

15 November 2021, Paris

# Évolutions réglementaires autour des modifications ciblées du génome



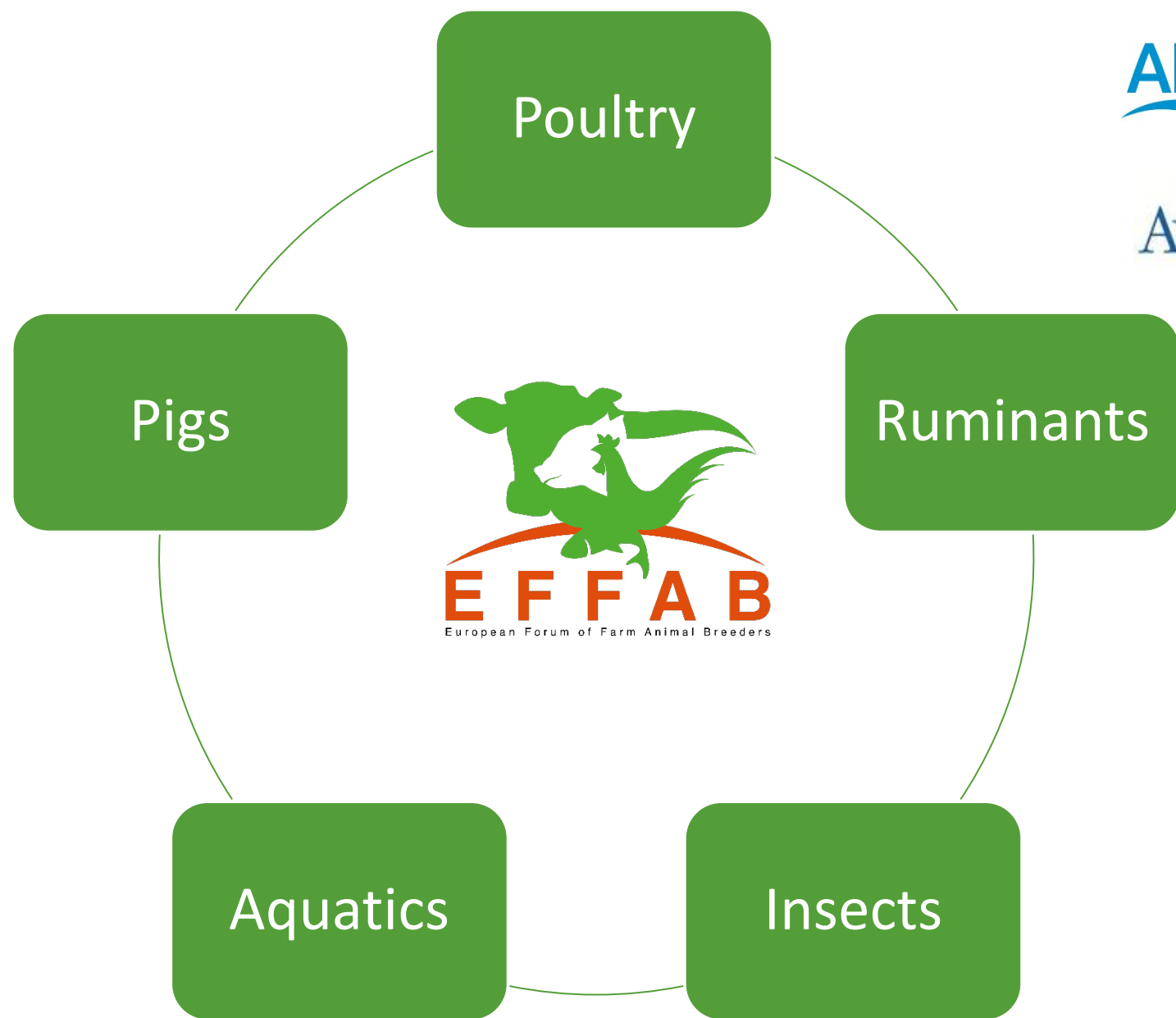
Ana Granados Chapatte  
Director of EFFAB



**EFFAB**  
European Forum of  
Farm Animal Breeders



# EFFAB stands up for animal breeding



# EFFAB

## Ensuring the representation of member interests at the EU level

- ▶ European policy and legislation
- ▶ Supporting and promoting responsible and balanced breeding - Code EFABAR
- ▶ Engaging dialogue about Animal Breeding and reproduction

**Knowledge provider in EU projects = “Translating science” + Stakeholders engagement + Dissemination**





# FABRE TP



## Connecting industry and knowledge institutes

- ▶ Develop research and innovation agendas and set priorities
- ▶ Support innovation
- ▶ Promoting research and innovation in animal breeding



# Engaging in dialogue

Increasing collaboration with  
AGRI-AQUA Food R&I



Increasing interaction between  
research and industry



Engaging dialogue on animal  
breeding practices and research



WEBINAR SERIES



BREEDERS TALK GREEN

- Animal Breeding and Climate Ambition
- Healthy and Happy Animals for Sustainable Societies
- Animal Genome Editing in the Spotlight
- **Session 5 : Dec 2021**

FABRE TP  
session at EAAP



# Engaging in dialogue

EU Platform on Animal Welfare 10.11.2021



## Bred to suffer: [ Broiler chickens ]

Unregulated genetic selection for fast growth

- Lameness
- Skeletal and muscular weakness
- Contact dermatitis

EURUGROUP  
FOR  
ANIMALS

## The silent suffering of [ Farmed Fish ]

- Injuries, diseases and congenital defects
- Overcrowded pens and poor water quality

Stagnant water for days at a time

Handled (= stress, injury and suffering)

1 billion fish on farms at any one time



## Bred to suffer: [ Dairy cows ]

- Unregulated genetic selection for high milk yields
- Lameness
- Mastitis
- Metabolic disorders (chronic hunger)
- Emaciated body

Numbers: 20.5 million dairy cows in the EU, not protected by species-specific legislation.

foraging, exploring

lesions

piglets

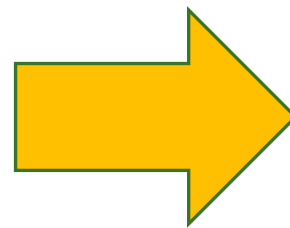
s in the EU, vast



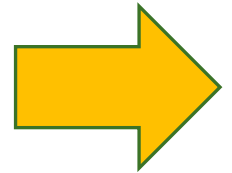


# What is Animal Breeding and why it's important

A breeding program  
=  
balanced and responsible  
combination of  
several traits



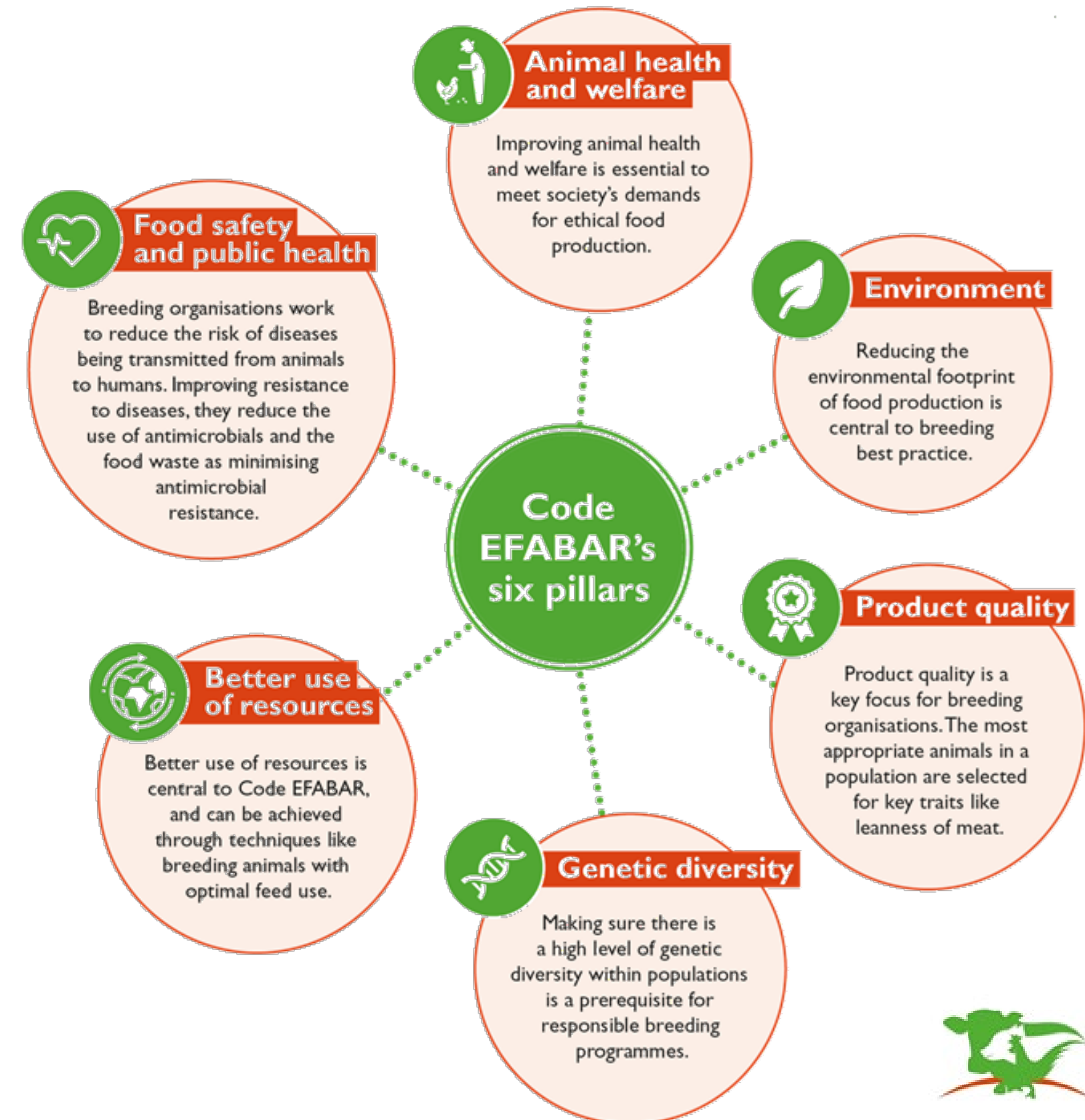
A complex and dynamic issue



The right balance in a responsible way  
based on recent research

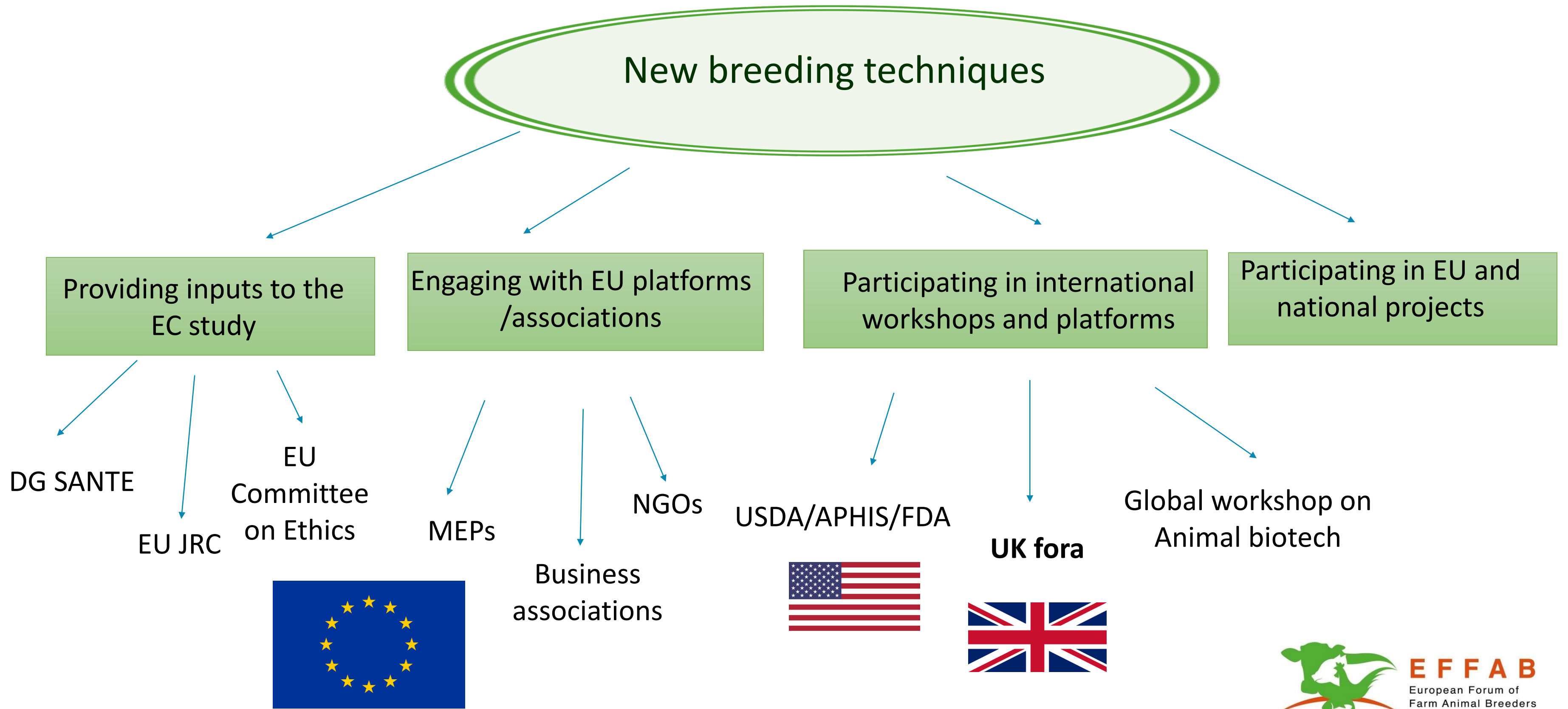
# Breeding activities

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

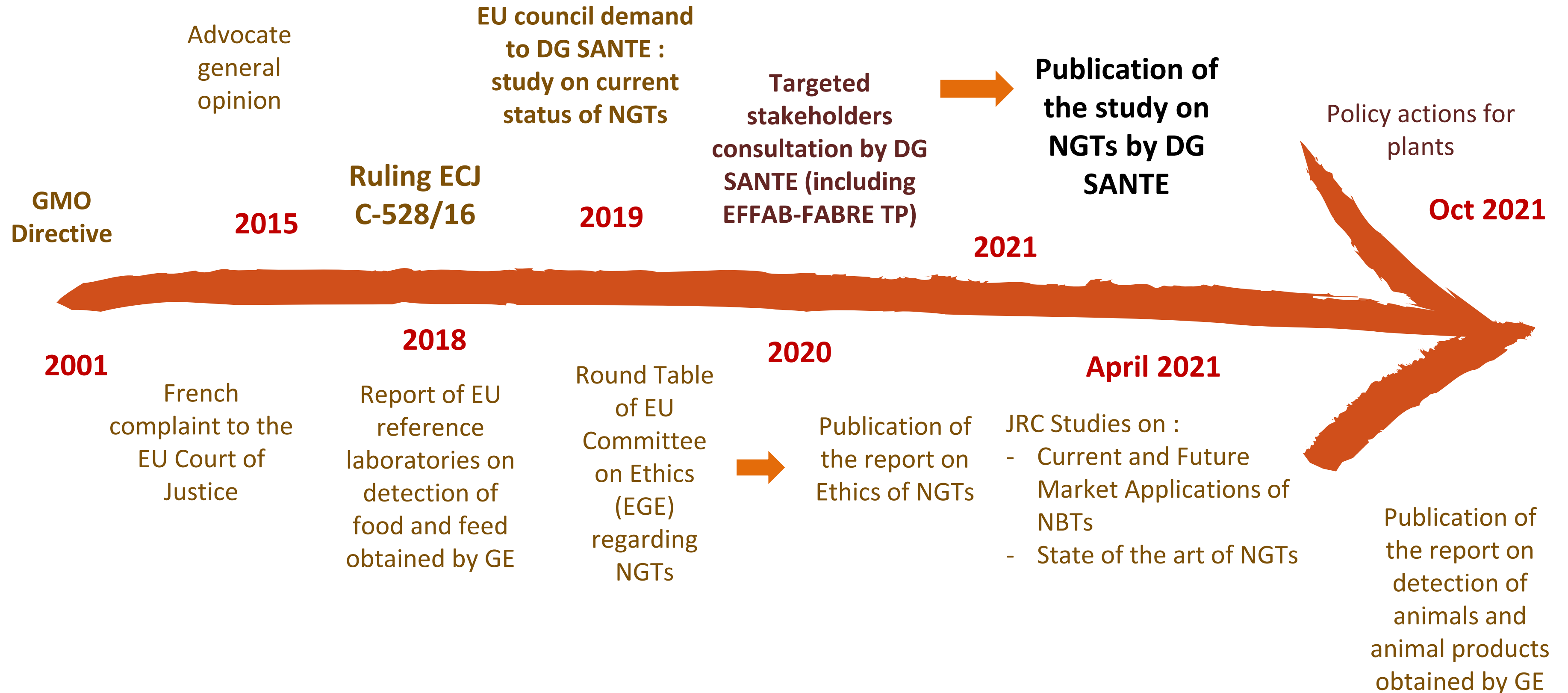




# EFFAB engaging dialogue around Genome Editing



# Overview of EU legislative framework



# The EC study on NGTs

## Objective

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

## Scope

Use of NGTs in plants, animals and micro-organisms, in a broad variety of potential applications, including in the agri-food, medicinal and industrial sectors.

## How

Targeted consultation of stakeholders (107 invited → 71 confirmed → 58 replied)  
In house study (DG SANTE) with the JRC, EFSA and the EU Committee on Ethics

Report on  
detection of  
animals and  
animal products  
obtained by GE

Report on  
Ethics of NGTs

Study on  
NGTs by DG  
SANTE (legal  
aspects)

JRC Study on  
current and  
Future Market  
Applications of  
NGTs

JRC Study on  
the state of  
art of NGTs

# The EC study on NGTs : What are NGTs?

## **Mutagenesis**

Changes without insertion of genetic material

## **Cisgenesis/Intragenesis**

Rearrangement of genetic material of same organism or insertion of genetic material from organisms that can cross in nature

## **Transgenesis**

Insertion of genetic material from other organisms that are sexually incompatible

## **Epigenomic changes**

Genetic material altered without change of the nucleic acid sequence



## Research and development

- **considerable interest** in research on NGTs in the EU, but most of development is taking place outside the EU
- **negative impacts** have been reported on public and private research on NGTs in the EU due to the current regulatory framework.

## Implementation & enforcement

- Implementation and enforcement challenges in the EU, in particular to the **detection of NGT products** that contain no foreign genetic material.
- Problems for enforcement authorities, operators and applicants.
- Different regulatory oversight for NGTs in other countries → potential impacts on trade.

## Safety aspects

- **Case by case** assessment is widely recognised as the most appropriate approach
- Need of flexibility, RA specific to NGTs
- EFSA sufficient safety data for plant applications of some NGTs; less information on other NGTs and microorganisms or animal applications

## Potential concerns

- Possible risk and environmental impact
- **Coexistence with organics and GM-free agriculture**
- Labelling and consumers' right to information

## Potential benefits

**Pest and animal diseases resistance** and other interesting applications, animal welfare and fish sterility

**Farm to Fork strategy targets** → - 25% of organic land (Organic sector rejects NBTs)  
- availability of new tools for farmers (including NGTs)  
- public perception because of the rejection of NGOs and growing concerns from retailers

# The EC study on NGTs : Main findings

## Ethical aspects

- The use raised ethical concerns but so does missing opportunities if not using them
- How the techniques are used rather than the techniques themselves
- Some NGOs ask for a moratorium for the use of NGTs in animals



## SMEs

Regulatory barriers for small and medium enterprises

## Patents

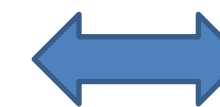
Benefits of patents and licenses = promoting innovation but also being a barrier

## Public dialogue

Interest to engage dialogue and increase public awareness and understanding

## Labelling

**Effectiveness** of labelling is controversial





## The EC study on NGTs : **Conclusions**



- GMO directive **is not fit for purpose** for some NGTs and products
- It needs to be **adapted to scientific and technological progress**
- Current risk assessment procedures are too **rigid** and difficult to adapt to new technologies
- NGTs can contribute to **sustainability** → EU Green Deal objectives !!
- Consider an appropriate mechanism to **evaluate benefits** of NGT products.
- NGT applications in the agricultural sector should not undermine other aspects of sustainable food production, e.g. as regards **organic agriculture**.
- **Knowledge gaps** identified in this study. More effort should be made to **inform and engage with the public** and assess their views.





## The EC study on NGTs : Next steps



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 plans to initiate policy action on plants derived from targeted mutagenesis and cisgenesis
- For other organisms (**animals**) and other NGTs, **continue to build up the required scientific knowledge, in view of possible further policy actions**
- Impact assessment to be done



## The EC study on NGTs : **EFFAB** and **FABRE TP**

### **EFFAB –FABRE TP has launched a call to the EC, the EU Parliament and the EU council**

- to collaborate to build up the required scientific knowledge the EC says is lacking for animals and animals products
- Participate in stakeholders open dialogue → we already engage with NGOs
- Draft new legislation based on science

WG in January 2022 to establish a regular contact with EC to provide what is already available, what is ongoing, and especially on what your organisation thinks could be further needed, also in view of the WP 2023-24 of Horizon EU.

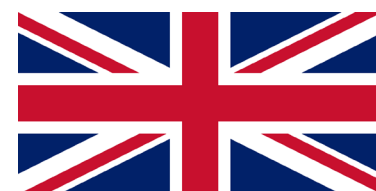
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# New breeding techniques legislation



- Policy action on plants derived from targeted mutagenesis and cisgenesis
- For other organisms (**animals**) and other NGTs, **continue to build up the required scientific knowledge, in view of possible further policy actions**
- Impact assessment to be done has started
- Conference on GE on the 29 Nov 2021



- Very similar to EU : public consultation published in Sept 2021
- Research and trial fields for plants easy to obtain for plants
  - Ethical and safety concerns for animals



- Highly regulated ; ongoing process for approval of PRRS resistant pigs  
GM/GE salmon approved

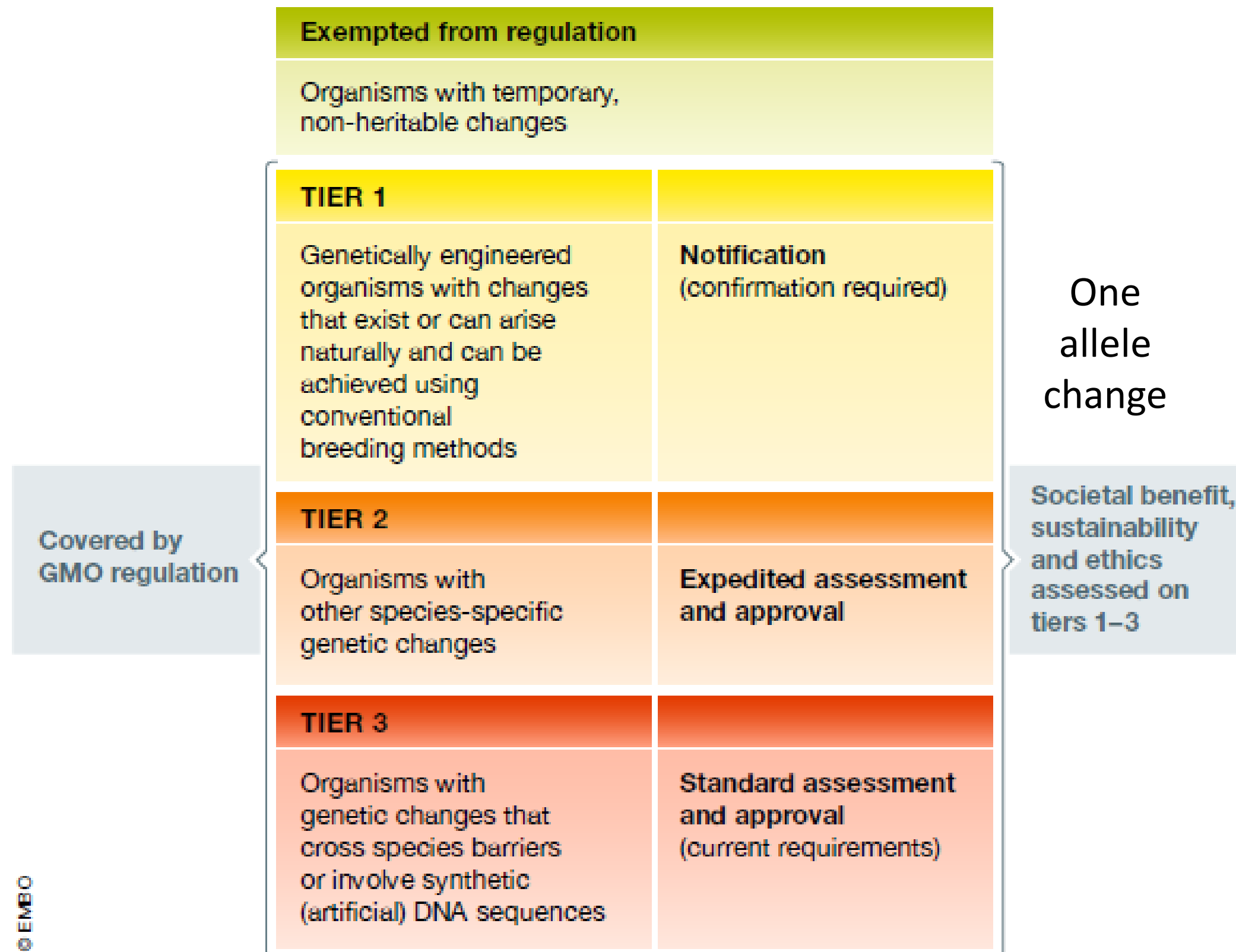


- Gene-edited organisms can be sold to consumers without safety evaluations as long as the techniques involved meet certain criteria, but developers must send notification to the government.

# New breeding techniques legislation : EU and more

## Other countries legislation :

- Legislation approved (Argentina, Brazil, Chile, Israel, Canada)
- Still proposals (Colombia, NZ, **Norway**, Australia)
- Case by case (most of them)
- Product based legislation or technology based
- Only for plants (Chile and Colombia) same or different but possible for both



# Take home messages

- Very few countries in which GE in animals is already possible
- High concerns on the Ethics
- High concerns on the benefits → high concerns on the benefits of breeding !!!
- High concerns on the safety → Plasmid inserted (Recombinetics case)
- Constructive dialogue and need to provide inputs
  - Benefits of balanced breeding
  - Responsible use of technologies
  - Societal benefits



# Merci

Let's stay in touch



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## Questions?

