of the WTO's Sanitary and Phytosanitary Committee, in 2018, 11 countries[76] co-signed an international statement on agricultural applications of precision biotechnology[77], acknowledging its role in addressing challenges facing agricultural production and calling for policy alignment in order to minimise unnecessary trade barriers.

1.5. Scope

The scope of this initiative are plants produced by targeted mutagenesis and cisgenesis (including intragenesis) and their food and feed products.

The choice of the scope is based on several reasons. There is significant demand in the EU and globally for NGT plants, in the context of their potential to contribute to current challenges in the agri-food system. Numerous advanced and early R&D applications concern plants, and several plant products are already on or very close to the market. Safety data are mainly available for plants obtained by targeted mutagenesis and cisgenesis (addressed in expert opinions from EFSA), whereas it is at this stage difficult to draw relevant conclusions

[73] Bundesversammlung der Schweizerischen Eidgenossenschaft (2022)
[74] Entine *et al.* (2021)
[75] Republic of South Africa (2021)
[76] Argentina, Australia, Brazil, Canada, the Dominican Republic, Guatemala, Honduras, Paraguay, Philippines, the United States of America and Uruguay.
[77] WTO (2020)

on other techniques and applications in animals and micro-organisms. Furthermore, similar plants can be obtained in certain cases with conventional breeding and targeted mutagenesis and cisgenesis, and the appropriateness of subjecting these products to the same regulatory requirements as transgenic organisms needs to be assessed.

1.6. Interaction with existing legislation and upcoming initiatives

This initiative is framed by the existing legislation on GMOs and has links to other legislation applicable to plants, food and feed, as well as with planned initiatives implementing the European Green Deal and the Farm to Fork Strategy. Section 7.3 describes the coherence with the relevant legislation and upcoming initiatives[78].

The initiative on NGT plants aims to establish specific rules applicable to the deliberate release and the placing on the market of these plants and derived food and feed, taking into account their specificity, while maintaining the objectives of the GMO legislation and ensuring coherence with it.

The planned initiative on a legislative framework for a sustainable food system (FSFS)[79] covers the entire food system, thus encompassing NGT plants used for food or feed and the derived food and feed products. The placing on the market and cultivation of plant varieties derived from NGT plants will also have to comply with EU legislation on the marketing of seeds and other plant and forest reproductive material (PRM, FRM), which is currently under revision[80]. In particular, the assessment of the value for cultivation and use (VCU) carried out under this legislation covers various aspects (e.g. yield, pest resistance, nitrogen-use and water-use efficiency) which may be linked to traits introduced by NGTs.

NGT plants could be among the tools that contribute to the reduction target on the use and risk of pesticides set out in the proposal for a regulation on the sustainable use of plant protection products ('SUR')[81].

EU legislation on organic production and labelling of organic products, the Organic Products Regulation'[82] bans the use of GMOs and GM food and feed in organic production[83], and allows organic operators to rely on the labels and accompanying documents available pursuant to the GMO legislation. In addition, organic operators have to implement precautionary measures to avoid the presence of products and substances not authorised for use in organic production. However, GMOs that are exempted today from the requirements of the GMO legislation (such as products obtained by random mutagenesis, i.e. old mutagenesis techniques) are treated as conventional for the purposes of organic production.

Legislation on IPRs will have an impact on the development and marketing of NGT plants. Two types of IPRs are of particular relevance for NGT plants: biotechnology patents and plant variety rights. The Biotechnology Directive[84] on the legal protection of biotechnology inventions provides for the patentability of subject-matter involving biological material which

[78] https://agriculture.ec.europa.eu/farming/organic-farming/legislation_en

[79] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13174-Sustainable-EU-food-system-new-initiative_en

[80] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13083-Plant-and-forest-reproductive-material-revised-rules-_en

[81] European Commission (2022b)

[82] Regulation (EU) 2018/848

[83] The Organic Products Regulation also prohibits the use of non-food and non-feed products produced from GMOs or by GMOs in organic food and feed. These categories of products are not subject to the EU legislation on the deliberate release of GMOs.

[84] Directive 98/44/EC

is new, involves an inventive step and is susceptible to industrial application. A patent can cover the biological material as well as the process to produce it, but not plant and animal varieties and essential biological processes for the production of plants and animals. The latter exclusion also extends to plants and animals obtained by such essentially biological processes.[85] Plant variety rights[86] can be granted for plant varieties that are distinct, uniform, stable and new. Breeders may use protected plant varieties for the purpose of breeding and marketing new varieties.

1.7. Previous studies on the EU GMO legislation with relevance to NGTs

Two external studies on the EU GMO legislation were carried out for the Commission in 2010 (on GM food and feed)[87] and 2011 (GMO cultivation and placing of GMOs on the market)[88]. They noted concerns that the legislative framework was only focused on risks and not suited for the EU to take advantage of new developments in biotechnology. They also referred to detection challenges resulting from the fact that products of targeted mutagenesis might not differ from those obtained via conventional breeding. The studies concluded that, as the rate of innovation in the global biotechnology sector was unlikely to slow down, ensuring that legislation remained relevant was likely to be an ongoing challenge, especially if the focus was on the techniques used rather than on the final products. The Commission 2021 NGT study, using the latest available evidence, confirmed that the findings of the previous studies remain relevant today and that the challenges have grown, especially as regards plants produced by targeted mutagenesis and cisgenesis. The 2010 and 2011 external studies and the Commission 2021 NGT study, have provided an analysis of the relevant problems and evidence. In that context, an additional evaluation of the GMO legislation at this point in time would not yield further information, in the absence of NGT products on the EU market.

2. Problem definition

2.1. What are the problems?

The current EU GMO legislation is not fit for purpose for NGT plants obtained by targeted mutagenesis or cisgenesis, and their food and feed products. This was highlighted already in the 2010/2011 external studies and confirmed by the Commission NGT study in 2021. This is also the view of most stakeholder groups in the public consultation for this impact assessment[89], where 191 (93%) of the respondent academic/research institutions, 102 (84%) of business associations, 66 (80%) of large enterprises, 70 (72%) of SMEs and 29 (83%) of public authorities found the existing regulatory provisions inadequate for these plants. However, other stakeholder groups (47 (58%) of non-governmental organisations (NGO), 16 (80%) of environmental organisations, 3 (60%) of consumer organisations) consider that the existing legislation is adequate. These results are similar to the outcome of the feedback received to the inception impact assessment (Annex 2).

The problem is composed of three main components:

[85] See Rule 28(2) of the Implementing Regulations to the European Patent Convention; Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03)
[86] Regulation (EC) No 2100/94
[87] Food Chain Evaluation Consortium (2010)
[88] GHK Consulting (2011)
[89] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

I) **The authorisation procedure and risk assessment requirements of the current EU GMO legislation are not adapted to the variety of potential plant products that can be obtained by targeted mutagenesis and cisgenesis, and as a result are disproportionate or inadequate in certain cases.**

Targeted mutagenesis and cisgenesis can produce a diversity of plant products with different risk profiles. Some are similar to plants occurring naturally, or produced by conventional breeding, including random mutagenesis techniques, for which there is no requirement to be authorised or risk assessed as GMOs. Others are similar to plants obtained by established genomic techniques. However, they are all subject to the same authorisation and risk assessment requirements in the current GMO legislation. This results in applying different regulatory oversight and risk assessment requirements to plant products with similar risk profiles or applying the same regulatory oversight and risk assessment requirements to plant products with different risk profiles.

The conclusions of scientific bodies in this regard (section 1.1) were shared by the majority view of stakeholders in the consultation activities. In the public consultation, 829 respondents, 23% of those replying that the legislation is not adequate, indicated as an underlying reason that the risk assessment approach cannot factor in the diverse risk profiles of the plants in question[90]; in addition, 61% (1331) of total respondents supported a risk assessment approach different from the current one[91]. On the other hand, 22% of respondents (480 responses)[92] were of the view that NGT plants need to be assessed using the current GMO legislation requirements.

II) **The current EU GMO legislation raises implementation and enforcement challenges for certain plants produced by targeted mutagenesis or cisgenesis.**

The EU GMO legislation currently requires applicants to provide an analytical laboratory method that is specific to the product for which they seek authorisation, i.e. it can both detect it and differentiate it from other products. The EURL and ENGL have concluded[93] that, if the genetic alteration is not unique for the relevant product, a specific detection method cannot be provided. When the same alteration can be introduced by NGTs or conventional breeding methods, the detection method may be able to detect it, but will not allow determining whether the product is a GMO subject to the GMO legislation or not. In such cases, applicants will be unable to comply with an

[90] 89 (21%) of the Academic/research institutions, 56 (24%) of the Business associations, 68 (25%) of company/business organisations, 2 (33%) of Consumer organisations, 560 (23%) of EU citizens, 2 (15%) of Environmental organisations, 19 (24%) of Non-EU citizens, 14 (19%) of Non-governmental organisations, 17 (22%) of Public authorities, 1 (7%) of Trade Unions and 2 (25%) of Other.

[91] 34% (738) of total respondents believed that risk assessment should have requirements adapted to the characteristics and risk profile of a plant (41% (84) of the Academic/research institutions, 11% (13) of the Business associations, 23% (41) of company/business organisations, 20% (4) of Consumer organisations, 37% (552) of EU citizens, 10% (2) of Environmental organisations, 50% (19) of Non-EU citizens, 10% (8) of Non-governmental organisations, 49% (17) of Public authorities, 14% (2) of Trade Unions and 20% (1) of Other). 27% (593) believed that risk assessment is not needed when these plants could have been produced through conventional plant breeding or classical mutagenesis (37% (76) of the Academic/research institutions, 54% (66) of the Business associations, 42% (75) of company/business organisations, 22% (328) of EU citizens, 10% (2) of Environmental organisations, 11% (4) of Non-EU citizens, 27% (22) of Non-governmental organisations, 31% (11) of Public authorities, 43% (6) of Trade Unions and 20% (1) of Other).

[92] 3% (6) of the Academic/research institutions, 16% (20) of the Business associations, 22% (39) of company/business organisations, 80% (4) of Consumer organisations, 22% (328) of EU citizens, 75% (15) of Environmental organisations, 18% (7) of Non-EU citizens, 54% (44) of Non-governmental organisations, 17% (6) of Public authorities, 36% (5) of Trade Unions and 20% (1) of Other.

[93] ENGL (2019)

authorisation requirement, and other food chain operators and authorities will not be able to implement or enforce the legislation. This has been confirmed by the fact-finding studies carried out by the Commission in 2022 in Germany[94] and the Netherlands[95] to gather information on the implementation of controls on organisms and products obtained through NGTs.

Furthermore, plants produced by targeted mutagenesis and cisgenesis, which could also occur naturally or be produced by conventional breeding, need to comply with the traceability (document-based with specific GMO identifier) and labelling (obligation to label the products as genetically modified) requirements of the EU GMO legislation. Consequently, in certain cases, plant products with similar genetic modifications might be subjected to different labelling and traceability requirements, depending on the breeding technique that was used to obtain them.

Finally, the emergence of targeted mutagenesis and cisgenesis techniques raises questions of interpretation of Directive 2001/18/EC (and other GMO legislation). That legislation lacks definitions of certain key terms or concepts such as 'mutagenesis' and 'genetic material [that] has been altered'. The potential ambiguities can lead to diverging interpretations, regulatory uncertainty and implementation challenges[96].

III) The current EU GMO legislation applied to NGTs is not conducive to developing innovative beneficial products.

NGTs can bring speed and precision to the development of improved plant varieties with traits that could support a sustainable and resilient EU agri-food system (section 1.1). However, as a result of the regulatory issues mentioned above, the current EU GMO legislation applied to NGTs is not conducive to developing these innovative products and to place them on the market in the EU. In the public consultation, 61% of the total respondents (1329)[97] believed that maintaining plants produced by targeted mutagenesis and cisgenesis under the current framework is expected to have short-, medium- or long-term consequences in their activity or sector. The large majority mentioned negative consequences, relating to loss of tools to achieve the goals of the Green Deal and the Farm to Fork Strategy, as well as obstacles to research and development of improved crops and loss of competitiveness. 19% (424) of the respondents[98] do not expect to experience any consequence.

Overall, the current GMO legislation meets the objective of safety, albeit with higher regulatory burden and cost than would be necessary for certain NGT products. It is not conducive to developing innovative NGT products and to place them on the market in the EU. Thus, contributions of these products to a sustainable transformation of the food system, and to the EU's strategic autonomy and international competitiveness, cannot be harnessed. See also problem tree (Figure 1 and Annex 9) and Section 3.

[94] https://ec.europa.eu/food/audits-analysis/audit-report/details/4543
[95] https://ec.europa.eu/food/audits-analysis/audit-report/details/4544
[96] European Commission (2021c), section 5.
[97] 80% of the Academic/research institutions, 89% of the Business Associations, 71% of the Company/business organisations, 40% of the Consumer Organisations, 55% of EU citizens, 30% of Environmental organisations, 63% on Non-EU citizens, 54% of NGOs, 71% of Public Authorities, 93% of Trade Unions.
[98] 9% (19) of Academic/research institutions, 9% (11) of Business associations, 22% (40) of Company/business organisations, 60% (3) of Consumer organisations, 20% (299) of EU citizens, 65% (13) of Environmental organisations, 21% (8) of Non-EU citizens, 36% (29) of Non-governmental organisations and 6% (2) of Public authorities.

2.2. What is the size of the problem and who is affected?

The problems identified above affect numerous operators across the agri-food system, especially breeders, the agricultural biotechnology innovation and research sector, conventional and organic farmers, bio-based industry, consumers, traders, and EU and national authorities. The overall risk is that the EU would be to a significant extent excluded from the technological developments and economic, social and environmental benefits potentially generated by these new technologies, thereby also weakening the EU's strategic autonomy. However, since specific regulatory frameworks were introduced in several non-EU countries only recently and given the limited number of products on the global market (none in the EU), very few if any data or estimates on economic, social or environmental impacts of different regulatory regimes for NGT products are available to date. Estimates of the size of the problems for different types of operators if the current GMO legislation continues to apply to NGTs thus depend to a large degree on comparison with past developments inside and outside the EU (e.g. for GMOs obtained by established genomic techniques), expert assessments, projections, stakeholder expectations and relevant data from the scientific literature.

In the targeted survey conducted for this impact assessment, respondents active in **plant breeding** (45.5%, 56 of 123) pointed to regulatory uncertainty, regulatory costs and time to market as the most important barriers to developing new plant varieties using targeted mutagenesis or cisgenesis. Due to uncertainty[99], the current regulatory regime is seen as inducing high risk for plant breeders to engage in NGT-related research and product development, in particularly for start-ups and SMEs. A significant share of companies (40%) replied that they delayed product development and release due to this regulatory uncertainty. Large companies respond to this uncertainty by moving R&D on NGTs to non-EU countries, while SMEs may not have the resources to pursue this strategy (100% of the large companies vs. 20% SMEs according to a recent survey)[100]. Regulatory developments in third countries (section 1.4) affect negatively the competitiveness of the EU biotechnology and breeding sectors, in particular of SMEs, on international markets which is also contributing to weakening the EU's strategic autonomy.

In the public consultation, **academic/research institutions** emphasised the negative impact of the current situation on the competitiveness of the EU research sector, compared to other countries with a more enabling environment. Researchers consider the current regulatory situation as hindering funding decisions by public and private funders and report that, since the CJEU ruling, several R&D projects were cancelled or shifted abroad. A recent survey suggests a reduction of 33-40% of R&D activities after the ruling[101]. Young researchers indicate that the EU has become less attractive for a career in agricultural biotechnology, leading to a brain drain and recruitment challenges[102]. This could further widen the already established patenting gap between the EU and US/China in agricultural biotechnology that emerged since 1998[103].

[99] Regulatory certainty is the predictability that a product fulfilling the requirements is authorised for placing on market in a given time.
[100] Jorasch (2020)
[101] Ibid.
[102] http;//www.genesproutinitiative.com/about-us/
[103] WIPO (2019)

Stakeholders from the **bio-based economy** consider genome-editing as a key enabling technology[104]. The existing regulatory framework is seen as an obstacle to innovation in this sector, which will increase the EU's dependence on technological developments coming from other parts in the world[105].

The existing regulatory problems affect also **farmers**. Farmers are deprived of tools and products that could contribute to improving the yield/input ratio, to dealing with the challenges of climate change and to meeting reduction targets for pesticides and fertilisers. Climate impacts have led to poorer harvests and higher production costs, affecting price, quantity and the quality of farmed products in parts of the EU. Climate change impacts on agriculture are projected to lead up to 1% average gross domestic product loss by 2050 but with large regional differences[106]. Plant breeding is one effective counter measure against such climate change impacts. Adapting crop varieties to rapid climate change by breeding requires making rapid incremental changes in the best adapted varieties to keep pace with changes in the biotic and abiotic environment, to ensure food security[107] and to support the transition to sustainable agriculture. While conventional breeding has led to a continuous improvement of a wide range of traits[108], NGTs are crucial technologies enabling a more rapid and targeted breeding progress.

Consumers prepared to accept products of biotechnology will have to forego benefits from products that could be designed to meet their expectations and needs (e.g. improved taste, improved nutrient profile or reduced allergen content). NGTs can improve the taste of green leafy vegetables, which are an important source of vitamins, minerals, and phenolic compounds[109], or reduce the content of the potential carcinogen acrylamide in wheat[110].

The current situation has also a negative impact on **international trade**. In practical terms, the current regulation is seen as an obstacle for the importation of commodities derived from NGTs[111]. The current GMO regulation has resulted in lost trade opportunities due to temporarily closed borders, testing costs, lawsuits, and disputes[112], whereas asynchronous authorisations create uncertainty for importers and exporters[113]. The situation for NGTs may be even more challenging compared to conventional GMOs due to the existing difficulties in analytical detection possibilities.

National public authorities will face enforcement challenges. For example, if the same genetic alteration can be introduced by NGTs or conventional breeding methods, the enforcement authorities, by detecting the alteration, will not be able to assess whether the product is a GMO subject to the GMO legislation or not.

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[104] Key enabling technologies are knowledge-intensive technologies that have been identified as drivers of innovation in different economic sectors and are characterized by a high degree of R&D.
[105] Wesseler *et al*. (2019).
[106] EEA (2019) Climate change adaptation in the agriculture sector in Europe.
[107] Challinor *et al*. (2016)
[108] Voss-Fels *et al*. (2019); this paper, importantly, shows that breeding for increased yields does not necessarily come at the expense of sustainability-related traits. In wheat, over the past 50 years, increased yield was accompanied by improved disease resistance, nutrient use efficiency and photosynthetic efficiency.
[109] Karlson *et al*. (2022)
[110] Raffan *et al*. (2023).
[111] Purnhagen & Wesseler (2021)
[112] Smyth (2017)
[113] Zimney & Sowa (2021); Eriksson *et al*. (2019); Purnhagen & Wesseler (2021).

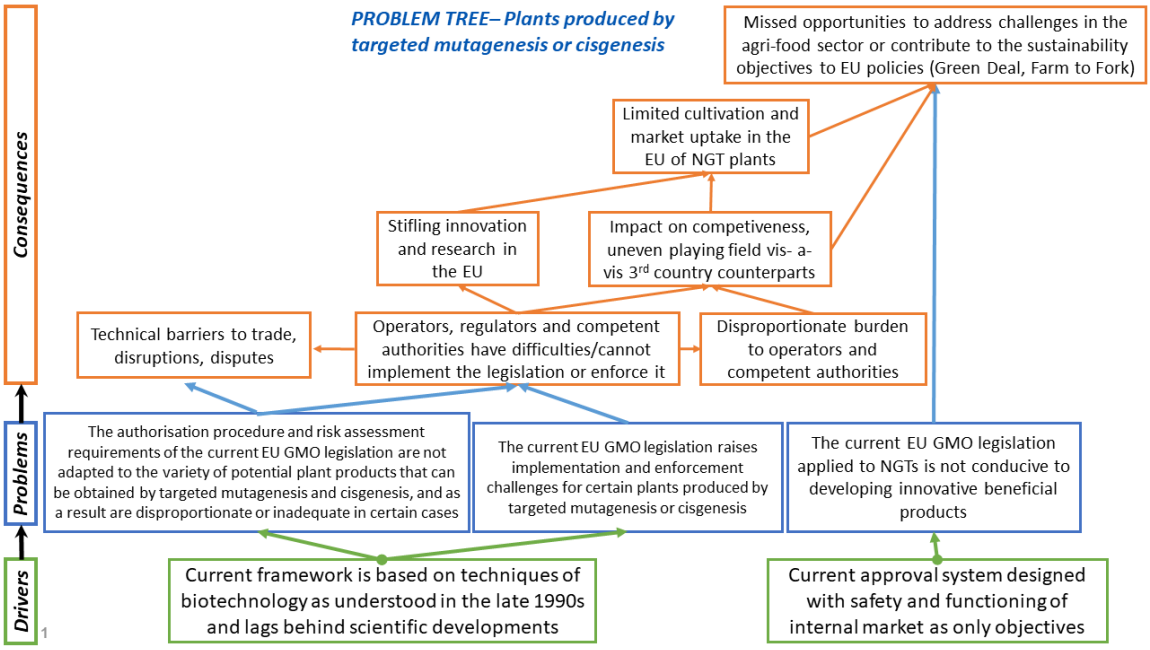

Figure 1. Drivers, problems and consequences for plants produced by targeted mutagenesis and cisgenesis.

2.3. What are the problem drivers?

There are two main drivers behind the problems presented above (Annex 9):

I) **The current framework is based on genetic modification techniques as understood in the late 1990s, and lags behind scientific developments.** After more than 20 years of rapid scientific progress in this field, the current legal framework is based on an outdated understanding of the technical possibilities offered by modern biotechnology, especially regarding plants produced by targeted mutagenesis and cisgenesis. The current system has been designed based on the experience with transgenic products, with requirements fit for products containing foreign genetic material from sexually incompatible organisms, and which therefore would not generally occur in nature. In addition, the legislation has limitations in keeping up with developments in this rapidly evolving field, where new techniques are discovered and applied.

II) The authorisation system in the current framework was designed with safety and the functioning of internal market as the primary objectives; **it is not conducive to developing innovative NGT products and to placing them on the market, and therefore, translating their sustainability potential to reality.**

2.4. How likely is the problem to persist?

If no action is taken, the problems described will persist and be aggravated. Plants obtained by targeted mutagenesis and cisgenesis will continue to be regulated under the current EU GMO legislation, with the current risk assessment, authorisation, traceability and labelling requirements. As the findings of the consultations suggested, limited research and development of NGT products in the EU is expected. A recent survey suggests that a significant share of companies (38%) has delayed product development following the clarification of the CJEU that these products fall under the current EU GMO legislation[114].

The cultivation and market uptake of these products would remain limited in the EU. The high costs and long time needed for authorisation of NGT products – in addition to the

[114] Jorasch (2020).

potentially high licensing costs for access to these technologies – would make these products unattractive for SMEs and the existing market structure, with only large companies having the resources to develop and bring them to the market, would persist. For example, according to the information from breeders provided in the targeted survey responses and interviews, in terms of time to market, the length of the current risk assessment for GMOs is estimated to be on average 6 years for cultivation and 4.5 years for food/feed respectively, making the total time to market (including R&D) under the current framework 16.5 years on average. Operators and consumers would face difficulties accessing new products that could meet their expectations and needs. Obstacles would remain for innovative plant biotechnology to contribute to the objectives of the European Green Deal and Farm to Fork Strategy.

In some cases, applicants will not be able to meet the detection method requirements as they stand today and the NGT plants concerned will not be able to obtain authorisation.

At international level, research and development and commercialisation of these products will increase in most major EU trade partners. With the existing difficulties in analytical detection, the above developments are expected to further complicate the enforcement and implementation of the EU GMO legislation, will negatively impact trade and could raise questions of compatibility with WTO law. More challenging and expensive identity preservation systems for both NGT and NGT-free products from the EU trade partners would be required. Regulatory divergence could lead to forced separation of entire agricultural value chains in and outside the EU, reduced availability of imports due to an unwillingness of trade partners to comply with labelling and segregation requirements, resulting in higher costs and input prices. The organic and GM-free value chain will continue to rely on the labelling and traceability requirements in the existing GMO legislation to build up reliable value chains and consumer trust for their products, and they consider that the current GMO legislation is the appropriate legal instrument to deal with these problems. However, they will also be affected by the challenge of avoiding unintended use of NGT-based inputs such as seed materials, feed, or food ingredients.

The persistence and aggravation of the problem is also illustrated by some of the megatrends identified[115] by JRC. In particular, the megatrends climate change, environmental degradation and aggravating resource scarcity are environmental changes that could create new challenges in terms of food availability and resilience. NGTs could be one tool contributing to the necessary adaptation of the food systems at global level.

3. Why should the EU act?

3.1. Legal basis

EU legislation on GMOs is based on Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU). These articles provide the legal basis for the EU to adopt measures which have as their objective to implement the common agricultural policy (Article 43), and to ensure the good functioning of the internal market (Article 114(1)) while maintaining a high level of human health protection in the veterinary and phytosanitary fields

[115] On 15 February 2022, the JRC (unit I.2, Competence Centre on Foresight) organised a Megatrends Analysis workshop in the context of this impact assessment. Megatrends are one of the tools used in foresight, i.e. the structured, systemic and participatory exploration of the future with the aim to better understand and anticipate possible developments, and to prepare for and shape the future. Out of the 14 megatrends 'Aggravating resource scarcity', 'Shifting health challenges', 'Climate change and environmental degradation' and 'Continuing urbanisation' were selected as highly relevant for the initiative. Furthermore, 'Trust' was identified as a major element for the future development and application of NGTs.

(Article 168(4)(b)). The objectives of this initiative are aligned with these legal bases and, in addition, this initiative tries to ensure that plants obtained by targeted mutagenesis and cisgenesis, and food and feed products produced from them contribute to the sustainability goals of the Green Deal and Farm to Fork strategies. In that regard, the EU's common agricultural policy's objectives of ensuring the rational development of agricultural production and the optimal use of the factors of production, as well as to assure food security and the availability of supplies have particular relevance.

3.2. Subsidiarity: Necessity of EU action

Plants obtained by targeted mutagenesis and cisgenesis are living organisms which, as any other plant, when released into the environment for experimental purposes or as commercial products, may reproduce in the environment and cross national borders. It is essential to achieve a harmonised, high level of protection of human and animal health and the environment in relation to these plants and of food and feed derived from them so that they may circulate freely within a smooth-functioning internal market. In addition, the EU Farm to Fork Strategy recognises the potential of NGTs as a possible tool to increase sustainability of the food system and bring benefits to society as a whole.

The requirements for the deliberate release and the placing on the market of NGT plants and their derived food and feed are already harmonised at EU level under the existing legal framework applicable to GMOs but need to be adapted to the specificities of plants obtained by these new techniques. Carving out NGT plants from the current EU legal framework and leaving it to Member States to regulate them would likely lead to different regulatory requirements and levels of protection in the EU Member States. Differing national requirements for NGT plants would hinder the free movement of these products, fragment the internal market and lead to uneven competition between economic operators. It would also impact access of NGT products to the market and thereby limit their potential to contribute to the international competitiveness, strategic autonomy and sustainability of the EU's food system.

3.3. Subsidiarity: Added value of EU action

Compared to individual action by Member States, EU intervention would provide uniform rules for the development and placing on the market of NGT plants and their food and feed products. Harmonised EU-wide rules on the marketing of such products would ensure a level-playing field for operators within the single market and a more predictable and efficient regulatory oversight. Furthermore, there is an urgent need to ensure availability to farmers, food operators and consumers of plant varieties that can cope with challenges of a global nature such as climate change and biodiversity reduction, which have been further aggravated by the present geopolitical and energy crisis in Europe, and to secure food security in the future. The Farm to Fork Strategy recognised the role that biotechnology can play in meeting those global challenges, which need an EU-wide response.

4. Objectives: What is to be achieved?

The intervention logic is presented in Annex 10.

4.1. General objectives

I) Maintain a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle.

II) Enable the development and placing on the market of plants and plant products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies.

III) Ensure the effective functioning of the internal market and enhance the competitiveness of the EU agri-food sector at the EU and global level, providing a level-playing field for its operators.

Compared to the current GMO legislation, general objectives (I) and partially (III) are the same, i.e. to protect human and animal health and the environment and to ensure the effective functioning of the internal market. In line with the European Green Deal and its Farm to Fork and Biodiversity Strategies, an objective on sustainability is also included (general objective II). It encompasses the three dimensions of sustainability: economic (e.g., higher yield/input ratio), social/health (e.g., improved nutrient content) and environmental (e.g., resistance to pests, less need for fertilisers). An additional objective relates to the competitiveness of the EU agri-food sector at EU and global level (included in general objective III), which contributes to food security and EU's strategic autonomy.

4.2. Specific objectives

I) Procedures for the deliberate release and placing on the market ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden.

This objective takes into account the diversity of NGT products, based on their risk profiles, and addresses current implementation and enforcement challenges, in particular for NGT plants that could also occur in nature or be conventionally bred.

In this respect, the objective addresses specifically problem components (I) and (II) and drivers (I) and (II).

II) Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers.

This objective is linked to innovation in plant breeding that 1) brings to the market products that cater for the diversity of needs of farmers and consumers and address local and regional specificities; 2) facilitates access of new players (such as SMEs, public institutes) to the market.

In this respect, the objective addresses problem component (III) and driver (II).

III) NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system.

This objective aims to steer plant breeding to plants with traits that have been identified as being useful in view of sustainability objectives (economic, environmental, social/health).

In this respect, the objective addresses specifically problem component (III) and driver (II).

Figure 2 presents the relationship between the general and specific objectives.

	GENERAL OBJECTIVE 1: MAINTAIN A HIGH LEVEL OF PROTECTION OF HUMAN AND ANIMAL HEALTH AND OF THE ENVIRONMENT IN ACCORDANCE WITH THE PRECAUTIONARY PRINCIPLE	GENERAL OBJECTIVE 2: ENABLE THE DEVELOPMENT AND PLACING ON THE MARKET OF PLANTS AND DERIVED FOOD/FEED PRODUCTS CONTRIBUTING TO THE INNOVATION AND SUSTAINABILITY OBJECTIVES OF THE EUROPEAN GREEN DEAL AND OF THE FARM TO FORK AND BIODIVERSITY STRATEGIES	GENERAL OBJECTIVE 3: ENSURE THE EFFECTIVE FUNCTIONING OF THE INTERNAL MARKET AND ENHANCE THE COMPETITIVENESS OF THE EU AGRI-FOOD SECTOR AT EU AND GLOBAL LEVEL, PROVIDING A LEVEL-PLAYING FIELD FOR ITS OPERATORS
SO1: Procedures for the deliberate release and placing on the market ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden	✓	✓	✓
SO2: Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers		✓	✓
SO3: NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system		✓	✓

Figure 2. General and specific objectives.

5. What are the available policy options?

To respond to the specific objectives, this impact assessment considers a range of policy elements: procedure for the release or placing on the market and risk assessment, traceability, labelling/transparency, detection method requirements and sustainability. Sustainability is a novel element, compared to the current GMO legislation, linked to general objective (II). The others are all elements of the current GMO legislation, and for these, in addition to the status quo, possible adaptations to the specificity of NGT plants are considered.

The possible choices for each of these policy elements reflect the full range of stakeholders' views submitted in the context of the Commission 2021 NGT study and the inception impact assessment as well as other consultation activities carried out in the context of this impact assessment. They take into account scientific opinions of EFSA and other scientific bodies and relevant scientific literature. Stakeholders concerned about the safety or other aspects of GMOs and NGTs in general favour the continued application of the existing GMO legislation to NGTs. This report takes these views into account by treating the baseline (no change) as a viable policy option with a full assessment of its impacts. Impacts on specific sectors (organic and GM-free) that express concerns about NGTs are specifically assessed for each policy option in section 6.

The key policy choices for each of the policy elements are presented in Figure 3.

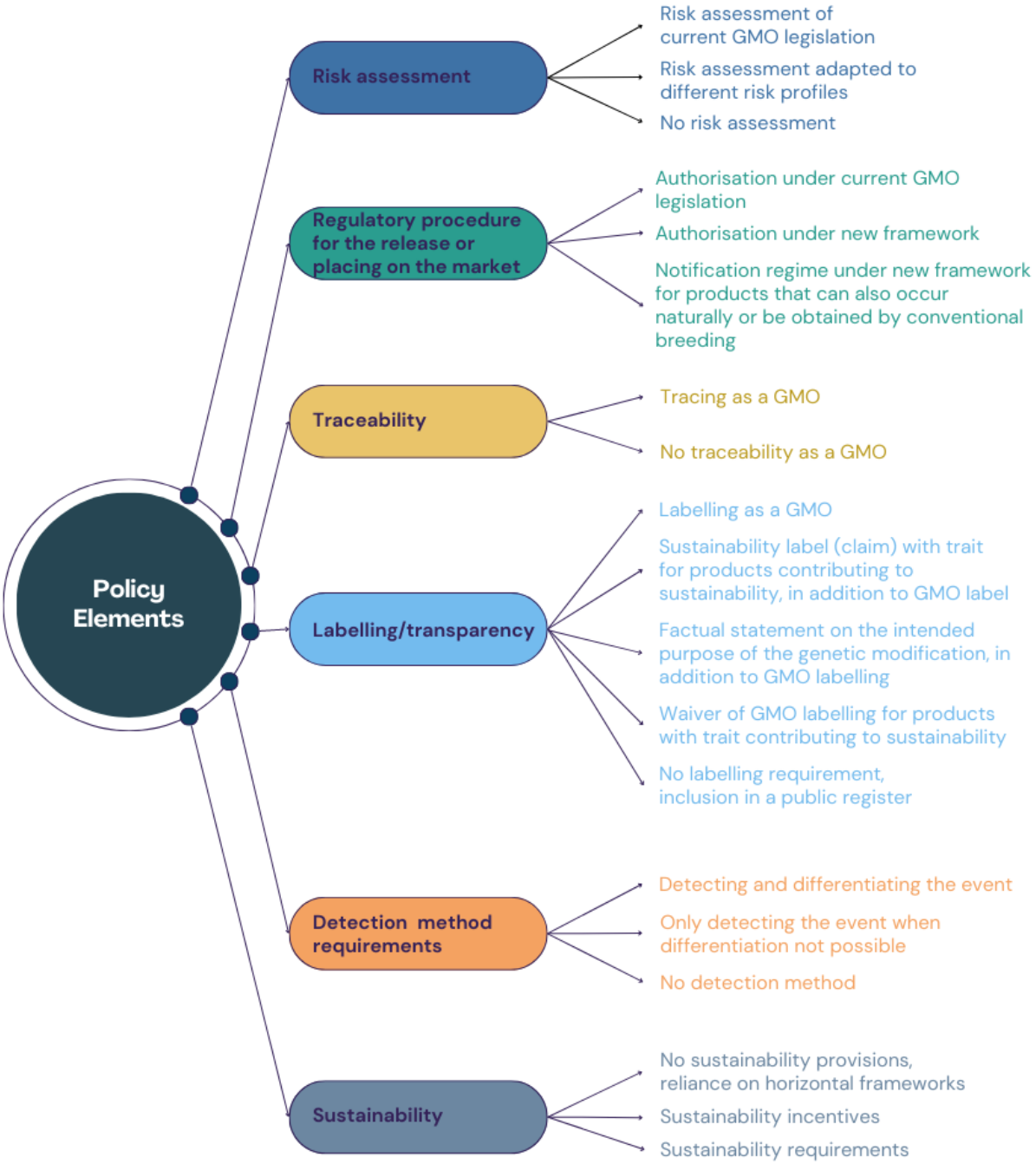

Figure 3. Policy elements.

The issue of how to steer the development of varieties with traits that contribute to sustainability is not specific to NGTs. It applies equally to conventionally bred plants and to GMOs not covered by this initiative. Therefore, the policy choices as regards sustainability include (in addition to the possibility of specific provisions in this initiative) addressing this issue in other, horizontal initiatives (FSFS; PRM/FRM) as a feasible option. Assessing such an option reflects the majority view among stakeholder groups resulting from the public consultation and the targeted survey that sustainability tests only in the context of the NGT initiative are not appropriate, and that a holistic assessment of performance – as done in value for cultivation and use (VCU) testing in the context of the PRM/FRM legislation to which NGTs are also subject – will be far more useful.

Certain of the policy choices above (no risk assessment, notification procedure[116], no tracing as GMO) have only been considered as feasible options for a limited range of NGT plants, namely those which could be obtained naturally or by conventional breeding methods, based on the risk profile of such NGT plants. Therefore, option 4 (which incorporates this policy choice) is only assessed as regards such NGT plants. All other options (baseline, options 1 to 3) are assessed as regards all NGT plants under the scope of the initiative (both those that could or could not occur naturally or be produced by conventional breeding).

The choices for each element have been combined into policy options (see Figure 4). These represent a range of distinct approaches to the regulation of NGTs. Their impacts including the trade-offs between elements are analysed in section 6. These options represent combinations of the different choices for the main elements (risk assessment, regulatory procedure, etc.) that have been considered feasible and coherent (see section 5.3 for a discussion on discarded combinations).

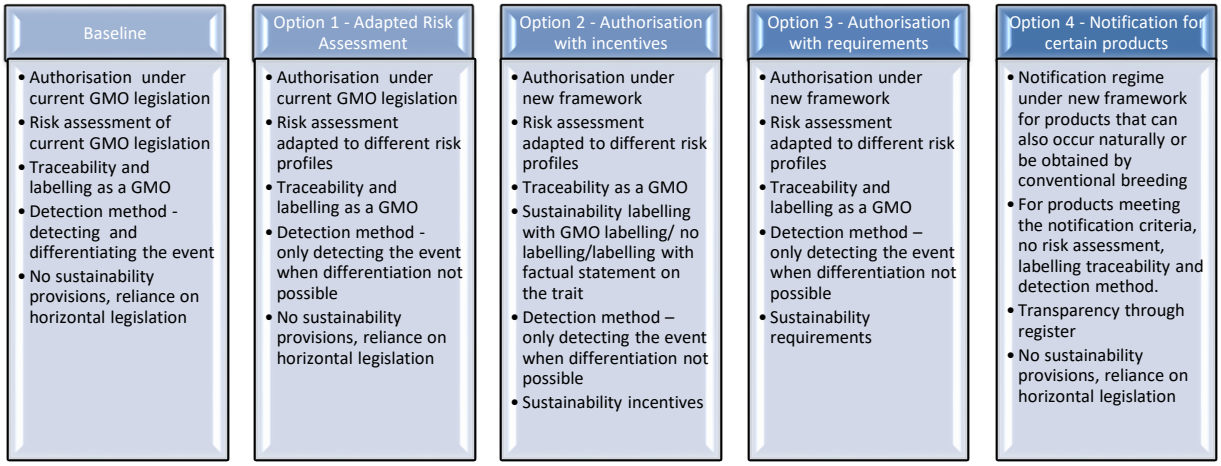

Figure 4. Policy options.

The policy instrument considered under all four policy options is a Regulation. The authorisation procedures in options 1 to 3 as well as the notification system in option 4 are based on fully harmonised criteria and requirements and procedures that should lead to the authorisation or acceptance of a notification for the whole EU, ensuring the same level of protection of health and the environment and the availability of the products concerned across the EU. A Regulation appears to be the most appropriate legal instrument to embody such procedures, as well as to achieve a uniform implementation of the policy intervention, which has an important internal market component. That instrument would be complemented by any necessary amendments of existing legislation

5.1. What is the baseline from which options are assessed?

The current regulatory framework would remain applicable, meaning that plants obtained by targeted mutagenesis or cisgenesis, whether cultivated in the EU or imported, and food and feed produced from them, would require authorisation for their release including placing on the market. An authorisation would also be required for field trials on such NGT plants carried out within the EU.

The authorisation procedure for the placing on the market of NGT plants (as such or in food and feed products) would be conducted at EU level (risk assessment by EFSA and decision by

[116] In the legislative proposal, 'notification procedure' is referred to as ‘verification procedure’.

the Commission), whereas the procedure to authorise the deliberate release of NGT plants for other purposes (e.g., field trials) would be conducted by Member States (national authority to which the application is submitted, with the involvement of EFSA in case of objections raised by the Commission or another Member State).

All current authorisation requirements would apply, i.e. risk assessment to show that the NGT plant does not present more potential hazards than its conventional counterparts, with current requirements that contain only limited scope to adapt according to the risk profile of the plant; the requirement to provide an event-specific detection method (that is, which can both detect the event and differentiate it from other events); tracing as a GMO (obligation to transmit and hold information for a period of five years that a product contains or consists of a GMO, including its unique identifier, and that food or feed is produced from a GMO, at each stage of their placing on the market); labelling requirement for products destined to consumers that contain or consist of GMOs and for food and feed produced from GMOs. Authorised products would be subject to post-market obligations (monitoring for a certain time-period, duty to submit new information relevant to the assessment of risks, renewal every 10 years).

Sustainability would be addressed by sustainability-related provisions included in the relevant horizontal and sectoral legislation (e.g. FSFS, PRM[117], FRM), where applicable.

5.2. Description of the policy options

5.2.1. Option 1: Authorisation with adapted risk assessment and detection method requirements

The legislation would be adapted to cater for the diverse risk profiles of plants obtained by targeted mutagenesis and cisgenesis and to address the implementation and enforcement challenges related to detection.

NGT plants and food and feed produced from them would require (as today) an authorisation to be used in field trials, cultivated or placed on the market, granted as today if the NGT plant is shown not to present more potential hazards than its conventionally counterparts. Risk assessment and detection method requirements, adapted to the diversity of these plants, would replace the current requirements, while maintaining the general principles and methodologies.

To that end, general principles for risk assessment would be set in the legislation. They would be accompanied by criteria to inform the adaptation of data requirements to risk profiles. An indicative list of criteria for an adapted risk assessment[118] is presented in Box 1. They provide the starting point for the design of an adapted risk assessment in the legislation. Specific data requirements based on the criteria would be set in tertiary legislation and/or by EFSA.

As regards the authorities competent for the regulatory procedures, as today, the risk assessment would be carried out by EFSA (for placing on the market, including cultivation, for food/feed uses) or by national authorities (for field trials and for placing on the market, including cultivation, for non-food/feed uses). Member States would remain responsible for granting consent for experimental releases within their territories (field trials). Authorisation for the placing on the market for cultivation and food and feed uses would be given at EU-level through an authorisation decision by the Commission.

[117] European Commission (2023b) Annex 5, Section 5.
[118] EFSA (2022c)

Box 1 - Criteria proposed by EFSA for adapted risk assessment of plants obtained by targeted mutagenesis and cisgenesis[119]:

The first four of the six criteria related to the molecular characterisation of the genetic modification introduced in the recipient plant. They evaluate:

1. If exogenous DNA sequence is present
2. If yes, whether the sequence is from the breeders' gene pool (if it is not, the plant is transgenic and therefore out of the scope of this initiative)
3. How the sequence is integrated, for example is it random or targeted?
4. If any host plant gene was "interrupted" (split) by the newly introduced sequence

Criteria 1-4 are designed to establish if cisgenic and intragenic sequences have altered the host plant's genes. If they have not, or if no risk is identified when an exogenous DNA sequence has been introduced, two further criteria apply:

5. Do the introduced or modified sequence and the associated trait have a history of use?
6. If not, the structure and function of the modified versions of the DNA sequence ("allele") should be carefully assessed.

These last two criteria apply also to plants produced by targeted mutagenesis.

The requirement for an event-specific detection method would be waived if the applicant can justify that developing a detection method that can, not only detect, but also differentiate a specific NGT product from conventional ones that contain the same modification(s) is not technically possible. The applicant would still need to submit an analytical method capable of detecting the product.

Other legal requirements, such as those on traceability, labelling and post-market provisions, would remain as in the baseline.

Sustainability would be addressed by sustainability-related provisions included in relevant horizontal and sectoral legislation (e.g. FSFS, PRM, FRM), where applicable.

5.2.2. Option 2: Authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability

The legislation would be adapted to cater for the diverse risk profiles of NGT plants and to address the implementation and enforcement challenges related to detection (as in Option 1) and to incentivise the development and placing on the market of plant products that could contribute to a sustainable agri-food system.

NGT plants and food and feed produced from them would require an authorisation to be used in field trials, cultivated or placed on the market, with adapted risk assessment and detection method requirements (as in Option 1). The competent authorities will be as in option 1.

In addition, regulatory incentives – granted by the authorities competent for the procedure concerned (at national or EU level) - would be introduced for NGT plants containing traits that could contribute to sustainability to encourage the development of sustainable products. The regulatory incentives considered in the impact assessment are: the provision of regulatory and scientific advice before and during the authorisation procedure (guidance on the overall development plan and the regulatory procedure, dedicated contact point in EFSA, scientific advice at key development milestones) and measures to facilitate the authorisation process

[119] EFSA (2022d)

(waiving of detection method validation fees, faster procedures). During the consultation activities various stakeholders, in particular breeders, considered waiving labelling as GMO as the measure that would have greater impact.

Incentives would be linked to the modified trait in the NGT plant and its potential impacts on sustainability (economic, environmental, and social). The basis for this comparison would be data provided by the applicant on the characterisation of the modified trait and a pre-defined list of desirable sustainability impacts to be set out in the legislation. NGT plants would also be subject to all sustainability-related provisions included in relevant horizontal and sectoral legislation (e.g. FSFS, PRM, FRM), where applicable.

Traceability and post-market provisions would remain a requirement as in the baseline. With a view to further steering development towards desirable traits from a sustainability perspective, in addition to the regulatory incentives, the following sub-options on labelling have been considered under this option:

- A sustainability label (claim) would be added to the GMO label for products that contribute to sustainability referring to the introduced trait.
- A factual statement on the intended purpose of the genetic modification would be added to the GMO label.
- The GMO labelling requirement would be waived for products with a modified trait that is considered to have the potential to contribute to sustainability.

5.2.3. Option 3: Authorisation with the requirement that products do not contain modified traits that can be detrimental to sustainability

The legislation would be adapted to cater for the diverse risk profiles of NGT plants and to address the implementation and enforcement challenges related to detection (as in Option 1) and to discourage the development of unsustainable products.

NGT plants and food and feed produced from them would require an authorisation to be used in field trials, cultivated or placed on the market, with adapted risk assessment and detection method requirements (as in Option 1). The competent authorities will be as in option 1.

A prerequisite for authorisation – verified by the authorities competent for the procedure concerned (at national or EU level) - would be that applicants show that the introduced trait is not detrimental to sustainability (economic, environmental, and social). The basis for this comparison would be data provided by the applicant on the characterisation of the modified trait and a pre-defined list of undesirable sustainability impacts to be set out in the legislation. NGT plants would also be subject to any sustainability-related provisions included in relevant horizontal and sectoral legislation (e.g. FSFS, PRM, FRM), where applicable.

The additional requirement of this option is not linked to potential safety issues of the specific NGT plant (i.e. risks to health or the environment that result from the genetic modification). This is addressed by the risk assessment that features in this option (as well as in the baseline and in options 1 and 2, and by the notification criteria in option 4). Rather, the concrete sustainability requirement of this option relates to the fact that NGTs could reach the market featuring traits that, ultimately may have negative effects (e.g. herbicide-tolerant traits that have been found to in some cases to lead to increased pesticide use or development of resistance in weeds).

Traceability, labelling and post-marketing provisions would remain as today (baseline).

5.2.4. Option 4: Notification of products that could also occur naturally or be produced by conventional breeding

Option 4 is intended to apply to only a part of the scope of this initiative, i.e. to NGT plants that could also occur naturally or be produced by conventional breeding. These would be treated similarly to conventional plants.

This option would introduce a notification procedure for NGT plants based on criteria set out in the legislation to verify whether a product could also occur naturally or be produced by conventional breeding. An indicative list of these criteria is presented in Box 2. The criteria are based on a scientific literature analysis and take into account the work of JRC and EFSA as well as feedback received in the consultation activities for this impact assessment. A thorough analysis of the literature confirmed that targeted mutagenesis and cisgenesis techniques can lead to genetic modifications that are similar to mutations occurring naturally or resulting from conventional breeding techniques (including random mutagenesis techniques). These mutations include substitutions, insertions (including translocations and inversions) and deletions of nucleotides in the DNA. Such mutations are commonly observed with conventional breeding techniques and span a range of sizes: substitutions and insertions of limited size as well as deletions of variable dimensions are frequently reported. Larger translocations, inversions and genome duplications may also occur naturally. Insertions of cisgenes or part of cisgenes are also possible through natural processes, crossing or conventional breeding; with natural crossing or conventional breeding, the insertion of a cisgene (or part of) generally takes place in locations where the gene is naturally occurring in its breeders' gene pool. As regards the total number of modifications introduced by conventional breeding techniques, literature shows that it is also variable depending on the organism and the method used.

The criteria are product rather than technique-based, reflecting the majority scientific view (including of EFSA) that the risk profile is not mainly dependent on the technique used but rather on factors related to the product itself. They are designed to cover the type and extent of modifications that are also observed with conventional breeding techniques, to ensure that the NGT plants fulfilling these criteria would not present more potential hazards for human or animal health and the environment than conventionally bred plants. They are also designed to be objective to ensure predictability for developers and uniform applicability by the assessment bodies (EFSA and Member States authorities).

As shown by the scientific literature analysis, conventional breeding techniques can lead to a high number of modifications. However, certain combinations of modifications would be less likely to occur by conventional methods. To take this into account, following a conservative approach and considering the novelty of new genomic techniques, the criteria would be complemented by thresholds for both size and combination of modifications, also to ensure that plants obtained by complex modifications are excluded from the notification procedure.

Box 2 - Indicative list of criteria for the notification procedure:

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than a maximum number of genetic modifications of the types referred to in points 1 to 5, in predictable DNA sequences. A predictable DNA sequence is any DNA sequence that shares sequence similarity with the targeted site.

1. Substitution or insertion of no more than a maximum number of nucleotides
2. Deletion of any number of nucleotides.
3. On the condition that the genetic modification does not result in an intragenic plant:
    a. Targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool
    b. Targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool
4. Targeted inversion of a sequence of any number of nucleotides
5. Any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points 1 and/or 2) in a species from the breeders' gene pool.

The regulatory status of the product would be subject to a decision based on the notification criteria. The authority responsible would be:

- If the determination of status is sought prior to conducting field trials, the verification of the criteria and determination of the status would be done by the Member State where the field trial is intended to be carried out. The national decision would have EU-wide effects.
- If the determination of status is sought prior to the placing on the market of NGT plants and products for which no field trials have been carried out in the EU, including imported NGT plants/products, the determination of the status would be done by the Commission, following verification of the criteria by EFSA.

In both cases, appropriate consultation procedures of Member States, the Commission and EFSA would be established. The procedure is illustrated in Annex 11.

For products that meet the notification criteria, no authorisation requirement would apply for the deliberate release, including placing on the market, or to field trials. In addition, there would be no GMO traceability, labelling and post-market monitoring requirements. Transparency would be ensured in a public register that would include information on the product and the modified trait and would link to the notification assessment. The General Food Law and other relevant legislation on traceability, labelling and monitoring of products on the market as applicable to conventionally bred plants would apply.

Sustainability would be addressed by sustainability-related provisions included in relevant horizontal and sectoral legislation (e.g., FSFS, PRM, FRM), where applicable.

There are two sub-options as regards the use in organic production of NGT plants/products fulfilling the notification criteria. In a first sub-option notified NGT plants/products would remain subject to the current ban of the use of GMOs in organic production (which applies in the baseline and options 1 to 3) (see section 1.6.). In a second sub-option, notified NGT plants/products would be treated as conventional products for the purposes of organic production (as is the case today for the products of random mutagenesis), and could be used under certain circumstances (permission to use non-organic agricultural ingredients in processed organic food and feed, the use of non-organic plant reproductive material). The Organic Product Regulation does not require coexistence measures for cultivation when it comes to conventional agriculture. Precautionary measures are used to segregate organic and non-organic during storage, transport, processing.

5.2.5. Combination of option 4 and one of the other options

Options 1, 2 or 3 apply to all types of NGT products. Option 4 applies only to NGT products, which could occur naturally or be obtained by conventional breeding. Therefore, option 4, if retained, would in all cases apply in combination with options 1, 2 or 3 or the baseline. The potential impacts of option 4 and of one of the other options chosen are independent and therefore can be assessed individually. Relevant cumulative impacts of the possible combinations, especially as regards specific objective I (ensuring safety while avoiding unnecessary burden) are discussed in section 7.

5.3. Options discarded at an early stage

An option to initiate a broader legislative action, which would have concerned all NGTs, and all organisms (plants, animals, micro-organisms) was discarded in the light of the Commission NGT study. The latter concluded that for other NGTs and for NGT applications in animals and microorganisms, the necessary scientific knowledge is still limited or lacking, especially on safety aspects. As a result, when announcing the follow-up to the study, the Commission indicated that, as regards animals and microorganisms and other NGTs, it intends to continue to build up the required scientific knowledge, in view of possible further policy actions[120].

An even broader action, covering all genetic modification techniques, was also discarded. This approach would have required an extensive evaluation of the EU GMO legislation, to analyse issues which were not addressed in the Commission NGT study. In its absence, there is no substantial evidence to suggest that the current requirements of the GMO legislation are not suited to the products of established genomic techniques.

The possibility of applying a notification procedure with no risk assessment (as in option 4) to all NGT plants developed with targeted mutagenesis and cisgenesis was discarded in light of the conclusion by EFSA and many other scientific bodies, that targeted mutagenesis and cisgenesis can produce a diversity of plant products with different risk profiles.

An option to exempt targeted mutagenesis from the scope of the GMO legislation entirely, by adding it to Annex IB of Directive 2001/18/EC, was also discarded, although it is requested by certain stakeholders given that random mutagenesis is already exempted in that way. This is linked to the diversity of plant products and risk profiles that can be achieved with all techniques under the scope of this initiative. On that basis, only options entailing a case-by-case regulatory procedure (authorisation or notification) were considered.

As explained above, the policy options each address several elements (procedure for the release or placing on the market and risk assessment, traceability, labelling/transparency, detection method requirements and sustainability) and, in turn, several policy choices were considered for each element. While theoretically this could have led to many different combinations and resulting policy options, policy options 1 to 4 presented above are those that have been considered feasible and internally coherent.

In this regard, it has been considered that products subject to risk assessment call for policy elements such as an authorisation procedure and traceability as GMOs, and these have been packaged together (in options 1, 2 and 3, as in the baseline). Conversely, in the option where risk assessment is not required (option 4), authorisation, traceability and labelling as GMO are not required, as the option is based on the logic of treating the products meeting certain criteria in the same way as the products of conventional breeding.

[120] European Commission (2021e)

6. What are the impacts of the policy options?

Economic, environmental and social (health) impacts of the options were assessed taking into consideration scientific literature, expert views, data collection from public and targeted stakeholder consultations, JRC case studies and quantitative modelling where possible, as explained in Annex IV on the analytical methods. One important input to the impact analysis is the development pipeline of NGT products, i.e. applications that are already being marketed, are at a confirmed pre-market development stage or are at R&D stage but showing market potential, as mapped by the JRC[121].

However, inherent limitations remain. Since specific regulatory frameworks were introduced in several non-EU countries only recently and given the limited number of products[122] on the global market (none in the EU), very few if any data on economic, environmental or social (health) impacts of NGT products are available to date. Furthermore, EU data on cultivation and coexistence with organic[123]/non-GM crops are very limited as almost no GM crops are cultivated in the EU. To address these issues, the impact estimates depend to a large degree on comparison with past developments inside and outside the EU (e.g. for GMOs obtained by established genomic techniques), expert assessments, projections and stakeholder expectations. Wherever possible, these assessments, projections and expectations were checked against relevant data from the scientific literature. In addition, the JRC has conducted three case studies to analyse the potential economic, environmental and social (health) impacts of selected NGT plants that are in the development pipeline[124].

Most findings are qualitative, though estimates of costs, especially regulatory, are provided. Potential benefits are explained and quantified to the extent possible throughout.

A number of fundamental rights enshrined in the Charter of Fundamental Rights of the EU can be impacted by this initiative. These concern the protection of human health (Article 35), of the environment (Article 37), of consumers (consumers' right to information) (Article 38) and the freedom to conduct business (for the agri-food sector and biotechnology operators and researchers) (Article 16). Impacts on those rights are addressed under the economic, environmental, and social impacts analysed below.

1.1. Analysis of the baseline

6.1.1. Economic impacts

Breeders – The current average time to market of an established, single event GMO (including R&D) developed between 2017 and 2022 is 16.5 years and the average costs are approximately EUR 121 m[125]. In the EU, authorisations may be for marketing of food and feed and derived products or for cultivation. Authorisation costs for food and feed uses range

[121] Parisi & Rodriguez Cerezo (2021)

[122] On the market are a higher oleic-acid soybean of Calyxt in the US ('Calyno') (ISAAA, 2019a), a tomato with a non-proteinogenic amino acid (GABA) commercialised under the name Sicilian Rouge High in Japan (Waltz, 2021), drought-tolerant soybeans in Brazil and Colombia (ISAA, 2023a), a waxy maize in Japan (ISAA, 2023b) and a non-browning banana in the Philippines (ISAA, 2023c). The commercial farm production of a modified pennycress (*Thlaspi arvense*), marketed as CoverCress™, started in autumn 2022 in the US. The seeds will be used for large-scale farm trials starting in 2023.

[123] See https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Organic_farming_statistics for data on organic farming in the EU

[124] Schneider *et al.* (2023a, b). Sanchez *et al.* (2023)

[125] AgbioInvestor (2022)

from ~EUR 6 m to EUR 20 m (for authorisations of single event GMOs)[126], and administrative costs range from EUR 2 - 2.7 m[127]. For GMOs developed between 2017 and 2022 by established genomic techniques, the genetic event construction and testing phase represented 55.8% of total costs and 35.6% of the total time. The regulatory phase had the longest duration of the overall process and accounted for 37.6% of total costs and 51.1% of the total time[128]. The time to place NGT products on the market would be shorter than for GMOs obtained by established genomic techniques, because of an accelerated R&D phase: for the latter, the R&D phase can be more than 10 years, while for NGT products the R&D phase is around 5 years[129], thereby reducing the costs of the most expensive phase in product development.

There is little experience with authorisation costs for cultivation in the EU[130], and therefore only approximations are available. Available estimates provided by one company give a range of costs of EUR 17.5 – EUR 28 m for authorisation plus EUR 0.7 – EUR 1 m per year for monitoring.

Breeders identified the regulatory uncertainty about a product being authorised after several years of R&D, regulatory costs and time to market as the main factors making the development of NGT products under the existing GMO framework unattractive. 54.5% of the stakeholders[131] in the targeted survey consider that attractiveness of developing plant varieties using NGTs will decrease and 43.2% consider it will stay the same under this option. Across all participating stakeholders[132], there is the expectation to see very few NGT products on the market for the period 2030-35. Breeders delayed product development and release due to regulatory uncertainty and high regulatory costs (40% response in targeted survey)[133].

It is expected that GMOs, including NGT products, mostly of large-scale commodity crops (e.g., maize, soybean, cotton), would continue to be predominantly developed by large multinational companies, while the high R&D costs, regulatory uncertainty and long duration and costs of authorisations will continue to act as a barrier to market entry for SMEs, which more often focus on niche crops[134]. The baseline is thus not conducive to the freedom of SMEs to conduct business and to their competitiveness by keeping new, innovative technologies out of their reach.

Academia/Research institutes – While there is only anecdotal evidence and warnings that academic mobility and migration of EU plant scientists may be affected by policies of regulating biotechnologies, according to the research sector, in the baseline the EU risks a brain drain when plant researchers leave Europe for better job opportunities abroad[135]. The sector expects a negative impact on the competitiveness of EU research, due to competition from other countries where NGTs are regulated differently, in particular for applied research

[126] Annex 7, section 4 in Technopolis Group *et al*. (2023)
[127] AgbioInvestor (2022)
[128] Ibid.
[129] Lassoued *et al.* (2019)
[130] There has only been one authorisation for cultivation in the EU (maize MON810).
[131] 47.7% (21) strongly decrease, 4.5% (2) moderate decrease, 2.3% (1) small decrease and 43.2% (19) no change. Stakeholder's categories are not included in the data.
[132] The median is overall 0. Across stakeholders the median is: Academic/research organisation = 0, Business association = 0, Consumer organisation = 12.5, Large company = 0, NGO = 0, other = 0
[133]See also Jorasch (2020)
[134] OECD (2018)
[135] The main root causes for academic migration to countries outside the EU are better salaries and better career structures for early-career scientists. See Khan (2021)

in plant pre-breeding and breeding. 41% (n=27) of respondents in the targeted survey expect a decrease in research funding for biotechnology under the baseline option.

Business associations see a negative impact on firm-level innovation in the agricultural biotech sector, also impacting biotechnology research capabilities in the food and feed sectors. However, in EU research activities, the use of NGTs is well established and notable funding is allocated to genomic research and biotechnology in plant and animal breeding.

Public authorities – With no regulatory change, the cost per authorisation (both for food and feed uses and for cultivation) is expected to remain stable. With very few NGT products expected to be authorised, it is likely that the overall costs for public authorities remain stable. National public authorities will face enforcement challenges when the same genetic alteration can be introduced by NGTs (subject to the GMO legislation), or conventional breeding methods.

Conventional farmers – Impacts on farmers concern increased imports of more competitively produced crops from non-EU countries and potential missed opportunities, in particular regarding reduced costs for inputs (reductions in the amount of pesticides, fertilisers), improved yield/input ratio, new income opportunities or better prospects for exports.

The shorter development time of NGT plants compared to conventional breeding not being realised also means that farmers will have to wait longer for new varieties with beneficial traits or offering new income possibilities if no or very few NGT plants come to the market. Farmers will have to forego potential improvements of the yield/input ratio, reduced input use or economic benefits from quality increases of crops. If farmers cultivate NGTs under this option, they have to implement the nationally applicable coexistence measures (for more detail see the analysis of coexistence under option 1).

Organic/GM-free farmers and value chain – The EU organic and non-GMO sectors consider that the baseline option is the one that best protects their sector. If the current situation is maintained, the labelling and traceability requirements in the existing GMO legislation, as well as national coexistence measures, will remain as today and continue to support EU value chains and consumer trust for organic and other GM-free producers. As few NGT products will reach the market, with very limited cultivation, only a small risk of admixture of NGTs can be expected.

However, certain negative impacts may also materialise. Increased costs for organic operators could arise from NGT products that cannot be analytically differentiated from products that can occur naturally or be produced by conventional breeding, despite the fact that specific GMO traceability and labelling obligations will apply to such NGT products. More challenging and expensive identity preservation systems for NGT-free products would be required, possibly leading to higher prices of GM-free products[136]. Research has shown that coexistence of GM and non-GM products within food supply chains leads to extra costs for the non-GM food product. Depending on the segregation strategy undertaken in rapeseed oil and maize starch supply chains, it was estimated that ensuring coexistence leads to increased prices for the non-GM product of between 7 and 14%[137]. For NGTs that cannot be analytically differentiated, these price increases could be higher as further steps might have to be taken to guarantee the integrity of the supply, such as additional documentation and third-party verification.

[136] IFOAM EU & FiBL (2017)
[137] Gabriel & Menrad (2015)

Regulatory divergence with non-EU countries (where NGT products may not be subject to traceability and labelling rules or to any transparency obligations) from which organic or other GM-free products are imported may also impact the organic sector. For example, Argentina, where many NGTs are neither traced nor labelled, has been a major exporter of organic products to the EU (in the range of 10 000 – 50 000 tons per year), in particular of fruits, wine and vegetables. To continue imports of NGT-free products from countries with a regulatory framework similar to Argentina's may require adjustments to supply chain management, for which no quantitative estimates of costs are available. Under the current EU regulatory framework, NGTs should not be used in organic products exported to the EU, therefore, the costs of segregated supply chains in the EU would remain unchanged.

Regulatory divergence may also impact the availability and development of organic varieties. Under the breeders' exemption[138], breeders are allowed to freely use protected varieties as sources of further variation for the development of new varieties. If protected varieties of interest for organic breeders originate in non-EU countries that have exempted NGT plants from GMO labelling and traceability obligations, then organic breeders may have no guarantee that those are not derived from NGTs. Consequently, sourcing such varieties may become difficult and in the longer term, organic breeders may thus experience a decrease in the availability of genetic resources for their breeding programmes, leading to fewer improved varieties adapted to the needs of organic agriculture[139].

Trade impacts – International trade with NGT products will be affected by regulatory divergence with trade partners. Several major trade partners of the EU have introduced exemptions from their GMO legislation – or are preparing to introduce them – for NGT products, and this may lead to asynchronous approvals of NGT products. This could lead to a costly need to separate entire agricultural value chains in and outside the EU[140]. As trade partners might be unwilling or unable to establish such separate value chains[141], most targeted survey respondents (60.7%, 37) expect a decrease of international trade under this option. The consequences of market disruptions caused by the unintended presence of unauthorised GMOs can be significant. For example, in 2009, a genetically modified flax from Canada, not authorised in the EU, was detected in EU food products[142] and the EU immediately stopped Canadian flax imports. This resulted in an estimated loss of EUR 40 m for the EU flax processing industry and 600 jobs lost[143].

Impact on SMEs – The current situation with large, multinational companies dominating the market for GMOs is likely to apply to NGTs as well. While R&D costs for NGT products will be considerably lower than for GMOs obtained by established genomic techniques, authorisation costs would remain in the range of EUR 6 – 20 m, which is a significant part of the yearly turnover of a SME.

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[138] Article 15(1)(iii): The breeder's right shall not extend to (...) (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

[139] IFOAM EU & FiBL (2017)

[140] Eriksson *et al*. (2019)

[141] Gabriel & Menrad (2015)

[142] The genetically modified flax ("Triffid flax") was a flax variety that was genetically engineered for resistance to soil residues of sulfonylurea-based herbicides. To ensure that Triffid flax would not jeopardize future export markets, the transgenic flax variety was deregistered in 2001. In late 2009, Triffid flax was detected in bakery goods, cereals, and other products made by companies throughout the EU. See Ryan & Smyth (2019)

[143] Ryan & Smyth (2012)

Competitiveness – The reduced costs of and time needed for R&D of NGT products could lead overall to lower costs for the EU breeding and biotech sector[144]. However, breeders in non-EU countries that exempt NGTs, can save all the costs related to GMO authorisations (35.8% of the total cost to develop and place on the market a GMO obtained by established genomic techniques) and place products faster on the market, while the regulatory entry barriers for NGT products remain higher in the EU. This will give competitors in non-EU countries a considerable advantage.

6.1.2. Environmental impacts

Among environmental impacts, a distinction should be made between environmental impacts specifically linked to the genetic modification or the introduced trait(s) and other environmental impacts that are associated to the use of the plant in the field in relation to its trait(s). While the first are specific for the NGT plant, the second may be common to other plants, regardless of the breeding method used, sharing the same trait and use (an example being the herbicide tolerant plants discussed further below).

As regards potential risks specifically linked to the genetic modification, NGT plants and their products will only be authorised and released in the environment if the risk assessment concludes that they are as safe as their conventional counterparts. In addition, NGT products released or placed on the market will be subject to various monitoring provisions intended to identify and take measures in response to any potential adverse effect.

As regards other environmental impacts, since no or only very few applications for cultivation of NGT plants are expected if they remain regulated by the current GMO legislation, the environmental impacts of these products will be limited. Impacts will be mostly restricted to missed potential benefits stemming from NGT plants contributing to, for example, lower pesticide use, lower fertiliser use, reduced need for agricultural land and more space for nature with higher biodiversity[145].

The vast majority of survey respondents expect no or moderate (positive or negative) impacts on non-target organisms (such as pollinators, microbial communities, etc.). Four out of five do not expect a change of potential impacts on the environment and biodiversity through gene transfer or accidental consumption during experimental release or placing on the market.

6.1.3. Social, health and safety impacts

Social health and safety impacts – Similarly to environmental impacts, products authorised for placing on the market and cultivation would be risk assessed (and monitored once released or placed on the market) to ensure they do not present more potential hazards to health than their conventional counterparts. The majority of survey respondents does not expect any change in the safety impacts (for example due to toxicity or allergenicity) of products entering the market under the current regulatory framework. Potential positive social and health impacts stemming from NGT products with improved nutritional and functional quality will be largely missed or delayed.

Impacts on consumers – The current GMO legislation ensures information to consumers about the use of genetic modification technologies on the product's label. This is the preference expressed by a majority of citizens (30%, 733[146]) in the public consultation, as also

[144] Lassoued *et al*. (2019)
[145] Phalan (2018), Grass *et al*. (2019)
[146] The second highest preferences, each at 19% (464), were for digital labelling, information on a website/public database, and no labelling needed if products were produced through conventional plant breeding or classical

confirmed by similar findings from research[147] . It guarantees freedom of choice for those not wishing to use GMOs and would do so in the same way for GMOs obtained by NGTs.

The current label would not inform specifically about NGTs or their applications, and established consumer attitudes to GMOs would likely extend to NGTs (in the absence of other sources of awareness and information on NGTs) and have a negative impact on NGT acceptance and consequently on uptake. This would be reinforced by the fact that NGTs would remain subject to the GMO legislation as it stands today and applies to transgenic GMOs (as research[148] suggests that governmental decisions also play a role in shaping consumer attitudes).

As no or very few NGT products will come on the market under this option, there could be missed opportunities for consumers willing to consume NGT products. This could be linked to consumer preferences not fulfilled, but also in some cases to health or other needs not being addressed (e.g. when NGTs can be used to reduce allergen or toxic content).

Furthermore, given that more costly identity preservation may need to be applied, the price of some products could rise[149].

1.2. Analysis of option 1 (Authorisation with adapted risk assessment and detection method requirements)

6.2.1. Economic impacts

Breeders – Significantly shorter development times and lower development costs for NGT products and, in some cases, lower costs and time linked to the generation of data for risk assessment and authorisation, could make the development of certain NGT products more attractive than GMOs obtained by established genomic techniques. For example, in conventional potato breeding, the timeline in which breeders operate is approximately 13-15 years[150]. The cost of developing a conventional potato variety is EUR 2-3 m per variety, while development of NGT potato varieties is expected to cost significantly less money and time, estimated at EUR 0.5 m per variety and introduction into the market within five years[151].

Generating the necessary data for risk assessment currently represents the largest share of authorisation costs. For a risk assessment that is adapted to different risk profiles, the costs of generating the application will decrease to a variable degree due to potentially reduced data requirements. In cases where data requirements remain the same as they are today for GMOs, no cost savings are expected, while maximum cost savings of 85% of this component could be expected in cases where minimum data requirements apply based on the product's risk profile[152]. An adapted risk assessment could also shorten time to market with earlier profit gains.

Breeders, however, expect only a small improvement concerning the attractiveness to develop NGT plants as this option would apply the current GMO labelling regime to NGT products for which they expect only limited consumer acceptance, and because of the perceived

mutagenesis; the rest 11% (269) indicated that transparency is not needed for any plant produced by targeted mutagenesis and cisgenesis and 2% (49) expressed no opinion.

[147] Food Standards Agency (FSA) (2021); YouGov (2022); Lindberg *et al* (2023)

[148] Sendhil *et al*. (2022).

[149] See Gabriel & Menrad (2015)

[150] Jansky & Spooner (2018)

[151] Annex 5, section 2.3.1. in Technopolis Group *et al*. (2023)

[152] Annex 7, section 4.2. in Technopolis Group *et al*. (2023)

uncertainty about the way the adapted risk assessment would be applied in practice. In this regard, they expect negligible reductions in administrative costs compared to the baseline.

In the targeted survey, respondents expect on average a small increase in NGT plants on the market in 2030-35 compared to the baseline.

Academia/Research institutes – This sector expects a limited impact on research funding from this option both for private and public R&D. Concerns with regard to plant scientists leaving the EU are similar to the baseline.

Public authorities – Member States competent authorities expect cost decreases for risk assessment ranging from 8% - 67% (see table 1). The wide range results from the fact that the adaptation of risk assessment will be case-by-case and is intended to lead to large variability of data requirements (several scenarios were modelled: the lower value is applicable to a risk assessment requiring almost the same data as today, and the highest saving is applicable to a scenario with molecular characterisation and post market monitoring only). There is also a large variability between the Member States which can in part be explained by different administrative set-ups.

Table 1. Estimated cost decreases for Member States if data requirements for risk assessment are adapted to the risk profile of the product (data gathered in the context of Technopolis Group *et al*. study).

						ESTIMATES		
SCENARIOS	SPAIN	NETHERLANDS	GERMANY	BELGIUM	FRANCE	**MIN**	**AVERAGE**	**MAX**
Scenario 1: Full data except for protein	-10%	-8%	-15%	0%	-5%	0%	-8%	-15%
Scenario 2: Molecular characterization and Safety data on the trait only	-49%	-26%	-35%	0%	-10%	0%	-24%	-49%
Scenario 3: Molecular characterization and post market monitoring (including environmental) only	-67%	-60%	-60%	0%	-10%	0%	-39%	-67%

Furthermore, Member States' authorities will face enforcement challenges in cases where the same genetic alteration can be introduced by NGTs and conventional breeding methods and such plants cannot be distinguished by analytical methods.

Conventional farmers – As, under this option, some NGT plants would reach the market, farmers would be able to benefit from these plants if they feature relevant traits, in particular regarding reduced costs for inputs (pesticides, fertilisers), improvements of the yield/input ratio, new income opportunities or better prospects for exports. For example, a case study[153] on cisgenic late blight resistant potatoes and apples, conducted by the JRC, shows that for potatoes a 50-80% reduction and for apples a 12-58% reduction of fungicide use may be feasible. This would translate into yearly costs savings ranging from (min-max) EUR 49-576 per hectare for potatoes and EUR 39-712 per hectare for apples (see Annex 7). A gene-edited pennycress (*Thlaspi arvense*) is a new oilseed crop (for which large-scale farm trials will take place starting in 2023 in the US) that can be grown with relatively low greenhouse gas emissions and without causing detrimental land use changes[154]. In the US, this crop is grown as a cash cover crop in maize-soybean rotations providing environmental benefits (preventing soil erosion and nutrient run-off, reduction of pesticide use, carbon sequestration) and

[153] Schneider *et al*. (2023a, b)
[154] Jarvis *et al*. (2021); the plant was developed for the market by a start-up company called CoverCress Inc. In August 2022, Bayer acquired a majority share of 65% in the company.

expected net returns to farmers from biofuel or animal feed uses of EUR 130-180/ha[155]. Similar efforts are underway in Europe for the establishment of camelina (*Camelina sativa*) as a cash cover crop[156].

In cases where the costs of the authorisation process are considerably reduced because of significantly lower data requirements, it is likely that SME breeders and farmers can benefit from this option and that NGT plants from small or neglected crop species will come to the market under the condition that the license cost for the use of the technologies is not prohibitive for SMEs and minor crops[157].

Combining stakeholder and expert estimates of adoption rates of the currently known pipeline of NGT-applications, as well as expert estimates regarding trait-level impacts, a quantitative exploratory analysis[158] of impacts shows, for a low adoption rate of NGTs (1-5% of the crop market), the following estimated mean and, in brackets, range of impacts on key agronomic parameters for several crop groups (Table 2).

Table 2. Trait-level impacts.

Crop group	yield change/ha	change in pesticide use/ha	change in fertiliser use	change in water use	change in energy use
Oil and fibre plants	5% (1% to 16%)	-10% (-35% to 5%)	-13% (-8% to -28%)	-3% (5% to -15%)	-3% (0% to -10%)
Vegetables	9% (6% to 24%)	-9% (-5% to -43%)	-	-	-
Cereals	7% (3% to 22%)	-14% (-10% to – 18%)	-10% (-3% to -17%)	-2% (1% to -5%)	-6% ((0% to -11%)
Legumes	9% (6% to 23%)	-9% (5% to -35%)	-10% (-5% to -20%)	-5% (3% o -16%)	-3% (0% to -10%)

These estimates show that considerable per hectare changes in key agronomic traits are expected by experts, but also indicate that there is disagreement about the direction of change in some of those traits, in particular in pesticide and water use, where some experts expect increased use.

Organic/GM-free farmers and value chain –The labelling and traceability requirements in the existing GMO legislation will continue to support value chains and consumer trust for organic and GM-free producers. However, the regulatory divergence with non-EU countries (where NGT products may not be subject to traceability and labelling rules or to any transparency obligations) from which organic or other GM-free products are imported and detection challenges will impact the organic sector as in the baseline. Under the current EU regulatory framework, NGTs should not be used in organic products exported to the EU, therefore, the costs of keeping segregated supply chains in the EU would remain unchanged.

Coexistence between conventional/organic/GM-free production and NGT production – As more NGT plants are expected to be cultivated in this option compared to the baseline, the risk of admixture will increase and with it the costs for segregation. The purpose of coexistence measures is to allow consumers and producers a choice between conventional, organic and GM production. These measures also take into account the wish of some farmers

[155] https//:www.covercress.com/farmers.cfm
[156] Zanetti *et al*. (2021)
[157] Section 3.3.10. in Technopolis Group *et al.* (2023)
[158] Annex 8, section 1 in Technopolis Group *et al*. (2023)

and operators to ensure that their crops have the lowest possible presence of GMOs, acknowledging that the potential loss of income for producers of particular agriculture products such as organic products is not necessarily limited to exceeding the labelling threshold set out in EU legislation at 0.9% for food and feed. In certain cases, and depending on market demand and on the respective provisions of national legislations (e.g. some Member States have developed national standards for different types of 'GM-free' labelling), the presence of traces of GMOs in particular food crops — even at a level below 0.9% — may cause economic damages to operators who would wish to market them as not-containing any GMOs[159].

Article 26a of Directive 2001/18/EC on the deliberate release of GMOs into the environment allows Member States to take appropriate coexistence measures. A framework for such measures is defined in the Commission Recommendation of 13 July 2010 on guidelines for the development of national coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops[160]. Member States have taken a diversity of approaches – legislative and non-legislative and a mixture thereof – to implement this recommendation (15 Member States have adopted some form of coexistence measures). Almost all Member States that have regulated coexistence consider the GMO grower as the operator responsible for the implementation of the measures. In addition to the coexistence measures set out in the GMO legislation and the Commission Recommendation, the Organic Products Regulation requires organic producers to implement precautionary measures to avoid the presence of products and substances not authorised for use in organic production (Article 28).

The analysis below is based on the assumptions that a certain level of NGT cultivation will take place, and first considers the impacts on farmers cultivating NGTs and organic farmers, then the impacts on the respective value chains downstream from the farm.

The SIGMEA project (2004 – 2006), funded under FP6, investigated the costs of measures for GM-cultivating farmers to ensure coexistence for GM and conventional oilseed rape and maize in several regions of the EU using spatially explicit simulation models[161]. At the level of the GM-cultivating farm, two types of coexistence cost are considered: (i) the cost of compliance with the *ex-ante* coexistence rules in place, developed to prevent cross-pollination and/or admixture, (ii) the expenses for *ex-post* monitoring, because the product has to be tested for the presence of transgenic DNA. In general, results obtained for different regions demonstrate that coexistence costs depend on the agricultural context (landscapes, cropping systems, field shape, climate), the share of GM crops in the Utilised Agricultural Area (UAA) and the willingness of GM and non-GM farmers to cooperate. The study also concludes that inflexible coexistence rules (such as standardised large isolation distances) impose a severe burden on GM cultivation, while flexible, context-dependent measures do not act as a disincentive to GM cultivation. In the latter case, GM crop adoption is not an issue of costs of compliance with coexistence measures but rather one of the incentives for adopting or rejecting the technology.

<u>Example: Oilseed rape in Beauce (France)</u>

Relative to the benchmark scenario, the study simulated six scenarios by varying (i) the GM crop adoption rate (scenarios 2 and 3), (ii) the share of oilseed rape in the arable area

[159] European Coexistence Bureau (2010-2018)
[160] OJ C 200, 22.7.2010, p. 1–5
[161] The final report is available at https://cordis.europa.eu/docs/results/501/501986/126792601-6_en.pdf

(scenarios 4 and 5), and (iii) the isolation distance requirement (scenario 6). Table 3 reports the estimated average cost for coexistence management.

Table 3. Simulated coexistence management costs of GM and non-GM oil seed rape under alternative scenarios (averages of 10 simulations varying the spatial allocation of crops in the landscape).

Scenario	Adoption Rate	Oilseed rape Share	Buffer zone width	Average cost per hectare GM (€/ha)*
1 (Benchmark)	50%	13%	10m	0.47
2	25%	13%	10m	0.75
3	75%	13%	10m	0.23
4	50%	6%	10m	0.33
5	50%	26%	10m	1.13
6	50%	13%	20m	1.21
7	50%	26%	20 m	2.72

Source: Based on SIGMEA Deliverable 5.2 and 5.3; *costs have been adjusted to take inflation since 2006 into account.

These data show that coexistence costs for GM-cultivating farmers can decrease with increasing adoption rate (see scenarios 2 and 3) and that they are highest if large shares of arable land are cultivated with oilseed rape, if the GM adoption rate is in the middle of the range and if isolation distances are large (scenario 7).

Example: Maize in Aragón (Spain)

For this case study the small area of Gurrea de Gallego was selected to implement simulations for coexistence between GM and non-GM maize. The municipality of Gurrea de Gallego has a total UAA of 964 ha cultivated in 489 fields, which results in an average field size of 1.97 ha. In 2005, maize was cultivated in 47 fields, corresponding to 105 ha or an average of field size of 2.2 ha.

Table 4. Coexistence costs of buffer zones for different adoption rates and distances in Aragón (Spain).

GM adoption rate (%)	Buffer zone	Cost per ha GM maize area (€/ha)*
10%	10m	34.64
	20m	62.51
	50m	101.71
	100m	117.30
30%	10m	29.95
	20m	54.23
	50m	94.25
	100m	116.61
50%	10m	30.64
	20m	55.89
	50m	97.43
	100m	116.89
90%	10m	29.81
	20m	54.37
	50m	97.15
	100m	117.16

*Costs have been adjusted to take inflation since 2006 into account

These data show that, for a given buffer zone size, the coexistence costs for GM farmers are of moderate size and quite insensitive to the GM adoption rate (Table 4). These findings are in line with the results of a simulation study of the costs of coexistence measures per hectare of GM in Switzerland, which finds that the costs amount to 1-3% of total product costs[162].

Organic operators also have the responsibility to put in place precautionary measures to avoid admixture with any product that is not authorised in organic production, and to regularly review these precautionary measures and to adjust these measures if necessary. A product for which EU law requires GM labelling, e.g. food and feed containing traces of GMOs above 0.9% (or even below 0.9% if the traces are not adventitious or technically unavoidable), must not be marketed under the EU organic logo (Art. 30(4) of Regulation 2018/848). For conventional products which are not subject to such labelling requirements, organic operators must require a vendor declaration to confirm the absence of any GMOs and derived products. However, certain NGT plants cannot be distinguished from conventionally bred plants. In such cases, the analytical control supporting the marketing prohibition under the organic logo might be difficult and in some cases not feasible. Organic farmers would not have direct economic losses in these cases where NGT presence cannot be established, however, there is a risk of loss of trust by some consumers if a certain level of NGT admixture cannot be analytically ruled out. Based on the work of the European Coexistence Bureau[163], it is reasonable to assume that risk of such admixture can be considered to be low for this option with a low to moderate adoption of NGTs, if NGT farmers comply with coexistence measures and organic farmers with the precautionary measures to avoid admixture required by the Organic Products Regulation.

There are no quantitative estimates of the costs for GM-cultivating and non-GM farmers in cases of admixture as these costs depend on the affected product (e.g. its gross margin and

[162] Vögeli *et al*. (2010)
[163] European Coexistence Bureau (2010 – 2018)

price premium) and (as liability is a component of the costs) on liability regimes, which are the exclusive competence of Member States[164]. For non-organic farmers, the financial risks of liability may tip the balance against the decision to cultivate GM crops[165]. The risk of admixture, and therefore the overall financial risk for organic producers, will depend on the overall adoption rate of NGTs – the higher the adoption rate, the more likely it is that fields neighbouring an organically cultivated field will be cultivated with NGTs, thus increasing the probability of admixture. However, experiences from Spain show that large scale cultivation of GM maize has not been an obstacle to the expansion of organic cultivation. From 2012 – 2021, the area cultivated with organic maize has increased in three regions with a dominant presence of Bt maize cultivation: in Aragón, the organic maize area increased from 159 ha to 526 ha, in Cataluña from 30 ha to 351 ha and in Navarra from 11 ha to 44 ha[166].

Coexistence in the value chain

As the analysis in the baseline shows, additional costs of 7 – 14% can be expected by organising coexistence between genetically modified and non-GM products in the value chain from production of farm crops up to the production/processing levels of single supply chains. These estimates are based on the assumption that GM can be identified by analytical tests. For NGTs that cannot be analytically differentiated, these price increases could be higher as further steps might have to be taken to guarantee the integrity of the supply, such as additional documentation and third-party verification.

Trade impacts – Under this option some NGT plants are expected on the market, but regulatory divergence with non-EU countries is likely to remain large if this option applies to all NGT plants, posing challenges for value chain management and identity preservation systems. Many targeted survey respondents expect a general decrease of international trade of agricultural products and commodities under this option (31% (21) expect moderate decrease and 15% (10) expect small decrease), but to a lesser extent than in the baseline (44% (27) expect moderate decrease and 16% (10) expect small decrease).

Impacts on SMEs – Certain NGTs are considered to be accessible tools for plant breeding due to their relatively low cost and complexity. The easily adaptable technology used in such NGTs could lead to a lowering of technological barriers to entry of the plant breeding sector, benefitting SMEs, provided that access to the technology and costs associated with IP remain affordable. This has been observed in Argentina after its regulatory shift to excluding certain NGT products from the GMO definition.

With a maximum of 85% reduction, significant cost reductions for adapted risk assessment, overall authorisation costs will, in case of the lowest data requirements, be in the approximate range of EUR 0.9-3 m (15% of costs for food and feed authorisation with full risk assessment). Administrative costs are not expected to change significantly. The combination of significantly lower development costs for NGT plants compared to varieties bred

[164] Austria, Finland, France, Germany, Hungary, Norway, Poland and Slovakia have specific liability provisions addressing damages arising from admixture. Compensations may differ substantially between Member States; they may be calculated on the difference in price between a GM-labelled product and a non-GM labelled product, while additional costs coming from covering the costs of quality scheme controls or the costs of a new organic certification process, which depend on the type and size of a farm and are variable between Member States, are not taken into account.

[165] Venus *et al*. (2017) In Germany, the cost of joint and strict liability for Bt maize (EUR 189/ha) were estimated to be higher than the average additional revenue (EUR 115/ha) and the additional gross margin (EUR 65/ha). However, farmers planted Bt maize because the GM seed company safeguarded potential economic damage if the GM farmer complied with the coexistence measures.

[166] https://www.mapa.gob.es/es/alimentacion/temas/produccion-eco/default.aspx

conventionally or developed with established GM technology (e.g., an estimated EUR 0.5 m for an NGT potato variety vs. EUR 2-3 m for a conventional variety) and the significant cost reductions for adapted risk assessment, may make it easier for SMEs in certain circumstances to compete with larger companies.

Competitiveness – This option will improve the competitiveness of EU operators as costs of and time needed for R&D of NGT products can be significantly reduced in comparison to the baseline. Compliance costs related to data requirements for risk assessment will range from negligible reduction (if a similar set of data, as today, is required) to a reduction of around 85% (if minimum data requirements apply). However, breeders in non-EU countries, which have exempted certain NGT products from the requirements of their GMO legislation, can save all the costs related to GMO authorisations for those NGT products, thus having a competitive advantage over breeders in the EU also under this option. Because of potentially higher prices for organic/GM-free products, this sector could experience reduced competitiveness compared to conventional producers[167].

Simplification – A risk assessment adapted to the diverse risk profiles of NGT plants would be on a case-by-case basis less burdensome for operators compiling the applications as well as for the authorities assessing them.

6.2.2. Environmental impacts

As regards potential risks specifically linked to the genetic modification, any NGT product coming to the market will be risk assessed using criteria and requirements adapted to the product's risk profile and designed to ensure environmental protection. As under the current legislation, potential risks of NGT plants/products will be assessed in comparison with their conventional counterparts. No change compared to the baseline with regard to safety for the environment is expected as products will only be authorised for placing on the market and cultivation if the risk assessment concludes that they do not present more potential hazards than their conventional counterparts, and post-market monitoring provisions will apply to identify and take measures in response to any potential adverse effect.

Positive environmental benefits are expected if authorised products contain relevant traits, such as the reduction in pesticide use as outlined in the case study presented in Annex 7, resilience to climate change or lower fertiliser input, depending on the number of NGT products placed on the market. Lower fertiliser input and the development of cash cover crops could lower greenhouse gas emissions of agriculture.

Regarding pest- or pathogen control, the expected change in pesticide use is highly controversial, in particular with respect to herbicide-tolerant (HT) crops. The main reasons for the adoption of HT crops have been improved and simplified weed control, less labour and fuel cost, no-till planting/planting flexibility, yield increase, extended time window for spraying, and decreased pesticide input[168]. On the other hand, a recognised negative impact of HT crops is the evolution of herbicide resistance in weeds, which may lead to higher use of other selective herbicides, with the attendant environmental and health externalities, and increased use of tilling and consequently higher GHG emissions[169]. By 2023, 57 weed species

[167] Gabriel & Menrad (2015); IFOAM EU & FiBL (2017)
[168] Sankula *et al*. (2015)
[169] Schütte *et al*. (2017); Benbrook (2012); Desquilbet *et al*. (2019); Lu *et al*. (2022)

have evolved resistance to glyphosate[170]. Herbicide-tolerant weeds also occur in production systems of herbicide-tolerant crops developed using conventional breeding methods[171].

HT crops do not represent a strong focus of R&D in the field of NGTs. Among NGT products in the pre-commercial and advanced R&D stage, herbicide tolerant plants account for 10 out of 172 products in development[172]. This trait can be developed by established GMO technology, NGTs and by conventional breeding methods[173]. Impacts of HT crops, irrespective of the breeding method used for their development, will depend on how they are used and managed in the field.

Experience with insect resistant GM crops in the EU (Bt maize producing the bacterial protein Cry1Ab, toxic to insects) has shown that, as of 2021, no decrease in the vulnerability to the toxic protein had occurred in the relevant pests[174].

Effects on the diversity of cultivated crops would depend on how much new varieties can benefit from the lower costs and lower administrative burdens stemming from adapted risk assessment. From 2002 to 2010, niche crops globally accounted for only 5% of approved GMOs[175], although there is considerable technology and valuable traits to be exploited. There is evidence that this is due in part to regulatory costs of GMO approval[176], but lack of demand or market rejection may play a role as well. The case study on chicory (see Annex 7) shows that NGTs can contribute to the development of new and improved plants and can further support the use of underutilised, neglected and local crop species[177], thus leading to increased agrobiodiversity.

Regarding local production systems and the diversity of local and traditional varieties, some stakeholders see a danger in the displacement of local production systems by NGT crops, arguing that increased cultivation of NGT plants would reduce the diversity of crops used in agriculture, as well as the local knowledge of crop species and varieties suited for the local climate[178]. However, in cases where adapted risk assessment leads to considerably lowered regulatory costs, development and cultivation of NGT varieties of niche and locally important crops may become economically more viable. NGT plants can provide more adaptation to climate change and thus could lead to the development of plants more suitable to local climatic conditions and thus maintain or enhance crop diversity[179].

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[170] Heap (1993-2023)
[171] Wedger *et al*. (2022)
[172] Parisi & Rodriguez-Cerezo (2021), time horizon 2030; in the pre-commercial stage, 7 out of 16 products are HT-traits; the high proportion of HT-traits in the pre-commercial stage reflects the fact this is a trait well-known to developers, with which the new gene-editing technologies can be more easily applied and tested than with new traits. This number may thus not reflect developer priorities (which is evident from the trait distribution in the early and advanced R&D stage, where HT-traits play a small role) in the medium and longer term.
[173] Fried *et al*. (2022); the following numbers of conventionally bred HT varieties deriving from the Clearfield technology are listed in the EU Common catalogue of varieties of agricultural species (status in December 2022): turnip rape (*Brassica rapa* var. *silvestris*) two out of 39 varieties (5.1%), swede rape (*Brassica napus*) 116 out of 1333 (8.7%), sunflower (*Helianthus annuus*) 276 out of 1635 (16.9%) and rice (*Oryza sativa*) 40 out of 449 (8.9%).
[174] García *et al*. (2023)
[175] Miller & Bradford (2011); however, a later analysis shows that developers from low- and middle-income countries are starting to enter the commercial with a broader spectrum of crops; see Parisi *et al*. (2016)
[176] Dobres (2008)
[177] Venezia & Creasey Krainer (2021); Yaqoob *et al*. (2023)
[178] Catacora-Vargas (2011)
[179] Lemmon *et al*. (2018)

60% of respondents in the targeted survey do not see potential risks for the environment and biodiversity under this option. This view is, however, disputed by certain stakeholders. Responses mostly coming from citizens, NGOs, consumer organisations and environmental organisations (18.8% of total participants in the public consultation) stress that the current risk assessment system has demonstrated its effectiveness.

6.2.3. Social, health and safety impacts

Social, health and safety impacts – Any NGT product coming to the market will be assessed to consider risks to human and animal health using criteria and requirements adapted to the product's risk profile and designed to ensure safety for human and animal health. Therefore, similarly to potential risks for the environment, no change compared to the baseline with regard to human and animal health is expected as products will only be authorised for placing on the market and cultivation if the risk assessment has concluded that they do not present more potential hazards than their conventional counterparts.

As some NGT products are expected on the market, certain social and health benefits are expected. Current R&D addresses traits like modified starch, protein and lipid content and composition or increased functional metabolites and traits enhancing market value (e.g. longer shelf life)[180]. In oilseed crops, for example, the most preferred target of genome editing is the production of monounsaturated fatty acids, such as oleic acid, which are generally considered healthier and more stable, and hence are associated with a longer shelf life. An example of a trait having an expected direct health effect is low gluten content in wheat produced by targeted mutagenesis and assessed in one of the JRC case studies (see Annex 7). Such low-gluten, celiac safe wheat can contribute to making low gluten diets more affordable[181], to a more balanced diet and to decreased costs of medical care[182]. In the JRC market study, modified content is the most common trait addressed in NGT product R&D (see Annex 7).

62% of respondents to the targeted survey expect no change in terms of social impacts under this option. This view is, however, disputed by certain stakeholders, representing 21% of respondents and coming especially from NGOs and consumer organisations, expecting increased potential hazards.

Impacts on consumers – NGT products would be labelled, and similar considerations as in the baseline apply. Since more NGT products than in the baseline would come on the market, if they contain relevant traits consumers could benefit from further choice of products with increased nutritional and functional qualities.

1.3. Analysis of option 2: Authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability

6.3.1. Economic impacts

Breeders – With regard to adapted risk assessment and the attendant cost reductions, the analysis of option 1 applies. This option is judged by breeders to have overall a neutral or negative impact on time to market or regulatory certainty compared to option 1, for several

[180] Ku & Ha (2020)
[181] Celiac-safe wheat derived products are expected to be 10 to 30% more expensive than those made from standard wheat, but still cheaper than gluten-free products, which are on average 200% more expensive than gluten-containing products.
[182] Sánchez *et al*. (2023)

reasons. In case operators decide to apply for incentives, specific costs will result from the need to comply with a sustainability-related verification and will depend on the criteria and data requirements necessary for that verification. Apart from the extra costs, breeders consider that any pre-market data generation may extend the preparation phase for the applicant, lengthen assessment timelines and diminish the potential benefits of NGTs to speed up plant breeding. This is also due to the view that the proposed incentives will not necessarily lead to a significant decrease of administrative burdens. However, if easily implementable criteria to trigger incentives are designed, stakeholders do see some merit in the sustainability incentives offered under this option. Data from the cost survey[183] identified potentially significant cost savings connected to regulatory (EUR 83300 – 833000) and scientific advice (EUR 35700 – 357000) and through the waiving of fees for the validation of the detection method (EUR 105000, EUR 52500 for SMEs). These cost savings (the estimated savings are dependent on the future data requirement for the sustainability-related verification) will be particularly relevant for SMEs, which, as a rule, do not have dedicated regulatory departments to support the authorisation process. In addition, as the use of incentives is voluntary, companies are free to choose whether to use this possibility or not based on an economic analysis of the costs and expected benefits.

65% of respondents in the targeted survey expect no change, while only 4% of respondents expect a moderate to strong decrease for the attractiveness of developing NGT products compared to option 1. Given that incentives are voluntary, and breeders can choose to operate under this option without triggering them, no decrease in attractiveness appears justified. The option is then equivalent to option 1. If the GMO labelling requirement were to be waived for products with traits that contribute to sustainability, this could have, according to 40% of stakeholders from business associations, companies, public authorities and academia/research organisations a moderate positive impact on the attractiveness to develop such NGT products. If a sustainability label is introduced, interviews with value chain stakeholders point out that such a label is, however, not likely to be used in practice if voluntary.

Academia/Research institutes – This sector expects positive impacts in private and public R&D funding if the GMO label for NGT products with traits that are verified to contribute to sustainability would be waived. This and other incentives are not specifically aimed at Academia/Research Institutes but support the regulatory procedures prior to the commercialisation of products. A regulatory system facilitating the placing on the market of NGTs will also increase the attractiveness of funding NGT research in academia and the research sector. This will in turn support the development of the agricultural biotech sector in the EU. If the GMO label is not waived, no significant positive impact on private or public funding is expected compared to option 1.

Public authorities – For adapted risk assessment, the analysis of option 1 applies. The verification how traits can contribute to sustainability is expected to increase the cost of the authorisation process. The competent authorities' support of the authorisation process with incentives for plants with traits that contribute to sustainability (e.g., guidance on overall development plan and regulatory procedure, dedicated contact point, scientific advice at key development milestones, fee waivers) is expected to increase costs. Alternatively, cost decreases are expected in cases when the GMO label is waived.

Conventional farmers – If more NGT products will to come to the market, farmers could harness their benefits to a larger extent than under option 1.

[183] See Annex 7 in Technopolis Group *et al*. (2023)

A quantitative exploratory analysis[184] of impacts shows, for a medium adoption rate of NGTs (10-23% of the crop market, depending on crop group), the following estimated mean and, in brackets, range of impacts on key agronomic parameters for several crop groups, showing a pattern comparable to option 1 (Table 5).

Table 5. Trait-level impacts.

Crop group	yield change/ha	change in pesticide use/ha	change in fertiliser use	change in water use	change in energy use
Oil and fibre plants	9% (4% to 20%)	-10% (5% to -35%)	-13% (-8% to -28%)	-3% (5% to -15%)	-3% (0% to -10%)
Vegetables	9% (6% - 24%)	-	-	-	-
Cereals	8% (6% to 22%)	-16% (-14% to -18%)	-11% (-5% to -18%)	-5% (-4% to -7%)	-7% (-1% to -12%
Legumes	9% (6% to 23%)	-10% (5% to -35%)	-10% (-5% to -20%)	-5% (3% to -16%)	-3% (0% to -10%)

The analysis of coexistence measures for conventional farmers cultivating NGTs from option 1 also applies for this option.

Organic/GM free sector – Under the sub-option that maintains a GMO label, the impacts on the organic/GM-free sector will be similar to option 1. The impacts from the costs of coexistence will be moderately higher than under option 1, as more NGT products are expected on the market. As in the baseline, the sectors will be impacted because of the regulatory divergence with non-EU countries (where NGT products may not be subject to traceability and labelling rules or to any transparency obligations) from which organic/GM-free products are imported into the EU. Under the current EU regulatory framework, NGTs should not be used in organic products exported to the EU, therefore, the costs of keeping segregated supply chains in the EU would remain unchanged.

The specific impacts of this option relate to labelling options for NGT products featuring traits that can contribute to sustainability. If a sustainability label is provided for, the focus group on sustainability[185] conducted in the context of the external contractor's study, found that a sustainability claim allowing for higher premiums would be to the disadvantage of sustainable conventional or organic products.

If NGT products with traits contributing to sustainability would not be labelled, a public register will enable organic operators to identify varieties developed using NGTs and traceability would remain as under current GMO legislation. In addition, as the traceability provisions would apply, the organic/GM-free operators would rely on the business-to-business obligations to be informed that no NGTs have been used.

Impacts on trade – The impacts on trade will be similar to option 1.

Impacts on SMEs – The impacts of the adapted risk assessment would be the same as in option 1. Regulatory incentives linked to scientific / regulatory advice or fee waivers would have the most impact as regards SMEs. Unlike larger companies, SMEs do in general not have dedicated, specialised staff for authorisations. The incentives may help to lower administrative burdens and allow more SMEs to benefit from NGTs. Some of the positive

[184] Annex 8, section 1 in Technopolis Group *et al*. (2023)

[185] Annex 6, section 1 in Technopolis Group *et al*. (2023)

impacts of incentives could, however, be counteracted by the additional burdens of producing the data for the verification of the sustainability contribution of the NGT trait.

Competitiveness – Like in option 1, this option will improve the competitiveness of EU operators as costs of and time needed for R&D of NGT products is reduced compared to the baseline. Incentives can decrease administrative burdens for SMEs and increase their competitiveness. Still, breeders in non-EU countries, which have exempted certain NGT products from the requirements of their GMO legislation, will not have any costs related to authorisations for such products, thus having a competitive advantage also under this option.

Simplification – Like in option 1, a risk assessment adapted to the diverse risk profiles of plants obtained by targeted mutagenesis and cisgenesis would lead to a range of reduction in compliance costs for applicants (from negligible reduction if similar data requirements apply as today to a maximum reduction of 85% in cases with minimum data requirements) and national competent authorities (reduction from 8 – 67%). If an applicant seeks to verify the contribution of the NGT product to sustainability additional procedural steps will be needed, partially cancelling out the simplifications gains made by adapted risk assessment.

6.3.2. Environmental impacts

As regards potential risks specifically linked to the genetic modification, any NGT product coming to the market will be risk assessed using criteria and requirements adapted to the product's risk profile (as in option 1). Therefore, no change compared to the baseline with regard to safety for the environment is expected as products will only be authorised for placing on the market and cultivation if the risk assessment concludes that they do not present more potential hazards than their conventional counterparts, and post-market monitoring provisions will apply to identify and take measures in response to any potential adverse effect.

With more NGT products on the market (coupled with incentives steering to certain traits), certain stakeholder groups expect positive environmental impacts, such as reduced pesticide and fertiliser use, while others expect negative impacts, such as more large-scale monocultures and a concomitant increased pesticide use. In the targeted survey, roughly equal number of stakeholders expect a positive (40%) or a negative (46%) impact. This polarisation is mostly due to divergent views on the sustainability of HT crops as outlined in section 6.2.1.

The consultations show that stakeholders consider that this option could make a contribution to pushing the application of NGTs to the breeding of crops more in the direction of preferential environmental traits; it was primarily supported by respondents from academia and public authorities and by citizens.

However, this option and option 3 were questioned from the perspective of how the sustainability contribution of a trait could be verified. A large majority of stakeholders, representing very different interests (biotech industry and breeders, farmers, NGOs and organic and GM-free sectors), agree in the public consultation, interviews, the focus group on sustainability and the targeted survey that the sustainability of a crop does not depend on its individual traits but on the interplay of the plant with its environment and the farming system that it is adopted in. There is wide agreement that the holistic, multi-site and multi-year test for value for cultivation and use (VCU), carried out during variety registration of agricultural crops under the PRM legislation is far more suitable to assess in a holistic manner the performance of new varieties[186]. Such an overall performance assessment should not be part of the procedures for the authorisation of GMOs which are focused on the effect of the

[186] Annex 6, section 1 in Technopolis Group *et al*. (2023)

genetic modification only. Moreover, it is considered that, should such a holistic assessment of the variety be introduced in the NGT authorisation, it would duplicate the VCU assessment to which NGTs are also subject. These stakeholders consider that sustainability analysis should be performed using a system approach rather than one at product level. Furthermore, the discrimination of plants produced by conventional or organic breeding causes concerns among stakeholders as these plants cannot benefit from a sustainability label.

6.3.3. Social, health and safety impacts

Social, health and safety impacts – Any NGT product coming to the market will be risk assessed using criteria and requirements adapted to the product's risk profile (as in option 1). Therefore, similarly to potential risks for the environment, no change compared to the baseline with regard to human and animal health is expected as products will only be authorised for placing on the market and cultivation if the risk assessment has concluded that they do not present more potential hazards than their conventional counterparts.

If more NGT products will come to the market (coupled with incentives steering to certain traits), social and health benefits, such as from the low gluten wheat presented in Annex 7, are expected. NGTs support healthy diets: examples are mustard greens (*Brassica juncea*) with a decreased content of pungent compounds[187] or rice lines with lower amylose content, which may reduce the risk of diabetes[188].

Impacts on consumers – In the public consultation, a majority of EU and non-EU citizens that responded supported the view that specific regulatory provisions for sustainability should be included in this initiative. Survey responses (70%) indicate that a sustainable trait label, also covering the purpose for which the NGT product was developed, could increase consumers' willingness to buy NGT products with such a label. Respondents to the targeted survey[189] and further studies indicate that sustainability-related labelling will increase clarity for the consumers, allowing them to choose products that contribute to societal benefits and sustainability, based on their preferences[190].Available research suggests that consumers may accept NGTs in particular when they promote societal benefits and sustainability[191].

In this regard, the sub-option to label NGT products as GM combined with a sustainability label linked to the introduced trait, would strengthen freedom of choice (by informing about the technology and its application) and increase consumer and market acceptance. Yet the focus group on sustainability[192] found that a sustainability claim allowing for higher premiums would be to the disadvantage of sustainable conventional or organic products.

The sub-option to waive the GMO labelling requirement for NGT plants with traits contributing to sustainability, but including these products in a publicly accessible database, makes accessing the relevant information more burdensome for citizens not using modern IT. This was also highlighted in the public consultation where a majority of the respondent EU citizens (30%, 733) expressed a preference for physical labelling on the final product. Also, not labelling products that, because of their characteristics, are made subject to mandatory risk assessment and authorisation could negatively affect consumer trust.

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[187] USDA APHIS (2020)
[188] Sun *et al*. (2017)
[189] Business associations, large companies, SMEs, some NGOs and academic/research organisations
[190] Swedish Gene Technology Advisory Board, Department of Plant biology (SLU), Novus. (2021); GENEinnovate (2020); Kato-Nitta *et al.* (2021); Baum *et al.* (2023)
[191] Swedish Gene Technology Advisory Board, Department of Plant biology (SLU), Novus. (2021)
[192] Annex 6, section 1 in Technopolis Group *et al*. (2023)

The sub-option to complement the GMO label with a factual statement on the intended purpose of the genetic modification (e.g. genetically modified for the purpose of improving drought resistance) could provide relevant information to consumers, without featuring claims that could be to the disadvantage of sustainable conventional or organic products. This sub-option could still drive the market demand for products with beneficial traits.

More NGT products than in the baseline would come on the market. If they contain relevant traits consumers could benefit from further choice of products with increased nutritional and functional qualities.

1.4. Analysis of option 3: Authorisation with the requirement that products do not contain modified traits that can be detrimental to sustainability

6.4.1. Economic impacts

Breeders – As for options 1 and 2, significantly shorter development times and lower development costs for NGT plants and, in some cases, lower costs and time linked to the generation of data for risk assessment and authorisation, could make the development of certain NGT plants more attractive than GMOs obtained by established genomic techniques. Additional, mandatory procedural steps such as the necessity to provide data on the characterisation of the modified trait to verify its potential impacts on sustainability are judged by stakeholders to have a mostly negative impact on time to market. More importantly, the possibility that the NGT product may be refused marketing authorisation because sustainability requirements are not met will affect regulatory certainty negatively.

Like in option 2, a wide range of stakeholders doubt that the sustainability impact of a single trait can be reliably verified. The issue of discrimination is also raised for this option, as conventionally bred plants are not subject to the requirement to demonstrate that the plant is not detrimental to sustainability. Therefore, the attractiveness of developing NGT plants under this option is decreased compared to options 1 and 2 because of the introduction of sustainability requirements. 68% of respondents in the targeted survey expect no change or decreased attractiveness of developing NGT plants compared to the situation today.

Public authorities – With regard to adapted risk assessment, the analysis of option 1 applies. In this option, lower savings can be expected as verifying that the modified trait is not detrimental to sustainability is a requirement for all authorisations. As harmonised standards and procedures for this verification would have to be put in place, cost increases for the competent authorities can be expected. However, in the cost survey, Member States' authorities were not able to provide quantitative estimates of these potential cost increases.

Other sectors – Because of the lower attractiveness of this option for breeders, NGT plants could achieve a lower market share than under options 1 or 2. Regulatory divergence with non-EU countries will be larger than under options 1 and 2, and additional requirements will increase the risk of trade disruptions. The reduction in attractiveness and lower market share would mean that the potential of NGTs might not be delivered to conventional farmers; at the same time, as showing that the trait is not detrimental to sustainability is a requirement, all NGT plants reaching the market will benefit farmers (or consumers). Organic/GM-free farmers would experience lower risks of admixture and attendant economic losses. Impacts on academia/research institutes will be similar to option 1.

Impacts on SMEs – While there can be significant cost reductions for adapted risk assessment, additional data are required to show that the trait is not detrimental to sustainability. Although no estimates for these additional costs are available, there is the risk that these extra costs could negate some of the positive impact of adapted risk assessment. Therefore, there is the

possibility that SMEs in the EU will have few or no incentives to develop NGT products under this option. There is furthermore the risk that a NGT product might be refused authorisation for not meeting the sustainability requirements and this leads to regulatory uncertainty, which is economically riskier for SMEs than for larger companies.

Competitiveness – Also under this option, costs of and time needed for R&D of NGT products are reduced in comparison to the baseline (same quantitative estimates as in option 1). Additional costs and administrative burdens will be imposed on breeders by the requirement to provide data demonstrating that the NGT trait is not detrimental to sustainability, thereby cancelling out some of the cost and time savings of option 1. Breeders in non-EU countries, which have exempted certain NGT products from the requirements of their GMO legislation and which have no specific requirements for sustainability, can save all the costs related to GMO authorisations, thus having a competitive advantage also under this option, but more pronounced than in options 1 and 2.

Simplification – Like in option 1, a risk assessment adapted to the diverse risk profiles of plants obtained by targeted mutagenesis and cisgenesis would lead in some cases to significantly reduced administrative costs and burdens for applicants and national competent authorities. Applicants are obliged to demonstrate, and competent authorities need to verify, that the NGT trait is not detrimental to sustainability, thereby fully or partially cancelling out the simplifications gains made by adapted risk assessment.

6.4.2. Environmental impacts

As regards potential risks specifically linked to the genetic modification, any NGT product coming to the market will be risk assessed using criteria and requirements adapted to the product's risk profile (as in option 1). Therefore, no change compared to the baseline with regard to safety for the environment is expected as products would only be authorised for placing on the market and cultivation if the risk assessment concludes that they do not present more potential hazards than their conventional counterparts, and post-market monitoring provisions will apply to identify and take measures in response to any potential adverse effect.

In addition to refusing authorisation to NGT plants presenting specific risks (as in the baseline and options 1 and 2), this option would refuse authorisation to NGT plants containing traits whose use could have negative environmental effects (e.g. increased use of pesticides). Therefore, in principle, this option would be the most demanding for operators and promising to deliver on sustainability objectives. However, as explained in section 7.3.2., plants with traits whose use could have negative environmental effects can be obtained with different breeding methods, including by conventional means and introducing such a requirement only for NGT plants would be discriminatory.

Since this option adds administrative burden compared to option 1, it is likely that a lower number of NGT products than under option 1 will be developed. Therefore, environmental benefits may be realised to a lower degree than in option 1.

6.4.3. Social, health and safety impacts

For social, health and safety impacts, the same reasoning applies as in section 6.4.2.

Impacts on consumers – NGT products would be labelled as GMO, and similar considerations as in the baseline and option 1 apply. Although this option does not provide for any sustainability-related label (as all NGT products would need to meet a minimum requirement and only the technology would be labelled), if there is widespread information and understanding of the legal framework and the fact that only NGT products with traits that

cannot be detrimental to sustainability can be authorised, consumer acceptance of NGTs could increase.

As only a small number of NGT products are expected to come on the market, there could be missed opportunities for consumers willing to consume NGT products with increased nutritional and functional qualities.

1.5. Analysis of option 4: Notification of products that could also occur naturally or be produced by conventional breeding

The impacts of this option (intended to apply in combination with one of the other options) will depend on the share of NGT plants/products that would fall under the notification regime. It is difficult to anticipate this number, as it cannot be predicted which products in the R&D pipeline will be pursued for placing on the market and whether they would meet the notification criteria (data allowing to perform the assessment against the criteria is in most cases not available for the product pipeline).

A hypothetical scenario for the purposes of the analysis, based on the number of products expected to come to the market in the next ten years in the JRC study on NGT applications, is presented in Annex 3.

1.5.1. Economic impacts

Breeders – Under this option, strong effects are expected on the attractiveness to develop and bring to the market NGT plants with genetic alterations that could also be produced naturally or by conventional breeding. Apart from an initial verification that the related criteria are met, such plants would be treated like conventional varieties and therefore the costs for market authorisation would be similar to conventional varieties[193], while time to market (development time + variety registration, which can be expected to be less than 10 years) would be shorter than for conventionally bred varieties, where variety development alone can take up to 15 years. Additional costs compared to conventional varieties would be due to the necessity to verify whether a product could also occur naturally or be produced by conventional breeding. The total cost savings for breeders will depend on the share of NGT products which will comply with the relevant requirements. As cost and time savings for each variety are considerable (see section 6.2.1.), there will be strong incentives for breeders to focus their R&D on varieties which can fulfill the criteria for a notification.

92% of overall stakeholders see an increase of attractiveness under this option. In a recent survey among European plant breeders, 100% of the larger, 86% of the medium sized and 70% of the small companies would further invest in NGT-related product development if the products would not be subject to the requirements of the GMO legislation[194].

Academia/Research institutes – Academia and research[195] expect this option to increase investments both from large multinational plant breeders as well as SMEs and public sector research, allowing for both a deeper and broader R&D-base in agricultural biotech due to lower total aggregate R&D-cost, reduced business risk and shorter time-to-market. This will increase research competitiveness of the EU and offer research and employment opportunities for plant scientists, addressing the perceived problem of brain drain.

[193] The total annual costs to businesses across the EU27 of registering varieties is estimated to be up to EUR 73 m with an average cost to businesses per registration of EUR 4434.
[194] Jorasch (2020)
[195] Section 3.1.23. in Technopolis Group *et al*. (2023)

However, stakeholders from environmental NGOs and the organic sector argue that such intensified R&D focussed on biotechnology might divert R&D from developing other more sustainable farming methods, where they already see a lack of investment.

Trade impacts – Unlike the baseline and options 1-3, this option will reduce regulatory divergence with other jurisdictions. Although different jurisdictions are applying different criteria and a degree of regulatory divergence will remain, in many third countries the equivalence to conventional products is the decisive criterion when adapting their regulation.

Public authorities – National authorities can expect significant cost savings per product (as compared to a situation where the NGT plants concerned would be subject to authorisation). The total amount of savings will depend on the proportion of NGT products that will comply with the requirements for the notification procedure. In the most extreme case, that is if all NGT products brought to market comply with the requirements for the notification procedure, then competent authorities will only have to bear the compliance costs of verifying that the product does indeed meet these requirements. However, the number of NGT products that go through regulatory procedures for the deliberate release including placing on the market could significantly increase compared to a situation where conventional-like NGT products remain subject to authorisation (baseline and options 1 to 3).

Conventional farmers – Conventional farmers could maximise benefits of NGTs as set out in section 6.3.1, for example with regard to pesticide reduction as biotic resistance is the second largest type of traits addressed in the R&D pipeline (113 of 489) thereby contributing to resilience and food security. However, as beneficial traits addressing abiotic resistance (water stress[196], heat) are generally genetically more complex and the expression of the involved genes are very dependent on environmental conditions it can be expected that many plant products incorporating such traits would not meet the criteria to be treated as a product that could occur naturally or be produced by conventional breeding and be subject to the rules set out for the baseline option or for options 1, 2 or 3[197]. A quantitative exploratory analysis[198] of impacts shows, for a high adoption rate of NGTs (10-27% of the crop market, depending on crop group), the following estimated mean and, in brackets, range of impacts on key agronomic parameters for several crop groups (Table 6).

Table 6. Trait-level impacts

Crop group	yield change/ha	change in pesticide use/ha	change in fertiliser use	change in water use	change in energy use
Oil and fibre plants	12% (9% to 21%)	-10% (5% to -35%)	-13% (-8% to -28%)	-3% (5% to -15%)	-3% (05 to -10%
Vegetables	9% (6% to 24%)	-	-	-	-
Cereals	16% (6% to 33%)	-26% (-19% to -32%)	-16% (-10% to -22%)	-11% (-10% to -11%)	-12% (-7% to -17%)
Legumes	9% (6% to 23%)	-10% (5% to -35%)	-10% (-5% to -20%)	-5% (3% to -16%)	-3% (0% to -10%)

Compared to the estimates for other options, expected gains are particularly pronounced for yield changes in oil and fibre plants and cereals. This reflects the experts' expectation that a

[196] Van de Wiel *et al*. (2022)

[197] There are some cases where single-gene approaches to abiotic stress-tolerance have been successful in transgenic GMOs, see for example González *et al*. (2020)

[198] Annex 8, section 1 in Technopolis Group *et al*. (2023)

higher adoption rate means that in these crop groups more NGT plants with traits affecting yields are expected to come to market than under the other options.

Some farming stakeholders warn that the widespread use of NGT plants could have a negative impact on them, especially small farmers, and their freedom of choice in the purchase of seeds, linked to patents in this area and the risk of oligopolistic situations[199].

Organic/GM free sector – Today, NGT plants are subject to the requirements of the GMO legislation and are banned in organic production. As noted in section 5.2.4, two sub-options are considered for NGT plants fulfilling the notification criteria: 1) they are treated like GMOs for the purposes of organic production and are therefore prohibited; 2) they are treated like conventional products for the purposes of organic production and can in some instances be used[200]. This second sub-option applies the logic of the legislation today, where GMO products produced by random mutagenesis and which are exempt from GMO requirements are treated as conventional for the purposes of organic production.

In both sub-options, the public register of notified NGT plants and information in the common catalogues of varieties will enable organic operators to identify varieties developed using NGTs allowing them to ensure that no such varieties are used on their fields and to keep supply chains free from them. This transparency would be based on the traceability system of the supply chain of plant reproductive material, which is based on maintaining a high level of varietal purity.

In this option, the risk of admixture will be higher than for options 1-3 as the highest number of NGTs are expected to be placed on the market/cultivated and the costs of segregation for organic operators will likely increase proportionally to the spread of NGTs. The consequences of such admixture, should it occur, will depend on the two sub-options.

In the **first sub-option**, the organic sector will rely on the organic traceability requirements and the preventive measures provided for in the Organic Products Regulation. In order to mitigate the impact on organic farming and ensure freedom of choice for farmers, further measures to support maintaining organic production free from NGTs and consumer trust may need to be introduced (e.g. the labelling of seeds could be considered). As in other options (including the baseline), where the admixture cannot be ascertained analytically, and organic producers are able to show they have complied with all necessary precautionary measures, there will not be direct economic losses linked to loss of the organic logo. However, the lack of analytical methods will raise specific challenges in the case of farmers who manage both organic and conventional production on their holdings[201]. These challenges might erode the trust of those consumers who are concerned about the adventitious presence of NGTs in organic products. However, the legal ban on the use of NGTs can also act as reassurance to consumers that all measures are being taken to avoid NGT presence.

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[199] CEJA (2022)

[200] As there is a lack of organic seeds for many crops, organic farmers are allowed to use non-organic untreated seeds authorised through derogation requests. For data on the use of non-organic seeds see Solfanelli *et al*. (2022). Organic production can also use organisms produced by classical mutagenesis, using irradiation or chemical mutagens, which are GMOs, but are exempted from the obligations of the GMO legislation. For example, the cherry variety 'Sunburst' was developed by hybridization with mutant variety 'Stella' obtained by irradiation with x-rays. Both these varieties are used in organic cherry production in the EU.

[201] Approximately 45% of agricultural holdings with organic production also have non-organically managed areas; see table 2 in https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Organic_farming_statistics#Organic_production

With regard to supply chains, there are currently a few areas of organic food production, where there are interfaces to the conventional market[202]. Special precautionary measures for the organic sector are, in particular, needed when purchasing organic raw materials such as maize, soya or rape seed from countries where GMO varieties are also produced or from traders who also trade in GMOs. In order to exclude as far as possible for these origins and purchasing routes possible admixture with GMO raw materials, appropriate contracts with producers and/or traders that define the critical points in production, transport and storage to minimise admixture are concluded. Some suppliers of raw materials or products offer the raw materials from so-called IP (Identity Preserved) programmes. If more NGTs products come the market, the number of interfaces of organic food production to the conventional market may increase, placing more demands on the IP programmes and the precautionary measures organic operators are obliged to take under the Organic Products Regulation in order to avoid products not authorised in organic production. This will place additional costs and burdens on organic operators who will bear segregation costs. There are, however, no quantitative estimates available.

In this first sub-option, as in all other options, the organic and GM-free sectors can be impacted because of regulatory divergence with non-EU countries (where NGT products may not be subject to traceability and labelling rules or to any transparency obligations) from which organic products are imported into the EU. Under the current EU regulatory framework, NGTs should not be used in organic products exported to the EU, therefore, the costs of keeping segregated supply chains in the EU would remain unchanged.

In the **second sub-option**, notified NGT products could be used in organic production under the applicable derogations for e.g. non-organic untreated seeds. However, organic producers would be able to exclude such plants from organic production through the use of information in the public register of notified NGTs and the precautionary measures provided for in the Organic Products Regulation.

In this sub-option, the organic sector could be impacted regarding imports of organic products, in cases where NGTs that have been considered equivalent to conventional varieties and are prohibited in organic production in third countries.

Moreover, as certain consumers may not accept allowing conventional-like NGTs in organic production, an erosion of consumer trust in the organic market and EU logo could also materialise, possibly leading to emergence of private standards. The same reasoning would apply to the GM-free sector (not regulated under EU law) if it decided to accept notified NGT products.

This sub-option could deliver positive impacts, as organic farmers would be able to benefit from the potential of NGTs supporting sustainable farming practices, in particular with regard to pest resistance and pest tolerance[203]. Organic breeders would also be able to decide to use notified NGT plants in their breeding programmes, if they see benefits in traits relevant to organic cultivation.

There are different positions among stakeholders from the organic sector about the use in organic farming of NGTs if they would be treated as conventional products. Certain stakeholders consider that NGTs are not compatible with the wider objectives of organic breeding laid down in Organic Products Regulation, and that these objectives inform consumer expectations with regard to organic products. Other stakeholders consider that, if

[202] IFOAM EU (2014, 2018)
[203] Andersen *et al*. (2015); Crespo-Herrera & Ortiz (2015)

certain products of NGTs are treated in regulatory terms as conventional products, this should equally apply as regards their possible use in organic production.

Impacts on SMEs –This option is the most advantageous for SMEs, other than those involved in organic and GMO-free production, and supports their freedom to do business, as administrative and compliance costs will decrease considerably for NGT products to which the notification procedure is applied. For these NGT products, development costs could be even lower than for conventional varieties. This option would allow SMEs to use advanced technologies to strengthen their competitiveness on European and global markets. In turn, an enabling framework for SMEs could be more conducive to R&D on niche crops and traits.

Competitiveness – A significantly lower regulatory burden will increase investments in R&D, both from large multinational plant breeders as well as SMEs. For plants meeting the notification criteria, development costs can be even lower than for conventionally bred varieties. This will allow operators to compete with operators from non-EU countries which have exempted conventional-like NGT products from their GMO legislation.

Simplification – This option results in a high degree of simplification and reduction of administrative burden for applicants and authorities. For plants meeting the notification criteria, the normal variety registration procedure applies. For agricultural crops undergoing DUS and VCU trials, these costs amount to an average of EUR 4434 per registration.

1.5.2. Environmental impacts

This option would maintain risk oversight through the case-by-case verification of the criteria to determine that a NGT plant would not present more potential hazards than plants occurring naturally or produced by conventional breeding.

The concerns of certain stakeholders about risks to the environment and biodiversity are intensified under this option due to an expected wider cultivation and the absence of risk assessment for products fulfilling the notification criteria. 65% of survey respondents do not see potential risks for the environment and biodiversity under this option, while 32% see potentially increased risks. However, the majority position in the scientific community and in an increasing number of jurisdictions globally is that certain NGT plants do not differ from those occurring naturally or obtained by conventional breeding, including in their level of risk for human, animal health and the environment. Although contested by certain stakeholders, this is confirmed by EFSA's scientific opinions and numerous other scientific reports. This option would entail verifying, case-by-case and based on predefined criteria (as indicatively presented in section 5.2.4, Box 2), whether risk assessment is necessary. When the NGT plant concerned meets these criteria, it would not present more potential hazards than plants occurring naturally or produced by conventional breeding. The criteria are designed to cover the type and extent of modifications that are also observed with conventional breeding techniques. The principle of comparative assessment against the conventional counterpart remains, therefore, under this option as in the baseline and in the other options. Under this option, the post-market monitoring provisions of the GMO legislation will not apply to products fulfilling the notification criteria. However, mechanisms will remain available under the new framework and in horizontal legislation (e.g. under the General Food Law) to handle any new information on potential risks.

This option offers the largest opportunities to realise the potential environmental benefits of NGTs, as it offers the strongest incentive to develop NGT varieties in the EU, although the development and marketing of NGT products, and the realisation of their potential, depends also on various factors other than an appropriate regulatory framework. Patents, access of public organisations and SMEs to the technologies and the market, access and affordability

for farmers (particularly small-scale), and factors driving consumer acceptance, will also have an important impact.

Agrobiodiversity could benefit from this option, as it can become less burdensome and costly to apply the techniques to small and local crops provided that access to the technology, in particular for SMEs and the public sector, is not restricted by high licensing costs. A recent modelling study found that NGT plants, when regulated like conventionally bred crops, required a 96% smaller potential cultivation area to break even on the financial investment when compared to established genetic modification[204]. In addition, the FAO reports that NGT crops are more diverse regarding varieties, traits and institutions developing them (more public organisations and SMEs) in comparison with first generation GM crops. However, some NGT crops with traits contributing to sustainability can face significant financial barriers for development and use[205]. Moreover, if NGT crops are subject to the same regulatory requirements as GM crops, the cost of regulatory approvals is often prohibitive for niche crops[206]. Therefore, it is expected that the reduction of burden and costs under this option would contribute to improve market access to NGTs for public organisations and SMEs that could in turn bring benefits associated to smaller area crops and/or niche traits.

1.5.3. Social, health and safety impacts

Social, health impacts and safety impacts – As regards risks for human health, the same considerations as for environmental risks presented in section 6.5.2. apply. When the NGT plant concerned meets the notification criteria, it would not present more potential hazards to human health than plants occurring naturally or produced by conventional breeding.

Furthermore, this option offers the largest opportunities to realise the potential health benefits of NGT products, as it offers the strongest incentive to develop NGT varieties in the EU.

On potential risks for human and animal health such as toxicity or allergenicity, 64% of respondents expect no change under this option, while 29% expect increased risk.

Impacts on consumers – In a similar way as random mutagenesis today, this option would treat NGT products that fulfil the notification criteria as conventionally bred products, and information would not be provided on the product's label about the technology used when marketing the product (although all notified products would be entered in a public register). In this regard, the ability to decide not to consume NGT products would not be ensured by this option to the same degree as in the baseline and options 1, 2 (where labelling is not waived) and 3. However, a GM label for products not subject to risk assessment and authorisation as GMOs, and which could occur in nature or be conventionally bred, could create confusion about the product's characteristics and safety profile. In any event, consumers actively wanting to avoid NGTs would be able to rely on the organic logo (in the sub-option where notified NGTs would remain banned in organic production).

This option would bring the highest number of products to the market. There could thus be more opportunities for consumers to access NGT products with increased nutritional and functional qualities and with other sustainability-relevant traits (e.g. pest resistance) which, according to available research, rank high among consumers' concerns.

As this option would entail the lowest costs to access the market, it could result in lower prices for NGTs compared to other options (see section 7.2 on efficiency).

[204] Bullock *et al*. (2021)
[205] Jordan *et al*. (2022)
[206] FAO (2022)

7. How do the options compare?

This section compares the expected impacts of the options in terms of their effectiveness to reach the initiative's objectives, efficiency, coherence and proportionality. This qualitative assessment of the options is based on the overall analysis of key impacts and the comparison is with the performance of the baseline. It takes the scoring of the multicriteria analysis[207] into account, as well as additional evidence gathered during this process. The overall comparison of the options against the relevant criteria is presented in Table 7.

Table 7. Overall comparison of policy options. Options 1-3 cover all NGT products, option 4 only products which could also be obtained naturally or by conventional breeding

Criteria	Policy Option 1	Policy Option 2	Policy Option 3	Policy Option 4
Effectiveness: contributing to achieving the policy objectives				
Procedures for the deliberate release and placing on the market ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden	+	+	+	+[208]
Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers	0/+	+ /++[209]	0	++
NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system.	0/+	+	0/+	++
Effectiveness: specific impacts				
Competitiveness	0/+	+	0	++
SMEs	0/+	+	0	++
Social & health[210] impacts	0/+	+	0/+	+ /++
Environmental impacts[211]	0/+	+	0 /+	+/++
Impacts on the organic sector	0/-	0/-	0/-	Notified NGTs treated as GMOs in organic production: 0/-
				Notified NGTs treated

[207] Technopolis *et al*. (2013), section 6, Table 11

[208] A combination of option 4 with an adapted risk assessment as envisaged in options 1, 2 and 3 would maximise this objective (++)

[209] The strong positive effect is due to the variant of waiving the GM label

[210] Only social and health impacts beyond the impacts specific to the genetic modification considered under the first policy objective

[211] Only environmental impacts beyond the impacts specific to the genetic modification considered under the first policy objective

				as conventional in organic production: -/+
Efficiency				
Administrative and compliance costs	0/+	+[212]	+/-	++
Savings and benefits	+/++	+[213]	+/- [214]	++
Coherence	+	+/-	-	Notified NGTs treated as GMOs in organic production: - Notified NGTs treated as conventional in organic production: +
Proportionality	+	+	-	++
Overall	**0/+**	**+**	**0**	**+/++**

* -- strong negative effect, - negative effect, 0 neutral effect, + positive effect, ++ strong positive effect; values separated by a slash mean that the size of the impacts can take negative, neutral or positive values depending on choices or alternatives within options.

1.6. Effectiveness

Contributing to achieving the policy objectives

Procedures that ensure safety while avoiding unnecessary administrative burden

The baseline would ensure safety, albeit with unnecessary burden, as it would continue to apply the current requirements of the GMO legislation to NGT plants, despite the fact that, according to the conclusions of EFSA and major scientific bodies (reported in section 1.1 and Annex 6), on a case-by-case basis, a lesser amount of data will be sufficient for the risk assessment of certain plants produced by these techniques. Certain NGT plants do not present more potential hazards than plants produced by conventional breeding. The impact analysis shows that options 1, 2 and 3 (which all feature the same adapted risk assessment to different levels of risk) would allow achieving safety for all NGT plants, however, with a disproportionate burden for NGT plants that could have been obtained naturally or by conventional breeding. Option 4, through the notification procedure, alleviates the burden on the operators for this type of products, while ensuring safety (but was not considered from the outset as an option that could deliver on the objective of safety for other NGT plants). Therefore, this specific objective is best achieved through a combination of option 4 for NGT plants that could have been obtained naturally or by conventional breeding and the adapted risk assessment approach of options 1, 2 and 3 for other NGT plants.

All options are based on the application of the precautionary principle. A regulatory oversight procedure applies in all options to ensure that only NGT plants that are considered as safe as their conventional counterparts are released or placed on the market.

The regulatory framework for NGTs also needs to be designed in a way that it ensures safety, when technologies evolve (**future-proofness**). The baseline does not achieve this objective. It

[212] Costs are linked to the voluntary provision of data on sustainability of the trait in order to use incentives
[213] Ibid.
[214] Costs are linked to the mandatory provision of data demonstrating that the trait is not detrimental to sustainability

entails the continued application of a legal framework that has been assessed not to reflect the latest scientific developments. It contains no mechanisms to adapt to scientific or technological progress, or to the wide diversity of NGTs and resulting products, in particular as regards their different risk profiles.

The adapted risk assessment that features in options 1, 2 and 3 contributes to ensuring safety when technologies evolve by recognising the diversity of products and risk profiles. Other aspects of the design of the adapted risk assessment in these options would also contribute to this: the criteria to adapt the risk assessment are based on the characteristics of the product, rather than on specified technologies (see section 5.2.1.); provision would be made to allow for the update by the Commission of the criteria over time based on scientific and technical progress and experience; specific data requirements based on the criteria would not be laid down in the basic act but would be developed subsequently in Commission tertiary legislation and complemented by EFSA guidance.

Future-proofness is embedded in the design of option 4 as well: the criteria to determine whether an NGT plant could have been obtained naturally or by conventional breeding are based on the characteristics of the product, rather than on specified technologies (see section 5.2.4); provision would be made to allow for the update by the Commission of the criteria over time based on scientific and technical progress and experience; the criteria would be complemented by thresholds concerning the size and combination of modifications, which would not be laid down in the basic act, but subsequently in Commission legislation and complemented by EFSA guidance.

Diversity of released and marketed NGT products and of developers

Under the baseline, regulatory costs and time to market will be the same as for GMOs obtained by established genomic techniques and NGT plants will be marketed as GMOs. Breeders, and, in particular, SME breeders in the EU will thus have very limited incentives to develop NGT plants and to go beyond the limited number of traits and crop species to which established genomic techniques have been applied.

A less burdensome, less costly and faster authorisation procedure can be expected under option 1 as a result of the adapted risk assessment. However, while the analysis of impacts shows that the combination of lower R&D costs, faster development time and lower regulatory costs could lead to a moderate to significant market uptake of NGT products from a wider diversity of crop species with more diverse traits, breeders expect only a small increase in the attractiveness to develop NGT products in the EU compared to the baseline. This is linked to the uncertainty perceived by stakeholders about the adapted risk assessment, and the concern that it will still be marked by complexity and lack of predictability (as well as by the GMO label requirement). In any case, the requirement for labelling as GMO under this option will limit the extent of its potential positive effects.

Options 2 adds the possibility of incentives for applications for NGT plants with traits that can contribute to sustainability. With easily implementable criteria to trigger regulatory incentives, stakeholders do see merit in them, especially for SMEs. Incentives would support the diversity of players, as well as the diversity of traits and crop species on the market. As a result, option 2 can have a positive impact compared to baseline. If the incentives are not used, this option is equivalent to option 1 in terms of impacts. Option 2 would considerably incentivise the development and placing on the market of NGT products if labelling as GMO is waived for products with a modified trait that is considered to have the potential to contribute to sustainability. Providing information on the purpose of the trait would increase transparency and could increase consumer acceptance.

The attractiveness of developing diverse NGT products under option 3 is reduced compared to options 1 and 2 through the introduction of sustainability requirements. The risk that authorisation could be refused on grounds related to a potential detrimental impact on sustainability, coupled with the current lack of horizontal definitions and frameworks to assess sustainability and the uncertainty of assessing sustainability based on a single trait, would act as a disincentive to apply. These risks are likely to affect SMEs in particular.

Option 4 has by far the strongest positive impact on enabling the development and placing on the market by SMEs and large companies of NGT products with diverse traits from a wide range of crop species, as it results in a higher degree of simplification and reduction of administrative burden and costs for applicants and authorities.

Contribution to sustainable agri-food systems

The ability of all policy options to contribute to this objective depends on the number of NGT products from diverse crop species, which will come to the market, and on the type of traits which will be developed (addressed by the previous specific objective). The development pipeline as described in the JRC report shows that research addresses a large diversity of crops and that a large share of traits under development could contribute to sustainability, in particular pest resistance, nutrient-use efficiency, tolerance to abiotic impacts (e.g. droughts and improved yield/input ratio, yield stability). This research pipeline is answering to the demand that in turn is also driven by current policy and regulatory developments, such as the revision of the PRM/FRM legislation (with a stronger sustainability focus) and the introduction of targets in initiatives such as the SUR, e.g., as regards a reduction of pesticide use.

Under the baseline, no or only very few NGT plants are expected to be authorised for cultivation or placing on the market, and therefore positive economic, environmental and social impacts of NGTs will be very limited, if any materialise at all.

Like the baseline, option 1 does not contain any provision that would specifically steer towards NGT products containing desirable traits from a sustainability perspective.

Option 2 has an additional, limited positive effect compared to option 1 on the attractiveness for plant breeders to develop in the EU NGT plants that contribute to sustainability objectives.

Option 3 was designed to deliver on this objective to the largest degree by ensuring that only plants with no detrimental effects on sustainability reach the market, but the risk that a NGT product might be refused authorisation for not meeting the sustainability requirements creates regulatory uncertainty and is a disincentive to develop and apply for authorisation.

An important reason why options 2 and 3 show limited gains (option 2) or negative impact (option 3) is because they cannot take into account that the sustainability of a crop does not depend solely on its individual traits but on the interplay of the plant with its environment and the farming system that it is used in, coupled with the fact that different breeding methods can be used to reach the same traits. Sustainability incentives, and even more so requirements, for isolated traits are thus considered not to be efficient. Requirements linked to specific traits but applicable only when the trait is obtained through biotechnology raise specific discrimination problems if the same traits can also be obtained by conventional breeding. However, breeders do see some merit in the regulatory incentives, especially for SMEs which are particularly vulnerable to regulatory complexity and uncertainty. In turn, incentives with a positive impact on SME access to the NGT market have the potential to steer R&D towards crops and traits with sustainability-relevant impacts, beyond the commodity crops with a limited number of traits developed with established genomic techniques. Also, if incentives as envisaged in option 2 are combined with a waiver of GMO labelling for products with a modified trait that

is considered to have the potential to contribute to sustainability, this objective would be achieved to a much more considerable extent.

By simplifying the framework for certain NGT plants, and given the traits in the R&D pipeline as well as the demand and policy pressures for traits that contribute to sustainability, option 4 will achieve this objective to the largest degree. However, this will only concern plants that could occur in nature or have been obtained by conventional breeding; this option on its own will not result in plants with more complex traits that could not be achieved conventionally.

Digital by default –labelling and traceability, where relevant, are addressed in a way allowing a wide range of implementations, including purely digital solutions where appropriate. The risk assessment process managed by EFSA is already largely digitalised in line with the 'digital by default' principle. This principle will be also applied for the notification procedure.

Other impacts

Competitiveness and SMEs

Certain NGTs are considered relatively accessible tools for plant breeding compared to established genomic techniques. In this regard, NGTs could lead to a lowering of technological barriers to entry of the plant breeding sector, benefitting SMEs in particular. This has been observed in Argentina after its regulatory decision to exclude certain NGT products from the GMO framework[215].

In the baseline, the current situation with large, multinational companies dominating the market for GMOs will also apply to NGTs, due to the high regulatory burden and costs, perceived regulatory uncertainty, and the fact that products would be marketed as GMOs.

In terms of the competitiveness of SMEs, under option 1 some improvement for SMEs could be expected compared to the baseline. SMEs are vulnerable to complex regulatory requirements. Adapting data requirements to the risk profile of a NGT product will reduce the complexity, duration and costs of the application for authorisation and this would benefit SMEs. Clarity and predictability of risk assessment criteria would be particularly relevant for the access of SMEs.

Options 2 and 3 have the same impacts as option 1 as regards risk assessment. The incentives envisaged under option 2 could provide some benefits to SMEs by addressing the need for support measures such as regulatory/scientific advice and for further cost savings such as fee waivers, while option 3 adds regulatory burden as regards providing mandatory data for verification of the sustainability contribution of a trait and increases regulatory uncertainty as products will not be authorised if they ultimately do not meet the sustainability requirement.

Option 4 is by far the most advantageous for SMEs, as administrative and compliance costs will nearly be eliminated for those NGT products to which the notification procedure is applicable. A clear definition of objective notification criteria would reduce uncertainties and render the regulatory process more predictable for SMEs.

However, the ability of SMEs to enter the NGT market will be also dependent on affordable access to intellectual property. For this reason, some stakeholders consider that their competitive position will not improve under any of the options, unless patent-related issues are resolved[216].

[215] Whelan *et al*. (2020); Goberna *et al*. (2022)
[216] Technopolis Group *et al*. (2023)

In terms of general competitiveness, in the baseline, negative impacts can be expected due to factors such as reduced access of the EU breeding sector to a global gene pool for plant breeding. A negative impact on the competitiveness of conventional farming can be expected due to reduced access to new tools developed through science and innovation efforts, and increase in input prices (e.g. for feed supply). Option 1 is expected to offer small improvements as regards competitiveness of breeders and farmers, while under option 2 some additional improvement is expected in particular if the GMO labelling is waived for products with traits contributing to sustainability. Option 3 is not expected to bring improvements. Option 4 has the strongest impact on competitiveness as a lower regulatory burden will enable investments in R&D and subsequent product development, both from large multinational plant breeders as well as SMEs. Equally, in terms of international competitiveness, it is option 4 which will have the strongest impact. In major trading partners of the EU (e.g. the United States or Argentina) NGT plants, and derived food and feed products, that can also result from conventional breeding are not subject to GMO regimes. The European seed sector is the largest exporter in the global seed market and using innovative technologies is a prerequisite for maintaining competitiveness. Option 4 also has the strongest impact on strategic autonomy and resilience of the EU food system. Under this option, NGTs are expected to be applied to a large range of crop species and traits by a diverse set of actors.

Social and health impacts

Impacts related to the protection of human and animal health are addressed above in the section on the specific objective of procedures that ensure safety while avoiding unnecessary administrative burden.

Under the baseline, potential positive social and health impacts of NGT products with improved nutritional and functional quality will be largely missed. Under options 1 and 2 and to a smaller extent under option 3, more NGT products are expected on the market and therefore certain of the social and health benefits of these products could be realised. This would be greater in option 2, with some gains resulting from incentives to NGT plants containing traits with potential positive social and health impacts, and further gains if the GMO labelling is waived for NGT plants with traits that can contribute to sustainability, as well as in option 4.

The baseline and options 1 and 3 ensure information to consumers about the use of genetic modification technologies on the product's label, according to consumer expectations as they result from consultation activities and available research. However, this could result in low levels of consumer acceptance of NGTs, if the negative connotations of the current GM label extend to NGTs, unless other initiatives are taken to inform and engage consumers about NGTs. In option 2, the sub-option to label NGTs with traits that can contribute to sustainability as GM combined with a sustainability label or a factual statement on the intended purpose of the genetic modification would support freedom of choice and increase consumer and market acceptance, whereas the sub-option in which the GMO label is waived if a product contributes to sustainability would make freedom of choice more burdensome and likely negatively affect trust. The absence of labelling in option 4 would also make freedom of choice more burdensome, but, on the other hand, a GM label for NGT products which could occur in nature or be conventionally bred could create confusion.

Opportunities for consumers to access NGT products with increased nutritional and functional qualities and with other sustainability-relevant traits which, according to available research, rank high among consumers' concerns would be greatest in option 4 followed by option 2.

Environmental impacts

Impacts related to the protection of the environment are addressed earlier in this section in the subsection concerning the specific objective of procedures that ensure safety while avoiding unnecessary administrative burden.

As no or only very few NGT plants are expected to be authorised for cultivation under the baseline and option 3, the environmental impacts of these plants will be limited. Impacts will be largely restricted to missed potential environmental benefits coming from NGT plants.

As a certain number of NGT products are expected to be placed on the EU market under option 1, some environmental benefits are likely to be realised. The same would apply in option 2, with additional gains resulting from incentives for NGT plants containing traits with potential positive environmental impacts, and further gains if the GMO labelling is waived for NGT plants with traits that can contribute to sustainability. This may in particular apply to plants with biotic resistance, as such traits can be obtained by relatively simple genetic modifications, leading to lower pesticide use. With more NGT products arriving on the market, certain stakeholder groups expect positive environmental impacts, while others expect negative impacts. In the targeted survey, roughly equal number of stakeholders expect a positive (40%) or a negative (46%) impact. However, this polarisation is primarily due to divergent views on the effects of herbicide tolerant crops, which, can, however, be developed by all methods (conventional breeding, established genomic techniques or NGTs), and not to negative impacts specific to the use of NGTs.

Option 4 offers the largest opportunities to realise the potential environmental benefits of NGTs. As for options 1 and 2, the expectation is that the most significant environmental impacts will come through NGT products with traits such as durable pest resistance. The concerns about risks to the environment and biodiversity are similar to those for options 1 and 2. Agrobiodiversity could benefit from this option, as it can become easier to apply the techniques to small and local crops.

All options are aligned with the ‘do no harm’ principle and include procedures to ensure that NGT plants are only released or placed on the market if they are considered to as safe as their conventional counterparts. Option 3 embeds this principle further by setting as a pre-requisite for authorisation that the introduced trait is not detrimental to sustainability.

Impacts on the organic and GM-free sectors

The labelling and traceability requirements in the existing GMO legislation, as well as the national coexistence measures adapted to local circumstances, will continue to apply and allow separate value chains and consumer trust in these sectors under the baseline as well as in options 1, 2 (if GMO labelling is not waived) and 3. The risk of admixture during cultivation, harvest, storage, transport and processing will depend on the adoption rate of NGTs and thus be moderately higher than the baseline in options 1 and 2 and similar to the baseline in option 3 and highest in option 4.

Under option 4, the traceability, labelling and coexistence measures of the current GMO legislation would not apply to notified NGTs. Impacts would differ if the NGTs under notification are treated for the purposes of organic production as GMOs or as conventional products. In the first sub-option organic operators would have the responsibility to put in place precautionary measures, supported by the public register of NGT plants and information in the common catalogues of plant varieties, to avoid the use of and admixture with any product that is not authorised in organic production. If NGT products subject to notification would be treated for the purposes of organic production as conventional products, they could

be used in organic production under the applicable derogations (and potentially contribute benefits). However, there is the risk that consumers would not accept NGTs in organic production, and a degree of erosion of consumer trust and related economic losses could materialise.

The labelling sub-options in option 2 would have specific impacts. Under the variant of this option that maintains a GMO label, the impacts on the organic/GM-free sector will be similar to option 1. There are concerns that the variant with sustainability labelling of NGTs would be to the disadvantage of sustainable conventional or organic products, which would not be able to use such a sustainability label. Such NGT products would in any case still be labelled as GM and identified as such by operators and consumers. If NGT products with traits contributing to sustainability would not be labelled, the organic logo would guarantee to consumers that the product is GM-free.

Under all options, some negative impacts on the organic and GM-free sectors can occur due to regulatory divergence with non-EU countries from which organic and GM-free products are imported into the EU, as sourcing of products may become more limited and as more challenging and expensive identity preservation systems for NGT free products in the EU trade partners may be required. Under the current EU regulatory framework, NGTs should not be used in organic products exported to the EU, therefore, the costs of keeping supply chains in the EU segregated would remain unchanged.

1.7. Efficiency analysis

This section compares the cost-effectiveness of the policy measures in the different options for important stakeholder groups, based on the data in Annex 3. The wide range of costs and savings are linked to the potential variability in data requirements, which depend on the risks/type of products.

Table 8. Current cost for authorisation procedure (baseline). The authorisation cost can be subdivided in cost for risk assessment, detection method, risk management and administrative cost.

Baseline (in thousands EUR)	Cost for breeders	Cost for administrations	Cost for farmers and food businesses
Full authorisation costs	n/a	209[217]	n/a
Risk assessment	12 194	n/a	n/a
Detection method	650	n/a	n/a
Risk management	156 [218]	n/a	Available data not sufficient for quantification[219]
Coexistence and segregation measures	n/a	n/a	Available data not sufficient for quantification[220]

[217] For administration, only costs for an authorisation procedure were estimated.
[218] For breeders, risk management refers to any post-adoption activities, such as post-market monitoring.
[219] Unquantifiable risk management costs for organic farmers are linked to practices and market monitoring of accidental presence of GM product.
[220] Coexistence measures, which are set up at national level, have costs for GM farmers, which are highly dependent on the crop species, on farm structure and on environmental conditions. In addition, currently only GM maize MON810 is authorised in the EU for cultivation, and its cultivation is limited to Spain and Portugal. Therefore, available data on the current costs for **co-existence measures** and their variability are extremely limited. The SIGMEA project (2004 – 2006), funded under FP6, mentioned in Section 6 estimates the costs of potential coexistence measures to GM farmers based on simulations.
Coexistence of GM and non-GM commodity in the value chain creates **segregation measures costs** for processing chain and for the food businesses. The current costs cannot be quantified with sufficient certainty as they vary greatly depending on the GM crop species, its processing and use in the EU. The Co-Extra research project (2008 – 2009) mentioned in Section 6 estimates the coexistence costs for the food businesses and the value chain in some products.

Assessment of sustainability claim	n/a	n/a	n/a
Administrative cost	4 940	n/a	Available data not sufficient for quantification[221]
Total balance for full authorisation costs	17 940	209	Available data not sufficient for quantification

Table 9. Costs and savings for authorisation under Option 1 in comparison to the baseline: Negative amounts correspond to financial savings while positive amounts correspond to costs.

Option 1 (in thousands EUR)	**Costs for breeders**	**Cost for administrations**	**Cost for farmers and food businesses**
Full authorisation costs	n/a	From 0 to -140	n/a
Risk assessment	From 0 to – 10 365	n/a	n/a
Detection method	No change compared to the baseline	n/a	n/a
Risk management	No change compared to the baseline	n/a	No change compared to the baseline
Coexistence and segregation measures	n/a	n/a	No change compared to the baseline
Assessment of sustainability claim	n/a	n/a	n/a
Administrative cost	From 0 to – 1 750	n/a	No change compared to the baseline
Total balance for full authorisation costs	From 0 to -12 115	From 0 to -140	No change compared to the baseline

Table 10. Costs and savings for authorisation under Option 2 in comparison to the baseline: Negative amounts correspond to financial savings while positive amounts correspond to costs.

Option 2 (in thousands EUR)	**Costs for breeders**	**Costs for administrations**	**Cost for farmers and food businesses**
Full authorisation costs	n/a	From 0 to -140	n/a
Risk assessment	From 0 to – 10 365	(+)[222]	n/a
Detection method	No change compared to the baseline	n/a	n/a
Risk management	No change compared to the baseline	n/a	(+) or no change compared to the baseline[223]
Coexistence and segregation measures	n/a	n/a	No change compared to the baseline
Voluntary assessment of sustainability claim	From +1 950 to +390 [224]	(+)[225]	n/a

[221] Unquantifiable administrative costs for food businesses due to the GM labelling obligation.
[222] Potential moderate to significant increases in costs for administrations, due to possible incentives to encourage the development of sustainable products such as scientific support given to the applicant during authorisation process.
[223] In the first scenario, the GMO labelling would be waived for products with a modified trait that is considered to have the potential to contribute to sustainability. In that case, an unquantifiable increase in costs is expected for organic farmers.
In the second scenario, the GMO labelling is maintained, but a possible sustainability labelling can be added to the GMO labelling. In this case, there is no change in costs compared to the baseline for organic farmers.
[224] Voluntary compliance cost. For this analysis, in the absence of reliable information, it is assumed that all applicants choose to provide data to support such a claim. Therefore, the amount is the same as in the corresponding entry in Table 11, where these costs are mandatory for all applicants.
[225] Potential moderate to significant increase in costs for Member States administrations due to the assessment of sustainability claim.

Administrative cost	From +247 to -1 725[226]	n/a	(+) or (-)[227]
Total balance for full authorisation costs	From +2 197 to -11 700[228]	Available data not sufficient for quantification	(+) or (-)[229]

Table 11. Costs and savings for authorisation under Option 3 in comparison to the baseline: Negative amounts correspond to financial savings while positive amounts correspond to costs.

Option 3 (in thousands EUR)	**Costs for breeders**	**Costs for administrations**	**Cost for farmers and food businesses**
Full authorisation costs		From 0 to -140	
Risk assessment	From 0 to – 10 365	n/a	n/a
Detection method	No change compared to baseline	n/a	n/a
Risk management	No change compared to the baseline	(+) or no changes compared to the baseline[230]	No change compared to the baseline
Coexistence and segregation measures	n/a	n/a	No change compared to the baseline
Mandatory assessment of sustainability claim	From +1950 to +390[231]	(+)[232]	n/a
Administrative cost	From +247 to -1 725	n/a	No change compared to the baseline
Total balance for full authorisation costs	From +2 197 to -11 700	Available data not sufficient for quantification	No change compared to the baseline

Table 12. Costs and savings for notification under Option 4 in comparison to the baseline: Negative amounts correspond to financial savings while positive amounts correspond to costs.

Option 4 (in thousands EUR)	**Costs for breeders**	**Costs for administrations**	**Costs for farmers and businesses**
Full notification costs	n/a	From 0 to -140[233]	n/a

[226] The administrative costs of the voluntary assessment of sustainability ranges from +247 000 EUR to +25 000 EUR.

[227] In the first scenario, the GMO labelling would be waived for products with modified trait that is considered to have the potential to contribute to sustainability. In that case, an unquantifiable saving in administrative costs for food businesses is expected.

In the second scenario, the GMO labelling is maintained, but a possible sustainability labelling can be added to the GMO labelling. In that case, a limited unquantifiable administrative cost increase is estimated due to the additional information in the label.

[228] The total balance presented in the table takes into account the potential voluntary data produced for the assessment of sustainability claim.

The total balance in case no assessment of sustainability is performed would range from 0 to -12 115 000 EUR.

[229] In the first the scenario, the estimated total would be an unquantifiable increase of costs for organic farmers and unquantifiable savings for food businesses.

In the second scenario, it is estimated that there is no change compared to the baseline for organic farmers and limited unquantifiable costs for food businesses.

[230] In the first scenario, the GMO labelling would be waived for products with modified trait that is considered to have the potential to contribute to sustainability. In that case, a slight increase in costs is estimated for the Member States administrations.

In the second scenario, the GMO labelling is maintained, but a possible sustainability labelling can be added to the GMO labelling. In that case, Member States competent authorities estimated that costs increase for risk management, due to the necessity to set up additional control systems, would range from negligeable to high.

[231] Mandatory compliance cost.

[232] Potential moderate to significant increase in costs for Member States administrations due to the assessment of sustainability claim.

[233] The full notification cost for administrations is to be compared for the authorisation cost in the baseline scenario.

Data for notification[234]	From -9 146 to -10 365	n/a	n/a
Detection method	-650	n/a	n/a
Risk management	-156[235]	(-)[236]	(+)[237]
Coexistence and segregation measures	n/a	n/a	(+)[238]
Assessment of sustainability claim	n/a	n/a	n/a
Administrative cost	From – 1 615 to – 3 750	n/a	(-)[239]
Total balance for full notification costs	From -11 567 to -14 921	From 0 to -140[240]	(+) and (-)[241]

1.8. Coherence

7.3.1. Coherence with GMO legislation

NGT plants fall under the scope of the current EU legislation on GMOs. The initiative on NGT plants will propose new measures specifically for NGT plants and food and feed containing, consisting or produced from such plants. Those measures will share the objectives of the GMO legislation to ensure a high level of protection of human health and of the environment in accordance with the precautionary principle and ensure the functioning of the internal market while addressing the specificity of NGT plants. All policy options are coherent with the existing framework as regards those objectives. Options 2 and 3 would add new sustainability elements in the GMO framework only for NGT products.

7.3.2. Coherence with other legislation and initiatives

Plant Reproductive Material (PRM) and Forest Reproductive Material (FRM) legislation – The objective of the on-going revision of the PRM and FRM legislation is to ensure the availability of PRM and FRM of high quality and diversity, that contribute to food security, sustainable production and protection of biodiversity and that are adaptable to climate change. The objectives of the NGT initiative and the PRM/FRM revision are fully compatible.

While the scope of the NGT initiative covers all plant species, the PRM/FRM revision covers only the economically most important species for European agriculture, horticulture and forestry. This is justified by the different rationales of the legislation on NGTs (regulatory oversight of products obtained by new biotechnologies) and on PRM/FRM (regulatory oversight to ensure the identity, quality and health of the economically most important marketed PRM and FRM regardless of the method by which they have been produced).

[234] The comparison was done between the estimated costs of the potential data requirements for the notification of an NGT plant compared to the current cost of data requirements for a GMO application.
[235] For breeders, risk management refers to any post-adoption activities, such as post-market monitoring activities.
[236] Significant unquantifiable savings are estimated for administrations in risk management due to the removal of the traceability and labelling requirements.
[237] Potential unquantifiable increase in costs is expected for organic farmers for risk management practices and market monitoring (for accidental presence of GM/NGT product) due to the uncertainties of potential presence of notified NGT plants in conventional seeds.
[238] Potential unquantifiable cost increase for organic farmers (and others not wishing to use NGTs) due to potential challenges regarding coexistence as the labelling threshold cannot be effectively checked and enforced.
[239] Unquantifiable savings in administrative costs for businesses is expected due to the removal of the traceability and labelling obligation.
[240] This total does not take into account the unquantifiable savings from risk management.
[241] Unquantifiable savings are expected for non-organic farmers and businesses while unquantifiable costs are expected for organic farmers.

Possible issues of coherence between the two initiatives are primarily related to the inclusion of sustainability provisions. Under all options of the PRM/FRM initiative, the assessment of sustainability characteristics will be extended to all crop groups/FRM categories beyond agricultural crops on a voluntary or mandatory basis, depending on the option chosen. Both the current VCU for agricultural crops and vine, and the envisaged extended sustainability assessment under the PRM initiative, examine the overall performance of new varieties compared to varieties in the national catalogues in relation to a number of characteristics that would go beyond one or more introduced traits. The same principle of an overall assessment of basic material in relation to a number of defined sustainability characteristics holds true for FRM. As today, the PRM/FRM systems will not provide for the possibility to reject a variety based on a single trait as inferior characteristics may be discarded if the variety/basic material as a whole offers clear improvements in comparison with existing varieties/basic material.

In the baseline option and options 1 and 4 no specific sustainability provisions will be introduced and no issues of coherence with the PRM/FRM revision would need to be considered.

In Option 2, the specific regulatory incentives considered would not raise a problem of coherence with the PRM/FRM revision, as they are specific to the authorisation procedure for NGT products. The sustainability-related procedures of the two systems should not interfere with each other, because the verification in option 2 relates exclusively to the potential sustainability impact of an individual trait introduced in a specific plant in comparison to the same plant without this genetic modification, while the PRM/FRM legislation considers the overall performance of new agricultural crop varieties. Moreover, assessing during the authorisation process the potential contribution to sustainability of a trait introduced using NGTs could trigger incentives in the NGT framework but would not prejudge the outcome of VCU trials during variety registration. On the other hand, a sustainability claim in the NGT initiative could raise coherence issues as it would be linked to an individual trait irrespective of the overall performance of the variety.

Option 3 would not ensure coherence with the PRM/FRM revision as it would lead to having sustainability as a requirement only for NGT plants, leading to the refusal of the authorisation to place on the market plants featuring certain traits, while conventionally bred plants featuring the same traits would not, for that reason alone, be excluded from the market. Should those plants be subject to VCU examination, the holistic assessment in that context would also not lead to rejection of a variety containing a trait that could have detrimental impact on sustainability, if other, superior characteristics are present.

Planned initiative on a legislative framework for a sustainable food system (FSFS) - Both the FSFS and the NGT initiatives share the objectives of the Green Deal and the Farm to Fork Strategy and are intended to set out enabling frameworks to achieve these common goals. Whereas the NGT initiative will set out a framework to encourage the development of NGT plants that can contribute to those objectives, at the same time ensuring a high level of protection of human and animal health and of the environment, the FSFS is envisaged as an enabling framework for an EU sustainable food system. While the main elements of both initiatives are still being developed, both initiatives will be mutually complementary and work in synergy to achieve their shared sustainability objectives.

Organic Products Regulation (Regulation (EU) 2018/848) and organic target in the Farm to Fork Strategy – That regulation bans the use of GMOs in organic production, and considers as GMOs for the purposes of that Regulation those that are not exempted from the requirements of the GMO Directive. Conversely, GMOs exempted from the requirements of the GMO legislation (e.g., plants obtained from random mutagenesis) are treated as conventional for the

purposes of organic production and may be used under certain circumstances. In the baseline, as well as options 1, 2 and 3, NGTs would remain subject to the requirements of the GMO legislation and would be considered GMOs for the purposes of organic production. If option 4 is retained, the proposal may need to clarify the status of NGT products falling under the notification in the context of the organic regulation. In any event, all options include provisions (traceability, labelling or public registries) to allow organic producers to comply with the Organic Production legislation.

The Farm to Fork Strategy aims for at least 25% of the EU's agricultural land to be under organic farming by 2030. This aim can be reconciled with increased NGT cultivation through transparency about NGTs to allow choice in the supply chain in all policy options and the use of appropriate coexistence/precautionary measures. Should organic operators accept the use of notified NGT plants with traits relevant to organic production (e.g. pest resistance, tolerance to drought, nutrient use efficiency, improved yield/input ratio), and if this becomes possible under the legal framework, this could support efforts towards the 25% target. On the other hand, this could also lead to the loss of trust of consumers in the organic EU logo and could impact progress towards the 25% target.

Regulation (EU) 2015/2283 on novel foods (NFR)[242] – This regulation does not apply to food subject to Regulation (EC) No 1829/2003 on genetically modified food and feed. In option 4, NGT food and feed products which meet the notification criteria and are not subject to authorisation as GMOs would no longer be excluded from the NFR. If there would be significant changes in the composition or structure of food derived from NGT plants affecting its nutritional value, metabolism or level of undesirable substances, the food would need to be risk assessed and authorised under the NFR in order to be placed on the market. This would contribute to the overall goal of ensuring safety.

Legislation on labelling: Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC Regulation)[243]*, Regulation (EC) No 1924/2006 on nutrition and health claims, (NHCR)*[244]*, Regulation (EC) No 767/2009 on the placing on the market and use of feed*[245] *and initiative on substantiating green claims*[246] – The sustainability label (if complementary to the existing GMO label) in option 2 for NGT products featuring a modified trait which contributes to sustainability could raise coherence issues vis à vis current requirements in the FIC Regulation, the NHCR and the Regulation on marketing of feed as well as with the green claims initiative. These regulations set out requirements that have to be met by voluntary information or claims included on the labelling of food intended for the final consumer. Therefore, any claim regarding the properties of the food derived from a NGT plant, and in particular on nutrition properties, would have to also comply with those requirements. As regards environmental claims, the Commission's green claims initiative would require companies to substantiate environmental claims about their products with a standard methodology to assess their impact on the environment. Any environmental claims made with regard to the modified trait of a NGT plant in option 2 would have to be

[242] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283
[243] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R1169
[244] https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32006R1924
[245] https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32009R0767
[246] Proposal for a Directive of the European Parliament and of the Council on substantiation and communication of explicit environmental claims (Green Claims Directive). COM/2023/166 final; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:0166:FIN

substantiated in accordance with the new rules on green claims, once adopted, in order to ensure coherence.

Directive 98/44/EC on the legal protection of biotechnological inventions, European Patent Convention and Regulation (EC) No 2100/94 on Community plant variety rights – The genetic modification made in a plant by means of a NGT is patentable, as well as the technique used to obtain the modification. Plant varieties obtained by NGTs can be protected by Community plant variety rights (CPVRs). In this regard, a balanced intellectual property system, including patent protection, is essential for innovation in agricultural biotechnology, i.e. by incentivising investments in research and development and promoting the dissemination of knowledge. At the same time, concerns have been raised by many stakeholders (farmers, breeders, in particular from the GM-free and organic sectors) on the possible proliferation of patents on NGT plants in the future and on potential claims being made by patent holders on conventionally bred plants that cannot be distinguished from NGT plants, fearing that this scenario could be further exacerbated if NGT plants are not subject to a GMO authorisation. While from the legal point of view the NGT initiative is independent from the rules on the protection of intellectual property and does not address matters relating to the application of the IPR legislation to GMOs, in particular to NGT plants, the Commission has taken note of the concerns brought forward by certain stakeholders on the need to ensure in particular the accessibility of farmers to patented seeds and of breeders to patented genetic material, and will carefully consider them.

1.9. Proportionality

The adapted risk assessment featured in options 1, 2 and 3 will be proportionate as it is intended that the criteria (and subsequent data requirements based on them) for the risk assessment of different NGT plants and derived food and feed are not stricter than necessary to ensure that the potential risks are properly identified and evaluated. This approach of adapted risk assessment would ensure proportionality for all NGT plants except those that could have been obtained naturally or by conventional breeding, where a notification regime as foreseen in option 4 (based on criteria allowing to identify NGT plants equivalent to conventionally bred plants) would suffice to ensure the objective of safety.

The granting of regulatory incentives in option 2 for applications for NGT plants with modified traits that can contribute to sustainability would be subject to a requirement to submit data to substantiate that claim, which would add an administrative and cost burden on operators wishing to benefit from such incentives. However, since the regulatory incentives would result in lower application costs (faster procedures, waiving of detection method validation fees, regulatory and scientific advice during the procedure), such a regime would not result in an overall increase of the regulatory burden, but a reduction thereof. The degree to which the burden would be reduced would depend on the amount of data required to obtain the incentive and on the actual incentives foreseen. Overall, as the incentives regime would be voluntary and not add an extra burden on operators not wishing to use it, such a measure would be proportionate.

Option 3 would impose sustainability requirements on NGT products as a condition for their authorisation and hence for their placing on the market. The fact that under that option NGT plants containing certain traits may not be allowed on the market for reasons related to the impact of the trait on sustainability while non-NGT plants containing a similar trait would not be subject to such a requirement, would render such a measure disproportionate.

Finally, for option 4 the indicative notification criteria (see section 5.2.4 box 2) are designed to reflect the equivalence of the NGT plant with plants that could occur naturally or be

obtained by conventional breeding methods, and (complemented by data requirements linked to those criteria) should be adequate to ensure proportionality.

8. Preferred Option

8.1. Description of the preferred option

The preferred option is a **combination of option 4 for products that could also occur naturally or be produced by conventional breeding and of option 2 for all other products.** This combination ensures to the largest possible extent that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden, that NGT plants and derived food/feed products featuring a wide range of plant species and traits by various developers are placed on the market and that these plants feature traits that can contribute to a sustainable agri-food system.

Option 4 provides for a **notification procedure** that would be accessible only to those **NGT plants that could occur naturally or be produced by conventional breeding**. It achieves the objective to maintain safety while ensuring that requirements are proportionate to the risk involved. The NGT plants concerned, due to their characteristics, would not present more potential hazards than plants produced by conventional breeding. The notification procedure includes a case-by-case assessment based on the molecular characteristics of the product against predefined criteria, and a decision by the relevant authority to establish the status of products (equivalent to conventional or not).

Option 4 is the best performing option to deliver on the objectives of this initiative and shows positive impacts in terms of innovation and interest of developers in marketing these products in the EU, enabling products to contribute to sustainability and food security. This option offers the largest opportunities to realise the potential benefits of NGTs, also bringing more diversity regarding species, traits and institutions developing them. This option reduces regulatory burden and access barriers to SMEs. It is comparable to the approach followed in an increasing number of third countries and would be the least disruptive of trade.

By treating NGT plants that could have been obtained naturally or by conventional breeding in a similar way to conventionally bred plants, this option scores best as regards coherence and proportionality.

Under this option, the NGT products that could occur naturally or be produced by conventional breeding would not be subject to GMO traceability and labelling but would be entered into a public register. This would increase transparency compared to the treatment today, of GMOs exempted from the requirements of the GMO legislation (e.g., the products of random mutagenesis) for operators (organic, GM-free) and consumers and allow operators at the beginning of the food chain – from breeding to seed production – to identify products obtained from NGTs and to avoid them if so wanted. The extent of the impacts of this option in the organic sector will depend on how notified NGT plants are treated for the purposes of organic production (either as GMOs or as conventionally bred plants). Considering the implications of each option as described in this impact assessment as well as the majority position in the organic sector, the policy choice has been made in the preferred option to treat such NGT products as GMOs for the purposes of organic production.

Option 4 is not designed to apply to all NGT plants, but only to those that could occur naturally or be obtained by conventional breeding. **Option 2** is the preferred option for **NGT plants that are not similar to conventional products**.

The option scores high in terms of ensuring safety and proportionality through requirements that are adapted to levels of risk of NGT plants that are not similar to conventional products.

An adapted risk assessment would bring a moderate improvement concerning attractiveness to develop NGT plants in the EU. Cost reductions for applicants compared to the baseline range from low to very substantial, depending on which risk assessment criteria need to be applied in specific cases. There would be variable but potentially significant cost decreases for risk assessment. To address concerns expressed about the potential uncertainty and complexity of this approach, work on the criteria for risk assessment (see section 5.2.1) is intended to ensure adaptability and predictability.

Regulatory incentives linked to the authorisation of NGT plants under option 2 would bring moderate positive impacts in terms of steering research and development towards traits with sustainability potential by facilitating access to and navigation of the regulatory framework, especially for SMEs, supporting their competitiveness. To avoid pre-empting the development of horizontal approaches to define and assess contributions to sustainability, and to address other difficulties of a sustainability assessment in the context of this initiative, option 2 would be adjusted to link the incentives to the traits conferred by the genetic modification, instead of linking them to an assessment of sustainability impacts. The incentives would be granted when the trait appears in a pre-defined list of traits selected because of their potential to contribute to sustainability objectives (desirable traits).

NGT plants subject to option 2 would also remain subject to traceability, and the related tools would remain available (as today) to supply chains that do not use GMOs (organic, GM-free sectors) until the final consumer. The impact of option 2 on the organic and GMO-free sector has been considered similar to the baseline when labelling is kept.

Regulatory divergence with non-EU countries is likely to remain large for NGT plants subject to option 2, posing challenges for value chain management and identity preservation systems in the exporting countries.

The current GM-label is perceived as a warning on possible risks (although only plants as safe as comparable conventional plants can be placed on the market) and would impact consumer acceptance, especially of food. It is also a key driver of negative consequences on the attractiveness to develop NGT plants in the EU. However, there is considerable demand for labelling and removing the labelling requirement for products subject to the requirements of risk assessment and authorisation would likely impact consumer trust. NGT plants subject to option 2 would therefore remain subject to labelling GMOs.

There is equally demand from citizens to use this initiative to actively steer the development of varieties with traits that support the Farm to Fork objectives, and to be informed about the sustainability impact of the products they buy. The intended application of the technology (and whether it delivers benefits to society at large) is relevant information to consumers and could be a factor influencing acceptability of NGTs. To this end, option 2 included the possibility to allow sustainability-related claims based on the trait to be mentioned on the label of the final product. However, a sustainability-related claim for certain NGT products raised concerns due to difficulty to assess sustainability based on a single trait, differential treatment vis-à-vis other products and coherence with other legislation on claims. Therefore, as preferred option, the claim will be replaced with the possibility to add a factual statement of the trait for NGT products subject to authorisation, i.e. the GM labelling could be complemented with information on the purpose of the genetic modification (e.g., genetically modified for the purpose of improving resistance to drought). This should allow operators and consumers to make informed choices and is expected to drive market demand for products with beneficial traits.

With the combination of option 2 with option 4, for the most part products subject to authorisation could be differentiated from plants obtained naturally or produced by

conventional breeding techniques. In such cases, applicants for authorisation would be able to comply with a requirement to submit a specific detection method, the competent authorities would be able to enforce the legislation and operators would be able to test raw material and products for traceability purposes.

The preferred option creates an enabling framework to meet the demands of farmers for the development and commercialisation of new varieties with beneficial traits to respond to the constraints of their soil and climatic context[247]. For NGT plants subject to notification, the development of such varieties is also steered by the objectives and provisions of other EU policy initiatives, in particular the SUR proposal (which has the objective to reduce the use of pesticides) to which pest-resistant crops can contribute, the PRM/FRM initiative (holistic assessment of the sustainability characteristics of a variety) and the FSFS initiative (steering the EU food systems towards sustainability). For NGT products requiring an authorisation, the preferred option steers developments towards desirable traits by providing regulatory incentives, which would be helpful in particular for SMEs. The factual label of such products could impact consumer choice, thus also steering indirectly the development towards desirable traits.

Consumer acceptance of NGTs is necessary for the benefits of NGTs to materialise. In this regard, initiatives to inform and engage consumers about NGTs need to be considered to accompany and explain the transparency measures – label in option 2, registry in option 4 – provided for in the legislation.

It will also be important to monitor closely the uptake of NGT products and the accompanying impacts, both positive and negative (see section 9).

The preferred option contributes to three of the four components of food security – food availability, stability and utilisation. It furthermore contributes to sustainability, the long-term ability of food systems to provide food security in a way that does not compromise the economic, social, and environmental bases that generate food security for future generations.

8.2 Simplification and burden reduction, supporting the one-in-one-out approach

The preferred option presents an important simplification of processes of the current authorisation procedure, notably through the adapted risk assessment (option 2) and the new notification procedure (option 4) for products that fulfil the criteria for equivalence to conventional breeding.

<u>Adjustment costs for the preferred option:</u>

For **breeders**, the preferred option would entail a significant reduction of adjustment costs. Based on the hypothetical scenario described in Annex 3 in which breeders would submit 10 notifications and 5 applications for authorisation per year[248], the total recurrent savings in adjustment costs per year are estimated to range from a minimum of EUR 99.5 m to a maximum of EUR 163.5 m[249].

For **national administrations,** a potential unquantifiable increase in adjustment costs was

[247] CEJA (2022)

[248] This estimate is based on the number of products expected to come to the market in the next ten years and on the assumption that, starting in 2015, 15 products per year will enter the regulatory approval process.

[249] The risk assessment will be proportionate to the risks/type of products, it will be variable, which explains the wide range of savings. This is mainly linked to the potential variability in data requirements as laid out in section 6.2.

identified due to the additional support (incentives) for applicants during the authorisation process for certain NGT products with traits that can contribute to sustainability. This potential increase in costs would be counterbalanced by the fact that the preferred option would entail at the same time a significant reduction of the adjustment costs for national administrations. The total recurrent savings in adjustment costs per year for **national administrations** are estimated to range from EUR 0 to EUR 2.1 m.

There is a wide range of savings for the breeders and for national administration as the risk assessment, which is the main source of adjustment costs for breeder, will be proportionate to the risks/type of products and the data requirements will vary.

For **farmers** using NGT varieties, recurrent savings in adjustment costs were estimated to range from EUR 22 m (for vegetable crops in the most likely scenario) to EUR 2.7 bn (for cereals in the most likely scenario) due to potential yield improvement of crops. Additional costs related to segregation (e.g. additional documentation, third-party verification) and coexistence measures might be added. These could not be quantified.

For **organic farmers,** the preferred option would entail a potential but unquantifiable increase in adjustment costs for risk management practices and market monitoring (for accidental presence of GM/NGT product) due to the uncertainties of potential presence of notified NGT plants in conventional seeds in the first sub-option, where notified NGTs remain banned in organic production. In the second sub-option, where notified NGTs would be treated like conventional products with regard to organic production, this cost increase would not occur. The second sub-option, though, could lead to the erosion of consumer trust and lead to economic losses of the organic sector.

<u>Administrative costs for the preferred option</u>

The preferred option would entail an annual overall administrative cost saving for **breeders** ranging from EUR 16.15 m to EUR 46.25 m. The range reflects the differences in data requirements for products with different risk profiles.

For **farmers,** including **organics farmers**, no administrative costs are identified.

For **food businesses**, a limited unquantifiable increase in administrative cost is expected due to additional information in the GMO label (identification on the label of the purpose of the genetic modification to the label) and related segregation costs. Recurrent savings in administrative costs are expected due to the removal of the traceability and labelling obligation for the notified products; however these could not be quantified.

9. How will actual impacts be monitored and evaluated?

In order to monitor and evaluate the progress made towards the objectives of this initiative and its economic, environmental and social impacts, indicators have been identified and are listed in the table below (Table 13). The Commission will review these indicators periodically.

Data on most indicators will be collected and published annually and will serve as the basis for regular monitoring reports, that will also be supported by external studies.

The indicators defined will support monitoring of potential risks to health or the environment, achievement of the initiative's objectives and impact of NGT plants on environmental, economic and social sustainability. Indicators are also proposed to monitor impacts on organic agriculture and on consumers acceptance of NGT products.

A first monitoring report should be presented no sooner than 3 years after the first products

have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. An evaluation should be carried out no sooner than 2 years after the first monitoring report has been published.

Table 13. Monitoring indicators. Indicators that need to be created are marked with '*'.

Specific objectives	Indicators	Data source/frequency	Actors responsible for data collection
S1: Procedures for the deliberate release and placing on the market ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden	Reported cases demonstrating risk to human and animal health and the environment due to genetic modification in authorised or notified product, and any regulatory action taken.	EC/Annually	EC
	Number of products authorised to be placed on the market	EC /Annually	EC
	Number of products notified to be placed on the market	EC/Annually	EC
	Time needed for risk assessment	EFSA and Member States/ Annually	EC
	Time needed for granting authorisation/notification	EC and Member States/ Annually	EC
	Assessment of encountered hurdles and barriers in particular for SMEs (qualitative)	External study/ 3 years after the first products have been notified/authorised	EC
	Costs for the notification/authorisation/risk assessment	External study/ 3 years after the first products have been notified/authorised	EC
S2: Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers	Number of crop-trait combinations (NGTs and GMOs) in notifications/authorisation applications	EC/Annually	EC
	Number of crop-traits combinations (NGTs and GMOs) and developers at global level*	External study/ 3 years after the first products have been notified/authorised	EC
	Number and proportion of SMEs/public institutions applying for field trials/notifications/authorisation applications*	EC/Annually	EC
	Assessment of the impacts of release and placing on the market of NGT products in the EU on organic agriculture in view of the 25% target in F2F* (quantitative / qualitative)	External study/3years after the first products have been notified/authorised	EC
	Consumer acceptance and willingness to buy NGT products*	Eurobarometer/ 3 years after the adoption of the new legislation – to be repeated every 4 years	EC
S3: NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system	Impact of NGT plants in the EU on economic, environmental and social sustainability, e.g., through pesticide use, fertiliser user, biodiversity, greenhouse gas emissions, yield, yield stability, health benefits *.	External study/ 3 years after the first products have been notified/authorised	EC

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ANNEX 1: PROCEDURAL INFORMATION

Lead DG: European Commission, Directorate-General for Health and Food Safety, DG SANTE

Decide reference: PLAN/2021/11456

The development of this initiative was announced under item 4) in Annex 1 to the Commission Work Programme 2023[1].

Organisation and timing

The inception impact assessment (IIA) on the "Legislation for plants produced by certain new genomic techniques" initiative[2] was available for feedback in the period 24 September 2021 - 22 October 2021. The IIA outlined the initiative's context and aim, problems and objectives to address them, policy elements to be considered for the development of policy options, whilst also discussing expected impacts and presenting the evidence base.

Nine Inter-service Steering Group (ISSG) meetings were held between September 2021 and February 2023, including participation from the Secretariat General, the Legal Service, the Joint Research Centre (JRC) and Directorates-General: AGRI, CLIMA, COMP, ENV, GROW, MARE, RTD and TRADE.

1. Consultation of the RSB

The file benefitted from an upstream meeting with the Regulatory Scrutiny Board (RSB) on 20 May 2022. A first version of this Impact Assessment Report was submitted to the RSB on 15 February 2023, the meeting took place on 15 March 2023 and the RSB written report was received on 17 March 2023. The Board's overall opinion was negative based on the following findings:

(1) The report does not present a clear, consistent, and hierarchical set of general and specific objectives.
(2) The report does not describe in sufficient detail what the main elements of the options and the key policy choices are.
(3) The report does not sufficiently assess the impact on consumer trust, the organic sector, the environment and health. It does not present a comprehensive overview of the costs and benefits.
(4) The report does not provide a comprehensive assessment of all relevant (combinations of) options in terms of effectiveness, efficiency and coherence.

The table below lists the changes in response to the recommendations of the RSB in its opinion. In addition, targeted corrections and amendments have been included in the new version of the impact assessment report to address the technical comments provided by the RSB to DG SANTE.

[1]https://ec.europa.eu/info/sites/default/files/com_2022_548_1_annexe_en.pdf
[2]https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/feedback_en?p_id=26519622

Table 1: Recommendations of the RSB and modifications made in the impact assessment report

RECOMMENDATIONS OF THE RSB	MODIFICATIONS IN THE IMPACT ASSESSMENT REPORT IN RESPONSE TO THESE RECOMMENDATIONS
(1) The report should present a more comprehensive overview of the current context including how NGTs are being developed at global level, the and the implications for sustainability and for EU strategic autonomy and competitiveness. It should better explain the magnitude of the problems and consequences identified.	Section 1.1 has been revised to better explain the scientific context (safety profile of NGT plants and stakeholder positions). Section 1.2 in the political context has been revised to include aspects of sustainability and strategic autonomy and to provide an overview of recent social science research and surveys on consumer attitudes towards NGT products. Section 2.2 has been expanded and revised to explain better the size of the problem and who is affected.
(2) The report should present a clear, consistent, non overlapping and hierarchical set of general and specific objectives. It should more clearly outline what the substantive key objectives of this initiative are. In particular, it should explain in more detail the significance of the sustainability objective, and whether this is a new objective requiring the revision of the Directive. The report should clarify to what extent EU strategic autonomy, including food security, is a key objective of this initiative based on the problems identified. The report should further improve the link between the problems and objectives. It should, clarify what objectives remain the same (e.g. human and animal health and environment in accordance with precautionary principle) and which ones emerge from the identified problems.	In section 4, general and specific objectives have been revised, clarifying which objectives are shared with the current GMO legislation and which are new, and explaining further the sustainability objective. Links between problems and objectives have been revised. Relationship between general and specific objectives has been clarified (section 4, figure 2). The Intervention logic (Annex 10) has been updated.
(3) The report should more fully describe the main elements of the options and explain who are the actors determining, implementing, and enforcing them. It should clearly outline how the notification regime and adapted risk assessment would work, what parameters would apply, who would decide, and what follow-up would be ensured. The report should set out how the sustainability objective is addressed in each option, and on whether there are further alternative elements or combinations of options. It should provide more detail on what the regulatory incentives and the different criteria presented would look like in their final form. It should provide a comprehensive explanation of why the choice of labelling requirement differs across the identified options. The report should be clear on the policy choices and trade-offs, and to how they are addressed in the policy options. In addition, the report should clarify the approach retained in the preferred option as regards the organic sector.	In Section 5, options have been explained more fully, including actors involved, how notification and authorisation criteria and procedures will work, approaches to sustainability and to labelling in each option, and concrete details on incentives considered in option 2. The different choices for each key element (risk assessment, traceability, labelling/transparency, sustainability) have been presented in figure 3 and policy options in figure 4. Explanation has been provided on the choice of combined options. In section 5.2.4, the two policy approaches for the organic sector for option 4 have been added. New section 5.2.5 has been added to explain why option 4 was designed to apply only to certain NGT products and, if retained, must be combined with options 1, 2, 3 or the baseline. In section 5.3 an explanation has been added on why other combinations have not been pursued.
(4) The report should further develop the assessment of the impact on health, environment, consumer trust and the organic sector. Concerning health and environment, the report should provide a more balanced analysis accounting for likely environmental and social benefits as well as possible risks for the environment and for human and animal health and how they will be monitored and mitigated. It should also explain how the impacts on sustainability are	In section 6 impacts on health and environment have been revised to explain further what the achievement of the objective means (assessment of options by comparison to baseline; NGT to be demonstrated to be as safe as conventional counterpart); further explanations have been added on the distinction between the safety aspects associated with the genetic modification and other potential impacts resulting from certain traits (irrespectively on the technique

assessed. The report should provide further evidence - coming from recent social science research and surveys - on consumer attitudes towards NGT products and assess how consumer trust may impact uptake of future NGT products. It should discuss the risk that benefits might not materialise as a result of lack of consumer trust. The report should further develop the analysis of the impacts on the organic sector including quantification of the costs for this sector.	used). In sections 6 and 7, the analysis of impacts on the organic sector has been considerably developed based on available evidence on coexistence between GMOs and conventional and organic farming (e.g. the work of the European Co-existence Bureau established by the Commission, further literature). The implications of the two scenarios for the treatment of notified NGTs (option 4) in organic farming are further discussed. The sections "Impacts on consumers" under each option in section 6 and in section 7 have been revised to elaborate further on how the different options may affect consumer uptake and trust.
(5) The report should present a clear and comprehensive overview of the costs and benefits for each option. It should better describe the uncertainties and limitations of the analysis based on hypothetical scenarios. It should further explain the credibility and reliability of the wide ranges of estimates presented.	In section 7.2 the cost analysis for each option was revised to include costs of coexistence and segregation measures for farmers and food business, however, due to limited data, those costs were not quantifiable. Regarding costs for the preferred option, Section 8.2. and Annex 3 were further developed to ensure a clear explanation of the hypothetical scenario for the future number of authorisations and notifications taken into consideration for the overall cost calculation.
(6) The report should provide a better comparison of options, with a consideration of different combinations of options. It should identify all relevant combinations upfront and assess and compare them along the individual options. The effectiveness analysis should be based on the revised set of specific objectives, avoiding any double counting. The comparison summary table should be critically reviewed to remove overlaps and inconsistencies. The efficiency analysis should include quantified and monetised cost and benefit estimates. The used scoring methodology should be better explained, and the individual scores better justified. The report should provide a clear assessment of coherence, in particular in light of concerns expressed by stakeholders as regards Farm to Fork and the role of organic farming.	As regards combinations of options, see (3). In section 7.1 and 7.2, effectiveness and efficiency analysis have been revised, making sure, in particular, that no criteria are double-counted or overlap. The efficiency analysis includes quantified and monetised costs and benefits wherever this information is available. All scores are explained in the detailed comparison of options in section 7.1. In section 7.3., the coherence analysis has been complemented regarding 25% organic target laid down in the Farm to Fork Strategy.

A revised version of the Impact Assessment Report was submitted to the RSB on 25 April 2023 for a final opinion. The Board concluded with a positive opinion with reservations on 26 May 2023. The table below lists the changes in response to the recommendations of the RSB in its second opinion.

Table 2: Recommendation of the RSB and modifications made in the impact assessment report

RECOMMENDATIONS OF THE RSB	**MODIFICATIONS IN THE IMPACT ASSESSMENT REPORT IN RESPONSE TO THESE RECOMMENDATIONS**
(1) The report should provide further information on the risk assessment via the notification procedure retained in the preferred option. It should better explain how the procedure will ensure that the NGTs covered are plants that could also occur naturally or be produced by conventional breeding. It should describe in more detail the key elements of the pre-	The notification criteria in Box 2 in section 5.2. have been updated and clarified, scientific considerations underpinning the criteria have been added and a diagram illustrating how the notification procedure would work in practice has been added to Annex 11.

determined notification criteria, their scientific basis and their implementation in practice.	
(2) As regards the use in organic production of NGT plants/products fulfilling the notification criteria, the report should be clear that the two scenarios presented are in fact policy sub-options. It should indicate the preferred sub-option as regards use in organic production and if no preferred sub-option is chosen, it should clearly state this, together with an explanation why. The policy choices, implications and impacts of each sub-option should be explained, including under what circumstances notified NGT plants/products could be used or not.	The two scenarios concerning the use of notified NGT products in organic production are now presented as sub-options. In section 8.1., the report now clarifies the preferred sub-option. The implications of the sub-options have been further explained in section 5.2.4.
(3) As regard the option "authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability", the report should be clear on the retained sub-options for labelling. It should also clarify how the label would identify those NGT as "product of biotechnology".	Section 8.1. of the report is further clarified as regards the retained sub-option on labelling.
(4) The report should clearly present the reasons behind wide ranges such as 'up to 85%' cost savings on the risk assessment, and provide further explanations of circumstances under which breeders might receive no savings.	The report now clearly identifies in the impact analysis (e.g. section 6.2.1.) the situations in which no or small and large cost savings are expected, and further explains the reasons for the ranges.
(5) The report should clarify the efficiency analysis. While the report includes elements of costs quantification, in particular on coexistence, based on relevant projects and studies, including the support study, it should clarify how these available cost quantifications should be taken into account in the efficiency analysis of options and in the overview of benefits and costs, referring, if appropriate, to uncertainties and data limitations. It should explain why the aggregate cost for option on "authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability" and option on "authorisation with the requirement that products do not contain modified traits that can be detrimental to sustainability" are identical when the latter introduces an additional 'trait-specific' requirement described as the most demanding for operators. The report should explain why the savings on incentives are excluded from the efficiency analysis.	Table 8 and the accompanying footnote 214 in section 7.2., addressing the baseline with a limited extent of NGT cultivation, now clarifies that available data on coexistence costs are too limited and uncertain to derive a quantitative estimate of expected future costs. The same consideration applies to Tables 9-11. In Table 12, addressing an option under which more extensive NGT cultivation is expected, an unquantified increase in coexistence costs is assumed. The costs for an assessment of the sustainability contribution of a trait or of showing that a trait is not detrimental to sustainability are assumed to be same. The fact that demonstrating the sustainability contribution of a trait is voluntary is reflected in footnote 222, which gives an estimate of the aggregate cost if the sustainability contribution is not assessed. The savings arising from incentives are included in Annex 3. They are not included in the efficiency analysis in section 7 as the monetary benefits are marginal in comparison to the other quantified costs and benefits.

2. Evidence, sources and quality

External expertise

A consortium led by Technopolis developed a study that contributed to the preparation of this IA. The study started in March 2022. The consortium provided support in gathering and analysing evidence, in conducting consultation activities (e.g., targeted consultation of stakeholders, organisation of focus groups, analysis of stakeholder feedback, interviews of stakeholders) and a combination of approaches to assess the economic, social and environmental impacts of the policy options (including case studies, economic modelling, modelling of environmental impacts and multicriteria analysis).

Consultation activities

The IA takes into account the input from a range of stakeholder consultation activities. A public consultation[3] was held between 29 April and 22 July 2022 (2300 contributions). It was complemented by a range of targeted consultation activities:

- Stakeholder interviews (25) to receive input on the initiative and on the impacts of policy options, including on costs.
- A targeted survey (from 28 June to 05 September 2022) to which 397 stakeholders and Member State authorities were invited. 123 responded and self-categorised as business associations (32), NGOs, environmental, consumer and other civil society organisations (28), public authority/body (23), large company/business (11), academic/research organisation (9), SMEs (8), other (12).
- Two expert focus groups on sustainability and traceability on 22 and 23 September 2022.
- Regulatory cost interviews (23) to map regulatory costs of operators developing and marketing NGT plants as well as to assess costs of risk assessment and enforcement authorities.

Annex 2 summarises feedback from stakeholder consultations.

Other studies and sources

- JRC case studies to analyse the potential economic, environmental and social (health) impacts of selected NGT plants that are in the development pipeline[4], conducted for the purposes of this impact assessment; the impact assessment also relies on the two JRC reports (on market applications[5] and latest scientific developments relating to NGTs[6]) supporting the Commission NGT study[7].
- EFSA. Two mandates were given to support this impact assessment (statement on criteria for risk assessment[8] and update of EFSA's 2012 opinion on cisgenesis[9].

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

[4] Sánchez, B., Barro, F., Smulders, M. J. M., Gilissen L. J. W. J., Rodríguez Cerezo, E. (2023) Socioeconomic impact of low-gluten, celiac-safe wheat developed through gene editing, EUR 31380 EN, Publications Office of the European Union, Luxembourg, Schneider, K.; Barreiro-Hurle, J.; Kessel, G.; Schouten, H.J.; Vossen, J.; Strassemeyer, J.; Rodriguez-Cerezo, E. (2023). Economic and environmental impacts of disease resistant crops developed with cisgenesis. EUR 31355, Publication office of the European Union, Luxembourg., Schneider, K.; Barreiro-Hurle, J.; Vossen, J.; Schouten, H.J.; Kessel, G.; Andreasson, E.; Phuong Lieu, N.; Strassemeyer, J.; Hristov, J.; Rodriguez-Cerezo, E. (2023). Insights on cisgenic plants with durable disease resistances under the European Green Deal. Trends in Biotechnology

[5] Parisi, C. and Rodriguez Cerezo, E., Current and future market applications of new genomic techniques, EUR 30589 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-30206-3, doi:10.2760/02472, JRC123830.

[6] Broothaerts, W., Jacchia, S., Angers, A., Petrillo, M., Querci, M., Savini, C., Van den Eede, G. and Emons, H., New Genomic Techniques: State-of-the-Art Review, EUR 30430 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-24696-1, doi:10.2760/710056, JRC121847 European Commission, Directorate-General for Research and Innovation, New techniques in agricultural biotechnology, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

[7] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C528/16. SWD (2021) 92 final

[8] EFSA Panel on Genetically Modified Organisms, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618

Other, previous relevant EFSA opinions (referenced in Annex 6) also underpin tis impact assessment.

- Desk research, including peer-reviewed literature, scientific reports and grey literature
- Position papers
- European Commission fact-finding studies on Member States official controls[10]

Limitations and robustness of findings

The data collection and analysis carried out have some intrinsic limitations, key among those the lack of historical data on the cultivation and commercial use of plants produced by targeted mutagenesis and cisgenesis, as the first of these products have only recently reached the markets of non-EU countries, and there is no experience within the EU. The impacts of such limitations on the robustness of findings have been mitigated to a maximum possible extent utilising a number of analytical approaches such as specific case studies, modelling, extrapolation from third countries etc.

[9] EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp., https://doi.org/10.2903/j.efsa.2022.7621

[10] https://ec.europa.eu/food/audits-analysis/audit-report/details/4543
https://ec.europa.eu/food/audits-analysis/audit-report/details/4544

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

1. Introduction

This report provides an overview of the consultation activities carried out in the context of the impact assessment (IA) of legislation for plants produced by certain new genomic techniques (NGTs). It provides an outline of the consultation strategy, lists the consultation activities and provides key results for each of them.

The following consultations took place:

- Feedback on the Commission's Inception Impact Assessment[1] (24 September 2021 - 22 October 2021);
- Commission's public consultation (PC) (29 April 2022 - 22 July 2022)[2];
- Targeted stakeholder survey (28 June 2022 – 05 September 2022);
- Interviews (June 2022 – December 2022);
- Focus groups on sustainability and traceability ((22 and 23 September 2022 respectively).

The first two consultations were carried out by the Commission services (but the external contractor analysed the replies to the PC); the last three consultations were carried out entirely in the context of the external study underpinning this IA.

The key objectives of the consultations were:

- Ensure that the public and all relevant stakeholders were given the opportunity to contribute to the policy initiative by providing informed insights.
- Obtain relevant information, views and expectations on the problems presented, the baseline scenario, and on the potential ways forward including the key components of the policy options (risk assessment, sustainability, labelling, traceability).
- Obtain evidence, views and expectations on the expected key impacts (economic, social, environmental).

The following key stakeholder groups were identified as targeted audience in the consultation strategy of the initiative:

- The general public (EU and non-EU);
- Operators active, from farm to fork, in the agri-food and feed system, including sectors such as farmers; seed and plant breeders; traders; processors; manufacturers, retailers and food services; GM-free and organic operators in all of the above sectors.
- Operators of plant and bio-based industries active in sectors other than the agri-food sector, including ornamental plants, forestry and industrial biotechnology.
- Academic and research stakeholders active in the field of biotechnology in general and agricultural/plant biotechnology in particular.

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

- Civil society/non-governmental organisations with interest in the topic, including environmental, grass-root farming and consumer organisations.
- EU institutions, European Food Safety Authority (EFSA), Member State and third country authorities
- Other stakeholders, such as consultancies and think tanks active or with interest on the topic.

2. Methodology of the consultation activities

a) Feedback on the Commission's Inception Impact Assessment (IIA)

The initiative was published on the Commission's Have Your Say[3] website. The IIA included the context, problem definition and subsidiarity check, presented the objectives and the main components of the policy options, contained a preliminary assessment of expected main impacts and referred to the evidence base and data collection.

70,894 contributions were received overall; 98% (69,414) of the replies were identified as coming from campaigns. The non-campaign replies amounted to 2% of the total (1,480). According to self-categorisation, most contributions in the non-campaign replies came from citizens (70%, 1,030 replies), followed by business organisations/associations, trade unions (14%, 203), academia/research institutions (8%, 115), NGOs and consumer/environmental organisations (5%, 81), public authorities (1%, 9) and others (3%, 42). Contributions (both campaign and non-campaign) originated from 91 countries, including the 27 Member States and 64 non-EU countries. Top contributions from Member States were from Germany (32,694), France (25,544), Belgium (2,732), Netherlands (2,251) and Austria (2,111). Most contributions from non-EU countries came from Switzerland (782), followed by United Kingdom (759), USA (228), Argentina (142) and Canada (114). The large number of contributions shows the high interest of citizens and stakeholders in the Commission's policy initiative.

b) Public consultation (PC)

The PC was published on the Commission's Have Your Say Error! Bookmark not defined. website. The survey included 11 closed questions with branching sub-questions and open text sections (with 500-800 characters). Furthermore, 7 questions were included as open questions (with 1500 characters). These 18 questions in the PC were analysed with quantitative and qualitative methods.

Overall, 2300 contributions were submitted, out of which 104 were identified as campaigns and 2196 as individual contributions. The bulk of the contributions came from 23 EU Member States (MS), with three-quarters of total consultation respondents coming from Germany (599; 27.3%), (Italy 515; 23.5%), France (335; 15.3%), and Spain (194; 8.8%). There were no responses from stakeholders from Cyprus, Luxembourg, Malta or Slovenia. There were 105 respondents from outside the EU and they account for 4.9% of the total. They came from Switzerland (33), the United States (17), the United Kingdom (15), and 40 contributions from 25 other countries. Most respondents self-identified as 'EU citizen' (1491; 65.1%), followed by academic/research institutions (206; 9.0 %), company/business organisations (179; 7.8%) and business associations (122; 5.3%), non-governmental organisations (NGOs - 81; 3.7%), non-EU citizens (38; 1.7%), public authorities (35; 1.5%), environmental organisations (20; 0.9%), trade unions (14; 0.6%), consumer organisations (5; 0.2%), and others (5; 0.2%). Out of the companies/business

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

organisations, 30.2% (54) self-identified as large companies and 69.8% (125) as small and medium sized enterprises (SMEs), comprised of medium companies (28; 15.6%), small companies (33; 8.4%), and micro-companies (64; 35.8%).

Views from the PC are not statistically representative.

c) Targeted Stakeholder Survey (survey)

The targeted survey[4] aimed to collect information from stakeholders on the performance of the baseline scenario and on impacts of the policy components. It was designed to complement the PC. Whereas the PC addressed a wider audience and therefore did not ask for detailed technical assessments, the targeted survey envisaged detailed information. The survey was sent to stakeholders and Member States representatives and included EU as well as non-EU stakeholders, yet with a clear focus on the former.

The survey was designed with a complex branching to include specific questions for all the categories of the targeted stakeholders. None of the questions was mandatory to be filled in. A total of 397 were stakeholders invited through Limesurvey These included academia/research, businesses and their associations (food, feed and non-food operators, including organic and GM-free ones, across all sectors of activity: plant protection products/fertilisers, seed/plant breeders, farmers, traders, processors, manufacturers, retailers/services, bio-based and biotechnology industries, ornamental plants, forestry), NGOs, environmental, consumer and other civil society organisations, and public authorities or bodies, including all EU relevant Member state national authorities. A detailed overview of invited survey participants can be seen in figure 1. Of invited stakeholders, 123 (31%) provided responses.

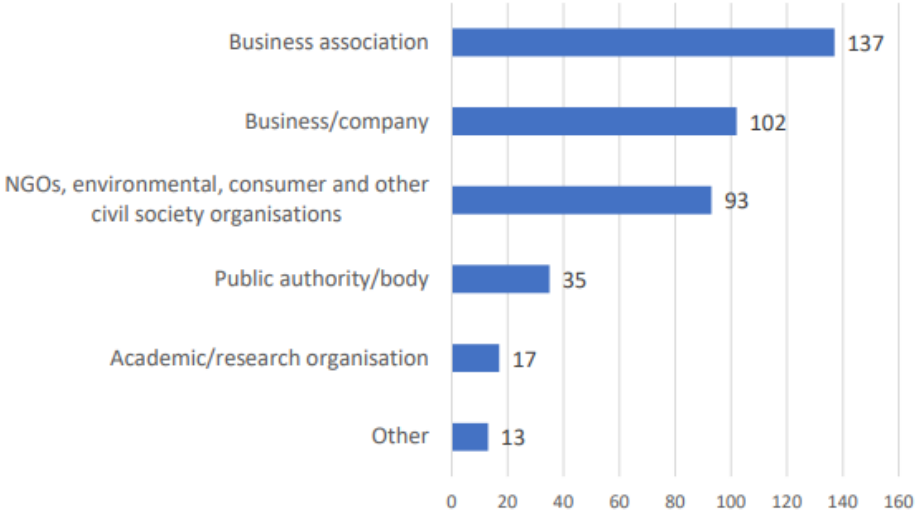

Figure 1: Stakeholders' categories invited to the targeted survey

[4] https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_targeted-survey-questionnaire.pdf

A detailed overview of participants that completed the survey, according to their self-categorisation, can be seen in Figure 2:

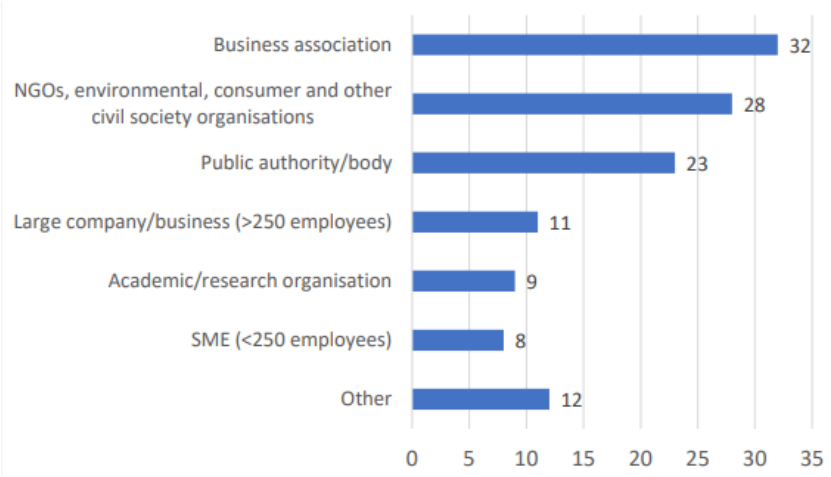

Figure 2:Stakeholder categories from the 123 participants that completed the targeted survey.

Concerning their sector of activity, the participants have self-categorised* as can be seen in Figure 3:

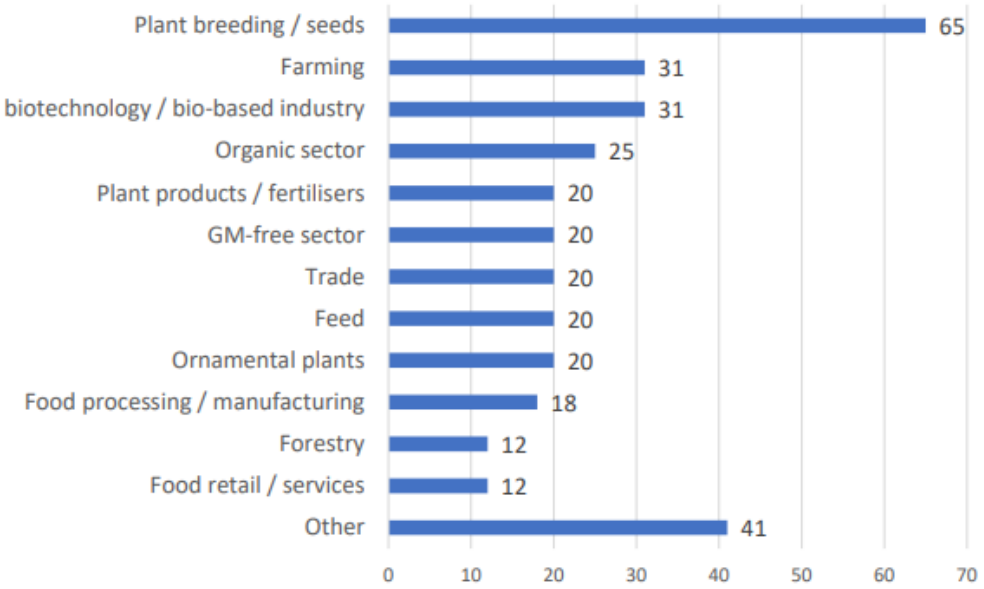

Figure 3: Activity of sectors for the 123 stakeholder participants of the targeted survey

Respondents originated mainly from Belgium (36, 29%), Germany (15, 12%), Italy (8, 7%), France (9, 7%), Netherlands (8, 7%), Spain (6, 5%), Austria (5, 4%), Romania (4, 3%), Denmark (4, 3%), Ireland (3, 2%), Sweden (2, 2%), Greece (2, 2%), Slovenia (2, 2%), Poland (2, 2%), Croatia (2, 2%), Luxembourg (1, 1%), Lithuania (1, 1%), Latvia (1, 1%), Hungary (1, 1%), Finland (1, 1%), Czech Republic (1, 1%), Bulgaria (1, 1%), Slovakia (1, 1%), Estonia (1, 1%), Cyprus (1, 1%) and Other countries (6, 5%).

d) Interviews

Interviews were devised to collect qualitative and quantitative data and information on costs, and to obtain insights and views on specific topics relevant to stakeholders.

Interviews were conducted by two study team members via MS-Teams. The notes of each interview were shared with the interview partners for agreement. Relevant information was coded and analysed. The insights from the interviews fed into the main study report's impact section.

For the cost interviews, the stakeholders were briefed about the needs and requirements of the interview. Dedicated meetings where the relevant cost templates were explained and discussed have been conducted. Once organisations had provided data, these were analysed and compared, and used for establishing ranges. The qualitative and quantitative information was integrated in a dedicated internal data file which was then further used to obtain robust cost estimates.

There were 25 interviews with key stakeholder organisations at EU-level and 23 cost interviews at company, national administrative and EU-levels. Several of the general interviews were also used to enquire about potential collaboration on cost assessments.

For the cost assessment interviews, overall, 23 different organisations throughout the regulatory trajectory (SMEs, large companies, public authorities, regulatory authorities, etc.) were approached. There were no one-off interviews but consecutive discussion rounds with the stakeholders.

Stakeholder categories' that took part in the general interviews were 20% (5) Academic/research institutions, 44% (11) business associations, 8% (2) consumer's associations, 16% (4) environmental organisations and 12% (3) trade unions. Stakeholder categories' that took part in the cost interviews were 13% (3) academic/research institutions, 30.5% (7) company/business organisations, 43.5% (10) public authorities and 13% (3) other. Organisations that took part in the general interviews were all based in Belgium (25, 100%). Organisations that took part in the cost interviews were based in Austria (1, 4.3%), Belgium (3, 13%), Czech Republic (1, 4.3%), France (1, 4.3%), Germany (4, 17.5%), Netherlands (1, 4.3%), Portugal (1, 4.3%), Spain (4, 17.5%), Sweden (3, 13%) and other (4, 17.5%).

e) Focus groups on sustainability and traceability

Two focus groups, on sustainability and traceability respectively, were conducted to complement the information obtained in interviews and the targeted survey. A concept note was developed for both focus groups. This included a few high-level questions which were developed based on results of the targeted stakeholder survey, as well as insights from the interviews. The focus groups were conducted under a rather strict protocol where the moderators asked questions and had the focus group members providing their views. In each group, two study experts joined. The summaries of the discussions were provided to the participants for validation. Insights from the validated reports fed into the impact analysis and helped triangulating findings on sustainability labelling and traceability vs transparency.

In total, 14 stakeholders participated in the two groups. 14% (2) of them were from academic/research institutions, 29% (4) from business associations, 43% (6) from public authorities and 14% (2) from trade unions. 42.9% (6) of them were based in Belgium, 7.1% (1) in Denmark, 21.4% (3) in France, 14.3% (2) in Germany, 7.1% (1) in Norway and 7.1% (1) in Spain.

3 Overview of responses

For a detailed analysis of the feedback received on the IIA see Annex 2A.

The consultation activities that followed the IIA were to a large extent complementary and were triangulated with findings from the literature and experts.

A summary report from the consultation outcome of the PC was published on 16 September 2022[5].

Key findings from the consultation activities of PC, targeted survey, interviews and focus groups:

a) Is the current legislation fit for purpose?

Most respondents to consultation activities from Member States authorities, business organisations/associations, trade unions, academia/research institutions and a few NGOs/consumer/environmental organisations, welcomed the policy initiative in response to the IIA. Among the economic sectors, this view was expressed by the large majority of operators from biotechnology and bio-based industry, farming, feed, ornamental plants, plant breeding and plant protection and fertilisers, and by the majority of operators from trade and food processing/manufacture.

The view that the current GMO legislation is fit for NGTs, and therefore does not need adaptation, was expressed by a large majority of environmental organisations, and by the majority of NGOs and consumer organisations. Among the economic sectors, this view was expressed by a large majority of operators in food retail/service, organic, GM-free and forestry.

Those indicating the legislation is not adequate find the GMO legislation not sufficiently clear or consider that the risk assessment approach of the GMO legislation cannot factor in the diverse risk profiles of plants obtained by NGTs. They find the current authorisation, traceability, and labelling requirements not appropriate, and they also indicate that the GMO legislation does not consider whether products have the potential to contribute to sustainability. Those in favour of the current legislation find it sufficiently flexible and still capable of keeping pace with technological progress. They also find the GMO legislation sufficiently clear and risk assessment rules, as well as authorisation, traceability, and labelling requirements appropriate. Sustainability, in their view, can also be taken into account under the current legislation.

The views of citizens that participated in the two consultation activities open to the public (feedback to the inception impact assessment and public consultation) varied. 98% (69,414) of the replies to the inception impact assessment were identified as coming from campaigns from respondents that self-categorised as citizens and opposed the initiative calling on the Commission to keep NGT plants and products subject to the current requirements of the GMO legislation. On the other hand, the majority of responses from citizens to the inception impact assessment (not coming from campaigns) and to the public consultation generally supported the adaptation of the legal framework.

b) Risk assessment

In an open question about the main aspects that should be addressed by this initiative (Question 4 of PC), "risk assessment" was the most frequently mentioned topic. A majority of respondents consider that the existing GMO requirements need adaptation for plants produced by targeted mutagenesis or cisgenesis.

[5] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

In the PC, 61% (1331) of total respondents supported a risk assessment approach different from the current one in the GMO framework: 34% (738) of total respondents believed that risk assessment should have requirements adapted to the characteristics and risk profile of a plant and 27% (593) believed that risk assessment is not needed when these plants could have been produced through conventional plant breeding or classical mutagenesis. The adapted risk assessment approach was the most selected reply by public authorities, academic/research institutions, EU and non-EU citizens. The approach that no risk assessment is needed when these plants could have been produced by conventional plant breeding or classical mutagenesis was supported by the majority of business associations; it was also the most selected reply of trade unions, companies/business organisations. This view was expressed by the majority of operators in ornamental plants and the large majority of the operators in plant protection products/fertilisers, plant breeding/seeds and biotechnology/bio-based industry; it was also the most selected reply among the farming, feed and trade sectors. These respondents emphasise the economic and scientific disadvantage for Europe compared to non-European countries if the current GMO legislation is applied to NGTs. Also, the view that the risk assessment should be primarily focused on the final product, rather than on the process, was expressed by various respondents.

On the other hand, the view that the risk assessment requirements of the current GMO legislation should be maintained was supported by the majority of NGOs and the large majority of environmental and consumer organisations. Among the economic sectors, this view was expressed by the majority of organic and GM-free operators and the large majority of food retail/services and forestry sectors; it was also the most selected reply of the food processing/manufacturing sector. These stakeholders, representing 22% (480) of total respondents in the PC, argue that the application of the current framework has demonstrated effectiveness regarding risk assessment, authorisation, traceability, and labelling, and safeguards the freedom of choice.

In the targeted survey, breeders (N = 56) identify regulatory costs (which include costs for risk assessment) and regulatory uncertainty as the most important factors in deciding whether to develop NGTs for the EU market in the baseline option. The high costs and the high perceived regulatory uncertainty mean that the attractiveness of developing NGTs under the baseline option is very low. A risk assessment adapted to the risk profile of the NGT is seen by breeders (N = 73) to improve the attractiveness of developing NGTs (expressed as the expected percentage of NGT varieties on the market in 2030 – 35) to some degree. Treating NGT plants that could also occur naturally or be produced by conventional breeding like conventional plants is increasing the attractiveness to develop NGT plants to the strongest degree.

c) Sustainability

Regarding the questions whether a future legislation should contain sustainability provisions, stakeholders from the farming (including organic and GM-free), breeding, processing, manufacturing and trading sectors all advocated for a horizontal and coherent sustainability analysis for all products regardless of the technique. Some consider that adding that it would be discriminatory to only assess the sustainability of NGT products and not of products of other breeding methods. Breeding and farming operators emphasise that the sustainability assessment would increase the administrative and financial burden. Operators from the breeding sector add that the value for cultivation and use testing, which most plant varieties have to undergo under the PRM legislation, considers sustainability. Public authorities, academia and research organisations and a majority of respondent citizens support, though, the inclusion of sustainability requirements in the legislation (51% of respondents in the public consultation).

In the PC, 41% of the respondents replied that introducing sustainability provisions in this initiative is unnecessary (replies to Question 5 of PC). This view was predominantly shared by various stakeholders, including business associations, NGOs, environmental organisations, trade unions, companies and consumer organisations. Moreover, a wide range of economic operators, including those in biotechnology/bio-based industry, feed, food processing/manufacture, food retail/services, GM-free, organic, ornamental plants, plant breeding/seeds, plant protection products/fertilizers, trade, farming, and forestry sectors, expressed a similar viewpoint.

PC respondents have evaluated the relevance of specific traits according to their contribution to sustainability. Traits on the better use of resources (64%), abiotic stress tolerance (63%), and biotic stress (58%) are considered the most relevant. Herbicide/insecticide tolerance (21%) and 'other quality-related characteristics' (15%) score the lowest (relatively among all stakeholder groups but consumer organisations) (Question 6 of PC). The targeted stakeholder survey suggests that the number of NGTs would be slightly higher with sustainability incentives than under a sustainability requirement scenario. Under sustainability incentives, plants with traits affecting abiotic and biotic stress tolerances would have a higher market share from 2030 onwards, than any other trait.

In the PC, 75% (155 out of 206) of academics and 68% (1014 out of 1491) of citizens are in favour to provide information about the sustainability contribution to consumers, while 76% (93 out of 122) of businesses, 65% (13 out of 20) of environmental organisations, 68% (55 out of 81) of NGOs, and 60% (3 out of 5) of consumer organisations do not agree (Question 8 of PC).

47% (28 out of 60) of the targeted survey respondents expect only a moderately higher willingness to buy NGT products and see only a small increase of clarity for consumers with an additional sustainability label. 55% (36 out of 66) expect a strong increase in compliance costs and administrative burden. The organic sector expressed in interviews that such a label would lead to unfair competition with the organic label.

The focus group on sustainability concluded that sustainability should not be linked to the plant breeding process but rather a holistic, systemic approach should be put in place. The group emphasized that sustainability encompasses various dimensions and is context-dependent, requiring consideration of trade-offs and avoiding discrimination between different breeding methods. They highlighted that sustainability is a multifaceted concept encompassing social, health, and economic dimensions, which vary depending on the specific traits and contextual factors. Balancing trade-offs and avoiding discrimination between different breeding methods were identified as challenges. They recommended addressing sustainability through a broader framework, such as the Sustainable Food Systems Framework, and highlighted the importance of transparency and information for the organic sector.

d) Traceability and information

There is broad agreement among stakeholders about the need to ensure transparency about NGTs, but views vary considerably on the means to ensure it. For consumer organisations, transparency should be provided through labels (80%, 4 out of 5) while 37% (65 out of 177) of the business associations and 32% (80 out of 251) of the companies do not find transparency necessary for plants produced by targeted mutagenesis and cisgenesis, when they could have been produced through conventional plant breeding or classical mutagenesis (Question 12 of PC). 46% (69 out of 149) of plant breeders and 61% (23 out of 38) of biotechnology/bio-based industries do not see a need for transparency for such plants, while for 55% (42 out of 77) of the organic, 66% (19 out

of 29) of GMO free, 58% (18 out of 31) of food retail and 62% (5 out of 8) of forestry sectors, a physical label could provide transparency. In interviews, the PC and the focus groups, the organic sector expressed a need for transparency underlining the importance of transparency so that organic operators have the freedom to avoid NGTs.

As regards what should be required when reliable analytical methods that can both detect and differentiate a product cannot be provided for plants produced by targeted mutagenesis and cisgenesis, responses varied in the PC (Q11). 30% (660 responses) consider that, in the absence of reliable analytical methods that can both detect and differentiate a product, operators should "not be allowed to place the product in question on the market" (a great majority of consumer and environmental organisations and the majority of NGOs; most selected view among citizens and trade unions; among economic operators, half of the forestry sector, the majority of the food retail/services sector, as well as the great majority of the organic and GM-free sector also expressed this view)

Conversely, 27% (599) of respondents considered that operators should "not be asked at all to provide an analytical method that can both detect and differentiate their product". This was the most expressed view among academic/research institutions, companies/business organisations and non-EU citizens; it was expressed by the great majority of the plant protection product/fertiliser, plant breeding/seeds and biotechnology/bio-based industry sectors, and was the most selected response among the trade, farming and ornamental plant sectors). 20% (431) believe that operators should "be asked to provide a detection method, but without the need to differentiate, if they can justify that the latter would be impossible" (the most selected response among public authorities, as well as half the forestry sector) and 16% (350) respondents consider that operators should "not be asked to provide an analytical method that can both detect and differentiate their product, if they can justify that this would be impossible".

The survey finds that the scenario requiring no labelling and traceability if a product is also obtainable naturally or by conventional breeding elicits the strongest expectations of positive impacts on total private R&D funding for plant breeding, for funding for biotech in academia, for the competitiveness of farming or the SME market share in the breeding sector.

The focus group on traceability, consisting of experts from various sectors, emphasized the importance of labelling NGT plant products using existing labelling schemes, especially if these products are not regulated as GMOs in the future. Certain participants highlighted that labelling should only be appropriate if there is a distinguishable difference between NGT plants and those obtained through conventional breeding. Otherwise, labelling would be misleading. The lack of analytical methods for identification and differentiation was considered to pose a significant enforcement challenge. Additionally, traceability requirements for NGT plants should be proportionate and verifiable by competent authorities through official controls. Document-based traceability systems, such as those used in the organic sector, can be valuable for enforcement and traceability, especially in the early stages of the food chain. Introducing a specific traceability system for NGT plants would be problematic due to the lack of distinction between NGT and conventional plants in many third countries. Alternative options such as public registries, leveraging existing databases like the EU Common Catalogues or national registers, and exploring cost-efficient methods like blockchain for traceability (not detection) would require international coordination. Some participants suggested that ruling out analytical methods prematurely may not be appropriate, as relevant research in this area is still in its early stages. The costs and administrative

burden associated with record-keeping systems should be proportionate and manageable, considering that the majority of NGT developers are SMEs.

e) Coexistence

The majority of conventional farmers emphasise the competitive advantage NGTs can bring to European farms, e.g. with plants adapted to climatic changes and reduced environmental impact during cultivation (less fertilizers, water and pesticide uses). Sharing these views, some organic farmers also see advantages in the use of NGTs, to enable wider environmental and economic sustainability, as indicated in interviews and the focus group on sustainability.

However, the majority position expressed by the organic sector is that NGTs are not compatible with the organic sector. Various points were raised on coexistence matters in an open question in the PC (Q15), as well as in interviews. Stakeholders from the organic sector suggest that measures safeguarding coexistence should be strengthened at EU level, e.g. maintain labelling and traceability, and in addition provide for measures to guarantee seed purity and protection against contamination, and that measures must encompass the entire chain from seed production to the finished product. Other stakeholders expressed the view that conventional-like NGT plants should be treated the same as conventional plants and therefore be suitable for all kind of agriculture, without the need of applying any specific coexistence measures.

In position papers submitted to the PC, some public authorities expressed the view that the current legislation on the traceability and labelling of GMO is key to enable and guarantee the co-existence with organic and conventional GM-free agriculture as well as for consumer information and liability issues. They call on the Commission to ensure research and development of detection methods in this context.

According to the targeted survey, strong and moderate negative impacts on organic farming are expected predominantly by NGOs (6), SMEs (4), two consumer associations, one public authority, one business organisation, and one public agency. No impact on the organic farmers (14) are predominantly expected from business associations (8), public authorities (2), as well as one NGO and one academic organisation.

For small scale farmers, the picture is very similar: out of the 14 respondents that expected strong or moderate negative economic effects on small scale farmers were NGOs (5), SMEs (4), consumer and business associations (each 2), and one ‘Other” (public agency). In essence, all respondents who saw strong negative economic effects on organic farmers, also expected them for small scale farmers.

f) Future-proofing

In terms of future-proofing of the legislation, the two most important aspects across all stakeholder groups (except consumer and environmental organisations, as well as NGOs) are to improve the legal clarity and to put in place mechanisms that facilitate adaptation to scientific progress (Question 14 of PC). In addition, an adapted regulatory framework that is “aligned globally with other commercial areas around the world to minimize commercial conflict potential and ensure EU competitiveness” and that is “proportionate and science-based” (Question 18 of PC) were key requirements mentioned by stakeholders.

Measures to facilitate the uptake of NGTs by SMEs put forward by various stakeholders during the consultations. According to the PC, “a reliable framework that gives them certainty concerning their investment” is needed, “the NGTs are suitable for local contexts”, and that SMEs currently “cannot afford the high costs of lengthy investment required for R&D and commercialisation of new crops” was shared by business

associations and academia while companies/business additional regulatory measures and citizens and public authorities are divided in their views.

4. Identified campaigns

a) Feedback on the Commission's Inception Impact Assessment (IIA)

98% (69,414) of the replies were identified as coming from campaigns; campaign contributors self-categorised as citizens. A user-modifiable, precompiled reply template was made available on several websites in different EU-countries.

The contributions from the campaign demand to apply the precautionary principle in accordance with the CJEU ruling of 25 July 2018 in Case C-528/16, *Confédération paysanne and Others*[6]. In the view of these respondents, all GMOs, including NGT products, must fall under the current GMO legislation, and no artificial distinction should be made between different forms of genetic engineering. A robust, process-based, case-by-case risk assessment for NGT products should be applied. Moreover, the Commission should implement policies that are in accordance with the objectives of the Farm to Fork strategy. More research on unexpected and unwanted effects of NGT plants, including long-term effects and on interactions of the plant with the environment, is demanded. It is stressed that sustainability and social criteria of NGTs should be assessed in a systematic way and the claim that NGTs can contribute to a sustainable food system is discarded. Campaigners stress the importance of traceability of NGTs and consider that NGTs should be labelled as GMOs to guarantee freedom of choice. According to the campaigns respondents, in case of a deregulation, the costs for the organic and the GM-free sector would drastically increase to avoid contamination of their products. They also express concerns about the patenting of NGT products, as they would restrict the rights of farmers and breeders, and only companies would be able to make profits from them.

A small part of campaigners further asks to ban products of and research on genetic engineering in the EU; some ask that their import should also be prohibited. Some state that genetic engineering should only be approved in medicine.

More details can be found in the summary report of the feedback from the inception impact assessment can be found in Annex 2a.

b) Public Consultation (PC)

Similar sets of replies that could potentially constitute campaigns were identified using a combination of statistical software and manual analysis of responses, based on the identification of more than ten identical contributions to closed questions and at least one open question. Overall, five such groups were identified from 109 respondents (4.7% of all consultation responses, **Error! Reference source not found.**). Their main messages were:

Groups 1, 2, 4 and 5: current provisions of the GMO legislation are adequate; risk assessment using the current GMO legislation requirements; no need for specific regulatory provisions on sustainability. Groups 1, 2 and 4: effective traceability can be ensured via documentation, public databases/registries and digital solutions, while Groups 1, 2 and 5 stated that transparency can be achieved via a physical label.

Group 3: current provisions of the GMO legislation are not adequate; no need for risk assessment when plants could have been produced through conventional breeding or

[7] https://demeter.net/keep-new-gm-food-strictly-regulated-and-labelled/

classical mutagenesis; no need for specific regulatory provisions on sustainability; effective traceability can be ensured via public databases/registries; transparency for operators and consumers is not necessary, when these plants could have been produced through conventional breeding or classical mutagenesis.

None of the campaigns identified had a significant weight on the overall outcome of the consultation, due to the relatively very limited number of respondents involved, ranging from 0.4% (10) to 2.1% (48) of the overall respondents.

Table 1: Overview of identified campaigns in the PC

Campaign number	Number of respondents / shares *	Stakeholder types								Sectors	Country of origin
		Academic / research	Business association	Company/business org.	NGO	EU citizen	Environmental org.	Non-EU citizen	Other		
1	13 / 0.6%				2	2		8	1	None	Switzerland: 10, Germany: 1, Italy: 2
2	18 / 0.8%		4	2	5	3		4		Food processing/manufacturing: 1, Plant breeding/seeds: 1. Farming: 4, Organic: 4, Trade: 1, Food processing/manufacturing; Food retail/services: 1	Australia: 1, Belgium: 1, Finland:1, France: 1, Germany: 2, Greece:1, Hungary:1, Italy:1 Spain: 1, Sweden: 1, Switzerland: 1, UK:1, US: 5
3	20 / 0.9%		5	7	4	4				Farming: 7, Ornamental Plants: 2, Plant breeding/seeds: 2, Food processing/manufacturing: 2.	Belgium: 3, Estonia 1, Germany: 2, Italy: 3, Portugal: 1, Romania: 9, Sweden: 1
4	48 / 2.1%		1		7	34	5	1		Plant breeding/seeds, Farming: 4. Food processing/manufacturing, Biotechnology/bio-based industry, Trade, Organic: 3. Wine: 1	Austria: 1, Belgium: 4, Denmark: 1, France: 2, Germany: 4, Hungary: 3, Poland: 1, Slovakia: 30, Spain: 1, UK: 1
5	10 / 0.4%		1		1	7	1			Organic: 1	Poland: 10
TOTAL	**109 / 4.7%**										
** Out of total responses: 2 300*											

5. Ad hoc contributions and outreach

Ad hoc contributions

141 stakeholders (including Member States) attached one or more position papers to the PC. Following a screening and de-selecting literature already analysed during desk research, lists of references, and duplicates, 50 papers were analysed in more detail.

Error! Reference source not found. presents the analyses of positions papers by stakeholder type.

Excluding the topics addressed by the questions of the PC, the position papers centred around the following topics: existing provisions for NGTs; short/medium/long-term consequences on the sector if no change in the current legislation; risk assessment; impacts (social / environmental / economic / other impacts) on sustainability; incentives to encourage sustainable NGTs; traceability of NGTs; on future-proofing of legislation; measures for coexistence with existing agricultural practices; accessibility to NGT technologies/resources.

In addition, contributions were received via e-mail. For the PC, these originated from France, Sweden, the United States of America, Community Plant Variety Office, Union Fleurs and IGTC, while for the targeted survey these originated from several Member States (Germany, Austria, Sweden, Poland, Hungary, Lithuania, Romania and the Netherlands). All contributions were analysed and considered in the analysis.

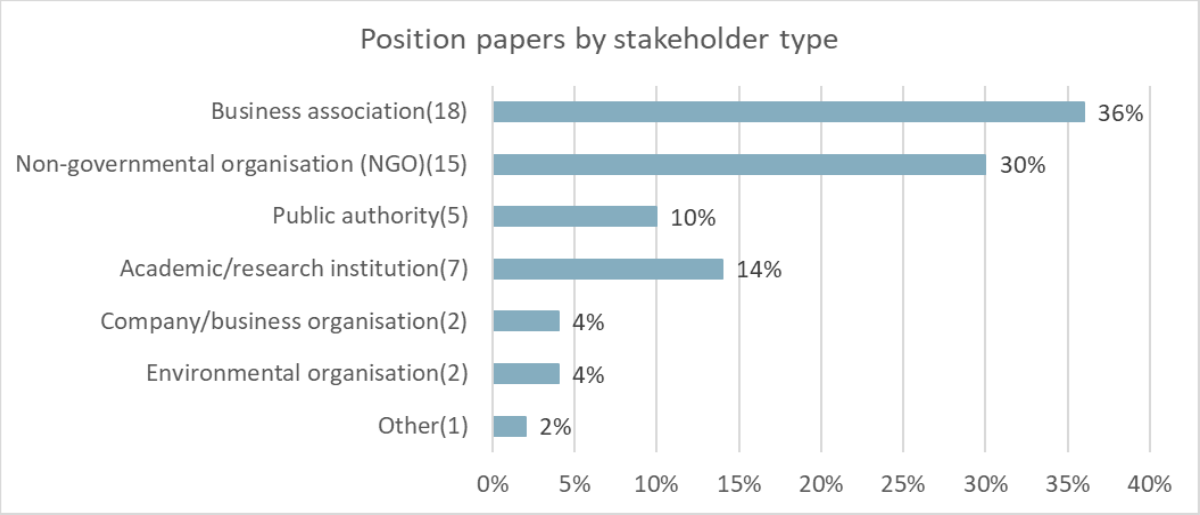

Figure 2: Position papers by stakeholder type

During the public consultation, an email campaign with 922 contributions from French citizens was addressed to the Commission. The campaign advocated that the current GMO-legislation should not be revised.

On 7 February 2023, the Commission received a petition[7] with 420 000 signatures from a coalition of 55 organisations in 18 Member States, asking the Commission to maintain risk assessment, traceability, and labelling for organism obtained by NGTs.

Outreach

On 29 November 2021, the Commission organised a high-level event on "New genomic techniques – the way forward for safe and sustainable innovation in the agri-food sector"[8]. Three panels, with speakers from the European Parliament, Member States, academia, NGOs, breeders and farmers, debated on the key elements of the policy action:

[7] https://demeter.net/keep-new-gm-food-strictly-regulated-and-labelled/
[8] https://commission.europa.eu/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-11-29_en

sustainability, risk assessment and information to the consumers. The event was followed by around 1000 people (registered or via webstreaming).

The Commission organised three dedicated meetings with the Member States' GMO experts to inform them on the progress on the impact assessment (25 May 2022[9], 24 October 2022[10] and 9 February 2023[11]). Furthermore, the Commission informed stakeholders on the progress of the impact assessment in the context of the Advisory Group on the Food Chain and Animal and Plant Health (6 May 2022[12]) and the Advisory Group on Sustainability of Food Systems (19 October 2022[13]).

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[9] https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_20220525_jwg_sum.pdf
[10] https://food.ec.europa.eu/system/files/2023-02/sc_modif-genet_20221024_jwg_sum.pdf
[11] https://food.ec.europa.eu/system/files/2023-06/sc_modif-genet_20230209_jwg_sum.pdf
[12] https://food.ec.europa.eu/system/files/2022-06/adv-grp_plenary_20220506_sum.pdf
[13] https://food.ec.europa.eu/system/files/2023-01/adv-grp_plenary_20221019_sum.pdf

ANNEX 2A: SUMMARY REPORT ON FEEDBACK RECEIVED ON INCEPTION IMPACT ASSESSMENT: LEGISLATION FOR PLANTS PRODUCED BY CERTAIN NEW GENOMIC TECHNIQUES

The Inception Impact Assessment (IIA) aimed to inform citizens and stakeholders about the Commission's policy initiative on plants obtained by targeted mutagenesis and cisgenesis. Citizens and stakeholders provided feedback from 24 September 2021 to 22 October 2021.

70,894 contributions were received; 98% (69,414) of the replies were identified as coming from campaigns; contributors self-categorised as citizens. It seems that a user-modifiable, precompiled reply template was made available on several websites in different EU-countries.

The non-campaign replies amounted to 2% of the total (1,480). According to self-categorisation, most contributions were from citizens (70%, 1,030 replies), followed by business organisations/associations, trade unions (14%, 203), academia/research institutions (8%, 115), NGOs and consumer/environmental organisations (5%, 81), public authorities (1%, 9) and others (3%, 42).

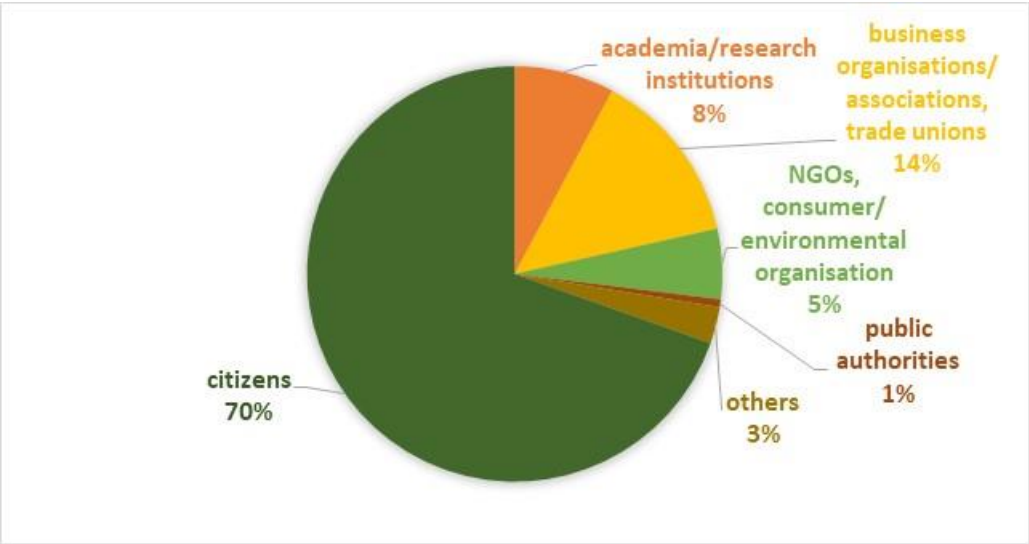


Figure 3. Breakdown of non-campaign replies (1,480 total)

Contributions (both campaign and non-campaign) originated from 91 countries, including the 27 Member States and 64 non-EU countries. Top contributions from Member States were from Germany (32,694), France (25,544), Belgium (2,732), Netherlands (2,251) and Austria (2,111). Most contributions from non EU-countries came from Switzerland (782), followed by United Kingdom (759), USA (228), Argentina (142) and Canada (114).

This large number of campaign and non-campaign contributions shows the interest of citizens and stakeholders on the Commission's policy initiative on plants derived from new genomic techniques (NGTs) and on the topic in general.

The following analysis distinguishes between the non-campaign and campaign contributions and, for the latter, between different stakeholders groups. It organises the

comments according to the following topics: the IIA/policy initiative in general, risk assessment, sustainability, traceability, information to consumers/awareness, liability/cost of contamination and intellectual property.

1. NON-CAMPAIGN CONTRIBUTIONS

1.1. Public authorities

Contributions from nine public authorities were received, among them the Member States Denmark (DK)[14], Estonia (EE)[15], Austria (AT)[16], Spain (ES)[17], Netherlands (NL)[18] and France (FR) as well as the Bavarian[19] and Flemish authorities[20]. Furthermore, one reply was from Argentina[21].

On IIA/policy initiative

All respondents welcome the policy initiative and support the IIA. ES, EE, FR and NL stress that an update of the current GMO legislation is needed. ES and NL emphasise that legal uncertainties must be removed of the GMO legislation. Furthermore, ES states that duplication of requirements, leading to administrative burden, that are already addressed in more specific legislation, should be avoided. The Flemish authority criticises that the IIA does not indicate how the net administrative burden for obtaining an authorisation will be reduced. FR is not in favour of developing new herbicide resistance varieties, which has to be considered in the regulatory framework in their point of view. Moreover, Argentina promotes to harmonise internationally the regulation of NGT products.

Concerning the timing of the policy initiative, the Bavarian authority suggests starting the public consultation in the 1st quarter of 2022. The action is considered urgent, given the rapid global developments in the field of NGTs. Regarding the scope of the initiative, DK, ES, NL and EE stress that knowledge of the use of NGTs in microorganisms and animals has to be built up.

Risk assessment

EE underlines the importance of carrying out a proportionate risk assessment for NGT products, which should be based on a case-by case approach.

Sustainability

EE and ES support the sustainability assessment of NGT products in the authorisation process. The Flemish authority states that safety and sustainability assessments must remain separate. Furthermore, it stresses that sustainability may not become too stringent so that innovation is possible. Argentina stresses that NGTs could contribute to the objectives of the European Green Deal and F2F.

Traceability

In the point of view of EE, there should not be excessive focus on traceability, given the impossibility in certain cases to trace the variety and the fact that plants obtained by new genomic methods are known to be as safe as those derived from conventional breeding.

[14] Ministry of Food, Agriculture and Fisheries; Ministry of Environment
[15] Maaeluministeerium
[16] Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz
[17] Ministerio de Agricultura, Pesca y Alimentación
[18] Ministry of Infrastructure and Water Management
[19] Bayerisches Staatsministerium für Umwelt und Verbraucherschutz
[20] Interdepartementaal overlegcomité Life Sciences, Vlaamse Overheid
[21] Ministerio de Agricultura, Ganaderia y Pesca

The Flemish authority stresses that the authorisation should not depend on an analytical detection method.

Information to consumers/awareness

In the opinion of EE, potential consumer attitudes should be assessed under the economic impact of the IA. Furthermore, consumers should be better informed about NGTs.

1.2. Business organisations/associations, trade unions

On IIA/policy initiative

Most respondents in this category (167 out of 205, mostly farming, breeding, processing, manufacturing and trading operators) support a future-proof adaptation of the GMO legislation to scientific and technological progress, stating that the upcoming proposal needs proportionate approval requirements, clear definitions and clarification of what falls under the GMO legislation, and that it should not add administrative complexities. Some suggest extending Annex 1B of Directive 2001/18/EC to NGT products not containing foreign DNA. Others propose to regulate phenotypes comparable to those of natural mutations or conventional breeding by the PRM legislation and not the GMO one. Some suggest that NGT products without added DNA should only be subject to a notification procedure like in Japan and stress the importance in their view to harmonise the EU GMO legislation with other non-EU countries. Some respondents in this group demand that the inter-institutional negotiation of the proposal should take place during the current legislative term of the European Parliament, and one suggests an ad hoc regulation as in the case of the COVID pandemic. Others ask that the scope of the policy initiative be enlarged to microorganisms and to all genomic techniques, including to those leading to transgenesis. Furthermore, in the view of some respondents the initiative needs to address also that the current GMO legislation allows EU countries to opt out of GMOs.

All organic, GM-free and related operators as well as some farmers' associations/movements and retailers (38 out of 205) believe that NGT products should remain subject to the current GMO authorisation procedure, and do not see a legal uncertainty that justifies the amendment of the current GMO legislation, which should continue to be applied. They argue that the GMO legislation is not a ban of NGT products, as research is possible and products of targeted mutagenesis and cisgenesis could be authorised. Some respondents ask to assess the costs for the GM-free and organic sector in case of potential contamination by NGT products; they demand that the impact on biodiversity of NGT products be assessed and that ethical considerations are included in the decision whether to allow NGTs in the EU.

Risk assessment

Farming, breeding, processing, manufacturing and trading operators for the most part support a proportionate product-based risk assessment on a case-by-case basis, stressing that neither risk assessment nor monitoring is needed if NGT plants could have been produced naturally. They further argue that it should be ensured that SMEs could meet submission requirements for the risk assessment of NGT products.

Organic, GM-free and related operators as well as some farmers associations/movements call for a proper comprehensive risk assessment for NGT products. They demand a process-based, case-by-case risk assessment; some propose that a product/trait-based assessment should be done additionally.

Sustainability

Several farming, breeding, processing, manufacturing and trading operators demand a consistent and coherent sustainability analysis for all products, adding that it would be discriminatory to only assess the sustainability of NGT products and not of products of other breeding methods. Furthermore, the sustainability criteria should be coherent with the sustainability food system framework. Breeding and farming operators emphasise that the sustainability assessment would increase the administrative and financial burden. Breeding operators add that the VCU testing, which most plant varieties have to undergo under the PRM legislation, considers sustainability. Two respondents of the biotechnology sector state that sustainability analysis should not play a role in NGT authorisation, but sustainability related information could be included in a label.

Some organic and GM-free operators support the assessment of the sustainability and socio-economic impacts of NGT products. However, two respondents of this group emphasise that the sustainability assessment should not be linked to the risk assessment.

Several farming, breeding, processing, manufacturing and trading operators agree that NGT products could contribute to the objectives of the Green Deal and the Farm to Fork Strategy. By contrast, organic and GM-free operators, as well as some farmers' associations, opposes this idea and stress the importance of traditional farming methods and agro-ecological practices in this regard.

Traceability

Breeders consider that, in order to ensure traceability, information could be provided in the EU common catalogue of varieties or the national variety registry. Furthermore, two respondents stress that product segregation based only on the breeding technique is very costly.

Organic and GM-free operators as well as respondents of the retail sector call for the development of detection methods for NGT products. Some organic and GM-free operators state that detection methods of NGT products must be a mandatory prerequisite for the approval of NGT products, while other organic and GM-free operators as well as some farmers' associations suggest that documentation traceability would be an option in case no detection methods are available.

Furthermore, three respondents call for the establishment of a transparency register for NGT products.

Information to consumers/awareness

Organic and GM-free operators as well as respondents of the retail sector want to maintain labelling of NGT products. They underline that labelling is important to ensure the freedom of choice of consumers and the organic and GM-free sector. Moreover, organic and GM-free operators further demand that animal products should be labelled if the animals were fed GMO feed. One respondent emphasises that the current GMO label should be used for NGT products, instead of introducing a new label.

Farming, processing, manufacturing and trading operators took the opposing position, arguing that labelling should be voluntary, underlining that products of traditional breeding methods would also need labelling, if NGT products are labelled; labelling similar products differently would breach the principle of non-discrimination and proportionality. Others add that if a method for production of a variety is not considered as GMO, it should not be labelled as such. Some emphasise that labelling must be

implementable and enforceable or suggest that it could be used to communicate the benefits of the NGT product.

On the one hand, two respondents stress that a majority of European consumers oppose genetic engineering in agriculture. On the other hand, one respondent argues that consumers differentiate between old and new GMOs and that the acceptance increases if NGT products show personal, health or climate benefits. Four respondents state that citizens should be better informed about NGTs.

Liability/cost of contamination

Organic, GM-free and related operators call for strict coexistence rules, arguing that even a partial deregulation of NGT products would make it more difficult for the organic and GM-free sector to trace them. As there is no "polluter pays principle" in place, the organic and the GM-free sector would have to bear the cost to avoid the contamination of their products with NGT products. Furthermore, these respondents stress that lack of information would also break the trust of the consumer in organic food.

Intellectual property

Especially breeders but also farming, processing, manufacturing and trading operators support a broad access to breeding technologies and suggest that the Commission should encourage licensing platforms that provide their members access to patented technology like the International Licensing Platform (ILP) Vegetable, Corteva's Open Innovation Platform and the Agricultural Crops Licensing Platform (ACLP). Some breeders that support these licensing platforms also acknowledge the importance of plant-related innovation by patent protection. Two farmers' associations call for free access to the entire gene pool and all breeding processes while one other supports access to the selection method used but the breeder should be allowed to keep confidential information. Three farmers' associations demand that patents should be applicable to plants containing DNA that cannot be found in nature or cannot be obtained by conventional breeding methods or old and new mutagenesis. Another suggestion is that the Commission should establish a research institute that will give access to the technology to all European firms by applying common property principles while the beneficiary company will pay a reasonable amount for it. One breeder calls for a change in the intellectual property landscape of plants with a broader interpretation of the definition of 'essential biological processes' in order to cover mutation breeding in both Directive 98/44 and the European Patent Office (EPO) framework.

Organic and GM-free operators are concerned that patents on NGT products can create damage to seed availability and lead to the privatisation of modified seeds. Furthermore, they argue that they would undermine the breeder's exemption. One farmers' association states that the patenting of genetic information contained in the seed would run counter to the implementation of the rights of farmers on seeds based on the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas and the International Treaty on Plant Genetic Resources for Food and Agriculture.

1.3. Academia/research institutions

On IIA/policy initiative

Most respondents of this group demand to modernise the current GMO legislation according to current knowledge, making it proportionate and future-proof. Legal uncertainties regarding terms like "mutagenesis", "conventional use in a number of applications" and "long safety record" should be removed and harmonised with the Cartagena protocol. Within this group some are for simplified or product-based

authorisation procedures for NGT products. Others ask that NGT products should be deregulated, or that NGT products should be deregulated if they are not transgenic; others support their deregulation only when they are also obtainable by conventional breeding.

Suggestions on how to change the GMO legislation were made. These include a pre-assessment procedure, regulated by a separate piece of legislation, to determine whether the product falls under the GMO legislation, like in Argentina. Others propose to modify the GMO definition to exempt NGT products by enlarging the mutagenesis exemption or introducing a new annex defining the exemptions. In addition, some ask that a future regulation of NGT plants should not allow individual member states to restrict their use. Moreover, the international perspective of the GMO legislation and its consequences on international trade must be considered, e.g. Distinctness, Uniformity and Stability (DUS) testing is challenging if NGT products are regulated as GMOs in the EU, as this is not the case in other countries. Regarding the scope of the initiative, some stress that microorganisms, forest-trees and forest biomass derived products should be included. Others ask that the impact assessment should consider the human right to benefit from scientific progress (Art 27 of the 1948 UDHR and Art 15 of ICESCR), as well as and positive and negative impacts for organic and GM-free agriculture. Moreover, a cost-benefit analysis of the deployment of NGTs on all the aspects mentioned in the IIA should be carried out.

Some respondents ask that NGTs continue to be covered by the current GMO legislation and that it is too early for a proportionate framework, as possible adverse effects of NGT plants are not reliably known. Furthermore, there is a call for more research on unintended impacts on environment and human health of NGT products.

Risk assessment

Some respondents call for a product-based risk assessment on a case-by-case basis. Furthermore, there are proposals for a specific risk assessment for NGT products based on defined categories of risks. For one respondent of this group the current risk assessment should apply to all NGT products, as it is too early to assume that they are safe.

Sustainability

Some respondents agree that NGT products could contribute to the objectives of the Green Deal, the F2F, the Biodiversity Strategy and the UN SDGs. Moreover, some propose that not only the risks but also the benefits to environment and to society should be considered in a legal framework.

Some commenters refer to the Norwegian Gene Technology Act that assesses the contribution to sustainability, social utility and ethical aspect of GMOs, which could serve as an example for the EU GMO legislation. Others demand that a sustainability analysis should not be limited to NGT products but be included in the evaluation of any new plant variety. Others emphasise that a sustainability analysis would increase the administrative and economic burden and would not contribute to international harmonisation.

Traceability

Some respondents highlight the importance of traceability for the GM-free and the organic sector, as a lack of transparency, traceability and labelling would set the wrong signal. Moreover, some call for more research on detection methods. As traceability is not always possible by analytical methods, respondents in this group suggest certification to trace NGT products. Others stress that the requirements for detection methods should

not be barriers in the approval process, or that NGT and conventional products should be treated equally regarding traceability.

Information to consumers/awareness

As for traceability, some emphasise that labelling is important for the GM-free and organic sector and needed to ensure the freedom of choice for consumers. Others mention that the public wants information about the breeding method. Finally, some call for no labelling of NGT products.

Some respondents ask for constructive public dialogs to better inform consumers about NGTs, arguing that the public attitude is positive on NGT products if they are beneficial for environment and society, and stressing that regulating NGTs as GMOs would sow doubts in the minds of consumers.

Liability/cost of contamination

Some respondents comment that NGT and conventional breeding products are indistinguishable. Therefore, there is no scientific basis not to use NGT products in organic farming.

Intellectual property

One respondent notes that, since GMO products seeking for a patent or Community Plant Variety Rights (CPVR) protection must meet intellectual property rights (IPR) criteria such as novelty, inventiveness, industrialisation, distinctiveness, stability and uniformity, by default such a product would also be characterised as non-conventional/traditional, unknown, unnatural/synthetic and could not legally be described or labelled as natural, organic, conventional, traditional, having a history of safe use etc. Others ask that NGT products be excluded from patenting.

1.4. NGOs, consumer/environmental organisations

On IIA/policy initiative

This group of respondents is very critical on the IIA. They argue that the IIA follows the unverifiable promises of the industry, as it downplays the risks and overemphasises potential benefits of NGT products, and it does not take into account the benefits for the food sector, farmers, the environment and the public of the current GMO legislation. Moreover, according to some of them, the IIA does not follow the CJEU ruling by not prioritising the precautionary principle and by suggesting that the current GMO legislation is no longer fit for purpose. Respondents in this group demand that the current GMO definition is maintained and to not distinguish between different forms of genetic engineering. They stress that if NGT products were exempt from the GMO legislation, this would conflict with the EU treaty (Art 169, Art 114,191 TFEU) and the key objectives of the Biodiversity Strategy. In this group, most respondents demand a thorough approval procedure for NGT products, rejecting a facilitated authorisation, suggesting that, like in the pharmaceutical authorisation, an evidence-based benefit assessment should be needed for the authorisation of a new GMO. Finally, some call for a general ban of all GMOs in the EU. One NGO claims that apart from the impacts mentioned in the IIA, the IA should also examine the impact on social justice, agrobiodiversity, circular economy and ecosystem services. Furthermore, it should contain a survey on the acceptance by citizens.

A few respondents from this group support an adaptation of the GMO legislation according to scientific knowledge, as it is not fit for purpose. One respondent supports a

product-oriented approach with a case-by-case assessment regardless of the breeding process.

Risk assessment

Several respondents demand a risk assessment for all GMOs, regardless of the technique used, supporting a process-based risk assessment on a case-by-case basis; some state that besides the process also the trait has to be assessed. In addition, one NGO stresses that also the plant species (e.g. reproduction methods, pollinators involved) has to be considered. Respondents emphasise that the risk assessment must include new and additional risks emerging from NGTs and should not be based on defined technique-based risk levels. They argue that genetic alterations of NGTs go far beyond of those of conventional breeding techniques.

Sustainability

In general, this group opposes the assumption that NGT products can contribute to sustainability, as they are part of an industrial agricultural system. Instead, they suggest that the Commission focuses on agro-ecology and organic agriculture. They argue that the Commission downplays the dominance of herbicide tolerance in current pre-commercial NGT crops and call for a ban of pesticide-tolerant varieties.

Within this group, some are in favour of a sustainability analysis for NGT products. They refer to the Norwegian law, where only GMOs contributing to sustainable development can be used. Furthermore, they demand the sustainability analysis be based on scientific evidence, follow strict quality requirements, be comprehensive, and not be limited to a specific category of GMOs.

Moreover, the importance of the coherence of the sustainability analysis with the policy action on a sustainable food system framework is emphasised.

Traceability

This group calls for traceability of NGT products to preserve the freedom of choice throughout the food chain and specifically for the organic and GM-free sectors. It considers that a weakening of the current traceability rules of NGT products would contradict the objectives of the F2F, according to which food information should be made more transparent. Companies should disclose full information about the genome sequence of their NGT products, and traceability and detection methods should be mandatory. The need for the development of detection methods was emphasised, asking in parallel that existing detection methods be used pro-actively in food and feed controls. Respondents criticise that, according to Commission's NGTs study, EU member states spent only 1,6% of their research funding in NGTs for detection methods, monitoring and risk assessment. If detection methods are not available, some suggest the introduction of a documentation-based traceability approach like in the organic sector. Finally, some call for the establishment of a public international registry including all GMO plant varieties.

Information to consumers/awareness

Respondents argue that labelling is important in order to ensure the freedom of choice throughout the food chain as well as the organic and GM-free sector; a weakening of the labelling rules would contradict the F2F. Furthermore, they argue that EU consumers are in favour of labelling of GMOs. This group of respondents opposes a new NGT-label that would replace the current GMO-label, and the replacement of GMO and NGT labelling by a sustainability labelling. They further ask for the labelling of animal products, if animals are fed with genetically modified feed.

Liability/cost of contamination
Respondents believe that deregulation of NGTs would make the coexistence of organic and GM-free impossible. Moreover, the cost to prevent and deal with contamination would rise dramatically in these sectors. In addition, the seed saving sector already has to handle the lack of transparency on NGT plants from third countries. Furthermore, it would contradict the General Food Law if the conventional, organic and GM-free sector had to account for all administrative and economic burden for testing and segregation while the potential benefits went to the biotechnology sector. They call for the introduction of the "polluter pays principle".

Intellectual property
Respondents of this group stress the negative consequences of patents, like monopolisation and concentration of the seed market, that apply to GM techniques. They ask that NGT research, that receives public funding, be free from patents.

1.5. Citizens

On IIA/policy initiative
Most of the respondents (815 out of 1029) believe the GMO legislation is not fit for purpose and support a future-proof update in accordance with current scientific knowledge. They ask to remove inconsistences, update definitions, align with global regulatory approaches and move to a product-based assessment. They argue that each EU country should not be able to prohibit the commercialisation of a GMO. Moreover, a separate approval process for NGTs from GMOs is proposed. They suggest including NGT products not containing foreign DNA in the Annex 1B of the Directive as a first step, or to consider them in the same way as those of traditional breeding. In the long-term, the legislation should be amended so that it is product-based. Others propose to introduce an authorisation for all plant varieties instead of just for GM varieties. Some further argue that the authorisation of transgenic plants should be simplified. Moreover, a heavy regulation on NGT products would deter small and medium-sized enterprises (SMEs) from using them.

A minority of respondents (198 out of 1029) oppose a change of the legislation for genetically modified organisms (GMOs). According to them, the GMO legislation is fit for purpose and there is no legal uncertainty that would justify an amendment. They stress that the ruling of the Court of Justice of the EU (CJEU) of July 2018 and the precautionary principle have to be respected. They oppose a deregulation of NGT products in order to prevent the risk of unintended consequences and to control misuse and propose to authorise NGT products only in the context of industrial and pharmaceutical biotechnology. Some demand that the EU should not allow the development of NGTs within its borders.

Some citizens state that societal, environmental and ethical consideration should be included in the debate on NGTs. Moreover, theological and anthropological research of the impact of NGTs is needed. Furthermore, the likely impacts on the fundamental right to freedom of the arts and science as well as the environmental and economic impact of refraining from biotechnological innovation should be assessed.

Risk assessment
Respondents have different opinions about the risk assessment of NGT products. Some do not support a change in the risk assessment of NGT products and stress that it should stay as it is now, but also additionally allow for a more stringent case-by-case assessment if needed. Some emphasise that no experimental data supports the assumption that NGT

products have the same risk profile as conventionally bred ones. They argue that NGTs differ from conventional breeding methods because of their non-randomness. Furthermore, they make the whole genome accessible for changes.

Others support a proportionate, product-based, case-by-case risk assessment, suggesting to introduce a preliminary assessment to determine whether a full risk assessment is necessary. Others propose to classify genetic engineering methods according to risk levels, leading to different risk assessment requirements.

Others believe that no risk assessment of NGT products is needed, as they are similar to conventionally bred ones.

Sustainability

Some citizens think that NGT products could contribute to the objectives of the Green Deal, the Farm to Fork Strategy (F2F) and the United Nations (UN) Sustainability Goals (SDGs). Others doubt the sustainability contributions of NGT products, as they are part of a farming model dependent on chemical use, and F2F aims at circular adapted agriculture instead of more agro-industry.

Some citizens support a sustainability assessment of NGT plants, stressing however that such an assessment should not apply only to NGT products. Others oppose the idea of a sustainability analysis, as they question the robustness and consistency of the approach, and as they consider that the Value for Cultivation and Use (VCU) testing already contains a sustainability assessment.

Traceability

Some citizens demand that traceability applies to NGT products, as it is important to guarantee a GMO-free supply chain. Others state that traceability should not lead to excessive evaluation costs. If NGT products are difficult or impossible to trace, practical solutions should be found instead of banning them from the market. Some suggest using document-based traceability if no detection method is available. Other citizens demand more research funding for detection methods.

Information to consumers/awareness

Some citizens demand that NGT products have to be labelled to guarantee the freedom of choice throughout the food chain and the GM-free sector, while others call for labelling animal products if the animals received GMO feed.

Other citizens suggest to distinguish between NGT and GM products on the label, to include the benefits of the NGT products on the label or to label every single product, GMO and non-GMO, with the breeding technique involved. In the point of view of some respondents, targeted mutagenesis and cisgenesis should not be labelled, or GMO products should not have to be labelled as they are safe. Some fear that labelling of NGT products could become a hindrance to their marketing in the EU or would make necessary imports of some food and feed impossible.

Some citizens call for better communication on NGT and GMO products in the EU. However, certain respondents also stress that, according to surveys, a majority of the European population opposes the use of genetic techniques, which has to be respected by the EU.

Liability/cost of contamination
Some citizens fear that a deregulation of NGT products would endanger the coexistence of organic agriculture, increasing the costs for farmers and processors of the organic and GM-free sector to ensure no contamination. In their view, the "polluter pays principle" should be enforced, i.e. that the GMO producer has to prevent and be held accountable for the contamination of non-GMO materials.

Intellectual property
Some citizens oppose the patenting of NGT products, proposing to make NGTs available to all public and private research institutions. The absence of patents is also essential in their view for SMEs to be competitive. They suggest to regulate NGTs according to the International Union for the Protection of New Varieties of Plants (UPOV) Convention, as there is no real difference between them and classical breeding technologies. Moreover, some citizens fear that the introduction of NGT products will create a dependent agricultural sector.

2. CAMPAIGN CONTRIBUTIONS

On IIA/policy initiative
The contributions from the campaign demand to apply the precautionary principle in accordance with the CJEU ruling. Therefore, in the view of these respondents, all GMOs, including NGT products, must fall under the GMO legislation, and no artificial distinction should be made between different forms of genetic engineering. Moreover, the Commission should implement policies that are in accordance with the objectives of the F2F. More research on unexpected and unwanted effects of NGT plants, including long-term effects and on interactions of the plant with the environment, is demanded. It is stressed that sustainability and social criteria of NGTs should be assessed in a systematic way.

A small part of campaigners further asks to ban products of and research on genetic engineering in the EU; some ask that also their import should be prohibited. Some state that genetic engineering should only be approved in medicine.

Risk assessment
The campaign demands a robust, process-based, case-by-case risk assessment for NGT products. Some respondents added that it should be accompanied by a trait-based risk assessment. An adaptation of the current risk assessment for NGT products would have to be based on scientific evidence and would have to assess new and additional risks emerging from NGTs.

Sustainability
The respondents of the campaign oppose the claim that NGTs can contribute to a sustainable food system. They are part of a farming system relying on massive chemical use. It is stated that, in countries producing GMOs, they have caused great damage to the environment and health of the population. The Commission should promote research on agro-ecology and organic farming as well as the breeding of peasant and farm seeds.

Traceability
The importance of traceability of NGTs is emphasised by the campaign respondents. They stress that farmers, breeders, food manufacturers, retailers and consumers must be able to avoid GMOs. According to them, the lack of traceability of NGTs would endanger the organic and GM-free sector. Moreover, to reach the 25% of organic agriculture announced in the F2F, it must be possible to avoid NGT products along the

food chain. Furthermore, the F2F aims to foster the transparency in the food chain for consumers. In their view, the traceability of NGT products should be a mandatory prerequisite for their approval; detection methods should be developed, and existing methods should be used pro-actively for food and feed controls. Finally, campaign respondents argue that traceability does not depend on detection methods and call for the establishment of a public global registry including all GMO plant varieties.

Information to consumers/awareness

The respondents of the campaign consider that NGTs should be labelled as GMOs to guarantee the freedom of choice. Otherwise, the organic and GM-free sector would be endangered. Moreover, animal products should be labelled if the animals were fed with GM feed.

Some stress that a majority of Austrians and Germans are against the cultivation of GMO plants, even if NGT were used, according to surveys

Liability/cost of contamination

According to the respondents, in case of a deregulation, the costs for the organic and the GM-free sector would drastically increase to avoid contamination of their products. For these two sectors, it is essential to know where GMOS are, and call for the introduction of the "polluter pays principle".

Intellectual property

Campaign respondents express concerns about the patenting of NGT products as they would restrict the rights of farmers and breeders and only companies would make profits from them. Companies would claim property rights on the millennia-long breeding work of farmers or on natural organisms, which have crossed with GMOs.

ANNEX 3: WHO IS AFFECTED AND HOW?

1. Practical implications of the initiative

The proposed measures guarantee safety and have positive implications for EU plant breeders, academic research, farmers, traders, consumers and regulators, while organic farmers will face challenges under certain conditions.

For **breeders**, from large companies and SMEs, NGTs will be a new tool allowing the rapid, more cost-efficient development of plant varieties with specific characteristics, thereby responding to the challenges of climate change, contributing to strengthening the sustainability of the food system and to meet diverse, evolving consumer demands. They will benefit from simplified and accelerated regulatory processes with regard to adapted risk assessment and with regard to NGT plants that are equivalent to plants that could occur naturally or be produced by conventional breeding. Certain NGTs are considered accessible tools for plant breeding due to their comparatively low cost and complexity. In this regard, NGTs are technologies, which could lead to a lowering of technological barriers to entry of the plant breeding sector, benefitting SMEs, in particular.

Academic researchers in the plant sciences expect increased funding from public and private sources as a result of a regulatory framework that is seen as enabling the marketing of the products resulting from research, contributing to the EU research base and innovation capacity in plant biotechnology and allowing researchers to use NGTs to support environmental and other challenges to the EU and global food system.

Farmers can benefit from varieties with increased resilience, improved pest tolerance and lower fertiliser needs, while delivering products satisfying the needs of processors, retailers and consumers. Innovative products can also open up new income sources for farmers.

Organic farmers will be able to rely on the tools of the GMO legislation available today as regards NGT plants subject to authorisation (traceability and labelling, coexistence measures implemented by the farmers cultivating NGT plants) and on transparency measures (public register, common catalogues of varieties) to identify those subject to notification as regards NGT plants subject to notification. The risk of admixture will depend on the adoption rate of NGTs.

Traders of NGT products will be able to offer competitive products and operate in a system that minimises regulatory divergence with trade partners.

Consumers can have an increased choice of products, including products with increased beneficial and decreased harmful compounds.

Regulators will benefit from simplified and accelerated regulatory processes.

2. Summary of costs and benefits

The two tables below summarise the benefits and the costs of the preferred option.

The preferred option is a combination of option 4 for products that could also occur naturally or be produced by conventional breeding and of an option 2 for all other products. Therefore, in general terms costs and savings for the notification correspond to

the costs and savings of option 4, while costs and savings for the authorisation correspond to the costs and savings of option 2.

However, not all the costs and savings from option 2 are directly applicable to the preferred option. In the preferred option there will be a list of traits contributing to sustainability which will not require additional data from the applicant and nor a specific assessment for administrations. Therefore, those costs, presented in table 5, are not necessary for the Annex 3.

In addition to calculate the aggregate saving and costs of the preferred option, a hypothetical scenario in which the breeders would submit 10 notifications and 5 authorisations per year.

The hypothetical scenario is based on the number of products expected to come to the market in the next ten years in the JRC study on NGT applications attached to the Commission NGT study. The JRC found 134 products at pre-marketing and advanced R&D phase, which correspond to products that could potentially reach the market by 2030, i.e. 27 per year from 2025 when legislation could be in place. We assumed that 55% would make it to a regulatory approval process, i.e. 15 per year from 2025. This is also consistent with the Argentina and US figures for the early years of notification-type systems and with the estimates from the UK 2022 impact assessment[1] for the new legislation on precision breeding organisms.

Regarding the number of products that would fall under the notification or authorisation, we were not able to rely on the pipeline data. We relied on the impact assessment conclusions of the expected attractiveness of each option and assumed that notification would entail 65% of the total applications and authorisation would entail 35% (10 notifications and 5 authorisations per year).

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
	Direct benefits	
Cost savings for breeders	**Notification:** Compared to the baseline breeders are expected to have a reduction in compliance costs, due to the removal of the detection method requirement, the removal of the post-market environmental monitoring and to the change in data requirements for the notification (data to show compliance with the notification criteria instead of data for a risk assessment). The savings for the breeders per notification are estimated to range from EUR 9 952 000 to EUR 11 171 000. **Authorisation:** Compared to the baseline, breeders are expected to have a reduction in compliance costs linked to the data requirement for the adapted risk assessment. These savings will be variable as the adapted risk assessment will not treat all products in the same way. The savings for the breeders per authorisation are estimated to range from EUR 0 to EUR 10 365 000. **Incentives**: The waiving of fees for the validation of the detection methods is considered as a potential incentive would add an extra saving for breeders in the authorisation procedure which would be of EUR 105 000 except for SME for which the savings would be of EUR 52 500[2]. **Total savings for breeders under the preferred option:** Total savings for notification are estimated to range from EUR 99	For the notification, the estimated savings are dependent on the future data requirements for the notification. For the authorisation, the estimated savings Are dependent on the future data requirements for the risk assessment and by the type of NGT **Total savings for breeders under the preferred option:** A hypothetical scenario was used in which the breeders would submit 10 notifications and 5 authorisations per year. These

[1] https://publications.parliament.uk/pa/bills/cbill/58-03/0011/GeneticTechnologyBill_IA_0526.pdf
[2] Fees for the validation of the detection methods for GMO by the EURL are described in Regulation (EC) 1981/2006. Article 4 of this Regulation currently sets up a 50% reduction of the fees for SMEs.

	520 000 to 111 710 000 per year. Total savings for authorisation are estimated to range from EUR 0 to 51 825 000 per year.	are recurrent savings per year.
Cost savings for administrations[3]	**Notification:** Compared to the baseline scenario, Member States administrations are expected to have cost reductions due to the change in data requirements for the notification and to the removal of the traceability and labelling obligation. The savings for administrations are estimated to be up to EUR 140 000 for the analysis of the data for notification. In addition, it is estimated that Member States would have significant savings in the enforcement, due to the removal of the traceability and labelling requirement, but these were not quantifiable. **Authorisation:** Compared to the baseline scenario, Member States administrations are expected to have costs reductions due to the adapted data requirement for the risk assessment. The savings for administrations are estimated to range from EUR 0 to EUR 140 000. **Total savings for administrations under the preferred option:** Total savings for notification are estimated to be up to EUR 1 400 000 per year. Total savings for authorisation are estimated to range from EUR 0 to 700 000 per year.	For the notification, no data were available for the savings as the notification is linked to new data requirements. The monetisation of this saving corresponds to a hypothetical scenario in which the only requirement would be the current requirements for molecular characterisation of a GMO. **Total savings for administrations under the preferred option:** A hypothetical scenario was used in which the breeders would submit 10 notifications and 5 authorisations per year. These are recurrent savings per year.
Net economic impact/market value for farmers	Range of 9% per hectare yield improvement (for oil and fibre crops) to 16% (for cereals) by 2030-2035. This represents, when including cost savings from reduced input use, a total annual economic market value of EUR244 m (for oil and fibre crops) to EUR2.7 bn (for cereals). Expected economic benefits to further grow afterwards as more NGT plants are authorised / accepted under the notification procedure and more crops are introduced.	
Time to market	**Breeders:** Reduction of the current 4.5-year risk assessment period for imports (6 years for cultivation). Reduction depends on case-specific data requirements. Application of NGTs leads to significant shorter development times and lower development costs. For example, the introduction into the market of a NGT potato variety is estimated to take five years, at a cost of EUR0.5 m instead of 13-15 years for a conventionally bred variety, at a cost of EUR2-3 m per variety.	
Regulatory certainty (likelihood that a product is able to be admitted to the market after the R&D-process)	Work on the criteria for risk assessment is intended to ensure adaptability (requirements proportionate to hazards on a case-by-case basis depending on the plant's risk profile), and predictability (ability of potential applicants to anticipate regulatory requirements). Work on the equivalence criteria for notification is intended to ensure predictability (ability of potential applicants to anticipate whether the requirement for notification would be met) and based on the product's molecular characterisation	
Trade	The preferred option minimises (compared to the other options) regulatory divergence with EU trade partners. For example, the detection of non-authorised GMO Triffid flax in EU food products and the subsequent import ban on Canadian flax led to a EUR40 m loss for the EU flax processing industry and 600 jobs lost	Differences in the regulation of NGTs increase the likelihood of regulatory asynchronicity.
Environmental benefits – pesticide reduction	According to the JRC study of Schneider *et al.* (2023a, b; see Annex 7): For cisgenic potatoes: 50-80% reduction of fungicide usage, or 9 kg per hectare, without impacts on yield or quality. For cisgenic apples bred with monogenic resistance against scab disease: reductions between 14% in the Netherlands and 58% in France could be achieved, the latter equivalent to 15 kg per hectare less fungicide use.	
Environmental benefits: fertiliser reduction	Projections 2030-2035 based on the contractor's study: A decrease of 0.1% and 4%, depending on crop species and rate of	

[3] Cost savings for the EU institutions were not considered for this table.

	adoption of NGT plants	
Environmental benefits: GHG reduction	Multipurpose use of gene-edited root chicory (production of inulin and health-beneficial terpenes): reduction of GHG emissions of around 10% compared to the current inulin production process when considering the entire value chain. Use of gene-edited pennycress (*Thlaspi arvense*) as a cash cover crop for biofuel production without displacing food crops Projections 2030-2035 based on the contractor's study: A decrease of up to 3.1% depending on crop species and rate of adoption of NGT plants.	
Social benefits – Health: nutritional impacts-food security	Health benefits for consumers would result from increased beneficial bioactive compounds in food and feed, such as increased levels of vitamin A, antioxidants, production of monounsaturated fatty acids and GABA. Moreover, harmful bioactive compounds such as cyanide, glycoalkaloids, allergens could be removed. NGTs may affect overall health benefits (in terms of QALYs) in different ways, including improving the accessibility to products that might lead to healthier diets. Such direct and indirect benefits are presented by the JRC study of Sanchez *et al*. (2023), described in Annex 7 on low-gluten wheat. Food security benefits are especially relevant for developing countries, as Annex 7 demonstrates with the example of Maize Lethal Necrosis (MLN) resistance, a severe threat to food security in Eastern Africa.	
Social benefits: consumer variety and choice	Consumers will experience improved product choice.	
Administrative cost savings related to the 'one in, one out' approach*		
Administrative cost savings for breeders	**Notification:** Reduction in administrative costs related to regulatory support is expected. The savings for breeders are estimated to range from EUR 83 300 to EUR 833 000. Reduction in administrative costs related to scientific support. The savings for breeders are estimated to range from EUR 35 700 to EUR 357 000. Reduction of the administrative costs as the data requirements for notification may not require studies to be performed under GLP/ISO guidelines. The savings for breeders are estimated to range from EUR 56 000 to EUR 1 120 000. Reduction of administrative costs as the notified NGT plant will not require the submission of post-market monitoring. The savings for breeders are estimated to be EUR 1 200 000. Reduction in administrative costs as the notified NGT plants will not be subject to a renewal procedure. The savings for breeders are estimated to be EUR 240 000. The total savings per notification is estimated to range from EUR 1 615 000 to EUR 3 750 000 **Authorisation:** Reduction in administrative costs related to regulatory support is expected. The savings for breeders are estimated to range from EUR 0 to EUR 833 000. Reduction in administrative costs related to scientific support. The savings for breeders are estimated to range from EUR 0 to EUR 357 000 Reduction of administrative costs as the data requirement in the adapted risk assessment for authorisation may not require or may require less studies to be performed under GLP/ISO guidelines. The savings for breeders are estimated to range from EUR 0 to EUR 560 000. The total savings per authorisation is estimated to range from EUR 0 to EUR 1 750 000 **Total administrative cost savings for breeders under the preferred option:** Total administrative cost savings for notification are estimated to	For the notification, the estimated savings are dependent on the future data requirement for the notification. For the authorisation, the estimated savings are dependent on the future data requirements for the risk assessment and by the type of NGT **Total savings for breeders under the preferred option:** A hypothetical scenario was used in which the breeders would submit 10 notifications and 5 authorisations per year. These are recurrent savings per year.

	range from EUR 16 150 000 to 37 500 000 per year. Total administrative cost savings for authorisation are estimated to range from EUR 0 to 8 750 000 per year.	
Administrative costs saving for food businesses	**Notification:** Unquantifiable recurrent savings are in administrative costs for food businesses is expected due to the removal of the traceability and labelling obligation.	

II. Overview of costs – Preferred option				
		Breeders	**Administrations**	**Farmers and food businesses**
Notification of a NGT product	Indirect costs	n/a	n/a	**Recurrent costs for organic farmers**. Potential unquantifiable increases costs risk management practices and market monitoring (for accidental presence of GM/NGT product) due to the uncertainties of potential presence of notified NGT plants in conventional seeds. **Recurrent costs for farmers**. potential unquantifiable costs for segregation/coexistence systems.
Authorisation of a NGT product	Administrative costs	n/a	n/a	**Recurrent costs for food businesses.** Limited unquantifiable cost increases due to additional information in the label (identification on the label of the purpose of the genetic modification to the label) and related segregation costs.

Incentive for NGT products with traits that can contribute to sustainability	Direct adjustment costs	n/a	**One-off costs:** Support given to the applicant during authorisation process due to sustainability incentive. Potential unquantifiable significant increase in cost for the administrations	n/a
Costs related to the 'one in, one out' approach				
Total	Direct adjustment costs	n/a	n/a	n/a
	Indirect adjustment costs	n/a	n/a	Unquantifiable increase for farmers.
	Administrative costs (for offsetting)	None	None	**Recurrent costs for food businesses.** Limited unquantifiable cost increases due to additional information in the label (identification on the label of the purpose of the genetic modification to the label) and related segregation costs.

3. Relevant sustainable development goals

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG no. 2 – End hunger, achieve food security and improved nutrition and promote sustainable agriculture	- The initiative facilitates the application of speedy innovative plant breeding to a wide variety of crops, including regionally important crops, and traits. - It contributes to three of the four components of food security – food availability, stability and utilisation – by providing a framework to address traits contributing to pest resistance, yield, yield stability, pesticide and fertiliser use and resistance to abiotic factors (e.g. drought, temperature). - NGTs could be relevant in low- and middle income countries, which would benefit from adapting traditional, local crop species so that they can withstand changing conditions. An enabling framework in the EU could also support use in those countries.	Examples are cisgenic potato and cisgenic apple as well as a virus-resistant maize presented in Annex 7.
SDG no. 3 - Good Health and Well-being	- The initiative facilitates the breeding of diverse nutritious and healthy foods. Health benefits for consumers could result from increased beneficial bioactive compounds in food.	One example is the low-gluten wheat presented in Annex 7.
SDG no. 9 - Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	- The initiatives promotes research in plant breeding, strengthens the research capacity in plant biotechnology and facilitates the development of innovative products - The NGT R&D pipeline contains plants with traits supporting sustainable farming practices and with novel functional traits with health benefits for consumers	One example is the root chicory presented in Annex 7.

SDG no 12 - Responsible consumption and production.	- NGTs can contribute to the sustainable management and efficient use of natural resources by addressing traits improving, for example, nutrient and water use efficiency.	One example is a modified maize that is more resistant to climate stress, for which the field trials are on-going in the EU[4].
SDG no. 13 - Take urgent action to combat climate change and its impacts	- NGTs can contribute to resilience adaptive capacity to climate-change related impacts by supporting sustainable farming practices (no tilling), the development of biofuel crops not requiring land use change and land saving.	Cover cress (*Thlaspi arvense*) is an example of a cover crop (thereby not requiring land use change) helping to restore soil fertility and which can also be used to produce biofuels

4 https://webgate.ec.europa.eu/fip/GMO_Registers/GMO_Summary.php?NotificationNum=B/BE/22/V3&Cat=gmp

ANNEX 4: ANALYTICAL METHODS

1. JRC CASE STUDIES

Objectives

The JRC conducted three case studies for the purposes of this impact assessment[1]:

- Economic and environmental impacts of disease resistant apples and potatoes developed with cisgenesis
- Socio-economic impact of low-gluten celiac-safe wheat developed by gene editing
- Biotic resistance in the context of smallholder farming in East Africa: a case on gene editing of maize to safeguard food security under the spread of the Maize Lethal Necrosis

Selection criteria for the JRC case studies

Different criteria were used to select the three JRC case studies included in this staff working document: economic importance of the crop, objective of the Green Deal to which it contributes, and type of technology used for its development. In addition, the product development stage and the information on the traits of the selected case studies had to be publicly available.

The first criterion was the socioeconomic importance of the crop at European and global level, as well as any potential contribution of the product developed to the European Green Deal objectives and the Farm to Fork and the Biodiversity Strategies. The fungal-resistant potato and apple case was selected because these crops are important for the European agricultural sector and cuisine. Both crops are currently intensively managed through pesticides, and the respective pathogens demand the majority of the pesticide treatments in those crops. The case of low-gluten, celiac-safe wheat was chosen because wheat is a fundamental crop for human consumption, and it is highly appreciated for its gluten which enables dough production for baking. However, in turn, gluten is the cause triggering gluten-related disorders in genetically predisposed individuals worldwide. Lastly, the virus-resistant maize was selected as case study because maize is a major staple crop that significantly contributes to the sustenance of millions in East Africa where the control of the MLN disease is challenging due to economic constraints.

A second criterion corresponded to the technology used. The three case studies use techniques that are under consideration in this policy initiative and were selected to include products both of cisgenesis and of targeted mutagenesis. In the case of the fungal-resistant potato and apple, both crops are notoriously challenging to breed using conventional approaches. In the case of low-gluten, celiac-safe wheat, it is extremely difficult to apply conventional breeding techniques to obtain comparable wheat varieties. Conventional breeding approaches to achieve MLN virus-resistant maize plants are estimated to take longer time and higher resources than the gene editing ones.

The last criterion was the product development stage and the availability of public information on the product. Several products in the development pipeline were just in

[1] See Annex 7 for details

proof-of-concept stage, or data were unavailable due to confidentiality provisions. In the case of fungal-resistant potato and apple, the developments are beyond a proof-of-concept with field-trials supporting the evidence collection, and the cisgenic varieties have been developed by European institutes. Low-gluten, celiac-safe wheat lines have already been cultivated in greenhouses, and the varieties have been developed by two main research centres in the EU with published scientific evidence. Virus-resistant maize plants are currently being tested in greenhouse trials, and the varieties have been developed by an international research organization in collaboration with an agricultural research company.

Approach

Economic and environmental impacts of disease resistant crops developed with cisgenesis

To compute potential hectare-level cost savings from the cultivation of the cisgenic varieties, a stochastic partial budgeting model was used to simulate changes in expenses for plant protection products. The model assumes that output and other costs remain unchanged, which is supported by the field-trial data. Country-specific, hectare-level, economic data for the years 2014 to 2017 was obtained from the IFM-CAP model and used to characterize costs and outputs of typical arable crop (fruit) farms with a revenue share of more than 60 % from potatoes (apples). The model assumes that the share of fungicides on total pesticide use equals the cost share of fungicides on expenses for plant protection products. Notably, this approximation is unable to account for potential price differences between fungicides, insecticides, and herbicides.

To aggregate the simulated hectare-level savings to a country-level across different scenarios for the adoption rate, the median parameter values for the partial budgeting model were used and aggregated the hectare-level results to the Member States' area of production multiplied by a given adoption rate.

To simulate potential sector-wide implications, the Common Agricultural Policy Regionalised Impact analysis (CAPRI) model was used to shock the cost curve under two adoption scenarios. For our discussion on the potential contribution to the national HRI reduction, we used estimates of the employed quantities of active substances in German potatoes and apples published by the Julius Kühn Institute. Through cross-referencing the database on the HRI-categorization, JRC derived that majority of the currently used active substances are in groups two and higher.

To simulated potential changes in greenhouse gas emissions related to agricultural activities under the adoption scenarios for the cisgenic potato variety, the CAPRI model was used to calculate N_2O-emissions and CO_2-equivalents due to land-use change under the two adoption scenarios.

To calculate country-specific distributions of minimum distances between fields and freshwater systems, spatial data from Copernicus and D'Andrimont *et al*. were used to calculate the Euclidean distances between land-use pixels and different types of freshwaters. To calculate changes in fungicide risk in Lower Saxony, the SYNOPS model was used in conjunction with the field trial fungicide spraying schedules, land-use, soil, and weather data. In SYNOPS, risk indices are expressed as the Exposure Toxicity Ratio, calculated as the ratio of the Predicted Environmental Concentration to the toxicity endpoints half maximum effect concentration, lethal concentration, lethal rate, lethal dose, and no-effect concentration for specific reference species.

Socio-economic impact of low-gluten celiac-safe wheat developed by gene editing

For the impact analysis, it is assumed that the gene-edited low-gluten, celiac-safe wheat has passed the mandatory regulatory risk assessment and is accepted for EU cultivation and market. It is assumed that low-gluten, celiac-safe wheat will be a niche product, likely bought by CD, NCWS and other patients and consumers willing to reduce gluten consumption. Given the lack of observable data since the product is not yet available on the market or cultivated in the EU, a literature review on similarities and differences with standard wheat and with other similar specific products (e.g. gluten-free products) already existing on the market was carried out. Data collected to be used in the impact analysis mainly come from scientific articles published in peer-reviewed journals listed in the Web of Science™, PhD theses and reports produced by different celiac and consumer associations. Data from the European Commission database on agricultural production and trade and the EU FADN (farm accountancy data network) were used for the economic analysis.

To assess the social and health impacts different parameters were calculated including i) a price comparison between the cost of the current gluten free diet and the current financial support to cover it, the standard diet cost, and the diet with low-gluten celiac-safe wheat cost; ii) the potential benefits of low-gluten, celiac-safe wheat from a nutritional perspective qualitatively measured; and iii) the estimation of costs for the healthcare system post-diagnosis for celiac disease patients consuming low-gluten, celiac-safe wheat and, the reduction of related work productivity loss. To assess the economic impacts, an analysis of whether potential cost fluctuations could be expected for the agricultural production of low-gluten, celiac-safe wheat in terms of crop yield changes, changes to the use of fertilisers and plant-protection products and changes to management practices was carried out. The potential impact of the adoption of the low-gluten, celiac-safe wheat on gross margins in the EU was calculated by comparing with a standard farm budget for standard wheat. Lastly, the impact of low-gluten, celiac-safe wheat adoption for the EU agri-food system was measured as i) potential benefits for the wheat value chain, and ii) changes on exports and imports depending on three levels of adoption considering the prevalence of gluten-related pathologies.

Biotic resistance in the context of smallholder farming in East Africa: a case on gene editing of maize to safeguard food security under the spread of the Maize Lethal Necrosis

For this case study, no original research was carried out. In this case, the JRC team reached out to the developers at CIMMYT obtain permission to summarize existing research undertaken at this institution both in terms of technology for development, comparison with conventional breeding and economic impacts based on modelling. The original sources are referenced in the case study.

Use

Insights from the case studies were integrated both in the contractor's study report and in the section 6 of the Staff Working Document, mainly supporting individual impact areas.

2. DOCUMENT REVIEW

Objective

Desk research was carried out to identify relevant reports, opinions, scientific and grey literature to provide further evidence for the problem analysis, to identify experts for interviews, focus groups, and surveys, and identify data to support potential quantitative gaps.

Approach

The document review followed a targeted search on documents related to impacts and main stakeholder categories. This resulted in a qualitative scanning exercise of 172 documents. A qualitative assessment of the content yielded 31 to 71 documents per impact category. The documents were processed in the Atlas.ti and coded. The relevant information per impact was then extracted to serve as information per impact area.

Use

The analysis of the documents helped in the design of interviews and consultations, to substantiate the various statements put forward in the survey and the identified impact areas and to analyse impacts. Furthermore, it was used to substantiate the findings through triangulation.

3. DESCRIPTION OF REGULATORY SITUATION IN OTHER JURISDICTIONS

Objective

The global regulatory situation may impact several aspects considered in the impact assessment, including trade, enforcement, availability of products, competitiveness. The objective was to identify countries that have recently adapted the regulatory oversight to genome edited products or have announced that they are considering it. In addition, examples were sought also on countries that have decided not to do adaptations.

Approach

For the description of the regulatory situation of NGTs in third countries, the Commission relied on available information from scientific publications, official websites, legislation (referenced in section 1.4.). The description covers the US, Japan, Argentina, India, the UK, China, Kenya, Nigeria, Switzerland, Canada, New Zealand and South Africa.

Use

The analysis of the documents was used to summarise the approach to regulatory oversight on genome editing in third countries and to assess impacts linked to regulatory developments outside the EU (in particular as regards trade and competitiveness).

4. STAKEHOLDER CONSULTATION STRATEGY

Objective

In line with Tool #53 of the Better Regulation Toolbox, the consultation strategy[2] was designed to gather evidence and views from the public and from a broad range of stakeholders across all levels of the agri-food chain, and beyond, who are impacted by or interested in the products under the scope of this initiative, and to reach a high degree of complementarity among the various consultation actions: Inception impact assessment, public consultation, targeted survey, targeted interviews, focus groups. More particularly, the consultation activities were designed to allow all interested parties to provide relevant information on the problems presented, the baseline scenario, and on the potential ways forward; to assist the Commission in understanding the implications of the possible policy options for the different stakeholders involved; to enable identifying additional policy elements and ensure that no impacts are overlooked.

The consultation activities also built on and took into account the information received during the comprehensive targeted consultation with Member State competent authorities and EU-level stakeholder associations carried out in the context of the Commission NGT study.

See detailed analysis of stakeholders' contributions in Annex 2 – Synopsis report.

Approach

Following the consultation objectives, a broad range of stakeholders were identified in the consultation strategy. This included operators active, from farm to fork, in the agri-food and feed system (including farmers, seed and plant breeders, traders, processors, manufacturers, retailers and food services, GM-free and organic operators), operators of plant and bio-based industries active in sectors other than the agri-food sector, academic and research stakeholders, civil society/non-governmental organisations, public authorities at EU and national level in the EU and third country public authorities. They represent stakeholder categories directly relevant, i.e. stakeholders affected by the legislation on GMOs, and stakeholders involved in the implementation or with a stated interest in the policy.

Stakeholders invited to participate in targeted consultation activities were identified by the external contractor, based on the objectives and stakeholder categories of the consultation strategy, and with the aim of ensuring representation of all stakeholder categories. Concerning the mapping of economic operators, country coverage and size of enterprises were two important aspects, which does not mean that all EU Member States would be equally represented but rather that economic characteristics would be taken into account. In order to capture the large spectrum of economic operators, EU-level associations were identified.

At national level, public authorities in charge of the implementation of the GMO legislation and enforcement of the Directive and market surveillance authorities were addressed in the consultation.

The mapping of the stakeholders was based on:

[2] https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_consultation-strategy-ngts.pdf

- desk research (see section 2)
- the contributions of the Member States and EU-level associations to the targeted consultation in the context of the 2021 Commission NGT study
- the analysis of the respondents of the inception impact assessment
- expert contributions
- the use of Crunchbase (for companies) and
- Scopus, for the identification of academic experts

An internal database of stakeholders was developed to include

- Research organisations
- Non-governmental organisations
- Competent authorities
- Private-sector organisations
- Stakeholder organisations (associations)
- Individual experts
- Other

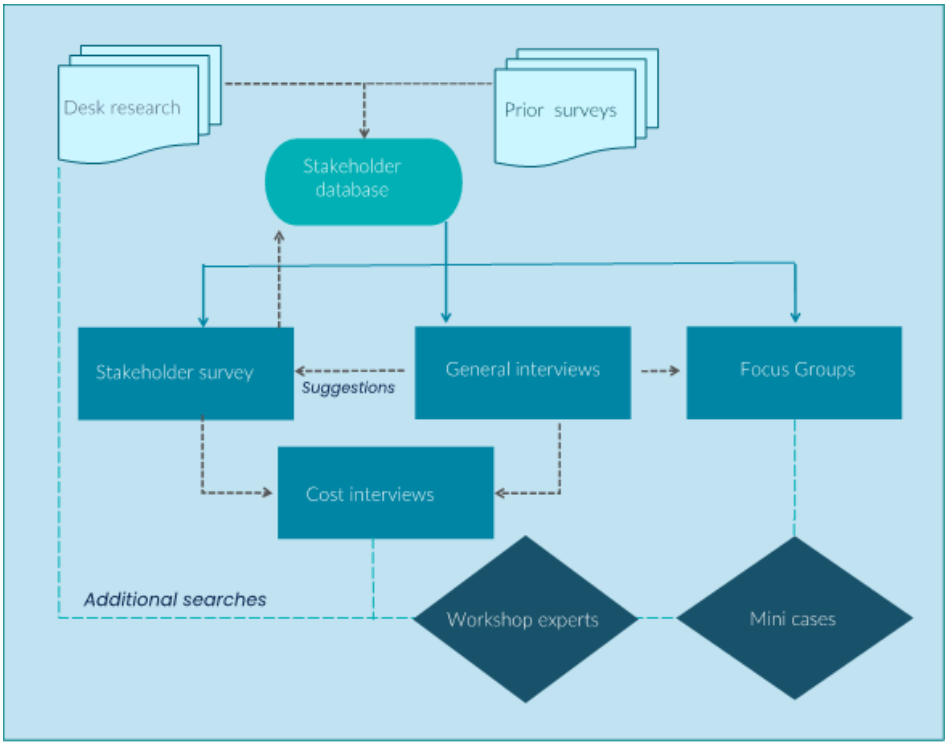
For national authorities, the national competent authorities for the purposes of GMO legislation were contacted.

The database structured the collected information into name, email, organisation, country, type of organisation and stakeholder type. It contained more than 650 individuals from around 570 organisations. In addition, about 1.100 researchers were identified through Scopus. This list served as a wide reserve in case of a need of academic experts.

Use

The stakeholder database was used as the basis for the selection of the targeted survey respondents and of the interview partners. Interviewees were asked to suggest individual organisations which could be invited to the stakeholder survey. The interviewed stakeholders were equally invited to the stakeholder survey. Cost interview partners were either addressed following the general interviews or based on further dedicated desk research. In view of workshops, case studies and focus groups, additional desk research was conducted to identify relevant experts. The focus groups benefited also from organisations which had been interviewed in the first phase.

Figure 1 Flow diagram of use of stakeholder in consultation



Source: Technopolis Group

5. INTERVIEWS

Objectives

An interview programme was set up by the external contractor. It involved a selection of the main stakeholder groups (economic operators, research, and non-governmental organisations, as well as authorities at EU and national levels). The 60 interviews were divided into three groups:

1. General interviews with key stakeholders.
2. Interviews focused on regulatory cost assessment (see section 4).
3. Interviews for the case studies (see section 8).

The objective of the interviews with (1) key stakeholders was to tap into the knowledge of the main stakeholder types regarding possible effects and impacts of the policy components. The second (2) group of interviews focused on current and potential regulatory and administrative costs. (3) For the case studies, technical experts were targeted. In case of third countries, relevant associations with the relevant geographic knowledge were approached.

Approach

General interviews

Through the desk research, document analysis, and exchange with the Commission as well as the project's internal experts, the external contractor identified relevant organisations and potential individual interviewees. They were selected based on their (1) expertise/knowledge and (2) strategic positioning in the debates on agricultural biotechnology, and with the aim of ensuring representation of the main stakeholder

categories. In addition, the economic operators were selected on the basis of their potential to act as 'multipliers' for the dissemination of the targeted survey.

General interview guideline

Box 1 provides the guideline for the general interviews used by the external contractor.

Box 1. Interview guideline for the stakeholder interviews

The objective of the stakeholder interviews is to collect expert opinions and data in order to map potential effects and impacts of the different components of the policy scenarios. We aim to tap into the knowledge of the federations and its members through these interviews. The objective of the stakeholder interviews differs from the open consultation survey. In the survey, each stakeholder has the opportunity to provide their position towards the possible components of the policy scenarios and the current GMO/NGT policy.
With the interviews, we would appreciate a neutral and open conversation regarding possible effects and impacts in the value chain and wider economy and society.
The interview will follow a semi-structured guide and is based on the Theory of Change developed during the inception phase of the study. Policy options reflect the public open consultation conducted by the Commission.
Responses are recorded in an interview report and kept anonymous unless indicated otherwise by the interviewee.

I Introduction

1. Introduction of interviewee
2. Introduction of the EU-level federation / association and its sectors and main activities
3. Relevance of NGTs for federation members
    a. (Expected) development and use of NGTs in respective section of the value chain
    b. General assessment of current obstacles and enablers of development and use of NGTs in respective section of the value chain

II Risk assessment and detection requirements

<u>Explain:</u> policy scenario components, implementation effects, value chain and wider impacts
Risk assessment and detection requirements: explanation of main elements
0: Unchanged policy and regulation
A1: Authorisation with risk assessment adapted to risk profile and adapted detection method requirements
Risk assessment proportionate to the NGT product's risk profile. Detection method required, but differentiation of NGT product from conventional product not required if not possible
A2: Pre-notification of products that are also obtainable naturally or by conventional breeding with decision on regulatory status
Risk assessment not needed if NGT product can also be obtained naturally or by conventional breeding. Detection not needed if NGT product can also be obtained naturally or by conventional breeding

<u>Topics to be discussed; probe with developed indicators in area of expertise:</u>

4. How do you expect regulatory product approval costs for applicants to change under option A1 and option A2?
5. To what degree do you expect the policy options to impact the attractiveness of introducing new plant varieties on to the market by plant breeders?
6. How will these options impact the availability and attractiveness of using new plant varieties by farmers?
7. In terms of safety of gene-edited/cisgenic crops and derived products, do you expect changes in safety under option A1 and A2?
8. Could you assess impacts of the policy options on the wider value chain, including

productivity, turnover and value added of economic operators (plant breeders, farmers, processors, etc.)?

9. Could you assess the impacts of changed risk assessment and detection requirements on:
   - EU competitiveness and trade?
   - Innovation and research?
   - SME competitiveness?

III Labelling and Traceability Requirements
Explain policy scenario components, implementation effects, value chain and wider impacts
0: Unchanged policy and regulation
B1: Additional sustainability label and traceability
Labelling as today, coupled with additional label for sustainability claims, referring to the sustainability contribution of the introduced trait. Traceability as today, coupled with additional traceability to ensure information on the sustainability contribution.
B2: No labelling if sustainable, with traceability and transparency requirements
No specific labelling needed, but inclusion in public registry, if NGT product contributes to sustainability. Traceability as today, coupled with additional traceability to ensure information on the sustainability contribution
B3: No labelling and specific traceability requirements if a product obtainable naturally or by conventional breeding. Transparency requirements
Labelling not needed if NGT product can also be obtained naturally or by conventional breeding, but inclusion in public registry. Traceability not needed if NGT product can also be obtained naturally or by conventional breeding

10. Could you assess the most significant impacts of the policy options in terms of
    - Labelling and traceability costs in the value chain?
    - Labelling and traceability quality in the value chain?
11. Could you assess the effect of the policy options on the enforcement quality and transparency?
12. Could you assess the impacts of the policy options on consumer trust and information rights?

IV Sustainability
Explain policy scenario components, implementation effects, value chain and wider impacts
0: Unchanged policy and regulation
C1: Sustainability incentives for authorisation
Positive regulatory incentives for authorisation: NGT plant products with traits that contribute to sustainability objectives receive regulatory positive incentives for authorisation, e.g. regulatory and scientific advice before and during the approval procedure, measures to facilitate the approval process (waiving of fees, faster procedures), allowing sustainability-related claims to appear on the final product.
C2: Sustainability requirement: no authorisation if detrimental to sustainability
NGT Plant products with traits that are detrimental to sustainability objectives are not authorised

13. Do you expect an increase in NGT plant products with traits that contribute to sustainability objectives in case of regulatory positive incentives for authorisation?
14. Could you assess potential environmental impacts under C1/C2 on:
    - Biodiversity
    - Pesticide use
    - Fertilizer use
    - Use of natural resources

V Collaboration in study

15. Do you have data on costs and benefits (qualitative and quantitative information) relevant to the impact assessment and would you be willing to share this

information?

Cost interviews

For the cost assessment interviews, 23 different organisations were approached (SMEs, large companies, public authorities, regulatory authorities, etc.). They were identified through the initial stakeholder mapping exercise. Following an initial list of suggested organisations and authorities, a first group of potential organisations were contacted. In the course of the study, more organisations were approached. The focus here was not on coverage of all stakeholder groups, but those involved in the regulatory approval process.

Consecutive discussion rounds with public and private entities have been conducted, where the purpose of the exercise was explained. During the discussions, several public and private entities dropped out from being prospective data providers. Some considered that the required level of detail of data was not feasible to provide. This was either due to time constraints or due to a mismatch of available company cost categories and the level of breakdowns required.

Overall, a caveat for the cost data was the limited to no experience with GMO applications in Europe at industry level, the large ranges within estimated cost categories and difficulties in triangulating rather patchy data with equally patchy evidence from literature and insights from experts.

Case study interviews

It has been extremely challenging to attract interview partners for the case studies, in particular those that dealt with third countries. Most cases identified relevant organisations during the concept-note phase, yet several did not respond when contacted, even after repeated reminders.

Use

The insights from the general interviews helped greatly to understand the expectations and concerns of various stakeholders and identify relevant impact areas. Together with insights from document analysis, interviews were also used to formulate several survey questions. Interviewees were asked to suggest relevant additional individual stakeholders (mainly breeders and retailers) which were added to the survey.

The cost interviews and the data gathered (calculations made and qualitative explanations) provided were the basis for the efficiency sections of the final report.

6. TARGETED STAKEHOLDER SURVEY

Objective

The goals of the targeted survey were primarily

- to collect the informed views and information from stakeholders on the performance of the current baseline scenario as a benchmark to support the assessment of efficiency
- to collect the views, information and assessments on the various impacts of the policy components
- to test the key elements of policy options on the impact indicators

- to collect information on costs or other pertinent data, e.g., on impacts of the elements of the policy options and the baseline (current situation).

The survey was envisaged as a targeted survey to complement the (partly in parallel running) public consultation (PC). Whereas the PC addressed a wider audience and therefore did not ask for detailed technical assessments, the targeted survey envisaged detailed information.

Approach

The selection of stakeholder groups to be targeted by the survey followed a further characterisation of the stakeholders collected in the contractors' database: all selected stakeholders either:

- had participated in the targeted survey carried out by the Commission in 2020 in the context of the Commission 2021 NGT study;
- had participated in the consultation carried out in the context of the inception impact assessment; or
- were suggested by interview partners - this served the purpose to address in particular SMEs - such as breeding companies - or retailers.

The majority of the invited participants could not easily be classified with one characteristic such as "public authority", "research organisation', "company", 'business/industry association", or "non-governmental organisation" (NGO) – but they combined two or more functions/roles. For example, a company could be in breeding, but also be a manufacturer, or selling. Therefore, the classification of the identified stakeholders focused on obtaining a reasonable allocation and leaving it up to the survey respondents to self-classify in the range of stakeholder types. Table 1 provides an overview of the invited stakeholders. The vast majority of stakeholders are set in Europe with a clear geographic focus of associations based in Belgium.

The following figures provide information about the invited respondents, using a classification according to the contractor's study team.

- Almost 400 public and private stakeholders (e.g., associations, authorities, networks, companies) were targeted to provide their insights and contribute via the survey.
- At EU-level, 101 organisations were invited, the majority (68) being associations representing different sectors of economic operators. A similar number of national industry associations were also targeted (63). These tend to be (conventional or organic) seeds, farmers, breeders, or biotechnology associations.
- Private sector organisations – large as well as small and medium-sized companies were altogether the second largest group. The latter group of SMEs brings together the range of actors of the value chain from breeders to processors to retailers. The third largest – and most heterogeneous group – is the one of non-profit organisations. As indicated above, this includes a range of type of organisations, including networks (e.g., (organic) seed networks, agroecological or researchers' networks), and a broad variety of interest groups (e.g., opposing GMO or not, consumer and environmental advocacy groups, etc.).
- Public sector organisations were distinguished from public authorities/ministries. These are often independent or sub-ordinate executive entities but have no political function like ministries.

- The delineation between research organisation and advisory body is somewhat artificial. As indicated, some research organisations (public research institutes or university entities) are equally officially advisory or competent entities for a public authority.

Table 1 Overview of invited survey participants

Type of stakeholder	EU	national	World	Total
Business/industry association	68	63	6	137
Private-sector organisation	5	66	31	102
Non-profit organisation	19	60	14	93
Political entity	2			2
Public sector organisation	2	2		4
National authority/Ministry		27	1	28
Research organisation	4	11	2	17
Advisory body	1	2		3
Other		9	2	11
Grand Total	101	218	52	397

The contractor's study team sent out personal invitations to 369 identified stakeholders through Limesurvey. The Commission forwarded individual survey links to the EU Member States and EEA countries (in total 28). Those were invited to consolidate responses per country.

The survey was translated from English and available also in Dutch, French, German, Italian, Polish, and Spanish.

It was sent to stakeholders and Member State representatives on 28 July 2022 and was planned to remain open for the stakeholders until 10 August and for Member States until 24 August 2022. Given technical problems and the vacation period hampering the availability of experts to be consulted, the survey closed on 5 September 2022.

The study team received mails from individual stakeholders who informed that they could not respond due to time constraints, due to no immediate relevance, or because they found the survey's scenario approach problematic.

Some Member States voiced that they had difficulties in filling in the survey without being able to include explanations; in some cases, they have also submitted an additional document. Out of the Member States, which did not fill in the survey, one submitted available relevant information in a dedicated document.

The survey was designed with a complex filtering: all respondents obtained the same survey but, depending on their self-classification, only specific questions appeared. None of the questions was mandatory to be filled in. This implies that for the analysis of the questions, the number of responses varies. Therefore, in the analysis the number of responses were provided per question. In questions where responses were not provided for all categories, the minimum number was indicated.

Of the 397 invitations that were sent out, 143 opened the survey and included some information on the respondent but did not proceed further. These entries were deleted and not taken into account. Two withdrawals were removed, so that in the end the analysis was based on 123 responses.

Use

The results of the stakeholder survey fed the impact assessment (main study report) by impact area, indicator, and across the various scenarios.

7. PUBLIC CONSULTATION (PC)

Objectives

Following the Inception impact assessment, the PC was carried out by the Commission (publication on 'Have Your Say' portal) and enquired about the current situation and tested the general key components of the potential options.

Approach

In line with the Better Regulation Toolbox, a number of small campaigns have been identified and analysed separately.

The PC replies were analysed by the external contractor with descriptive statistics for the closed questions by stakeholder group and provided a mixed qualitative/quantitative approach for the open questions, equally by stakeholder group. A number of position papers, statements and links to additional references and literature were provided by respondents. These were classified, analysed and summarised.

Use

A PC as such is not a representative survey and therefore, the results need to be taken as what they are: a snapshot of views and opinions of individual people and organisations with a strong interest in the subject matter (self-selection bias). The results from the PC fed into the main study. They complemented the targeted survey, in particular through contributions from the research communities and individual citizens. Given the limited number of questions and their broad level, the PC results fed mainly environmental impact areas and less so economic or social impacts.

8. FOCUS GROUPS

Objectives

Two focus groups, one on 'Sustainability' and the other on 'Traceability' were conducted by the external contractor. They were intended to complement the information obtained in interviews and the targeted survey. The focus groups aimed at providing specific feedback and expertise on the topics of:

- **Traceability and enforcement systems in the agri-food chain** (including tools, registries and procedures used when analytical methods are not available or not reliable);
- **Approaches to sustainability analysis in food and agriculture related areas** (including approaches to assess potential positive or negative contributions to sustainability, and regulatory mechanisms to promote sustainability).

Approach

A concept note was developed for each of the focus groups. This included a few high-level questions which were developed based on results of the targeted stakeholder survey as well as insights from the interviews.

Relevant potential focus group participants were contacted and invited.

The focus groups' planning started following the analysis of the targeted stakeholder survey. In terms of development of key questions, the groups could address, results from the PC and the targeted survey were used.

Following prior agreement of the participants, the two focus group meetings were recorded. The recordings were used to inform the summary reports. These were sent for validation to the members. Suggested amendments were integrated in the reports.

Selection/invitation process

A list of potential participants has been identified on the basis of the stakeholder database and dedicated desk research. The following selection criteria have been used:

- Balance among geographic expertise (different Member State perspectives);
- Balance among different crop/value chains expertise;
- Balance among different technical sub-fields expertise.

The list included experts from Member State ministries or authorities, relevant stakeholders, including operators and academia.

Use

The insights from the focus groups fed into the main report, predominantly in the relevant impact sections. Arguments raised in the focus group (such as the needed system's approach in the sustainability group or the need for transparency in the traceability group) were included in the analysis.

9. COMPLEMENTARY ANALYSIS

Objectives

Complementary analysis was carried out for specific impacts for which more detailed information was lacking.

Approach

Three types of cases were envisaged:

- A comparative case (geography), looking at third countries where comparable regulatory changes have already led to economic, environmental, and societal impacts *(Regulatory developments for novel genomic techniques: a case study of Argentina)*
- Comparative cases (domain/sector), looking at other sectors and regulatory areas where similar challenges/problems are present.
- Deepening cases, where we develop impacts for specific product/application areas to arrive at more concrete (e.g., quantitative) estimates relating to the policy options. *(Value chain dynamics: the case of potatoes in the Netherlands; Root chicory).*

The analysis was developed by the external contractor based on desk research and document review. A short concept note was developed and discussed with one or two of the technical experts within the team in order to discuss the focus of the case. Ideas on

potential interview partners and/or further literature were exchanged and in case of identified interviewees, they were contacted and in case of agreement, interviewed eventually.

Use

The insights were integrated in the contractor's final study report, mainly supporting individual impact areas.

10. EFFICIENCY /COST BENEFIT ANALYSIS

Objectives

Identification and measurement of current and potential regulatory costs.

Approach

In the absence of NGTs on the market (commercially, neither in Europe nor in the rest of the world), there is no quantitative data available that allows us to measure directly regulatory costs. Therefore, an approach was designed that mixes qualitative and quantitative information and draws from experience with GMO authorisation. Since also GMO products are not available on the European market, the contractor aimed to address all stakeholders that have or had relevant experience.

The activities with regulatory cost implications during the lifecycle of a GM crop include the submissions for field trialing, cultivation, for the authorisation of the use of food and feed, and the importation into the territory of the European Union.

Identification of stakeholders

Stakeholders covered in the cost assessment: biotech industry/ plant breeders, national public authorities, European institutions/bodies; processors, food industry, retail, organic and GMO-free farmers, consumers. For the plant breeders/ plant biotech industry and national public authorities, costs were monetised while for organic and non-GM farmers, processors, the food industry, and retail, costs are described qualitatively.

The typology of costs follows the Better Regulation Guidelines, Tool #56. A distinction is made between monetised costs and those cost categories that remain with a qualitative description.

Table 2 Mapping of costs (monetised/described)(1)

Cost typology		Biotech/ Plant Breeders	Nat'l Public Authorities	EC & Agencies	Organic and GMO -free farmers	Processors	Retail
DIRECT Compliance	Administrative costs						
	Adjustments costs – capital expenditures						
	Adjustments costs – operation and maintenance costs						
	Hassle costs						

ENFORCEMENT costs	Monitoring; Inspection; Adjudication/Litigation	
INDIRECT costs	Indirect compliance costs	
	Transaction costs	
	Offsetting/substitution costs	
	Opportunity costs (e.g. alternative solutions are neglected	
	Market Access	
	Reduced innovation or investment (research, field trials relocated outside the EU)	
	Other indirect costs – Competition	

Note (1): monetised described

Cost assessment - process

The process is broken down to phases for which costs are estimated (see Better Regulation Guidelines, tool #56) as indicated below. The process was used for the BAU and the policy options where applicable and possible.

Table 3 Cost assessment – Phases

Steps	Description
Phase I: Preparatory analysis	
1	Identification and classification of information obligations
2	Identification of required actions
3	Classification by regulatory origin
4	Identification of relevant cost parameters Qualitative assessment of significant burdens
5	Identification of target group(s)
6	Choice of data sources
Phase II: Data capture and standardisation	
7	Assessment of the number of entities concerned
8	Assessment of the performance of a 'normally efficient entity' in each target group, taking into account cost parameters identified in step 5
Phase III: Calculation and reporting	
9	Extrapolation of validated data to EU level
10	Final reporting and transfer to the database

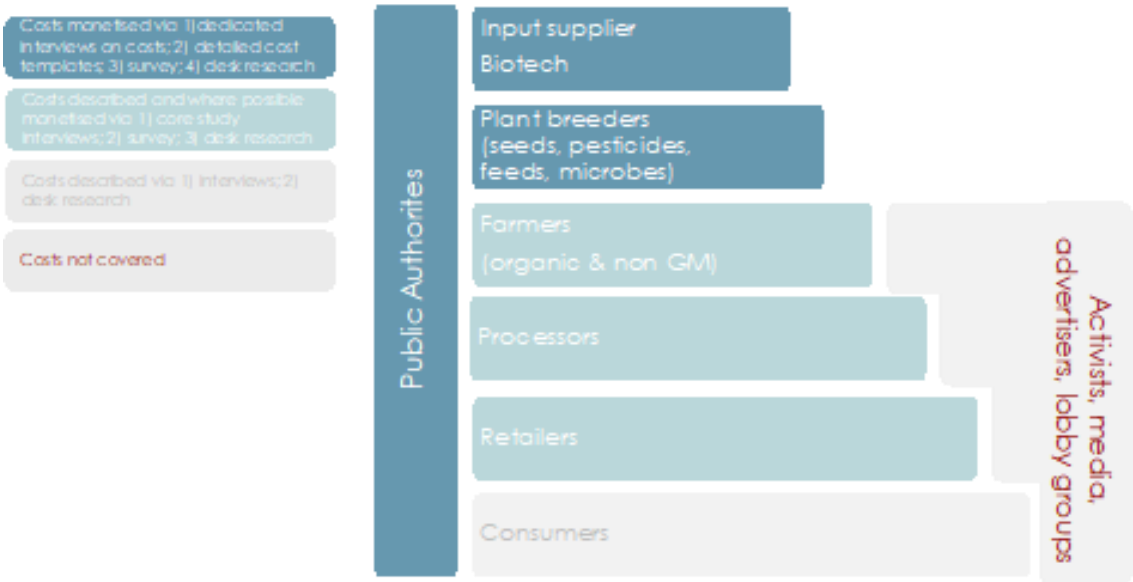
Cost assessment – consultation strategy

Four stakeholder categories were distinguished:

1) Biotech industry and plant breeders: Costs were estimated using inputs from dedicated interviews (based on detailed cost templates), the targeted stakeholder survey and desk research.
2) Farmers (GMO free and organic), Processors and Retailers: Costs are described qualitatively using inputs from interviews, the targeted stakeholder survey. They were monetised where possible with the combined inputs of desk research and interviews.
3) Consumers: Costs can only be described qualitatively, based on interviews and desk research.

The three stakeholder groups were asked on costs for BAU and 'components' of the policy options via the targeted stakeholder survey.

Figure 2 Consultation strategy – per stakeholder type



Use

The results from the cost assessment were directly incorporated in the final report in the efficiency analysis of the options.

11. MULTICRITERIA ANALYSIS

Objective

Aggregation and analysis of individual impacts into an assessment for each key policy objective so that policy scenarios and options can be compared more easily and systematically.

Approach

The approach was based on a multicriteria decision analysis (MCDA), while integrating some aspects of the social multi criteria evaluation (SMCE). A formal SMCE requires a

detailed mapping of values and preferences of each main actor type. However, the targeted consultations showed that stakeholders have often very idiosyncratic and specific views regarding the policy options, being in favour of some elements and not others, highlighting or not specific criteria etc., and therefore it was concluded that a formal SMCE is not viable. Instead, it was observed that the objectives of the initiative themselves already provide a clear framework for analysis, as stakeholders were typically aligned around specific objectives. We thus used the MCDA, which does pay attention to different stakeholder categories' views and interests as part of the criteria. It is important to note that the translation to assessment of policy options itself was carried out based on a synthesis of these outcomes (see Chapter 6, main study report). The multicriteria analysis itself was analysed at the level of impact areas (which reflect key stakeholder perspectives and (parts of) potential subobjectives). Further aggregation (at the level of dimension or policy option overall) required weights that involved political choices. Within the impact areas, we therefore assigned equal weighting to each criteria, as a default option in absence of a credible alternative. As a further step, we concluded a sensitivity analysis which is described further below.

The full overview of criteria per impact area is presented in Annex 11 of the contractor's final report[3].

The individual scoring of the individual criteria was carried out at the ordinal level, with a 5-point scale (--, -, 0, +, ++), with the possibility to introduce a range reflecting uncertainty. The scoring directly mirrored the impact assessment as carried out in the main study report (Chapter 4) for each impact criterion.

As such, the output is a table with an individual score for each criterion, and an aggregated score for each impact area, for each policy scenario. We then translated this back to the policy options, each consisting of a combination of one A-scenario, one B-scenario and one C-scenario. In order to add up the aggregated score per impact area for each option, we applied a weighting of 4:2:1 for A:B:C. This weighting was mainly based on the relative importance of factors for determining the uptake of NGTs as indicated by stakeholders in the targeted survey (SQ11) and the targeted interviews. The weights do not reflect any judgement on the importance of related impact areas, but rather on the degree to which these regulatory components are likely to engender change in economic behaviour.

Use

The multicriteria analysis contributed to the comparison of the effectiveness of policy options.

[3] Technopolis Group, Arcadia Int. & Wageningen UR (2023)

ANNEX 5: THE TECHNIQUES

1. INTRODUCTION

The DNA is the genetic material (genome) of organisms that carries the information for the development, functioning, growth and reproduction of all known organisms and many viruses. The information is stored and transmitted to progeny in DNA sequences based on a four-"letter" code. Changes in these sequences are called mutations. These can be substitutions/deletions/insertion of "letters" or of longer DNA sequences. These changes may have no effect or may result in new or altered functions or loss of functions in the organisms. Mutations are ubiquitous and natural phenomena that form the basis of plant breeding providing plant variety and food diversity.

Genomic techniques are techniques that can alter the genetic material of an organism. For the purpose of this document, the term new genomic techniques (NGTs) is used to refer to technologies that have been developed over the past two decades after adoption of the current GMO legislation.

New genomic techniques constitute a diverse group of techniques that can be used in various ways to change the genome of an organism and achieve different results and products. The objectives of the user and the technique determine the type and magnitude of the genome modification, which can range from limited changes, that might also occur in nature or through conventional breeding, to multiple and more extensive modifications.

Among NGTs, **targeted mutagenesis** techniques induce mutation(s) in selected target locations of the genome without insertion of foreign genetic material. **Cisgenesis** or **intragenesis techniques** insert genetic material into a recipient organism from a donor that is sexually compatible (crossable). The exogenous genetic material can be introduced without (cisgenesis) or with modifications/rearrangements (intragenesis).

NGTs can also be used in the same way as older, established techniques of genetic modification, i.e. to insert foreign genetic material into a recipient organism from a donor organism that is sexually incompatible (**transgenesis**), e.g. a gene from an insect into a plant. Transgenesis is however out of the scope of this initiative, which covers only targeted mutagenesis and cisgenesis (including intragenesis).

More details on mutagenesis, cisgenesis/intragenesis and transgenesis, and the different technologies that can be used to affect the respective outcomes, are provided below.

2. MUTAGENESIS TECHNIQUES

In plants, substitutions/deletions/insertion of "letters" of the plant's genome may take place **under natural conditions** or **by human intervention** through different techniques:

a) by **conventional breeding techniques**[1]**:**
   i) combining, by crossing, the genetic material of different organisms that are sexually compatible;

[1] For a detailed description of conventional breeding techniques see SAM explanatory note on new techniques in agricultural biotechnology - https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/new-techniques-agricultural-biotechnology_en

ii) by techniques of **induced random mutagenesis**, i.e. by using chemicals or radiations that increase the frequency of mutations introduced randomly in the genome;

b) by **new genomic techniques** of **induced targeted mutagenesis** (e.g. type 1 and 2 genome editing, see below, oligonucleotide directed mutagenesis[2], base editing, prime editing[3]) that target the mutations to (a) specific region(s) in the genetic material of an organism.

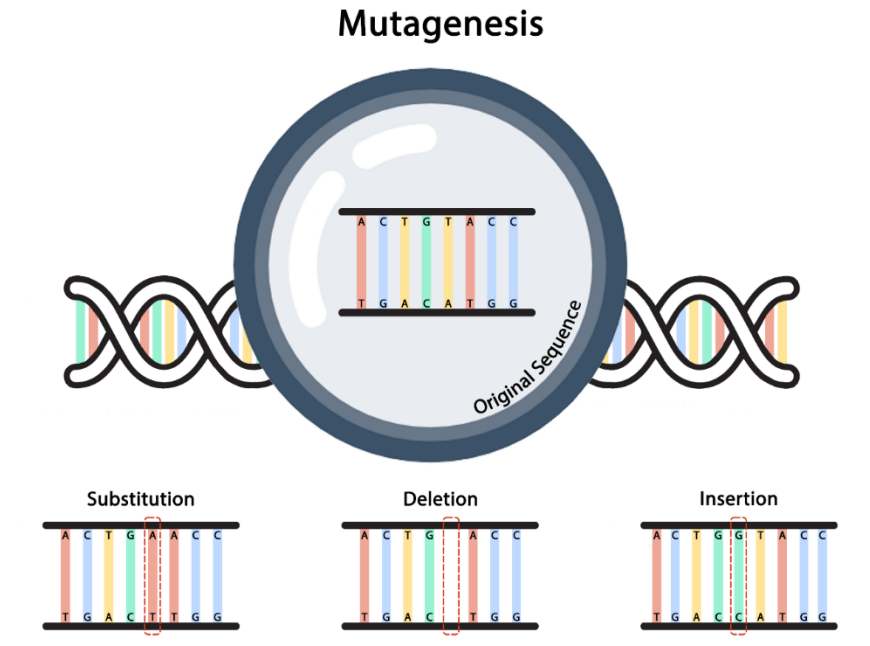


Figure 1: Mutagenesis under natural conditions or by human intervention

3. CISGENESIS AND INTRAGENESIS TECHNIQUES

In addition, modifications of the genetic material of plants may occur through the insertion/translocation of longer DNA sequences from the same species or a crossable species. This may take place **under natural conditions** or **by human intervention** through different techniques:

c) by **conventional breeding techniques**, e.g. combining, by crossing, the genetic material of different organisms that are sexually compatible

d) by **new genomic techniques** of:

i) **cisgenesis**, inserting an exact copy of a DNA sequence derived from the same or a crossable species;

ii) **intragenesis**, inserting a re-arranged copy of a DNA sequence derived from the same or a crossable species.

In conventional breeding, by crossing, the desired trait is introduced, but together with other unintended/undesirable traits from the donor organism. Removal of these unintended/undesirable traits requires several steps of backcrossing (i.e. repeated

[2] Oligonucleotide directed mutagenesis (ODM) is based on the use of oligonucleotides for the induction of targeted mutations in the genome, usually of one or a few adjacent nucleotides.

[3] Base editing and prime editing are other targeted mutagenesis techniques introducing specific genetic changes in a targeted sequence without the use of any template DNA.

crossing with the original plant). This can be a long process taking several years (e.g. 8-10 years for wheat up to 20-25 years for apple[4]).

Cisgenesis and intragenesis techniques are able to introduce the desired trait only, without other unintended/undesirable traits. The introduction of the trait can be done through **random insertion technologies** (which are technologies used for GMOs authorised so far, such as *Agrobacterium-mediated transformation*[5] or biolistic technologies[6]) or **targeted insertion technologies** (type 3 genome editing, see below). The process is generally more precise and efficient (taking from 2 to 8 years[7]) compared to conventional breeding techniques.

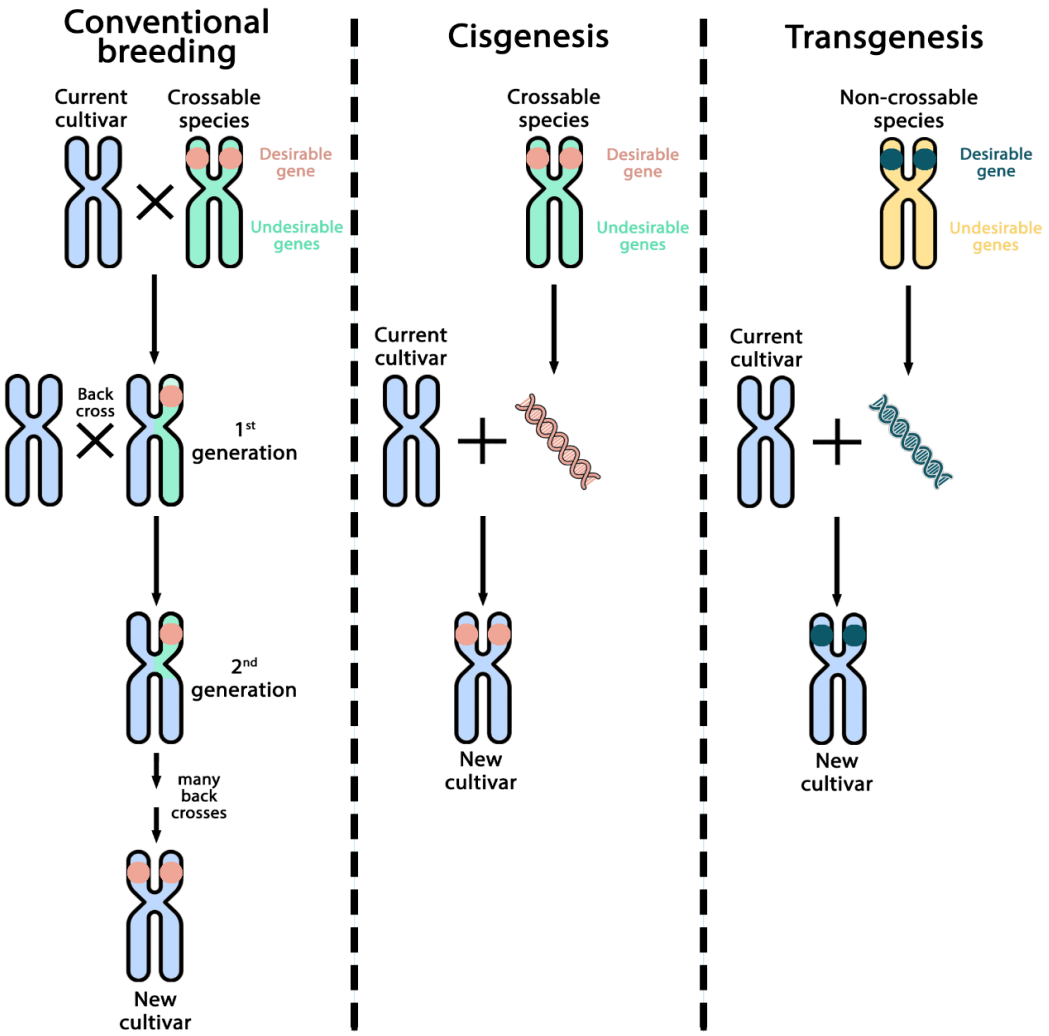
Cisgenesis and intragenesis have been included among NGTs since 2007, regardless of the technology used to produce them (either random or targeted). At that time, a working group of Member States' experts was established by the Commission to evaluate whether certain new techniques result in GMOs subject to the EU GMO legislation. For this evaluation, the competent authorities provided a list of new techniques that included cisgenesis and intragenesis. Cisgenesis and intragenesis were described as new breeding techniques that, while using the same genetic modification technologies as transgenesis, opened new possibilities through the insertion of genetic material from crossable species. A similar description of cisgenesis and intragenesis as new breeding techniques was also provided in the 2011 JRC study "New plant breeding techniques - State-of-the-art and prospects for commercial development"[8] and in the 2017 SAM explanatory note on new techniques in agricultural biotechnology[9].

4. TRANSGENESIS TECHNIQUES

Finally, modifications of the genetic material of plants may also occur through the insertion of foreign genetic material into a recipient organism from a donor organism that is sexually incompatible (non-crossable). This generally may only take place **by human intervention** through **transgenesis techniques**. Also in this case, the introduction of the trait can be done through random insertion technologies or targeted insertion technologies.

[4] JRC case studies.
[5] Technologies using Agrobacterium tumefaciens, a bacterium infecting plants, for its natural ability to transfer DNA to plant cells.
[6] Technologies involving microscopic particles coated with the DNA that is to be inserted into the plant. These particles are then "shot" under high pressure into the plant tissue. The DNA penetrates the cell where it is sometimes spontaneously incorporated into the genome.
[7] JRC case studies.
[8] https://publications.jrc.ec.europa.eu/repository/handle/JRC63971, page 24-25
[9] https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/new-techniques-agricultural-biotechnology_en, page 67-68

Figure 2: Conventional breeding vs Cisgenesis vs Transgenesis



5. GENOME EDITING

Genome editing is an umbrella term covering several technologies that can be used for targeted mutagenesis, cisgenesis, intragenesis and transgenesis. Genome editing includes Site-directed nuclease (SDN) technologies, whose mechanism is based on the use of enzymes (nucleases) that cut the DNA at specific locations (cleavage sites), as well as other technologies such as oligonucleotide directed mutagenesis (ODM), base editing, prime editing, site-directed recombination[10]. These technologies can produce precisely located alterations to DNA sequences, ranging from 'point mutations' (changes of one or a few DNA “letters”, which may be either random or non-random) to the insertion of genes (cisgenes, intragenes, transgenes).

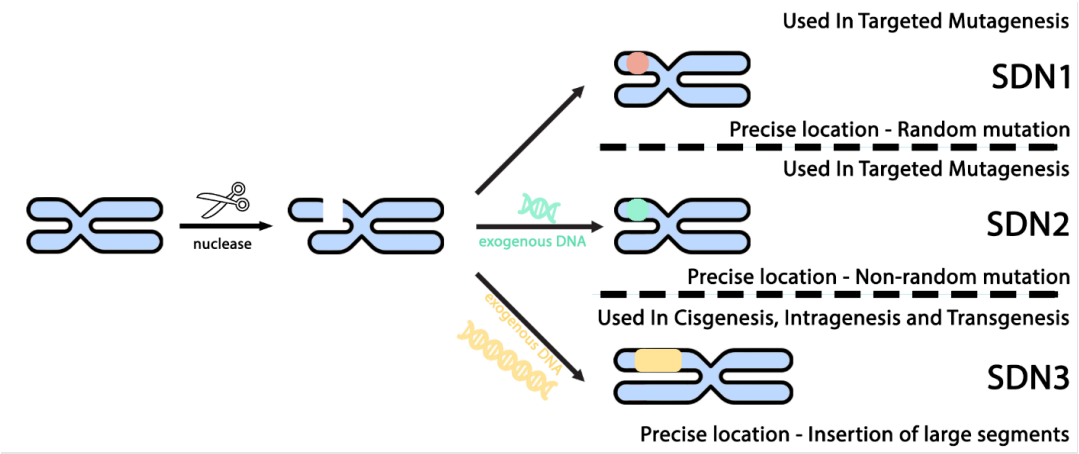
Depending on their application, SDN technologies, which are currently the most widely used genome editing technologies, can be classified in three types of categories:

1) type 1 (SDN-1): introduction of random mutations in precise locations;
2) type 2 (SDN-2): introduction of non-random mutations in precise locations;
3) type 3 (SDN-3): insertion of large segments (such as genes) in precise locations.

[10] Broothaerts *et al*. (2021)

Type 1 and 2 are used for targeted mutagenesis, while type 3 is used for cisgenesis, intragenesis and transgenesis.

Figure 3: Targeted technologies: Genome editing



Genome editing does not exclude 'off-target' modifications, where a change occurs to a DNA sequence identical or similar to that in which the change is desired, but in another location. However, these off-target modifications are fewer than those occurring with most random mutagenesis techniques. Where they do occur, these changes are of the same types as those produced by conventional breeding techniques[11].

6. Overview of the techniques

	Mutagenesis Creation of mutation(s) in an organism without insertion of foreign genetic material	Cisgenesis Insertion of exogenous genetic material, without prior rearrangement, from a crossable organism/species	Intragenesis Insertion of exogenous genetic material, with prior rearrangement, from a crossable organism/species	Transgenesis Insertion of foreign genetic material from a non-crossable organism/species
Random technologies	Irradiation or treatment with chemicals	Random integration via Agrobacterium tumefaciens, gene gun	Random integration via Agrobacterium tumefaciens, gene gun	Random integration via Agrobacterium tumefaciens, gene gun
Targeted technologies	SDN (e.g. CRISPR) type 1 or 2, ODM, base editing, prime editing, etc.	SDN (e.g. CRISPR) type 3 site-directed recombination	SDN (e.g. CRISPR) type 3 site-directed recombination	SDN (e.g. CRISPR) type 3 site-directed recombination

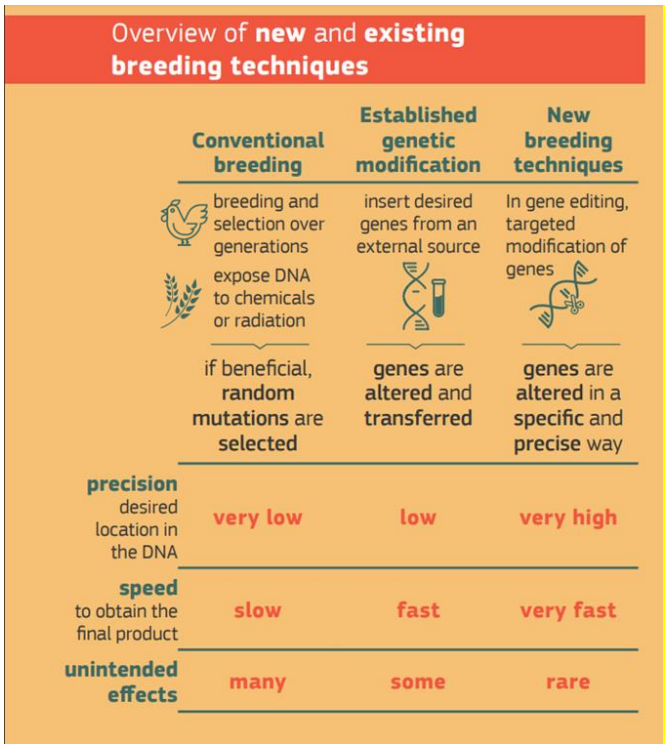
For an extensive description of the techniques, see JRC Technical Report on New genomic techniques: state-of-the-art review[12] and the Explanatory Note on new

[11] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H,Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, MullinsE, NogueF,Sanchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta J, Gennaro A,Paraskevopoulos K, Raffaello T and Rostoks N, 2020. Applicability of the EFSA Opinion on site-directednucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1and 2 and oligonucleotide-directed mutagenesis. *EFSA Journal* 2020;18(11):6299, 14 pp., https://doi.org/10.2903/j.efsa.2020.6299

[12] Broothaerts, W., Jacchia, S., Angers, A., Petrillo, M., Querci, M., Savini, C., Van den Eede, G. and Emons, H., New Genomic Techniques: State-of-the-Art Review, EUR 30430 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-24696-1, doi:10.2760/710056, JRC121847

techniques in agricultural biotechnology by the Commission's Scientific Advice Mechanism High-Level Group (SAM HLG)[13]. The latter provides also a comparison of the various techniques, in particular as regards precision, speed and unintended effects as shown in the figure below (see figure 4 below).

Figure 4: Overview of new and existing breeding techniques (source: SAM HLG)



[13] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, **https://data.europa.eu/doi/10.2777/574498**

ANNEX 6: OPINIONS OF SCIENTIFIC ADVISORY BODIES AND SCIENTIFIC ORGANISATIONS ON NGTS

Over the last decade, there have been numerous scientific reports and publications on NGTs. A non-exhaustive overview of relevant opinions of EU scientific advisory bodies and scientific organisations is provided below. It reflects a diversity of views, but with majority positions emerging on relevant scientific issues.

In 2017, the Scientific Advice Mechanism High-Level Group (SAM HLG) issued an explanatory note on new techniques in agricultural biotechnology applied to plants, animals and microorganisms[1]. The note describes the nature and characteristics of NGTs known at that time and their similarities and differences compared to conventional breeding techniques and established genomic techniques, in particular as regards precision, efficiency, detectability, cost and speed of product development. The SAM HLG also issued a statement[2] in 2018 on a "Scientific perspective on the regulatory status of products derived from gene editing and the implications for the GMO Directive" where they considered that new scientific knowledge and recent technical developments have made the GMO legislation no longer fit for purpose.

EASAC, the European Academies' Science Advisory Council, formed by the national science academies of the EU Member States, Norway, Switzerland and the United Kingdom, issued a report in 2017 on scientific opportunities, public interests and policy options in the EU on genome editing[3].

The Commission Joint Research Centre (JRC) analysed in 2021 the latest scientific developments[4] relating to NGTs.

The European Food Safety Authority (EFSA) published scientific opinions on NGTs applied to plants, in particular on SDN type 1 and 2 and oligonucleotide-directed (ODM) mutagenesis[5], and on cisgenesis and intragenesis (with a recent opinion updating a

[1] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

[2] European Commission, Directorate-General for Research and Innovation, Group of Chief Scientific Advisors, *A scientific perspective on the regulatory status of products derived from gene editing and the implications for the GMO Directive : statement by the Group of Chief Scientific Advisors*, Publications Office, 2019, https://data.europa.eu/doi/10.2777/407732

[3] EASAC (2017) Genome editing: scientific opportunities, public interests and policy options in the European Union https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Report_31_on_Genome_Editing.pdf

[4] New Genomic Techniques: State-of-the-Art Review https://data.europa.eu/doi/10.2760/710056

[5] EFSA Panel on Genetically Modified Organisms, 'Applicability of the EFSA Opinion on SDNs type 3 for the safety assessment of plants developed using SDNs type 1 and 2 and oligonucleotide-directed mutagenesis', *EFSA Journal* 2020;18(11):6299. https://doi.org/10.2903/j.efsa.2020.6299

previous one from 2012)[6]. EFSA also published scientific opinions on plants obtained through synthetic biology, where certain applications make use of SDN technologies[7].

Overall, these opinions and reports recognise the variety of techniques and of different products with different risk profiles they can generate. They confirm that NGT products may or may not contain foreign DNA. They also recognise similarities of certain organisms produced by NGTs with conventionally bred organisms, while others would resemble organisms produced by established genomic techniques. NGTs may also introduce into an organism sequences derived from the same species or from other species, either crossable or uncrossable. In this respect, NGTs may produce modifications that could or could not be obtained in nature or by conventional breeding. In the former case, products obtained by NGTs and those occurring naturally or produced by conventional breeding might be indistinguishable from each other.

The above-mentioned bodies also report on the increasing precision of certain NGTs compared to conventional breeding approaches. In particular, genome editing enables small, precise and specific changes, such as point mutations, or makes it possible to target insertions, resulting in comparatively fewer unintended effects. Variations to the genome may be entirely novel or may occur already in other individuals of the same or of another species. When changes are small and directed by similar desirable changes known in other organisms, the resulting products are expected to display more predictable characteristics. For these reasons, many NGTs make it possible to shorten the development time for organisms with desired phenotypes. Also, the assessment of the characteristics and potential risks might be facilitated on a case-by-case basis.

As regards risks, EFSA concluded that there are no new hazards specifically linked to the genomic modification produced via SDN-1, SDN-2, ODM as compared with both SDN-3 and conventional breeding. In assessing different contributions to potential hazards in cisgenic/intragenic plants, EFSA concluded that no new risks are identified in cisgenic and intragenic plants compared with plants obtained with conventional breeding or established genomic techniques. However, intragenic plants may present more hazards than cisgenic plants.

EFSA also considered that on a case-by-case basis, a lesser amount of data might be needed for the risk assessment of plants produced by SDN-1, SDN-2, ODM, cisgenesis and intragenesis and therefore there is a need for flexibility in the data requirements for risk assessments. EFSA also concluded that in targeted mutagenesis, the potential for unintended effects, such as off-target effects, may be significantly reduced compared to random insertions or conventional breeding. Off-target modifications would be fewer

[6] EFSA Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561. EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. *EFSA Journal* 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

[7] EFSA Panel on Genetically Modified Organisms, 2022. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology. EFSA Journal 2022;20 (7):7410, 25 pp. https://doi.org/10.2903/j.efsa.2022.7410 EFSA Panel on Genetically Modified Organisms, 2021. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology. *EFSA Journal* 2021;19(2):6301, 21 pp. https://doi.org/10.2903/j.efsa.2021.6301 [8] Modrzejewski, D., Hartung, F., Sprink, T., Krause, D., Kohl, C., Wilhelm, R (2019): What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: A systematic map. *Environmental Evidence*, 8(1):

than those occurring with most mutagenesis techniques and, where such changes occur, they would be of the same types as those produced by conventional breeding techniques.

The scientific literature on off-target effects indicates that there are fewer such effects for certain targeted mutagenesis methods compared to conventional mutation breeding. Out of 1328 studies analysed using different genome editing techniques, 252 investigated off-target mutations. These were detected in around 3% of the analysed potential off-target sites[8]. Case studies on rice[9] and cotton[10] showed that no off-target sequences were found with CRISPR/Cas but conventional tissue culture resulted in ~100-250 single nucleotide variations. Nevertheless, some scientists consider that there are new types of risks resulting from targeted mutagenesis techniques compared to previous applications of genetic engineering[11].

To address the possible need for flexibility in data requirements for risk assessment, EFSA, upon a request from the Commission, published a statement where six main criteria are proposed to assist the risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis[12] (see section 5.2.1, box 1). These criteria relate to the molecular characterisation of the genetic modification introduced, to the available knowledge based on the history of use and to the structure and function of the modified DNA sequence(s). In the statement, EFSA reiterated that for plants in which the newly modified DNA sequence is successfully targeted there are cases where the potential for unintended effects, such as off-target effects, is significantly reduced compared to random insertions or conventional breeding. When that happens, the data requirements for the risk assessment may be reduced on a case-by-case basis.

The European Union Reference Laboratory for GM food and feed (EURL GMFF) and the European Network of GMO Laboratories (ENGL) issued in 2019 a report on the detection of food and feed plant products obtained by new mutagenesis techniques[13]. They concluded that validation of a specific detection method and its implementation for market control is feasible only for genome-edited plant products carrying a known DNA alteration that has been shown to be unique. Under the current circumstances, market control will fail to detect unknown genome-edited plant products. An updated report by the EURL-ENGL is expected in mid-2023[14].

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[8] Modrzejewski, D., Hartung, F., Sprink, T., Krause, D., Kohl, C., Wilhelm, R (2019): What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: A systematic map. *Environmental Evidence*, 8(1):

[9] Tang, X., Liu, G., Zhou, J., Ren, Q., You, Q., Tian, L., *et al*. (2018). A large-scale whole-genome sequencing analysis reveals highly specific genome editing by both Cas9 and Cpf1 (Cas12a) nucleases in rice. *Genome Biol*. 19, 84. doi:10.1186/s13059-018-1458-5.[10] Li, J., Manghwar, H., Sun, L., Wang, P., Wang, G., Sheng, H., et al. (2019): Whole genome sequencing reveals rare off-target mutations and considerable inherent genetic or/and somaclonal variations in CRISPR/Cas9-edited cotton plants. *Plant Biotechnol*. J. 17, 858–868. doi: 10.1111/pbi.1302

[10] Li, J., Manghwar, H., Sun, L., Wang, P., Wang, G., Sheng, H., et al. (2019): Whole genome sequencing reveals rare off-target mutations and considerable inherent genetic or/and somaclonal variations in CRISPR/Cas9-edited cotton plants. *Plant Biotechnol*. J. 17, 858–868. doi: 10.1111/pbi.1302

[11] Kawall, K. The Generic Risks and the Potential of SDN-1 Applications in Crop Plants. Plants 2021, 10, 2259. https://doi.org/ 10.3390/plants10112259.

[12] EFSA Panel on Genetically Modified Organisms, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618

[13] European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289). https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-reportENGL.pdf

[14] [reference to be added when available]

The European Group on Ethics in Science and New Technologies (EGE) published in 2021 an opinion on the ethics of genome editing, which focuses on applications in the human, animal and plant domains[15]. Among its conclusions on plants, EGE recommends a systems approach to evaluate costs and benefits (including the impact of continuing current agricultural practices) in any future use. It also recommends regulation proportional to the risk: light touch regulation should be used where the change in the plant could have been achieved naturally, or where genetic material from sexually compatible plants is introduced. Where genes from non-sexually compatible organisms or multiple changes are introduced, there should be a comprehensive risk assessment.

Some scientific organisations and agencies, such as the German Federal Agency of Nature Conservation[16], the European Network of scientists for social and environmental responsibility (ENSSER)[17] and TestBiotech[18], disagree with the above opinions. They raise the concern that NGTs pose specific risks to the environment and human health. They consider that NGTs can be used to achieve genomic changes beyond what is known from conventional breeding and can alter the genome to a much greater extent than with any previous breeding method. Furthermore, they refer to unintended genetic changes that, according to them, would be specific to the processes of NGTs and unlikely to occur via random processes or conventional breeding. Furthermore, these organisations question that NGTs are precise, controllable and predictable and have a sustainability potential as claimed.

EFSA has evaluated the scientific literature provided by these organisations in the public consultations and considered that it does not provide new evidence challenging the validity of the assessment and conclusions of EFSA scientific opinions[19].

[15] https://ec.europa.eu/info/files/ethics-genome-editing_en

[16] https://www.bfn.de/en/publications/position-paper/new-developments-and-regulatory-issues-plant-genetic-engineering[17] https://ensser.org/publications/2021-publications/enssers-response-to-the-inception-impact-assessment-iaa-on-new-genomic-techniques/

[17] https://ensser.org/publications/2021-publications/enssers-response-to-the-inception-impact-assessment-iaa-on-new-genomic-techniques/

[18] https://www.testbiotech.org/en; https://www.vzbv.de/sites/default/files/2022-11/vzbv-report_final_final.pdf

[19] https://www.efsa.europa.eu/en/news/faq-criteria-risk-assessment-plants-produced-targeted-mutagenesis-cisgenesis-and-intragenesis

ANNEX 7: APPLICATIONS OF NGTS IN PLANTS AND CASE STUDIES ON POTENTIAL IMPACTS

1. OVERVIEW OF APPLICATIONS OF NGTS IN PLANTS

The Commission Joint Research Centre (JRC) analysed in 2021 the current and future market applications[1] relating to NGTs.

The JRC report illustrates the wide range of traits and plant species in the focus of NGTs (see Table 1 and 2 and Figures 1 and 2). Regarding developed traits, disease resistance is targeted to more types of pathogens and pests. Abiotic stress tolerance is widely explored and includes resistance to drought, salinity and heat stress. Modified composition goes beyond starch and oil content, where many crops are in development with improved nutrition properties (fibres, vitamins content) together with the reduction of potentially harmful compounds (toxins, allergens, acrylamide, etc.) or gluten. Also, several applications are dedicated to obtaining higher and more stable yield (in terms of plant production and/or size of fruits and grains). Regarding targeted plants species, these cover a wider range of plant groups from cereals to fruits, legumes and vegetables, compared to GMOs from established genomic techniques, which mainly concern few cereal (maize, rice) and oil and fibre crops (soybean, cotton, oilseed rape).

Tables 1 and 2 and figures 1, 2 and 3 summarise the plants and traits identified in the JRC market review and reflect the situation in 2020.

Table 1. Summary of plants identified in the JRC database of NGT products.

Plant groups	Plants included (not exhaustive)
Cereals	Maize, Wheat, Rice, Barley, Sorghum, Millet
Forage and grasses	Alfalfa, Ryegrass, Switchgrass, *Setaria viridis*
Fruits	Apple, Banana, Orange, Groundcherry, Grapefruit, Grapevine, Kiwifruit, Melon, Watermelon, Berries, Stone fruits, Avocado
Legumes	Beans, Chickpea, Peanut, Pea, Pigeon Pea
Oil and fibre crops	Soybean, Rapeseed, Cotton, Camelina, Flax, Pennycress, Sunflower, Mustard, Strawberry
Ornamentals	Chrysanthemum, Dandelion, Orchid, Petunia, Poinsettia, Poppy, Japanese morning glory, Wishbone flower, Jasmine tobacco
Sugar crops	Sugar beet, Sugarcane
Trees	Poplar, softwood trees
Tubers and root vegetables	Potato, Sweet potato, Cassava, Beetroot
Vegetable crops	Tomato, Broccoli, Cabbage, Cucumber, Eggplant, Lettuce, Pepper, Chicory
Other plants	Cacao, Coffee, Tobacco, Salvia

[1] Parisi, C. and Rodriguez Cerezo, E., Current and future market applications of new genomic techniques, EUR 30589 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-30206-3, doi:10.2760/02472, JRC123830.

Figure 1: Distribution of NGT plant entries in the database by plant group and development stage (commercial, pre-commercial, advanced and early R&D stages)[1].

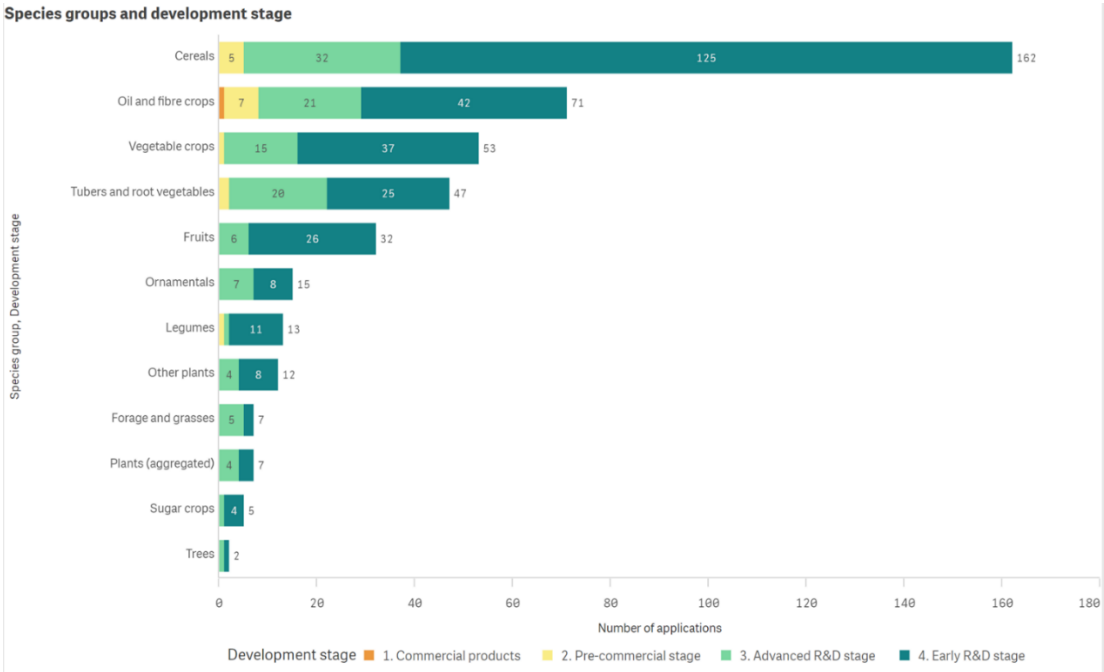


Table 2. Trait categories in the JRC NGT plant products database.

Trait category	Description
Biotic Stress Tolerance	Resistance to biotic stressors like, nematodes, fungi, bacteria, viruses and other pests, pathogens, or parasites
Abiotic stress tolerance	Resistance to abiotic stressors like drought, heat, salt, rain or UV radiation.
Herbicide tolerance	Tolerance to different types of herbicides
Modified colour/flavour	Modified colour or flavour
Modified composition	Modified content of substances like starch, oil, proteins, vitamins, fibres, toxic substances, allergens etc. to improve food/feed quality of for a better industrial use. It includes seedless fruits as a quality characteristic.
Plant yield and architecture	Yield increase (or yield stability) related to higher number of flowers/seeds/fruits, to fruit size/weight and to photosynthetic efficiency. It also includes other changes in plant architecture including plant height and shape, fruit shape, and growth pattern, among others.
Storage performance	Improvement of characteristics like shelf life and storage conditions (e.g. cold storage), including non-browning and reduced black spot.
Other traits	Remaining traits, not classified in the previous categories, including, among others, production of molecules of industrial interest, flowering time for agronomic purposes and nitrogen use.
Breeding tools	Reproductive/flowering characteristics including, among others, induction of sterility, early flowering, and haploid techniques

Figure 2: Distribution of NGT plant entries in the JRC database by trait category and development stage (commercial, pre-commercial, advanced and early R&D stages)[1].

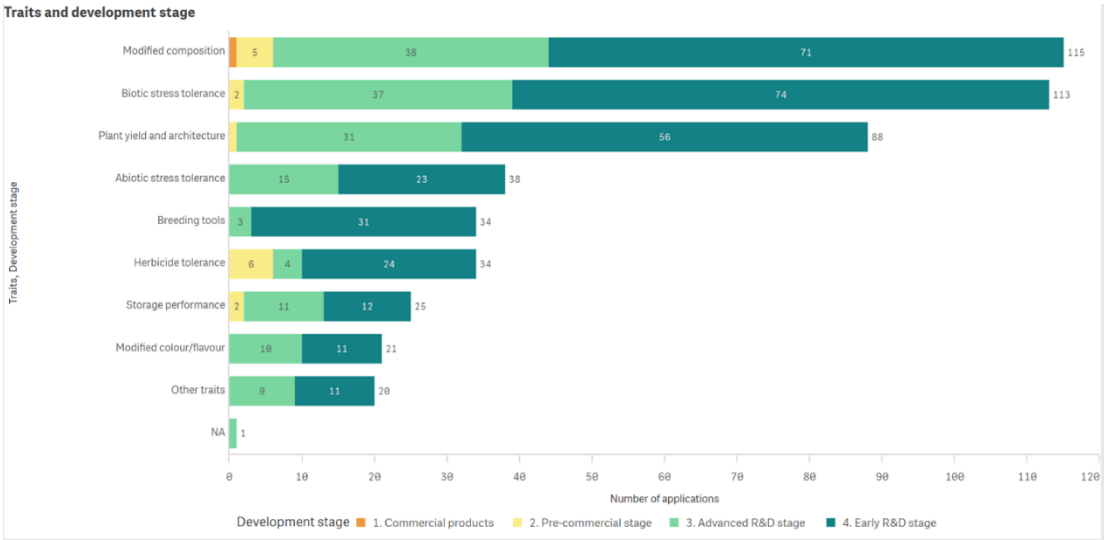
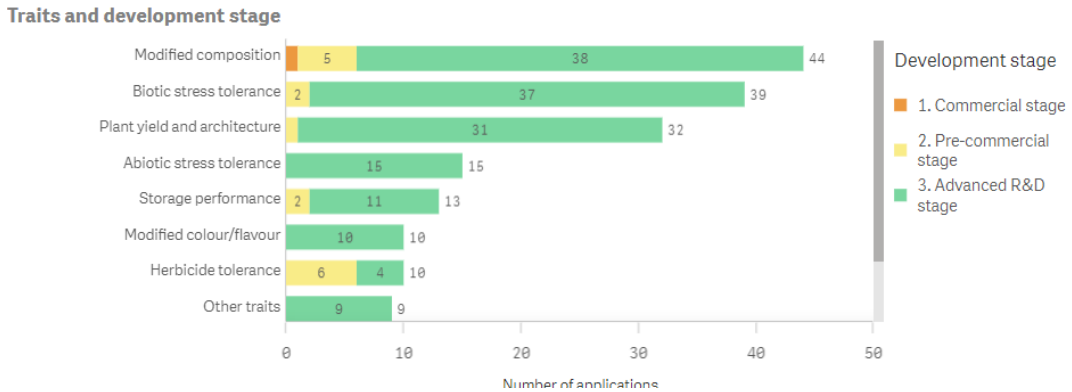


Figure 3: Distribution of NGT plant entries in the database by trait category and development stage (commercial, pre-commercial, advanced R&D), limited to a 2030 horizon.



An overview of applications of NGTs in plants is also provided by the **database of published literature on the use of genome editing in crop plants maintained by the EU-SAGE network**[2], which contains information on genome-editing research and provides details on crop plant species and traits addressed and the techniques used and is kept up to date. Genome editing applications are identified in more than 60 different crops with the vast majority in rice, tomato, maize, soybean, wheat and potato. The traits introduced in the improved crops are diverse and relevant for farmers (e.g. agronomic value) as well as consumers (e.g. nutrition). Table 3 describes the distribution of these traits for the time-period 1996-2022.

[2] https://www.eu-sage.eu/genome-search

Table 3. Distribution of genome editing applications according to different trait categories in the period 1996–2022[2].

Trait category	%
Plant yield and growth	22.2% (144)
Improved food/feed quality	21.9% (142)
Industrial utilisation	14.4% (93)
Biotic Stress Tolerance	8% (117)
Abiotic stress tolerance	7.9% (51)
Herbicide tolerance	7.7% (50)
Modified colour/flavour	5.9% (38)
Storage performance	2% (13)

The **Food and Agriculture Organization of the United Nations** (FAO) also includes examples of applications in their recent paper on 'Gene editing and agrifood systems'[3], for all of these trait categories (see Table 4).

Table 4. Applications of genome editing technologies in agrifood systems.

Species	Trait	Research Organisation
Camelina	Improved fatty acid composition	Department of Plant Sciences and Plant Pathology, Montana State University, Bozeman, MT 59717, USA
Lettuce	Increased vitamin C content	State Key Laboratory of Plant Cell and Chromosome Engineering, Center for Genome Editing, Institute of Genetics and Developmental Biology, Chinese Academy of Sciences, Beijing, China
Oilseed rape	Improved fatty acid composition	National Key Laboratory of Crop Genetic Improvement, Huazhong Agricultural University, Wuhan, China
Potato	Reduced acrylamide formation	Cellectis plant sciences Inc., New Brighton, MN, USA
Soybean	Improved fatty acid composition	Calyxt, Roseville, MN, USA
Tomato	High content of γ-aminobutyric acid (GABA)	Sanatech Minato-ku, Tokyo, Japan & University of Tsukuba, Ibaraki, Japan

[3] FAO. 2022. Gene editing and agrifood systems. Rome. https://doi.org/10.4060/cc3579en

Wheat	Low gluten content	Instituto de Agricultura Sostenible (IAS-CSIC), Córdoba, Spain
		Wageningen University, Wageningen, Netherlands
Wild tomato	De novo domestication – High antioxidant content	Several universities from Brazil, Germany and the USA
Brewer's yeast	Flavour improvement in fermented beverages	Centre of Microbial and Plant Genetics, Leuven, Belgium
Alfalfa	High yield	National Institute of Agricultural Technology, Argentina
Banana	Fungus protection	Queensland University of Technology, Brisbane, Australia
	Protection against bacterial wilt, fusarium wilt and banana streak virus	International Institute of Tropical Agriculture, Nigeria
	Protection against bunchy top virus	Agricultural Research Council, Pretoria, South Africa
Cacao	Protection against fungal disease	Pennsylvania State University, USA
Cassava	Reduced cyanide levels	University of California, Berkeley, CA, USA
	Virus resistance	
Cherry	Virus resistance	Department of Horticulture, Plant Biotechnology Resource and Outreach Center, Michigan State University, East Lansing, MI, USA
Citrus	Protection against citrus canker	Chinese Academy of Sciences, China
Cucumber	Protection against multiple viruses	Department of Plant Pathology and Weed Research, ARO, Volcani Center, Bet-Dagan, Israel
Flax	Herbicide tolerance	Cibus, San Diego, CA, USA
Grapevine	Drought tolerance	Stellenbosch University, Stellenbosch, South Africa
Maize	Fungus resistance	DuPont Pioneer, Johnston, IA, USA
Oilseed rape	Herbicide tolerance	Key Laboratory of Plant Functional Genomics of the Ministry of Education, Yangzhou University, Yangzhou China
Potato and Sugar beet	Disease-resistant varieties	Russian Academy of Sciences, Russian Federation
Rice	Salt tolerance	National Institute for Plant Biotechnology, New Delhi, India
	Fungus protection	Department of Genetics, Development & Cell Biology, Iowa State University, Ames, Iowa, USA
	Salt tolerance	Key Laboratory of Rice Genetic Breeding of Anhui Province,Rice Research Institute, Anhui Academy of Agricultural Sciences, Hefei, 230031, China
Sorghum	Increased protein content	University of Queensland, Queensland, Australia
	Striga resistance	Kenyatta University, Kenya
Soybean	Nematode resistance	Evogene, Rehovot, Israel & TMG, Cambé, Brazil
Tomato	Bacterial resistance	Department of Plant and Microbial Biology, University of California, Berkeley, USA
	Provitamin D3 enhanced	John Innes Centre, Norwich, United Kingdom

Wheat	Fungus protection	State Key Laboratory of Plant Cell and Chromosome Engineering, Institute of Genetics and Developmental Biology, Chinese Academy of Sciences, Beijing, China

2. CASE STUDIES

JRC case studies

Very few NGT plants have been commercialised so far and therefore there is limited knowledge and assessment of their field performance, environmental effects and benefits for consumers.

For the purposes of this impact assessment, the JRC developed three case studies to showcase the potential impacts, positive or negative, on the social, environmental and economical dimensions of sustainability. The studies involved commercially important plants produced via targeted mutagenesis or cisgenesis that are currently in various stages of development in the EU or elsewhere and which feature traits with potential to contribute to sustainability objectives:

- disease resistant apples and potatoes (box 1);
- low gluten wheat (box 2);
- a virus-resistant maize (box 3).

Box 1: Economic and environmental impacts of disease resistant potatoes and apples developed with cisgenesis[4]

A key tool in agricultural management are pesticides, as significant shares of harvests are lost to plant diseases. To achieve the objectives of the Green Deal, Farm to Fork and the Biodiversity Strategies which aim at reducing the use of pesticides, the development of disease resistant varieties is crucial. The case study focuses on fungal resistant potato and apple varieties as both plants are difficult to breed and because the fungal diseases are severe and can break down resistances. Due to the low availability of varieties with durable resistances, potatoes and apples are among the most intensively treated crops in terms of pesticide use. For the potential direct economic impacts, the study focused on the five EU Member States with the largest average production from 2015 to 2020. For potato these are France, the Netherlands, Belgium, Germany, Poland and for apple France, Italy, Germany, Poland, Spain.

The NGT-based potato variety presented here has been developed and extensively tested in multi-year field trials in the Netherlands. In contrast to the potato variety, the cisgenic apple variety analysed is still in the early research and development stage. The project did develop a cisgenic apple as proof of concept, however, only based on an introduction of a single resistance gene. In addition, a cisgenic construct harbouring three genes against scab was developed and would be readily available. Both plants are notoriously challenging to breed, making it time consuming to develop pest resistant varieties. *Phytophthora infestans* and *Venturia inaequalis* are key pathogens causing late blight disease (PLB) in potatoes and scab disease in apple, respectively. In potatoes, the average (maximum) number of annual fungicide treatments ranges from 3 (17) in Poland, over 7 (18) in Germany, to 13 (21) in the Netherlands, and 14 (23 and 25) in France and Belgium. This corresponds to 1.4 kg of fungicides per hectare in Poland, 5.2 kg in Germany, 7.1 kg in France, 7.5 kg in the Netherlands, and 11.2 kg in Belgium. In apples, the average (maximum) number of fungicide treatments is over 20 (30) and the applied quantities range from 2.9 kg in Spain, over 8.7 kg in Poland, to 25.6 kg in France, and 31.7 kg in Germany.

Varieties with durable resistances to these diseases could allow for sizable reductions of fungicide without affecting yields. In potatoes, a 50-80% reduction of fungicides may be feasible under commercial conditions. In apples, depending on the region, a reduction of 12-58% is suggested by the

[4] Schneider, K., Barreiro-Hurle, J., Kessel, G. *et al*., 2023. Economic and environmental impacts of disease resistant crops developed with cisgenesis. EUR 31355, Publication office of the European Union, Luxembourg.

literature. The fungicide reductions may generate cost savings for farmers. In PLB resistant potatoes, the simulated 90%-confidence-interval of the savings per hectare are EUR350-576 (7.8 to 14.7 % of total costs) in France, EUR326-535 (6.3-11.2%) in the Netherlands, EUR292-463 (8.2-13.8%) in Belgium, EUR189-323 (5.9-10.9%) in Germany, and EUR49-99 (3.7-7.9%) in Poland. In scab resistant apples, the estimates are EUR271-712 (2.7-8.5%) in France, EUR207-556 (2.4-7.3%) in Italy, EUR151-516 (1.5-5.6%) in Germany, EUR65-234 (2.3-8.7%) in Poland, and EUR39-242 (0.9-6.2%) in Spain.
At country-level, the rate of adoption of the resistant varieties largely determines the total annual cost savings. If only the largest farms with more than 20 hectare of potatoes under cultivation were to adopt the PLB resistant potatoes, the total annual cost savings are estimated at EUR53 million in France, EUR47 million in Germany, EUR47 million in the Netherlands, EUR8 million in Belgium, and EUR3 million per year in Poland. If only farms with more than 30 hectare of fruits under cultivation were to adopt the scab resistant apples, the total annual cost savings are estimated at EUR8.9 million in France, EUR3.2 million in Germany, EUR2.7 million in Poland, EUR2.3 million in Italy, and EUR0.9 million in Spain. At EU-level, the PLB resistant potatoes are estimated to increase the total potato supply by up to 5%, reduce the producer prices by up to 6%, increase the human consumption by up to 0.8%, increase the use for feed by up to 3.5%, decrease the potato imports by up to 4.6%, and increase the potato exports by up to 6.2%.
In terms of environmental impacts, in Germany in 2019, the five most used active ingredients in potatoes belong to three Harmonised Risk Indicator (HRI)-1 groups[5]: group 2[6] (3 substances), group 3[7] (1), and group 4[8] (1). In the case of apples, the five most used active ingredients belong to group 2 (4) and group 3 (1). Therefore, the potential reduction in fungicide use in both crops could have significant effects on the national risk indicators. The environmental risks of the active ingredients currently used in both crops are suggested to be strongly related to their presence in freshwater systems. Fruit orchards less than 1 km away from any freshwater system correspond to approximately 3-15% of the area of production in the different countries. For potato fields in 2018, fields less than 1 km away from freshwater systems corresponded to approximately 3-11% of the countries' area of production. No effects from the large-scale adoption of PLB resistant potatoes on the total greenhouse gas emission related to agricultural activities in the EU were found.

[5] Harmonised Risk Indicator-1 is used to estimate the trends in risk from pesticide use. HRI 1 is calculated by multiplying the quantities of active substances placed on the market in plant protection products by a weighting factor.
[6] Group 2: Active substances approved or deemed to be approved under Regulation (EC) No 1107/2009, and not falling in other categories, and which are listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011
[7] Group 3: Active substances approved or deemed to be approved under Article 24 of Regulation (EC) No 1107/2009, which are candidates for substitution, and which are listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011
[8] Group 4: Active substances which are not approved under Regulation (EC) No 1107/2009, and therefore which are not listed in the Annex to Implementing Regulation (EU) No 540/2011

Figure 4: Presentation of the JRC case study on cisgenic potato.

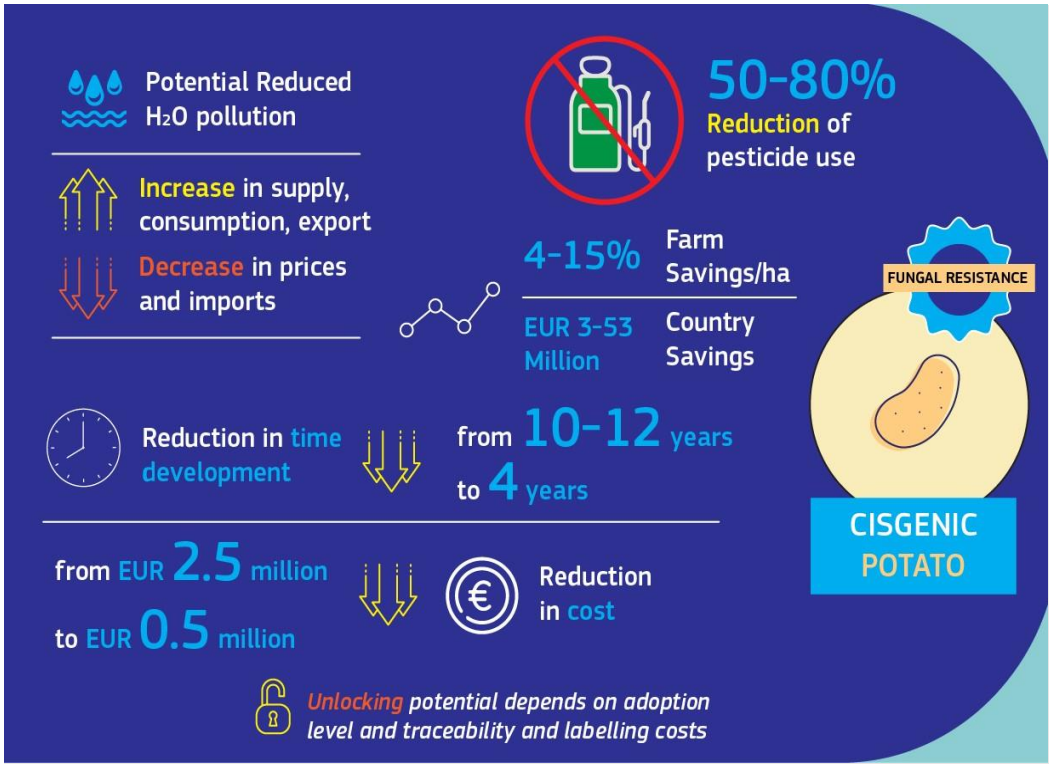
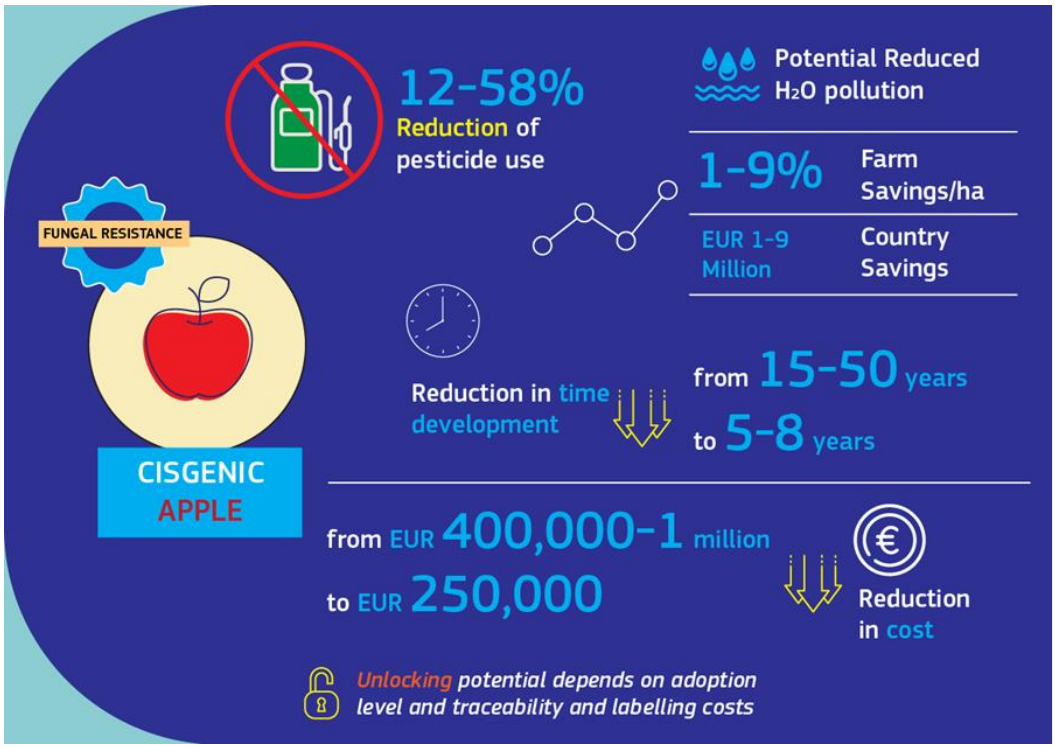


Figure 5: Presentation of the JRC case study on cisgenic apple.



Box 2: Socioeconomic impact of low-gluten celiac-safe wheat developed by gene editing[9]

1 to 2% of the human population (4.5 million in the EU) suffer from coeliac disease (CD), a life-long autoimmune disorder, triggered by gluten and similar storage proteins in wheat, rye and barley, with severe underdiagnosis, leading to chronic small intestine inflammation. Next to CD, a large group of people suffer from non-coeliac wheat sensitivity (NCWS), with overlapping symptoms to CD but without elevated level of intestinal damage. Current management is through life-long gluten-free diets, which often lead to unbalanced nutrient intake, due to counterbalancing the lack of gluten with high salt, fat, and carbohydrates.

Gluten-free products are 200% more expensive than their normal counterparts. The economic aid offered differs among Member States. Patients and their relatives have as a rule little or no financial support. Costs for the health care system and productivity are difficult to quantify due to lack of data. After diagnosis and following a gluten-free diet, quality of life is reported to improve, and post-diagnosis medical costs reduced by 39%.

It is difficult to generate a low gluten variety via conventional breeding (high copy of genes, structural complexity).

Researchers from the Institute for Sustainable Agriculture of the Spanish National Research Council of Córdoba designed a first gene-edited wheat targeting alpha gliadins, which are the most immunoreactive, to achieve a variety that is not immunogenic for patients with celiac disease and possibly useful also for those with non-celiac wheat sensitivity. These gene-edited wheat lines reached a reduction in the alpha-gliadin content from 32% to 82%, while immunoreactivity was reduced by 85%. These lines have already been cultivated in greenhouses.

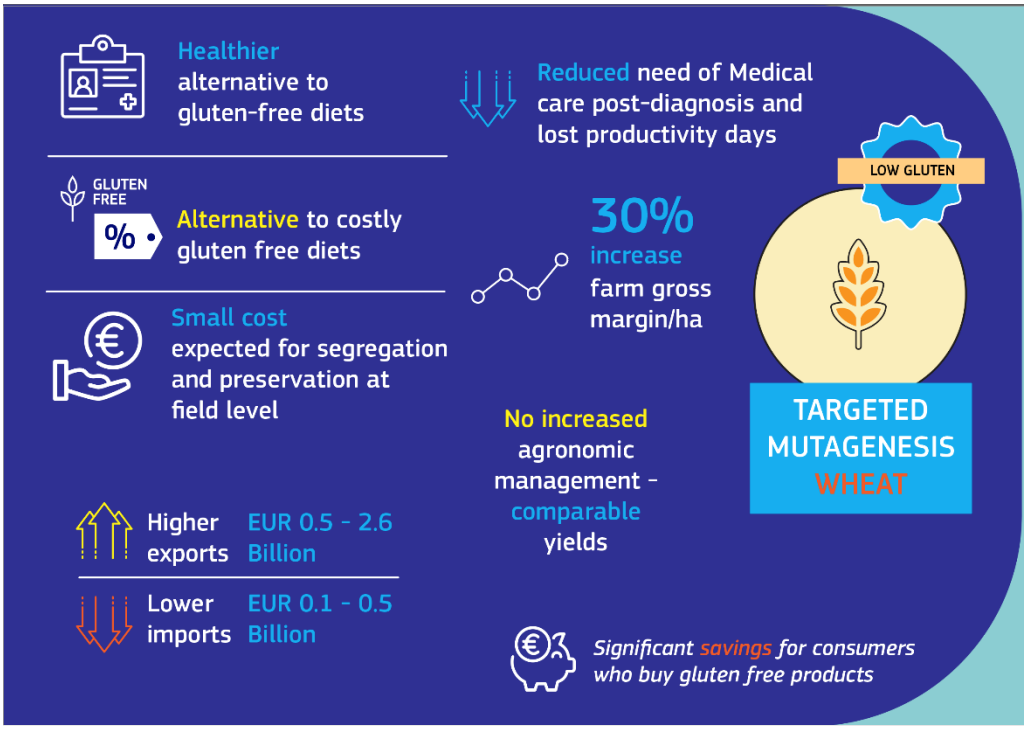
In addition, a second gene-edited wheat was obtained targeting gamma- and omega-gliadins, and achieved a reduction of 70% and 90% in the gamma and omega-gliadins, respectively. These lines are not yet being tested in greenhouses. Lastly, cross-breeding between gene-edited lines to combine all gliadin mutations in a single soft wheat genotype was carried out. These lines are currently being analysed, and the final selection of genotypes containing all mutations is expected to be completed by mid-2023. After this, clinical trials are planned using the best line.

After diagnosis, outpatient costs are estimated to be reduced by 29% (and total medical cost of care by 39%) and QALY (quality-adjusted life year) scores are estimated to improve based on adequate gluten-free diet. Gene edited low-gluten celiac-safe wheat provides a safe alternative to the gluten-free products for celiac disease patients and reduces possible nutrient deficiencies and imbalance in gut bacteria often associated with wheat avoidance. In addition, while conventional gluten-free products are on average 200% more expensive, products based on gene-edited low-gluten non-celiac wheat are expected to be only 30% more expensive. More affordable safe gluten-free diets will contribute to reducing medical costs post-diagnosis and improving quality of life.

In addition, the adoption of low-gluten celiac-safe wheat could increase gross margin of farmers per ha in average by 30% compared to conventional wheat. Finally, the competitiveness of the EU agri-food system might be enhanced by increasing export volumes (EUR0.5 to 2.6 billion) and lower import volumes (EUR0.1 to 0.5 billion) of this product, if eventually cultivated in the EU.

[9] Sánchez, B., Barro, F., Smulders, M. J. M. *et al*. 2023. Socioeconomic impact of low-gluten, celiac-safe wheat developed through gene editing, EUR 31380 EN, Publications Office of the European Union, Luxembourg.

Figure 6: Presentation of the JRC case study on targeted mutagenesis wheat.



Box 3: Biotic resistance in the context of smallholder farming in East Africa: a case on gene editing of maize to safeguard food security under the spread of the Maize Lethal Necrosis

Maize Lethal Necrosis (MLN) is a complex viral disease, spread recently to East Africa from the Americas. The disease is highly damaging, putting local food security at risk (majority of calory intake in the region comes from maize), as well as inflicting critical economic repercussions. MLN causes immense annual losses (~500 K tonnes in Kenya alone) in the production of maize, which is a main product on the Sub-Saharan African agricultural market. Maize agriculture provides the livelihood of 98% of smallholder farmers. With existing preventive measures and if MLN expands to susceptible countries, the impact of MLN could lead to an additional 122,000 additional people experiencing severe food insecurity.

Because small farmers in Africa lack the right management tools to handle MLN, resistance is considered the most economically and sustainably effective way in the battle against this disease and could save 0.5 Mio people from falling under the poverty line. Given the large variety of cultivates used in East Africa highly adapted to regional conditions and the faster development compared to conventional breeding, NGTs provide a valuable tool in fighting MLN and reduce yield penalty, consequently reducing the number of persons experiencing food insecurity and safeguarding smallholder farmers' livelihoods.

The gene-edited virus-resistant maize, currently in development, could prevent a deterioration of the severe food insecurity in East Africa, as well as deliver economic benefits.

The references are listed in footnote 10.

[10] Contribution based on a literature review:

Awata, L. A. O., Beyene, Y., Gowda, M. et al., 2019. Genetic Analysis of QTL for Resistance to Maize Lethal Necrosis in Multiple Mapping Populations. Genes 11, 32. https://doi.org/10.3390/genes11010032

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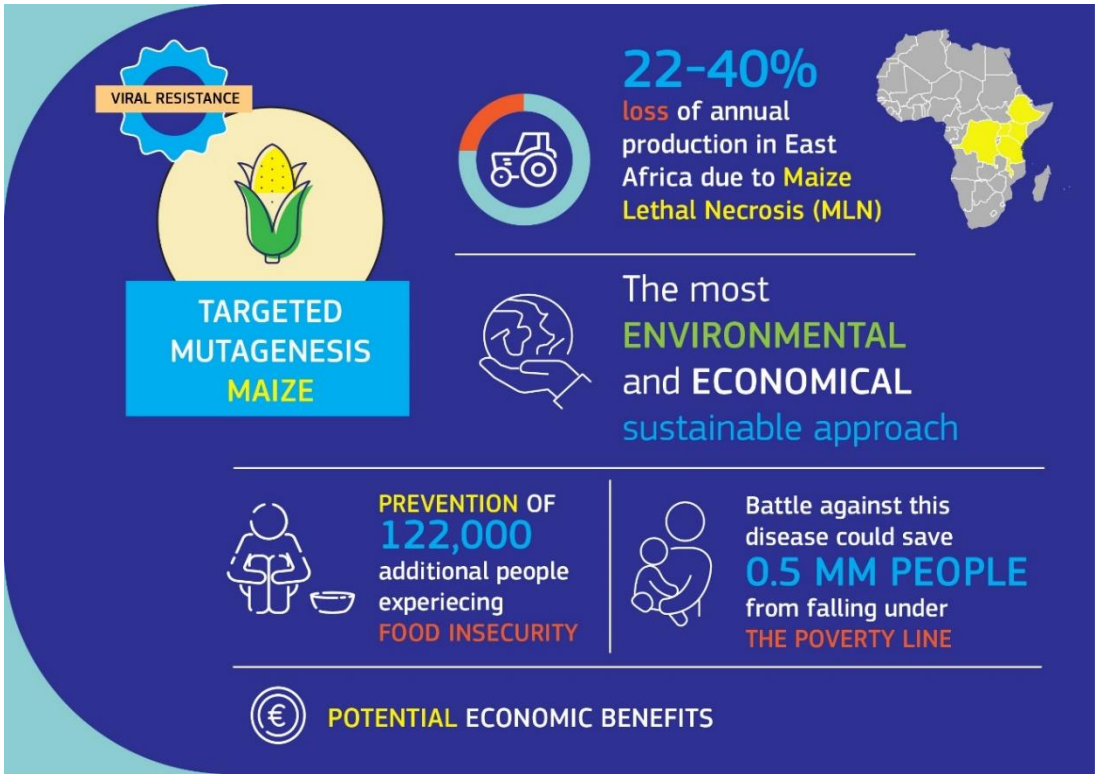
Figure 7: Presentation of the JRC case study on targeted mutagenesis maize.



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Horizon 2020 projects and other research concerning NGT applications

A Horizon 2020 project has considered an NGT root chicory for inulin production (box 4), and presented an environmental and socio-economic assessment of the whole value chain of the new chicory variants and their derived products.

Box 4: Root chicory for inulin production (H2020 project)[11]

Root chicory (*Cichorium intybus*) is a specialty crop, nearly exclusively cultivated in Belgium and the Netherlands where the growing conditions for this crop species are best, and which experiences increased demands as a source of food ingredients. Root chicory is cultivated for the food fibre inulin, a chain of fructose molecules – fibre is extracted from the root and included in foods such as yoghurts and cereal bars as low-calorie sweetener – and for the production of terpenes, which are able to inhibit, like antibiotics, the growth of fungi or bacteria, or are reported to prevent cancer cells from growing. The CHIC project[12] employed targeted mutagenesis to develop chicory varieties that (1) produce more and healthier inulin fibres and (2) produce sufficient amounts of medicinal terpenes.

A socio-economic and environmental impact assessment, using a multi-regional input-output (MRIO) analysis and life-cycle assessment (LCA), assumes that the NGT-based root chicory would not be regulated as a GMO. Three scenarios are modelled:

- A baseline scenario which uses the current situation of chicory yield, cultivation practices, energy use, and the current levels of inulin and terpene extraction;
- a chicory with a higher inulin content and reduced terpene content;
- a chicory with higher inulin and terpene content.

According to the project's conclusions, the two scenarios based on new chicory varieties both show positive socio-economic impacts (production and employment effects) compared to the baseline scenario. The study found that the higher inulin and terpene content of the NGT chicory varieties can lead to more jobs, can generate higher added value, can reduce GHG emissions and can reduce primary energy demand. Despite the market value of inulin, chicory is still an underdeveloped crop in the EU. NGT varieties of chicory with a higher inulin content and the additional production of terpenes can increase the competitive value of chicory in comparison to other crop species.

Furthermore, a new Horizon Europe project GeneBEcon[13], started in September 2022, will examine the innovation potential of gene editing in enabling a sustainable bioeconomy in Europe. Through the application of this technology in potato and microalgae, GeneBEcon intends to promote energy-efficient, low-input, and zero-pollution agricultural production and clean industrial processing. First, the technical potential will be explored by applying gene editing to develop 1) a virus-resistant potato with an industrial tuber starch quality, and 2) microalgae-based production of industrially relevant mycosporin-like amino acids. Second, the risk-regulatory aspects, economic incentives, and social perceptions will be investigated. In the latter, comparative analyses will be enabled by two different production systems: open-field agricultural crop and contained-system microalgae.

Other national research projects are also investigating the potential of genome editing (e.g. GenEdit in Belgium[14]). A COST Action (PlantEd, 2019-2023)[15], involving over 330 experts from 36 European countries and beyond, is aimed at advancing the technology

[11] Hingsamer M., Kulmer V., de Roode M. &Kernitzkyi M. (2022) Environmental and socio-economic impacts of new plant breeding technologies: A case study of root chicory for inulin production. *Frontiers in Genome Editing* **4**, doi: 10.3389/fgeed.2022.919392

[12] https://cordis.europa.eu/project/id/760891/results

[13] https://cordis.europa.eu/project/id/101061015

[14] https://www.sciensano.be/en/projects/development-and-evaluation-approaches-detection-organisms-modified-new-genome-editing-techniques

[15] https://plantgenomeediting.eu/

and assessing its impact, discuss regulatory options, monitor public perceptions and develop educational and outreach activities.

ANNEX 8: EU LEGAL FRAMEWORK ON GMOS

The GMO legal framework has as main aims to protect human and animal health and the environment in accordance with the precautionary principle and to ensure the effective functioning of the internal market. It regulates the deliberate release (including the placing on the market) of GMOs and of food and feed produced from GMOs, the contained use of GMMs, as well as the export of GMOs to third countries (in application of the EU's obligations under the Cartagena Protocol on Biosafety to the UN Convention on Biological Diversity[1]). The GMO acquis rests on five main pieces of legislation, namely:

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms[2]
- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms[3]
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[4]
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms[5]
- Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms[6].

The EU GMO legislation applies to GMOs as defined in Article 2(2) of Directive 2001/18/EC, i.e. *'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'*. The definition is further refined by a non-exhaustive list of genetic modification techniques set out in Part 1 of Annex IA to the Directive and by excluding the techniques listed in Part 2 of that annex, which are not considered to result in genetic modification under certain conditions. Furthermore, Article 3(1) of the Directive excludes from the scope of the Directive GMOs that result from the techniques/methods listed in Annex IB (i.e. mutagenesis and certain types of cell fusion), provided that they do not involve the use of recombinant nucleic acid molecules or GMOs.

In 2018, the Court of Justice of the EU clarified the interpretation of the scope of the mutagenesis exemption (judgment of 25.7.2018, Case C-528/16 *Confédération paysanne and Others*[7]). The Court ruled, firstly, that organisms obtained by means of mutagenesis

[1] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted on 29 January 2000, concluded on behalf of the EU by Council Decision 2002/628/EC of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety, OJ L 201, 31.7.2002, p. 48.

[2] *OJ L 106, 17.4.2001, p. 1*

[3] *OJ L 125, 21.5.2009, p. 75*

[4] *OJ L 268, 18.10.2003, p. 1*

[5] *OJ L 268, 18.10.2003, p. 24*

[6] *OJ L 287, 5.11.2003, p. 1*

[7] See footnote 14.

techniques/methods constitute GMOs as they meet the definition in Article 2(2) of Directive 2001/18/EC and are not included in the exhaustive list of techniques not resulting in genetic modification set out in Part 2 of Annex IA to that directive, and, secondly, that the mutagenesis exemption in Annex IB to that directive must be interpreted as only covering organisms obtained by means of mutagenesis techniques/methods which have conventionally been used in a number of applications and have a long safety record, and that new techniques/methods that have appeared or have been mostly developed since Directive 2001/18/EC was adopted are not exempted. Accordingly, the Court concluded that organisms obtained by means of random mutagenesis techniques/methods are excluded from the scope of the Directive, whereas organisms obtained by techniques/methods of targeted mutagenesis are not exempted (judgment of 25.7.2018, Case C-528/16 *Confédération paysanne and Others*, paragraphs 48, 51, 54). In a recent judgment, the Court further clarified that organisms obtained by *in vitro* random mutagenesis techniques/methods are exempted from the GMO legislation (judgment of 7 February 2023, Case C-688/21 *Confédération paysanne and Others*)[8].

Although the above-mentioned 2018 judgment only concerned the mutagenesis exemption, its conclusions apply also to organisms produced by means of other NGTs, such as cisgenesis. Indeed, organisms obtained by those techniques alter the genetic material in a way that does not occur naturally by mating or natural recombination and, therefore, constitute GMOs. Since those techniques are neither listed in Part 2 of Annex IA nor in Annex IB to Directive 2001/18/EC, it must be concluded that organisms obtained by those techniques are subject to the GMO legislation[9].

The main elements of the GMO acquis are described in the next paragraphs (see also diagram in the end of the section).

- **Directive 2001/18/EC on the deliberate release of genetically modified organisms**

Directive 2001/18/EC requires the relevant national authorities' prior consent for the deliberate release of GMOs into the environment. In order to obtain consent, an application ('notification') has to be submitted to the national competent authority, accompanied *inter alia* by an environmental risk assessment. The risk assessment must comply with the general principles and the methodology set out in the Directive and must draw conclusions for each relevant area of risk. The requirements are different for the placing on the market of GMOs as or in products (Part C of the Directive) and for other purposes, such as experimental releases (Part B).

The authorisation procedure for the placing on the market of GMOs other than food and feed is conducted by Member States. The national competent authority to which the notification has been submitted must deliver an assessment report on the submitted notification. In cases where the Commission or another Member State have expressed objections to the assessment report and no agreement has been reached, the Commission adopts a decision after obtaining the scientific opinion of EFSA. The national competent authority that prepared the report rejects the notification or gives written consent for the placing on the market of the GMO and sets out the conditions, as well as labelling and monitoring requirements. The consent can be valid for a renewable period of up to 10 years.

[8] ECLI:EU:C:2023:75
[9] European Commission (2021c), sections 4.2.2, 4.2.3 and 4.2.4.

The Directive allows Member States to ban the cultivation of GMOs in their territory or part thereof based on compelling grounds (such as grounds relating to town and country planning, land use, etc) other than those concerning the safety of GMOs for health or the environment. So far this provision has been applied as regards the authorisation for the cultivation of one GM plant[10], from which 18 of the 27 Member States[11] excluded all of part of their territory.

- **Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs)**

This Directive defines a GMM as '*a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'* (Article 2(b)). It requires a notification to the national competent authorities and in some cases their prior consent for the contained use of GMMs. To that end, the user has to carry out an assessment of the contained uses as regards risks to human health and the environment.

Directive 2009/41/EC only applies to GMMs. The contained use of other GMOs is currently not regulated at EU level, but is subject to national legislation in most Member States.

- **Regulation (EC) No 1829/2003 on GM food and feed**

This Regulation requires authorisation for the placing on the market of food and feed consisting of, containing or produced from GMOs ('GM food and feed'). The authorisation procedure is centralised, providing for a single application to be submitted to a national competent authority for all the intended uses of the GM food or feed in question (including cultivation). It is based on an independent risk assessment carried out by EFSA. Authorisation may be granted only if the risk assessment demonstrates that, under its intended conditions of use, the product has no adverse effects for human and animal health and for the environment compared to its conventionl counterparts, does not mislead the user or the consumer and is not nutritionally disadvantageous compared to the food or feed it is intended to replace.

Authorisations are granted by the Commission for a renewable period of ten years. They may impose conditions or restrictions, including post-market monitoring requirements, and must set out the method for detecting the transformation event, as provided by the applicant and validated by the EU Reference Laboratory for GM Food and Feed (EURL), as well as the place from which the reference material may be obtained. The Regulation also provides for mandatory labelling of authorised GM food and feed, so that final users and consumers can make an informed choice, but exempts food and feed containing traces of GMOs or GM material in a proportion no higher than 0.9% of the food/food ingredient/feed/feed component provided that this presence is adventitious or technically unavoidable.

[10] Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (Zea mays L.) MON 810 (MON-ØØ81Ø-6) (OJ L60, p 90).

[11] AT, BE (Wallonia), BG, CY, DE, DK, EL, FR, HR, HU, IT, LV, LT, LU, MT, NL, PL, SI

- **Regulation (EC) No 1830/2003 on the traceability and labelling of GMOs and the traceability of food and feed products produced from them**

Under this Regulation, operators placing GMOs and GM food and feed on the market must inform the operators receiving the products, in writing, that the products contain or consist of GMOs. They must provide an indication of each ingredient/material produced from GMOs or, for products without an ingredients list, an indication that the product is produced from GMOs. They must keep that information for five years and be able to identify the operator(s) by whom and to whom the products have been made available. Traceability requirements allow for close monitoring of potential effects of the product on environment and health, and where necessary for the withdrawal of products if an unexpected risk to human health or to the environment is detected.

Furthermore, the Regulation requires that all products consisting of or containing GMOs are labelled as GMOs.

The Regulation exempts from the traceability and labelling requirements products containing traces of GMOs intended for direct use as food, feed or for processing and food/feed containing traces of GMOs or GM material in a proportion not higher than 0.9% provided that these traces are adventitious or technically unavoidable.

- **Regulation (EC) No 1946/2003 on transboundary movements of GMOs**

At international level, the EU is a party to the Cartagena Protocol on Biosafety. The purpose of the Protocol, in line with the precautionary approach, is to ensure an adequate level of protection in the safe transfer, handling and use of GMOs that may have adverse effects on biodiversity and human health. To that end, it sets out common rules to be followed in transboundary movements of GMOs and provides for a central database (Biosafety Clearing House) to allow parties to exchange information on GMOs and help them to comply with their obligations under the Protocol. The Protocol's procedures concerning exports of GMOs are implemented in the EU by Regulation (EC) No 1946/2003 on transboundary movements of GMOs. In particular, the Regulation requires EU operators to notify the competent authorities of importing countries of exports of GMOs intended for deliberate release into the environment and to seek their consent prior to the first export. It also requires the Commission and Member States to inform the Biosafety Clearing House of relevant legislation and decisions on GMOs.

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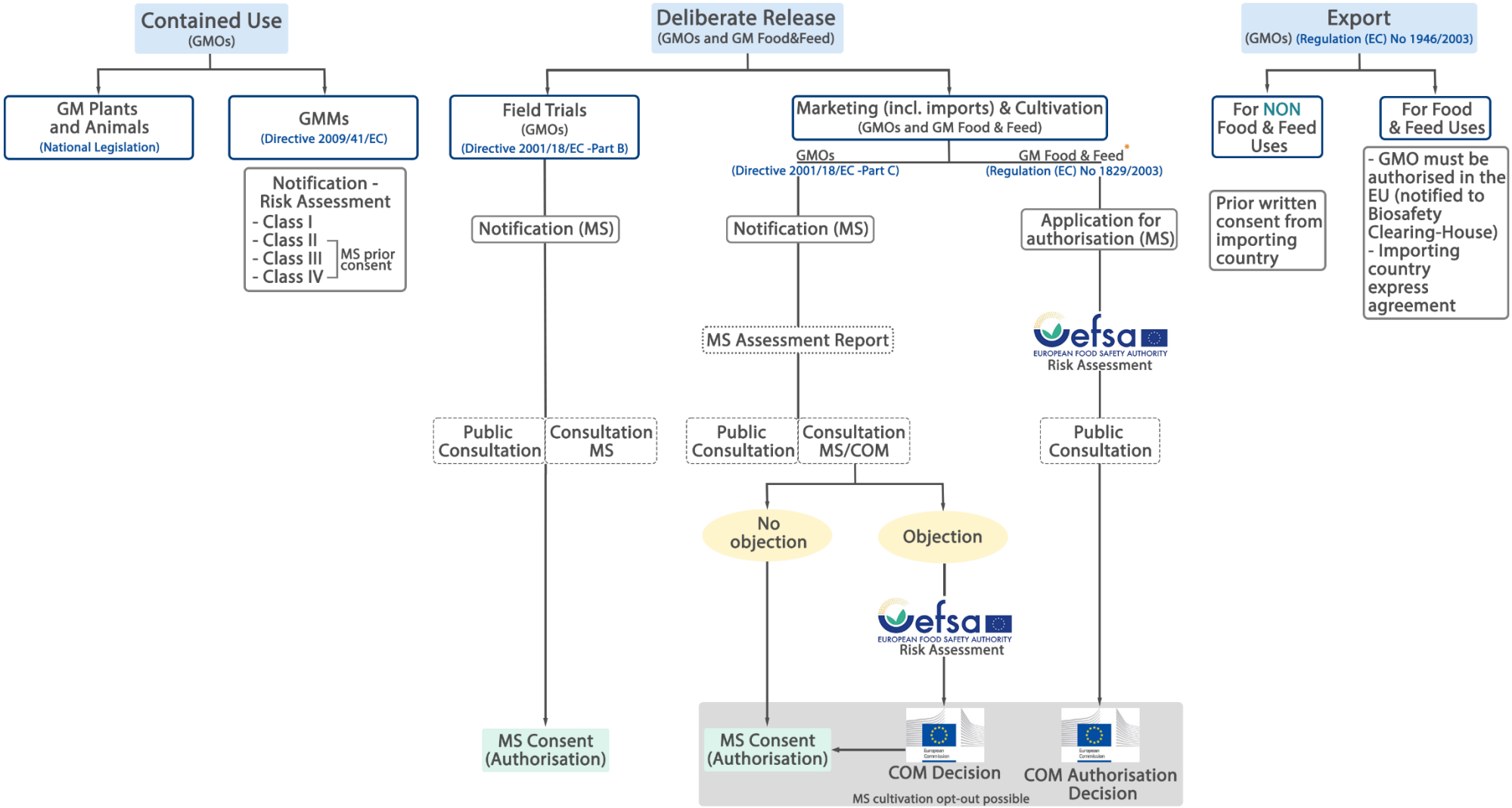
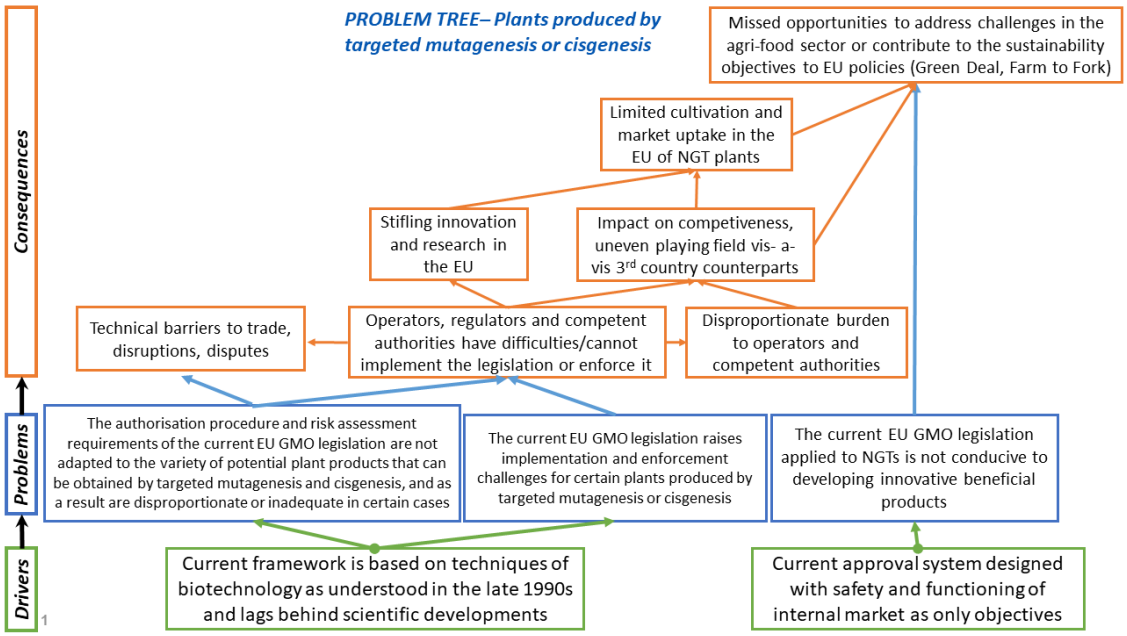
LEGAL FRAMEWORK ON GMOs AND GM FOOD & FEED



*GM Food & Feed: GMOs for food or feed use, food and feed containing or consisting of GMOs and food and feed produced from GMOs

Abbreviations: GMO - genetically modified organism, GMM - genetically modified microorganism, GM - genetically modified, MS - Member State, COM - European Commission, EFSA - European Food Safety Authority

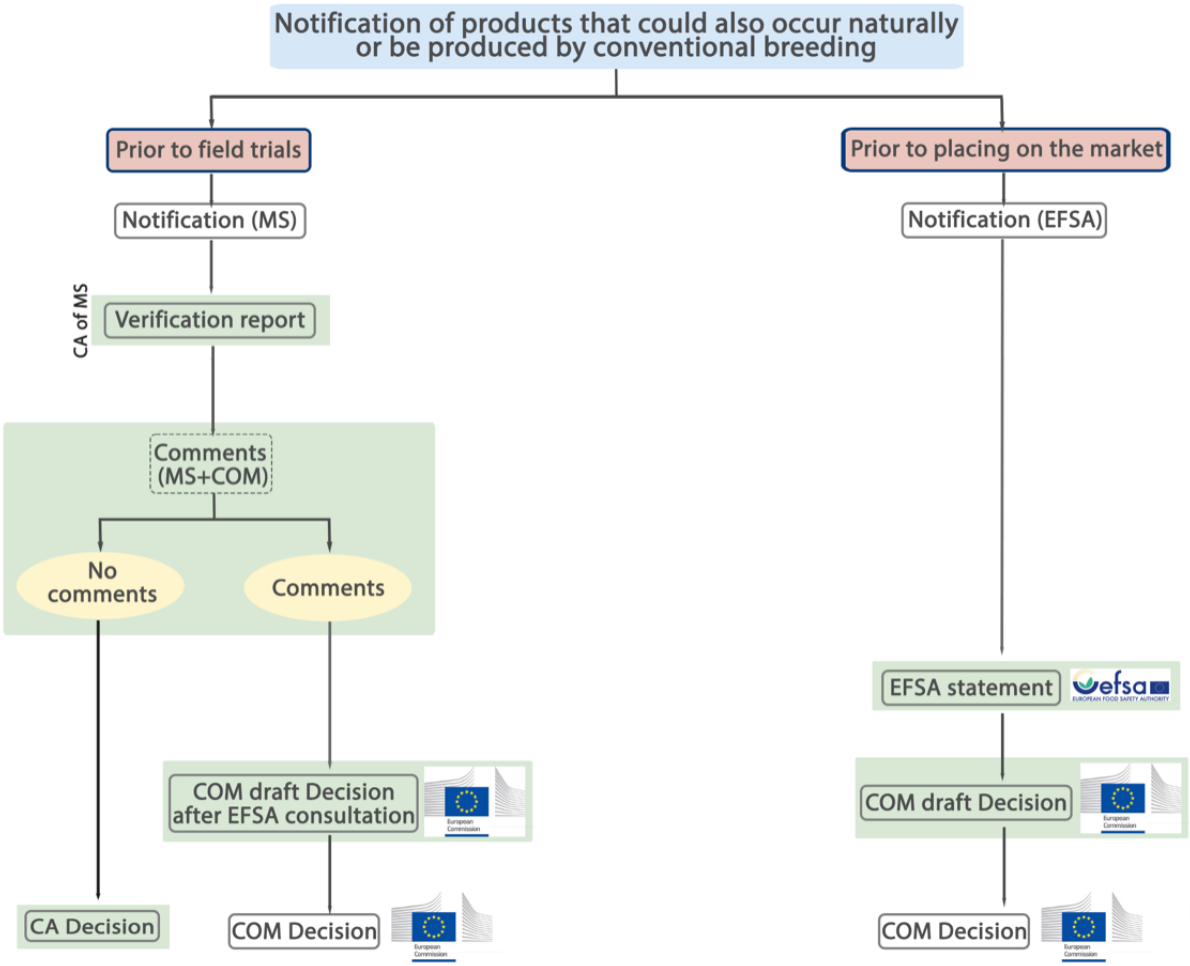
ANNEX 9: PROBLEM TREE



ANNEX 10: INTERVENTION LOGIC

Drivers	Problems	General Objectives	Specific Objectives	Results	Impacts
Current framework is based on techniques of biotechnology as understood in the late 1990s and lags behind scientific developments	**PROBLEM 1** The authorisation procedure and risk assessment requirements of the current EU GMO legislation are not adapted to the variety of potential plants/products that can be obtained by targeted mutagenesis and cisgenesis, and as a result are disproportionate or inadequate in certain cases	Maintain a high level of protection for human and animal health and for the environment in accordance with the precautionary principle.	Procedures for the deliberate release and placing on the market ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden	Authorisation procedure and risk assessment requirements fit the diversity of products	Operators, especially SMEs, see reduced burden and costs as well as more predictable timeline to develop new products
Current approval system designed with safety and functioning of internal market as only objectives	**PROBLEM 2** The current EU GMO legislation raises implementation and enforcement challenges for certain plants/products produced by targeted mutagenesis or cisgenesis	Enable the development and placing on the market of plants/products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies	Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers	Regulatory costs and administrative burden are reduced	Authorities have reduced administrative burden and more effective enforcement
	PROBLEM 3 The current EU GMO legislation applied to plants/products produced by targeted mutagenesis or cisgenesis is not conducive to developing innovative beneficial products	Ensure the effective functioning of the internal market and enhance the competitiveness of the EU agri-food sector at EU and global level, providing a level-playing field for its operators	NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system	Entry barriers to SMEs and public insitutions in plant breeding are reduced	Farmers have more varieties adapted to current needs
				Legislation is able to cater for scientific and technological developments	Consumers benefit from wider choice of products with desirable characteristics
				Academic/research institutions see more (funding) opportunities in the EU for their research in the area	Diversity of crops and traits is increased compared to crops developed with established genomic techniques
					More plant traits developed that contribute to a sustainable agri-food system

ANNEX 11: PROCEDURE FOR NOTIFICATION (OPTION 4)



Abbreviations: CA - Competent Authority, MS - Member State, COM - European Commission, EFSA - European Food Safety Authority

ANNEX 12: SME TEST

Step 1/4: Identification of affected businesses

SMEs form an important part of the plant breeding sector, with over 90% in some Member States of plant breeders being SMEs . The majority of EU farmers are small (and micro) enterprises. Under the current GMO legislation, the SMEs in NGTs and GMO plant breeding seeking authorisation for the release or placing on the market of products have, though, a very limited presence. This signals that the current legislation affects them negatively, with the exception of the organic sector. The latter is dominated by micro and small farmers and small organic breeders.

Key question: **To what extent is the initiative relevant for SMEs?** (not relevant, relevant, highly relevant)

This initiative is considered relevant for SMEs. Policy objectives of the initiative are aimed at reducing regulatory costs and regulatory uncertainty, both of which disproportionately affect SMEs. Moreover, there is an expectation that measures aimed at a level playing field vis à vis non-EU countries will benefit the internal market players, including SMEs. The initiative also aims at facilitating the application of NGTs to wider range of traits and of niche or locally important crop species, which often are the focus of SMEs, thereby opening the market to a greater diversity of players.

Step 2/4: Consultation of SME Stakeholders

SMEs have been explicitly integrated in the consultation strategy. For the different consultation methods, the following numbers (shares) of SMEs or associations representing SMEs participated:

- General Interviews: 11 business associations representing the various value chain segments which represent SMEs as well as large companies. 3 interviews with farmer organisations. 2 interviews with organic business stakeholders, mainly representing small companies (including farmers). Thus 16 out of 25 (64%) of the general interviews concerned business organisations that represented SMEs.
- Cost-benefit analysis (CBA): the CBA mapped costs for the biotechnology industry, processors, farmers, and retail. While regulatory costs are the same for all size classes of companies, SMEs have – for reasons already mentioned above- more difficulties to cover them. This is covered qualitatively. To understand the situation, out of five interviewed companies for the CBA, two were small firms.
- Targeted Survey: 8 out 122 respondents (6%) identified as SMEs
- Public consultation (PC): out of 179 companies/business associations 125 (69.8%) identified as Small and Medium Sized Enterprises (SMEs), comprised of medium companies (28; 15.6%), small companies (33; 8.4%), and micro-companies (64; 35.8%).
- Focus Groups: in two focus groups, six sector and farmer representatives joined (out of 14 participants). In particular, the small farmer's perspectives were taken into account through the inclusion of two farmer/organic farmer organisations.

Given that neither SMEs nor larger companies have much experience with GMOs and NGTs in the EU, most of the quantitative effects are based on expectations and qualitative assessment.

Step 3/4: Assessment of the impact on SMEs

Views from the public consultation in response to a question on necessary regulatory measures to facilitate the uptake of NGTs by SMEs indicate that mainly a stable, reliable, inexpensive framework is needed. Farmers voice that 'lower fees and easier and faster procedures will facilitate the uptake by SME' and it would be essential to 'secure a quick and low-cost administrative process'. The plant breeding/seeds sector indicated that 'the financial and bureaucratic hurdles should be kept as low as possible in order to grant SMEs the opportunity to use NGT'.

A potential loss of competitiveness is widely felt among the respondents of the PC in case there is no change in the current legislation, e.g.: "if we continue GMO regulation, it would mean that we as a small/medium-sized processing company do not in any way have a chance to use NGT" and that would imply a "loss of competitiveness with large competitors". NGTs have the characteristics of a less costly platform technology that could lead to an opening up of the plant breeding landscape from which a variety of SMEs could benefit. This has been observed in Argentina after its regulatory shift to excluding certain NGTs from the GMO definition.

The current GMO legal framework is not fit-for purpose for certain NGTs and their products (Commission NGT study, 2021). Costs for the required evidence and procedures do not differ between large companies and SMEs but large companies have different advantages and mitigation measures at hand: SMEs tend to be more vulnerable to regulatory requirements than larger firms, which benefit from economies of scale, in-house legal departments, diversification of risks, etc.). Under the current situation, SMEs are more likely to reduce their NGT-development effort. They are also less likely to shift product development to non-EU countries and are particularly sensitive to uncertainty. They have fewer financial reserves and cannot spread their risks over a broad portfolio. Any risks that might result in a lack or delayed market authorisation are therefore particularly affecting SMEs.

The preferred option is by far the most advantageous for SMEs compared to the current situation, as administrative and compliance costs will nearly be eliminated for those NGT products to which the notification procedure is applicable. Furthermore, the clear definition of objective notification criteria would reduce uncertainties and render the regulatory process more predictable for SMEs. It also has the strongest impact on competitiveness as a lower regulatory burden will enable investments in R&D and subsequent product development, both from large multinational plant breeders as well as SMEs. Regulatory incentives linked to the authorisation of NGT plants under the preferred option would facilitate access to and navigation of the regulatory framework, especially for SMEs, supporting their competitiveness.

The impact analysis shows that NGTs offer opportunities for small farmers, depending on the developed traits and plants. With (potentially) less land needed to obtain higher yield, less pesticides used to maintain healthy crops, less water is needed for irrigation, or crops being more resistant to biotic and abiotic stress, farmers expect to have economic gains. The gains will be somewhat offset by expected higher seed prices, but overall a positive economic impact is envisaged. In parallel, positive environmental effects (in particular on soil, water, air use and quality) would allow farmers to transform current farming practices into more sustainable ones.

In the preferred option, which is expected to result in the highest number of NGT plants on the EU market and where notified NGT plants would not be subject to labelling and traceability as GMOs, the highest negative impact on SMEs from the organic and GM-free sectors in the sector is expected, should notified NGT plants remain banned in the organic sector.

While from the legal point of view the NGT initiative is independent from the rules on the protection of intellectual property and does not address matters of application of the IPR legislation to NGT plants, the Commission has taken note of the concerns brought forward by certain stakeholders on the possible impacts on SMEs relating to the application of the IPR legislation, and will carefully consider them.

Step 4/4: Minimising negative impacts on SMEs

The preferred option maximises the positive impacts on SMEs in the breeding sector. The notification procedure in the preferred option would minimise costs for breeder as they undergo the same process as conventionally bred plant varieties. SME operators developing plants subject to the authorisation procedure with adapted risk assessment can benefit from regulatory incentives such as the additional regulatory advice and guidance or waiving of detection method validation fees and faster procedures. This particularly relevant for SMEs, which as a rule lack a regulatory department with dedicated staff. These will help lower barriers to market access and thus support SMEs competitiveness in the breeding sector.

As regards SMEs in the organic and GM-free sectors, in the case of authorised NGT products, the current mechanisms of the GMO legislation relied on by organic and GM-free operators will remain in place (traceability, labelling, national coexistence measures) and will impose obligations on all actors in the supply chain dealing with NGT plants. As regards notified products, a public register of NGT plants subject to notification will support the establishment of supply chains free from NGT products. As regards negative impacts resulting from, if NGT products subject to notification, which could be produced also by conventional breeding, were accepted in organic production, this would reduce the burden of establishing NGT free supply chains and the consequences of possible accidental admixture.