Study to support the impact assessment of legislation for plants produced by certain new genomic techniques

Final report

Written by Technopolis Group, Arcadia International and Wageningen University & Research

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Abbreviations

AOA	Area of Adaptation
AT	Austria
BE	Base editors
BE	Belgium
BG	Bulgaria
bn	Billion
CG	Cisgenesis
CRISPR	Clustered regularly interspaced short palindromic repeats
CS	Case study
CZ	Czech Republic
DE	Germany
DG SANTE	Directorate-General for Health and Food Safety
DK	Denmark
DNA	Deoxyribonucleic acid
DUS	Distinct, Uniform and Stable
EC	European Commission
ECJ	European Court of Justice
EE	Estonia
EFSA	European Food Safety Agency
ES	Spain
EU	European Union
FG	Focus Group
FI	Finland
FR	France
FSFS	Framework for Sustainable Food Systems
GM	genetically modified
GMO	genetically modified organism
IPRs	Intellectual Property Rights
IT	Italy
JRC	Joint Research Centre
LV	Latvia

MS	Member States
n.a.	not available
NA	National authorities
NBTs	New Breeding Techniques
NGT	New Genomic Technique
NGTs	New Genomic Techniques
NL	Netherlands
NPBT	New Plant Breeding Techniques
ODM	Oligonucleotide-directed Mutagenesis
PC	Public consultation
PL	Poland
PMEM	Post-Market Environmental Monitoring
PT	Portugal
Q	Question
QR	Quick response
R&D	Research and innovation
RO	Romania
SDGs	Sustainable Development Goals
SDN	Site-directed Nuclease Technology
SE	Sweden
SI	Slovenia
SK	Slovakia
SMEs	Small and medium size companies
SWD	Staff Working Document
SQ	Survey question
TALENs	Transcription activator-like effector nucleases
TM	Targeted mutagenesis
UAA	Utilised agricultural area
UK	United Kingdom
US	United States of America
VCU	Value for Cultivation and Use
ZFN	Zinc-Finger Nuclease

1 Introduction

The present study contains the findings of the work undertaken on behalf of the European Commission (EC) to support an Impact Assessment of legislation for plants produced by certain new genomic techniques. The study is carried out under the Framework Contract SANTE/2021/E3/086. It is accompanied by a set of annex documents which provide the details on approaches, methods used, as well as results.

This report includes within this introductory chapter a table on the methodology applied. Eight annexes, included in one document, provide more details. Annex 1 provides the synopsis report while details on the methodology are included in Annex 2. The analysis of the targeted stakeholder survey is included in Annex 3, the analysis of the public consultation (PC) and its summary are both integrated in Annex 4. Developed mini case studies are included in Annex 5 and the focus groups' reports are integrated in Annex 6. The costs are included in the accompanying Annex 7 while the modelling details are covered in Annex 8. A data file (in MS-Excel) is provided separately to Annex 7.

1.1. Scope of the study

The evidence collection for this support study was carried out between April and December 2022. Changes in the formulation of the policy objectives which were put forward following this period are introduced in this study, however, findings from the study period may not reflect those changes.

The structure of this final report follows the Commission's Better Regulation Guidelines on impact assessment reports.

1.2. Methodologies applied

The following provides an overview of the methods used. Details on the data collection (e.g., selection criteria, analytical processes, difficulties encountered), as well as results are included in several individual annexes, which are accompanying the main study report.

Table 1 Data and information collection and analysis

Method	Implementation	Use	Relevant Annex with details
Desk research	Identification of relevant documents, systematic analysis, screening of documents on impacts	Identification of impact areas, data, experts.	Annex 1 – Synopsis Annex 2 – Methodology
Stakeholder interviews	Interviews carried out with different stakeholders	Insights/findings included in full analysis	Annex 1 – Synopsis Annex 2 - Methodology
Regulatory cost assessment	Exploratory interviews with various cost related relevant stakeholders. Interviews, data collection, validation with agreeing organisations.	Insights/data from regulatory cost interviews core to efficiency (costs) analysis.	Annex 1 – Synopsis Annex 2 – Methodology Annex 7 – Cost assessment
Public consultation	Implemented by DG-Sante, study team to analyse and synthesise results	Insights from PC to feed the relevant impact sections	Annex 1 – Synopsis Annex 2 - Methodology Annex 4 - PC

Method	Implementation	Use	Relevant Annex with details
Targeted stakeholder survey	Development of a survey for wide set of targeted stakeholders. Collection and analysis of survey results	Insights feed into all sections of the study report	Annex 1 – Synopsis Annex 2 - Methodology Annex 3 – Targeted stakeholder analysis
Case studies	Case studies developed to obtain further insights on specific aspects for which survey was not conceived. Implemented through desk research, literature analysis, and interviews	Insights from cases included in background and impact sections.	Annex 1 – Synopsis Annex 2 - Methodology Annex 5 – Case studies
JRC case studies	JRC provided two in-depth case studies.	Analysis and integration of all the two cases integrated in impact sections (illustrative examples).	To be published by the JRC
Focus groups	Two focus groups on *Sustainability* and *Traceability* with set of stakeholders	Insights to be integrated in the draft final report.	Annex 1 – Synopsis Annex 2 - Methodology Annex 6 – Focus groups
Data modelling	Developed model, validation workshop with experts, collected of data	Insights integrated in the impact sections.	Annex 1 – Synopsis Annex 2 – Methodology

1.3. Impacts considered for this assignment

Based on the desk research and document analysis, internal expert workshops, and the guidance of the Better Regulation Tool #18, the Study Team selected impact areas along different causal layers and across economic (section 4.2), environmental (section 4.3), and social impacts (section 4.4). Health and fundamental rights were also addressed and included in social impacts. For economic impacts, detailed analysis was done at the level of value chain actors, distinguishing between conventional, organic, and GMO-free value chains. Regulatory costs (section 4) were assessed following the Better Regulation Tool #56.

1 Background and problem analysis

1.1 Background

Considering the facts that 1) NGT are new technologies that can be used to develop new crop varieties, and that 2) there are currently no NGTs on the market in the EU and very few ones at international level, the NGT market can only be presented via the characteristics of the European seed market in the global context (Section 1.2) and the presentation of the R&D pipelines on NGTs (Section 1.3).

1.2 Key sectoral figures

The global commercial seed marketplace, which continues to experience a robust growth, approached a value of US$ 63 billion (€57 bn) in 2021 and is projected to grow at a compound annual growth rate of 6.6% to reach US$ 86.8 billion (€79.6 bn) in 2026.

The seed marketplace includes 'true' seeds of plant varieties but also seed potatoes, tubers, bulbs and fruit and ornamental trees that are propagated vegetatively, summarized in legal terms as plant reproductive material. The growing demand for seeds from the food, beverage, animal feed, and biofuels industry is driving the growth of the market (USDA 2022). Maize and soybean, representing nearly 50% of the global seed market, are by far the two largest seed crop markets. Traditionally, the seed markets were national markets with quite a low volume of international exchanges. This has changed during the last 50 years. The seed trade is estimated to have more than tripled between 1970 and 1994, quadrupled between 1985 and 2005, and tripled again between 2005 and today.

The European Union is the third-largest **seed market** in the world after the United States and China, accounting for approximately 20% of the global market (Ragonnaud 2013). The EU's seed market is currently valued at around €10 billion. Net exports stand at €2.5 billion for 2020, with an export market around €10 billion, and imports of €7.5 billion (International Seed Federation, n.d.). Within the EU, France, Germany, Italy, Spain, and the Netherlands combined account for two-thirds of the EU market (with France accounting for nearly one-third of the EU market's total value) (EC 2013). A widely used figure is that an estimated 7.000 firms are active in the seed industry across the various stages of the supply chain in the EU. Next to large multinational companies, powerful family-owned companies (and cooperatively owned companies, most of the SME's active throughout the seed market (about 80% of the total number of companies), from breeding to production and distribution, are listed in Poland, Romania and Hungary (EC 2013). The European seed association (Euroseeds) estimates that the EU commercial seed (true seeds only) market value has reached approximately about €10 billion and represents more than 20% of the total worldwide market for commercial seed. The EU is the largest seed exporter with an estimated export value of €2.7 billion representing more than 60% of the total worldwide export value of €4.9 billion. This evolution is unique in the agri-business sector, especially when comparing the European seed market evolution with other agricultural inputs where the market has been relatively flat during the last 15 years.

For several decades after plant breeding emerged as a recognised field of science in the late 19th century, almost all plant breeding activities took place in public institutes with a gradual shift of breeding activities to the private sector during the 20th century. The seed industry matured due to the introduction of hybrids, especially hybrid maize in North America, hybrid sugar beet in Europe, and hybrid vegetables in South-East Asia. In North America and Europe, the hybrid seed industry grew from regionally based family businesses. The profitability of hybrids far outstripped that of non-hybrid open pollinated varieties. This led to eventual consolidation in the industry and the dominance of several key companies in particular crops, notably in the major field crops. In the 1970s, these high margins attracted the attention of several agrochemical companies, waiting to exploit possible synergies of the seed business with their own line of business (e.g., the acquisition of Northrup King (USA) by Sandoz (Switzerland)). The emergence of biotechnology in agriculture in the 1980s has led to a complete reorganisation of the sector. Today, leading seed groups are largely owned or allied with the world leading chemical/plant protection companies. Consolidation through mergers and acquisitions took place in major field crops and in the vegetable sectors. Chemical companies' interests in investing in biotech are linked to the fact that many pesticides used in agriculture may be replaced by transgenic crops, which have a biologically inbuilt resistance. In 1996, the world top 10 seed companies were representing about 37% of the worldwide market value; in 2004, the top 10 accounted for nearly 50% of the value of the worldwide-certified seed market. Monsanto (now Bayer), the actual market leader was not present in the top 10 in 1996.

The European seed sector with about 52.000 employees, is characterised by a large segmentation (from specialised SMEs to international companies with a multi-crops approach). The "seed sector" is not one sector but several crop sectors in constant

evolution, which are becoming more and more differentiated in terms of type of products, type and number of actors, competitiveness, product life cycle, R&D efforts, added value, and return on investment. The EU seed sector is still made up of a majority of small and medium size companies (SMEs) which predominantly use Plant Breeders' Rights as a means to protect their varieties. As mentioned above, industry consolidation that started about 20 years ago happened in field crops areas and vegetables. Genetic material, biotechnologies, and their associated Intellectual Property Rights (IPRs) like the introduction of patents on plant species in Europe have been in fact leading to a new restructuring of the relations between agrochemical, biotech, food processing, and seed companies. Plant breeding, performed in more than 750 R&D stations all over the EU, considered in the past as a "secret" and "non-scientific" activity, is moving to a high-tech industry involving more and more trans-national companies. This consolidation has created a visible break between biotech-in and biotech-out companies[1] between those entities with biotechnological capacity inside of their own structure, and those which need to outsource such capacity to third parties.

In the EU15 member states[2], the number of employees in the private seed sector amounts to around 30.000. The personnel involved in private R&D (plant breeding) are around 5.000 and these are working in around 600 major research stations according to Euroseeds' figures. Plant breeding is essential for the release of plant varieties well-adapted to diverse growing conditions, capable of reacting to biotic and abiotic stresses notably through resistance to pests and diseases and fulfilling the quality requirements of the food and feed industry. We observe two major groups of breeders as follows:

- The SMEs -they breed for their local/national markets and to develop partnerships with foreign seed partners for the purpose of testing/positioning and, when relevant, for the marketing of their existing cultivars in other countries characterised by specific growing conditions (breed locally - test globally). Among this group are also dedicated so-called biotech firms.

- Larger companies - their breeding strategy follows mainly a wide European and/or a global approach (e.g., maize). This consists in breeding for a given Area of Adaptation (AOA), which could be defined as an area where agro-climatic and plant growing conditions are uniform (breed globally - test locally). Many of these large companies use or buy out specialised, often small so-called biotech companies to support the breeding process.

- As of 2019, farmers cultivate approximately **190 million hectares of GM biotech crops** in the world (ISAAA, 2019)[3]. GM crops are currently planted in 34 countries (Genetics Literacy Project, n.d.). The highest growth rates were seen in Asia and Africa (ISAAA, 2020) where the number of adopting countries (countries that allowed GM cultivation) doubled in 2019. The four primary crops are soybeans (~50%), maize (~30%), cotton (~13%) and canola (~5%) (ISAAA, 2019). The products are not traditionally destined for human consumption. Soybean crops for example provide soybean oil as well as industrial adhesives, solvents and lubricants whilst the soybean meal is a high protein constituent in animal feed. GM cotton accounts for 79% of total cotton cultivation and remains an important natural source of fibre. The oil of the remaining seed is also used for human consumption. Maize has shifted from animal feed to ethanol production in the last two decades. Of the total global production of maize, 55%

[1] Agricultural biotechnology is an area of agricultural science involving the use of scientific tools and techniques, including genetic engineering, molecular markers, molecular diagnostics, vaccines, and tissue culture, to modify living organisms: plants, and microorganisms. Biotech-in companies are using such techniques, biotech-out are not.

[2] Consolidated data for the other 12 member states are not available

[3] The Land Area of the World is 13,003 million ha. 4,889 million ha are classified as 'agricultural area' by the FAO (this is 37.6% of the Land Area).

was utilized as feed, 20% to other non-food uses and only 12% as food (Turnbull et al, 2021 using FAO data).

In the EU, the only transgenic event commercially grown is maize MON810. MON810 is mainly cultivated in Spain since 1995. GMO imports are more common. Currently, 290 single and stacked transgene events are authorised for imports. Since 2015, 19 of the 27 EU member states have applied for "demands for restriction of the geographical scope of a GMO application or authorisation", which restricts/prohibits the cultivation of GMOs in their country.[4] The stringency manifests itself also in the number of field trials: between 2008 and 2014, 387 trials were counted, while from 2015 to 2022 only 63 were counted (JRC, 2021).

The EU's **organic market** is now estimated to be worth about €37.4 billion per year. Although the EU's organic farmland has increased over the years, from 10 million hectares in 2012 to 14.7 million hectares in 2020 (Eurostat, n.d.), it still only uses 9.1% of the total agricultural area in 2020. Countries with the highest share of total utilised agricultural area (UAA) in 2020 were Austria, Estonia, and Sweden, while the lowest shares are found in Bulgaria, Ireland and Malta. In Austria, the share of organic farming area was 25.7% of the total UAA in 2020, followed by Estonia (22.4%), Sweden (20.4%) and 16% in Italy. The lowest shares are found in Ireland (1.7 %), Bulgaria (2.3%), Romania and Poland (3.5% each) and the Netherlands (4%). The number of organic operators by status of registration across the EU27 was close to 300.000 in 2016, with the highest numbers found in Italy (approx. 65.000 operators) Spain (36.000 operators), followed by France (approx. 32.000 operators, while Sweden accounted for 5.700 operators in 2016, a number which has decreased to 5.500 in 2020, despite the growth in organic farming area in the country. According to sectoral data, retail sales of organic products of both products produced in the EU and imported products is valued at €44.9 billion in 2020 across the EU-27, showing an increase of 151% between 2011 and 2020[5].

The difference between demand and production of organic products is covered by increasing imports. Total imports of organic agri-food products in the EU have increased from 2.79 million tonnes in 2020 to 2.87 million tonnes in 2021, showing an increase of 2.8% (EC, 2022a). The EU organic seed market is valued at around €1 billion today. While the required amount of organic propagated seeds to be used in organic production in the EU was estimated at 167.270 tonnes, data on the supply and demand of organic seeds remains disparate (Solfanelli et al, 2022, Solfanelli et al, n.d). Based on results of the survey of LIVESEED on major field, fodder, vegetable, and fruit crops, it is estimated that the supply of organic plant reproductive material covers only half of the demand (Solfanelli et al, 2022).

1.3 NGT Market Update

Scientific developments of plant breeding technologies have continued and have reached - by scientific means - extraordinary speed, posing regulatory concerns. Discoveries such as CRISPR-Cas9 and their technological uptake, were adopted by the plant breeding scientific communities as new breeding techniques (NBTs) or new genomic techniques (NGTs). In comparison to older biotechnological methods developed mainly before the year 2000 ("classic", or "established genomic techniques", GMOs) they use genetic modification techniques but do not introduce genes from outside the gene pool, i.e., transgenes of unrelated species into the final varieties. The European Commission's study on new genomic techniques (2021) and the JRC study titled "current and future market applications of new genomic techniques" (2021) provide a thorough overview of the R&D pipelines regarding NGT based traits. In addition, the EU-SAGE

[4] For Belgium: this applies to Wallonia only.

[5] Data provided by IFOAM Organics Europe, compiled by Research institute of organic agriculture (FibL) supported by Agricultural Market Information Company, based on Eurostat and national data sources, see https://www.organicseurope.bio/about-us/organic-in-europe/

database[6] provides also robust evidence on the agriculture-relevant research pipelines. The three sources of information show genome editing is used in over 60 crops to improve diverse characteristics, many of which are aiming to contribute to more sustainable agriculture. A major difference with GMO-related R&D is being observed in terms of a higher number of crops in which NGTs are being applied, a wider range of R&D actors (ranging from SMEs to large companies), and greater diversity of traits present in NGTs compared to 'classic' GMOs.

There is already a large pipeline worldwide of more than 427 applications of genomic techniques for at least 28 different plant species (JRC, 2021), although only a few have reached the market so far: a higher oleic-acid soybean of Calyxt, commercialised in the USA ('Calyno') (ISAAA, 2019a), an herbicide-resistant canola (CIBUS, 2009), and a tomato with a non-proteinogenic amino acid (GABA) commercialised under the name Sicilian Rouge High in Japan (Waltz, 2021).

According to IHS Markit (2020) (cited in Global 2000/IG Saatgut, 2022), there were nine companies active in NGTs in the area of food ingredients; Ricroch et al (2022) identified several more.[7] They are predominantly spin-offs of companies and research institutes which target more often niche crops such as hemp, berries, mustard, avocado etc., while the large agro-seed companies such as Bayer, BASF, Corteva or Syngenta focus on the cash crops such as soybeans, maize, or rice (Global 2000/IG Saatgut, 2022).[8] The majority of the NGT-based, approved (not necessary all marketed) plants in the USA (74) have a 'nutritional improvement' (49), while 15 are on biotic and two on abiotic stress. Four are on herbicide tolerance (Ricroch et al, 2022).

In the demonstration phase are field pennycress in the USA (CoverCress, n.d.), and a vitamin-D tomato underwent field trials in the UK (Vaughan 2022). A mustard green (*Brassica juncea*) is currently tested on the market and expected to be available in 2023 (pairwise, 2022).

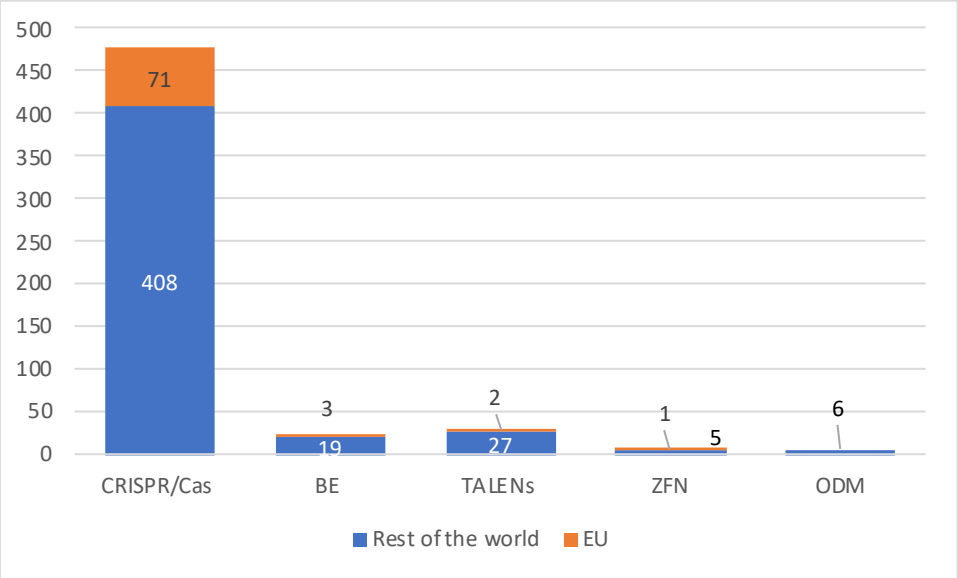
Out of the 427 covered studies in the EU-SAGE database (as of 06.08.2022), 16 are in pre-commercial stage, 117 in advanced R&D, and 292 in early R&D. Only 90 applications are developed in the EU, of which zero in pre-commercial stage, 28 at the advanced stage R&D and 62 at the early-stage R&D. The EU-SAGE initiative maps and continuously updates the development and use of new genetic techniques globally. Today, about 88% of current world plant research uses CRISPR/Cas. In terms of the research on trait categories, about 23% are on traits on improved food/feed quality and increased plant yield and growth. This is followed by biotic stress tolerance (18%), and 14% for industrial utilisation (see Figure 2).

[6] https://www.eu-sage.eu/

[7] The identified companies are predominantly from the US, yet, there are equally companies from Israel, Japan, and Korea with Arcadia Biosciences, Agrivida, Benson Hill Biosystems, Calyxt, Cellectis Plant Sciences, Cibus, Corteva Agriscience, CoverCress, Donald Danforth Plant Science Center, DuPont Pioneer, Evogene, Green Venus, Inari Agriculture, J.R. Simplot Company, Pairwise Plants, Precision Biosciences, Sanatech Seed, Soilcea, ToolGen, Tropic Biosciences and Yield10 Bioscience.

[8] The JRC (2021) market update study equally noticed that among the "rich pipeline" are "*also plants that usually do not receive a great deal of attention from developers and researchers because of smaller turnovers*" (p.17)

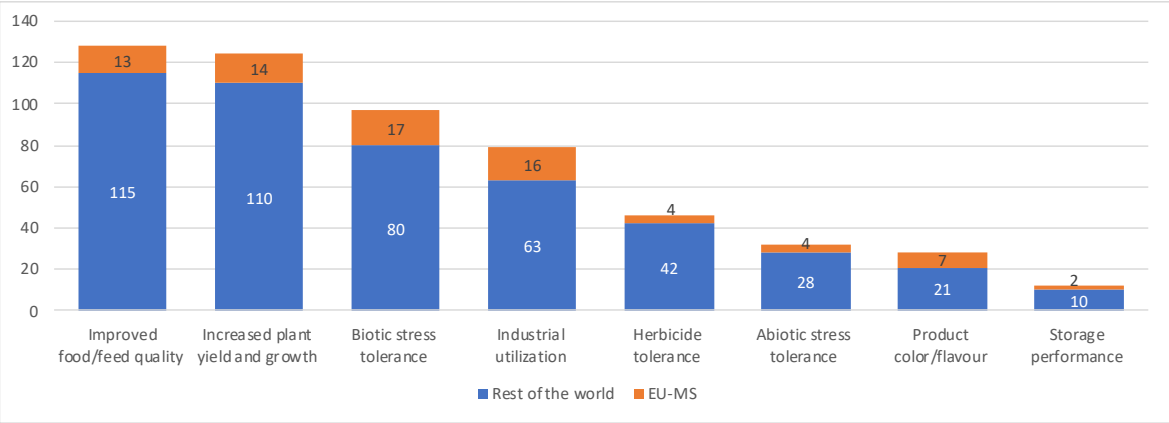
Figure 1 Current main genome editing techniques in crops



Data: EU-SAGE; database accessed 6.8.2022

Note: BE – Base editors, ZFN – Zinc-Finger Nuclease, ODM - Oligonucleotide-Directed Mutagenesis, TALENs - Transcription activator-like effector nucleases, CRISPR/Cas - clustered regularly interspaced short palindromic repeats/CRISPR associated protein

Figure 2 Research on traits by objective (2022)



Data: EU-SAGE, database accessed 6.8.2022

According to the EU-SAGE database, globally, the majority of the research on crops using NGTs is conducted in China, followed at some distance by the US. Only 14% of the research on crops using NGTs takes place in the EU. Main EU-research Member States are France, Germany, Italy, and the Netherlands. In terms of species, 19 research teams focus on tomatoes, followed by 10 on rice, and 9 on potatoes. Barley, oil seed rape, maize, tobacco, and apples are researched by three to seven groups. About 12 other plant species are researched by one or two studies.[9]

European-level research on potential risks and detection methods has not been funded throughout the Horizon 2020 research programme despite some calls for action (Foote 2022, Meunier 2021). EU-level research on genome editing was, however, funded in

[9] Data of EU-SAGE as of 6.8.2022.

H2020 projects, in COST actions and through the ERC. The survey of the EC in 2020 on NGTs and the monitoring of the OECD 2022 provide insights on national-level projects.[10]

1.4 Challenges of detection

The present GMO regulation has been reported to be challenged by technological developments already in 2010-2011, and with NGTs, this situation has become even more noticeable. Common or specific genetic characteristics that are being used as a target to detect and to quantify GM plants are often not available in genome edited plants. The Commission Study (2021) confirmed that such genomic changes challenge the implementation and enforcement of the current regulatory system in the EU, including coexistence. If the genetic alteration introduced by NGTs is not unique for the relevant product, a specific detection method cannot be provided. Although existing detection methods may be able to detect small alterations in the genome, this does not necessarily confirm the presence of a regulated product, as the same alteration could have been obtained by conventional breeding. Therefore, it requires information about the application of NGTs and the introduced alterations in order to identify NGT products.

1.5 State of the regulation

Regulations in 36 countries[11] where transgenic or gene edited crops and animals are commercially allowed are guided partly by two factors:

1. **Adoption of the Cartagena Protocol on Biosafety** of 2003. The protocol ensures the safe handling, transport and use of living modified organisms and considers potential risks to human health. It applies a precautionary approach. The protocol was not signed by the US, Canada, Australia, Chile, and the Russian Federation.[12]

2. **Product versus process regulation**. The distinction applies to regulations based on the genetic *process* used to create the trait (mutagenesis, transgenesis, gene editing, etc. and the methodology for introducing these NGTs into the plant cell) or the final *product.* The US, Canada, Argentina, Uruguay, the Philippines, and others use a product-based regulation while the EU, Brazil, India, China, South Africa or New Zealand use process regulation.

1.5.1 The situation in the EU

In the EU, the legal framework regulating GMOs is centred around the protection of human health and the environment. It is based on the precautionary principle stemming from the development of international environmental law. Equally, it emphasises the need for a comprehensive and transparent legislative framework, and the need to ensure an efficient common market under harmonised rules (Bruetschy 2019).

The first law for authorising experimental releases and for placing on the market of genetically modified organism (GMOs) in the European Community was the Directive 90/220/EEC[13] in 1990. The Directive requested Member States to perform an

[10] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques/stakeholders-consultation_en#replies-from-member-states; OECD (2022), for COST actions, see e.g., https://plantgenomeediting.eu or https://iplanta.univpm.it

[11] Argentina, Australia, Bangladesh, Bolivia, Brazil, Burkina Faso, Canada, Chile, China, Colombia, Costa Rica, Czech Republic, England (UK), Estonia, Finland, Flanders (Belgium), Honduras, India, Ireland, Kenia, Mexico, Myanmar, Pakistan, Paraguay, Philippines, Portugal, Romania, Slovakia, South Africa, Spain, Sudan, Sweden, Uruguay, USA, Vietnam. See: https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/ the overview refers to 2015 data. Added: EU-MS allowing GMO cultivation, Kenia (allowing GMOs in 2022).

[12] The application of the precautionary principle is perceived by some countries as being in conflict with a science-based risk assessment method and thus a potential trade barrier (see Falkner 2000).

[13] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

environmental risk assessment prior to authorisation. Several Member States established guidelines and requested clear labelling and traceability system for GM foods (Fernando-Macvean 2013). Directive 90/220/EEC was amended and reviewed and repealed through Directive 2001/18/EC in 2001.

Especially around the time of the adoption of Directive 2001/18/EC,[14] Member States had opposing and persistent views. The EU legal framework remained at an impasse regarding authorisations to import but especially authorisations to cultivate GMO's (Wesseler & Kalaitzandonakes 2019), despite numerous attempts to resolve the deadlock of the comitology procedure, including granting more flexibility to Member States at national level (Inghelbrecht et al 2014).

The **precautionary principle** is the most common and influential argument for placing techniques under the EU regulations for GMOs: "Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs." (Article 4 of Directive 2001/18).

Beside the precautionary principle, the European law provides for the **right of freedom of choice** and demand of society for improved transparency along the value chain. This principle is anchored in the EU legal system and applies irrespective of safety considerations. It provides citizens consumers, farmers, food producers, etc. with the right to choose between products with and without genetic engineering. Safeguarding the choice regulates the cultivation, handling, transport, and processing of GM products so that uncontrolled mixing with conventional production is not allowed. The principle allows for adventitious presence (0.9%) of authorised GMOs in non-GMO products. Up to this tolerance level, labelling is not required.

1.5.2 Changes in legislation - EU neighbourhood countries and abroad

On 18 March 2022, the **Swiss** parliament debated that those plants bred with new methods such as the CRISPR/Cas, in which no new transgenic genetic material has been inserted, might no longer be treated as conventional GMOs. Switzerland had banned the use of genetically modified plants in the country since a referendum in 2005. In 2016, when the moratorium was extended for the third time, the Swiss Cabinet included a recommendation for the creation of separate GM crop zones from 2021, depending on farmer interest. In essence, this enables a coexistence of GM crops and GM-free agriculture. By mid 2024, the Federal Council will submit a proposal for "risk-based authorisation". This development is also supported by a Swiss study analysing consumer opinion (Saleh et al 2020) which suggests a new generation of consumers more open to innovative solutions in agriculture.

The **UK** announced that future field trials with precision-bred techniques will no longer fall under the GMO-regime.[15] Instead, a simple application will suffice. New rules for approval and cultivation are to follow. The British government aims to promote the research and development of new plant varieties that significantly reduce the use of pesticides and herbicides and make them more resistant to weather conditions and climate change.

Many **other third countries** have adapted their legislation following the shared view that if no foreign DNA is present in a genome-edited plant and if it could have been created through natural, random mutation, it is treated like a conventionally bred plant. If foreign genes or larger DNA segments have been inserted into the genome with genome editing techniques, then these plants are considered GMOs and fall under the

[14] 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 and repealing Council Directive 90/220/EEC

[15] Genetic Technology (Precision Breeding) Bill, see https://bills.parliament.uk/bills/3167

relevant safety requirement legislation. Countries like Argentina, Australia, Israel, and more recently China and India apply this as a principle. Countries such as the US, Canada, or Brazil follow a case-by-case approach.[16]

1.5.3 The 2018 ECJ ruling

In 2018, the European Court of Justice (ECJ) ruled that organisms obtained by means of targeted mutagenesis techniques/methods are subject to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. This Directive legislates genetically modified organisms. created by inserting genes from another species (e.g., transgenic crops). Also the introduction of genes from the same or related species (e.g., cisgenic crops) falls under that definition. In the 2018 ruling, the ECJ interpreted the meaning of the mutagenesis exemption (Annex IB) in the sense that it "*must be interpreted as meaning that genetically modified varieties obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are exempt from the obligations laid down in that provision*." (C-528/16). The exemption applies to more than 3.000 plant varieties which were created through other forms of 'classical' mutagenesis since the 1930s.[17]

The ECJ based its decision on a specific understanding of the precautionary principle in relation to risks legally associated with GMOs. The precautionary principle has been the most influential argument for interpreting that techniques of directed mutagenesis fall under the EU regulations for GMOs. As specified in Article 4 of Directive 2001/18, "*Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs*."

The ruling received a mixed reception. It was welcomed by various consumer organisations, GMO-free and organic agriculture sectors alike since it confirmed that directed mutagenesis has to be treated as a GMO technique and thus, the strict GMO regulation applies as well to the new techniques. A significant share of the scientific community was critical toward the ruling, arguing that gene editing is not "genetic modification" because the changes introduced into the DNA are no different from changes that can occur during conventional breeding or in nature (Turnbull et al 2021). In 2019, the three national German scientific societies, the German National Academy of Sciences Leopoldina, the Union of German Academies of Science, and the German Research Foundation (DFG)—published recommendations for a "scientifically justified regulation" of genome-edited plants in the EU.

Following the ruling, the Council of the European Union requested a study and proposal on the status of "new genomic techniques". This study by the EC was submitted in April 2021. It concluded that the current legal framework is not fit for purpose for some NGTs, and that it needs to be adapted to scientific and technological progress.

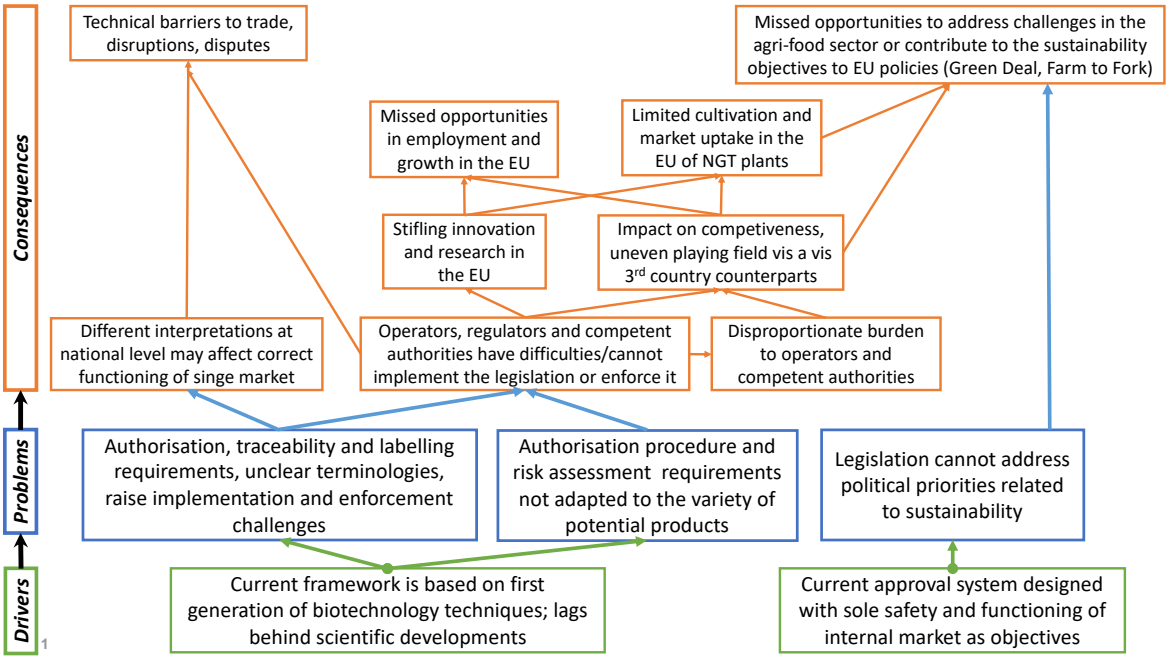
[16] For the US, the 'Am I regulated' process was replaced in 2020 by the SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient) Rule, see https://www.wiley.law/alert-USDAs-New-Rule-Modernizing-the-Regulation-of-Biotechnology-A-Practical-Legal-Summary. Canada regulates any product that contains novel traits regardless of the process used to develop the product. In Brazil every product is evaluated on a case-by-case-basis. Gene-edited crops and food are regulated as conventional plants unless they contain foreign DNA, after a dossier is submitted to determine if they are exempt.

[17] 'Classical' mutagenesis falls under a GMOs but was exempted for a "history of safe use". The exemptions are listed in the IAEA database. See also https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/european-union-crops-food/

1.6 Problem assessment

The following Figure 3 provides the overview of the problem, its drivers and effects, as developed by DG SANTE.

Figure 3 Problem tree



Source: DG Sante

2 Policy options

Based on the initial policy options stemming from the inception impact assessment of the EC in 2021, general and specific objectives were formulated. The EC developed slightly revised formulations which are integrated as well. Yet, for the empirical work of the support study (interviews, targeted survey, focus groups) the initial general and specific objectives served as the basis.

2.1 General objectives

The general objectives of a new legislative proposal are equally embedded in the current legal framework: maintaining a **high level of protection of human and animal health and of the environment in accordance with the precautionary principle.** The connectedness between these different aspects is often summarised under the 'One Health' concept.

The framework equally aims to provide a level playing field and thus **enhance the competitiveness of the EU** agri-food market and to ensure the effective functioning of the internal market.

A new objective is added following the policy priorities of the European Commission. Its aim to attain the Sustainable Development Goals (SDGs) with its overarching European Green Deal policy and the integrated Farm to Fork and Biodiversity strategies require adaptation of existing policy and legal frameworks to effectively **contribute to sustainability**. Enabling the development and placing on the market of plants and derived food/feed products that can contribute to the innovation and sustainability

objectives of the Green Deal and of the Farm to Fork and Biodiversity strategies is thus a new general objective.

2.2 Specific and operational objectives

The general objectives can be broken down into a number of specific objectives. For the purpose of the Impact Assessment, we further separated these specific objectives in operational objectives. To some extent, they are reflecting the impact areas considered (e.g., environmental, health). They are not explicitly taken into account in the summary analysis of the policy options (Chapter 6). Yet, they are key in the impact analysis. Both are presented in Table 2 below.

Table 2 Objectives, specific and operational objectives

General objectives	Specific objectives	Operational objectives
G1: Maintaining a high level of protection of human and animal health and of the environment	**S1:** The regulatory requirements for plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products need to be proportionate to the risk involved. This suggests tailored risk assessments compared to the current assessment requirements.	S1A: Authorisation procedure and risk assessment requirements need to fit the diversity of products (fit for purpose)
G2: Effectively **contribute to the sustainability goals of the EU**	**S2:** The new/amended legislation is conducive to the development and placing on the market of plant products that can contribute to a **sustainable agri-food system**. This specific objective addresses several interlinked aspects such as a sustainable agri-food system in Europe that **limits environmental pressures**. In an international perspective, the EU agri-food sector is equally exporting beyond the EU and can thus contribute to global sustainability.	S2A: Development of traits contributing to a sustainable agri-food system S2B: Increased diversity of crops and traits compared to the crops developed with established genomic techniques *Additional: Contribution to a sustainable agri-food system* *Additional:* Limit environmental pressures
G3: Obtaining a legislative framework to **improve the competitiveness** of the EU agri-food sector and **ensure a level-playing field**	**S3:** So far, GMOs and possibly in the future NGTs are mostly cultivated in third countries and imported into the EU. The current legislation hampers the EU agri-food sector in researching, cultivating, and bringing NGTs to the market. The specific objective is to design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products **S4:** Enable a **future-proof legislation** to keep up with scientific developments and ensure that the	S3A: Reducing Regulatory Costs and administrative burden S3B: Reducing entry barriers to SMEs in plant breeding S4A: Legislation able to cater for scientific and technological developments *Additional*: Improve the competitiveness of the EU agri-food sector and ensure a level-playing field *Additional*: Other Social Impacts

General objectives	Specific objectives	Operational objectives
	legislation provides legal clarity and certainty, is enforceable and uniformly applied and has efficient and transparent procedures.	

The EC (2023) re-grouped and slightly reformulated the specific objectives for the Staff Working Document (SWD) as below:

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

2.3 Baseline Scenario

Under a baseline scenario the current regulatory framework continues to apply, meaning that all products derived using NGTs, whether cultivated in the EU or imported, are treated as GMOs and subject to the provisions of the EU GMO legislation. Following the findings from the EC Study on NGTs, this means that cultivation and import for food purposes will continue to follow the lengthy and costly regulatory approvals required to enter the market. This means there is a significant hurdle for cultivation (and import) of NGT applications for food purposes. Also, the EU will be excluded to a significant extent from the technological and economic developments generated by these new technologies, as is already evidenced by the fact that a significant share of companies (38%) has already delayed product development due to the regulatory uncertainty induced by the ECJ ruling (Jorasch, 2020), as well as the permanent uncertainty induced by the extensive risk assessment and Member State opt-out mechanism (Purnhagen & Wesseler, 2020). This de facto barrier to engage with the new technology will likely result in a loss of competitiveness against countries where NGTs are expected to be increasingly used, easily brought to the market, and exported also to the EU (for feed purposes). In the absence of a worldwide regulation for traceability and detection methods, it is plausible that NGT crops will enter the EU markets unnoticed (e.g., through unintended admixture, or because a variety was not recognised as having been made with a NGT at one point in its breeding history, or in rare cases intended evasion).

This will have negative implications for international trade (Zimney & Sowa, 2021; Eriksson et al., 2018; Purnhagen & Wesseler, 2021), competitiveness of EU agricultural firms (Smyth, 2017), as well as research & innovation efforts (Rathenau, 2021) on these technologies in the EU. The regulatory barriers also prevent those farmers that aim to pursue opportunities for products contributing to sustainability, climate adaptation, and health benefits (JRC, 2023). Given the traceability requirements in the current legislation, the regulatory divergence with other countries will result in substantial burdens (traceability costs, value chain adaptation costs, market efficiency reduction) for the conventional agri-food value chain. The organic and GM-free value chain is also affected by the challenge of avoiding unintended use of NGT-based inputs such as seed materials, feed, or food ingredients (via imports).

This baseline scenario at first glance fails to meet all policy goals set above, leading to the need for alternative policy options. The next section will introduce the policy options proposed by the European Commission which are the basis of this support study. It is important to note that the area being assessed is a young technological development with uncertainties and limited empirical evidence as such. The baseline option is therefore also fully subject to empirical impact assessment, providing more depth and detail that will supersede the introduction above.

2.4 Policy options

Next to the present situation which presents the baseline option, the European Commission has developed four main policy options and sub-options to be assessed in this study. These options comprise of a mix of components including changes in risk assessment, traceability, and labelling, and sustainability incentives. Table 3 below presents the content of these policy options. Note that Option 4 implies a mixed option set, as other options apply in case the product is not considered to be derivable from natural/conventional breeding techniques (either Option 1, 2A, 2B, 2C or 3).

Table 3 Overview of Policy Options

Policy Option	Risk assessment	Detection	Labelling	Traceability	Sustain-ability incentives
Option 1: Baseline	No change	No change	No change	No change	No change
Option 2: Adapted Risk Assessment	Proportionate risk assessment	Differentiation requirement waived if applicant can prove no differentiation method exists	No change	No change	NA
Option 3A: Authorisation with sustainability incentive					Range of support incentives (e,g., guidance, accelerated risk assessment, reduced fees etc.)
Option 3B: Authorisation with sustainability label			Sustainability claim with associated labelling	Document-based trace-ability for sustainability claim	
Option 3C: Authorisation -Label waived for sustainability claims			No labelling require-ments for products with sustainability claim		
Option 4: Authorisation with requirements					No author-isation of traits detrimental to sus-tainability
Option 5: Notification for certain products	Notification regime instead of authorisation and risk assessment for products that can also be obtained by conventional or natural breeding. Otherwise propor-tionate risk assessment.	No detection and differentiation requirements for products that could have also been obtained by natural/ conventional breeding. Otherwise waived detection requirement when no method is available.	No labelling requirements for products that could have also been obtained by natural/ conventional breeding. Otherwise, no change	No traceability for products that could have also been obtained by natural/ conventional breeding. Otherwise, no change	No change

The options were then 'translated' into more distinctive *scenarios* that do not combine (to a significant degree) these elements but isolate the effects of individual changes. This has led to the formulation of three policy scenarios for risk assessment and detection methods, four scenarios for labelling and traceability, and three scenarios for sustainability assessments. Table 4 below presents an overview of the mapping of policy options against the scenarios.

Table 4 Mapping of scenarios to policy options

Scenarios / Options	Baseline	1 Adapt. Risk Assess.	2A Sustain. incentive	2B Sustain. label	2C Label waived	3 Sustain. require.	4 Notificati on regime
A0: No change to Risk Assessment & Detection Requirements	■						
A1: Proportional Risk Assessment & Adapted Detection Requirements		■	■	■	■	■	
A2: Notification regime for products also obtainable with conventional/natural breeding							■
B0: No change to labelling & traceability	■	■	■				
B1: Additional Sustainability Label				■			
B2: No labelling if sustainable					■		
B3: No labelling & traceability if a product is also obtainable through conventional natural plant breeding							■
C0: No change to Sustainability incentives	■	■					
C1: Sustainability Incentives for authorisation			■	■	■	■	
C2: Sustainability requirements for authorisation: no authorisation if detrimental to sustainability						■	

2.5 Key Assumptions

All scenarios are assessed with the following key assumptions in mind:

- We focus our analysis of impacts on the period of 2030-2035, when the first wave of NGTs is expected to reach adoption levels (worldwide) that would start to have significant economic, environmental, and social impacts. Earlier periods would see specific impacts on some sectors (Research and Innovation, Plant Breeding), but relatively contained. For later periods, the lack of knowledge regarding the expected realisation of current and future R&D-pipeline for plant varieties developed using NGTs would lead to extreme uncertainties. Nevertheless, the impact directions are likely to extend in the same directions after 2035 in the same direction as the impacts found in this report.
- Other EU strategic frameworks, policies and regulations remain as they are, or follow their logical development as currently foreseen.
- Regulatory developments outside the EU follow the current trajectory as expected by the stakeholders, see section 1.5.2 for more detail.

- Proposed regulatory changes are implemented swiftly and consistently across the entire EU. There will be no opting-out of market authorisation at the Member State level.
- The organic sector in Europe remains in line with its principles and is for the time being not considering allowing the use of NGTs. Obviously, much of the conflicting lines would not exist and several impacts would be different.

2.6 Key Limitations

This study is subject to a number of key limitations. Detailed information is presented in Methodological Annex 2 but the following aspects are important to keep in mind when reading this report:

- **Very limited data on impacts of NGTs**: Due to the relative recency of the introduction of these technologies, and even more recent opening up of some regulatory frameworks in specific jurisdictions, there is simply virtually no economic, social or environmental data on the performance of NGTs. This means that impact estimates are – more so than for more 'typical' impact assessments – dependent on comparison with past developments (e.g., for traditional GMOs), expert assessments and projections, stakeholder expectations, and use of fundamental logic. In particular this means that most of our findings are qualitative (though of ordinal nature) rather than quantitative or monetary, although some key estimates of key costs and benefits are provided, in particular regulatory costs.
- **A small and polarised field**: New Genomic Techniques is a relatively specialised, technical and young field, with a relatively limited set of stakeholders and experts with deep expertise on the topic. More so, it has inherited to a significant extent the highly polarised debate around traditional GMOs. Stakeholders often hold diametrically opposite understandings of the situation, values and normative frameworks, with limited neutral ground. As an independent study team, we have engaged with and used evidence and views produced by all sides without prejudice. In this impact report, we build where possible first and foremost on academic research from peer-reviewed journals, yet also use and present concerns and views from these different stakeholders.
- **Mediation of systemic aspects:** Many of the second-order benefits and costs related to the regulatory framework for NGTs depend on their implementation in practice. This is particularly true for environmental impacts. NGTs present (the potential of) a toolkit of technologies that results in plants with traits associated with environmental sustainability, but actual environmental outcomes depend on how farmers use the plants in practice. How these mediation effects play out is very contested. Many NGOs and representatives of the organic sector expect that NGTs will only contribute towards a further shift towards a more industrial approach to agriculture with potentially worse environmental outcomes, while representatives of conventional plant breeders and farmers expect that NGTs will be used in a mode that will primarily benefit efficiency and sustainability. The conditions for uptake of NGTs and the wider farming system depend on future development of regulatory frameworks for sustainable farming systems. However, the outcomes of these regulatory developments are still highly uncertain. For this study, the challenge is that we will have a relatively high uncertainty on higher-order outcomes where such systemic mediation is present, in particular environmental outcomes.

3 Assessment of the impact areas

The following findings are based on the methodologies applied during the study. This includes data and information obtained from desk research (DR), targeted stakeholder as well as targeted cost interviews, the public consultation (PC), the targeted survey (S), data from JRC cases as well as case studies carried out by us (CS), focus groups on sustainability and traceability (FG), and impact modelling. Detailed results are integrated in dedicated, separate Annexes.

3.1 Impact area: Economic impacts

In this section we discuss the economic impacts on various parts of the food and feed value chain. We can distinguish four sub-parts:

- Attractiveness, development, and adoption of new plant varieties by using NGTs (3.1.1)
- Impacts on the conventional value chain actors (3.1.1 - 3.1.11)
- Impacts on organic value chain actors (3.1.13 and 3.1.14)
- Impacts on the GM-free value chain actors (3.1.15 and 3.1.16)
- Strategic impacts, including competitiveness, SME competitiveness, international trade, internal market, and research & innovation impacts (3.1.17 - 3.1.23)

The assessments are provided through a five-point Likert scale ranging from strong negative (--) to strong positive (++). In case the scenario does not apply, it is marked with N.A. The scenario abbreviations (A0, A1 etc.) refer to the descriptions in Table 4 above.

3.1.1 Attractiveness of development and introduction of new plant varieties by plant breeders

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Time to market	--	-	+	--	--	-	+	0	0	-
Regulatory certainty	-	-/--	+	0	-	-	+	0	-	-
Aggregate attractiveness	--	-	+	--	--	-	+	0	0	-

In order to assess the attractiveness of the development and introduction of new plant varieties developed using targeted mutagenesis / cisgenesis (TM/CG), we look more closely at time to market, regulatory certainty and total attractiveness (regulatory costs are discussed under a separate impact area). The targeted survey (SQ11) shows that regulatory costs (22%), regulatory uncertainty (22%) and time to market (20%) are indeed considered by all stakeholders collectively to be the three most important factors for the attractiveness for plant breeding, ahead of other aspects such as R&D costs (15%), labelling & traceability requirements (14%), consumer demand (11%), availability of detection methods (10%) and other factors (8%).

In terms **of time to market**, the current baseline situation for risk assessment (A0) clearly has a negative impact with current timelines for risk assessment of 6 years for cultivation and 4.5 years for imports respectively, making the total time to market (including R&D) under the current framework 16.5 years, according to interviewed plant breeders. Targeted survey respondents indicate on average 22.4 years for authorisation for cultivation and 8 years for authorisation for food and feet use and importation respectively (Q65). The PC (Q2) also identifies the current regulatory framework as a barrier for a fast time to market. According to plant breeders and researchers, A2 could positively impact the time to market as it would significantly reduce the 4.5-year period

of risk assessment. Scenario A1 could also lead to faster time to market, although to a lesser degree according to most plant breeders and researchers. In terms of the B and C scenarios, those with the same (B0; C0) or introducing additional requirements and assessments (B1; B2; C1; C2) would have neutral or negative impacts on time to market accordingly.

In terms of **regulatory certainty,** i.e., the likelihood that a product is able to be admitted to the market after the R&D-process, the current regime of market assessment (A0) is seen as inducing high risk and uncertainty for plant breeders to engage in NGT-related research and product development. A significant share of companies (38%) delayed product development and release due to this regulatory uncertainty (Jorasch, 2020). Most plant breeders and researchers do not consider scenario A1 to be a significant improvement in terms of improving attractiveness to do R&D/plant breeding in the EU, as proportional risk assessment is arguably even more uncertain in terms of scope (at least in the beginning as guidelines have to be developed), and the perceived tendency by regulators to always push for maximum assessment, meaning the new situation will de facto resemble the current one. This is confirmed in the targeted survey, only 12% of stakeholder see an improvement of regulatory certainty under this scenario (S27). Scenario A2 (and B3) provides improvement according to some (40% of stakeholders (S27)), but plant breeders are still concerned that the cumulative criteria are so narrowly defined that only a very small range of product would fall under it, and that the 'vague' definition would create yet more uncertainty for plant breeders. Some sources also fear the underlying political uncertainty that may affect future legislation and consistent implementation (without opt-outs) due to the divided positions of Member States on the issue (Purnhagen & Wesseler, 2020). In terms of the B and C scenarios, those with the same (B0; C0) or introducing additional requirements and assessments (B1; B2; C1; C2) would have neutral or negative impacts on time to market accordingly.

In terms of **total aggregate attractiveness** of developing plant varieties using TM/CG for the European market, the current baseline scenario (A0/B0) is considered highly negative by stakeholders. The targeted survey (Q27) shows that 97% of stakeholders believe that total attractiveness will decrease or stay the same under A0. Since the ECJ ruling, several R&D projects were cancelled or shifted abroad (Jorasch, 2020). A lighter regulatory risk assessment (A2 in particular) has a positive impact on the total attractiveness for plant breeding using NGTs according to most stakeholders. 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 be no longer regulated as GMOs (Jorasch, 2020). Scenario A1 is considered less attractive (only 20% of the stakeholders see a potential increase in attractiveness (SQ27), primarily due to the risk assessment challenges mentioned above. Some plant breeders also consider A2 too restrictive due to the challenging implementation of the natural/conventional definitions, although 92% of all stakeholders see an increase of attractiveness (SQ27). For the labelling scenarios, B0 (baseline) is considered to have a negative impact on aggregate attractiveness due to the stigma associated with GMO labelling. Scenario B1 (sustainability label) is viewed equally negative due to its complicating nature and the fact that any label will come with an associated stigma (stakeholders also cite definition, implementation, and discrimination challenges). The situation with no label (B3) is considered to be positive for attractiveness as it would not put a downward pressure on consumer demand, but it does not provide for the societal demand for transparency and freedom of choice. Plant breeders – and other stakeholders – see no impact of the C1-2-3 scenarios as they indicate that sustainability traits are already a primary focus of plant breeders. This is in line with the findings from the targeted survey showing that respondents expect primarily no change or decrease of attractiveness (75% of respondents) for C1 and for C2 as well (68%) (SQ59).

3.1.2 Development of new plant varieties by plant breeders

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Number of new plant varieties developed using NGTs developed in EU.	--	-	+	--	--	-	+	0	0	-

There is already a large potential pipeline of more than 427 applications of genomic techniques for at least 28 different plant species (JRC 2021), although only a few have reached the market so far (a higher oleic acid soybean, an adapted canola and a tomato with fortified amino acids (GABA), see section 1.3). Out of the 427, only 16 are in pre-commercial stage, 117 in advanced R&D, and 292 in early R&D. In total 90 applications are developed in the EU, of which none in pre-commercial stage, 28 at the advanced stage R&D, and 62 at the early-stage R&D. Virtually all stakeholders agree the current situation (A0, B0) is greatly limiting the development and use of NBTs in breeding of plant varieties in the EU. Some plant breeders claim that since the ECJ ruling all development in NBTs has practically stopped, whereas a recent survey showed a reduction of 33-40% after the ruling (Jorasch, 2020). This is in line with the PC (Q2), where on average, the majority of respondents (in all stakeholder categories except of forestry and GM-free sectors) see the current regulatory framework impacting negatively research and the development of new varieties (Q2).

For plant breeders Scenario A2 has potential positive impacts on inducing the development of a broader set of plant varieties. This is in line with the results of the targeted survey (S17). Under Scenario A0, stakeholders expect a low use of NGT techniques among plant breeders (1% median), slightly more expect under Scenario A1 (2.5% median) and significantly more under Scenario A2 (10% median). For Scenario C1 respondents expect a similar (10% median) share of use of NGT techniques compared to A2, while for Scenario C2 respondents expect a lower share (5% median) (S53).

3.1.3 Plant breeders introducing new plant varieties on the market

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Number and of new varieties developed using NGTs launched on the market	--	-	+	--	--	-	+	0	0	-

The current regulatory environment is considered highly restrictive in terms of market access by most stakeholders (S2, O2, interviews, desk research). The current regime has resulted in only one GMO (MON810 Bt maize) to be effectively launched on the market for cultivation within the EU since 1998, and none in the last 20 years. Plant breeders expect the same level of impact if the current regime (baseline A0, B0) is maintained. Most plant breeders and researchers see no or limited increase in products reaching the market under A1, as it is considered de facto similarly restrictive, while A2 would be resulting in an increase (depending on the exact interpretation of the criteria). The targeted survey (SQ16) shows that under Scenario A0, on average, stakeholders expect to see very few (median of 0) products on the EU market, with slightly more (median of 5) under Scenario A1, and significantly more (median of 108) under Scenario A2. The current labelling regime (B0) is also considered to have a strong negative impact on the launch of new products. This is due to the perceived negative impact on consumer trust in the product and the cost of labelling and traceability. Stakeholders expect no effect of the Sustainability Label in Scenario B1 (95% indicate no change in number of products launched (SQ38). For scenario B2 stakeholders are more mixed (38% respond

an increase; 62% no change (SQ39)), and for B3 77% of respondents expect an increase in the number of products on the market and used for cultivation (SQ40). For scenario C1, respondents expect a limited number of products on the market (median of 5), and very few/none for scenario C2 (median 0) (S52).

3.1.4 Use of new NGT varieties by farmers

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Market share of varieties developed using NGTs	--	-	+	--	--	-	+	0	0	-

The actual use of a product by farmers depends on many factors, including expected demand, seed cost, other input costs, price premiums, specific agronomic traits etc. Some farmer representatives indicate that there is a strong latent demand for products developed using NGTs, as they could offer key tools to deal with the challenges of the Green Deal implementation. Other interviewed farmer representatives are more sceptical of latent demand, indicating that the promises of GMO have not been fulfilled in practice. The targeted survey shows that the average respondent expects a low uptake among farmers of NGT products in Scenario A0 (median 1%), more for Scenario A1 (median 10%), and significantly more under Scenario A2 (median 20%). This is in line with the PC results where on average all respondents indicate to anticipate less uptake of new innovations/varieties under the baseline scenario (O4). For Scenario B1, stakeholders expect no change (95% of the targeted stakeholder respondents (Q38)), for scenario B2 stakeholders are more mixed (38% responds an increase; 62% no change (Q39)), and for B3 77% of respondents expect an increase in the number of products on the market and used for cultivation (Q40). For scenario C1, respondents expect an uptake of 12%, for C2 8% on average (S49).

3.1.5 Net economic impact on plant breeders

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact (turnover, profits) on plant breeders	-	-/+	++	-	-	-	+	0	-	-

The regulatory situation regarding NGTs can impact plant breeders economically through several pathways: reducing development costs, decreasing authorisation costs, increasing licensing costs, affecting other costs and increasing margins due to higher quality or product competitiveness. There are also specific impacts to consider for SME plant breeders and organic/non-GM plant breeders.

Firstly, there is clear evidence that NGTs present opportunities for reducing the development cost by substantially shortening the breeding time required for new plant varieties by facilitating speed breeding (EC 2021; Annex 5, case study on potatoes; Samantara et al., 2022). Secondly, regulatory costs are currently an important barrier to gene-edited plant development (see section on regulatory costs; PC Q2) and have a clear negative association with the economic situation of plant breeders developing products using NGTs. Thirdly, NGT technologies such as CRISPR/Cas require licences from a select set of patent holders. There are both direct costs of the licensing agreement (licensing fee) and indirect costs (time and human resources needed to access and negotiate licences). Licensing fees are relatively accessible during the development stage but tend to become very high during the commercialisation stage, with figures as high as 5-10% of total turnover being reported (Annex 5, mini-case on potatoes). The development of licensing platforms by the industry may palliate some detrimental aspects, by allowing easier access to patented technology and products, but

their impact on licensing costs may be limited. Fourth, plant breeders (in general) may be confronted with additional costs as NGTs become more prevalent, as customers tend to request information on detectable levels of GM/GE traits, which can result in substantial costs, in particular for smaller plant breeders (OSA, 2022). Other costs that may rise for other plant breeders are a narrowing of availability of varieties for subsequent own breeding due to increased intellectual property[18]. Fifth, NGTs present opportunities for plant breeders to increase margins as these technologies allow them to develop high-value added plant varieties (see for instance the chicory case study in Annex 5), cost-saving or yield increasing opportunities for customers (pest resistance etc.), for which they can charge a premium. It can also allow plant breeders to develop a more heterogeneous and unique range of products which can reduce competition.

The likely cumulative effect of these impacts depends on the type of plant breeder and the policy scenario. Overall, in terms of the policy scenarios, a change in regulations towards a more flexible regulatory environment for NGTs is considered economically beneficial for plant breeders *for the sector as a whole*. The current option (A0) makes precision breeding using NGTs inaccessible, both due to its costs and the regulatory uncertainty. Attractiveness of development of new varieties using NGTs under scenarios A0, A1, B0, B1 and B2 is lower than under more relaxed regulation (A2, B3). Thus, it is assumed that under such regulatory regime, the sector will not benefit from economic growth related to NGT crop development. In the stakeholder survey, the large majority (70%) expect a positive association between higher adoption of NGTs and economic impacts for plant breeders (Q13). Overall, A2 & B3 scenarios are considered most beneficial for breeders as it will allow for a larger introduction of NGTs in the development process. The total costs of breeding are expected to come down under the A2 & B3 scenario given the potentially more efficient development process. The policy scenarios on sustainability mostly have a negative effect, as they introduce additional requirements, and thereby costs and uncertainty.

Despite the overall aggregate economic benefit, there are a few important caveats. Firstly, firms without adequate access to IP, in particular SMEs, may benefit only in specific situations (see Section 3.1.17 on SMEs for an extensive discussion). Secondly, organic plant breeders are faced with specific challenges and increasing costs (documentation, testing, isolation distances, etc.) to keep their breeding material free from NGTs. In particular traceability (through labelling from the early stages of the value chain, i.e., seeds and transparency about cultivars through a public register and the common catalogues) (Scenario A0, B0) supports organic plant breeders. In addition, they may experience reduced participation of the general breeding gain, as they cannot use the new varieties derived from NGT in their breeding programmes (see Section 3.1.13). However, also conventional plant breeders that do not use NGTs may be faced with additional costs due to increasing demands regarding presence of GE/GM traits.

3.1.6 Net economic impact on conventional farmers

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact on farmers (total sector profits)	-	-	+	-	-	-	+	0	0	0

Economic impacts on farmers can arise through several pathways: yield increase, cost reductions, quality increase, cultivation risk reductions or coexistence measures. Given that there is no direct evidence of the economic impact of crops developed using NGTs

[18] This is partly addressed by the breeders' exemption, allowing breeding with varieties with patented traits prior to obtaining a license on the trait, but mainly by making trait licenses more easily available through licensing platforms, notably ILP Vegetable and ACLP for arable crops.

yet, we first reflect on evidence of impacts from GM technology, then stakeholder expectations and expert-validated projections of potential impacts of NGTs specifically.

The data on direct economic benefits from GM crops is mainly limited to third countries. Despite significantly higher seed costs associated with GM crops of up to 50% compared to conventional (Greenpeace, 2015) and technology fees (+100%) as reported in a meta analysis by Hall et al (2013), review studies consistently report positive economic impacts on farmers via yield increases, mostly through lower insect and weed population pressures (Areal, 2013; Smyth, 2017; Brookes, 2021). The cost of coexistence measures can be factored in although they vary by required isolation distance/buffer zones and flexible measures (SIGMEA 2007).

Klümper and Qaim (2014), who undertook a meta-analysis of 147 studies on the impacts of GM crops, found that chemical pesticide use decreased by 37%, crop yields increased by 22%, and farmer profits increased by 68%. These benefits arise in particular for large farmers (Zilberman et al., 2018; Smith et al., 2021) and are equally expected for developing countries (ISAAA 2019). Comparing the costs and the economic benefits, Grace (2015) found a 75% profit increase and an average cost increase of 40% when changing from conventional to GM crops. Recent academic research has shown that the economic benefits of GMO have been limited by a third of their potential due to regulatory restrictions (Hansen & Wingender, 2022). However, in the long run these benefits may evaporate as pest resistance develops (Kranthi, 2020), for a broader discussion, see section 3.2.2 on pesticides.

In terms of stakeholder expectations for NGT specifically, about 20% of survey respondents expect a negative impact of more NGTs on farmers whilst over 80% expect positive economic impacts (Q13). Combining stakeholder and expert estimates of adoption rates of the currently known pipeline of NGT-applications, as well as estimations regarding trait-level impacts, our quantitative explorative analysis (Annex 7) of impacts shows a range of 0.04% yield improvement (for Oil and Fibre crops in the most pessimistic scenario) to 9.1% (for Cereals in the most optimistic scenario) by 2030-2035. This represents, when including cost savings from reduced input use, a total annual economic market value of €3 million (for Vegetable crops in the most pessimistic scenario) to €5.7 billion (for Cereals in the most optimistic scenario). It is expected that these economic benefits would further grow afterwards as more applications for more crops are introduced, and faster plant breeding times provide cumulative benefits. In addition to yield savings and cost reductions presented here, NGTs also provide expected opportunities for realising economic benefits through quality increases, such as higher nutritional value or specific compounds. While these provide concrete potential business cases (see for instance Annex 5, the case study on chicory), there is currently limited evidence on this type of benefits. Recently one of the first commercialised products developed using NGTs, high oleic soybean oil with health benefits, was discontinued by its developer plant-based biotech company Calyxt due to lack of interest from farmers after yields were disappointing, highlighting that commercialising such specific use-case products can be faced with challenges.

It is important to note, however, that due to the inherent properties of competitive commodity markets, surplus profits tend to mainly benefit early movers. Over time, as adoption rises, these profit surpluses tend to shift either to other parts of the value chain (with more pricing power) and/or consumer surplus through lower prices (see for instance JRC Case Study on phytophthora resistant potatoes). While still delivering economic benefits, it is not expected that adoption structurally increases farmer incomes, although the reverse may be true: EU farmer incomes may reduce if other countries do adopt these crops and the EU does not.

Coming to the policy scenarios, we can conclude that less restrictive legislation associated with higher development rates adoption of NGT varieties (A2, B3) could allow farmers to increase their yields and become more efficient and technologically

advanced, and more restrictive/uncertain scenarios (A0, A1, B0, B1, B2) that hinder development and adoption could result in negative or neutral impacts due to worsening competitive situation on the world market. It is important to note that it is likely that benefits in particular accrue to larger, already productive farms, due to the investment costs related to changing to a new way of working, as well as higher upfront seed costs. Organic farmers are also discussed separately. As described in 3.1.1, the C-scenarios on sustainability do not substantially affect development and adoption, and therefore also have limited wider economic effects.

3.1.7 Net economic impact on the feed industry (conventional)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Net economic impact on the feed industry (total sector profits)	--	-	0/+	-	-	-	+	0	0	0

In the conventional feed industry, robust and consistent access to affordable feed ingredients (cereals, soy etc.) is essential. Europe is dependent on imports of these commodities for livestock feed (Karlsson et al.; 2020). Due to the opportunities NGTs present to produce crops at a lower cost or with specific qualities, these technologies also present opportunities for the feed industry. The feed industry itself therefore is in favour of substantially lighter NGT regulation in Europe (A2). Over 80% of survey respondents (from the feed industry) expect a positive impact of more NGTs on the feed industry while about 20% of respondents expect a negative impact. PC respondents are less in favour: respondents representing the feed industry had mixed views (half pro, half against) on the need for regulatory incentives to increase the adoption of NGTs in the EU (Q7). In targeted interviews, feed industry representatives highlight that the downside of trade disruptions in the case of divergent regulation are in the short/medium term more important than the upside of better/cheaper inputs. In targeted consultations, representatives from the feed industry stressed the difficulty associated with any segregation of product streams in more highly regulated scenarios, as that increases compliance costs, but perhaps more importantly decreases flexibility of supply chains (see also section 3.1.20 on trade). Given the concerns expressed elsewhere regarding the sustainability criteria, these representatives are in general negative regarding the impact of scenarios including specific criteria and labelling aspects for sustainable products (C).

3.1.8 Net economic impact on food processors (conventional)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact on processors (total sector profits)	--	-	0/+	--	--	--	0/+	0	0	0

As with the feed industry, impact on processors is at the moment primarily determined by seeking to avoid negative regulatory consequences of segregation and compliance rather than seizing opportunities. A large majority of processors in the targeted survey (70%) expect positive impacts of increased adoption of a lighter regulatory environment for NGTs, with 20% expecting the reverse (Q13). A lighter NGT environment (A1/A2/) could lead to increased costs on processors in Europe as it would require strict segregation of crops to avoid admixture. At the same time, the current option (A0) would lead to a situation where European processors were excluded from international trade as they would not be able to use/ or have access to new products. PC respondents stressed that small and medium-sized processors will not be able to use NGT under A0 (Q2) – see also 3.1.17 *(SME competitiveness) and 3.1.20 on International Trade).*

3.1.9 Net economic impact on food and bio-based industry (conventional)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact on food and biobased industry (total sector profits)	-	-	0/+	-	-	-	0/+	0	0	0

NGTs present opportunities for cheaper inputs and for specific applications also products with specific nutritional qualities, of which the food and bio-based industry sector can take advantage (see for instance the example of the chicory case). Sector representatives themselves also in large majority (70%) expect positive impacts of more relaxed regulation for NGTs (A1/2, B3), with 15% expecting the reverse. In the PC, the sector biotechnology/bio-based industry also shows a higher agreement than disagreement with regulatory incentives for development of products using NGTs (Q7). This group does not support additional risk assessment for products that could have been developed through means of conventional breeding (Q13). Like with processors, avoiding costs and sourcing challenges that may arise in case of international divergence is (at least) as much a concern as the opportunities presented by NGTs.

3.1.10 Net economic impact on traders (conventional)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact on traders (total sector profits)	--	-	0/+	--	--	--	0/+	0	0	0

Traders, in particular those for commodities, are not inherently affected by the quality or nature of the product, but more so on the regulatory environment. Traders are heavily affected by the risk of international divergence in the regulatory status of NGTs (see NGTs), in particular in terms of (implicit) segregation and traceability requirements (see also section 3.1.20 on international trade). Stakeholders representing the trading sector confirm the negative impacts if the current regulatory system is maintained for NGTs (A0). Concerns about the current negative impacts on international trade featured prominently in an open question regarding economic and social impacts (Q4). About 10% of the survey respondents expect a negative impact of more NGTs on the traders while around 90% expect a positive impact. (Q13).

3.1.11 Net economic impact on retail (conventional)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact on retail (total sector profits)	±	±	±	±	0/-	±	±	0	0	0

As with processors, retailers are not inherently directly affected by the properties of the plant varieties that are the basis of their products (in competitive environments, cost savings are likely to be passed on to consumers fairly rapidly). Retailers are, however, affected by regulatory requirements surrounding NGTs (in particular labelling and traceability) and consumer reactions to NGTs. Regarding regulatory requirements, retailers do indeed bear some of the costs of labelling & traceability systems, but these are relatively limited compared to those borne by others in the value chain.

Representatives of the retail sector stress that retailers are particularly concerned with the consumer perspective and their readiness to purchase GM/GE products as well as the safety profile of modified products. A significant number of retailers also sells organic

products, which value chain is affected by a potential adoption of NGTs (see also sections 3.1.13 on Organic / 3.1.15 on non-GMO impact areas). Stakeholders stress that the consumer perspective is the leading determinant of retailers' position on the subject. In the PC, the retail representatives indicated that transparency and labelling are crucial in the products produced using NGTs (Q12). Under scenarios B1 and B2, survey respondents do not expect that additional labels or a lack thereof will lead to substantial increases in the willingness to buy these products. A recent review has shown that customers typically view products based on plants derived via NGT-techniques as of lower value, although this effect is reduced if the NGT-techniques were used to improve quality, rather than production cost-savings (Beghin and Gustafson, 2021). The impacts on the retail sector in the EU is likely to depend on the different and evolving perceptions of consumers. The review by Woźniak-Gientka_et al (2022) showed marked differences in Europe in terms of GM consumer perception, educations level, age and information provided (see also section 3.3.5). Some -not necessarily organic-focused- retailers in specific markets (i.e., Germany, Austria) have indicated not to introduce such products (ENGA, 2021). As such, the impact on retailers can be considered as context dependent. Retailers indicated in targeted interviews that including sustainability dimensions in labels is likely to create confusion or negative reactions. However, the literature indicates an increased consumers' willingness to buy genome edited food when they are informed that the latter had less pesticide use than conventionally grown plants (Borello et al 2021).

3.1.12 Net economic impact on non-food and non-feed business operators, including the ornamental plants, forestry, bio-based industry sectors

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Economic impact on non-food business operators, including the ornamental plants, forestry, bio-based industry sectors.	-	-	+	-	-	-	+	0	0	0/-

Impacts for non-food operators seem to be generally in line with those for food and feed sectors. About 15% of survey respondents expect a negative impact of more NGTs on non-food and non-feed operators whilst over 78% expect positive impacts. (Q13) Industry representatives posit that risk assessment for ornamental plants should be different as their products are not eaten.

3.1.13 Net economic impact on organic agriculture

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Net economic impact on organic farmers and areas under organic farming	0	0/-	-	0	0/-	0/-	--	0	0	0

Economic impacts of coexistence of NGT and organic/non-GM agriculture and value chains can occur in all policy options under consideration, including the baseline, although to a different degree due to varying expected uptake and spread of NGTs in agriculture. These additional costs are due to preventive segregation measures put in place across the value chain to avoid admixture of GM/NGT products in both organic and GM-free pipelines, in addition to the direct costs of compliance with regulatory requirements as pointed out in interviews and focus groups. Legal requirements stem not only from the GMO legislative framework and its national implementation, but also the requirements of the Organic Regulation. These can be supplemented by voluntary measures, with some additional requirements at Member State levels. In agricultural

production, these requirements impact the sourcing of breeding material, include restrictions in sowing and production (isolation and buffer), extensive voluntary testing, and potentially, the investment in separate machinery or equipment cleaning, although their importance differ according to crop species and equipment cleaning serves also the purpose to avoid pests.

Some, including the majority of identified campaigns in the public consultation consider that detailed rules on coexistence and traceability of NGTs should be enacted at EU level (through a registry of NGT products, national measures to avoid the presence of NGTs in organic agriculture) and highlight that the financial and administrative burden should not be borne by organic breeders and producers, referring to the "polluter pays principle" in Article 191 TFEU. Some respondents also stress the need for coherence with the target set out in the Farm to Fork Strategy to increase organically farmed production areas to 25%. The latter goal would in their view be jeopardised by the increase of NGT cultivation. On the other hand, an important share of respondents (mostly from academia) points out that coexistence measures would not be needed with regard to NGTs, especially those that could have been obtained by conventional breeding methods, classic mutagenesis, or could have occurred in nature. Stakeholders representing organic farmers consider that adventitious presence of NGTs is an important risk to their businesses, since the principles of organic agriculture centre around the integrity of life (respecting natural crossing barriers in plants and animals), and the minimization of ecological risk, which lead the sector to exclude the use of GMOs and NGTs from organic production (IFOAM, 2019). Segregation measures to be adopted to avoid admixture are the main economic impact identified by organic operators with regards to NGTs, with some arguing that admixture would threaten the viability of their business as indicated in interviews. The issue of coexistence is debated and studied[19] at global and EU level. However, experiences in the US, Australia and the EU with regards to coexistence are quite diverse. The two former jurisdictions rely on self-regulation, private standardization and controls and neighbouring relations rather than regulatory action, relying on the effectiveness of judicial compensation mechanisms ingrained in common-law traditions. In contrast, the EU adopts a regulatory approach applying the principle of subsidiarity, with recommendations at EU level, and the adoption of specific coexistence measures at national level, according to the local growing conditions and the needs of the crop species. Within the EU, experience of coexistence is mainly limited to Portugal and Spain. Yet, the processing and interpretation in particular on the experience of coexistence of organic agriculture with the cultivation of GM Bt maize in Spain are quite divergent. According to Eurostat data[20], areas under organic production have increased in Spain by 38.8% between 2012-2020, (EU average: 55.6%). Spain provides 16% of organic area in the EU (2020), the second largest in the EU-27. Certification for organic operators is a problem since the system differs by region and requirements regarding paperwork do not differentiate between small and large producers, discouraging small farms (Greens 2013).

Today, preventive coexistence measures are adopted in organic agricultural production and value chains to react and avoid potentially costly GM admixture (IFOAM, 2017). In agricultural production, these costs are linked to the difficulties in the sourcing of breeding material, include restrictions in seed availability and production restrictions (isolation and buffer), extensive voluntary testing and documentation, the investment in separate machinery, and the risk of withdrawal of the organic certificate due to GM admixture (IFOAM, 2017). Despite an agreement on the different impact areas, there is nonetheless consensus, both in the literature and stakeholder interviews, on the lack of

[19] Relevant large-scale EU funded research projects were SIGMEA (Sustainable Introduction of GM Crops into European Agriculture) or (2004-2007), CO-EXTRA (GM and non-GM supply chains: their co-existence and traceability) (2005-2009).

[20] Eurostat data accessed in April 2023.

precise empirical data related to the economic costs of coexistence measures taken by organic farmers (and breeders) to minimise admixture in the EU.

A study based on the US (Green at al 2016) indicated that the costs of organic farmers of on-farm practices such as the use of certified non-GE seed, buffer strips, alternative planting dates and cleaning equipment vary. In particular, obtaining certified non-GE seed ads to search costs. The crop-dependent different, required buffer zones are opportunity costs. Devos et al (2009) pointed out that the divergent buffer zones applied in some EU countries are from a scientific point of view potentially excessively large and thus increasing these opportunity costs unnecessarily. Based on surveying 1.500 US organic grain producers, the study by Food&Water Watch and OFORM (2014) calculated $6.532-$8.500 (€5.980- €7.780) as total median annual cost of avoidance practices per farm. This includes $2.500 (€2.288) for buffering strips, $3.312-$5.280 (€3.0300-€4.833) for delayed planting, $200 (€183) for testing, and other measures $520 (€476). Other economic losses due to unintended presence of GMO material was reported by 1% of all US certified organic farmers during 2011 – 2014 (USDA, National Agricultural Statistics Service, 2014 Organic Production Survey). Their survey showed that economic losses vary by US States – and the different cultivated crops. In States that produce organic corn, soybean and other crops with GE counterparts, the economic losses were 6-7% whereas in States with a dominant organic production of fruits, vegetables and other specialty crops that mostly lack a GE counterpart, the economic losses were less than 1% (see Greene 2016).

Segregation costs calculated for US soybeans identified the tolerance levels governments set as the major cost factor. While cleaning and testing costs were less high per acre/ bushel for the farmer, most of the costs were coming from the shuffling and handling of grains. Product loading and shipment practices include proper documentation, maintenance of representative samples, and inspection of cleanliness. It is however expected that the costs of US handlers (and exporters) decreases since they have by and large established separated grain handling paths (Bullock et al, 2000).

Admixture risks, and thus their potential detrimental impacts on organic agriculture differ from one crop species to another, with gene flow and persistence of GM and NGTs showing differences according to the characteristics of the GM/NGT, but also on the ecological and social context where they are introduced (SIGMEA 2007). According to survey results, areas under organic farming would potentially be negatively impacted under A1 and A2, as organic farmers would abandon certain market segments where NGT products would be strongly represented and/or due to high risks of admixture, or where it will become increasingly difficult to find land parcels where organic production could technically take place. Interviewees from the organic sector consider that scenario A1 would lead to a reduction of breeding material available for use by organic breeders due to segregation of breeding lines, the high costs of additional seed testing costs estimated to add up to €40.000 a year per breeding programme, and potential loss of parental lines to GM admixture (IFOAM, 2017). These stakeholders also do not agree that coexistence measures could only become an obligation if the products can be analytically differentiated. In their view, it should rather be an obligation of transparency and traceability through the provision of best possible efforts which is in line with the process-based quality certification system implemented in organic agriculture (IFOAM, 2020). Coexistence in GMO and GMO-free breeding and seed production (with a threshold of 0.0%) is considered unfeasible for certain crops (Oehen et al, 2017). The scientifically acknowledged absence of analytical methods, which can both detect and differentiate certain NGTs, affects all scenarios including the baseline. Yet, A2 is flagged by organic stakeholders as having potentially a major detrimental effect for organic agriculture. This is due to the looming coexistence with NGTs and the potential costs. Furthermore, controlled segregation of each production system largely depends on the availability and costs of suitable biological detection tests and on the requirements imposed on producers and breeders, who would have to develop their own testing protocols (provided that NGTs are not allowed under the Organic Regulation). The

organic sector represented by IFOAM Organics Europe and IFOAM Organics International state that the organic sector will refrain from genetic engineering techniques including NGT (IFOAM, 2019). At the time of writing, other farmers associations such as Copa Cocega and the European Council of Young Farmers (CEJA) – both also representing organic farmers – had not yet issued official statements.

Although rules on NGT labelling are requested by organic stakeholders, the sustainability label envisaged under B1 is considered to lead to unfair competition with the organic label. According to stakeholders from the organic sector, the organic label reflects holistically sustainability from seed to retail rather than the effect of single traits, with potential harmful side effects or unsustainable production processes. The organic voices also mention that farmers may opt-out from organic certification if it requires a far more difficult certification process compared to receiving a NGT sustainability label. The lack of a label under scenarios B2 and B3 is also considered to have strong negative effects on organic production. Note that a label in this early phase of the value chain concerns seeds (certified GE-free seeds), feed etc. that helps the organic production process to guarantee identity-preservation. In its absence, the organic breeding and production would be severely hampered since it could not anymore guarantee GMO/NGT free production processes. Especially B3 is viewed as potentially discriminatory and difficult to implement, entailing additional costs to differentiate between breeding and production lines in a fourth (NGT) category. Survey results indicate that a clear decrease of areas under organic farming is to be expected under scenario B3. Economic theory suggests that a decrease in organic farming could happen if the additional premium (rent) of the organic sector decreases to the level of conventional farming. This does however not take into account behavioural aspects of farmers which are not only rent seeking.

As coexistence and freedom of choice is mainly related to traceability and detection methods to allow segregation of production lines, there is little to no insight directly related to the topic with regards to scenarios C0, C1 and C2. No change is foreseen on the topic of coexistence under these options, albeit here is a more general concern of seeing more NGT products on the market, accompanied by a rise of economic costs in preventive measures and admixture events. According to the targeted survey (Q25, 26 and 27), there is consensus that the net economic impact on farmers using NGTs will be considerably more positive. Yet, there is also a clear trade-off due to the negative effects for organic farmers especially under scenario A2 (37% of respondents identify a positive economic impact for farmers using NGTs under scenario A1, while 66% of responses do so under Option A2) and scenario B3 (no labelling and traceability).

3.1.14 Net economic impact on organic labelling and the wider value chain

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Impact on costs of and trust in organic labels	0	0/-	-	0	0/-	-	- -	0	0	0
Economic impact on organic traders, processors, food/feed industry and retailers	0	0/-	-	0	0/-	0/-	--	0	0	0

The ability to trace NGT products is important in the organic production chain, since it is claimed that admixture can damage the image of the organic sector, both by derecognition of organic produce and by loss of consumer trust, since organic consumers are considered to be against the use of NGTs for organic products (Mandolesi, 2022 and stakeholder interviews). This premise leads non-GM operators to undertake additional testing and reinforced traceability mechanisms. For the majority of NGO respondents to the PC, some representatives of the organic value chain, as well as public authorities, current EU legislation on the traceability and labelling of GMOs is a key enabler and

guarantee of coexistence with organic and conventional GM-free agriculture (i.e. cultivation and trade). Legislation is equally important for consumer information and liability (although the latter is dealt with at MS-level). Along the organic value chain, increased efforts are today made to ensure traceability, with estimated additional costs up to 13% of total product turnover, notably for product testing, careful cleaning at every processing stage, process certification, export requirements and significantly higher administrative burden (Co-Extra 2009). According to interviews, an increase of NGT products and complex regimes (especially A2) are considered to lead to difficulties in implementation for operators of organic certification schemes. Scenario A1 is considered to give more legal certainty for certifiers and growers alike, while A2 would make it more difficult to guarantee the absence of NGTs and Scenario B3 would make it impossible. Disruptions of international trade of organic products are also expected under this scenario. While 30% of survey respondents point to an increase of the cost of organic certification under scenario A1, the share increases to 37% under scenario A2 (Qs 25 & 26). Although the majority of survey respondents highlight that scenarios B1 to B3 would have no impact on the costs and trust in organic labels, these findings are not shared by PC results and interviews conducted with organic stakeholders. The latter point to a significant negative impact on these indicators, especially under scenarios B2 and B3, reiterating in interviews that coexistence could only be achieved in the presence of an EU labelling and traceability system. In the PC, organic food producers and retailers indicate that a new sustainability label may raise questions about the organic label and thus damage it (Q13).

Stakeholders from the organic value chain are in general not extremely concerned by coexistence measures during processing and distribution, but more on the consequences on the markets if non-certified raw products enter the downstream value chain. The rise of NGT products globally would make it more complicated to source organic-compliant feed in the future and expose operators to greater risks of fraud, even if organic production was to rise in the EU. Although survey results point to contradicting results, with the majority of the answers pointing to the lack of change in terms of impacts of different scenarios, in the interviews, A2, B2 and B3 were flagged as having a potentially major detrimental effect for the organic value chain by organic stakeholders. Coexistence and segregation in each value chain largely depends on the traceability as well as on the availability and costs of suitable technical detection tests and on the requirements imposed on different actors of the value chain. The latter would have to develop their own testing protocols (provided that NGTs are not allowed under the Organic Regulation). Stakeholders expressed worries regarding their expanding organic and conventional non-GMO product lines, which would be under particular threat of being compromised. Under the baseline scenario, the mandatory development of a detection method could be applied by the organic value chain. Technically feasible for breeding companies are unique genetic identifiers for NGT events which can be used for detection, labelling, and IP claims. Without a requirement to disclose NGT events, it is not feasible to develop detection methods for undisclosed events.

3.1.15 Net economic impact on GM-free agriculture

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Net economic impact on non-GM farmers & areas under non-GM farming	0	0/-	-	0	0/-	0/-	-	0	0	0

Non-GM agriculture relies on private standards that exclude the use of GMOs, but also NGTs across their supply chain, without necessarily relying on the organic label (ENGA, 2021). Although non-GM labelling and production shows differences between operators and Member States, they adopt a threshold of 0.1% GM/NGT presence in the products, and have experienced up to 12% growth, with the share of non-GM products

representing 60 to 100% of products in some markets, especially Germany and Austria (ENGA). Economic impacts of coexistence of NGT and non-GM agriculture and value chains are considered to be considerable for non-GM stakeholders, notwithstanding the different policy options under consideration (ENGA, 2021). It should be noted that most of the conclusions that apply to organic agriculture and value chains seem today applicable also to non-GM agriculture and value chains. Indeed, as indicated above, both organic and non-GM stakeholders (including farmers and retailers with both conventional and non-GM production/value chains) consider that the segregation measures that today apply to GM products would also apply to those developed with NGT's. This premise is nonetheless contested by some stakeholders, mostly stemming from research and the seed/ biotechnology industry, which state that non-GM operations could use and benefit from NGTs and their products.

Notwithstanding these differences, there is however consensus on the lack of precise empirical data related to economic costs of coexistence measures taken by non-GM farmers to minimise admixture in the EU. While targeted survey results seem to mainly indicate that no change is foreseen on the indicators under the different scenarios, whether A1/A2 or B1/B2. Other consultation results point out that scenarios A1 and A2 are considered to be unfair for organic and conventional farmers as they would not be able to differentiate whether they are GM-free and would not be able to fulfil the demand for non-GM or non-NGT products from actors of value chain. Notwithstanding the different policy options, stakeholders from the organic sector, those self-identifying as non-GM actors, civil society and public authorities stress expect difficulties in finding sufficient cultivation areas for both organic and non-GM/NGT agriculture if GM and NGT cultivation significantly expands. [21]With regards to the impacts of a labelling scenario, although survey results point to no change for organic agricultural production, interviews with organic stakeholders highlight that the lack of traceability in scenario B3 would have the most detrimental effect on organic farmers.

3.1.16 Net economic impact on GM-free labelling and value chain

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Impact on costs of and trust in GM-free labels	0	0/-	-	0	0/-	-	- -	0	0	0
Economic impact on GM-free traders, processors, food/feed industry and retailers	0	0/-	-	0	0/-	0/-	0/-	0	0	0

The ability to trace GM-free production and value chains is important since admixture risks damage to the image of the sector, which, in the absence of regulatory oversight and control, is completely dependent on consumer trust, which is assumed to be against the use of NGTs in non-GM products (Habets, 2019). Non-GM operators thus rely on their own traceability system and with extensive protocols and testing, both for production, processing and imports. In their view, Scenario A2 would mean investing in the development of detection methods and traceability regimes from scratch, without the ability to rely on public risk assessment and management bodies for guidance. Label confusion and competition is also flagged as a major concern with regards to B1. For the majority of NGO respondents and also public authorities, current legislation on the traceability and labelling of GMOs is key to enable and guarantee the coexistence with GM-free agriculture (i.e., cultivation and trade) as well as for consumer information and all questions concerning liability issues. Although survey results point to contradicting results depending on the approach of respondents to the inclusion or exclusion of NGTs

[21] Suggestions to mitigate have been pointed out in the literature (e.g., SIGMEA 2007) or the European Coexistence Bureau.

from GM-free agriculture, there seems to be consensus that under most scenarios (especially B1 to B3), the cost of GM-free certification may considerably increase, and issues of consumer trust may also arise.

The vast majority of non-GM operators today tend to assume that their customers do not want to buy products developed through NGTs. For some stakeholders, the undesired presence of an NGT product would be a form of adulteration of the non-GM product and risk damaging consumer trust, whereas for others, coexistence measures would only apply with regards to Directive 2001/18/EC. Processed products manufactured with or containing up to 0.9% of GM ingredients could lead to a utility loss of 38% of retail price (based on consumers' willingness to pay), resulting in losses varying from €403 million to €574 million/year (Catacora, 2011). The risk of admixture of non-GM/NGT commodities is likely to increase with the number of operators in the supply chain with mills being a part of the food chain particularly vulnerable to GM/NGT admixture, which would lead to avoidance of commodities where GM/NGT products exist. There is nonetheless a lack of consistent data and available information on the cost of coexistence at supply chain level.[22] For organic and non-organic GM/NGT-free operators of the food chain, the most important coexistence costs are product testing, careful cleaning at every processing stage and certification; and it is common practice to source commodities from well-known suppliers or safe origins and operating only organic feed or spatial segregation in specific plants. The decrease of areas under both organic and non-GM/NGT farming areas would thus jeopardise the existence and development of value chains.

The absence of detection methods under A2 is flagged as a potentially major detrimental effect for the non-GM value chain in interviews carried out in this study, since the feasibility of coexistence and controlled separation of each value chain largely depend on the availability and costs of suitable biological detection tests and on the requirements imposed on different actors of the value chain, who would have to develop their own testing protocols. Stakeholders express worries regarding their expanding conventional non-GMO product lines, which would be under particular threat of damage or destruction. It is generally considered that A2 would lead to a significant decrease of non-GM production and products. Although survey results in majority seem to indicate that no change is foreseen on any indicators, they also contain contradicting results, depending on the approach of respondents to the inclusion or exclusion of NGT's from GM-free agriculture. It can nonetheless be said that the expected negative impacts of scenario B1 are less important than in B3.

3.1.17 SME competitiveness in the seed sector

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
SME market share in plant breeding / seed industry	±	±	±	±	-	0	++	0	0	0/-

SMEs form an important part of the seed sector, with over 90% in some MS of plant breeders being SMEs (NBT Platform, 2018), although consolidation (see market concentration) in the seed sector has relatively decreased their importance in recent decades. The likely impact on SMEs is complex with different mechanisms coexisting in different scenarios.

Firstly, NGTs are considered relatively accessible tools for plant breeding due to their relatively low cost and complexity (compared to traditional GMOs). As such, NGTs have some characteristics of a less costly platform technology (i.e. group of technologies that can be used as a base for other technologies to be built on) that could lead to an opening

[22] The CoExtra FP5 research project concluded that for most value chains, the question on co-existence is a theoretical one (CoExtra 2009). See https://cordis.europa.eu/project/id/7158/reporting

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 (Whelan, 2020).

Secondly, while NGTs are relatively cheap at the development stage, some NGT techniques (and in particular CRIPR) are expensive to licence for commercialisation (Licensing Case; Montenegro de Wit, 2022). The smallest SMEs involved in plant breeding may not be able to navigate either the R&D-opportunities, let alone commercialization, deteriorating their relative competitive position (Wesseler, 2019). There is a risk this gap would exacerbate existing power and competitiveness gaps between well-established SMEs and firms with fewer resources, such as those in developing countries (Montenegro de Wit, 2022). Affordable access to IP is an important precondition that is not always guaranteed, and the importance of IP in NGT-based plant breeding is likely to favour large companies (Jorasch, 2020; Habets et. al 2019). It also needs to be considered, that licencing of a protected technique and later of a patented product is the exclusive decision of the patent holder, which gives him or her additional power to dominate the market.

Third, we find that SMEs are particularly vulnerable to regulatory requirements, which are more easily navigated by larger firms (by virtue of having scale benefits, in-house legal departments etc.). This is evidenced by the fact that for the baseline situation for risk assessment has resulted in SMEs being somewhat more likely (40% vs 33%, Jorasch, 2020) to reduce their NGT-development effort compared to large companies. SMEs were much less likely to move their product development primarily to other countries (20% vs 100%, Jorasch, 2020).

Fourth, SMEs are particularly sensitive to uncertainty, as they have fewer reserves and cannot spread their risk over a broad portfolio. Any risks that might result in a lack or delayed market authorisation are therefore particularly affecting SMEs.

Due to the above, consulted stakeholders disagree about the expected aggregate effects on SMEs within the various regulatory scenarios. Some stakeholders (most plant breeders, conventional value chain actors) believe SMEs will benefit while others (primarily NGOs and organic sector stakeholders) believe all scenarios will see a deterioration of SME competitiveness. In the baseline scenario (A0), the majority of survey respondents sees a negative impact on SME competitiveness. On average, respondents see a positive impact of scenario A2 (not A1) and B3 (less so for B2/B1). In general, we see less strong effects of the C scenarios, although interviewees do indicate that any additional requirements (such as under C2) are especially burdensome in terms of uncertainty and regulatory costs for SMEs. Negative impacts on SME competitiveness were also mentioned in the PC (Q2). The potential of a lighter regulatory framework to be particularly advantageous for SMEs was also clearly present in Q17 on measures to boost SME competitiveness. Should a regulatory situation arise which is navigable for large biotech companies but not for SMEs, competitiveness of SMEs in the plant breeding sector would likely further deteriorate over time. Although there is potential for economic benefits under A2, there is also a concern that the new genomic techniques would remain only available to multi-national companies that have the resources and knowledge needed to apply them. Most survey respondents also indicate that under scenario B1 and B2, the share of SMEs active in the NGT plant breeding will decrease (Q38, Q39).

In contrast to the above results, SME active in organic breeding expect to be negatively affected. Especially scenario A2 and B3 could have a large negative effect as it will be costly to keep breeding material GMO free, threatening their business as a whole. For organic farmers and plant breeders, coexistence costs threaten to be that high that the extra profit margin from being organic may decrease substantially. The production of NGTs in restricted, certain areas may be the only solution. The example of the Chilean coexistence model of the seed market is based on spatial isolation, voluntary

deployment of a strategy between sexually compatible crops and GPS-based supervision by the national seed trade association (Sanchez & Campos, 2021).

In conclusion, scenarios associated with higher NGT development (A2; B3) will likely induce SMEs to significantly increase their plant breeding activities, but it is uncertain whether this will also lead to strong commercialisation efforts or rather an active acquisition landscape for large multinationals. Much will depend on the evolution of the IP-landscape (see section 3.1.22 on technological sovereignty). Scenarios that raise uncertainty due to additional requirements (and therefore risk of rejection/delay), such as B1, C2, are likely to be negative for SMEs in any case.

3.1.18 General competitiveness of the overall supply chain

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Cost/price competitiveness of the EU seed sector and conventional farming vis-à-vis rest of world	-/--	-/-	0/+	-	0/-	0/-	++	0	0	0/-

Several countries are pursuing regulatory frameworks that have reduced risk assessment requirements and short timelines compared to the current EU regulatory framework of NGTs. Most stakeholders and sources agree that the effect of the EU's current framework (baseline scenarios) is negative for the EU's general competitiveness for plant breeding. Negative impacts on competitiveness were mentioned by PC respondents as part of an open question on economic/social impacts (Q4), adequacy of risk assessment (Q1), and impact of the baseline scenario (Q2). Among the survey respondents there is a disagreement on the degree and nature of impact on competitiveness under the baseline scenario, whereas a large majority sees positive impacts of A2 (not A1) and B3 (not B2/B1). In general, we see less strong effects for most of the C scenarios when it concerns wider economic impacts (4.16-4.22). This is due to the fact that some stakeholders (in particular plant breeders) indicate that the large majority of NGT-applications already aim at sustainability characteristics. Therefore, this will neither change the actions of stakeholders nor the economic outcomes to a major extent. Other stakeholders (across all stakeholder types) expect limited effects because they believe the scenarios are not implementable and will in practice not impact the scenario outcomes.

A majority of plant breeders (61%) and Member states expect a negative impact of the current regulatory environment (A0) due to factors such as a more uneven level-playing field and reduced access to a global gene pool (germplasm) for plant breeding due to difficulties to use regulated germplasm in breeding programmes (Wesseler, 2019; Jorasch, 2020). In terms of impact on competitiveness of EU farming, some stakeholders claim a negative impact on conventional farming due to an uneven level-playing field (in particular when enforcement would be weak), reduced access to new tools developed through science and innovation efforts, and increase in input prices (e.g. for feed supply). Some stakeholders, however, argue that the EU's competitiveness stems from its high regulatory standards (food safety etc.) and its organic/GMO-free sectors, or argue that competitiveness in itself is not a goal. In terms of the impact of the scenarios, scenarios A2 and B3 are considered an improvement in terms of conventional competitiveness.

3.1.19 Competition effects

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Seed market concentration; NGT technology IP concentration	±	±	±	+	+	+	0/+	0	0	0/-

The seed sector has shown strong patterns of consolidation and vertical integration in the past 20 years (WIPO, 2019; OECD, 2018). In the current baseline situation, the effective ability to launch NGT-products on the market is highly concentrated in a few large firms that can navigate the complexities and timelines of the GMO-regulation. Relevant IP is also highly concentrated (Testbiotech, 2019), although NGT-applications are developed (not commercially exploited yet) by a broad variety of R&D-actors. The competitive landscape of NGTs is discussed in more detail in section 3.1.17 on the position of SMEs.

The majority of survey respondents sees an increase of market concentration under the baseline (A0), a small majority also for IP. Under A1 and A2 we see patterns of market concentration (least in A2). B0-1-2 scenarios are on average seen as increasing the market concentration. For B3, there is uncertainty whether the condition for complying to the exemption of a labelling requirement are sufficient for SMEs to compete. In general, we see less strong effects of the C scenarios in terms of wider economic impacts (see also discussion in section 3.1.17).

3.1.20 Strategic impacts on international trade

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
International trade (incl. asynchronous authorisation aspects)	--	--	-/0	--	--	--	+	0	0	-/0

The effect of the baseline situation (A0, B0) on international trade is clearly negative. In practical terms, the current regulation does not facilitate the importation of commodities derived from NGTs (Purnhagen & Wesseler, 2020). The current GMO-regulation has resulted in lost trade opportunities due to temporarily closed borders, testing costs, lawsuits, and disputes (Smyth, 2017). Asynchronous authorisation creates uncertainty for importers and exporters and may expose plant breeders to liability claims (Zimney & Sowa; 2021; Eriksson et al., 2018; Purnhagen & Wesseler 2021). The situation for NGTs may be more challenging compared to conventional GMOs, as limited (or no) detection methods exists. Therefore, more challenging and expensive functioning identity preservation systems for both NGT and NGT-free products from the EU's trade partners are required (Eriksson et al, 2018). This holds true for all scenarios, though to a varying extent depending on the degree of regulatory divergence. 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 (perceived) impossibility of trade partners to comply with labelling and segregation requirements (see, e.g., the Argentina case study), resulting in higher costs and input prices, according to traders. The EU's relatively strict regulatory position globally may also make negotiating future Free Trade Agreements with third countries more challenging (Hundleby & Harwood, 2018).

Stakeholders agree with this assessment. In the PC, concerns about the current negative impacts on international trade featured prominently in an open question regarding economic and social impacts (Q4). Consistently, majority of survey respondents sees a decrease of international trade under the baseline scenario. Stakeholders find that scenarios with lighter regulations (A2, B3) may alleviate some of

these concerns but not all, as the A3 scenario still implies (in its current format) stronger regulatory requirements then elsewhere in the world. Respondents on average see a positive impact on international trade under scenario A2 (not A1), and to some extent also for B3 (not B1/B2). In general, we see less strong effects of the C scenarios (see discussion in 4.2.16), although sustainability requirements (C2) could result in reduced availabilities of imports, as not all crops may meet these criteria or pursue market authorisation.

It is important to note that for organic and non-GMO trade specifically, the effects of lighter regulation are perceived to be clearly negative by stakeholders (see also Sections 3.1.13 and 3.1.15). It is also important to note that some stakeholders argue that trade is neither a goal in itself nor a potentially negative factor due to environmental or decentralisation (local rural economies) considerations.

3.1.21 Strategic impacts on the internal market

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Functioning of the internal market	--	-	+	0	0	0	0	0	0	0

Stakeholders point out that the current system of Member State opt-outs results in a fragmented internal market. This has a negative impact on food producers, comparable in character to the discussion as presented under international trade (see 3.1.20), but of smaller scope. Survey respondents report limited impact on internal EU trade under most scenarios. This effect is likely also the case due to the assumption that new legislation will be implemented EU-wide without opt-outs (see section 2.5 on key assumptions and 2.5 on limitations.)

3.1.22 Self-sufficiency / strategic autonomy

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Technological sovereignty	-	-/0	+	-	-	--	+	0	0	0
EU Food Security	--	-/0	0	-	-	--	0	0	0	0

In terms of strategic autonomy from a **technological perspective**, we can distinguish two opposing impacts of the baseline and potential lighter regulation. On the one hand, plant breeders and other stakeholders argue that the current regulation is reducing EU actors' technological absorption capacity for new genetic techniques (see section 3.1.23 on innovation & research), making the EU potentially too reliant on foreign agricultural biotechnology in the future. A lack of access to innovation under the baseline scenario is mentioned in the PC (Q4). On the other hand, other stakeholders argue that lighter regulation might lead to an overreliance on specific technologies (Catacora Vargas et al., 2011) of which critical IP is in the hands of a few firms, which may be owned in majority by non-EU stakeholders, now or in the future. However, others expect that there will be an increasing variety of technological offers, some of which off-licence, especially as key patents will start expiring in a decade (see Argentina case). While the concerns of such path dependency are to some extent logical, they are not inherently a result of a lighter regulatory framework for NGTs, and are therefore future risks that could (and should) be managed (see section 2.5), as opposed to the very concrete present negative impact on technological sovereignty due to reduced R&D efforts in the EU.

In terms of strategic autonomy from an **EU food security** perspective, conventional plant breeders, farmers and other value chain stakeholders (such as feed manufacturers) see very negative effects of maintaining the baseline scenario. In the baseline scenario (A0), a majority of survey respondents sees a negative impact on food

security, as well as negative impact on access to technology. A majority of respondents sees an increase under scenarios A2 (not A1) with B3 more divided results. In general, we see less strong effects of the C scenarios. Stakeholders representing conventional farmers argue that access to new varieties with improved traits can help farm productivity and resilience and therefore reduce the reliance on imports. Some also see opportunities for 'reshoring' certain crops that might become economically feasible to grow in Europe with adapted traits (Sanguanini, 2018), as happened already with soybean (Donau-soya). More generally, the reduced competitiveness (see general competitiveness) of the food and feed sectors could also undermine the robustness of the EU food system according to these stakeholders. According to these stakeholders, lighter regulation (scenario A2/B3) could be a step in the direction of preventing these outcomes. Other stakeholders, however, see negative impact on the EU food security in these scenarios, as NGTs could in their view increase the reliance on a small number of (sometimes foreign) biotech companies, undermining regional networks/markets (Then et al., 2021). Moreover, these stakeholders associate NGT-based farming with intensive agricultural practices with limited varieties which while productive are not (always) sustainable and resilient, thereby endangering EU food security. As with technological sovereignty, the negative effects of a tight regulatory framework are more direct, and tangible compared to the more long-term risk of such dependency (see section 2.5).

3.1.23 Innovation and research

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Private R&D, EU patenting; Funding for research in academia/institutes;	--	--	+	--	--	--	+	0	0	0

In terms of **private R&D-**activities on NGT-related research, we have already seen a negative effect of the recent ECJ decision with firms moving much of their associated R&D overseas, where regulatory approval for field trials and cultivation is faster, easier and less risky from a business perspective. Stakeholders see a negative impact on firm-level innovation in these sectors, also impacting a broader base of biotech research capabilities in the food and feed sectors. Private sector representatives estimate the annual impact at €210 million (NBT Platform, 2019). In the long-term this may also decrease the absorptive capacity of EU agricultural biotech industry and its capacity to evaluate international developments in gene editing (Rathenau, 2021). Young researchers indicate that the EU has become less attractive for a career in agricultural biotech, leading to a brain drain and recruitment challenges (Interviews; German National Academy of Sciences Leopoldina, 2019). This could further widen the already established patenting gap between the EU and US/China on agricultural biotechnology that emerged since 1998 (WIPO, 2019). Through PC, business associations stress the need for regulatory change in order to sustain a R&D-base in Europe.

Of the different scenarios, only scenario A2 (if sufficiently broadly defined) elicits expectations of positive impact from these stakeholders, as a lower regulatory burden will increase investments both from large multinational plant breeders as well as SMEs (see also SME competitiveness), 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. However, other stakeholders argue that such intensified R&D might distract from R&D on developing more sustainable farming methods, where they already see a lack of investment.

The impact on the **wider research base, including available funding for biotechnology R&D in academia/research,** is also mostly seen as negative. While the academic performance of the EU in on NGT-related research is very high (45% of the total of worldwide publications, 81% of which produced by public institutes),

researchers see the current regulatory situation as hindering funding decisions by both public and private funders. Researchers also cite the negative impact on the possibility for in particular early-career researchers. Survey respondents see a negative impact on private R&D found under A0. Impact on available funding for public R&D institutes seems to be considered less strong. On average, respondents see lighter regulation (Scenario A2/B3 in particular) as having a (more) positive impact on available funding, in particular from private channels. However, others argue that the strict IPR requirements limit the potential for research collaboration (Sanguinini, 2018), access to key knowledge for researchers, and therefore see a reduced effect of such a change. Some also argue that public authorities should invest more in (local) public R&D focused on serving regional agricultural systems instead (EC, 2021).

3.2 Impact area: Environment / Sustainability

3.2.1 Environmental trait preferences

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Market share of traits affecting pesticide needs per area; fertilizer needs per area; energy use; natural resource use	0	0/+	++	0	+	++	++	0	0/+	±

The baseline scenario makes it more costly to produce NGTs, regardless of the (environmental) trait. Scenario A2 would make it more likely that NGTs with various environmental traits preferences would be produced. Most stakeholders agree that there is a potential in NGT crops to have traits related to positive environmental impact (see Table 5 below). The agreement on the potential positive environmental impact is the highest around the traits on increased pest-resistance and to some extent on reduced need of fertilizer. The targeted survey shows that the typical respondent expects that certain traits related to sustainability will be more present under certain scenarios, in particular pesticide reduction (20% under A2 vs. 3.5% under A0), fertilizer need reduction (10% under A2 vs. 0% under A0), with energy use and natural resource use being somewhat less prominent (range of 5% under A2). There is less agreement on whether drought-resistant plants and plants with higher nutrient efficiency leading to higher yields and lower fertilizer use per area of land could (easily) be developed, as these environmental traits depend on the interaction of various genes and the specific environment in which the crop will be planted. The labelling scenarios (B) moderate this effect positively in particular for the scenario B2 (no labelling if sustainable). For B1 (sustainability label), the targeted survey finds a minority of stakeholders seeing a (small) positive effect, but interviews with value chain stakeholders point out that such a sustainability label is not likely to be used in practice if voluntary. The impact of the scenarios focusing on sustainability incentives is less clear-cut. Most stakeholders interviewed doubt the possibility of arriving at implementable sustainability criteria, and are worried of raising false expectations, since actual sustainability is achieved during implementation within a specific context.

Should this be resolved, stakeholders do see some merit in the sustainability incentives offered under C1, with C2 showing a more mixed response. While some stakeholders point to the focusing effect of a sustainability requirement, plant breeders in interviews point to the uncertainty created by such an additional requirement, potentially deterring overall investment.

Most stakeholders interviewed see a potential value in Scenario C2, and limited potential value in Scenario C1 because these scenarios might be able to push the "application of NGTs to breeding of crops more in the direction of preferential environmental traits".

However, there are questions on how the sustainability of a trait could be determined, as all stakeholders agree that the sustainability of a crop depends not on its individual traits but on the interplay of the plant with its environment and the farming system that it is adopted in. Interviewees mentioned in this regard that there is still a lot unknown about the effects of NGTs on sustainability, as it is highly dependent on trait. Also, crops might perform better on one trait, but less on a different trait. These trade-offs would make it even harder to assess whether a newly developed NGT crop could be called sustainable and therefore pass the tests proposed in scenario C1 and C2.

Table 5 Trait market shares under scenarios (in %)

Trait affecting	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Pesticide reduction	3.5	10	20	3.5	+	++	20	20	20	20
Fertilizer needs	0	5	10	0	+	++	10	10	10	10
Energy use	0	5	5	0	+	++	5	5	5	5
Natural Resource Use	0	5	5.5	0	+	++	5.5	5.5	5.5	5.5

Note: Median estimates, based on targeted survey
+/++ is compared to the B0 scenario, no percentage estimate available.

3.2.2 Pesticide use

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Total consumption reduction of pesticides, Water quality – pesticide pollution	0	±	±	±	±	±	±	0	0/+	0/+

The possible impacts of the various policy options on pesticide use and pesticide pollution are contested. Three different NGT crop traits could lead to an impact on pesticide use: pest (and disease) resistance, herbicide tolerance, and Bt/toxin-producing (the wording depends on the stakeholder group) crops. Given that there is no direct evidence of the environmental impact of crops developed using NGTs yet, we first reflect on evidence of impacts from GM technology, then stakeholder expectations and expert-validated projections of potential impacts of NGTs specifically.

Regarding pest- or pathogen resistance, it is clear from the literature and discussions with experts that the actual increase or decrease in pesticide use depends on the specific traits, and the systems in which the NGT plants are applied in (pest/pathogen resistance management is highly important). Some literature shows that pest-resistant NGT crops can lead to suppression of regional populations of pests leading to lower pesticide use (see e.g. ALLEA, 2020; Purnhagen & Wesseler, 2021; Jenkins et al., 2021). A clear example of a case in which pesticide use decreased using the cisgenic technique, is provided in the inset below. Literature reviews have found the range of pesticide use change from the adoption of GM crops in the past to be between a decrease of 36.9% and an increase of 7% (Benbrook, 2012; Klümper & Qaim, 2014).

Case: Phytophthora-resistant potato and scab-resistant apples

The case study shows that so far, all monogenic resistances that were introduced into potato have eventually been overcome by *P. infestans*. Research has found that stacked resistances against *P. infestans*, a major potato pest, derived using cisgenesis, can result in 50-80% reductions of fungicides 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.

Source: JRC (2022). Economic and environmental impacts of disease resistant crops developed with cisgenesis

Concerning herbicide tolerant fibre crops, the literature is also divided. Do note that the scientific literature is based on GM crops as there are (hardly) any NGT crops on the market[23]. There is academic literature that states that herbicide-tolerant GM crops lead to increased pesticide use (most often in the long term), e.g., because of the development of herbicide-resistant weeds that require more / other pesticides (e.g., Rizwan et al., 2019; Kwon & Kim, 2008; Eckerstorfer et al., 2019; Kranthi & Stone, 2020). Some older literature shows that the applied pesticides on herbicide-tolerant GM crops and/or the toxins produced by the GM crops themselves could be more toxic to the environment (see e.g. Catacora-Vargas 2011 for the reasoning behind this). More recent research points out that herbicide-tolerant GM crops need less rounds of herbicides application, leading to less herbicides use, or that the planting of herbicide-tolerant GM crops could lead to the substitution of herbicides by less-toxic active ingredients (Purnhagen & Wesseler, 2021; Zilberman et al., 2018; de Lima Seixas, da Silveira & Ferrari, 2022; Romeis et al., 2019). The literature review found that on average, pesticide use increased for herbicide tolerant GM crops with 2.4%, with ranges in literature varying between a decrease of 20% and an increase of 25% (although this result was not statistically significant due to the small numbers of herbicide tolerant GM crops analysed) (Klümper & Qaim, 2014), while another study showed that for herbicide-tolerant GM crops the use of herbicides increased by 56% (de Lima Seixas, da Silveira & Ferrari, 2022). What increases the complexity, is that the impacts are likely to vary across crops and local conditions of cultivation (Zilberman et al., 2018). In a very recent study by Brookes (2022), global environmental impacts of pesticide use change due to GM crop use over 24 years concludes that the widespread use of insect resistant and herbicide tolerant seed reduced pesticide use of active ingredient by -7.2% and decreased the environmental impact quotient by 17.3%. Worldwide, the use of insect resistant cotton accounts for one third less use of active ingredients.

The disagreement on whether pesticide use would increase or decrease is also visible in the PC, in particular in the differences in responses between business associations and environmental organisations. Regarding pest- or pathogen resistance, most stakeholders agree that this group of traits could lead to less pesticide use, but the opinions are varied when it comes to the application of the NGT. The business associations see NGT crops as a solution to decrease overall pesticide use, while environmental organisations do not think NGT crops are part of the solution, but organic farming techniques are. Some respondents also see a combination of NGTs and organic farming as a possible solution for decreased pesticides use. The targeted survey also confirms this dichotomy: for both the total consumption of pesticides as well as the water quality due to pesticide pollution, around 60% of the survey respondents expects the more widespread availability of NGT plants to decrease pesticide use and pollution, while around 30% of the respondents expects the use of NGTs to increase pesticide use and pollution, again highly split by stakeholder type (Q28). A substantial majority of PC respondents (>75%) does see a positive contribution to sustainability overall of pesticide-related traits that are potentially available via NGTs, although some groups report lower agreement (e.g., environmental NGOs 20%, non-GM actors 30%).

Finally, there are some concerns among stakeholders concerning the adoption of NGT crops within the agricultural system. One concern is that the adoption of NGT crops will

[23] It should be noted there are also herbicide tolerant crop varieties bred using conventional techniques. These also are faced with issues of weed resistance, see for instance Wedger et al, 2022.

follow the pattern of the adoption of GM crops: in tandem with adoption of monocultures and industrialized farming systems (see e.g. Catacora-Vargas & Myhr, 2011). Secondly, a concern is that among NGT crops that will be developed when the legislation changes there will be many herbicide-tolerant crops. In the JRC database, currently 6 out of the 17 products in the pipeline (35%) that are in (pre)commercial stage and thus to be expected to be on the market in 2030/2035 are products with herbicide tolerant traits.

In short, there are a number of crucial assumptions that lead to stakeholders having different arguments on how pesticide use might change under different scenarios, where stakeholders typically equivocate scenario A0 with a 'low/no NGT crops on the market situation' and A2 'availability of NGT crops on the market scenario'. Depending on the stakeholder group and the evidence, each of the A scenarios could lead to a higher or lower pesticide use and pollution. The impact of the labelling (B) scenarios is less clear, due to lack of clarity whether and which pesticide reduction related traits would qualify under the scenarios. Regarding scenario C1 and C2, there are mixed expectations for the impact on pesticide use. Most stakeholders agree that the scenarios could lead to a decrease in pesticide use and pollution, even more so for C2 than for C1. However, for some stakeholders this potential value hinges on the assumption that herbicide-tolerant NGT crops would not be allowed in C2, as they argue assumption 1) is true: herbicide-tolerant NGT crops lead to more pesticide use. Also, as said above, most stakeholders agree that it is not an individual trait that makes an NGT crop more sustainable, but rather, it is the interplay of various genes and the crop's environment.

Outputs quantitative analysis

The quantitative analysis based on the targeted and expert surveys shows that the expectations regarding changes in pesticide use due to NGT crop adoption in the EU in 2030-2035 could be in the range between an increase of 0.9% and a decrease of 5.7%, depending on the specific type of trait, crop and the policy scenario. For policy scenarios 0 and C2, expected changes range from an increase of 0.1% (Legumes and Oil and Fibre crops) to a decrease of 0.8% (Oil and fibber crops). For policy scenarios A1, B1, B2 and C1, expected changes range from an increase of 0.5% (for Legumes) to a decrease of 3.5% (also Legumes). For policy scenarios A2 and B3, expected changes range from an increase of 0.5% (Legumes) to a decrease of 5.7% (Cereals).

3.2.3 Fertiliser use

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Total consumption reduction of pesticides, Water quality – pesticide pollution	0	±	±	±	±	±	±	0	0/+	0/+

There is agreement on the potential to develop crops with NGT traits to reduce the need of fertilisers, but there is less agreement on whether the actual production process of NGT crops with this trait will also lead to less fertilizer use. According to some stakeholders (mainly biotechnology researchers and breeders), NGT crops could be developed that minimize inputs such as fertilisers.

Mainly environmental organisations, NGOs and some researchers are not convinced that NGT crops will reduce fertilisers, as increased nutrient efficiency (that leads to less fertiliser) is a complex trait that depends on many genes and the crop's interaction with the environment. If the NGT crops could have the potential to reduce fertiliser use, this would not hold for every crop and every circumstance. In fact, the actual impact would depend on the farming system they are applied in. The mentioned stakeholders argue

that in organic farming systems, substantially less inorganic fertilisers are used than in conventional agriculture. NGT crops that require less fertilisers would only decrease fertiliser use slightly. These differences in expected effects are present in the PC as well as in the targeted survey. From the first, there is no quantitative evidence, but some of the respondents provide insights in the debate in their open answers (e.g. Q4). Especially business associations argue that NGT products could have less environmental impact due to decreased fertilizer use, while NGOs and environmental organisations argue the opposite. Under the assumption of the more widespread availability of NGT plants, around 60% of the targeted survey respondents expect a decrease in the use of fertilisers, while around 30% expect an increase. Slightly more than half expect a positive impact on the water quality due to (less) nitrate pollution, around 30% of the respondents expects the impact to be negative. The effects of the B and C scenarios are in line with the argumentation for pesticide use as discussed above. The baseline scenario limits the potential of these NGT crops being introduced to the EU market.

Outputs quantitative analysis

The quantitative analysis based on the targeted and expert surveys shows the expectations regarding changes in fertiliser use due to NGT crop adoption in the EU in 2030-2035. In general, a decrease is expected in the range of 0.1% and 4%, depending on the type of crop and the policy scenario. For policy scenarios 0 and C2, expected changes range from a decrease of 0.1% (Legumes and Cereals) to 0.6% (Oil and fibre crops and Cereals). For policy scenarios A1, B1, B2 and C1, expected changes range from a decrease of 0.5% (Oil and fibre crops and Legumes) to 2.7% (Cereals). For policy scenarios A2 and B3, expected changes range from a decrease of 0.5% (Legumes and Oil and fibre crops) to 4% (Cereals).

3.2.4 Use of natural resources

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Water use efficiency in agriculture; Impact on supporting services of soil	0	±	±	±	±	±	±	±	0/+	0/+

There is little agreement on the potential effect of the various policy options on the use of natural resources (most importantly soil and water). Although the large majority of the PC respondents (over 80%) expect a positive impact on better use of resources, this does not hold for stakeholder groups such as consumer organisations (40%) and trade unions (36%). On the one hand, there are stakeholders (mainly biotechnology researchers and breeders) that argue in the targeted survey that the baseline scenario inhibits them from introducing NGT crops that have a higher water use efficiency and/or that are drought resistant. According to them, in scenario A2 these crops could prove to use fewer natural resources. A majority of targeted survey respondents (60%) agrees with this assessment. In the literature, the main argument for this is that NGT crops have the potential to reduce land use for crop production (Smith, Wesseler & Zilberman, 2021; Jenkins et al., 2021; Camerlengo, Frittelli & Pagliarello, 2022). Also, representatives from these groups argue that herbicide-tolerant crops lead to weeds being less of a problem, which means that reduced- and zero-tillage systems are possible in industrialised monoculture systems, and therefore soil erosion and moisture loss from tillage can be prevented (for literature on this argument, see e.g., Purnhagen & Wesseler, 2020; Zilberman et al., 2018). On the other hand, there are stakeholders (mainly researchers, public authorities and environmental organisations) that argue that herbicide-tolerant crops lead to an increase in the use of pesticides (see section on pesticide use), which impoverishes soils. Also, they do not believe that drought-resistance can be promised as an NGT crop's trait, as this characteristic depends on the interplay of various genes and of the crop with its environment. Therefore, they see

limited value in scenario A2. The effects of the B and C scenarios are in line with the argumentation for pesticide use discussed above.

Outputs quantitative analysis

The quantitative analysis based on the targeted and expert surveys shows that the expectations regarding changes in water use due to NGT crop adoption in the EU in 2030-2035 could be in the range between an increase of 0.4% and a decrease of 2%, depending on the type of crop and the policy scenario. For policy scenarios 0 and C2, expected changes range from an increase of 0.1% (Oil and fibre crops) to a decrease of 0.4% (Oil and fibre crops). For policy scenarios A1, B1, B2 and C1, expected changes range from an increase of 0.4% (Oil and fibre crops) to a decrease of 1.6% (Legumes). For policy scenarios A2 and B3, expected changes range from an increase of 0.4% (Oil and fibre crops) to a decrease of 2% (Cereals).

3.2.5 Air quality and greenhouse gas emissions

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Energy use efficiency; Greenhouse gas emission reductions	0	±	±	±	±	±	±	±	0/+	0/+

There is again disagreement on the potential effects of the various policy options on greenhouse gas emissions. Most of the stakeholders who have written about this topic are mostly (biotechnology) researchers and a couple of breeders. Both these stakeholder groups argue that pest and weed resistant as well as herbicide-tolerant NGT crops have the potential to reduce the number of times herbicides need to be applied as well as the amount of tillage. Therefore, they argue that scenario A0 inhibits, and scenario A2 could support, the increased uptake of reduced- and zero-tillage systems, and thus to reduce greenhouse gas emissions both through the reduction of fuel needed to manage the crops, and through sequestering carbon in the soil and not being released from the soil (Benbrook, 2022). Also, yield gains can be land-saving, preventing greenhouse gas emissions from land use change (Hansen & Wingender, 2022). Finally, they argue that NGT crops could be developed that require less fertilizer or energy during the production, and therefore less greenhouse gas emissions. The inset below provides an example.

Root chicory can be improved through NGTs to produce more inulin and more terpene than through conventional breeding, and thus obtain two food ingredients with nutritional benefits in larger quantities per AOC. The extraction of terpene requires a more elaborate process, but by mass allocation, the GHG emissions and total primary energy use for the production of higher levels of terpene are lower than for conventional root chicory.

See case study on chicory, Annex 5

On the other hand, a limited number of researchers and environmental organisations write that the adoption of more NGT crops would lead to higher greenhouse gas emissions. They argue that the use of NGT crops is associated with industrialized agricultural systems, which means that the production system is associated with higher use of synthetic fertilizers and more global transport of the crops than in the organic sector (Catacora-Vargas & Myrh, 2011). Therefore, increased adoption of NGT crops, which is likely to happen in scenario A2, would increase greenhouse gas emissions. In the targeted survey**,** almost 60% of the survey respondents (consisting mainly of

business associations (20 out of 26 respondents), large companies (7 out of 8), the 'Other' stakeholders (8 out of 9), academic/research organisations (3 out of 5), and consumer organisations (2 out of 2)) expects the more widespread availability of NGT plants to cause a decrease in greenhouse gas emissions, 1 in 4 of the respondents expects the impact to be the opposite (mainly NGOs (10 out of 21), public authorities (3 out of 5), academic/research organisations(2 out of 5), and business associations (3 out of 26)) (Q14). Slightly more than half of the respondents (consisting mainly of business associations (20 out of 25), 'Other' stakeholders (9 out of 10), large businesses (7 out of 8), NGOs (6 out of 21), and academic researchers (3 out of 7)) expects the more widespread availability of NGT plants to decrease energy use, almost 30% of the respondents expects the impact to be the opposite (consisting mainly of NGOs (10 out of 21), academic/research organisations (4 out of 7), public authorities (4 out of 5), and business associations (3 out of 25)) ((Q14). The impacts for the B and C scenarios are in line with the argumentation in the pesticide impact subarea.

Outputs quantitative analysis

The quantitative analysis based on the targeted and expert surveys shows that the expectations regarding changes in energy use due to NGT crop adoption in the EU in 2030-2035 could be in the range from no change to a decrease of 3.1%, depending on the type of crop and the policy scenario. For policy scenarios 0 and C2, expected changes range from no change (all relevant crops) to a decrease of 0.4% (Cereals). For policy scenarios A1, B1, B2 and C1, expected changes range from no change (Oil and fibre crops and Legumes) to a decrease of 1.8% (Cereals). For policy scenarios A2 and B3, expected changes range from no change (Oil and fibre crops and Legumes) to a decrease of 3.1% (Cereals).

3.2.6 Biodiversity

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Pest or Pathogen pressure evolution; Impact on non-target organisms; Impact on crop diversity	0	±	±	±	±	±	±	0	0/+	0/+

The impact of the various policy options on biodiversity is contested. In the targeted survey, roughly equal number of stakeholders expect a positive (40%) or a negative (46%) impact. In the PC, environmental organisations and NGOs point to the risks that NGT crops bear for biodiversity, without a chance of the developer being held responsible, as the NGT crops cannot always be unequivocally identified, and to the danger of monocultures of NGT crops, but other type of stakeholders argue that NGTs have the potential to support biodiversity protection.

Biodiversity could be impacted through three different angles: pest or pathogen pressure evolution, impact on non-target organisms (such as pollinators, microbial communities, etc.), and crop-diversity. We investigate these aspects separately below.

Regarding pest or pathogen evolution, the arguments differ around the impacts of mainly herbicide-tolerant NGT crops. The arguments depend again on whether the stakeholder assumes: these crops lead to more or less pesticide use and pollution. Increased pesticide prevalence in the environment can be detrimental for biodiversity. Also, herbicide-tolerant weed plants could disperse and persist more easily and therefore become a dominant species, outcompeting other species in an environment where the herbicide-tolerant weeds would have an advantage, i.e. in the field where the herbicides are applied (EC, 2021; Eckerstorfer et al., 2019). The majority of

stakeholders in the targeted survey (60%, consisting mainly of business associations (20 out of 26), 'Other' stakeholders (8 out of 9), large companies (7 out of 8), NGOs (6 out of 12), and academic/research organisations (5 out of 7) (Q14) expects the more widespread availability of NGT products to decrease pest/pathogen evolution. Almost 30% of the stakeholders who expect the opposite effect (consisting mainly of NGOs (12 out of 21), business associations (5 out of 26), public authorities (3 out of 5), and academic/research organisations (2 out of 7). We can therefore observe that scenario A0 has a likely negative impacts and scenario A2 positive.

Regarding non-target organisms, the arguments differ around the impact mainly of herbicide tolerant NGT crops, and gene flow. On the one hand, if one assumes that herbicide tolerant NGT crops reduce the quantity of herbicides use as well as the quantity of tillage, this creates a positive impact for non-target organisms as well as microbial communities living in the soil (Purnhagen & Wesseler, 2020). Thus, scenario A0 has negative impacts, and scenario A2 positive. On the other hand, if one assumes that herbicide-tolerant NGT crops lead to higher herbicide use, this increases the herbicide exposure of non-target organisms, and of natural pest-predator species that are crucial to natural pest management, and which can lead to a feedback loop in which increasingly more pesticides are necessary to keep pests under control (e.g. Greenpeace, 2015). Thus, scenario A0 has positive impact on biodiversity, and scenario A2 negative. The possible effects in multiple directions make it difficult to estimate an aggregate impact. This is also observed in the targeted survey, where 46% of the stakeholders (consisting mainly of Business associations (14 out of 24), NGOs (9 out of 21), 'Other' stakeholders (7 out of 10), large companies (4 out of 8), and academic/research organisations (3 out of 7) expect a positive impact and 37% a negative impact (consisting mainly of NGOs (9 out of 21), Business associations (7 out of 24), SMEs (4 out of 5), and large companies (3 out of 8)).

Finally, regarding crop diversity, the arguments differ around the impact on yields from NGT crops and impacts on local production systems. Regarding yield, yield gains from NGT crops can slow down the expansion of agricultural land and there can be more space for nature with higher biodiversity (Hansen & Wingender, 2022; Jenkins et al., 2021)). In that case, scenario A0 has negative impacts on biodiversity, and scenario A2 positive. Regarding local production systems, some stakeholders see a danger in the displacement of local production systems by NGT crops (Habets, van Hove & van Est, 2019; EPRS, 2020). This would reduce the diversity of crops used in agriculture, as well as the local knowledge of crops suited for the local climate (Catacora-Vargas & Myhr, 2011). In that case, scenario A0 has positive impacts on biodiversity, and scenario A2 negative.

3.2.7 Environmental risks (ERA)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Limited impact on non-target organisms (horizontal gene-transfer; accidental consumption; invasive species) during the field trial phase and during the market cultivation phase	0	0/-	0/-	0	0	0	0	0	0	0

The vast majority of survey respondents sees in scenario A0 only no or moderate (positive or negative) impacts on non-target organisms. While 20% expect moderate or strong negative impacts, 80% see rather small or moderate positive impacts. Strong positive or negative impacts are mainly seen by non-governmental organisations while

the remainder opted for less pronounced impacts. For almost 50% of the respondents, sustainability incentives for authorisation as included in C1 have no impact. For 39% the expected impacts are moderate while 13% expect strong impacts. Strong impacts were mainly seen by non-governmental and consumer organisations but also organic business associations. Under C2 with its requirements for authorisation and no authorisation if detrimental to sustainability, 55% expect no impact while 34% expected small or moderate impacts on non-target organisms. Strong impacts were only expected by two non-governmental organisations (3%).

Asked about the potential impacts on the environment and biodiversity for example through gene transfer or accidental consumption during the field trial or release phase, four in five do not expect a change under the A0 scenario while 13% expects increases in impacts. Under A1 which offers proportionate risk assessment and adapted detection method requirements, 60% do not see a change while 26% see potential increased impacts. This view comes predominantly from non-governmental and consumer organisations (11 out of 16), but also public authorities and business organisations. These rates grow slightly for A2 where 65% do not see a change and 32% (21) expect increases, including 11 non-governmental and consumer organisations, and six business associations and SMEs (Q18-20).

There is broad consensus among academic researchers and research organisations (PC, literature, interviews) that there is no difference between the risk profiles between plants derived from targeted mutagenesis and from conventional breeding, thus the current regulatory regime (A0) would not be proportional (EFSA, 2020). From the scientific literature, the potential impacts on non-target organisms via horizontal gene-transfer (HGT) is very limited (Modrzejewski et al., 2020). The frequency of HGT, e.g., from GM crops to non-target organisms, is expected to be lower than background rates. It is considered even less likely to occur with imported or processed plant material (EFSA, 2017), see also further section 3.3.1. on risks and hazards of products entering the market.

Overall, no impact on non-target organisms is to be expected under the various scenarios with a proportionate risk assessment, since this should cover potential risks. Special attention might be required for scenarios taking sustainability aspects into account if an "accelerated risk assessment" for crops with sustainability attributes would make inspectors tend to overlook specific items. The definition for the notification regime in A2 is broader than the categories established by the EFSA GMO Panel. While EFSA focused on traits that are already present in the food supply chain and hence have a "history of safe use", the notification regime refers to all available traits that can be obtained naturally or by conventional breeding. Consequently, the notification option might allow the introduction of traits without a history of safe use, and a full risk assessment might still be needed.

The majority of the PC respondents expressed the need for a change of the current risk assessment of plants produced by targeted mutagenesis and cisgenesis. 34% - mainly citizens, academia, and public authorities - are favouring the option that these plants need to be risk assessed using requirements adapted to their characteristics and risk profile (scenario A1). 27% - mainly business associations, companies, trade unions but also academia - think that no risk assessment is needed if NGTs could have been produced through conventional plant breeding or mutagenesis (A2), and 13% do not see the need for a risk assessment at all. (Q3). The status quo (A0) is favoured by 22% which are mainly consumer and environmental organisations, NGOs and trade unions.

3.3 Impact area: Health, Safety and Social Impacts

3.3.1 Risk and hazard profile of products entering the market

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Limited impact on non-target organisms (horizontal gene-transfer; accidental consumption; invasive species) during the field trial phase and during the market cultivation phase	0	0/-	0/-	0	0	0	0	0	0	0

The majority of survey respondents does not expect any change in the risk and hazard profile of products entering the market under the current regulatory framework (A0: 83%) and both scenarios with less strict regulation (A1: 59% and A2: 62%). In both A1 and A2, 16-17% of the respondents (mostly representatives from NGOs and consumer organisations) expect a moderate or strong increase in potential hazards such as off-target mutations or unintended effects of genetic modifications) (Q19-Q20). The share in A0 is smaller with 6% (Q18).

Biodiversity and 3.2.7 on Environmental risks). PC respondents expressed the need to reframe the current risk assessment of NGT plants, either by a risk assessment adapted to their characteristics and risk profile (selected by 34%) or by a risk assessment that excludes NGT pants that could have been produced also through conventional plant breeding (selected by 27%) (Q3) (see above section 3.2.7). Furthermore, the majority of respondents in the PC (70%) either strongly agree (47%) or tend to agree (23%) that a risk assessment that takes into account the characteristics and risk profile of a final product is necessary for a future-proof legislation (Q14).

The survey responses mirror the scientific literature. The scientific literature on off-target effects indicates less effects for certain new GE methods compared to conventional mutation breeding: The EFSA GMO Panel concluded that plants obtained by NGTs do not pose any additional hazard and have less often off-target effects. Holme, Gregersen & Brinch-Pedersen (2019) point out that a high load of off-target mutations is an intrinsic property of conventional mutagenesis. Out of 1328 studies using CRISPR/Cas, TALENs, base editing, ZFN, and ODM, 252 of them investigated off-target mutations. In around 3% of the analysed studies, potential off-target sites, unintended mutations were detected (Modrzejewski et al., 2019). Case studies on rice (Tang et al, 2018) and cotton (Li et al., 2019) showed that no off-target sequences were found with CRISPR/Cas but conventional tissue culture resulted in ~100-250 single nucleotide variations.

3.3.2 Safety of gene-edited/cis-genic crops and derived products

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Limited presence of potential hazards (toxicity; allergenicity; negative nutritional impacts)	0	0/-	0/-	0	0	0	0	0	0	0

Based on the targeted survey results, the majority of respondents do expect no change on potential risks such as toxicity or allergenicity. For A0, 83% expect no change. Slightly less respondents expect no change in A1 (62%) and A2 (64%). For the latter two, 21% (A1) and 29% (A2) expect an increased presence of potential hazards. These are mainly NGOs and consumer organizations (A1: 10 out of 16; A2: 9 out of 15) or public authorities (for A2: 4 out of 10)) (Q18-20).

More than half of the survey respondents expects health risks to decrease (50% choosing strong or moderate negative association, 9% still indicate a small negative association) if NGTs were on the market (Q15). Health risks are associated to toxicity, allergenicity and negative nutritional impacts,

In the PC, most respondents (34%) support the option that 'NGT plants need to be risk assessed using requirements adapted to their characteristics and risk profile', a smaller percentage (27%) selected that 'NGTs do not need to be risk assessed when they could have been produced through conventional plant breeding or classical mutagenesis'. The opinion that these 'plants need to be assessed using the current GMO legislation requirements' is chosen by 22% of respondents. 13% of the respondents believe that 'no risk assessment is needed at all.' (Q3)

The main international and national scientific organisations accept the scientific consensus that food produced from GM crops is safe (Wozniak-Gientka et al, 2022). Apart from the direct effects from gene-edited plants described in 4.4.1, there is the possibility of unintended effects being caused by the genetic modification, and these vary according to the tool used. Some scientists argue that there is no evidence of unique risks inherent to NGT derived products, and that regulations should instead use science-based criteria to assess the safety of new plant varieties independently of the technique used to create them. The EFSA GMO Panel has considered the applicability of its safety assessment approach to plants obtained through various NGT techniques, including several types of targeted mutagenesis (site-directed nucleases 1 and 2, oligonucleotide-directed mutagenesis) and cisgenesis, amongst others. For the latter, it is considered that plants obtained with these techniques have the same kind of unintended mutations with an equal or lesser frequency as plants obtained from conventional mutagenesis breeding (Modrzejewski et al., 2020) (see also section 3.3.1 above).

3.3.3 Enforcement quality / post-market monitoring

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Limited risk of non-compliance of products on the market / test fields	--	--	+	0	--	-	+	0	0	0

Considering the use of analytical methods for market control, current knowledge, and the state of the art of GMO testing, it is highly unlikely that enforcement laboratories would be able to detect new genome-editing plant products with unknown modifications. These challenges were also recognised in the PC (Q1.2). Despite efforts towards the development of alternative analytical control strategies, which involve sequencing data from EU and trading partners, the implementation of such complex control mechanisms could result in disproportionate costs and administrative burden. For instance, the organic sector argues that it is still possible to regulate what is currently on the market and additional costs would be justified by the consumers' demand to have clarity on food production. According to survey respondents this would affect less the risk of non-compliance of field trials (A0-2), while 55% expect moderate or strong increases in the risk of non-compliance on the market in the A0 scenario. This view is shared by all types of stakeholders with business associations (13), large companies (7), SMEs (4), as well as NGOs (7), public authorities (7), academia (2), and other (6).

For A1 this is similar with 56%. Mixed responses were given for A2 (Q20): 34% of the respondents expect no change, 42% expect small or moderate decreases and 25% expect increases in the risk of non-compliance. There is a rather clear dichotomy in terms of stakeholders: decreases are mainly expected by large companies (7), one SME, business organisations (8), public authorities (4), academic organisations (3), NGOs (3), and other (4) while increases are expected by NGOs and consumer organisations (9), business associations and SMEs (3 each), and two public authorities.

Since different regulatory regimes exist in non-European countries, e.g., fewer restrictions for NGTs at the breeding level, less strict regulation of NGTs at the European market might reduce the risk of non-compliance (similar to the 0.9% acceptance level for unintended admixtures). Insights from the FG suggest that some large companies outside the EU may have a global regulatory strategy and they may be able to register genome editing events and provide relevant tracking information about the plants to the testing stations in the EU. However, small parties such as universities, small breeding companies, and local producers may neither feel compelled to register their genome edits nor freely provide data on the edits to the EU; in particular, if they focus on their domestic markets only. Additional traceability requirements for sustainability claims (B1-2) will negatively impact the ease of compliance and strongly increase the administrative burden according to the survey (Q37). Less requirements (B3) limit the risk of non-compliance but this scenario depends on the choice under scenarios A0-2. In general, transparency requirements are well acknowledged while enforcement of additional traceability requirements is considered difficult given that there is no detection method (interviews and discussion in traceability focus groups) nor global harmonised transparency regulation.

3.3.4 Traceability of quality in the value chain

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Quality of source, traceability of NGT-based products	-	±	±	-	-	-	±	0	0	0

Authorisation, traceability, and labelling requirements which are included in the current GMO legislation, raise implementation and enforcement challenges for plants obtained by targeted mutagenesis or cisgenesis. Traceability via the detection of small DNA changes is difficult: some argued that traceability would be possible based on the availability of adequate reference material and detection methods (e.g. Greenpeace), while the vast majority of scientists and science bodies insist that without prior knowledge it is technically impossible to distinguish genome-edited plants from plants selected for spontaneous mutations or plants that are obtained through mutation breeding. Consequently, if the identification of the product that needs to be regulated cannot be distinguished from the conventional equivalent, it is unclear how regulations can be enforced (in scenario A1/2). Survey respondents did not select the availability of identification and detection methods as well as labelling and traceability requirements under the current scenario as one of the most important factors for plant breeders in deciding to develop new plant varieties using NGTs (Q11). Participants who responded to the PC that the current regulation is adequate – a limited share of 17%, mostly think this is because 'authorisation, traceability and labelling requirements are appropriate for these plant products' (26% out of 17%) (Q1.1). A conclusion from the focus group on traceability is the usefulness of public databases as a means to enable traceability PC, Q10). This would require compulsory information provision on the seeds/traits/cultivars.

Traceability could also be based on process documentation (paper trail or digital, *e.g.*, blockchain, see Dionysis, et. al., 2022). Traceability requirements, however, would have economic implications (e.g., costs of compliance) (PC, Q10) and a strong increase in administrative burden (for more detail on the extent on change in traceability costs see

section 8.4.1). Moreover, 80% of the respondents see a decrease in ease of compliance in case of additional traceability requirements for sustainability claims (Q37). This was equally confirmed in the FG on Sustainability (see Annex 6).

The organic sector demands that agrochemical companies should have their products registered and recognizable. Plant breeders, however, see additional labels for products that are similar to conventionally bred products (scenario B1/0) as discriminatory. They agree with researchers that scenarios B2 and B3 (preferred) are less problematic as they inform the consumer about the content of the product and not about the technology that was used to create it.

3.3.5 Consumer variety and choice

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Total Consumer Choice; Availability of products free from NGTs	-	±	±	-	+	0/-	0/-	0	0	0

Consumer variety and choice will be affected differently. The survey responses indicate that while an increased availability and adoption of plant varieties developed using NGT methods has largely positive impacts on total consumer choice, while there are no negative impacts with the availability of NGT-free products (Q15). In the present situation (A0), the consumer has factual no choice since neither GM nor NGT products are available in European countries. However, given the imports of authorised GMOs for food and feed use, the expectation is realistic that NGTs which cannot be detected without prior knowledge, will find their way into the feed process and ultimately be on the consumer plate. Thus, for the organic and GMO-free sector a true freedom of choice would require a labelling as provided under AO and B3 while the retail ecosystem is not in favour of a mandatory label, envisaging that this results in a low presence of NGT products (see Annex 6 focus groups) and despite the long history of GM safety.

Under the current scenario (baseline A0, B0) the range of products is expected to be limited, due to trade disputes between the EU and other countries and due to restrictive labelling. Lighter regulations will allow more NGT products on the market, thereby expanding the range of options that are partly 'designed' to meet consumers' preferences. This includes new products with (new) features that are important to customers, for instance, reduced allergenicity. Survey responses (70%) indicate that a sustainable trait label increases consumers' willingness to buy NGT products with such a label (scenario B1). Both, transparency (e.g., via front-of-pack nutrition labelling) and the wider availability of nutritionally improved NGT products will have a positive impact on consumers to make healthier choices. Respondents to the targeted survey indicate that sustainability labelling will increase clarity for the consumers, hence the lack of labels (scenarios B2/3) might have negative effects (Q35). At the same time, the range of GMO-free and organic products for consumers might be reduced due to increased prices and/or efforts to ensure GMO-free production (Greiter et al., 2011; Nuijten et al., 2016). The focus group on sustainability clearly was against a sustainability label exclusively for NGTs. This would be to the disadvantage of sustainable conventional or organic products since the sustainability label allows for higher premiums (see Annex 6).

3.3.6 Consumer rights

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Overall trust in European Food Safety	0	0/-	0/-	0	-	-	-	0	0	0

Overall trust in European Food Safety is an essential prerequisite for consumers' 'food sovereignty', a system in which consumers define the production, distribution, and consumption of food they want to consume. Consumers should be enabled to make informed decisions when purchasing and consuming food. This could be facilitated via two regulatory systems: one on safety assessment and one on tracing and labelling. Overall, survey responses were mixed, while the highest share of the respondents (30%) see no change of increased availability of NGT with overall trust in EU food safety, 26% see a negative and 18% a positive change (Q15). To 60% of respondents of the PC information should be made available to the consumer while 30% do not share this view (Q8). 38% of the respondents indicate that transparency can be achieved through information available elsewhere, for instance via a website or public database (20%) or via a digital label (link to a website or QR code, 18%). 29% of the respondents replied that transparency for operators and consumers can be achieved via a physical label on the final product while 22% think that transparency is not necessary for NGTs (Q12). Yet, when information is not available on the label, consumers' willingness to obtain this information from a website or QR code is expected to decrease (Q35).

Studies have shown that consumers are willing to purchase more expensive products labelled as genome-edited when these are safe and/or of higher quality (Zilberman et al. 2018; Smith et al. 2021), or beneficial in terms of improvements of nutritional value or taste, sustainable production processes such as a reduction in pesticide or water use (Norwegian Biotechnology Advisory Board 2020). Representatives of the wider value chain, including Traders, Processors, Manufacturers, and Retailers believe that consumer trust would depend on the confidence in the techniques that were used for risk assessment and detection under A1 and A2.

Interviewees from the organic sector argue that consumers care about correct labelling especially regarding GMO-content and suggest similar regulation for NGT products. Other stakeholders, including researchers, farmers, and part of the organic sector, claim that additional labelling might negatively influence consumer trust, for instance, if sustainability claims on labels are not maintained or sustainability labels wrongly imply that only NGTs are sustainable. Based on these views, it is apparent that labels need to be clear and easily understandable to provide consumers with the necessary correct information when they make their purchasing decisions, and the claims made also need to be attainable. More complex information could be provided through a link to a website or a QR code. Some members of the organic sector however argue that no labelling (Scenarios B2/3) restricts the consumers' rights regrading transparency.

3.3.7 International development cooperation impacts

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Global South food security; Reduction of hunger worldwide (drought-tolerant maize); Improved nutritional quality in Global South	-	+	+	-	-	-	+	0	0	0/-

Global South food security is a complex topic of great concern as it procures to improve the amount and quality of life of food-insecure communities. The EU has committed itself to the UN sustainable development goals (SDGs), including GOAL 2: Zero Hunger, and GOAL 3: Good Health and Well-being, by 2030. In general, utilization of NGTs could positively contribute to food security since this leads to enhanced quantity and efficiency of food production. This view is shared by 64% of the survey respondents (Q15). Stakeholders, including academia, public institutions, and environmental organisations believe it is necessary for the EU to allow innovative gene-editing technologies that alleviate food scarcity. In the PC, decreased food security in the

context of climate change was listed as one of the negative consequences if plants obtained by targeted mutagenesis and cisgenesis are continued to be regulated under the current GMO framework (Q2). NGTs offer the means to optimize desired characteristics of plants, including drought and salt tolerance, which increases potential cultivation area, as well as resistance to diseases or pests, and thus can help **reduce world hunger**. Along these lines, overall food quality can be increased with NGTs (see also 4.4.4), thereby improving **nutritional quality in the Global South**. On the other hand, patented seeds may weaken the position of individual farmers and decrease local food production, as was reported for countries after GM crops were introduced (Catacora-Vargas & Myhr, 2011). This can further be associated with a reduced variety of locally available food and can lead to malnutrition due to oversimplified diets. The strong focus on NGT bears the risk that other breeding innovations are neglected which are much more important for food security as most important traits are determined by large number of genes, and regulatory mechanisms that cause adjustment in the different environments (GxE interaction). Moreover, present food insecurity is mainly due to improper distribution and accessibility of food.

A clear example on the benefits of NGT plants in this context is provided below:

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) 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.

MLN resistance is considered the most economically and sustainably effective way in the battle against this disease and could safe 1-3 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.

Source: MLN JRC case study

The impact of the different labelling scenarios (B0-3) on the above-mentioned indicators might be predicted via the results provided for the international trade (see 4.2.18). International trade will be negatively affected by labelling and traceability requirements under scenarios B0-2, whereas the conditions under scenario B3 could have a positive impact.

3.3.8 Labour rights and income redistribution

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Less income and wealth inequality (due to concentration of market power)	-	-	0/±	0	-	-	±	0	0	0

The various policy options might affect labour rights and income redistribution differentially depending on the type of stakeholder in the value chain and the type of crop. This is reflected in the mixed survey responses regarding the association of more NGTs with income and wealth distribution (Q15). While less strict regulation of NGTs

may be more beneficial for large enterprises active in plant breeding and farming of cash crops, smaller companies might be at a disadvantage given their more limited financial and technical resources. Yet, from the breeders' perspective, larger companies as well as SME breeders consider the technology as attractive. GM crop cultivation may be well suited for industrial agriculture, while in particular environmental organisations claim that this may lead to fewer production and employment opportunities for farmers due to the mechanisation and the concentration of land ownership as observed in some Latin American countries (Pengue, 2005; Catacora-Vargas & Myhr 2011). Farmers may have to spend more on specialised and high-priced seeds, yet, under optimal growing conditions, higher crop yield could result in higher income for farmers and less spending on herbicides or pesticides. Other stakeholders such as traders and processors might be similarly affected by increased costs for seeds, and they may risk losing competitiveness depending on the respective policy option, if they cannot pass on the costs to the consumers. Crops cultivated for dietary aspects and ingredients with value added may well have positive income effects and also small positive employment effects further upstream the value chain (CS6). Changes in labelling requirements (B1/B2) are expected to increase market concentration which could contribute to income and wealth inequality, this view is shared less under scenario B3 (Q38-40). Scenarios C1/2 are not expected to have an impact on market concentration and hence are not likely to contribute to income and wealth inequality (Q57/58). Reduced employment opportunities caused by industrialized agriculture and increased competition for small farmers, for example, when producing organic products.

3.3.9 Health and nutritional aspects

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Health benefits (intolerance; allergen reduction; nutrients); Health benefits (QALY); Food Safety; Aggregate risk to human and animal health	0	0/+	+	0	0	0	0	0	+	+

Malnutrition affects about 2 billion people worldwide according to the World Health Organization (WHO, Geneva, Switzerland) and has severe health, economic and social consequences, especially in underdeveloped and developing countries (WHO, 2009). Precise genetic modification brought about by NGT could create healthier products, including plants with traits modifying content that could affect health as well as plants with traits that modify the nutritional profile (Q31, Q33/34). Health benefits for consumers could result from increased beneficial bioactive compounds in food and feed, such as increased levels of vitamin A, antioxidants, and GABA. Moreover, harmful bioactive compounds such as cyanide, glycoalkaloids, allergens could be removed. One example is Calyxt, whose NGT soybean is used for an oil with a qualitatively improved composition of fatty acids and is thus healthier than its conventional counterparts. NGTs may affect overall health benefits (QALY) in different ways, including the accessibility to products that might lead to healthier diets. This is in line with the survey responses (61%) indicating a (mostly strong) positive association with health benefits, and a negative association (53%) with health risks (Q15). One example is provided in the following inset:

Socioeconomic impact of low-gluten celiac-safe wheat developed by gene-editing

Celiac disease (CD) is a long-life autoimmune disease that affects about 1% of the world population. Gluten-free products are currently the only treatment for this disorder. 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 CD 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 GE 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 and improving quality of life.

Source: JRC 2023 Science for Policy report

Although less relevant in the EU, another benefit can be associated with fewer cases of pesticide poisoning in cases of NGT cultivation where pesticide use was reduced (i.e., less exposure to pesticides), while other benefits are related to less labour time spent on the field as reported for countries of the Global South. Accordingly, risks were assessed in the survey with mixed associations related to occupational health (Q15). Survey results indicate that plant traits modifying content (incl. nutritional profiles) that could benefit health will be increasingly adopted by farmers under Scenarios C1 and C2 compared to the baseline (Q50/51) (see also the root chicory case in Annex 5).

3.3.10 Freedom to conduct business (Art. 16 CFR)

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Plant breeders' rights; Farmers' Rights (UN Declaration of Peasants)	±	0/±	0/±	0	0	0	0/±	0	0	0

In the PC short-, medium- or long-term consequences were expected by respondents from business associations if the current regulation is maintained (Q2). Whereas survey responses were mixed, with most respondents associating no change and less respondents associating either an increase or decrease for plant breeders and farmers' rights with increased availability and adoption of NGT plant varieties (Q15). According to plant breeders the time-consuming and expensive application for licensing GM crops hampers innovation. Scenario A1 of proportionate risk assessment and A2 of notification are associated with more NGTs. If this would be associated with patents this may worsen the situation particularly for small and medium plant breeding companies who lack the necessary financial resources and expertise. Breeders might have better access to new techniques; however they still have to obtain the license which might be costly. The same is true for breeders who want to use a product that falls under a NGT product patent, they cannot make use of the 'breeders' exemption'. Larger multinationals, on the other hand, are better prepared for this process. Furthermore, less strict regulations (A1/2) might also negatively impact farmers' rights, especially regarding biotechnology patents. According to one of their fundamental rights, farmers are allowed to save seeds, but concerns are raised regarding intellectual property through patenting, which affects the legal basis for the innovative part of their work. Farmers might also lose independence in their choice of seeds and might be further impacted by the feasibility of coexistence that ensures the cultivation of GM-free and organic plants. A revised framework for NGTs should make the system more easily accessible for farmers (CEPM)

and with faster approval procedures, relying on the scientific measures and data (see PC in Annex 4). Overall, breeders' and farmers' rights are differently impacted under the different scenarios and depending on their sector, i.e., organic/GM-free or not. The current regulation might hamper the business of plant breeders and farmers, while changes in policy and especially the removal of labelling for NGT products are undesirable for the organic/GM-free sector (B3).

3.3.11 Extension of breeder's and farmer's portfolios to new, neglected and locally important crop species

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Expected change in breeders' and farmers' portfolio size due to new, neglected and locally important crop species	0	+	+	0	0	0	0	0	+	0/+

NGTs contribute to the development of new and improved plants and can further support the use of neglected and local crop species. With these new varieties breeders and farmers are able to extend their portfolio, this is reflected by the responses in the targeted survey (Q15/Q28-30). For instance, NGTs allow for the domestication of wild plant species, which may lead to improved seeds. Hybrid seeds that are locally produced might be a solution to protect against reduced pest and disease resistance incurred through large-scale sowing of clonal plants. An example where a GMO variety enabled the local production to survive can be found on Hawaii: due to the ringspot virus a collapse of the papaya threatened its disappearance (Lemarié & Marette 2022). However, the burden of the risk assessment under scenario A1 could be too high, especially for SMEs working on local/smaller varieties. Eliminating the need for risk assessment (Scenario A2) will positively impact breeders' and farmers' portfolio due to improved accessibility of techniques for SMEs. For both scenarios, stakeholders are concerned that less regulation will lead to an increase in IPRs. Plant breeders would register their locally important plants only if there is a sufficient market for them. Regarding scenario C1 an increase in breeder's and farmer's portfolio size and no change or minor increase under scenario C2 is expected (Q47/48).

3.3.12Social tensions between farmers

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Increase in tensions between organic, non-GM and other farmers (e.g. neighbouring disputes)	0	-	-	0	-	-	- -	0	0	0

Undisclosed farming of GMOs and proximity of GM and non-GM production systems have created tensions between adopters and non-adopters of GM crops, and are also expected to be mirrored for NGTs and organic production systems, provided NGT's are not allowed to be used in the Organic Regulation, but also potentially beyond, since personal value systems would also lead numerous farmers to avoid NGT admixture in production. As organic farmers seeking compensation are obliged to identify the entity responsible for the damage, this creates further tension among the different actors in the agricultural sector, usually located in the same community. Stakeholders from several countries expect conflicts between neighbours within countries as well as between neighbouring countries to rise under A1 and A2. Tension is based on gene flow; the identification of sources within the same community entails economic and non-

monetary damage. Furthermore, linked to gene flow are rising numbers of often costly liability cases. Coexistence will still be a challenge (see above) and land management might be the only solution to reduce conflicts, for example if NGT varieties are only cultivated in defined areas, or through voluntary transparency in local farming areas that leads to plantation of sexually non-compatible crops in vicinity, as practiced in the Chilean seed production (Sanchez & Campos, 2021).

4 Impact area: Regulatory Costs

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 the experience with GMO authorisation. Details on the approach and methodology are included in Annex 2 while detailed results are included in Annex 7.

4.1 National Authorities

Impact indicators	A0	A1	A2	B0	B1	B2	B3	C0	C1	C2
Increase in tensions between organic, non-GM and other farmers (e.g., neighbouring disputes)	0	0/	-	0	-	-	- -	0	0	0

Risk assessment

The consulted National Competent Authorities (NAs) under the current EU GMO regulatory framework estimate that each NA incurs **yearly risk assessment costs of € 1 726 765**. With an estimate of 11.4 authorisations per year per NA, each authorisation's **single risk assessment cost amounts to €209 391**.

- If subjected to different new regulatory oversight or verification, costs may change accordingly:
    - Full data except for protein (Example of a product: No newly expressed protein. Off-types have not been segregated out, no history of safe use): **May decrease NAs risk assessment costs by 8%**
    - Molecular characterization and Safety data on the trait only (Example: No newly expressed protein and off-types have been segregated out. No history of safe use): **May decrease NAs risk assessment costs by 24%**
    - Molecular characterization and post market monitoring (including environmental only) (Example: No newly expressed protein, off-types have been segregated out and history of safe use): **May decrease NAs risk assessment costs by 39%**

Traits contributing to sustainability and detrimental impacts

The verification of the sustainability traits as well as potential detrimental impacts imply increased risk assessment costs by the NAs, driven by the need to set up new administrative procedures, standards, harmonisations, and controls.

The traits contributing to sustainability in this study are genetic modification delivering a trait that - compared with the product before genetic modification - provides a positive contribution to sustainability. The assessment of traits contributing to sustainability, if it is up to the NAs to perform, it is expected to invariably increase the number of tasks

associated to the authorisation processes. This is specially expected if NAs need to assess the pre-defined list of desirable or undesirable sustainability impacts (i.e. Reduction in use of plant protection products; Reduction in use of fertilizers; Reduction in use of natural resources; Tolerance/resistance to environmental conditions (abiotic stresses); including climate change effects; Tolerance/resistance to plant diseases (biotic stresses) such as nematodes, fungi, bacteria, viruses or pests), as well as if the NAs are expected to support the authorisation process with incentives for plant with traits that contribute to sustainability (e.g. guidance on overall development plan and regulatory procedure, dedicated contact point, scientific advice at key development milestone).

Regarding the introduction of sustainability labelling or traceability systems for plants that receive regulatory incentives or bear a sustainability labelling, most NAs expected to see the cost of the authorisation procedures to increase, as it will be necessary for them to set up systems in place for their relevant controls. Similarly, reducing the GMO labelling obligation may still be associated to authorisation costs increases if the NAs are required to assess the sustainability claims.

Table 6 Costs by scenario – National Authorities

Scenarios	National Authorities
A0: No change to Risk Assessment & Detection Requirements	Regulatory costs Min: €48 749 Max: €608 610
A1: Proportional Risk Assessment & Adapted Detection Requirements	Min: no change Max: -67%
A2: Notification regime for products also obtainable with conventional/natural breeding	
B0: No change to labelling & traceability	
B1: Additional Sustainability Label	Min: Negligible increase Max: High increase
B2: No labelling if sustainable	Min: No change Max: Slight increase
B3: No labelling & traceability if a product is also obtainable through conventional natural plant breeding	
C0: No change to Sustainability incentives	NA
C1: Sustainability Incentives for authorisation	Min: Moderate increase Max: Significant increase
C2: Sustainability requirements for authorisation: no authorisation if detrimental to sustainability	Min: Moderate increase Max: Significant increase

For the Netherlands however, cost increases may materialise only if the sustainability assessment becomes obligatory, as standards, harmonisations and systems will need to be put in place with relevant cost increases. If such assessments are voluntary, then cost increases may be limited. Thus, currently it is not possible to estimate the direction of the cost change.

For France, even though there may be cost reductions of not needing to control for the labelling obligations, the main part of control costs will remain, as traceability obligations

remain. Member States will still have to control that only authorised products (GMO or NGT) are on the market.

Regarding the costs associated to the analysis of traits based on the pre-defined list of detrimental impacts to sustainability NAs estimate they may increase, as it follows the same considerations as with the assessment of the sustainability claims.

4.2 European Institutions

Three organisations with obligations under current EU GMO regulatory framework were consulted, DG Health and Food Safety (SANTE), risk assessment performed by the European Food Safety Authority (EFSA), and validation of the detection methods, performed by the European Union Reference Laboratory (EURL). The average yearly authorisation procedures costs are estimated €1 282 880. With an estimate of 9 authorisations per year, each single authorisation cost amounts to €150 288.

Compared to the current situation, when considering hypothetical requirements for the experimental release and the placing on the market of plants obtained by targeted mutagenesis and cisgenesis and their food and feed, costs:

- **Risk management** costs for DG SANTE would **decline by 75% in case of notification** regime for TM and CG products that can be also obtained naturally or by conventional breeding techniques.
- **Risk assessment** costs for EFSA would:
    - Decline by 20% in scenario 1.
    - Decline by 60% in scenario 2.
    - Decline by 80% in scenario 3.
- Validating detection methods costs for EURL would not change overall.
- The verification of the sustainability traits would mainly increase the costs for DG SANTE in case of supporting the applications, introducing obligations of labelling for sustainability claims, and to record keeping plants in an EU public registry. Cost would decline in case of removal of time limits for authorisations and the need for renewals.

Table 7 Costs by scenario - European Institutions

Scenarios	EU bodies (EFSA, SANTE & EURL)
A0: No change to Risk Assessment & Detection Requirements	Risk Assessment EFSA: €170 000 (1) EURL: €220 00 Risk Management SANTE: €60 864
A1: Proportional Risk Assessment & Adapted Detection Requirements	Risk assessment Min: -20% Max: -80% Detection method validation No change
A2: Notification regime for products also obtainable with conventional/natural breeding	Risk management ~: -75% Detection methods validation: 5% Increase

Scenarios	EU bodies (EFSA, SANTE & EURL)
B0: No change to labelling & traceability	
B1: Additional Sustainability Label	Risk management 5% Increase
B2: No labelling if sustainable	Risk management 5% increase
B3: No labelling & traceability if a product is also obtainable through conventional natural plant breeding	Risk management 5% increase
C0: No change to Sustainability incentives	NA
C1: Sustainability Incentives for authorisation	Risk management Min: -25% (removal of time limit) MAX: +10% (Regulatory incentives)
C2: Sustainability requirements for authorisation: no authorisation if detrimental to sustainability	NA

(1): Estimations provided by EFSA representatives do not necessarily represent the formal position of EFSA.

4.3 Industry

4.3.1 Baseline

Cost estimations

- The **food and feed use authorisation costs range between ~€ 6 to €20 million** (for registration of single edit products) and **~€2.04 to €2.72 million administrative costs** if assessed under the current EU GMO regulatory framework.
- These estimates represent under-estimations as they do not account for:
    - The complete range of administrative costs, for instance GLP compliance and certification.
    - Adjustment costs, for instance costs related to the capacity and capability of an organization to perform regulatory studies, e.g., availability of internal databases, cost of access to databases, GLP and/or ISO certifications etc.
    - Costs of additional regulatory studies that need to be performed during the risk assessment process due to Authority requests. For instance, requests to perform new field trials or toxicological studies will have a very high cost associated.
    - Stacked products which require an individual assessment for every single trait as well as the stacked product itself increasing costs substantially. For instance, the currently estimated average of €13 million can increase 2.8 times for a stacked product with 2 single events expressing 2 new proteins each.
- The **cultivation authorisation costs** are higher than food and feed uses due to the environmental risk assessment (ERA) requirements. Limited inputs have been provided by plant breeders given the lack of experience with GM authorisations for cultivation according to Directive 2001/18/EC or Regulation (EC) 1829/ 2003. An estimate has been provided by one company indicating a range of **~€ 17.5 - € 28 million, plus ~€ 0.7 to € 1 million per year** (for registration of single edit product and annual monitoring) if assessed under the current EU GMO regulatory framework. Differences in costs are min +20% to max +60%.

Authorisation costs

- The **main cost driver of total authorisation costs is hazard identification and characterisation** and more specifically **the studies on toxicology, allergenicity and comparative analysis**. There is large variability regarding toxicity testing as one of the elements that has a substantive impact on the cost is the ease with which the protein can be produced, extracted, and shown to be equivalent to the plant produced newly expressed protein. For products for which newly expressed proteins are difficult to produce/extract additional cost will be applicable.
- The **second highest cost is the detection method**. Costs relate to:
    - Development of seed/grain samples that are free of adventitious presence (multiple kg) to comply with requirements related to DNA extraction validation.
    - Providing large amount of DNA.
    - Difficulty in developing a detection method which is compliant to the EURL minimum requirements but also makes use of such reagents that are preferred by EURL. This often requires multiple optimisation rounds by the applicant to develop a method that EURL considers fit for purpose.
    - Development of a DNA extraction method that complies with the EURL requirements on ease of use and resulting in the needed purity, which can be used on different matrixes.

A summary of authorisation costs is provided below. They are linked to a set of assumptions which are included in section 4.3.2 below.

Table 8 Summary of authorisation costs - Baseline

Costs	Share in total authorisation %	Minimum	Maximum	Average
TOTAL AUTHORISATION COSTS (excl. administrative and adjustment costs)		6 000 000	20 000 000	13 000 000
HAZARD IDENTIFICATION AND CHARACTERISATION				
Information relating to the recipient or (where appropriate) parental plants (Crop biology)	0.15	9 000	30 000	19 500
Molecular Characterisation	16.00	960 000	3 200 000	2 080 000
Comparative analysis	24.50	1 470 000	4 900 000	3 185 000
Toxicology & allergenicity	40.00	2 400 000	8 000 000	5 200 000
Nutritional assessment	4.00	240 000	800 000	520 000
EXPOSURE ASSESSMENT		-	-	
Estimated intake by humans and farmed animals	1.40	84 000	280 000	182 000

Costs	Share in total authorisation %	Minimum	Maximum	Average
ENVIRONMENTAL ASSESSMENT		-	-	
Potential changes in the interactions of the genetically modified plant with the biotic and abiotic environment resulting from the genetic modification (Interaction studies)	6.50	390 000	1 300 000	845 000
ADDITIONAL INFORMATION RELATING TO THE SAFETY OF GENETICALLY MODIFIED FOOD AND FEED		-	-	
Additional Information Relating to The Safety Of Genetically Modified Food And Feed (Systematic literature review)	0.25	15 000	50 000	32 500
TRACEABILITY AND LABELLING		-	-	
General information including a unique identifier assigned to the GM crop as described by the Commission Regulation (EC) No 65/2004	5.00	300 000	1 000 000	650 000
Event specific detection method and information on the certified reference material				
Proposal for labelling				
Information concerning the Cartagena protocol				
ENVIRONMENTAL MONITORING PLAN				
Environmental monitoring plan	0.90	54 000	180 000	117 000
POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED		-	-	
Post market monitoring on the genetically modified food or feed	0.30	18 000	60 000	39 000
AUTHORISATION RENEWAL		-	-	
Authorization renewal processes every 10 years	1.00	60 000	200 000	130 000

Administrative costs

- Cost drivers of administrative costs include
  - The need for a **dedicated regulatory department** of highly qualified and specialised in EU authorisations personnel.
  - The new **EU transparency Regulation** which increases administrative costs as it requires specific expertise for EU submission.
  - **GLP compliance and certification**: Any wet lab/field study complying with the EFSA definition of a study (see Article 2 of EFSA practical arrangements linked to transparency regulation) is required by the Reg 503/2013 to be conducted as GLP or within ISO facilities. For academia or plant breeding companies, these requirements to do studies under GLP or ISO requires significant cost and investments in order to have the plant re-characterised by a contractor who is able to comply with the GLP & ISO requirements.

A summary of administrative costs is described below.

Min	Max	Average
€2 040 000 Regulatory affairs support: 45 696 hours Regulatory science support: 12 240 hours	€2 720 000 Regulatory affairs support: 60 928 hours Regulatory science support: 16 320 hours	€2 380 000 Regulatory affairs support: 53 312 hours Regulatory science support: 14 280 hours
Assumptions • All costs are internal - no outsourcing. • All costs are staff costs. • The average cost for a single food and feed use authorisation (single event) is €13.6 million. • A minimum of 15% and maximum of 20% of total authorisation costs represents the range. • A 5 years average duration of authorisation applies. However, as dossier preparation starts approximately 2 years before submission, we account for 7 years • 30% of the costs derives from staff that performs scientific research (Regulatory science support) and development (with yearly wage excluding apprentices of €80K). • 70% of the costs derives from staff that performs office administrative, office support and other business support activities (Regulatory affairs) (with yearly wage excluding apprentices of €50K). • However, the division of work between scientific research and (Regulatory Science support) and office administration (Regulatory affairs) differs greatly depending on the nature of the product and the rounds of additional information requested by the Risk Assessor • Administrative costs related to the performance of activities which include costs of the building/offices, IT equipment, hence beyond salaries are excluded		

Adjustment costs

Adjustment costs are challenging to quantify especially for large breeders with global operations. They are related to the capacity and capability of plant breeders to perform regulatory studies, e.g., availability of internal databases, cost of access to databases, GLP and/or ISO certifications etc. These costs are significant. More specifically, substantive costs include:

- Laboratories for generation of regulatory data (different than R&D processes). Major seed producers have such laboratories in house which support their global operations.
  - The current GMO authorisation requirements require the generation of a comprehensive regulatory data package (especially for bioinformatic studies and sequencing) with numerous data elements requiring a very large group of experts. To put this in perspective, a safety data centre, responsible for product characterization and safety data packages, accounts for approx. 200 employees. Their data are used for GMO approvals globally including the additional data requirements and studies

with more expansive protocols, and additional endpoints requested by the EU.

- Licenses to scientific databases to meet requirements for literature searching for GM applications as EFSA demands that a wide variety of sources is screened.
- GLP and ISO certifications.

Variability in costs

- The variability in costs is reflected in the provisional results presented in the table below in terms of absolute values. The results presented are work in progress as we are still in contact with industry to better understand how to interpret large differences in the relative costs i.e., costs expressed as a percentage share in total authorisation costs. We also aim at collecting additional data on authorisation, administrative and substantive costs.
- The overall cost of regulatory studies for fulfilling the regulatory requirements in the EU varies, notably depending on the **specific product**, the **crop**, the **trait(s),** the **number and characteristics of the newly expressed proteins** and/or of any new constituent.
- In case of new constituents, depending on the regulatory requirements, the cost is expected to increase significantly

Assumptions

- Technology developers have an internal 'stage-gate' process that acts as a funnel to select and advance only desirable product candidates through the successive development phases. Advancement decisions are based on the lead candidates meeting target product concepts, with stringent internal safety, agronomic, technical, financial and other selection and prioritization criteria. A key Phase transition is the Regulatory handoff process for a GM trait development, which triggers the generation of the regulatory studies and activities. While previous phases of the product development process provide relevant information on the product safety and efficacy that guides the subsequent regulatory data development, the cost analysis does not consider these "pre- regulatory handoff activities" and only assesses the cost of the regulatory studies, personnel and activities to generate the EU regulatory dossier.
- When activities serve more than one purpose (e.g., production of materials that serve multiple studies) or more than one product (e.g., regulatory affairs staff costs), an estimate of the attributable cost to each set of activities or dossier is made. However, not all companies have provided this leading to some gap in the estimates. Even in those cases where such data are provided they need to be considered as an approximate estimation of the costs as they can fluctuate from product to product.
- Four companies have provided detailed information on authorisation and administrative costs. They are all international companies providing agricultural solutions globally. They have several years of experience in preparing and submitting regulatory dossiers of GMOs for import and food and feed use. While the sample is small it accurately reflects the plant science industry with experience in GMO authorisations in the EU. All companies are members of CropLife. The cases provided are described below.

Company 1	Company 2	Company 3	Company 4
single GM trait: TM or CG plant	Single event: GMO product with 2 newly expressed proteins	Stack soybean product with 2 single events expressing 2 new proteins each, with no new constituents other than NEPs. The data for a stacked products should be viewed as a separate case.	Single events with agronomic traits

Other

The costs for implementation of **GMO traceability and labelling** (with the exception of detection method) and the **environmental monitoring plan** affect namely the entire food and feed value chain, starting at farmers' gate. The costs and complexities along the value chain are considered by breeders to be significant. The costs for breeders are however not significant. Membership to associations facilitates the collaboration with traders and hence reduces the costs of engagement, alignment, recurrent discussions with traders on surveillance.

4.3.2 Scenarios

The assessment of authorisation costs for each scenario is summarised as follows:

- Plant breeders' preferred scenario is A2: Notification of products that are also obtainable naturally or by conventional breeding. However, the idealised system proposed by plant breeders goes beyond the criteria formulated by the EFSA GMO Panel as described in the study.
- Plant breeders strongly reject A1: Authorisation with proportionate risk assessment. The tiered approach presented by the study team is said to subject the plants that could have been developed by conventional breeding or spontaneous mutation to costly and discriminatory risk assessment schemes. Only minor to no reductions in costs are therefore expected. Equally there is no support of a detection method for plants developed by targeted mutagenesis and cisgenesis that could have been developed by conventional breeding.
- The scenarios under B affect the costs along the entire food and feed value chain. The costs and complexities of traceability and labelling are said to be significant but the direct costs for plant breeders are negligible in comparison to the regulatory studies.
- On sustainability incentives and requirements under scenario C there is significant concern over the regulatory uncertainties, timelines and regulatory costs. Specific costs for an applicant to comply with sustainability criteria will depend on the criteria and potential requirements. Apart from the extra costs, any pre-market data generation is expected to extend the preparation phase for the applicant and delay submission, lengthen assessment timelines and diminish the potential benefits of NGTs to speed up plant breeding.

Table 9 Costs by scenario - Breeders

Scenarios	Costs
A0: No change to Risk Assessment & Detection Requirements	**Authorisation** Min: €6 mi**o** Max:€20 mi**o** **Administrative** Min: €2.04 Max: €2.72
A1: Proportional Risk Assessment & Adapted Detection Requirements	Min: no change Max: -85%
A2: Notification regime for products also obtainable with conventional/natural breeding	Min: -70%[e] Max: -90% [e]
B0: No change to labelling & traceability	Min: €400 000 Max: €700 000 [detection method]
B1: Additional Sustainability Label	Negligeable
B2: No labelling if sustainable	Negligeable
B3: No labelling & traceability if a product is also obtainable through conventional natural plant breeding	Min: -2.7%[e] Max: -6.7%[e]
C0: No change to Sustainability incentives	NA
C1: Sustainability Incentives for authorisation	Min: +3%[e] Max: +15%[e]
C2: Sustainability requirements for authorisation: no authorisation if detrimental to sustainability	Min: +5%[e] Max: +25% [e]

5 Coherence analysis

The different policy options and scenarios identified regarding the regulation of NGTs have several interlinkages with existing and upcoming European legislation, which have all been highlighted by stakeholders in different consultation tools, whether in position papers, open text fields of the targeted survey, or in interviews. The main EU legislative tools highlighted by stakeholders in this context are the EU Organic Regulation, the EU seed marketing acquis, and the EU sustainable food system initiative.

5.1 The EU Organic Regulation: impact on coexistence pathway

As a regulated and strictly controlled quality label, the organic sector needs to follow the stringent requirements of the EU Organic Regulation 2018/848 throughout the production and processing chains. The Regulation forbids "*the use of ionising radiation, [..] genetically modified organisms ('GMOs'), as well as products produced from or by GMOs*" as it is "*incompatible with the concept of organic production and consumers' perception of organic products*". It defines 'GMO' as "*a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC, which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive*", while products produced from GMOs are defined as those "*derived in whole or in part from GMOs but not containing or consisting of GMOs*", those that are produced by GMOs are defined as "*derived by using a GMO as the last living organism in the production process,*

but not containing or consisting of GMOs nor produced from GMOs". (Preamble of Organic regulation, paras 58, 59 and 60). Article 5 of the Regulation thereafter "*excludes the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products*", while article 11 stresses that "*GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro- organisms or animals in organic production*", prompting operators to rely on the labels "*affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 [on GM food and feed], or Regulation (EC) No 1830/2003 [on traceability and labelling of GMOs]'.*

The linkages to be made with Directive 2001/18/EC (or lack thereof) in the future NGT legislative framework regarding the definition itself of NGTs, along with linkages (or lack thereof) with labelling and traceability obligations established under Regulations 1829/2003 and 1830/2003 will thus be of primordial importance for organic stakeholders. The EU Organic Regulation itself does not provide unambiguous response to the question, only defining "organic breeding" as activities "*conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions*" (Annex II, Point 1.8.2). The EU Organic regulation also enshrines specific principles that might relate to NGTs, stating that "*in the choosing of plant varieties, having regard to the particularities of the specific organic production systems, focussing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect for the natural crossing barriers*" should be respected in agricultural activities in organic production. From responses to the PC, targeted surveys and interviews, it appears that the majority of organic and non-GM stakeholders would wish to use the prohibitions included in articles 5 and 11 of the EU Organic Regulation to apply to NGT products, while some stakeholders, mostly representing researchers and non-organic business operators stress the opposite. The majority of organic and non-GM operators (as well as large retailers with non-GM product lines) do equate all NGT's to GMOs, either for ethical reasons, or because they fear the loss of certification and consumer trust in their production and value chains. Both organic and non-GM stakeholders thus consider that all segregation measures that apply today to GM products would also apply to those developed with NGT's. This premise is nonetheless contested by some stakeholders, mostly stemming from research and the seed/ biotechnology industry which do not think that there is a contradiction between organic agriculture and NGTs. There are thus considerable differences in the foreseen impacts of the different NGT policy options, which will depend on the interlinkages between the GM and new NGT Regulation and the Organic Regulation, and mainly on operators' own value systems and perceptions about consumer trust and behaviour.

5.2 The EU Seed marketing acquis: impact on transparency, traceability and sustainability assessment of NGTs

The marketing of seeds and other types of plant reproductive material in the EU is governed by twelve different crop or group of crops- specific directives at EU level (EU Seed Marketing Directives)[24]. Even though there are notable differences between the EU Seed Marketing Directives, they rely on a general principle of mandatory pre-marketing variety (and/or supplier) registration, all the while establishing seed quality criteria and labelling rules. Varieties are commonly tested by public authorities at national level, before being listed in national seed catalogues and the common EU catalogues for agricultural horticultural and ornamental species. Only seeds from listed

[24] Directives 66/400/EEC (beet seed), 66/401/EEC (fodder plan seed), 66/402/EEC (cereal seed), 66/403/EEC (seed potatoes), 68/193/EEC (vine), 69/208/EEC (seed of oil and fiber plants), 70/457/EEC (vegetable seed), 98/56 (ornamentals), 1999/105 (forest), 2002/53/EEC (common catalogue agricultural plant species), 2002/55 (vegetable seed), 2002/56 (seed potatoes), 2008/73 (vegetable propagating and planting material) and 2008/90/EC (fruit propagating material).

varieties can be marketed in the EU, with the exception of organic heterogeneous material which can be commercialized after notification ((EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848). Currently, the national and common EU catalogues only names the plant variety, the registration date and the maintainer of the variety, with no mention of the breeding or selection technique used to develop it. During the interviews conducted in this study, along with their responses to the targeted survey, numerous stakeholders have flagged the possibility to use the variety registration system set up by EU Seed Marketing Directives as a potential entry point to ensure transparency of NGTs. They argue that information about the breeding technique used, including but not limited to NGTs, could be included in these national and EU lists, and as a result ensure stakeholders, especially from the organic and non-GM agriculture sectors, who do not wish to use these products, to take an informed decision.

EU Seed Marketing Directives not only have interlinkages with the issue of transparency and traceability of NGT's, but also the sustainability assessment scenarios proposed for these products. Indeed, as a precondition for national and/or EU listing, variety testing protocols determine whether the variety is Distinct, Uniform and Stable ("DUS" testing). For agricultural crop species only, these DUS tests are coupled with so-called VCU tests, that determine whether the variety has Value for Cultivation and Use, the testing protocols of which are all determined at national, rather than EU level. The majority of VCU testing protocols do not include complete sustainability assessments *per se* but include some elements of economic sustainability by looking at productivity (yield) or physiological (earliness in flowering) criteria or technological use value (such as protein content). Some Member States have added an environmental component to their VCU protocols. In France, national authorities thus examine whether the variety is resistant to pests or diseases, climatic conditions, water or nitrogen efficiency, or its dependency on inputs.

It should be noted that the EU Seed Marketing Directives are also currently ongoing a reform process, which was kick-started in parallel to the European Commission study on NGTs in November 2019, and that a proposal for a new legislative framework is expected in June 2023.

5.3 The EU sustainable food system initiative: impact on sustainability assessment and labelling of NGTs

To accelerate and facilitate the transition towards sustainable food systems and ensure that food placed on the EU market increasingly becomes sustainable, the 2018 Farm to Fork Strategy announced a horizontal framework law. **The EU sustainable food system initiative (Framework for Sustainable Food Systems, "FSFS"),** to be put forward by the European Commission in the second half of 2023, will aim to establish new foundations for future food policies by introducing sustainability objectives and principles based on an integrated food system approach and lay down general principles and objectives, together with requirements and responsibilities for all actors in the EU food system.

Aside from horizontal elements that will define the objectives and principles of the FSFS, three policy measures are also envisaged: minimum sustainability requirements, sustainability labelling and sustainable public procurement. Different policy options for each of these measures are currently being discussed in a wide-ranged stakeholder consultation.

The first 'push' measure will introduce **minimum sustainability requirements** for food products and related operations, with the objective of gradually pushing the least sustainable foods and operations from the EU market. It is however currently unknown whether the policy measure will rely on voluntary norms (relying on codes of conducts or guidelines), include a revision and alignment of applicable food legislation, or directly include minimum requirements within the FSFS (whether optional, or mandatory,

applying or not to imports). Any sustainability assessment of NGT products shall thus need to be in line with the requirements set out in the FSFS, which aims to take into account the three dimensions of sustainability (economic, social and environmental). With regards to **sustainability labelling**, the policy options under consideration also range from voluntary approaches, the reinforcement of existing legislation, or the establishment of a new EU framework for sustainability labelling (whether optional or mandatory, including or not imports). Stakeholders have highlighted numerous times that additional sustainability assessment or sustainability labelling requirements for NGT products compared to other products that would fall solely under the remit of the FSFS measures (whether voluntary or regulatory) could be potentially **discriminatory**.

6 Assessment of the policy options

We assessed each of the policy options against the specific and operational objectives, as described in Section 2.4. (Table 2, p. 12).

We commence with first aggregating and analysing the impact per impact area and policy option using a multicriteria decision analysis (MCDA) (for the methodological details, see Annex 8).

Table 10 presents the mean score per impact area per scenario, thereby averaging the impact scores as presented in the individual impact section in Chapter 4. Each individual impact is part of one of the 13 impact areas, divided in three domains (Economic, Social and Environment). For each scenario we present a minimum average score and a maximum average score. This represents the range of uncertainty. All scores are rated individually on a five-point scale (--=-2 (expected very negative), -=-1, 0,+=1, to ++ =2 (expected very positive), and since we take the simple unweighted mean, the average scores are also within that range.

We then translated this back to the policy options, which each consist 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 is 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 results are presented in Table 11.

Table 10 MCDA at Scenario Level

	Economic								Environment			Social	
Values	Plant Breeders	Farmers	Wider value chain	SMEs	Organic & GM-Free	Consumers	Competitiveness & Trade	Innovation	Regulatory Costs for Authorities	Environmental pressures	Environmental Traits	Protection of Human and Animal Health	Social
Average of A0 - Min	-1,3	-0,3	-0,5	-1,0	0,0	-0,3	-1,8	-2,0	0,0	0,0	0,0	-0,5	-0,6
Average of A0 - Max	-1,3	-0,3	-0,4	1,0	0,0	-0,3	-1,5	-2,0	0,0	0,0	0,0	-0,5	-0,4
Average of A1-Min	-0,9	-0,3	-0,4	-1,0	-0,7	-1,0	-1,3	-2,0	-2,0	-0,8	0,0	-1,0	-0,5
Average of A1-Max	-0,1	-0,3	-0,3	1,0	0,0	1,0	-1,0	-2,0	1,0	0,8	1,0	0,0	0,3
Average of A2-Min	1,3	-0,5	0,0	-1,0	-0,9	-1,0	0,3	1,0	0,0	-0,8	2,0	-0,5	-0,1
Average of A2-Max	1,3	1,0	1,6	1,0	-0,8	1,0	0,8	1,0	0,0	0,8	2,0	0,5	0,5
Average of B0-Min	-1,2	-0,3	-0,5	0,0	0,0	-1,0	-1,0	-2,0	0,0	-0,7	0,0	-0,5	-0,3
Average of B0-Max	-1,2	-0,3	-0,4	1,0	0,0	-1,0	-0,8	-2,0	0,0	0,8	0,0	-0,5	-0,3
Average of B1-Min	-1,3	-1,0	-1,5	0,0	-1,0	1,0	-1,0	-2,0	-2,0	-0,7	1,0	-0,5	-0,6
Average of B1-Max	-1,3	-0,3	0,3	0,0	0,0	1,0	-0,8	-2,0	0,0	0,8	1,0	-0,5	-0,6
Average of B2-Min	-0,8	-0,3	-0,5	0,5	-0,7	-1,0	-1,3	-2,0	-1,0	-0,7	2,0	-0,5	-0,8
Average of B2-Max	-0,8	-0,3	-0,4	0,5	-0,2	0,0	-1,0	-2,0	0,0	0,8	2,0	-0,5	-0,8
Average of B3-Min	0,8	0,3	0,5	1,0	-1,8	-1,0	1,0	1,0	-1,0	-0,7	2,0	0,0	-0,5
Average of B3-Max	0,8	1,0	1,5	1,5	-1,3	0,0	1,0	1,0	0,0	0,8	2,0	0,5	0,0
Average of C0-Min	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	-0,3	0,0	0,0	0,0
Average of C0-Max	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,5	0,0	0,0	0,0
Average of C1-Min	-0,3	0,0	0,0	0,0	0,0	0,0	0,0	0,0	-1,0	0,0	0,0	0,0	0,1
Average of C1-Max	-0,2	0,0	0,0	0,0	0,0	0,0	0,0	0,0	2,0	0,8	1,0	0,0	0,1
Average of C2-Min	-0,9	0,0	-0,1	-1,0	0,0	0,0	-0,5	0,0	-2,0	0,0	-1,0	0,0	-0,1
Average of C2-Max	-0,8	0,0	-0,1	0,0	0,0	0,0	0,0	0,0	-1,0	0,8	1,0	0,0	0,1

Table 11 MCDA at Policy Option level

Values	Plant Breeders	Farmers	Wider value chain	SMEs	Organic & GM-Free	Consumers	Competitiveness & Trade	Innovation	Regulatory Costs for Authorities	Environmental pressures	Environmental Traits	Protection of Human and Animal Health	Social
Baseline (A0; B0; C0) - Min	-1,1	-0,2	-0,4	-0,6	0,0	-0,4	-1,3	-1,7	0,0	-0,2	0,0	-0,4	-0,4
Baseline (A0; B0; C0) - Max	-1,1	-0,2	-0,3	0,9	0,0	-0,4	-1,1	-1,7	0,0	0,3	0,0	-0,4	-0,3
Option 1(A1; B0; C0) - Min	-0,9	-0,2	-0,4	-0,6	-0,4	-0,9	-1,0	-1,7	-1,1	-0,7	0,0	-0,7	-0,4
Option 1(A1; B0; C0) - Max	-0,4	-0,2	-0,3	0,9	0,0	0,3	-0,8	-1,7	0,6	0,8	0,6	-0,1	0,1
Option 2A(A1;B0; C1) - Min	-0,9	-0,2	-0,4	-0,6	-0,4	-0,9	-1,0	-1,7	-1,3	-0,7	0,0	-0,7	-0,3
Option 2A(A1;B0; C1) - Max	-0,4	-0,2	-0,3	0,9	0,0	0,3	-0,8	-1,7	0,9	0,8	0,7	-0,1	0,1
Option 2B(A1;B1;C1) - Min	-0,9	-0,4	-0,7	-0,6	-0,7	-0,3	-1,0	-1,7	-1,9	-0,7	0,3	-0,7	-0,4
Option 2B(A1;B1;C1) - Max	-0,5	-0,2	-0,1	0,6	0,0	0,9	-0,8	-1,7	0,9	0,8	1,0	-0,1	0,0
Option 2C(A1;B2;C1) - Min	-0,8	-0,2	-0,4	-0,4	-0,6	-0,9	-1,1	-1,7	-1,6	-0,7	0,6	-0,7	-0,5
Option 2C(A1;B2;C1) - Max	-0,3	-0,2	-0,3	0,7	-0,1	0,6	-0,9	-1,7	0,9	0,8	1,3	-0,1	-0,1
Option 3(A1;B0;C2) - Min	-0,9	-0,2	-0,4	-0,6	-0,6	-0,9	-1,1	-1,7	-1,7	-0,7	0,4	-0,7	-0,5
Option 3(A1;B0;C2) - Max	-0,4	-0,2	-0,3	0,7	-0,1	0,6	-0,9	-1,7	0,4	0,8	1,3	-0,1	-0,1
Option 4(A2;B3:C0) - Min	1,0	-0,2	0,2	-0,3	-1,0	-0,9	0,4	0,9	-0,3	-0,7	1,7	-0,3	-0,2
Option 4(A2;B3:C0) - Max	1,0	0,9	1,3	1,0	-0,8	0,6	0,7	0,9	0,0	0,8	1,7	0,4	0,3

6.1 Analysis of the Baseline option – no action at EU level

6.1.1 Effectiveness

In terms of reaching the policy objectives as set by the EC (see Table 2 and Table 12), **the baseline option does not achieve the specific objectives**. Given the findings of the EFSA panel on GMOs, the current framework is not proportional to the risk for NGTs (S2A not achieved), which in its view require a case-by-case risk assessment. The current GMO regulatory regime acts as a hurdle for the cultivation (and to a significant extent also importation) of NGT-based plant varieties (S1 not achieved). This also inhibits the development of traits contributing to a sustainable agri-food system, although these traits may still be developed via other conventional means (S2 partially achieved). The baseline option would not reduce regulatory costs or administrative burden and therefore not induce the development and market introduction of plant varieties using CG/TM (S3 not achieved), and costs will likely increase for all agro-food value-chain actors. This happens as enforcement and traceability become more challenging due to regulatory divergence. The option is negative in terms of future proofing, as it reduces research and innovation in plant breeding in the EU (S4 not achieved).

In terms of **other impacts**, we find substantially negative impacts on plant breeders, competitiveness & trade, innovation, and more moderately negative impacts on farmers, and the wider value chain. The relative competitiveness of SMEs in plant breeding remains uncertain. The difficulty in enforcing the regulation– due to limited detection possibilities of many NGTs without cooperation of the plant breeder – could result in unwanted presence of NGTs in imported (and subsequently processed) food

products. As such, there is possibly a small negative impact on the protection of human and animal health. Consumer variety and consumer rights would change little in this scenario. Social and environmental opportunities on improving health, environment, and global food security may not be realised. We expect limited negative impacts on the organic and GM-free sectors due to increased coexistence costs to avoid unwanted presence and more difficult access to plant breeding material globally.

Table 12 Effectiveness analysis of the baseline option

Specific objective	Degree of achievement (rating)[25]
S1: Ensure that the regulatory requirements for plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products are proportionate to the risk involved.	Not achieved (0)
S2: Ensure that legislation is conducive to the development and placing on the market of plant products that can contribute to a sustainable agri-food system.	Not achieved to Partially achieved (0 to +)
S3: Design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products.	Not achieved (0)
S4: Provide a future proof legislation	Not achieved (0)

6.1.2 Efficiency

Regulatory costs remain relatively stable in this scenario in terms of market authorisation (and due to limited activity, the total costs for society are limited). Assuming that the current EU GMO risk assessment and authorisation process applies to genome edited plants, costs outweigh economic benefits for existing and prospective plant breeders.

GMO breeders in particular bear costs per year for registration of single edit product and annual monitoring ranging from €6 mio to € 20 mio for food and feed uses while for cultivation estimates provided indicate a minimum increase of +20% and a maximum increase of +60% of costs plus ~€ 0,7 to € 1 mio. Variability in costs is explained by differences on the specific product, the crop, the trait(s), the number and characteristics of the newly expressed proteins and/or of any new constituent. As a result, the market is concentrated in a few large players with international dossiers.

For SMEs and newcomers, the authorisation costs are prohibitively high. The main barrier however is the uncertainty of the time required before delivering new products on the market. Predictability in terms of time and total costs are the key factors for SMEs to enter the market.

Most stakeholders agree that substantial investment in enforcement (in particular through traceability) would be needed over the coming period to maintain the current regulatory regime.

[25] For comparative purposes, the baseline option's achievement ratings are quantified (on a five-point scale from -2 to 2, visualised as -- to ++) at zero. Other policy options are then rated compared to the baseline.

6.1.3 Internal and External Coherence

In terms of internal coherence, we can rate the coherence of the baseline option as medium. While the underlying principle to this option of treating NGTs as GMOs are consistently applied through the risk assessment, labelling and traceability, and sustainability requirements, the added difficulty in detecting unwanted presence of NGTs compared to traditional GMOs when the source of the change is not reported could result in reduced internal coherence. The maintained differentiation requirement means that there is a potential risk of an incentive for avoiding risk assessment and market authorisation.

In terms of external coherence, the overall situation is mixed. In terms of one the main policy framework (Farm to Fork, F2F), the baseline option lacks coherence as this option would reduce the chances of the plant varieties that have the potential to reduce pesticide or fertilizer use. Reversely, as this scenario is comparatively protective of the organic sector, it is in line with the F2F's ambition to increase the share of organic agriculture. A lack of reform would also mean a missed opportunity to align transparency requirements with the processes as present in the EU Seed Marketing Directive. There is no explicit coherence with the new initiative on Protected Areas, but the baseline option is also likely to have limited negative nor positive impact on biodiversity.

6.1.4 Proportionality

For the assessment of proportionality, we apply the guiding questions as defined in Better Regulation Toolbox 5, presented in the Table below. We can conclude the overall policy option is only partially sufficiently proportional.

Table 13 Proportionality assessment baseline option

Guiding question	Degree of proportionality
Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test)	Sufficient
Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?	Insufficient
Does the initiative create financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objectives of the initiative?	Insufficient
Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?	Sufficient
Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?	Sufficient
While respecting Union law, are special circumstances applying in individual Member States considered?	Sufficient

6.2 Policy option 1: Adapted Risk Assessment and Detection Requirements

6.2.1 Effectiveness

In terms of reaching the policy objectives as set by the EC, Policy Option 1 achieves the specific objectives to a limited extent. Given the findings of the EFSA panel on GMOs, the proposed option is in line with the objective, although stakeholders indicate that in its prospective implementation, a case-by-case authorisation regime will in practice lead to a higher burden (S1 partially achieved - achieved). It is expected that this new regime will result in an increased rate of development and commercial application of new traits using NGTs. Yet, the rate would not be very high since industry stakeholders expect that the de-facto application would still mean a high regulatory burden for many applications, in particular as labelling and traceability requirements would remain unchanged (S3 limited-partial achievement). Furthermore, the regulatory uncertainty of approvals as well as the labelling and traceability requirements would inhibit investment and entrepreneurial activity. This also impedes the speedy development of traits contributing to a sustainable agro-food system, although these traits may still be developed via conventional means (S2 achieved to a partial extent). Although an adapted risk assessment system is inherently more flexible to accommodate future technological and scientific developments, a sometimes costly authorisation procedure would also impede research and innovation investments and capabilities into NGTs in the EU (S4 partially achieved).

In terms of **other identified impacts**, compared to the baseline option, we note similar economic impacts on the conventional sector in terms of plant breeding, farming, trade, competitiveness, innovation, and wider value chain effects, albeit all of them to a moderate extent. Environmental and social impacts remain uncertain and limited due to the restricted introduction of NGTs in this option. The negative impacts for organic and non-GM sectors would be slightly higher compared to the baseline option. This would be due to the limited degree of cultivation of NGT-crops under this option. Impacts on SMEs would again depend on the implementation mode of the adapted risk assessment. This could have potential benefits, but the uncertainty around the new system could also result in a negative effect (S3B highly uncertain)

Table 14 Effectiveness analysis of policy option 1

Specific objective	Degree of achievement (rating)
S1: Ensure that the regulatory requirements for plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products are proportionate to the risk involved.	Partially achieved to substantially/fully achieved (+ to ++)
S2: Ensure that legislation is conducive to the development and placing on the market of plant products that can contribute to a sustainable agri-food system.	Partially achieved (+)
S3: Design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products.	No to partially achieved(0 to +)
S4: Provide a future proof legislation	Partially achievemed (+)

6.2.2 Efficiency

Regulatory costs for market authorisation would increase slightly for national authorities, as the results show only a very limited increase in NGT-based plant breeding activity and subsequent applications for market authorisation. Plants breeders are reluctant to support this policy option 1 due to the risk of changes in EFSA's interpretation of requirements - even if costs savings for plant breeders are theoretically possible especially in cases where for instance only molecular characterization and post market monitoring (including environmental) requirements would apply reaching savings of 85% of total authorisation costs.[26] Costs for EFSA are expected to decline by 20%, 60% and 80% under progressive data requirements for risk assessment. EURL's costs of validating the detection method to detect and differentiate the product from conventional products may not change much. At most, there may be a maximum 5% cost increase due to additional costs associated to assess that the information provided by the applicant justifies a waiver for the method's ability to differentiate are fulfilled. Qualitatively, some stakeholders point out that an increased demand for an adapted risk assessment would require extensive investment in the capacity of EFSA to process applications. In addition, the same enforcement challenges persist as presently in the baseline.

6.2.3 Internal and External Coherence

In terms of internal coherence, we can rate the coherence of the Policy Option 2 as medium. The adapted risk requirement and detection and differentiation requirements are coherent, offering both a market authorisation approach that is more in line with the characteristics of the technology. The continued presence of similar traceability and labelling requirements is only partially consistent with the approach under market authorisation, as there is no element of proportionality for labelling and traceability in this policy option.

In terms of external coherence, the overall situation is mixed. In terms of one of the main policy frameworks, the Farm to Fork, this option has a partial degree of coherence: under this option, there is a higher chance of the development of sustainable plant varieties. Reversely, this scenario could lead to increased costs for the organic sector, hindering the target to increase its market share. A lack of reform of labelling and traceability requirements would also mean a missed opportunity to align transparency requirements with the processes as present in the EU Seed Marketing Directive. There is no explicit coherence with the new initiative on Protected Areas, in practice this option would introduce a modest degree of uncertain impacts of NGTs on biodiversity.

6.2.4 Proportionality

For the assessment of proportionality, we apply the guiding questions as defined in Better Regulation Toolbox 5, presented in Table **15**. We can conclude the overall policy option 1 is mostly sufficiently proportional.

[26] The study designed a tiered approach (namely: 1. Full data except for protein; 2. Molecular characterization and Safety data on the trait only; 3. Molecular characterization and post market monitoring (including environmental) to cover progressive data requirements for risk assessment.

Table 15 **Proportionality assessment policy option 1**

Guiding question	Degree of proportionality
Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test)	Sufficient
Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?	Mostly sufficient
Does the initiative create financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objectives of the initiative?	Mostly sufficient
Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?	Sufficient
Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?	Sufficient

6.3 Policy option 2: Authorisation with incentives

6.3.1 Effectiveness

This policy option contains three subsets of options, those with only general support incentives (S3A), with an additional sustainability label (S3B) or with no label in case of meeting the sustainability assessment (S3C). It is important to note that these are primarily extensions/adaptations of policy option 2, with proportionate risk assessment and waived differentiation requirements in case of no availability in place (so S1 is not affected). In general, stakeholders point out that the risk assessment and detection requirements are the most important barriers, more so than other factors. Given that the findings of option 2 show only modest effects on the attractiveness for plant breeders to develop NGTs, these policy option's extensions can only moderate the outcomes in terms of impacts and achievements of policy objectives to a minor degree.

When looking at the policy options proposed, the general support incentives (S3A) are considered useful by stakeholders, but in terms of their scope are not expected to outweigh the still relatively high regulatory burden of the market authorisation procedures. The degree of achievement of objectives is therefore not changed under this option compared to option 1.

A sustainability label (S3B) is not supported by the vast majority of stakeholders and is seen to generate additional regulatory burden and uncertainty (in particular for SMEs – objective S3B affected). Plant breeders and conventional value chain stakeholders (including retail) do not consider that such a label will result in additional consumer interest – on the contrary – it does not introduce an inducement effect for trait development (S2, S3 and S4 only achieved to a limited to partial extent, depending on the implementation). The exemption of a label - when a product fits certain sustainability criteria - could potentially reduce regulatory costs for plant breeders and wider value

chain stakeholders using NGTs but is equally opposed for different reasons (see paragraph below).

A widely raised concern by various stakeholders is that the sustainability criteria at this point raise significant questions on what would in practice count as a sustainable trait. Stakeholders are also fearing that these may not align with actual sustainability in farming systems. For this reason, many/most interviewed stakeholders (from various stakeholder types) are sceptical or outright negative about including the possibility of sustainability claims and/or labels based on traits. The PC has shown that a small majority (51%) of respondents are in favour of the general principle of introducing sustainability principles into the legislation, most stakeholders consulted in the targeted consultation fear it is not implementable and would in practice undermine consumer trust. In addition, the focus group on sustainability pointed out that unsustainable production methods may foil the potential benefits of a sustainable trait.

In terms of **other impacts**, they remain roughly the same compared to Option 3.

Table 16 Policy Option 2

Specific objective	Degree of achievement (rating)
S1: Ensure that the regulatory requirements for plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products are proportionate to the risk involved.	Partially achieved – substantially/fully achieved (+ to ++)
S2: Ensure that legislation is conducive to the development and placing on the market of plant products that can contribute to a sustainable agri-food system.	Partially achieved (+)
S3: Design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products.	Partially achieved Partial achievement (+)
S4: Provide a future proof legislation	Partially achieved Partial achievement (+)

6.3.2 Efficiency

This policy option would come with additional administrative costs from both authorities and applicants, to develop, implement, administer, and engage with the incentive scheme. Although the costs of ideas presented so far in the policy option are likely to be relatively limited, but at the same time given the modest effectiveness described above, efficiency would not be optimal. Cost savings from incentives are minor compared to regulatory studies and have a limited or no effect at all if the current EU GMO risk assessment and authorisation process applies to genome edited plants.

6.3.3 Internal and External Coherence

In terms of internal coherence, we can rate the coherence of the baseline option as low to medium. The adapted risk assessment requirements and detection & differentiation requirements are coherent, offering both a market authorisation approach that is more in line with the characteristics of the technology. The coherence between the sustainability aspects other than the sustainability incentives (which are neither coherent nor incoherent, and positively received) in term of labelling are not fully

consistent with the market authorisation approach. The option for label exemption, and to a similar extent the sustainability label option, are not consistent with the philosophy behind the overall approach to labelling in the scenarios where there is an explicit proportional risk assessment, which provides to consumers a choice to avoid (or chose) these products. Sustainability traits (or even outcomes) are not intrinsically related to this consumer right within this framework.

In terms of external coherence, the overall situation is mixed. In terms of the Farm to Fork strategy, the baseline option has a partial degree of coherence as this option would increase the chances of the plant varieties that have the potential to reduce pesticide or fertilizer use. Reversely, this scenario could lead to increased costs for the organic sector, hindering the target to increase its market share. A lack of reform of labelling and traceability requirements would also mean a missed opportunity to align transparency requirements with the processes as present in the EU Seed Marketing Directive. There is no explicit coherence with the new initiative on Protected Areas, in practice this option would introduce a modest degree of uncertain impacts of NGTs on biodiversity.

6.3.4 Proportionality

For the assessment of proportionality, we apply the guiding questions as defined in Better Regulation Toolbox 5, presented in the Table below. We can conclude the overall policy option 2 ranges from partiy to mostly sufficiently proportional.

Table 17 Proportionality assessment policy Option 2

Guiding question	Degree of proportionality
Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test) –	Sufficient
Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?	Partially sufficient
Does the initiative create financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objectives of the initiative?	Mostly sufficient
Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?	Sufficient
Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?	Sufficient

6.4 Policy option 3: Authorisation with requirements

6.4.1 Effectiveness

This policy option is in practice a variant of the policy Option 2, with the main difference that authorisation is now conditional on the absence of traits that are detrimental to sustainability. Due to the fact that the proportionate risk assessment is the basis for this policy option, and the current findings of limited change under this condition, the

findings regarding the achievement of the objectives remains very similar to Option 2. The main difference is that the sustainability requirement introduces significant extra risk and uncertainty, which discourages plant breeding using NGTs overall, and in particular SMEs (S3 negatively affected). Although some stakeholders see this option as a way to avoid unwanted traits with perceived risks of negative environmental side effects (in particular herbicide resistance), these traits can also be developed using conventional methods and are arguable better legislated (if needed and desired) at a general level.

Table 18 Effectiveness analysis Policy option 3

Specific objective	Degree of achievement (rating)
S1: Ensure that the regulatory requirements for plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products are proportionate to the risk involved.	Partially achieved – achieved (+ to ++)
S2: Ensure that legislation is conducive to the development and placing on the market of plant products that can contribute to a sustainable agri-food system.	Partially achieved (+)
S3: Design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products.	Not achieved to partially achieved (0 to +)
S4: Provide a future proof legislation	Partially achieved (+)

6.4.2 Efficiency

This policy option would come with substantial additional administrative cost for authorities, as a new sustainability assessment system would need to be developed, implemented, and administered. Due to the legal consequences of these decisions, more rigorous standards and processes would need to be developed compared to policy option 2. Due to the limited effectiveness of this option as described above, its efficiency can be described as low. For breeders, the costs for an applicant to comply with sustainability criteria will depend on the criteria and potential requirements. Apart from the extra costs, breeders raised concerns about the need for pre-market data generation which is likely to extend the preparation phase for the applicant and delay submission further, lengthen assessment timelines and diminish the potential benefits of NGTs to speed up plant breeding. The incentives considered are received positively but are said to have a limited or no effect at all if the current EU GMO risk assessment and authorisation process applies.

6.4.3 Internal and External Coherence

In terms of internal coherence, we can rate the coherence of the baseline option as high. The adapted risk assessment requirements and detection & differentiation requirements are coherent, offering both a market authorisation approach that is more in line with the characteristics of the technology. The continued presence of similar traceability & labelling requirements is only partially consistent with the approach under market authorisation, as there is no element of proportionality for labelling & traceability in this policy option. The coherence between the sustainability requirement and risk assessment and labelling approach is suboptimal, as sustainability requirements introduce additional uncertainty, costs, and time in terms of market authorisation, which the adapted market authorisation aimed to reduce.

In terms of external coherence, the overall situation is mixed. In terms of the Farm to Fork strategy, policy option 3 has a partial degree of coherence as this option would increase the chances of the plant varieties that have the potential to reduce pesticide or fertilizer use. Reversely, this scenario could lead to increased costs for the organic sector, hindering the target to increase its market share. A lack of reform of labelling and traceability requirements would also mean a missed opportunity to align transparency requirements with the processes as present in the EU Seed Marketing Directive. There is no explicit coherence with the new initiative on Protected Areas, in practice this option would introduce a modest degree of uncertain impacts of NGTs on biodiversity.

6.4.4 Proportionality

For the assessment of proportionality, we apply the guiding questions as defined in Better Regulation Toolbox 5, presented in the Table below. We can conclude the overall policy option is only partially sufficiently proportional.

Table 19 Proportionality assessment of policy option 3

Guiding question	Degree of proportionality
Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test)	Sufficient
Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?	Partially sufficient
Does the initiative create financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objectives of the initiative?	Partially sufficient
Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?	Sufficient
Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?	Sufficient

6.5 Policy option 4: Notification for certain products

6.5.1 Effectiveness

As with the other options, the main precursor to impacts is whether or not the regulatory change leads to a significant change in the development and adoption of NGTs. The immediate evidence here is nuanced: some interpret the criteria as proposed in this policy option as still (far) too restrictive (narrow coverage), whereas others interpret the option as a general move towards 'declassifying' these NGTs from GMOs. This would apply to the majority of products (broad coverage). These perceptions are mostly due to the cumulative character of the criteria proposed and the general lack of clarity for stakeholders on what 'obtainable by conventional/natural breeding' means in practice.

If one follows the interpretation of the broad coverage, we can see a significant shift of impacts and achievement of policy objectives vis-à-vis the baseline. It is relevant to note that several stakeholders indicate uncertainty in terms of the interpretation whether this system is 'fit-for purpose' in terms of risks and if a notification scheme would qualify as a 'case-by-case assessment' (S1A partially achieved – achieved).

Regulatory costs would be significantly reduced for plant breeders seeking to use NGTs (S3 substantially achieved). An improved attractiveness to develop and use NGTs would see their adoption rise substantially, starting in the period 2030-2035. A substantial share of these traits would have potentially positive environmental effects (S2A substantially achieved). A key uncertain factor in this growth is the evolution of consumer preferences and awareness on the NGT topic prior and during this period, as this could greatly impact demand for these products.

The system would in its design be more able to cater for new scientific and technological developments and generate a positive impact on research and innovation investments and capacities in the EU (S4A substantial achievement). Whether or not the impacts are positive for SMEs is highly uncertain. This is due to the uncertainty around sufficient future access to affordable licences to these technologies and the associated market dynamics (S3B uncertain, small deterioration – small improvement).

In terms of **other identified impacts**, the economic impact on the wider conventional value chain is likely to be positive due to improved competitiveness and international trade. The impact on the organic sector and non-GMO sector is, depending on the level of adoption, negative to highly negative (assuming the organic and non-GMO sectors maintain their current ban on the use of NGTs) due to high coexistence/segregation costs. In terms of environmental impacts, we denote a positive but uncertain potential to reduce some environmental pressures (fertiliser use, water, energy) but also where a positive or negative effect cannot yet be established (pesticides). Real environmental sustainability outcomes depend on the context of implementation and farming system conditions (see note on systemic mediation effects in Chapter 2.6). Finally, we note some potential positive social impacts (health, consumer variety, international food security) but also some negative impacts (increased tensions among farmers).

Table 20 Effectiveness analysis Policy option 4

Specific objective	Degree of achievement
S1: Ensure that the regulatory requirements for plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products are proportionate to the risk involved.	Partially achieved – substantially/fully achieved (+ to ++)
S2: Ensure that legislation is conducive to the development and placing on the market of plant products that can contribute to a sustainable agri-food system.	Partially achieved(+)
S3: Design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products.	Substantially/Fully achieved (+ to ++)
S4: Provide a future proof legislation	Substantially/Fully achieved (++)

6.5.2 Efficiency

A new system for notification would need to be developed, implemented, and administered by the authorities. DG SANTE's costs of risk management may decline by

75% in case of a notification regime. Due to the anticipated increased plant breeding activity using NGTs, it is however not likely that total regulatory costs for risk assessment will necessarily decline. The cost per risk assessment process will however, on average, fall, providing efficiency gains. On the other hand, governments may in some instances choose or be forced to bear additional costs in the mitigation of the challenges faced by the organic/non-GM sector, reducing these efficiencies. Plant breeders are supportive of a notification of products also obtainable naturally or by conventional breeding as it translates to substantial cost reductions (between 70% to 90% of total authorisation costs depending on the system put in place). For SMEs such substantial cost reduction of regulatory science and registration, and regulatory affairs is expected to lead to more SMEs and newcomers entering the market of NGTs.

6.5.3 Internal and External Coherence

In terms of internal coherence, we can rate the coherence of the baseline option as high. The adapted risk assessment requirement, detection requirements and pre-registration approaches are coherent. This option introduces some proportionality in the labelling and traceability requirements, thereby increasing the internal coherence between market authorisation and labelling and traceability scenarios.

In terms of external coherence, the overall situation is mixed. Relating to the Farm to Fork strategy, one the main policy frameworks, policy option 4 has a strong degree of coherence as this option would increase the chances of the plant varieties that have the potential to reduce pesticide or fertilizer use. Reversely, this scenario could lead to substantial increased costs for the organic sector, hindering reaching the target to increase the area cultivated organically. A reform of labelling and traceability requirements could mean an opportunity to align transparency requirements with the processes as present in the EU Seed Marketing Directive, although this is not currently foreseen. There is no explicit coherence with the new initiative on Protected Areas, in practice this option would introduce a modest degree of uncertain impacts of NGTs on biodiversity. The coherence analysis shows that this policy option potentially results in challenges for the EU Organic Regulation. In this policy option, certain NGTs will no longer be classified as GMO, and therefore technically also be permitted under the EU Organic Regulation (unless an explicit ban would be included in the legislation). However, most organic stakeholders (not all) have indicated in the targeted consultations that they will still consider these products as GMO, resulting in potential consistency issues that are compounded by the lack of traceability requirements in terms of challenges for the organic sector.

6.5.4 Proportionality

For the assessment of proportionality, we apply the guiding questions as defined in Better Regulation Toolbox 5, presented in the Table below. We can conclude the overall policy option is overall sufficiently proportional, although with some uncertainty due to the uncertain costs for segregation.

Table 21 Proportionality assessment of policy option 4

Guiding question	Degree of proportionality
Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test) –	Sufficient
Is the form of Union action (choice of instrument) as simple as possible, and coherent with	Sufficient

Guiding question	Degree of proportionality
satisfactory achievement of the objective and effective enforcement?	
Does the initiative create financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objectives of the initiative?	Partially sufficient / Uncertain
Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?	Sufficient
Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?	Sufficient

Table 22 Summary table on the achievement of operational objectives by options

	S1: Ensure regulatory require-ments are proportion-ate to risk involved	S2: Ensure legislation is conducive to (…) sustainable agri-food system	S3: Design legislation enabling develop-ment and placing on the market of NGT plants	S4: Provide a future proof legislation
Baseline option (current GMO regulation)	0	0	0	0
Option 1: Adapted Risk Assessment	+ / ++	+	+ / ++	+
Option 2: Authorisation with incentives	+ / ++	+	+	+
Option 3: Authorisation with requirements	+ / ++	+	+	+
Option 4: Notification for certain products	+ / ++	+	++	++

6.6. Final reflection on uncertainty, sensitivity, and assumptions

When revisiting the key assumptions and limitations (see sections 2.5 and 2.6 respectively) in light of the final assessment of impacts and appraisal of the policy options, we can add a few key observations.

Firstly, the impacts are calculated for the period 2030-2035. This is sufficiently medium-term so that the results are to some degree based on current developments and extrapolations. The findings support a continued and cumulative effect on impacts and effectiveness in the same direction in the immediate period thereafter.

Secondly, the assumption that other legal frameworks will remain unchanged, could highly impact the outcomes of this impact assessment, in particular regarding the organic sector.

Should the organic sector follow an EU classification of NGTs in those scenarios where they would no longer fall under the GMO-framework, a substantial share of the negative impacts and trade-offs with this sector would be avoided. While there is some debate among organic stakeholders (as evident in the stakeholder interviews) whether to accept NGTs or not, the official position of the sector's representative organisations is currently that NGTs need to remain classified as GMOs and they will not be allowed under organic farming rules. We therefore maintain the assumption in the assessment of impacts and effectiveness but do highlight the sensitivity of the findings with respect to this assumption.

Thirdly, we noted upfront that many desired outcomes, in particular, around environmental sustainability, depend on systemic farming and implementation practices. They were confirmed during the impact assessment, leading to relatively high uncertainty in impact findings for those elements. To some extent, the same applies for SME impacts, where the IP-landscape highly affects the outcomes. These two aspects are crucial, yet they are covered in other legislative frameworks. Promoting synergies and coherence between the final policy option and other current and future legislative efforts in the area of environmental sustainability as well as competitiveness and intellectual property rights in the area of plant breeding would be advised.

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