European Commission

RSB upstream meeting

Impact assessment on legislation for plants obtained by certain new genomic techniques

20/05/2022

DG SANTE

Context for the initiative

What are New Genomic Techniques (NGTs)?

- Techniques, capable of altering the genetic material of an organism, that have emerged or have been developed since 2001, when Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted
- Diverse group of techniques to achieve different results, from limited changes that could also occur in nature or with conventional breeding to multiple and more extensive modifications.

Mutagenesis

Changes without insertion of genetic material

Cisgenesis

Insertion of genetic material from organisms that can cross in nature

Transgenesis

Insertion of genetic material from other organisms that are sexually incompatible

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Background

2018 - EU Court of Justice's judgment in Case C-528/16

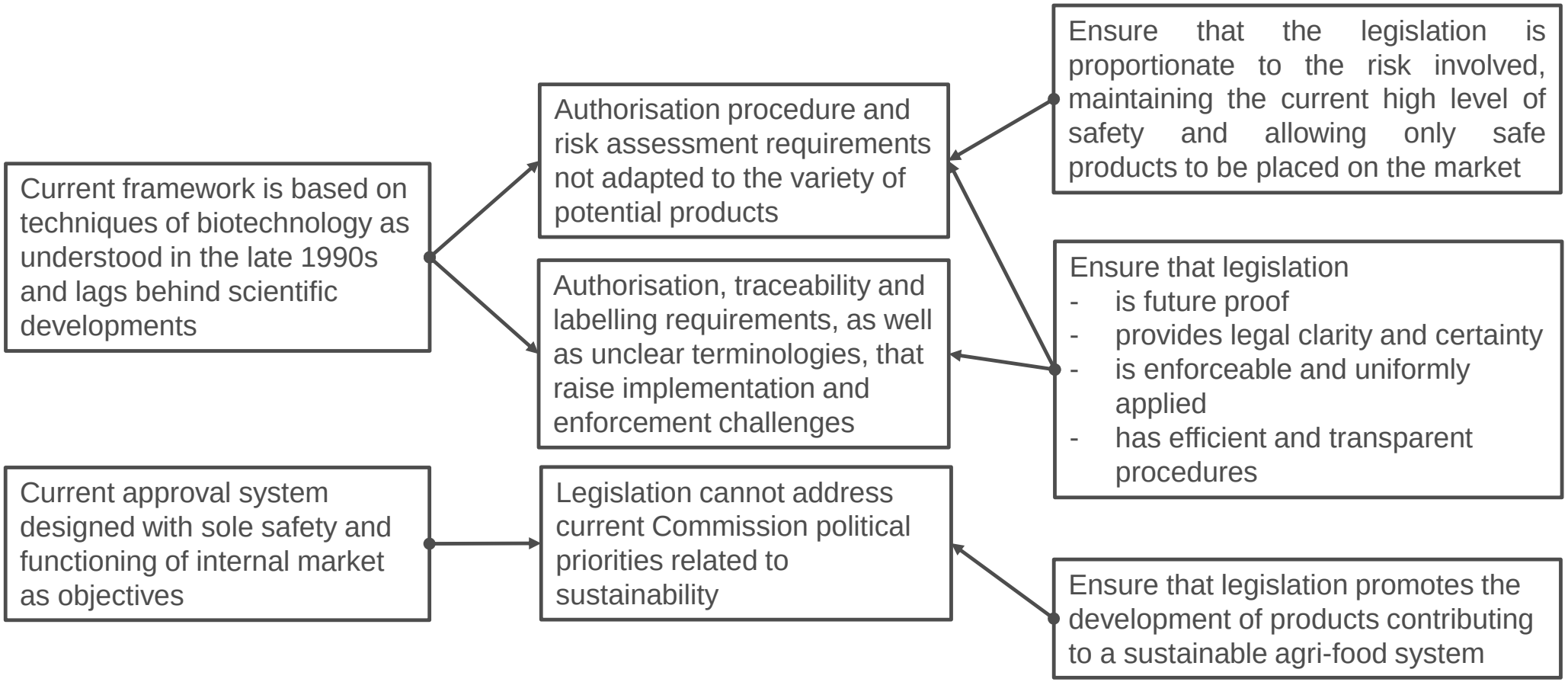
2019 - Council Decision (EU) 2019/1904

04/2021 - Commission's study on new genomic techniques

Farm to Fork Strategy

Legislation for plants obtained by targeted mutagenesis and cisgenesis

INTERVENTION LOGIC – Plants produced by targeted mutagenesis or cisgenesis

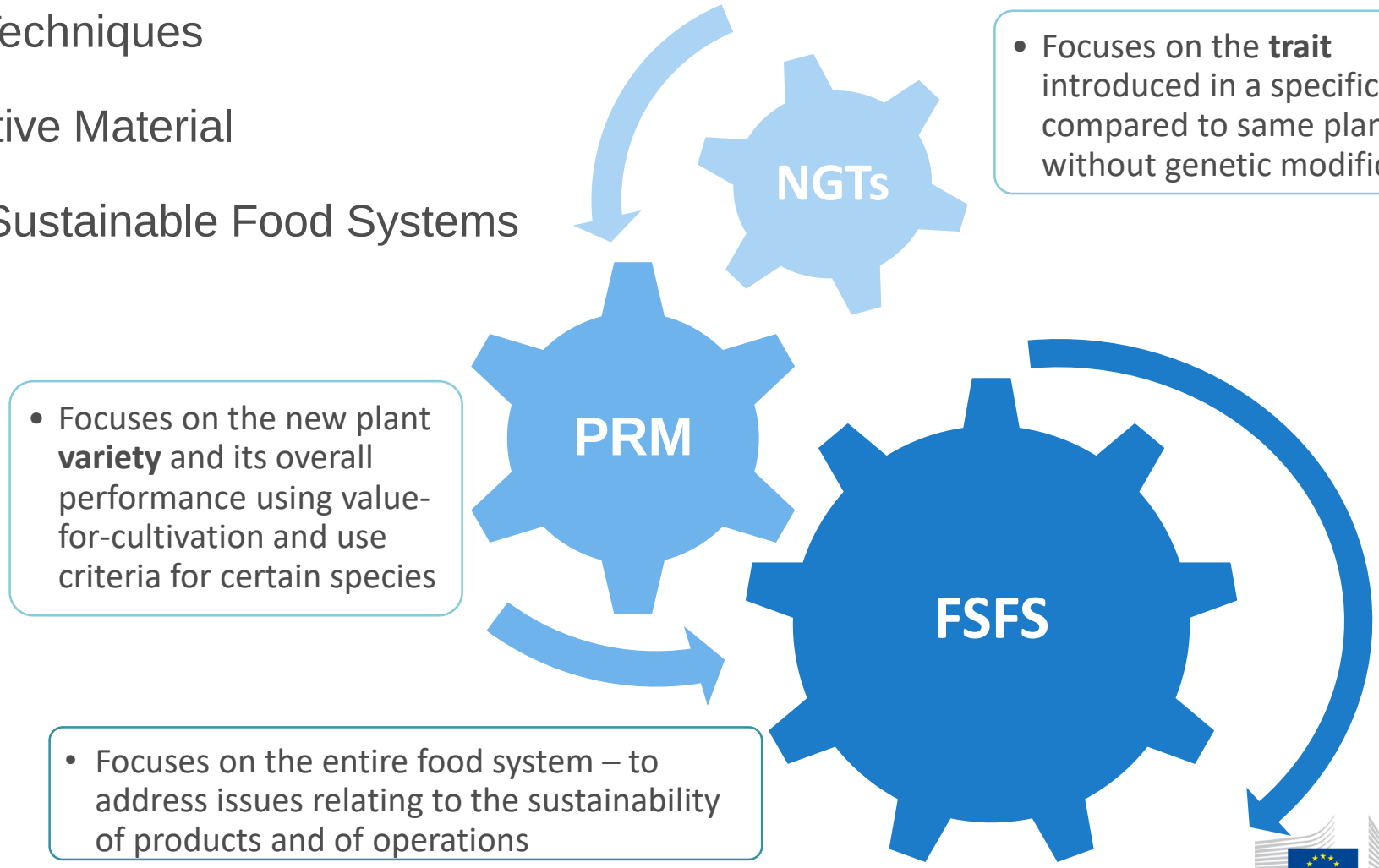


Policy options overview

Option 1 – Authorisation with adapted risk assessment	➓Authorisation required ➓Proportionate and tailored risk assessment; adapted detection method ➓Traceability and labelling requirements as for GM products today
Option 2 - Authorisation with sustainability **incentives**	➓Authorisation required ➓Proportionate and tailored risk assessment; adapted detection method ➓For products contributing to sustainability: • regulatory incentives • labelling as today as GM products with sustainability claim, OR no GM labelling
Option 3 - Authorisation with sustainability **requirements**	➓Authorisation required ➓Proportionate and tailored risk assessment; adapted detection method ➓No authorisation for products with traits detrimental to sustainability ➓Traceability and labelling requirements as for GM products today
Option 4 - Pre-notification for certain products	➓Pre-notification for products that can also be obtained naturally, by conventional breeding or classical mutagenesis, and exemption from authorisation by COM Decision ➓For the remaining products, authorisation as described in Options 2, 3 or 4

Sustainability in NGT and other initiatives

- New Genomic Techniques
- Plant Reproductive Material
- Framework for Sustainable Food Systems



- Focuses on the **trait** introduced in a specific plant, compared to same plant without genetic modification

- Focuses on the new plant **variety** and its overall performance using value-for-cultivation and use criteria for certain species

- Focuses on the entire food system – to address issues relating to the sustainability of products and of operations

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Potential impacts of policy options

Economic	Primary agricultural production, including yields, levels/cost of inputs and natural resources
	Food security
	Organic and GM-free agriculture, SMEs
	Innovation and research in the agri-food system, bio-based and biotechnology industry
Social	Content of toxins or allergens in foods of plant origin
	Nutritional profile of foods of plant origin
	Effects on local/traditional varieties, minor or orphan crops, rural areas, supply chains
	Variety of products meeting demands for sustainable food production
Environmental	Resilience and sustainability of agri-food systems
	Sustainability and biodiversity impacts, including on levels of use of pesticides/fertilisers, effects on traditional varieties, effects on other aspects of sustainable food production
Fundamental rights	Health and environment protection
	Right to information
	Freedom to conduct business
Simplification & administrative burden	Streamlining of framework including proportionate risk assessment
	Increase legal certainty
	Introduction of new requirements
	Reduction of costs/administrative burden (researchers, applicants, operators and authorities)

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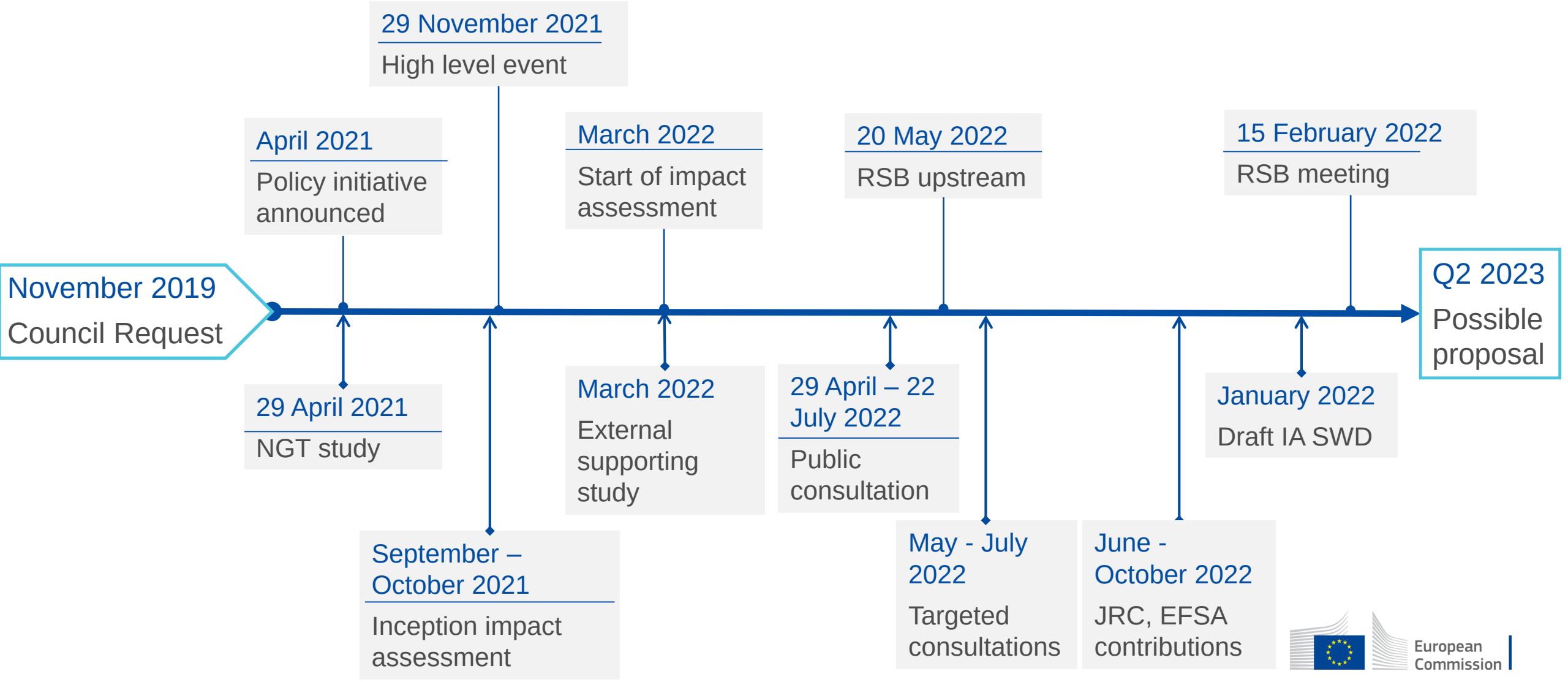
Timeline, milestones & inputs



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Data sources - Consultation Strategy

Public Consultation

Current situation/baseline
- Problem definition
- Impacts of current legislation

Future: policy element choices and impacts
- Risk Assessment
- Sustainability
- Provision of information

Future: other aspects
- Future proofing
- Co-existence
- Intellectual property access
- SMEs

Targeted stakeholder consultations

Targeted Surveys
- Data for baseline scenarios
- Assessing impacts of policy options
- Costs and burdens

Interviews
- Understanding positions
- Data on costs
- Other in-depth information

Focus groups
- Traceability
- Sustainability
- Data validation

Mini case studies
- On impacts, using equivalent situations in EU or 3rd countries
- Running JRC case studies through policy options
- Filling potential data gaps

Data sources - Further support

JRC

Megatrends Workshop

- Exploration of potentially relevant future trends
- Understanding baseline, future-proofing policy options, setting objectives

Values and Identities

- Analysis of stakeholder position papers, IIA feedback
- Investigation of values behind expressed views
- Points of convergence or divergence between stakeholders
- Shaping communication messages

In-depth case studies

- Plants in advanced development stage
- Address lack of historical evidence
- Identification/quantification of impacts
- Feed into contractor analysis

EFSA

Relevant scientific opinions

- Cisgenesis
- Synthetic biology (to what relates to targeted mutagenesis)

EFSA + MS working group + JRC

Risk assessment support

- Assistance in defining criteria for risk assessment for IA and proposal
- Criteria to assess which plants obtained from targeted mutagenesis and cisgenesis could also have been produced in nature o using conventional breeding

Challenges and sensitivities

- Politically-charged file with polarised stakeholder views;
- Highly technical topic with complex scientific aspects;
- Lack of historical data on use and impacts of NGT plants; few marketed products, only recently emerged in EU trade partners;
- Potential issues with provision of detailed data from stakeholders due to confidentiality.

Thank you

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