

# Environmental Safety Aspects of Regulations for GM Animals

in ARGENTINA

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*Ministry of Agriculture, Livestock and Fisheries*

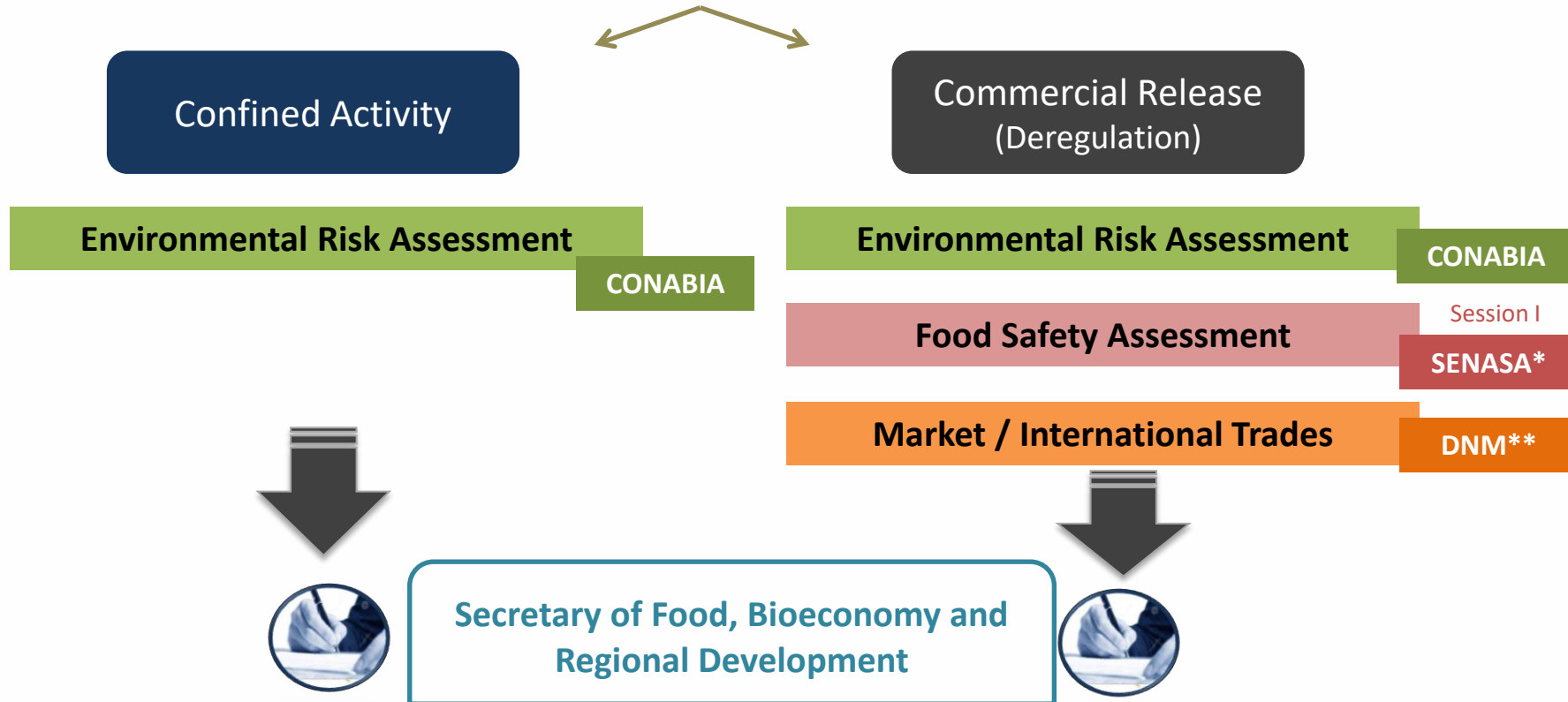


Ministerio de Agricultura,  
Ganadería y Pesca  
**Argentina**

# // National Authority for GM Animal Activities

(Regulatory Framework)

## Types of Authorizations for GMO:



- The **Secretariat** is the national authority that **authorizes GMO Activities**.
- To make decisions, the **Secretariat is advised** by different Committees or Commissions.

\*SENASA: National Service for Agrifood Health and Quality

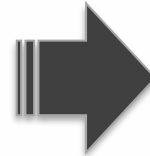
\*\*DNM: National Directorate of Markets

# // National Authority for GM Animal Activities

Ministry of Agriculture, Livestock & Fisheries

National Advisory Commission on  
Agricultural Biotechnology (**CONABIA**)

**Environmental Risk Assessment**



**Secretary of Food, Bioeconomy and  
Regional Development**



- **CONABIA assesses** applications for **Confined Activities** and **Commercial Release**.
- **CONABIA members** are **scientists, professionals and specialists** from different institutions (public and private)
- **CONABIA** submits a **non-binding advisability report** (allowing or denying) on the activities required.

- After CONABIA's report, the **Secretariat grants or denies** the authorization.



## CRITERIA APPLIED TO ENVIRONMENTAL RISK ASSESSMENT FOR GM ANIMALS

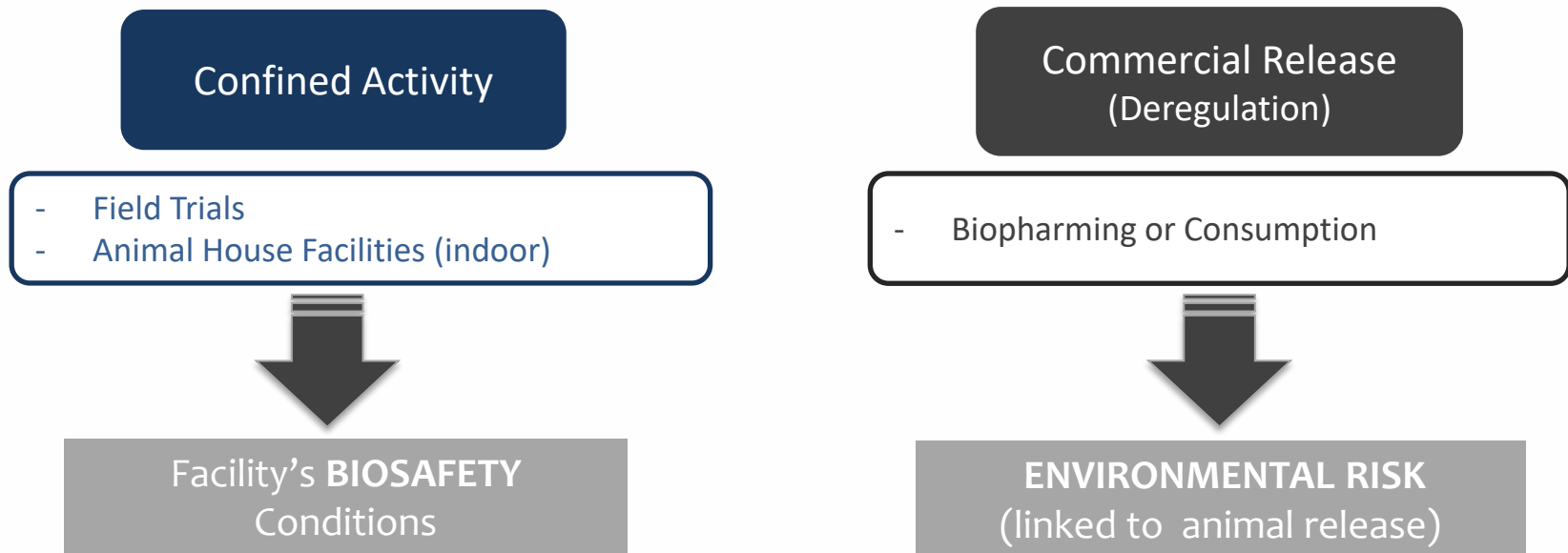


- **Flexible:** case by case
- **Data Quality:** data and information must be of sufficient quality and quantity.
- **Scientific Base:** data and information based on sound scientific principles.
- **Comparative Approach:** use of a suitable conventional counterpart.

# // Environmental Risk Assessment (ERA)

## CONABIA

- Its **main goal** is to protect biodiversity, human and animal health and agroecosystems.
- CONABIA bases its evaluation on **risk analysis**.
- The **assessment focus** depends on which **activity** is required.



# // ERA – Confined Activities

## Modules of Application Form



### Host Organism

- Species
- Objective of trait



### Molecular Characterization

- Objective of trait
- Description of the genetic modification.



### Planned Activities

- Animals to generate
- Material storage
- Final disposition method



### Sites & Facilities

- Location
- Storage place
- Final disposition site

Biosafety conditions and measures are determined by risk hypotheses

Facility's **BIOSAFETY**  
Conditions

# // ERA – Confined Activities

Facility's BIOSAFETY Conditions are determined to:



- **Keep a safe environment** during and after the project.
- **Prevent mating** outside the project.
- **Avoid trespassing** or animal **escaping**.
- **Avert** them **entering** the **Argentine food chain** or **commercialization**



**CONABIA**

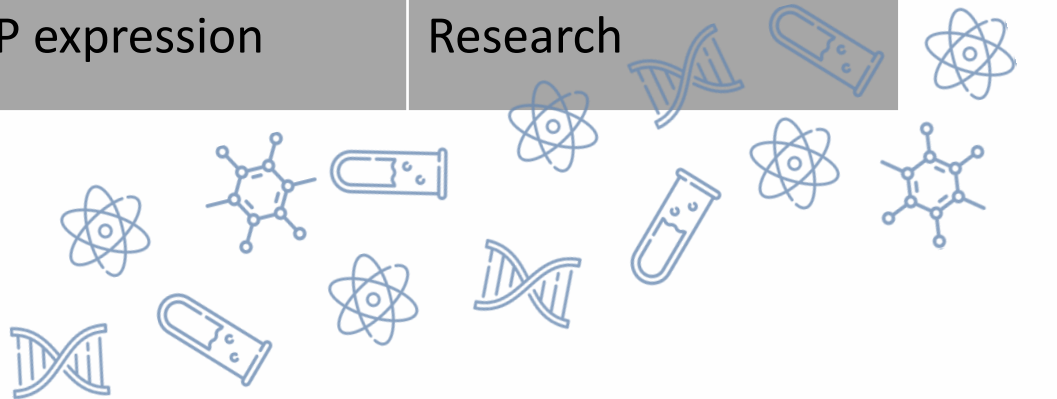
Entering the **Argentine food chain**, or **commercialization** of regulated animals, their derivative products and reproductive materials, **IS NOT ALLOWED**.

- **Oversees biosafety conditions** and **activities** during the project.

# // ERA – Confined Activities

Cases presented in Argentina (since 2005):

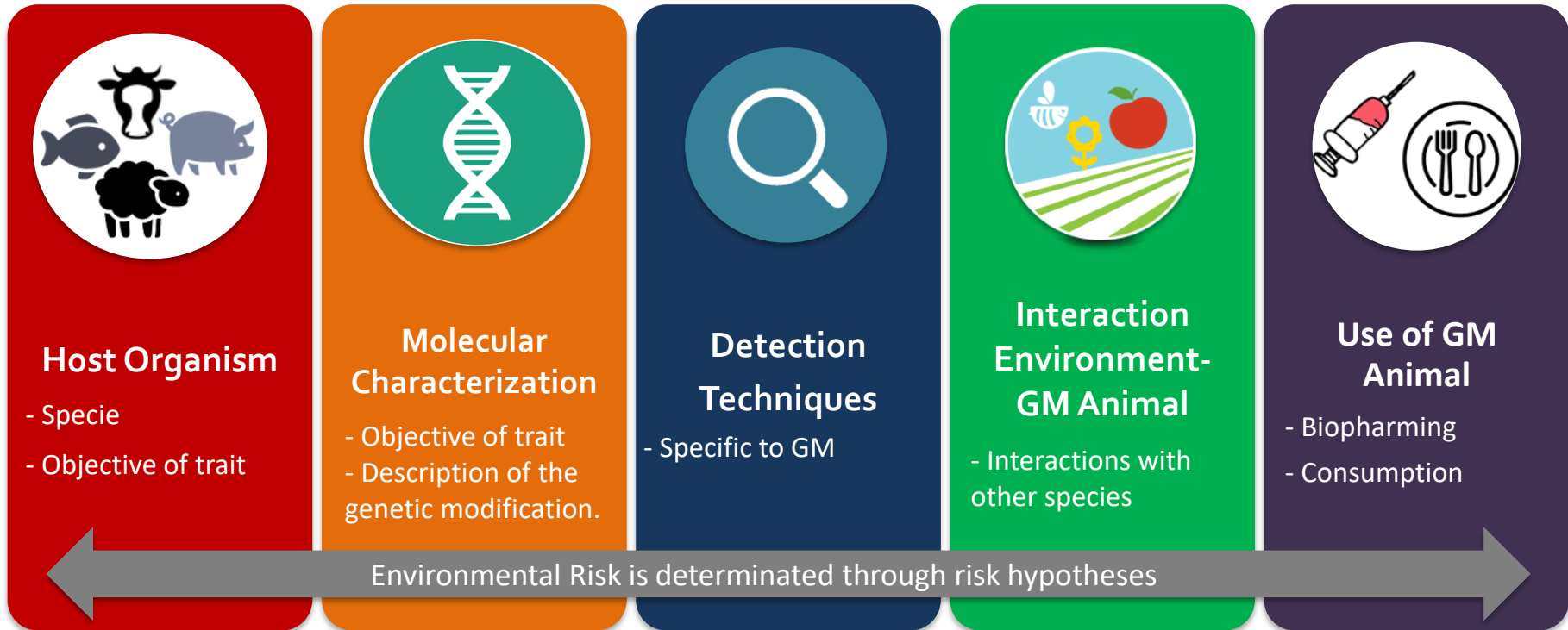
Specie	Trait	Purpose/Use
Fish	Growth hormone	Consumption
Cow & Sheep	Differences in milk composition	Biopharming or Consumption
Sheep	GFP expression	Research





# // ERA – Commercial Release / Approval

## Modules of Application Form



**ENVIRONMENTAL RISK**  
(linked to animal release)

# // ERA – Commercial Release / Approval

ENVIRONMENTAL Risk is determined:

- **CRITERIA:**
  - **Case by Case**
  - **Data Quality** (quality and quantity)
  - **Scientific Base**
  - **Comparative Approach** (changes in GM animal behaviour)
- **MAIN GOAL** (to protect biodiversity, human and animal health and agroecosystems)
  - Assessing **GM Animal Interaction** with the environment.

**There Are No Requests** for Commercial Release of GM Animals in Argentina  
**Yet!**

# // SUMMARY

(Regulatory Framework)

## Types of Authorizations for GMO

Confined Activity

Environmental Risk Assessment

BIOSAFETY Conditions

CONABIA

Commercial Release  
(Deregulation)

Environmental Risk Assessment

Possible Environmental IMPACT

CONABIA

Food Safety Assessment

SENASA

Market / International Trades

DNM

Secretary of Food, Bioeconomy and  
Regional Development

The Secretariat is advised by CONABIA.

CONABIA

oversees the project's conditions

The Secretariat is advised by  
CONABIA, SENASA and DNM.



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**Argentina**