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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	WP Innovation in Agriculture – Meeting of 10 July 2023 – Item 2: Presentation of the proposal and impact assessment by the Commission

Following the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 10 July 2023, delegations will find in annex the presentation given by the Commission on the above subject.


Commission proposal
on plants obtained
by certain new genomic
techniques (NGTs)
#EUFarm2Fork
#EUGreenDeal
European
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1

Context

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Recent developments on NGTs

EU Court of Justice's judgment in Case C-528/16

Council Decision (EU) 2019/1904

Commission study on NGTs


European Commission
Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed products
COM(2023) 411 final
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Structure

- Chapter I – General provisions
- Chapter II – Category 1 NGT plants and products
- Chapter III – Category 2 NGT plants and products
- Chapter IV – Final provisions

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Chapter I
General provisions

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Subject matter & scope (Arts.1, 2)

	of…
• **Deliberate release** into the environment for any other purpose than placing on the market (e.g. field trials)	• Plants obtained by targeted mutagenesis and cisgenesis, including intragenesis (‘**NGT plants**’)
• **Placing on the market**	• **NGT plants** • NGT **food/feed** • **Other products** containing/consisting of NGT plants



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Two regulatory pathways (Art. 4)

Category 1 – NGT plants equivalent to conventional

- Verification procedure based on objective criteria
- Subject to the rules applicable to conventionally bred plants
- Seeds labelled as NGT
- Information available in a public database and variety registers

Category 2 – NGT plants not equivalent to conventional

- Authorisation procedure with adapted risk assessment and detection method requirements
- Traceability and labelling as GMO.
  Voluntary statement on purpose of modification
- Regulatory incentives for NGT plants with desirable traits
- Coexistence measures; no opt-out



Monitoring and reporting

Prohibition in organic production

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Chapter II
Category 1 NGT plants

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Verification criteria (Annex I)

NGT plants that could have been obtained naturally or by conventional breeding methods

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

(1) substitution or insertion of no more than 20 nucleotides;

(2) deletion of any number of nucleotides;

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

  (a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

  (b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

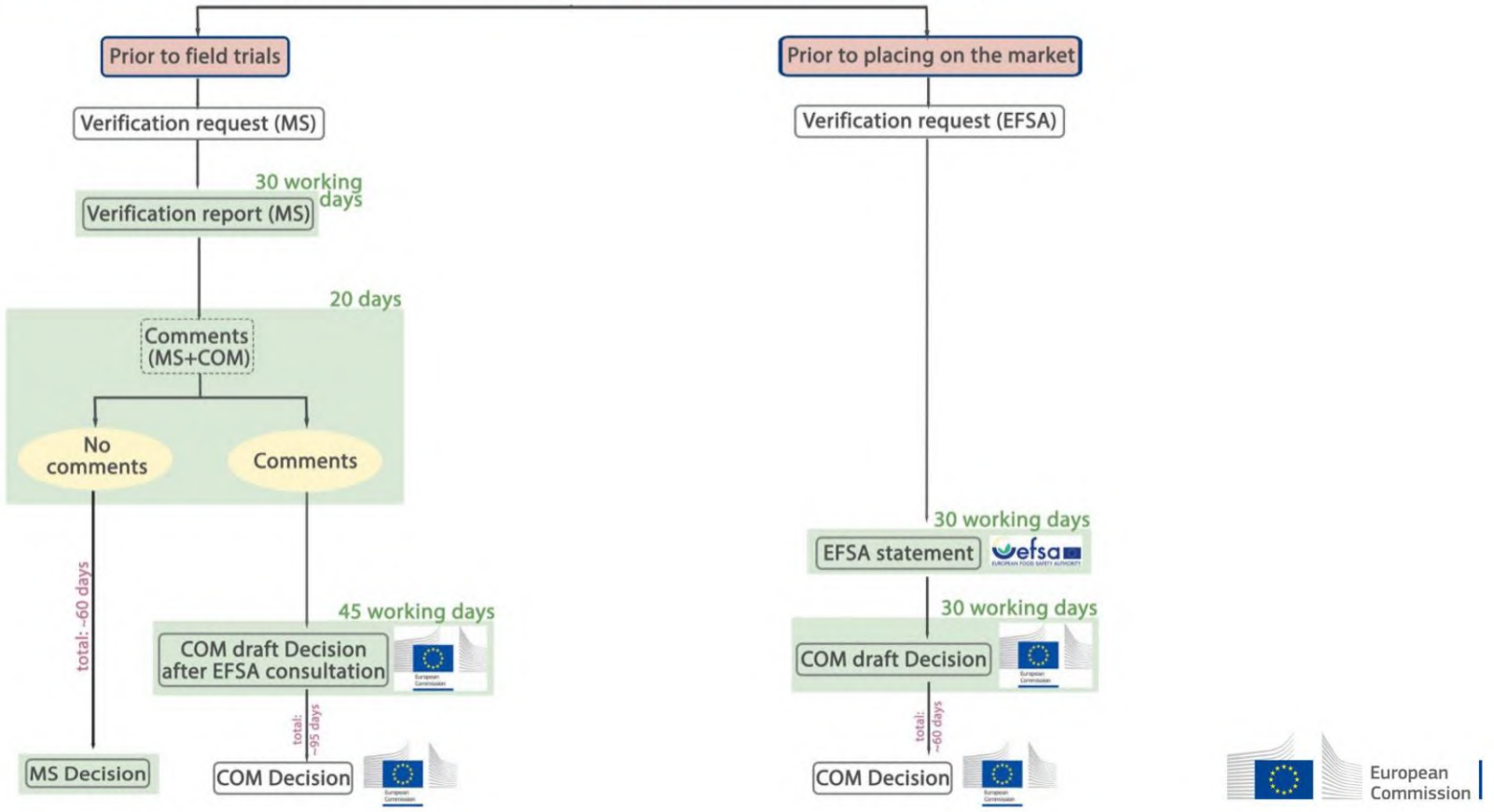
(4) targeted inversion of a sequence of any number of nucleotides;

(5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.

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Verification procedure (Arts. 6, 7)



Rules applicable to category 1 NGT plants

- **Rules for GMOs** do not apply (Art. 5)
- Prohibition of use in **organic production** (Art. 5)
- **Transparency**
  - ♦ Public database lists verification decisions and attributes ID number (Art. 9)
  - ♦ Category 1 NGT varieties are included in registers under seed legislation (provisions in PRM and FRM proposals)
  - ♦ Plant reproductive material labelled as 'cat 1 NGT' + ID number(s) (Art. 10)

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Chapter III
Category 2 NGT plants

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Outline

Section 1 – Deliberate release for any other purpose than placing on the market (specific provisions to D2001/18 Part B)

Section 2 – Placing on the market of category 2 NGT products other than food/feed (specific provisions to D2001/18 Part C)

Section 3 – Placing on the market of category 2 NGT plants for food/feed use and of category 2 NGT food/feed (specific provisions to R1829/2003)

Section 4 – Common provisions for category 2 NGT plants/products

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Section 1 – Deliberate release for any other purposes than placing on the market (specific provisions on D2001/18 Part B)

Main changes compared to D2001/18 (Art. 13):

- Adapted risk assessment (Annex II)

  → Adaptation of risk assessment to the diversity of category 2 NGT plants (detailed methodology and data requirements to be laid down by implementing act)

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Section 2 – Placing on the market of category 2 NGT products other than food/feed (specific provisions on D2001/18 Part C)

Section 3 – Placing on the market of category 2 NGT plants for food/feed use and of category 2 NGT food/feed (specific provisions on R1829/2003)

Main changes compared to D 2001/18 and R1829/2003:

- Adapted risk assessment (Annex II)
- Detection method requirements adapted when necessary and justified (Arts. 14/19)
- Environmental monitoring plan only where appropriate (Arts. 14-15/19)
- Once renewed, the authorisation is valid for an unlimited period unless otherwise provided (Art. 17/21)

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Risk assessment of category 2 NGT plants and their food and feed (Annex II)

Part I - General principles for the risk assessment

In accordance with Annex II/III to D2001/18/EC

Type and amount of information vary on a case-by-case basis. Factors to be considered are, *inter alia*, those proposed by EFSA in their 2022 statement on criteria for risk assessment.

Part II - Hazard identification and characterisation: specific information for environmental risk assessment

Part III – Hazard identification and characterisation: specific information for food and feed risk assessment

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Section 4 – Common provisions for category 2 NGT plants/products

- **Incentives** for traits relevant for sustainability (Art. 22, Annex III)
  - ♦ Food & feed: Fast track assessment by EFSA
  - ♦ Pre-submission advice on risk hypotheses
  - ♦ SMEs: - Extended pre-submission advice (also on studies)
    - Food & feed: no financial contribution for detection method validation
- Voluntary **labelling of traits** conveyed by the genetic modification (Art. 23)
- **Coexistence** measures (Art. 24)
- **No opt-out** (Art. 25)

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Traits qualifying for incentives (Annex III)

Traits **justifying the incentives**:

- yield, including yield stability and yield under low-input conditions;
- tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;
- tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;
- more efficient use of resources, such as water and nutrients;
- characteristics that enhance the sustainability of storage, processing and distribution;
- improved quality or nutritional characteristics;
- reduced need for external inputs, such as plant protection products and fertilisers.

Traits **excluding the application of incentives**:

- tolerance to herbicides

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Chapter IV
Final provisions

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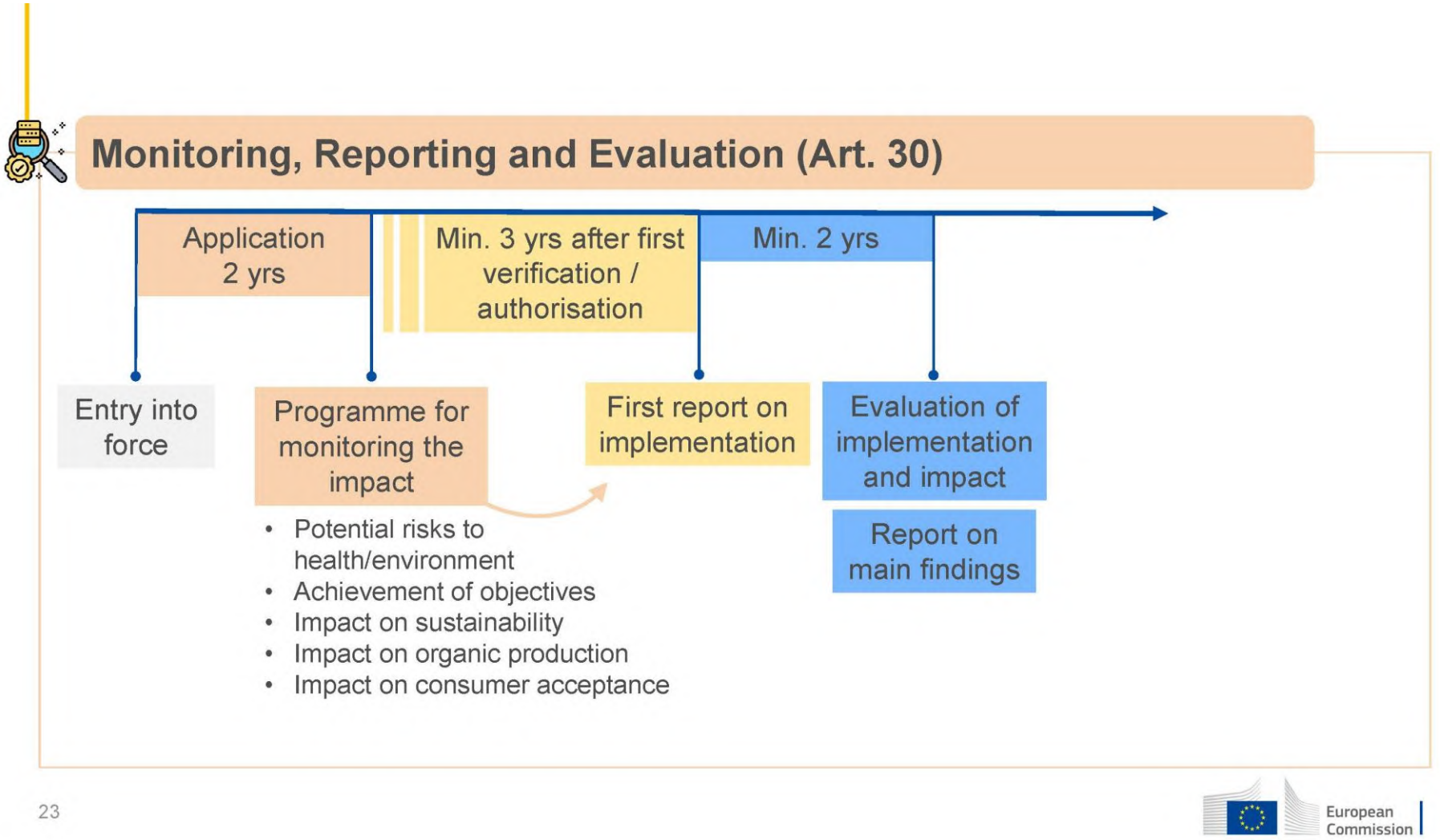


Empowerment (Arts. 26-29)

- **Delegated acts** to adapt to scientific and technological progress:
  - ♦ Criteria of equivalence (Annex I)
  - ♦ Traits qualifying for incentives (Annex III)
- **Implementing acts** and **guidance** for:
  - ♦ Information to demonstrate that a plant is a NGT plant
  - ♦ Preparation and presentation of verification requests and applications for GMO authorisation
  - ♦ Environmental and food/feed risk assessments
  - ♦ Adapted modalities for analytical method requirements

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Monitoring, Reporting and Evaluation (Art. 30)
Application 2 yrs
Min. 3 yrs after first verification / authorisation
Min. 2 yrs
Entry into force
Programme for monitoring the impact
First report on implementation
Evaluation of implementation and impact
Report on main findings
• Potential risks to health/environment
• Achievement of objectives
• Impact on sustainability
• Impact on organic production
• Impact on consumer acceptance
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Impact Assessment Report
SWD(2023) 412 final
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Problem definition

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What are the problems?

Authorisation procedure and risk assessment requirements not adapted to the variety of potential plant products that can be obtained by targeted mutagenesis and cisgenesis

Implementation and enforcement challenges for certain plants produced by targeted mutagenesis or cisgenesis

Current EU GMO legislation is not conducive to developing innovative beneficial products when applied to NGTs

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Who is affected



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Objectives

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General and specific objectives

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

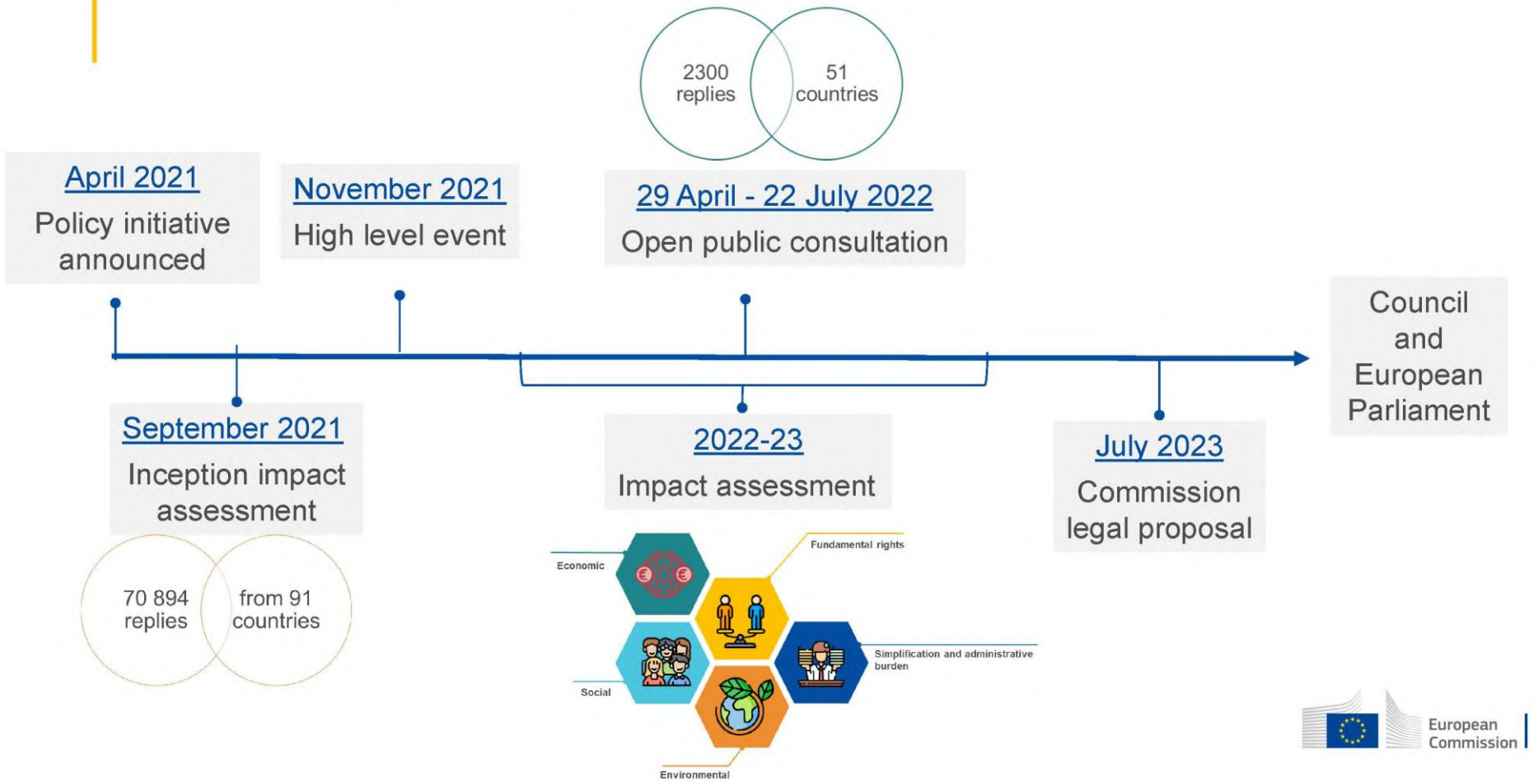
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Methodology

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Process and timeline



Evidence

- ✓ Two 2021 reports
- ✓ Case studies (2023)
- ✓ EURL,ENGL (2019, 2023)



- ✓ Two fact-finding studies on MS official controls

- ✓ Opinions on NGTs
- ✓ Statement on risk assessment criteria

- ✓ Targeted interviews
- ✓ Targeted survey
- ✓ Focus groups
- ✓ Desk research
- ✓ Case studies

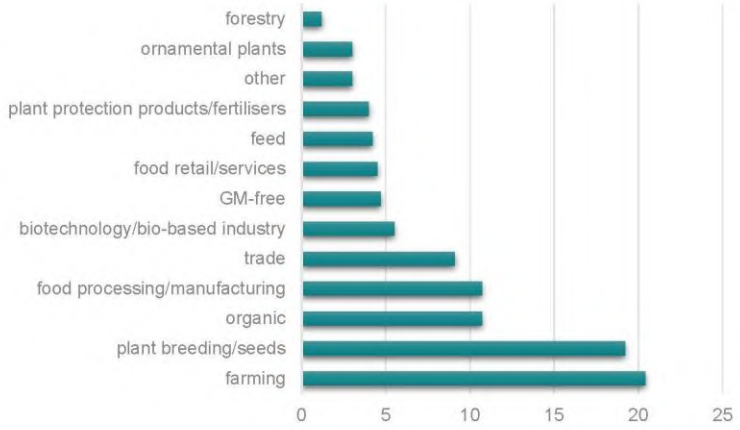
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Public consultation

Contributions by stakeholder category







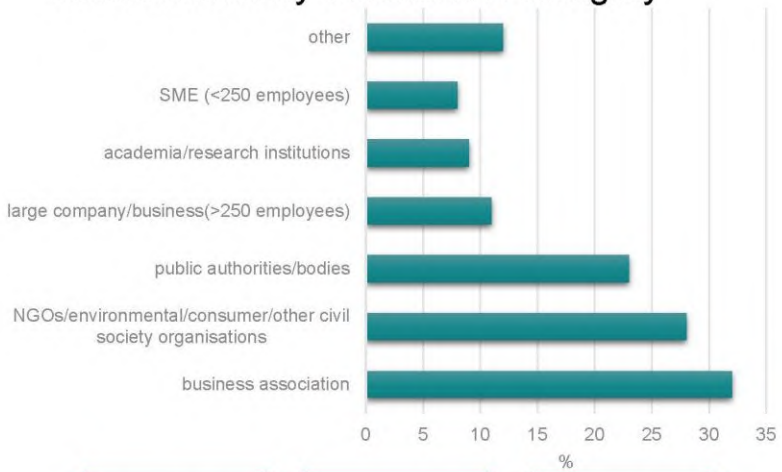
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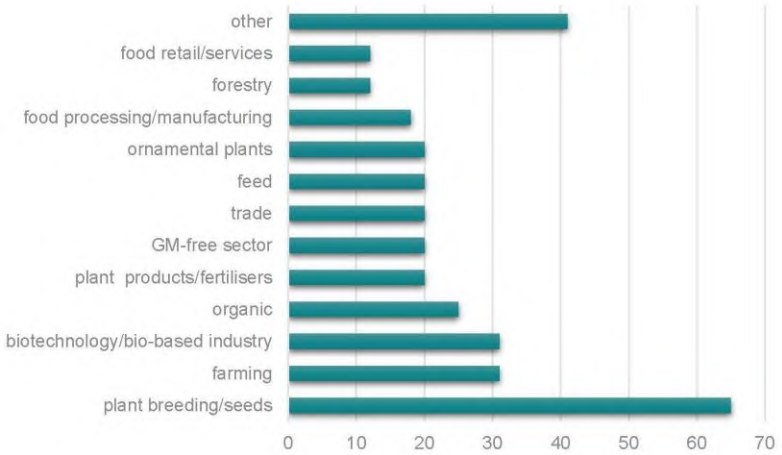
Contributions by economic sector for company business organisations, business associations and trade unions

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Targeted stakeholder survey

Contributions by stakeholder category





397	123	23
Invited	Replies	MS

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Sector of activity*:

*Participants could select more than one sector

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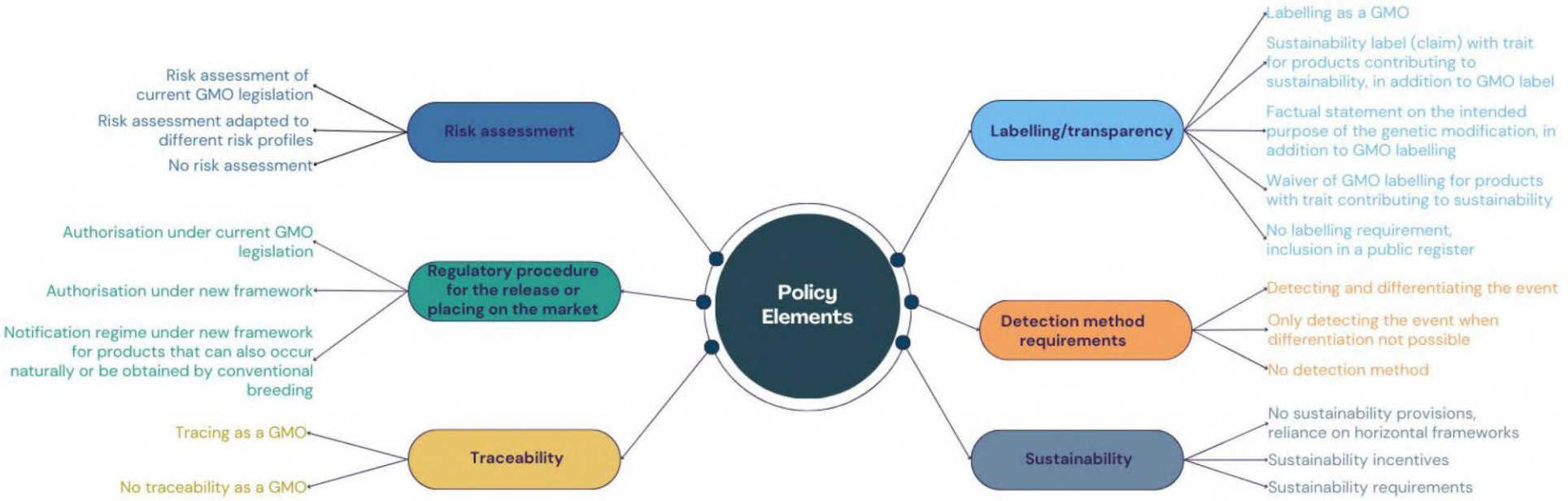
Member States involvement

3 Joint Working Groups



Policy options

Policy elements



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Policy options

Baseline	Option 1 - Adapted Risk Assessment	Option 2 - Authorisation with incentives	Option 3 - Authorisation with requirements	Option 4 - Notification for certain products
• Authorisation under current GMO legislation • Risk assessment of current GMO legislation • Traceability and labelling as a GMO • Detection method - detecting and differentiating the event • No sustainability provisions, reliance on horizontal legislation	• Authorisation under current GMO legislation • Risk assessment adapted to different risk profiles • Traceability and labelling as a GMO • Detection method - only detecting the event when differentiation not possible • No sustainability provisions, reliance on horizontal legislation	• Authorisation under new framework • Risk assessment adapted to different risk profiles • Traceability as a GMO • Sustainability labelling with GMO labelling/ no labelling/labelling with factual statement on the trait • Detection method – only detecting the event when differentiation not possible • Sustainability incentives	• Authorisation under new framework • Risk assessment adapted to different risk profiles • Traceability and labelling as a GMO • Detection method – only detecting the event when differentiation not possible • Sustainability requirements	• Notification regime under new framework for products that can also occur naturally or be obtained by conventional breeding • For products meeting the notification criteria, no risk assessment, labelling traceability and detection method. • Transparency through register • No sustainability provisions, reliance on horizontal legislation

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Ensuring safety while not entailing unnecessary regulatory burden

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Expert opinions



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Key conclusions

- ✓ Variety of different products with different safety profiles.
- ✓ No specific hazard associated to these techniques.
- ✓ Similar products obtained by different techniques are not expected to present significantly different risks.
- ✓ Lesser amounts of risk assessment data on a case-by-case basis.
- ✓ Potential for reduced unintended effects.

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Regulatory costs and time



- Baseline: average authorisation costs - in the range of EUR 6 to 20 million. For cultivation – EUR 17.5 – 28 million.
- Adapted risk assessment – savings ranging from negligible to 85% depending on the case-specific data requirements
- If incentives are used, it can lead to additional savings through the waiving of fees for the validation of the detection method (EUR 105000, EUR 52500 for SMEs)
- Verification regime – authorisation costs similar to conventional varieties. Savings for breeders up to EUR 15 million.

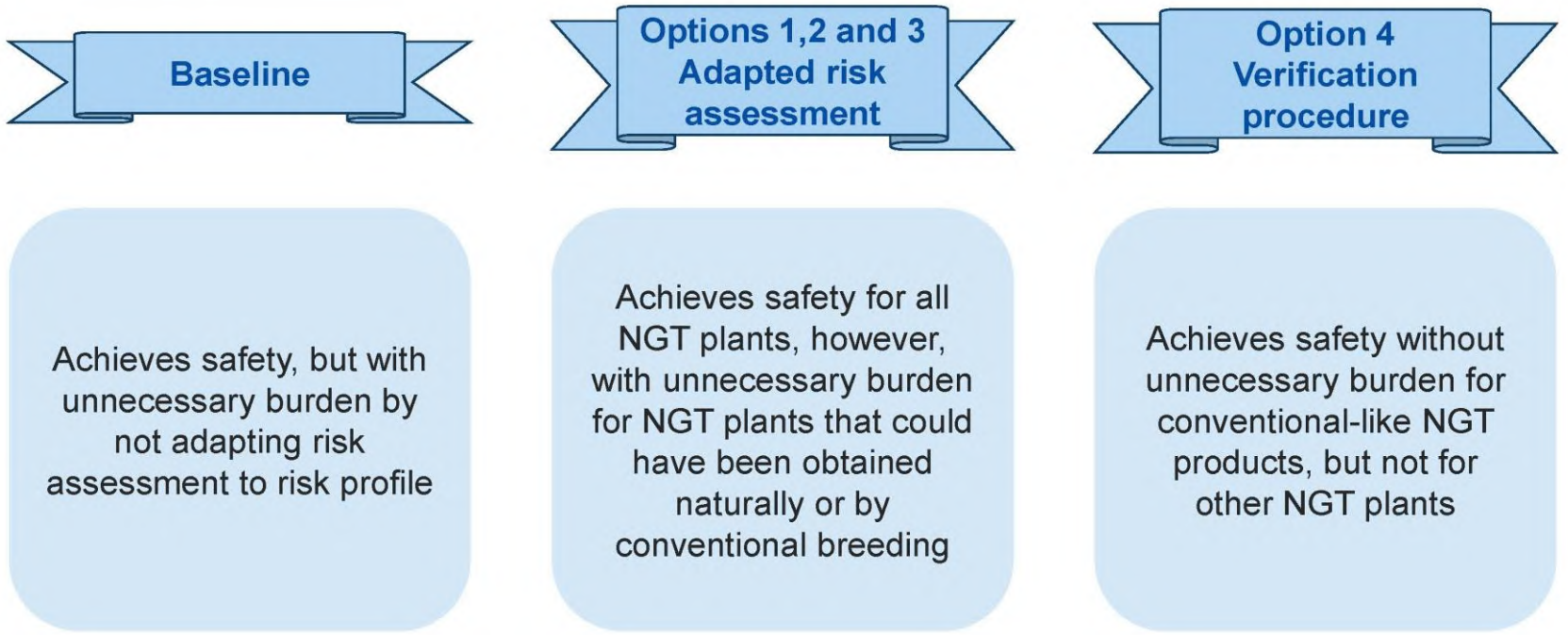


- Shorter timelines expected as the procedures are simplified. This will be most noticeable for the verification procedure.

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Impacts: safety and regulatory burden



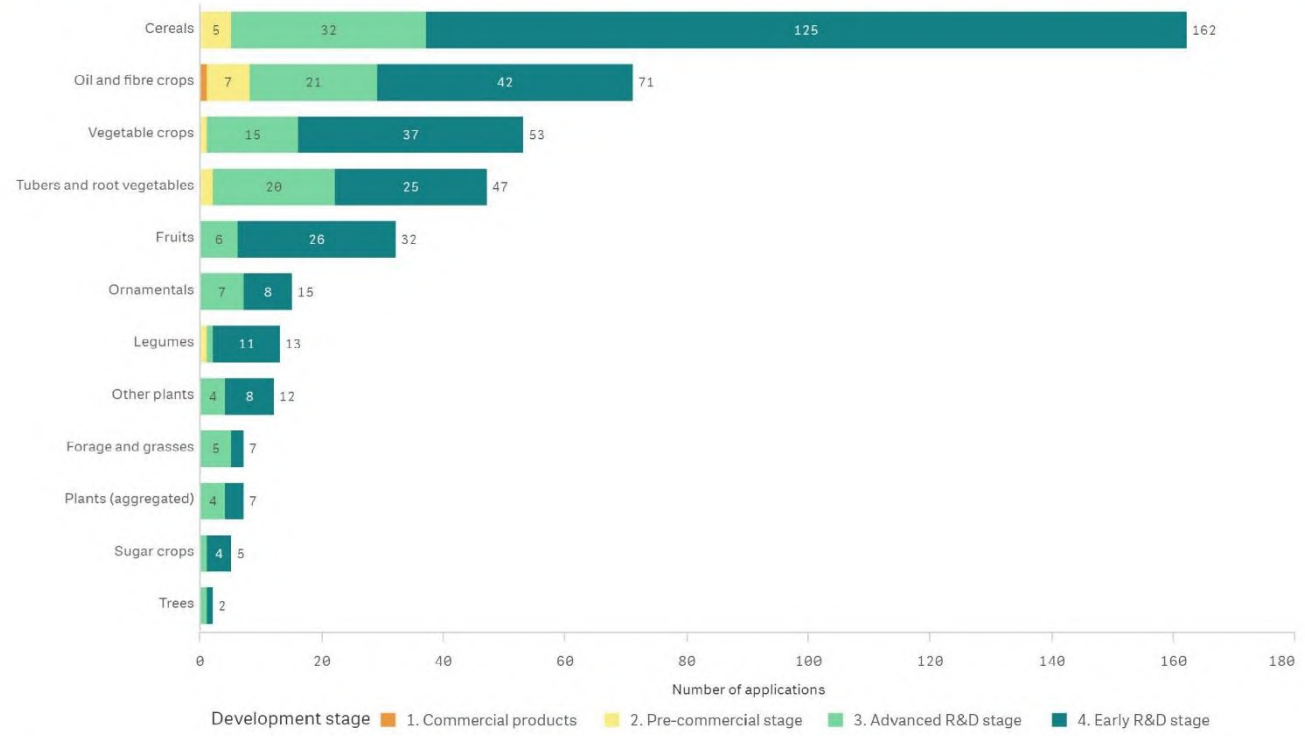
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Contribution to sustainable agri-food systems

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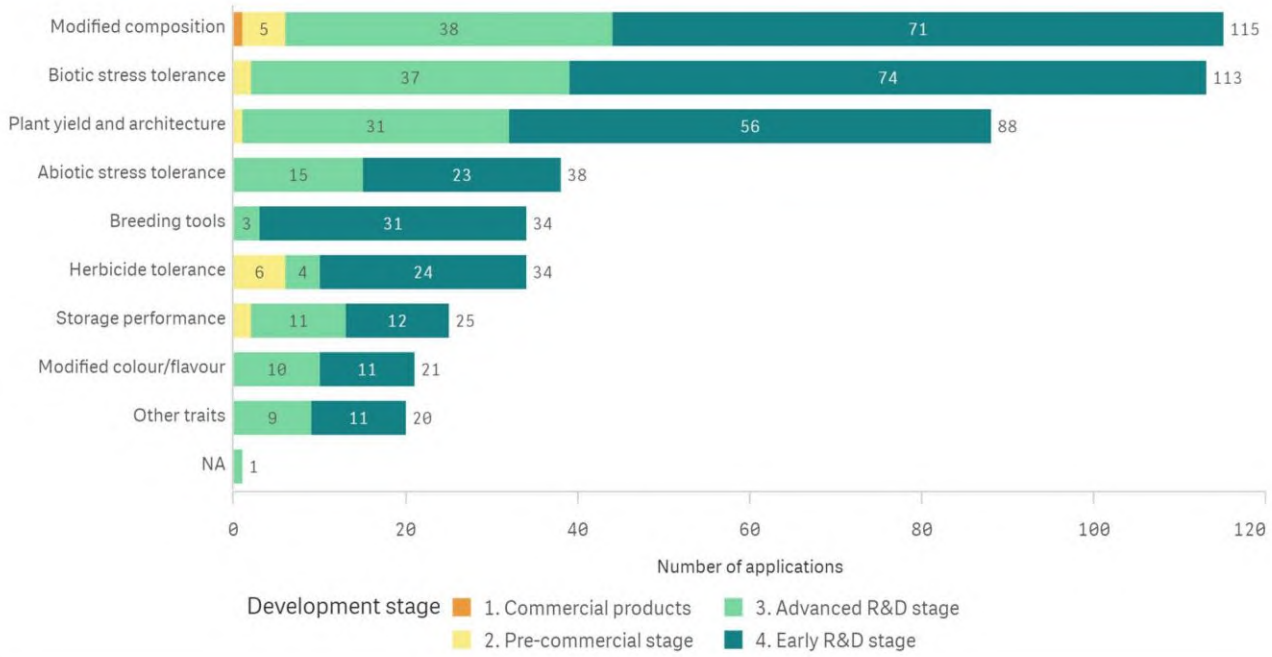
NGTs plants – applications by crop groups



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NGTs plants – applications by traits



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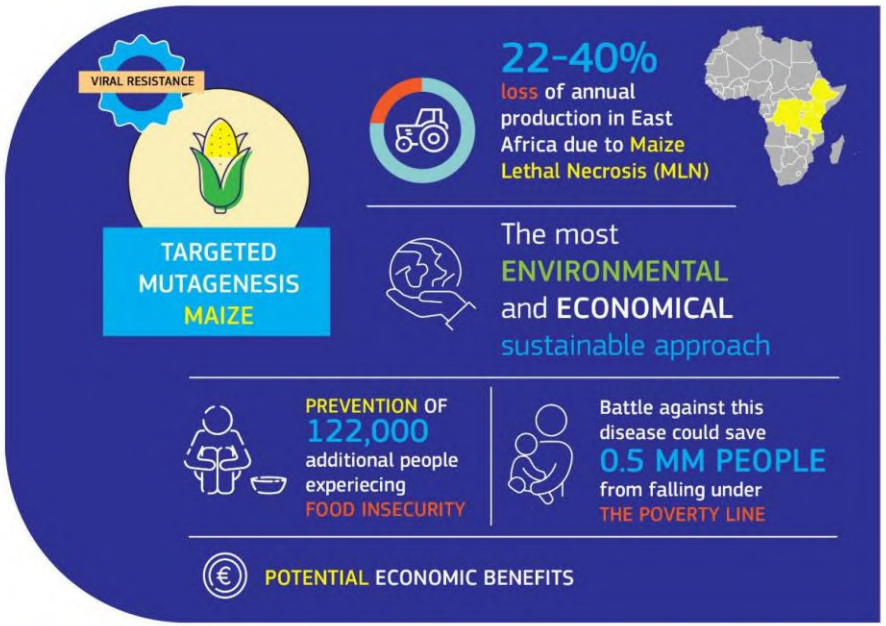
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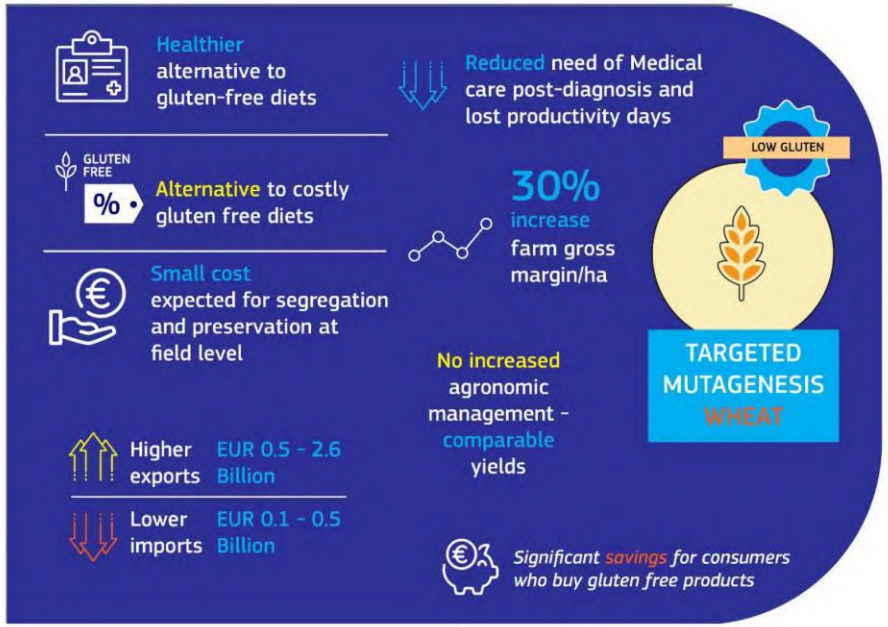
JRC case studies



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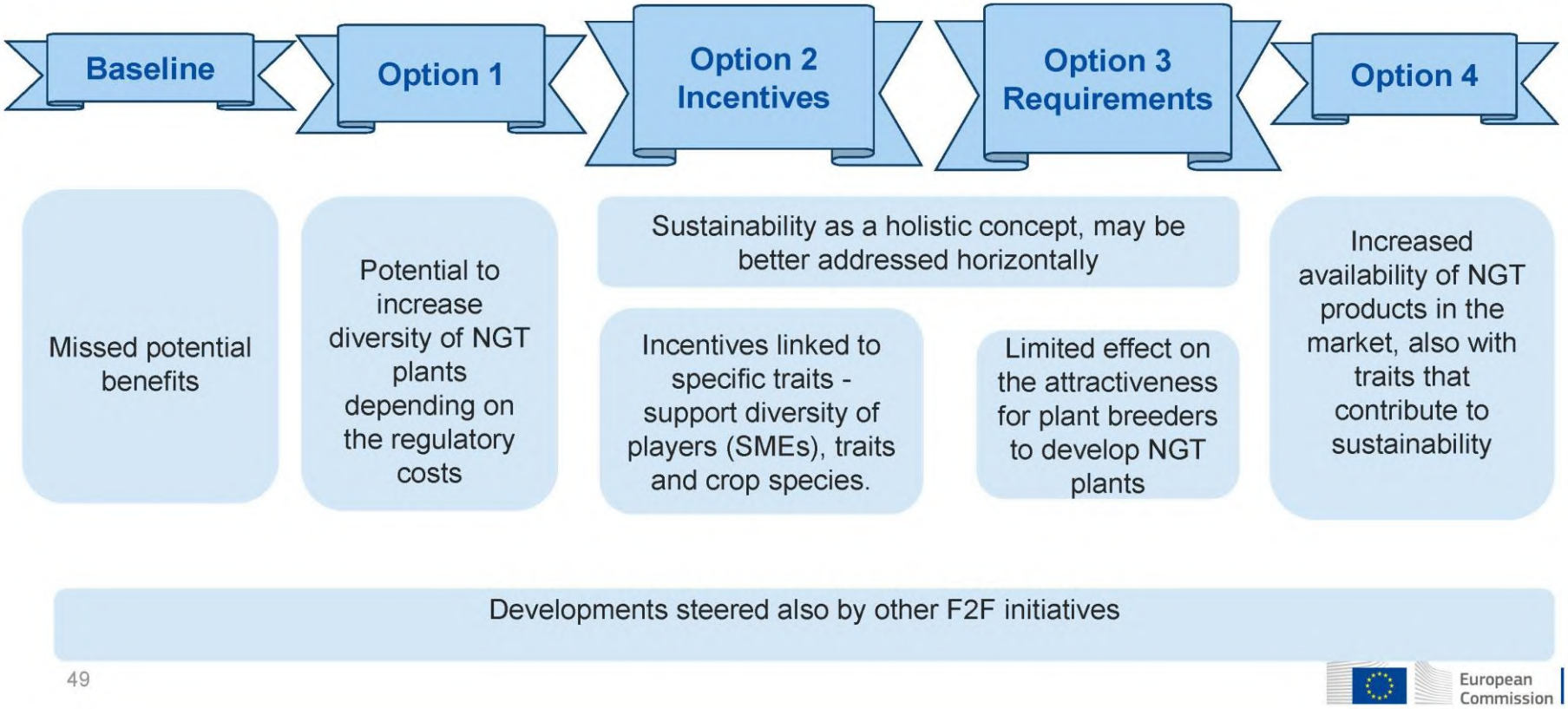
JRC case studies





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Impacts: sustainability

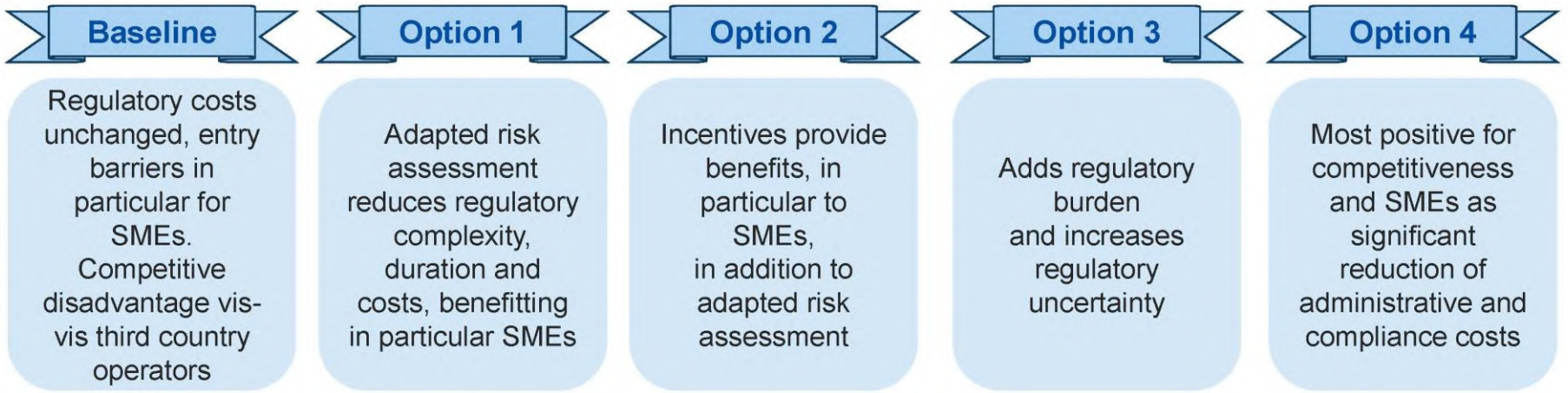


Competitiveness and SMEs

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Impact: Competitiveness and SMEs



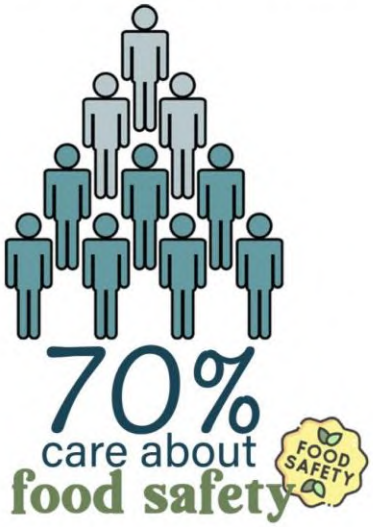
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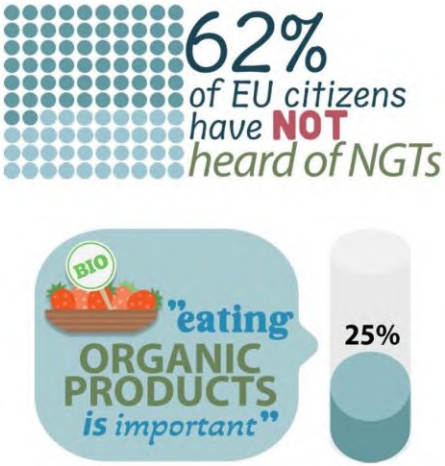
Consumers

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Consumer attitudes





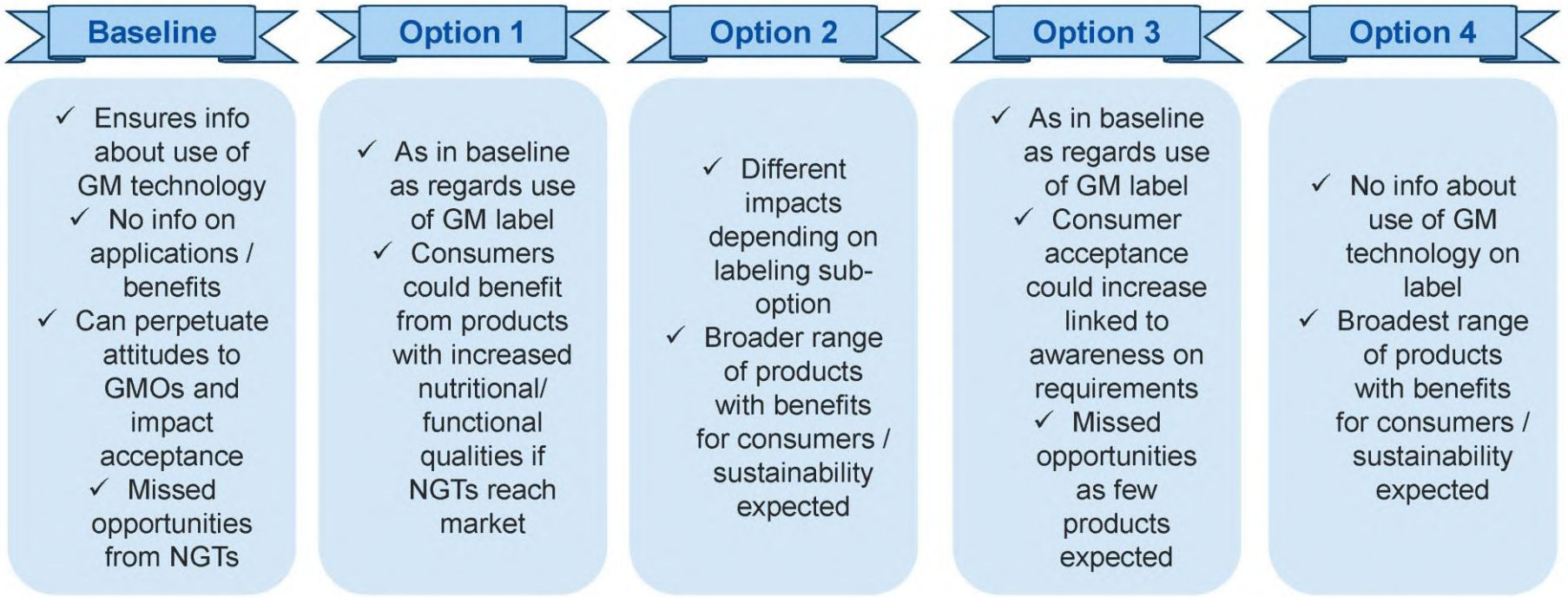




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Impacts: Consumers



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Organic/GM free sector

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Impacts: Organic production

Baseline	Option 1	Option 2	Option 3
Labelling and traceability requirements of GMO legislation, and strengthened coexistence measures, allowing separate value chains and consumer trust in sector			
Risk of admixture depends on the adoption rate of NGTs (lowest for baseline and option 3, higher for options 1 and 2)			
Farmers to implement coexistence measures. Coexistence costs are highly context dependent (farm structure, topography, environment etc.)			
Some negative impacts can occur due to detection challenges and regulatory divergence with non-EU countries			

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Impacts: Organic production

Option 4

- ✓ Transparency measures (register, variety catalogues, seeds label) enables identification of NGTs and allows exclude them in organic production
- ✓ Impacts to depend on whether the use of NGTs determined to be equivalent to conventional products is:

Treated as GMOs and banned in organic production:

- ✓ Organic sector to tale precautionary measures to main separation of value chains
- ✓ As in all options, certain challenges linked to detection and regulatory divergence
- ✓ Missed opportunities from NGTs

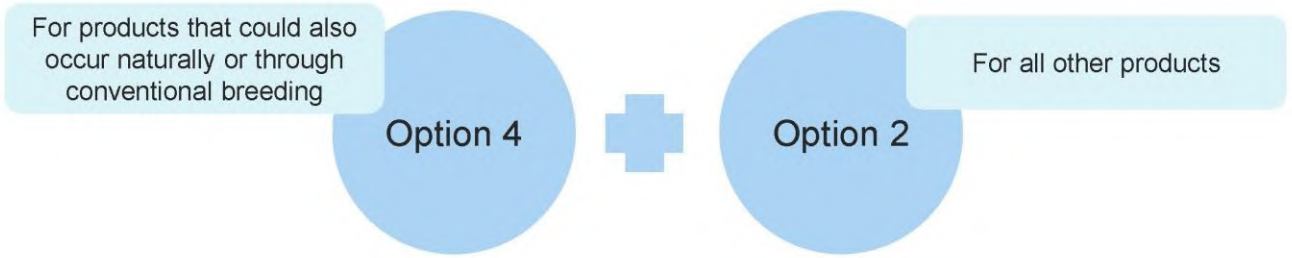
Treated as conventional products for the purpose of organic production:

- ✓ Established value chain separation between organic and conventional production to operate based on transparency measures
- ✓ Risk of non-acceptance and erosion of consumer trust
- ✓ Possibility to use under the same conditions as conventional products and potentially contribute benefits

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Preferred option



Tailored regulatory procedures to ensure NGT products reaching the market are as safe as conventional counterparts

Wide variety of plant species and traits

Plants that could contribute to sustainability

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Thank you

Useful links:
https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3568
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques
https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en



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