

# ANNEXES to the RSB upstream meeting on

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

*DG SANTE*

*20/05/2022*

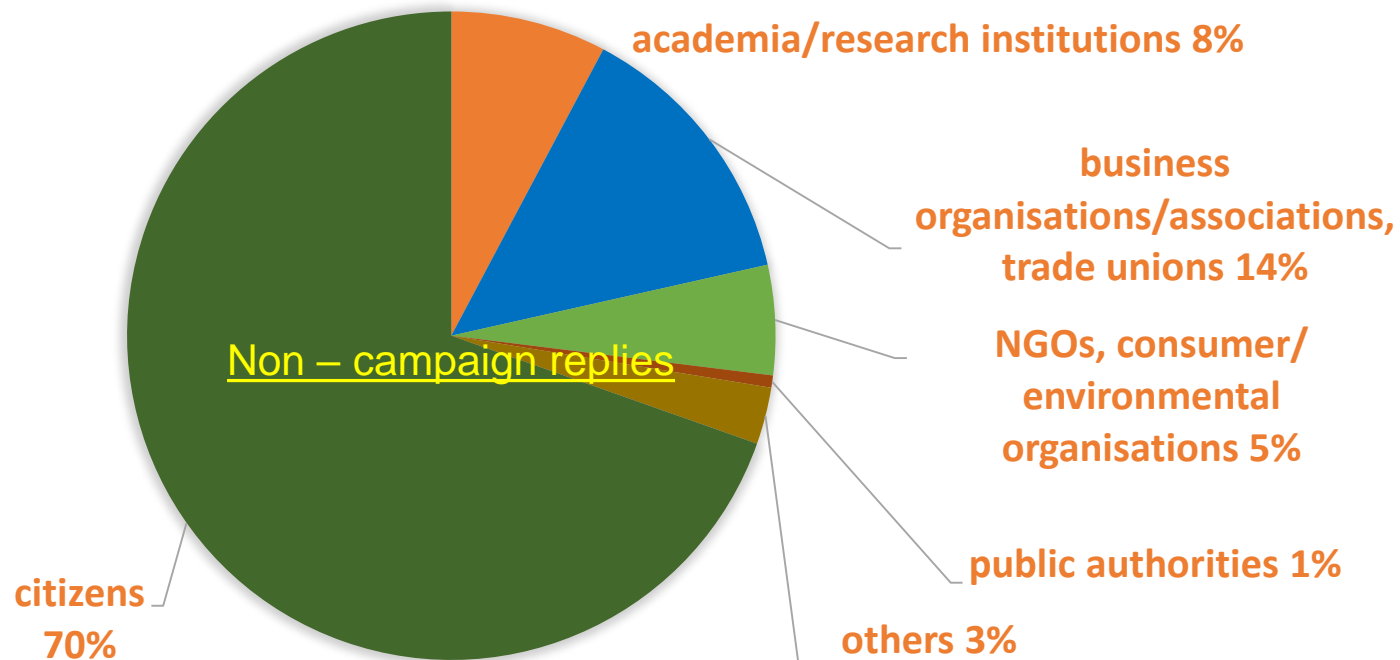
# Commission NGT study – main findings

- ✓ Confirmed the conclusions of the past evaluations of the GMO legislation as regards new genomic techniques (NGTs).
- ✓ Identified a series of challenges relating to the GMO legislation's capacity to keep pace with scientific developments, which affect its implementation.
- ✓ NGTs have the potential to contribute to the objectives of the European Green Deal, Farm to Fork and Biodiversity Strategies, and United Nations' Sustainable Development Goals for a more resilient and sustainable agri-food system.
- ✓ NGT applications in the agricultural sector should not undermine other aspects of sustainable food production, e.g. organic agriculture.
- ✓ There are strong indications that the GMO legislation not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress.

# Inception Impact Assessment feedback

✓ High interest: approximately 71.000 replies

- 98% from campaigns (opposing initiative, ask not to proceed)
- 2% from non-campaign (most supportive to initiative): 1030 citizens, 450 stakeholders



✓ Main feedback topics

- Expressing support or opposition
- Views on policy elements: risk assessment, provision of information, traceability, sustainability
- Additional interest in liability and cost of contamination, intellectual property issues

# Range of IIA views –Initiative

- Most non-campaign citizens and business associations (most farmers, plant breeders, traders, processors/manufacturers), trade unions, companies, and academic/research stakeholders **welcome the IIA and support the initiative**
- Some business operators (organic/GM-free sector, small/grassroot farmer associations and retailers), some academic/research stakeholders, some non-campaign citizens, most NGOs and all campaign respondents **are critical of the IIA, oppose the initiative and ask not to proceed**

# Range of IIA views – Risk assessment

- not necessary for products that could have also been obtained by conventional breeding
- product based, case-by-case and proportionate to risk profile of specific products
- comprehensive, for all NGTs, process-based, as in current GMO legislation
- case-by-case trait assessment on top of existing GMO risk assessment

# Range of IIA views - Sustainability

- agree on potential contribution to GD, F2F and Biodiversity strategies, UN SDGs
  - welcome considerations on sustainability/benefits in legal framework
  - need for consistent/coherent analysis for all products, not only NGTs; risk of discrimination
  - increased burden for operators
  - need for coherence/avoidance of duplication with FSFS and seed variety testing
  - support for assessment of sustainability impacts in general, but see no sustainability potential in NGTs
- 6 ■ no trade-offs between risk and sustainability assessment

# Range of IIA views – Traceability

- all agree on importance of traceability in general
- document based traceability, certification systems and EU/national registries/catalogues can be used, even if analytical laboratory methods are not available
- lack of analytical methods should not be a barrier for approval
- analytical detection methods should be mandatory, development prioritised
- important to guarantee freedom of choice for operators (especially organic and GM-free agriculture) and consumers; weakening traceability would be against F2F transparency objectives

# Range of views IIA – Provision of information

- No need for GMO labelling (hindrance in market uptake, not justified scientifically/from safety point of view when equivalent to conventional plants, not implementable/enforceable)
- Introduction of specific NGT-labelling, potentially tied to mentioning benefits/claims
- Maintain current GMO labelling (Ensure freedom of choice/public in favour of GMO labelling, ensure consumer trust in organic/GM-free agriculture, information on breeding method needed on label)
- Need to raise awareness of public on NGTs, e.g. on safety and benefits

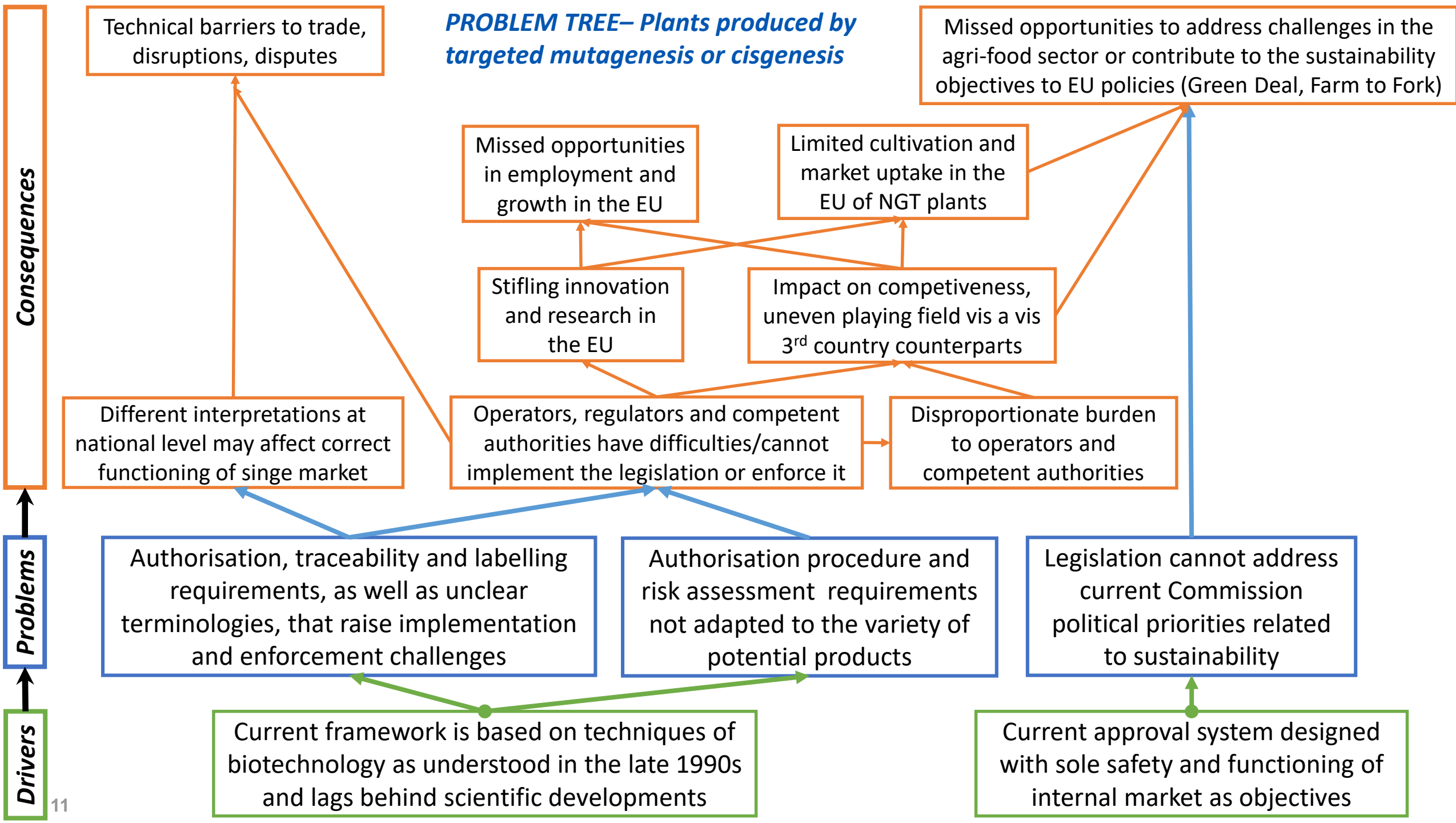


# Range of IIA views – Liability/contamination cost

- no scientific basis not to use NGT products in organic farming (when equivalence to conventional plants)
- strict coexistence rules needed to safeguard organic/GM-free agriculture
- deregulation of NGTs would make coexistence impossible
- lack of transparency on NGT plants from third countries
- organic/GM-free sector would bear the cost to avoid contamination
- Introduce the ‘polluter pays’ principle

# Range of IIA views - Intellectual property

- publicly-funded NGT research should be free from patents; research institutions to give access to technologies
- patents only for plants that can't be obtained also by conventional breeding, broader definition of 'essential biological processes'
- ask for facilitated access (from limited to completely free) to gene pools and breeding technologies; encourage licensing platforms initiated by companies
- negative consequences of patents in GMOs, like monopolisation and concentration
- threat to rights of farmers and breeders



# General & specific objectives

Maintain high level of protection of human and animal health and of the environment

- Ensure that the legislation is proportionate to the risk involved, and allowing only safe products to be placed on the market

Enable safe plants to provide benefits and contribute to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies

- Ensure that legislation promotes the development of products contributing to a sustainable agri-food system

Enhance the competitiveness of the EU agri-food sector and ensure a level-playing field for its operators and ensure the effective functioning of the internal market.

- promote a future-proof legislation that is able to keep up with scientific developments and ensure that the legislation provides legal clarity and certainty, is enforceable and uniformly applied and has efficient and transparent procedures.

# Range of choices per policy element

## Placing on the market

- ⑩ As today, authorisation always needed
- ⑩ Pre-notification for products that can be also obtained naturally

## Risk assessment

- ⑩ As today, same requirements for all GMOs
- ⑩ Proportionate requirements tailored to risk
- ⑩ No need for risk assessment under certain conditions

## Sustainability

- ⑩ As today, no specific provisions under this initiative
- ⑩ Incentives for traits positively contributing to sustainability
- ⑩ Requirement that trait is not detrimental to sustainability

# Range of choices per policy element

## Labelling

- ⑩ Labelling as a GM product
- ⑩ Introduction of a sustainable trait labelling
- ⑩ No specific labelling (under certain conditions), but inclusion in public register

## Traceability

- ⑩ Traceability requirements as for GM products
- ⑩ Possible additional traceability related to sustainability
- ⑩ No specific traceability requirements (under certain conditions)

## Detection method

- ⑩ Detection method with the capacity to differentiate required
- ⑩ Detection method required, but with a possible waiver on the capacity to differentiate
- ⑩ Not required (under certain conditions)