



New Genomic Techniques (NGTs): update from the EC on the next steps

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The context



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



**Council Decision
(EU) 2019/1904**



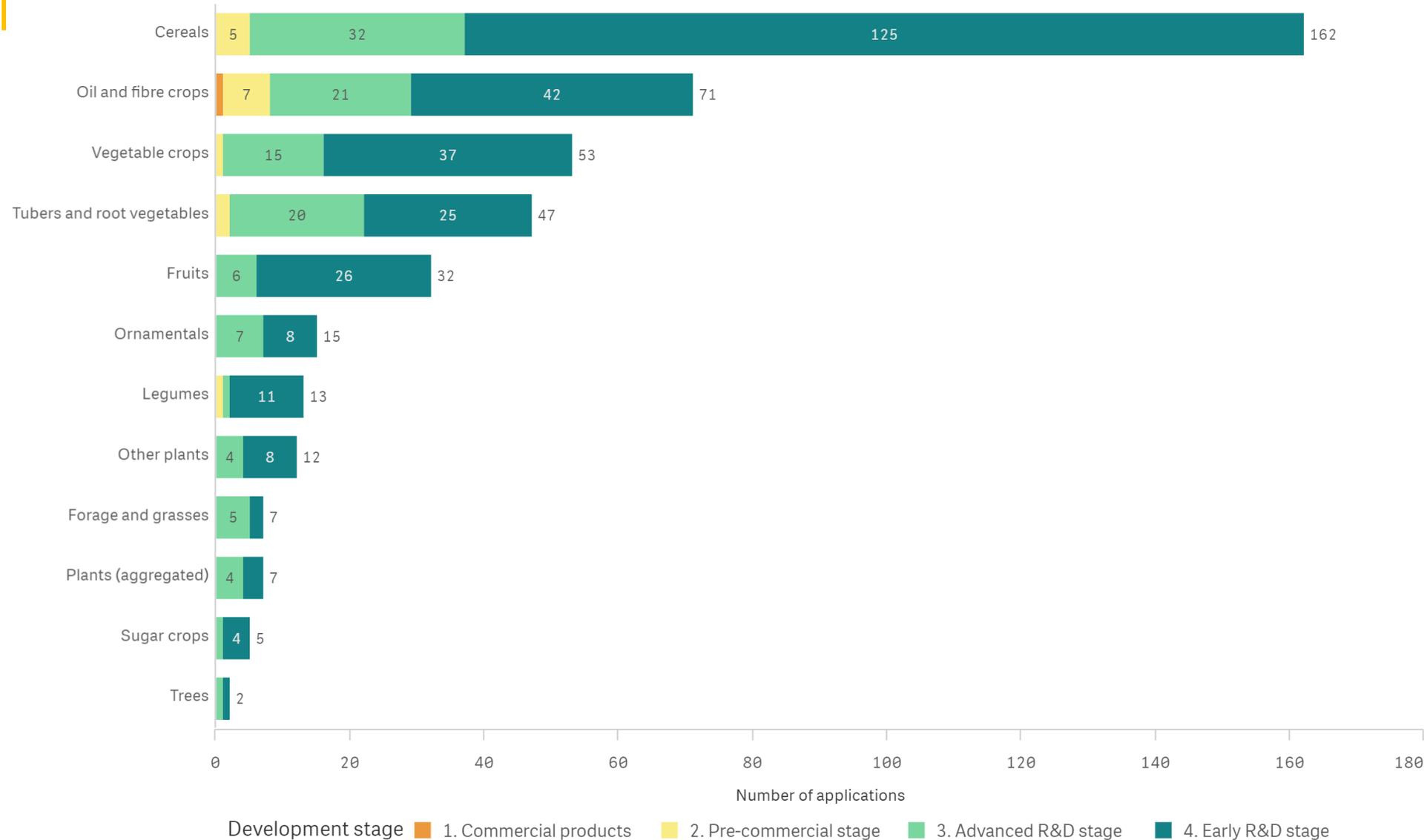
**The Commission's study
on NGTs**



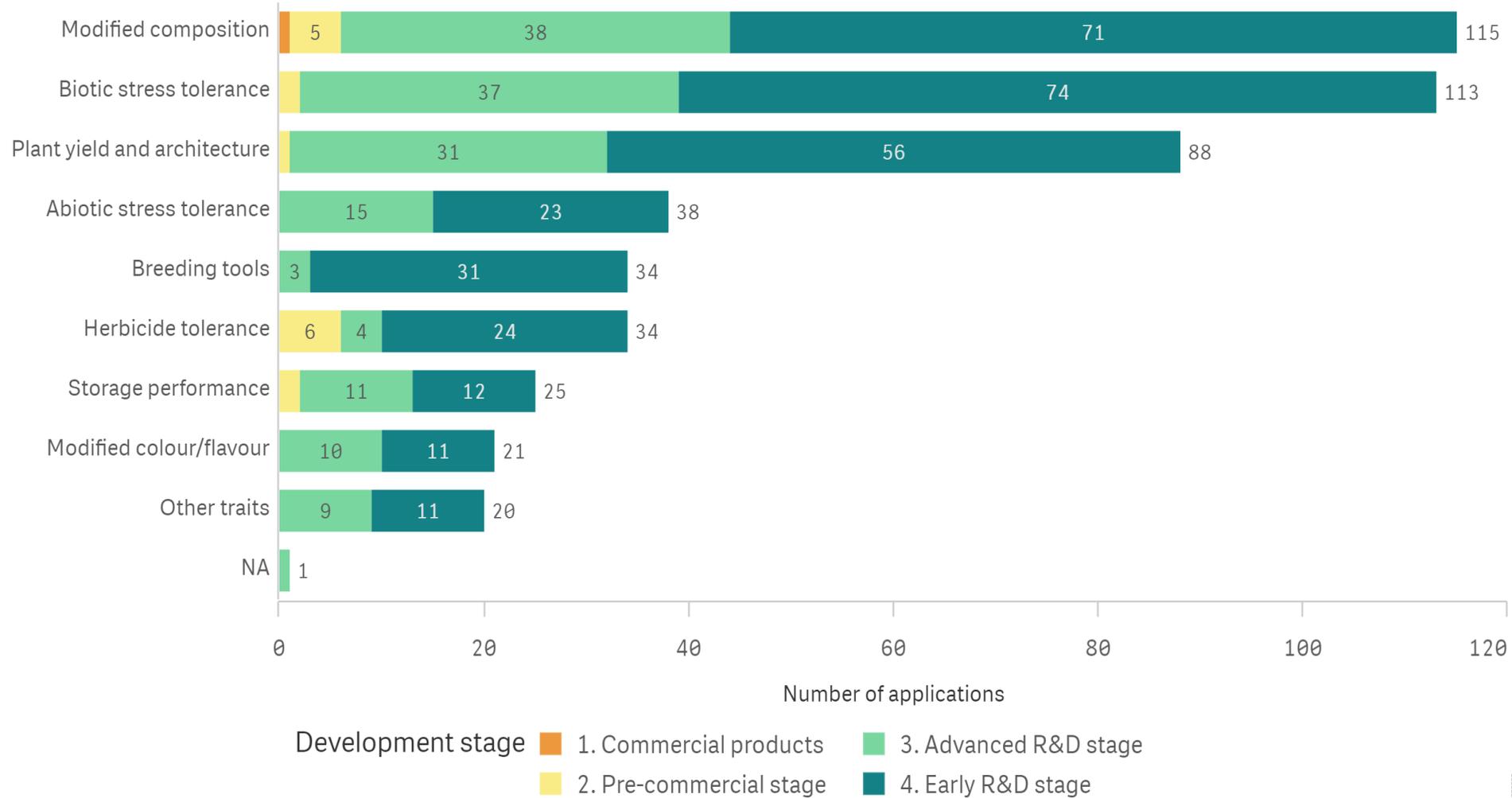
**Policy initiative on plants
obtained by
targeted mutagenesis
and cisgenesis**

Commission study on new genomic techniques

NGTs applications in plants: crops



NGT applications in plants: traits



Potential benefits



Plants resistant to effects of climate change or to pests and diseases



Production of useful substances from microorganisms



Vegetables with improved nutrient content or reduced content of harmful substance



Farm animals resistant to certain diseases or climate conditions



New vaccines and therapies

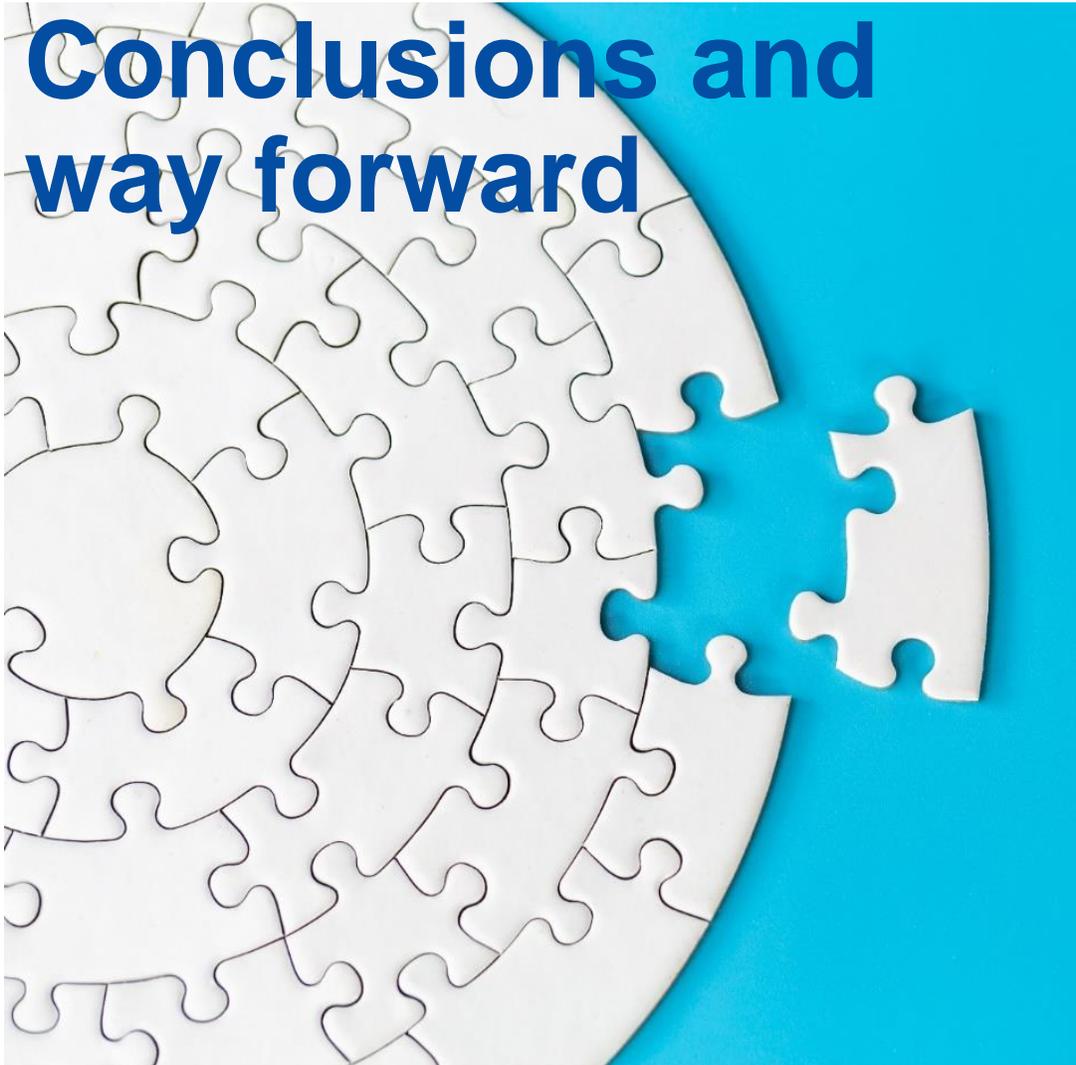
Potential concerns

- possible risk and environmental impact
- coexistence with organic and GM-free agriculture
- labelling and consumers' right to information



Some stakeholders consider that benefits are hypothetical and achievable by other means.

Conclusions and way forward



- GMO legislation and risk assessment needs adaptation to scientific and technological progress to be suited to certain NGTs and their products.
- Current regulatory oversight and risk assessment requirements are not tailored to diverse risk profiles.
- NGTs can contribute to Green Deal and Farm to Fork objectives, as well as to a more competitive economy.
- Concerns expressed should be addressed in any future action. NGT applications in the agricultural sector should not undermine other aspects of sustainable food production, e.g. as regards organic agriculture.

The Commission follow-up action

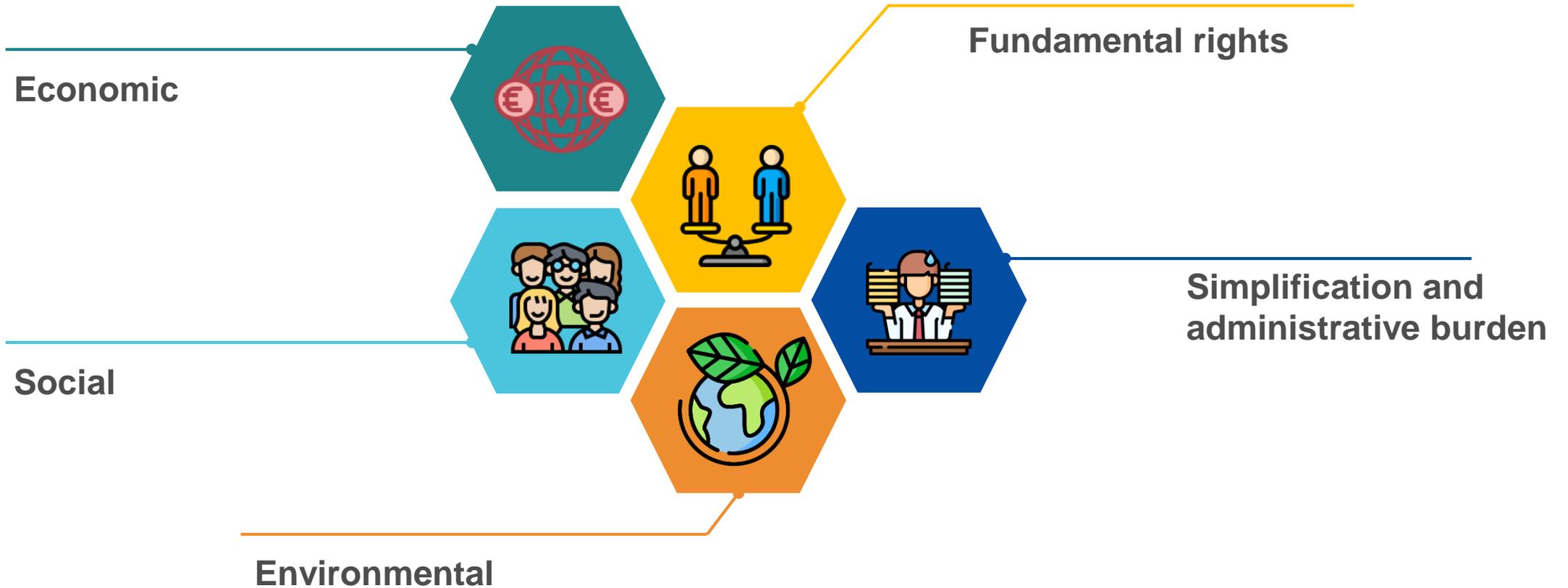
The Commission's follow-up action

- ✓ The Commission announced policy action on **plants derived from targeted mutagenesis and cisgenesis**.
- ✓ For **other organisms and other NGTs**, continue to build up the required scientific knowledge, in view of possible further policy actions.
- ✓ Considerations related to **medicinal products** will be addressed in the **Commission's Pharmaceutical Strategy**. Solutions will be explored to ensure that the regulatory requirements for the authorisation of medicines for human use that contain or consist of GMOs are fit to address the specificities of medicines and the conduct of clinical trials with those products in the EU.

Policy action on plants derived from targeted mutagenesis and cisgenesis

- ✓ The policy action **aims at** a proportionate regulatory oversight, which would:
 - maintain a high level of protection of human and animal health and the environment
 - allow reaping benefits from innovation and the contribution of safe NGTs to a sustainable agri-food system
- ✓ **Policy elements** to be considered in the development of policy options:
 - risk assessment and approval requirements proportionate to the risk involved
 - an analysis of products' contribution to sustainability
 - appropriate traceability and labelling provisions
 - mechanisms to provide for a future-proof regulatory framework

Impacts to be examined



Main steps

- ✓ Publication of the **inception impact assessment (roadmap)** on 24 September 2021 for feedback (4 weeks, until 22 October 2021) in the Commission's 'Have Your Say' portal https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
- ✓ **Impact assessment**, including consultation activities, during 2022
- ✓ Possible **legal proposal** 2Q 2023

Outreach

- ✓ High-level event “New genomic techniques – way forward for safe and sustainable innovation in the agri-food sector“, 29 November 2021
 - ✓ Three panel discussion on key elements of the roadmap: sustainability, risk assessment and information to consumers.
 - ✓ https://ec.europa.eu/info/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-nov-29_en



Thank you

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Slides 2,6. 8 and 12: Pictures, source: Gettyimages