



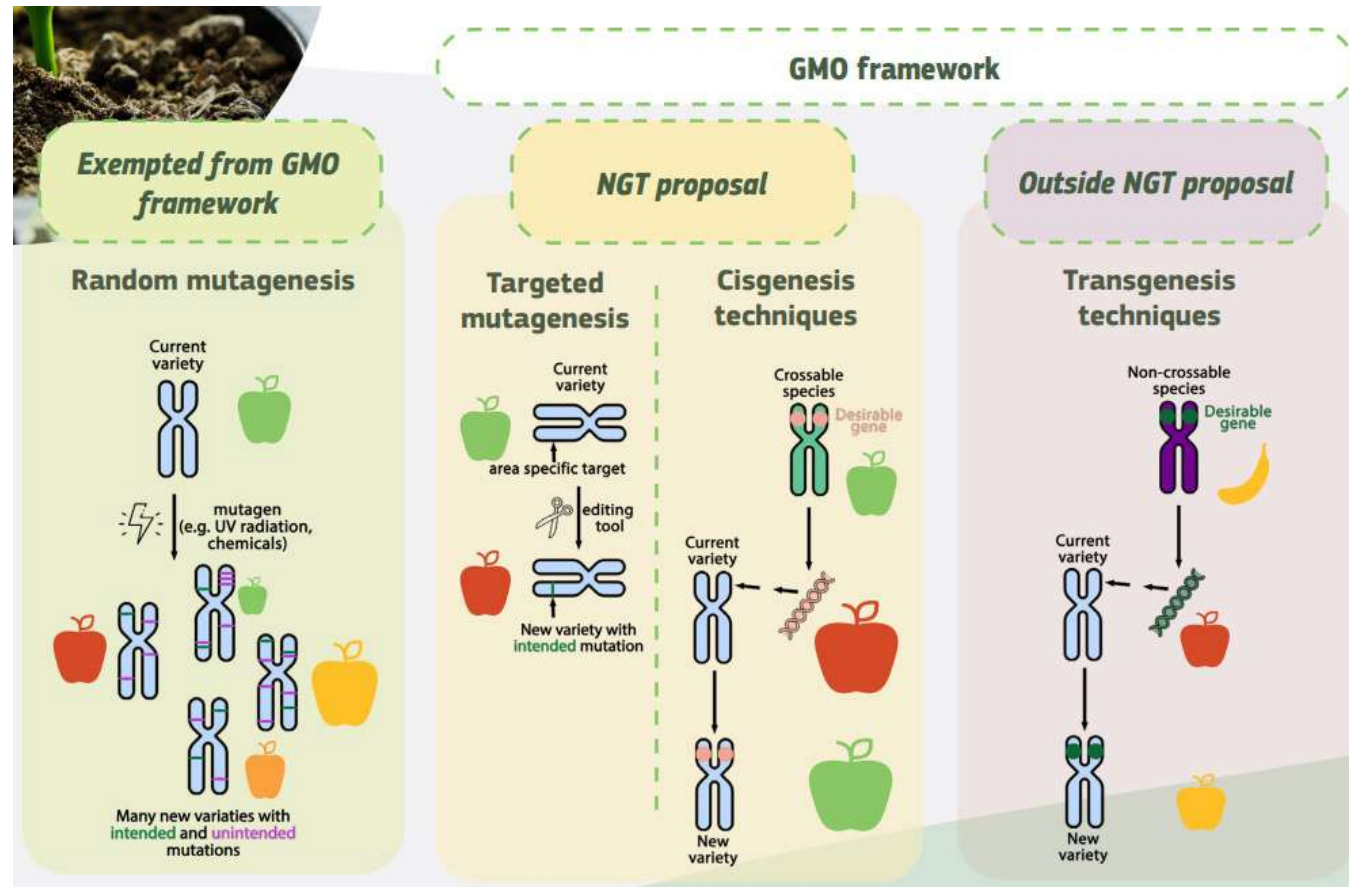
Commission proposal on plants obtained by certain new genomic techniques (NGTs)

#EUFarm2Fork
#EUGreenDeal

WHAT ARE NEW GENOMIC TECHNIQUES?

NGTs are techniques of genetic modification that can help breed new plant varieties faster, and with higher precision than conventional breeding techniques.

NGTs can produce a wide diversity of plant products. These plants may have only small changes that might also occur in nature or through conventional breeding or they may have more complex modifications.

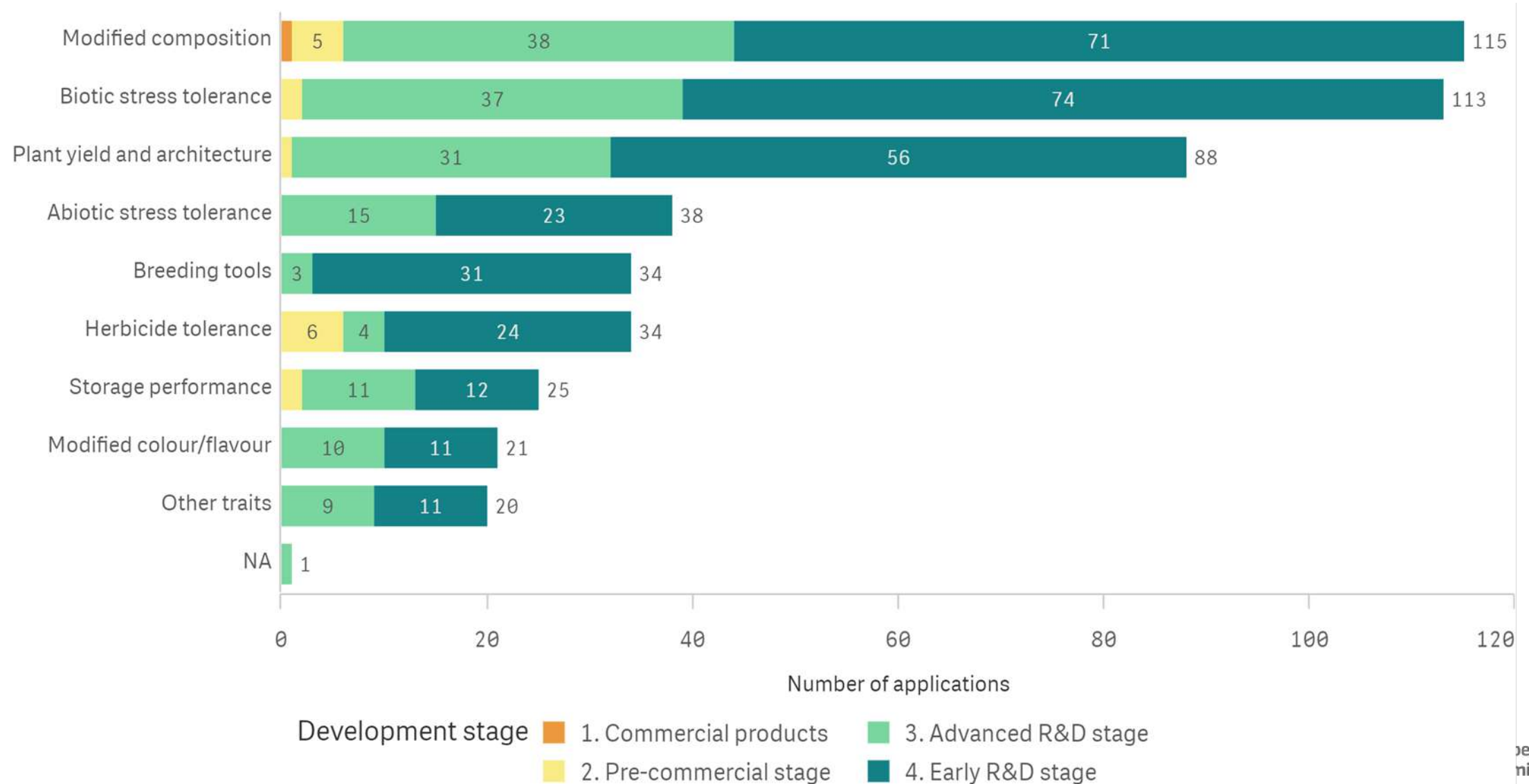


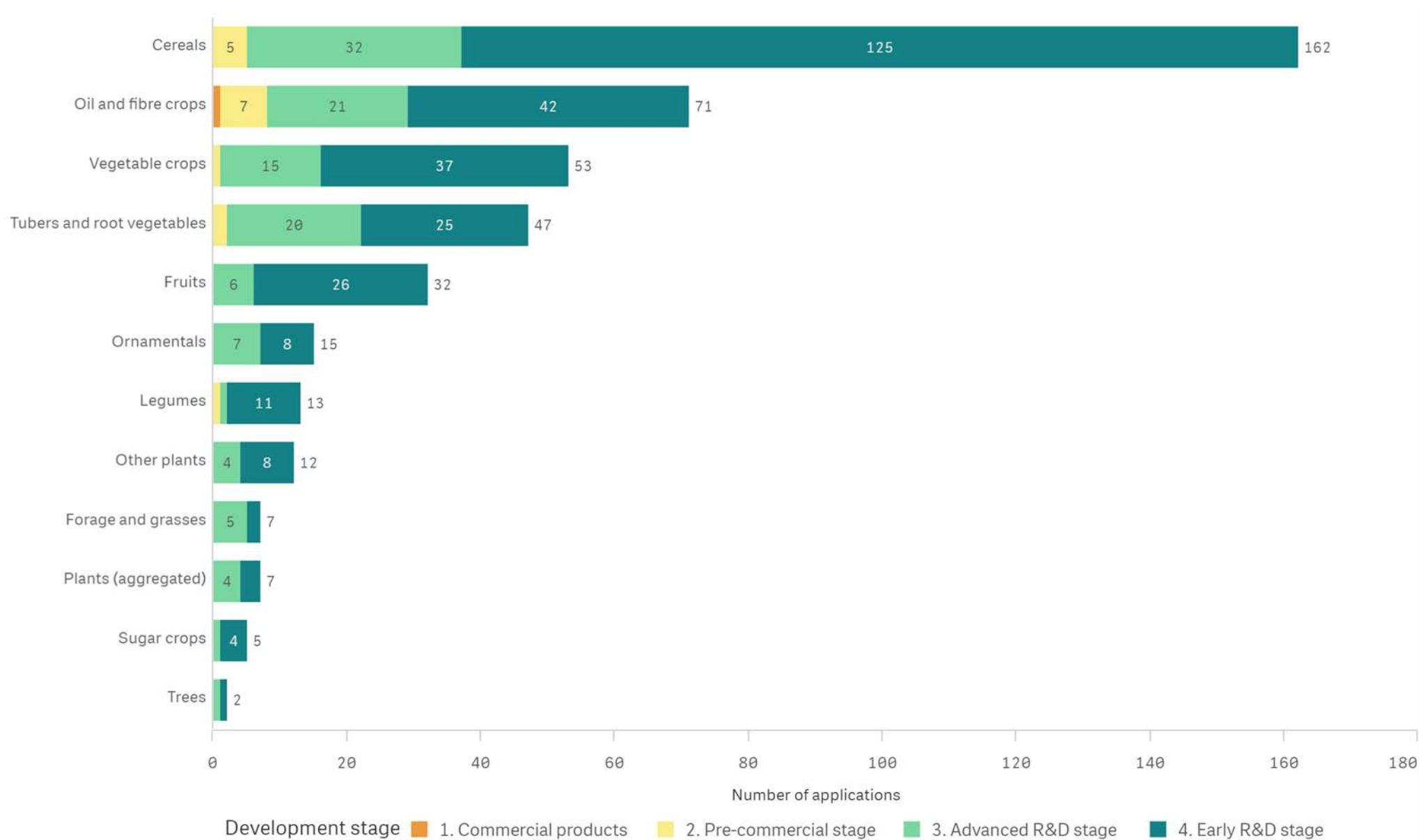


Safety (EFSA)

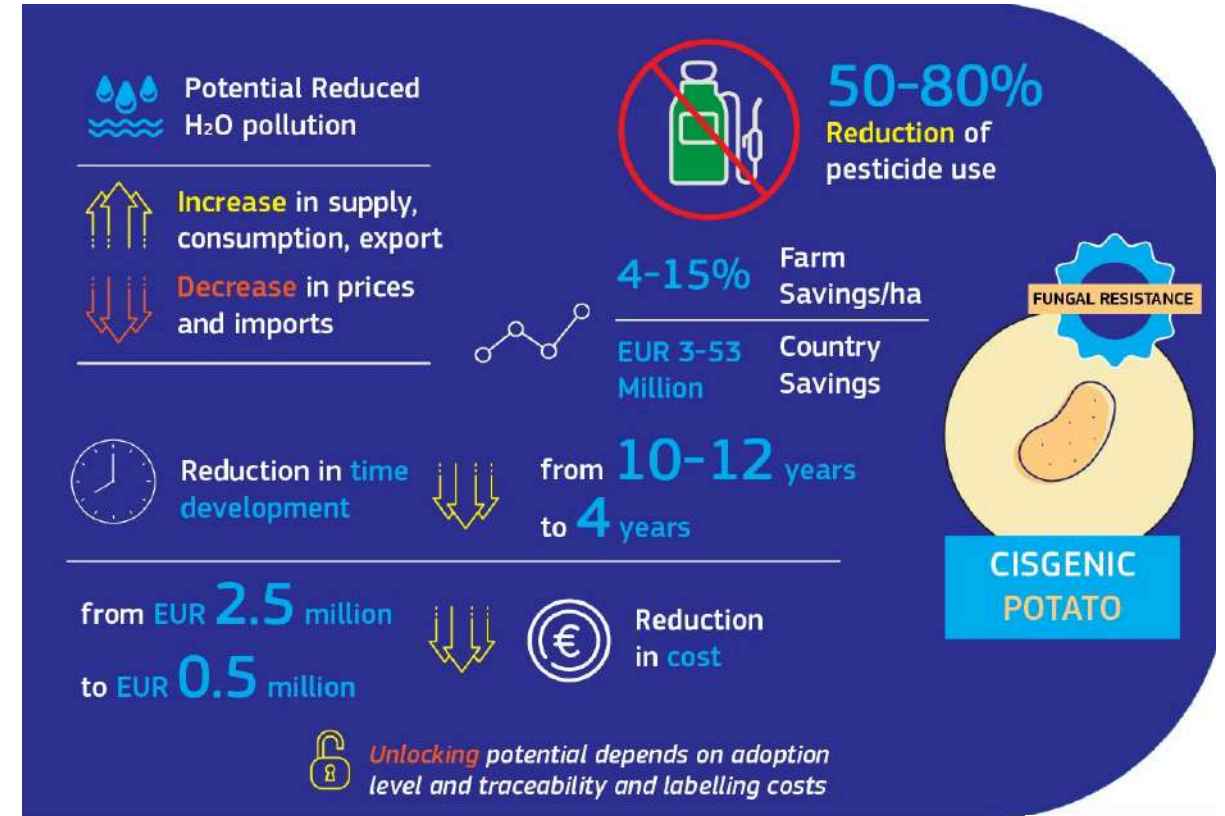
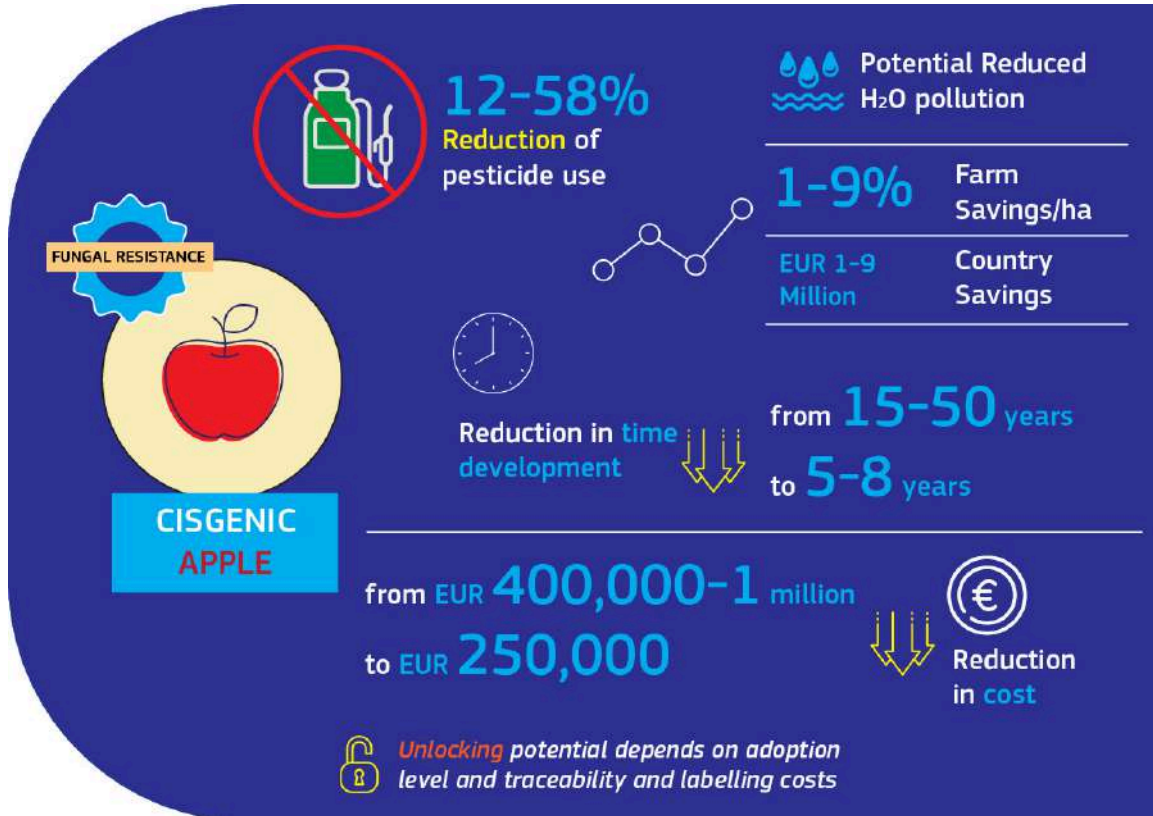
- ✓ Variety of different products with different safety profiles.
- ✓ No specific hazard associated to these techniques.
- ✓ Similar products obtained by different techniques are not expected to present significantly different risks.
- ✓ Lesser amounts of risk assessment data on a case-by-case basis.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

Plants in R&D (JRC, 2021)





Examples of case studies (JRC, 2023)



VIRAL RESISTANCE



TARGETED
MUTAGENESIS
MAIZE



22-40%
loss of annual
production in East
Africa due to **Maize
Lethal Necrosis (MLN)**



The most
ENVIRONMENTAL
and **ECONOMICAL**
sustainable approach



PREVENTION OF
122,000
additional people
experiencing
FOOD INSECURITY



Battle against this
disease could save
0.5 MM PEOPLE
from falling under
THE POVERTY LINE



POTENTIAL ECONOMIC BENEFITS



Healthier
alternative to
gluten-free diets



Reduced need of Medical
care post-diagnosis and
lost productivity days



Alternative to costly
gluten free diets



30%
increase
farm gross
margin/ha



Small cost
expected for segregation
and preservation at
field level

No increased
agronomic
management -
comparable
yields



Higher
exports **EUR 0.5 - 2.6
Billion**



Lower
imports **EUR 0.1 - 0.5
Billion**



Significant savings for consumers
who buy gluten free products

LOW GLUTEN



TARGETED
MUTAGENESIS
WHEAT

Why new rules?

- Current rules lag behind scientific and technological progress and are not designed to facilitate the development and placing on the market of innovative NGT products.
- The EU needs an adapted framework for safe NGT plants tailored to their specificities to provide benefits to farmers, consumers and the environment.

Objectives

- 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



Subject matter & scope

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



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



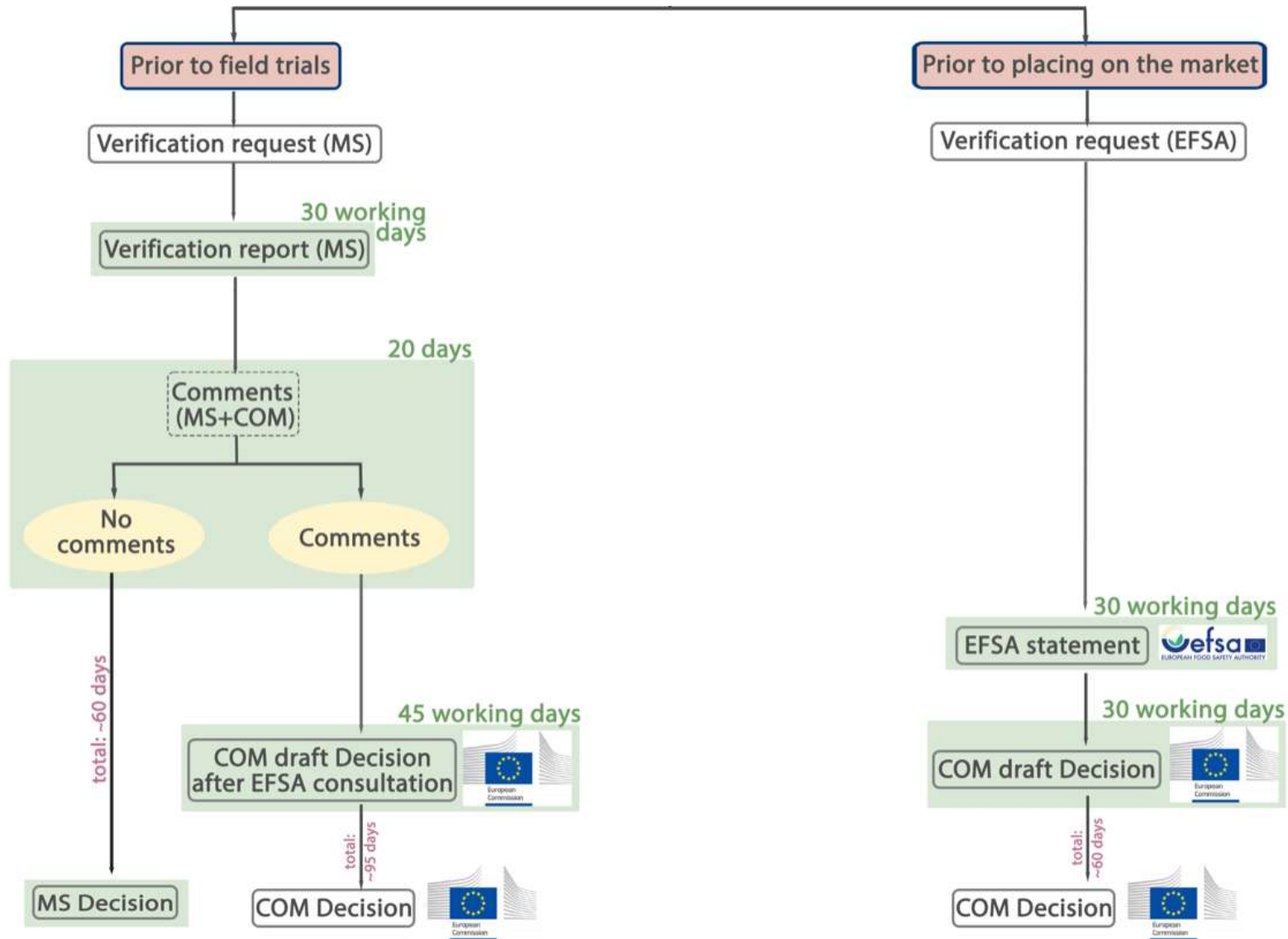
Verification criteria (Annex I)

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.

Verification procedure



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Regulatory incentives for category 2 NGT plants and products

Relevant traits (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

More information:

<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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