Regulatory landscape for NGTs in farm animals: Status in Europe

Ana Granados (EFFAB/FABRE TP)

3rd November 2025

Research institutes & academia

Private sector (EFFAB members)

EFFAB
European Forum of Farm Animal Breeders

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FABRE-TP
Farm Animal Breeding & Reproduction Technology Platform

EFFAB and FABRE TP activities

Members of EFFAB & FABRE TP

EU authorities, NGOs and stakeholders

Engaging in dialogue with policymakers and stakeholders

QUALI VETS
Optimal quality of semen

REPVET
Reproduction Veterinarians

Advocating for proportionate and science-based policy and legislation

agri-food chain coalition

EPRUMA

EATIP

atf

EUROPEAN LIVESTOCK VOICE

ICAR

NAAB

Supporting and promoting responsible animal breeding through CODE EFABAR

CODE • EFABAR
The commitment to responsible breeding

Promoting and supporting Research & Innovation

FABRE • TP
Farm Animal Breeding & Reproduction Technology Platform

* KNOWLEDGE PROVIDER FOR EU PROJECTS

PIGWEB · GERONIMO · Rumigen · HoloRuminant · EuroFAANG · DETECTIVE · Digi4Live · STOPUP · HOLICOW · Transform Dairy Net · INSECT-IMP

Engaged in transparency

CODE • EFABAR
The commitment to responsible breeding

EFFAB
European Forum of Farm Animal Breeders

A BREEDING PROGRAM

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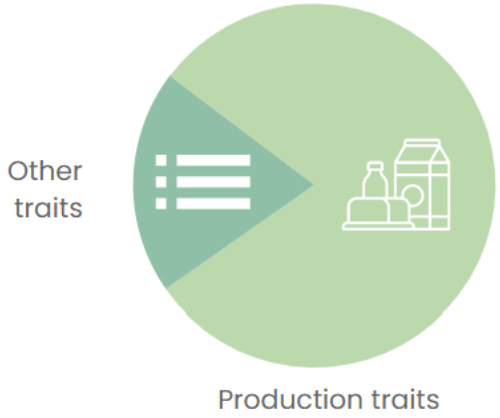
A BALANCED AND RESPONSIBLE COMBINATION OF MANY DIFFERENT TRAITS

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**

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Farm Animal Breeding & Reproduction Technology Platform

EFFAB Animal Breeders

EFFAB
European Forum of Farm 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

3

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

4

ENHANCING ANIMAL HEALTH AND WELFARE

Animal Welfare traits prioritised

Disease resistance enhanced

Antibiotic use reduced

Regulatory landscape for Gene Editing

2001

GMO directive

2019

EU council demand to the EC for a study on NBTs

- EGE publication
- ENGL report of detection of food & feed obtained by GE

2015-2018

French complaint and EU Court of Justice Ruling

2020

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

Brexit

2021

Publication of the study on NGTs by DG SANTE

- Precision Breeding Bill (for plants and animals) in UK
- Proposal in Norway

2023

2023

Mandate to EURL GMFF on detection of GM / NGT animals

EC proposal for targeted mutagenesis and cisgenesis in plants

2025

EFSA Scientific Opinion on NGTs in Animals

Animal welfare study and proposal for animals in the UK

efsa EUROPEAN FOOD SAFETY AUTHORITY

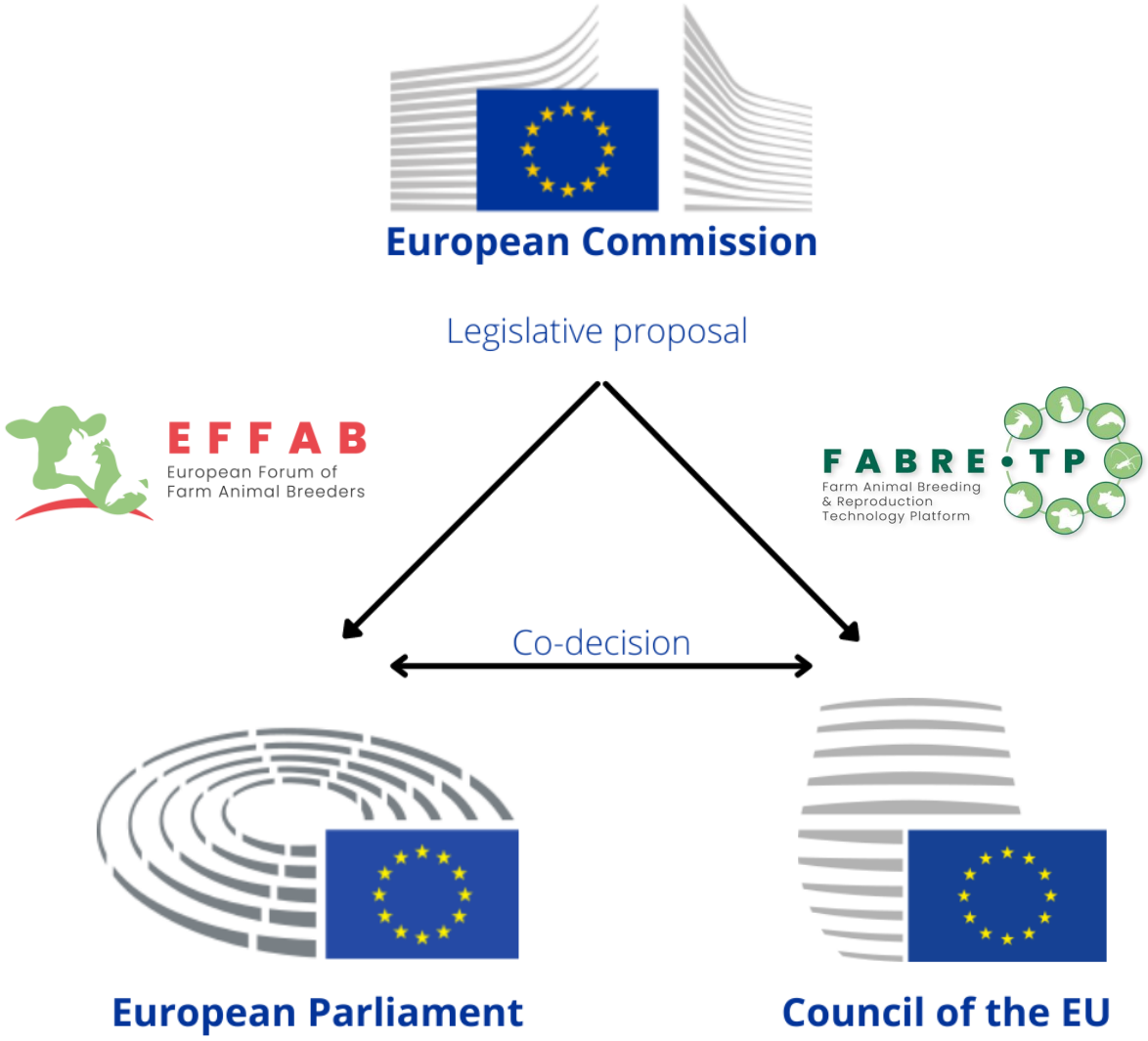
DETECTIVE

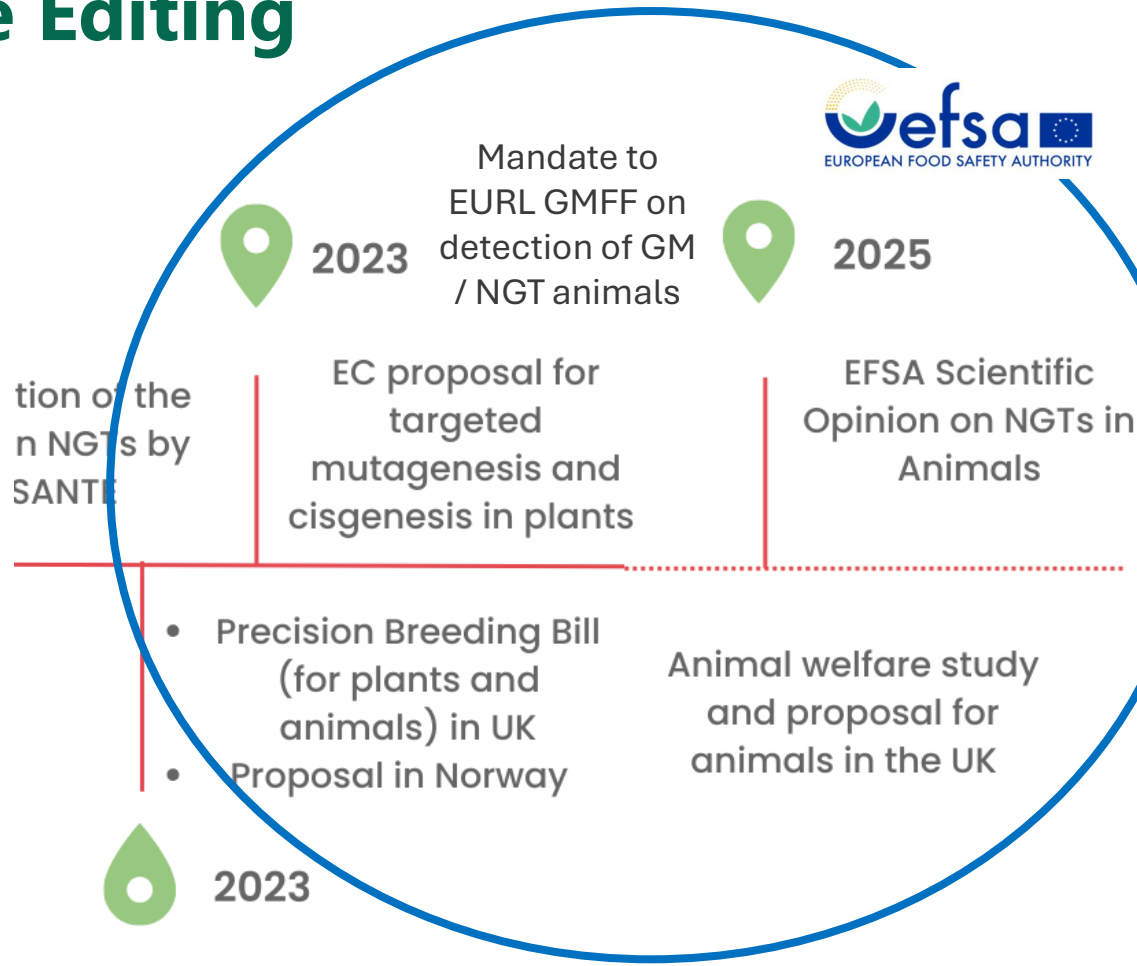
GERONIMO GENOME AND EPIGENOME ENABLED BREEDING IN MONOGASTRICS

Rumigen

EuroFAANG RESEARCH INFRASTRUCTURE

Regulatory landscape for Gene Editing





NGTs in plants in the EU

European Commission

Public Consultations & EC study on NGTs

Inter-service Consultation

EC Proposal

July 2023

Draft opinion

Amendments

Committees Vote

European Parliament

Council of the European Union

Council Experts Working Group Meetings

Ministers General Approach

Plenary Vote – December

Trialogue Negotiations

We are here

Official Journal Publication

Delegated Acts

After the first Trilogue, following meetings were cancelled, due to the divergence of opinions, and now started again with a new one in Nov 2025

EFFAB
European Forum of Farm Animal Breeders

EFSA Scientific Opinion on NGTs in farm animals

FABRE•TP
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Current Status in the EU for farm animals

Strict separation between risk assessment and risk management

European Food Safety Authority

European Commission & Member States

- Authorisation: EU Commisssion
- Enforcement: Member States

- Submission through an electronic submission platform to a national authority within whose territory the release is to take place
  - Purpose and scope, relevant data, studies and analysis of the results
  - Monitoring plan, detection method, labelling proposal
  - Indication of confidential information
  - Reference material & detection method
- **Transfer to EFSA for risk assessment**
- EFSA makes application summary available to the public

No animal applications received so far

NGT/GE animals = GM animals (legal definition)

Current Status in the EU for farm animals

- 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)

- Lack of EFSA guidelines for new breeding techniques in Animals (as Gene Editing) to submit an application to EFSA
- Lack of detection methods for animal products
  - ✓ For authorisation purposes
  - ✓ Traceability to enable consumer choice
  - ✓ For border control
  - ✓ Unknown, or unauthorised, NGT products

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

EC Mandate on NGTs applied to animals

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

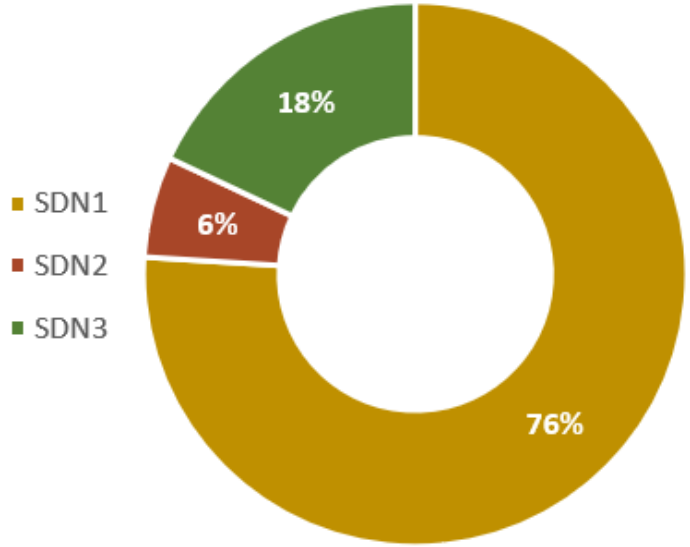
Part 2. EFSA Scientific opinion on *"NGTs"* applied to animals for agri, food and feed purposes, covering aspects of MC, FF, AHAW and ERA risk assessment

Working group for GMA-NGTs under the EFSA GMO Panel

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

External Procurement awarded to Alison Van Eenennaam

Review of applications of NGTs applied to animals involved in the production of agri/food/feed products (2023).



External Scientific Report
APPROVED: 31 July 2023
doi: 10.2903/sp.efsa.2023.EN-8311

New Genomic Techniques (NGT) in animals and their agri/food/feed products

Alison L. Van Eenennaam

Abstract

This report presents a review of the commercial and pre-commercial stage applications of new genomic technologies (NGT) applied to farm animals and their agri/food/feed products. Additionally, a literature review was performed to compile a comprehensive listing of peer-reviewed research and development stage gene edited animals for food and agricultural applications. A total of 195 publications resulting in live animals were compiled. To date, several developed or ongoing research applications have been authorized for commerce, or judged to be "non-GMO" hence conventional, in at least one country including knockout tiger pufferfish and red sea bream in Japan; tilapia, cattle, pigs and horses in Argentina; cattle and tilapia in Brazil; and two gene-edited cattle were granted enforcement discretion in the United States meaning their products can enter the food supply. One application, the targeted *exon* deletion of a gene resulting in porcine respiratory and reproductive syndrome virus resistance in pigs is formally in the precommercial stage. There are proof-of-concept applications in multiple food species testing gene targets for traits of commercial interest. The most common trait category targeted was meat and fibre yield (31%), followed by reproduction (24%), biotic stress (18%), multiple traits (7%), colour (6%), production of hypoallergenic products (5%), product quality (4%), abiotic stress (1%), and other (4%). The majority of these were SDN-1 applications using Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)/Cas9 to introduce small insertions and deletions to inactivate a gene. The large number of applications focused on reproduction is due in part to interest in both single-sex offspring in numerous industries (e.g. females in the case of egg production), and infertility coupled with germline complementation chimeras (where germline-competent donor cells are used to replace the germline of an otherwise sterile host of a different genetic background) in multiple species including finfish, chickens, cattle, goats, and pigs.

Key words: (new genomic techniques, CRISPR/Cas, genome editing, livestock, farmed animals)

Question number: EFSA-Q-2023-00534
Correspondence: nif@efsa.europa.eu

Working group for GMA-NGTs under the EFSA GMO Panel

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

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

EFSA Scientific Opinion: definitions

- **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**

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EFSA Scientific Opinion: outcomes

- **No novel hazards have been identified** that are linked to either the modification process or the newly introduced trait when SDN-1, SDN-2 and comparable techniques (e.g., base editing or prime editing) were compared to **established genomic techniques (EGTs)** or conventional breeding.
- Future guidelines should focus on the introduced trait or product instead of the technique
- **Off-target mutations** from genome editing are similar to those from conventional breeding and do not pose novel hazards.
- Consequently, based on currently available data, **no new potential hazards and no new risks to humans, animals, or the environment have been identified**.

EFSA Scientific Opinion: outcomes

- Animal health and welfare hazards in EGT and NGT animals related to pre-commercial phases should be addressed **case by case**, as early procedural steps may lead to unintended phenotypes.

- The existing EFSA guidance (2012, 2013) provides a solid basis for assessing the risks of NGT animals for food, feed, and other agricultural uses.

- However, the current texts only **partially cover several key areas**, such as animal health and welfare, and may require **updates, adaptations, or enhancements** on an ad hoc basis to fully address the risk assessment of NGT animals.

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
- African swine fever
- Bovine tuberculose
- Hornless cattle
- Sterile fish to avoid mixing with wild species
- Heat stress

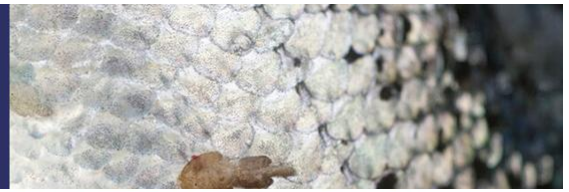
Precision engineering for PRRSV resistance in pigs: Macrophages from genome edited pigs lacking CD163 SRCR5 domain are fully resistant to both PRRSV genotypes while maintaining biological function

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

CrispResist

Harnessing cross-species variation in sea lice resistance



A Sterile Solution: How Crispr Could Protect Wild Salmon

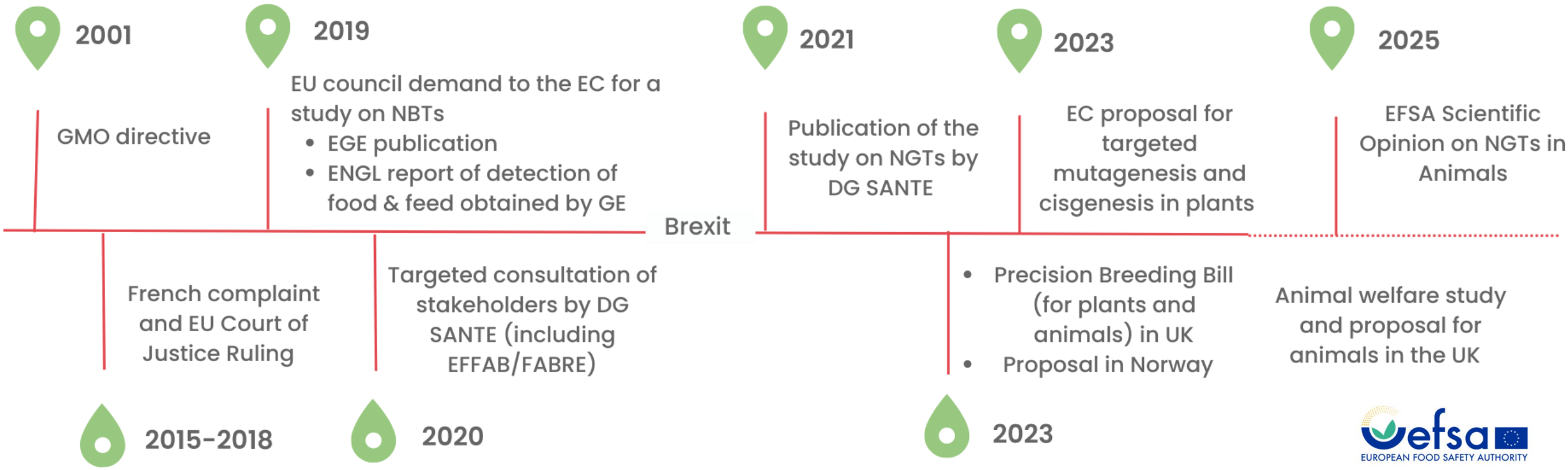
Partners in research

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



- Animal welfare assessment?
- EU and UK plant legislation coming

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 ➔ 6th IWRAAAB – Nov 2025

THANK YOU

If you have any questions our door is always open

Please get in touch with us at ana.granados@effab.info geena.cartick@effab.info & Barbara.barbosa@effab.info

or through our social media channels

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