

# The European Commission's study on New Genomic Techniques

#### 26 March 2021 – Online event

BREEDERS TALK GREEN Animal Genome Editing in the Spotlight



- CJEU C-528-16
- Council request (EU) 2019/1904



# CJEU C-528-16: Mutagenesis exemption versus NBTs/NGTs?

- Organisms obtained by mutagenesis are GMOs within the meaning of Directive 2001/18/EC
- Mutagenesis exemption only applicable for conventional methods used in a number of application and with long safety history
  - ➔ Organisms obtained by new mutagenesis techniques are subject to the obligations of the GMO legislation



### Council request (EU) 2019/1904

- A study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law
- "NGTs": techniques capable to change the genetic material of an organism and that have emerged or have been developed since 2001
- To be delivered by April 2021



## Study on NGTs – Content (1)

- A state-of-play on the implementation and enforcement, based on
  - Contributions from targeted consultations of the Member States and stakeholders;
  - Work of the European Union Reference Laboratory, together with the European Network of GMO Laboratories, on the detection of products obtained by new mutagenesis techniques.



## Study on NGTs – Content (2)

- Info on status and use of NGTs in plants, animals and microorganisms for agri-food, industrial and pharmaceutical applications.
- Overview on the risk assessment of NGT plants (EFSA)
- Overview of current and future scientific and technological developments in new genomic techniques & NGT products, marketed or expected to be (DG Joint Research Centre (JRC))



#### Take home

#### • CJEU C-528-16

- Organisms obtained by new mutagenesis techniques are subject to the obligations of the current GMO legislation
- Council request (EU) 2019/1904
  - Almost there
  - Participate in the debate



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