



# Commission proposal on plants obtained by certain new genomic techniques (NGTs)

89th Meeting  
EFSA ADVISORY FORUM  
5 October 2023

#EUFarm2Fork  
#EUGreenDeal



European  
Commission

# Objectives of the proposal



- High level of protection of health and environment
- Developments to contribute to sustainability and climate adaptation in a wide range of plant species, especially for the agri-food system
- Opportunities for research and innovation, including for SMEs

# Scope of the proposal

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**

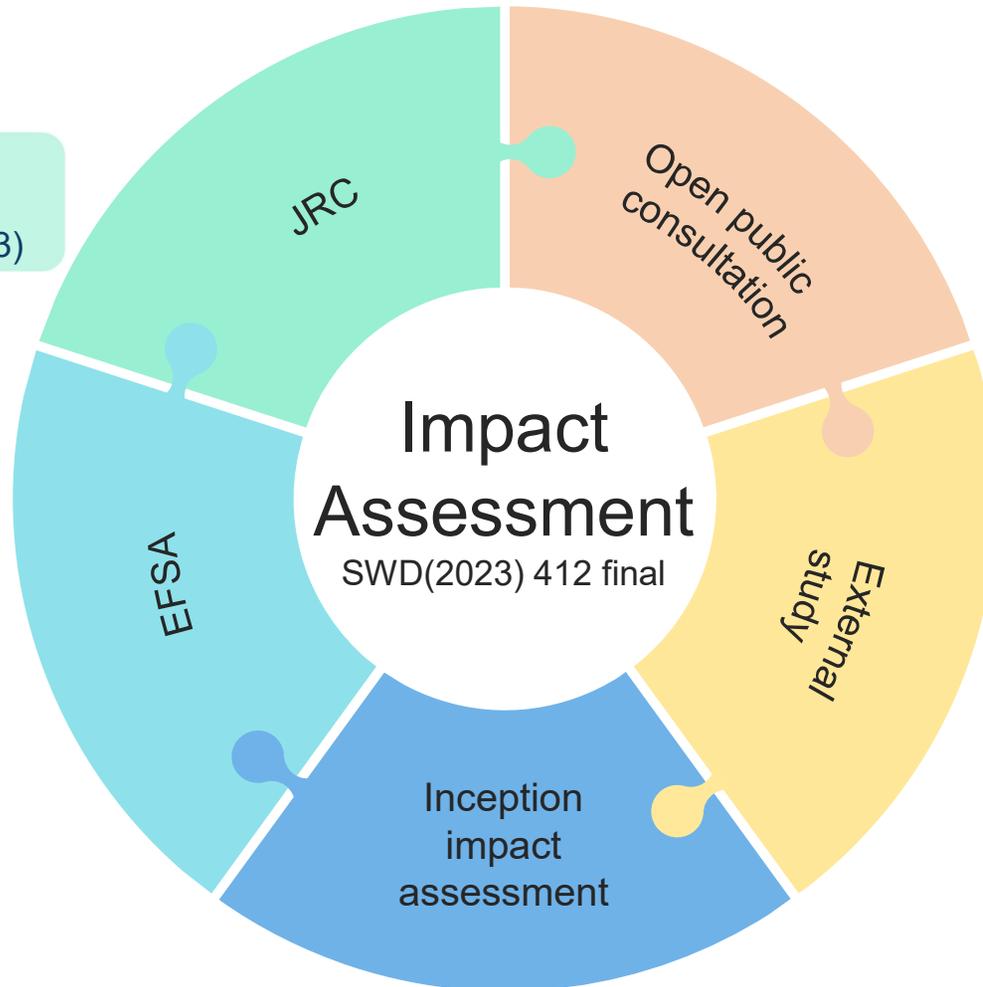
- **NGT plants**
- **NGT food/feed**
- **Other products** containing/consisting of NGT plants



# Evidence

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

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



Two fact-finding studies on official controls in Member States

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



# Safety

- ✓ 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.

# Two regulatory pathways

## 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

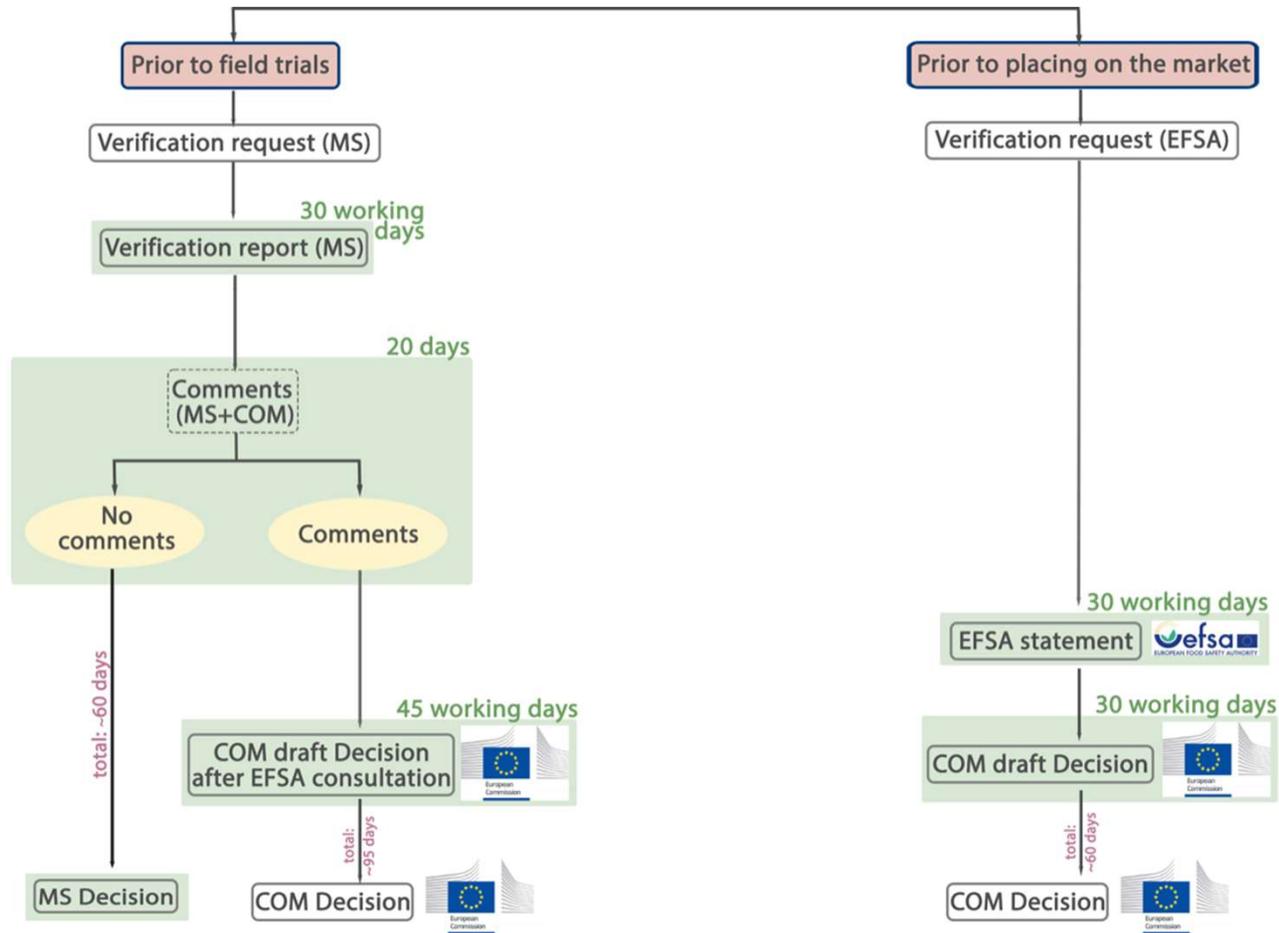


Monitoring and reporting

Prohibition in organic production



# Category 1 NGT plants: verification procedure



# Category 2 NGT plants and their food and feed: risk assessment



General principles and information 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.



Hazard identification and characterisation: specific information for environmental risk assessment to be required if justified by plausible risk hypothesis



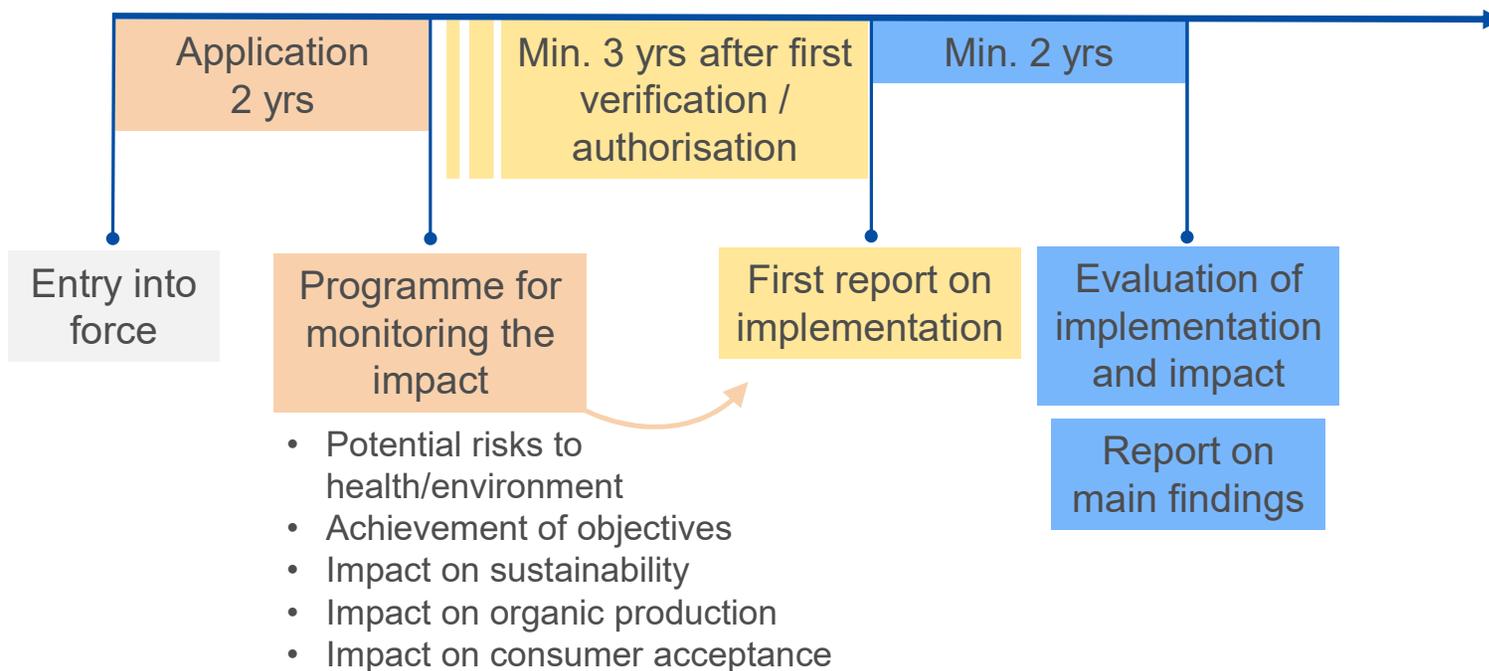
Hazard identification and characterisation: specific information for food and feed risk assessment to be required if justified by plausible risk hypothesis

## Category 2 NGT plants: incentives for traits relevant for sustainability

- ◆ 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



## Monitoring, Reporting and Evaluation (Art. 30)



# Thank you

Useful links:

[https://ec.europa.eu/commission/presscorner/detail/en/qanda\\_23\\_3568](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](https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en)



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