



# The Commission's Study on New Genomic Techniques – the next policy steps

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# The context



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



Council of the  
European Union

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



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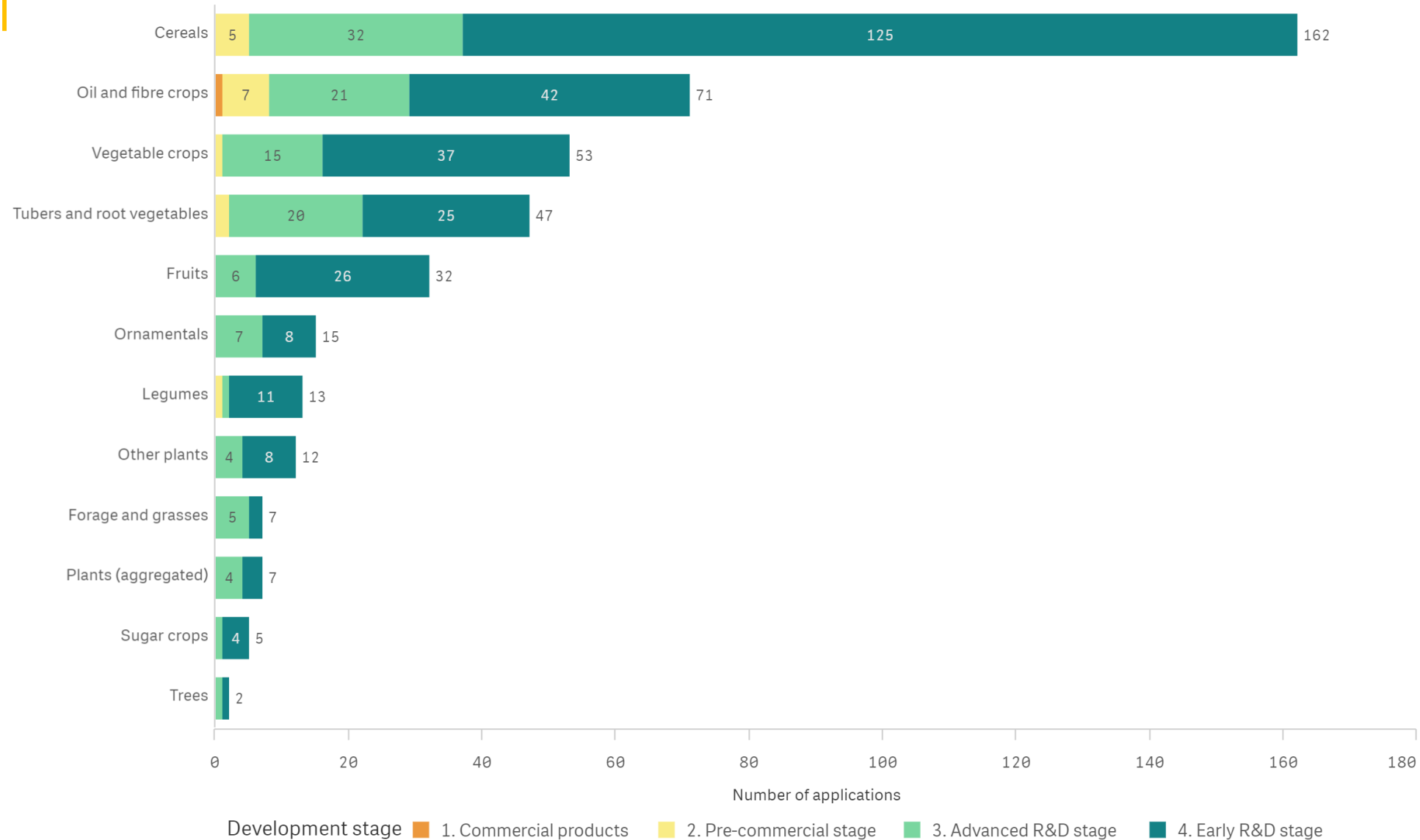
**The Commission's study  
on NGTs**



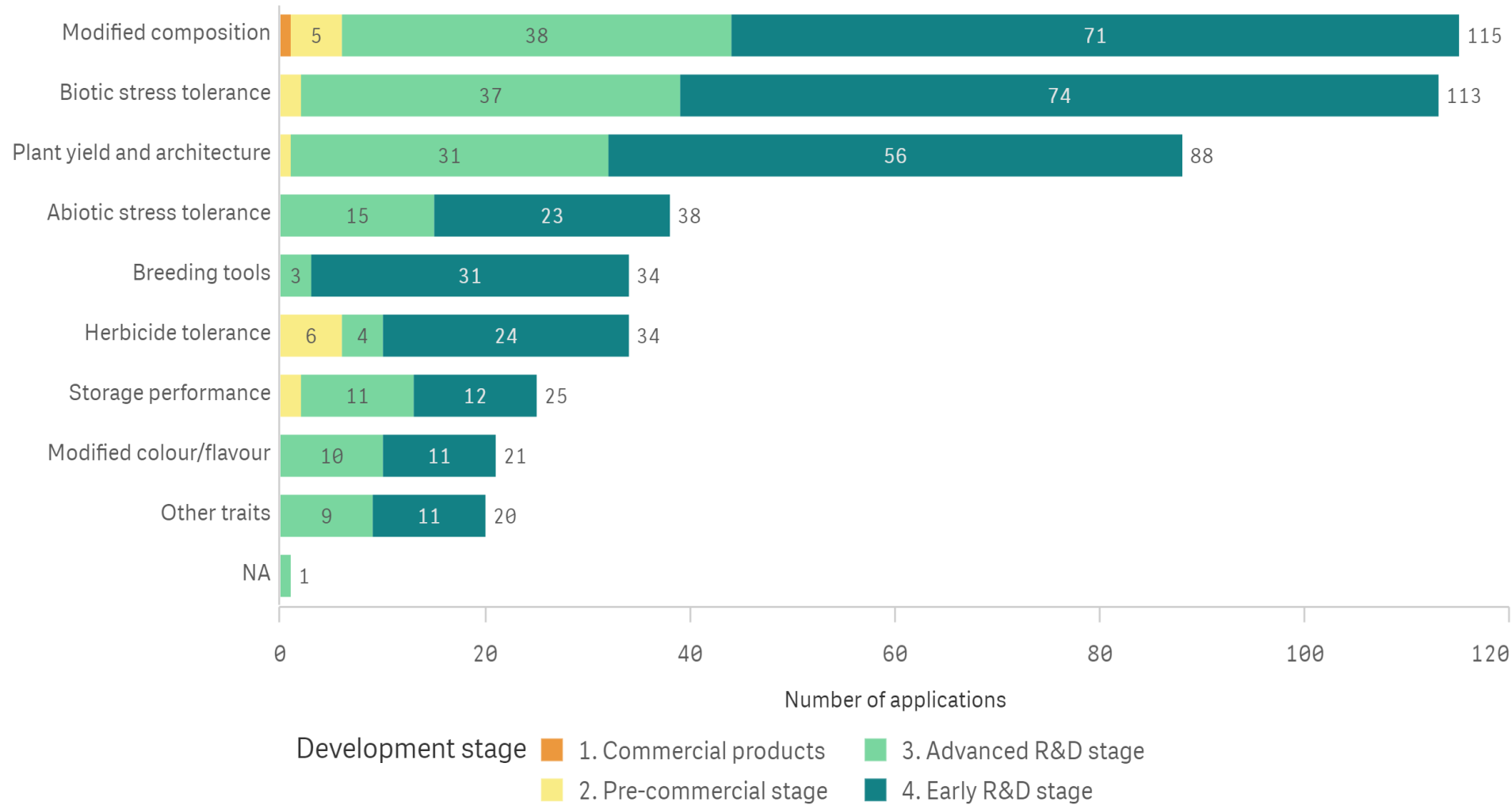
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**Policy initiative on plants  
obtained by  
targeted mutagenesis  
and cisgenesis**

# 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'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

# Have Your Say

- ✓ **Plants obtained by certain NGTs** - roadmap open for feedback until 21 October 2021

[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en)

- ✓ **Sustainable food system framework** - inception impact assessment (roadmap) open for feedback until 26 October 2021

[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13174-Sustainable-EU-food-system-new-initiative\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13174-Sustainable-EU-food-system-new-initiative_en)

# The Commission's follow-up action (3)

- ✓ **Impact assessment**, including **public consultation**, will be carried to:
  - Describe the problem, set objectives and develop policy options
  - Assess their impacts, including concerns expressed during the study consultation
  - Impact assessment during 2022, with public consultation – 2<sup>nd</sup> Q 2022
  - Supported by an external study
- ✓ **Possible proposal** - summer 2023
- ✓ The Commission continues to discuss the findings of the study and next steps with the EU institutions and stakeholders in dedicated meetings.
  - High-level event “New genomic techniques – way forward for safe and sustainable innovation in the agri-food sector” 29 November

# Thank you

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Slides 2, 5, 6 and 7: Pictures, source: Gettyimages