



# Regulatory landscape for NGTs in farm animals: Status in Europe

Ana Granados (EFFAB/FABRE TP)
6th November 2025





#### **Research institutes** & academia

### **Private sector** (EFFAB members)























ROSLIN









































AquaGen

MQWI







SSS DANBRED





HENDRIX GENETICS









Aviagen







**IRTA** 



UNIVERSITÀ DEGLI STUDI DI MILANO

LA STATALE









DEGLI STUDI









Farm Animal Breeders





Cherry Valley®



GRIMAUD FRÈRES











CRV"

BETTER COWS > BETTER LIFE



Orvia















VIKINGGENETICS



Hatch Africa







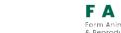












#### **EFFAB and FABRE TP activities**

**Engaging in dialogue with** policymakers and stakeholders



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Advocating for proportionate and science-based policy and legislation















\* KNOWLEDGE PROVIDER FOR EU PROJECTS











































### **Engaged in transparency**



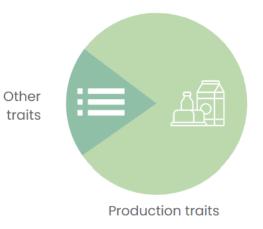


# A BREEDING PROGRAM



A BALANCED AND RESPONSIBLE COMBINATION OF MANY DIFFERENT TRAITS

1970's - 1980's



2000's - Today



The commitments of Animal Breeders for responsible and balanced breeding are reflected in CODE EFABAR; the code of good practices for sustainable animal breeding



#### **EFFAB Animal Breeders**



#### Addressing the 3 Pillars of Sustainability and Animal Health and Welfare

1

# THE ENVIRONMENTAL BENEFITS OF BREEDING

Methane emissions reduced by 1% annually

Nitrogen excretion cut by 3.5% every 5 years

2

# POSITIVELY IMPACTING THE ECONOMICS OF FARMS

30% less feed usage compared to 30 years ago, boosting environmental and economic outcomes

SOCIAL IMPACT IN OUR FARMS AND COMMUNITY

High-quality germinal products and breeding animals for diverse farming systems **support farmers' livelihoods** in European rural and coastal areas



ENHANCING ANIMAL HEALTH AND WELFARE Animal Welfare traits prioritised

Disease resistance enhanced

Antibiotic use reduced







# **EU Legislative initiatives**

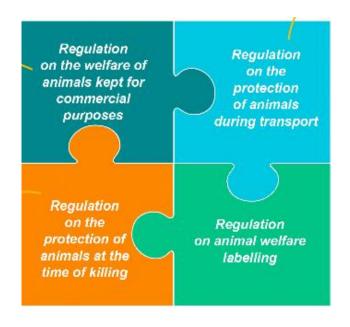


#### **LEGISLATIVE INITIATIVES (2019-2024)**





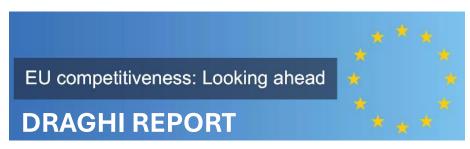








#### LEGISLATIVE INITIATIVES (2024-2029)



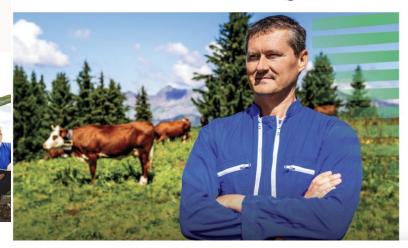




Strategic Dialogue on the Future of EU **Agriculture**  Commission launches new Livestock Workstream as Part of the Vision for Agriculture and Food



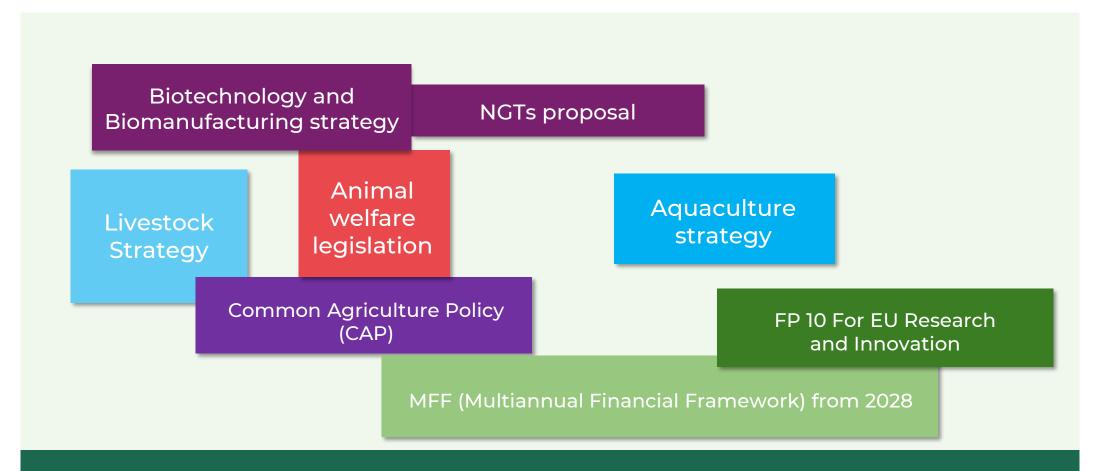








#### LEGISLATIVE INITIATIVES (2024-2029)



Building a more resilient, competitive and sustainable Europe



#### **EU Legislative Process- Triangle of Decision**







European Commission (main Executive Body) "Promoting the common interest"

Proposes/ executes legislation





**Committee of the Regions** 

**European Economic and Social Committee (EESC)** 

**Advisory Roles** 



European Parliament (co-deciding power) "Voice of the People"



Council of the EU
(co-deciding body)

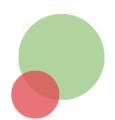
''Voice of the Member States''





# **EU NGTs approach**





## Regulatory landscape for Gene Editing







2019

EU council demand to the EC for a study on NBTs

- EGE publication
- ENGL report of detection of



2021



Mandate to **EURL GMFF on** detection of GM / NGT animals



2025

**GMO** directive

food & feed obtained by GE

Brexit

Publication of the study on NGTs by **DG SANTE** 

EC proposal for targeted mutagenesis and cisgenesis in plants

**EFSA Scientific** Opinion on NGTs in Animals

French complaint and EU Court of **Justice Ruling** 

Targeted consultation of stakeholders by DG SANTE (including EFFAB/FABRE)



animals) in UK Proposal in Norway

• Precision Breeding Bill

(for plants and

Animal welfare study and proposal for animals in the UK



2015-2018



2020

2023





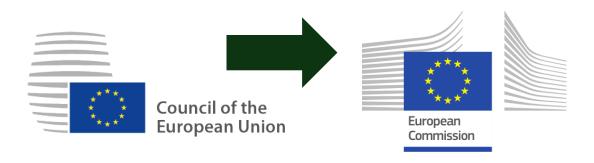




#### **EU Legislative context for NGTs**

#### **Objective of the 2021 EU Study on NGTs**

- Provide clarity on NGTs after the ruling in 2018 (EU Council request)
- Assist in deciding on any further action in this policy area, if appropriate
- In the political context of the European Green Deal Farm to Fork strategy



Report on detection of animals and animal Report on Ethics of products obtained by **NGTs** GE Study on NGTs by **DG SANTE** (legal aspects) JRC Study on current and JRC Study on the **Future Market** state of art of NGTs Applications of NGTs



#### **EU Legislative context for NGTs**

- GMO directive **is not fit for purpose** for some NGTs and products: Current risk assessment procedures are too **rigid** and difficult to adapt to new technologies
- It needs to be adapted to scientific and technological progress
- NGTs can contribute to sustainability
- Consider an appropriate mechanism to **evaluate benefits** of NGT products
- Knowledge gaps identified in this study. More effort should be made to inform and engage with the public and assess their views.
- Safety data available for a number of techniques in plants
- For other organisms (animals) and other NGTs, continue to build up the required scientific knowledge, in view of possible further policy actions



Farm to Fork

#### **EU Legislative context for NGTs**



The EU Council requested **to submit a proposal or other measures**, if

appropriate, as a follow-up to the

study

NGTs can contribute to the Green Deal and Farm to Fork objectives of innovation and sustainability of the food systems, as well as to a more competitive economy, which are at the centre of current priorities of the European Union.

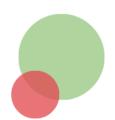
 The Commission published a proposal on plants derived from targeted mutagenesis and cisgenesis



- Impact assessment
- JULY 2023
- For other organisms (animals) and other NGTs, continue to build up the required scientific knowledge, in view of possible further policy actions







## Regulatory landscape for Gene Editing

Brexit







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- EGE publication
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2021



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2025

**GMO** directive

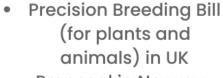
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Proposal in Norway

Animal welfare study and proposal for animals in the UK



2015-2018



2020



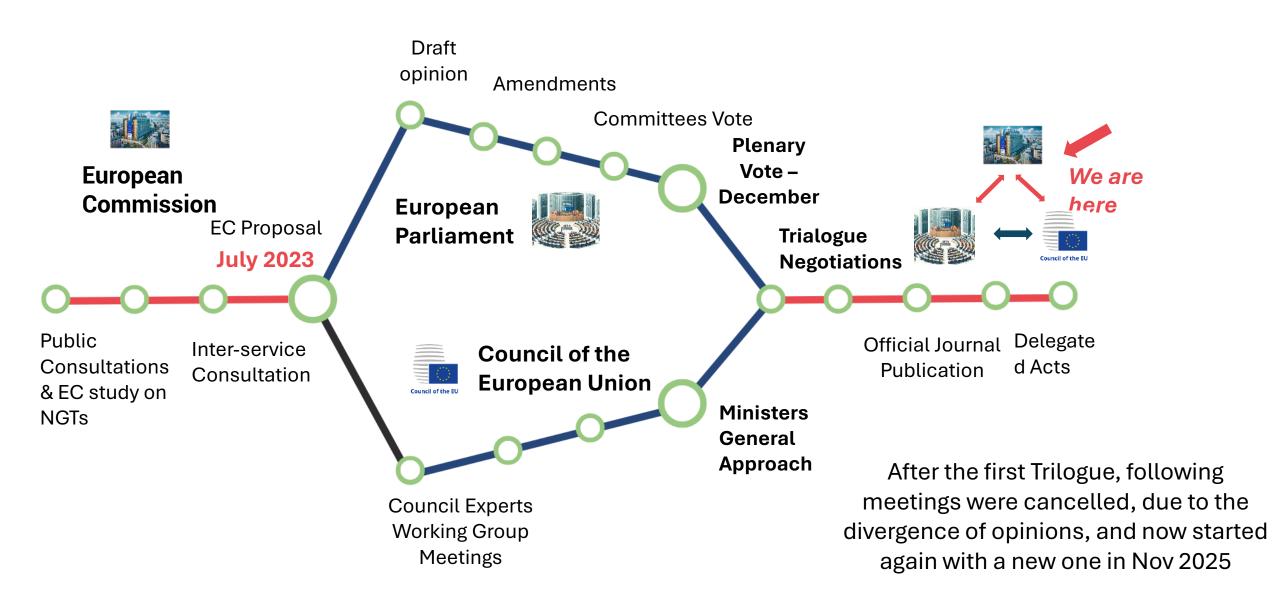








### NGTs in plants in the EU







# EFSA Scientific Opinion on NGTs in farm animals





#### **Current Status in the EU for farm animals**

Strict separation between <u>risk assessment</u> and <u>risk management</u>

European Food Safety Authority





- Guidance on the risk assessment of food and feed from GM animals and AHAW aspects (2012)
- Guidance on the environmental risk assessment of GM animals (2013)

No animal applications received so far NGT/GE animals = GM animals (legal definition)



# European Commission & Member States

- Authorisation: EU Commisssion
- Enforcement: Member States







### **EC Mandate on NGTs applied to animals**







Risk management

Risk assessment

- 1. to identify potential novel hazards/risks from new developments in biotechnology applied to current and near-market animals
- 2. to assess the adequacy of the current EFSA risk assessment guidance covering all aspects of molecular characterisation, food feed safety & welfare and environmental impact





# Working group for GMA-NGTs under the EFSA GMO Panel



# Public consultation

Dec 2022 Sept 2023 Jan-March 2025 August 2025



Part 1. Mapping of known cases of "NGTs" applied to animals for agri, food & feed uses

EC Mandate on NGTs applied to animals

Part 2. EFSA Scientific opinion on "NGTs" applied to animals for agri, food and feed purposes, covering aspects of MC, FF, AHAW and ERA risk assessment





### **EFSA Scientific Opinion: definitions**

Adopted: 30 June 2025 DOI: 10.2903/j.efsa.2025.9566

SCIENTIFIC OPINION



New developments in biotechnology applied to animals: An assessment of the adequacy and sufficiency of current EFSA guidance for animal risk assessment

- ETGs: established genomic techniques (before the publication of Directive 2001/18/EC) ("GMO directive")
- NGTs: new genomic techniques (after the publication of Directive 2001/18/EC)
  - targeted mutagenesis (e.g. SDN-1 or SDN-2 to induce nucleotide modification, insertion, deletion or inversion) and
  - targeted insertion of a DNA cassette encoding a transgene, intragene or cisgene of interest. (e.g.: SDN-3)
- Conventional breeding







### EFFAB and FABRE TP GE potential applications

- Porcine Reproductive Respiratory Syndrome (PRRS)
- Foot and mouth disease
- Avian influenza
- Sexing in ovo
- Sea lice resistance
- Infectious anaemia
- Classical swine fever
- Bovine tuberculose
- Hornless cattle
- Sterile fish to avoid mixing with wild species
- Heat stress

Precision engineering for PRRSV resistance in pigs: Macrophages from genome edited pigs lacking CD163 SRCR5 domain are fully resistant to both PRRSV genotypes while maintaining biological function

Christine Burkard, Simon G. Lillico, Elizabeth Reid, Ben Jackson, Alan J. Mileham, Tahar Ait-Ali, C. Bruce A. Whitelaw, Alan L. Archibald

Published: February 23, 2017 • https://doi.org/10.1371/journal.ppat.1006206



A Sterile Solution: How Crispr Could Protect Wild Salmor



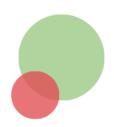
Published on June 30, 2022



New partnership to study innovative sex sorting technology for the egg laying industry

Hendrix Genetics is partnering with Australia's national science agency, CSIRO, to test the viability of an innovative point of lay sex sorting technology for the egg laying industry.





## European Regulatory landscape for Gene Editing



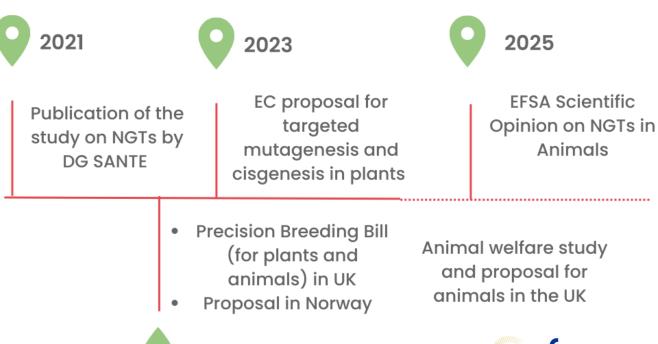
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**Justice Ruling** 

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Animal welfare assessment?

2023

EU and UK plant legislation





### In Summary:

- The EU plant proposal opens opportunities for farm animals
- EFSA Scientific opinion →
  - to update EFSA guidelines?
- Challenges for traceability and labelling, which remain as defined in current legislation
- EFSA welfare Scientific Opinions
- Collaboration at the International level is key → 6<sup>th</sup> IWRAAAB Nov 2025







# THANK YOU If you have any questions our door is always open

Please get in touch with us at <a href="mailto:ana.granados@effab.info">ana.granados@effab.info</a> geena.cartick@effab.info & <a href="mailto:Barbara.barbosa@effab.info">Barbara.barbosa@effab.info</a> or through our social media channels







