

Argentina: regulatory framework for GM Animals

2022

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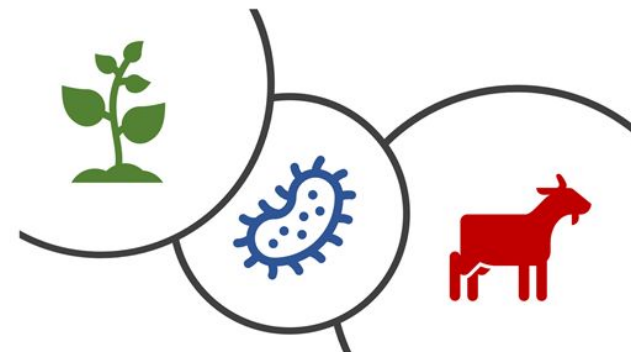
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1991

- Argentina begins to regulate GMOs species for agricultural use.
- Creation of CONABIA



2003

- First requests in order to initiate activities to develop **GM animals for agricultural use.**
- 2005 first activity authorization for GM animals.



01

Case by case:

Each application submitted is thoroughly evaluated on an individual basis

02

Scientific Base:

The only application of scientific-technical criteria

03

Data Quality:

The documents supporting the applications must have the quality of documents published in scientific journals of international prestige

04

Familiarity:

Possibility of comparison or that behave in a similar way

05

Safe Usage History

Related to consumption habits and the massive consumption of the GMO in other countries for years

¿What we regulate in GM animals?

Genetically modified animals

Species of agricultural use or impact



¿What is the regulatory path followed by a GM Animal?

Request Types

Phase 1
(Regulation)

Phase 2
(Deregulation)

Investigation

Confined Production

1

CONABIA: Bioseguridad

Control /Inspection
Animal welfare

SENASA
CICUAE

1

CONABIA: environmental risk

2

SENASA: food aptitude

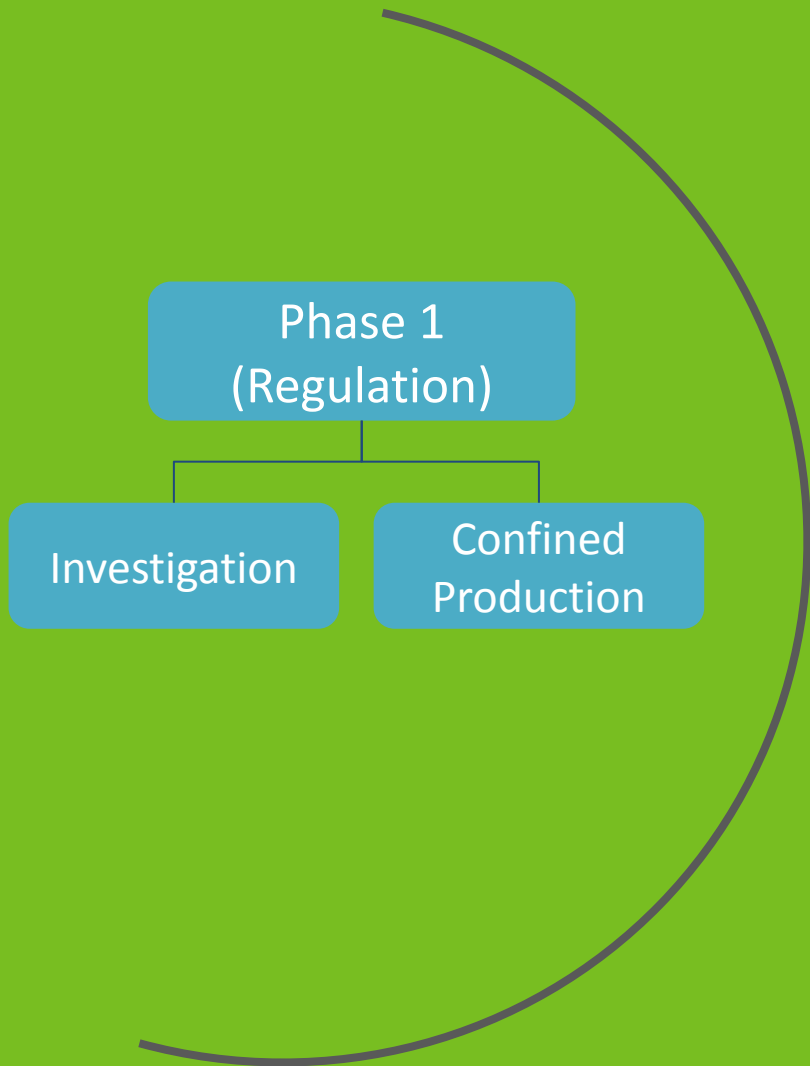
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SsMA: international markets

NON-BINDING Opinion

Secretary of Food, Bioeconomy and Regional Development





BIOSAFETY evaluation

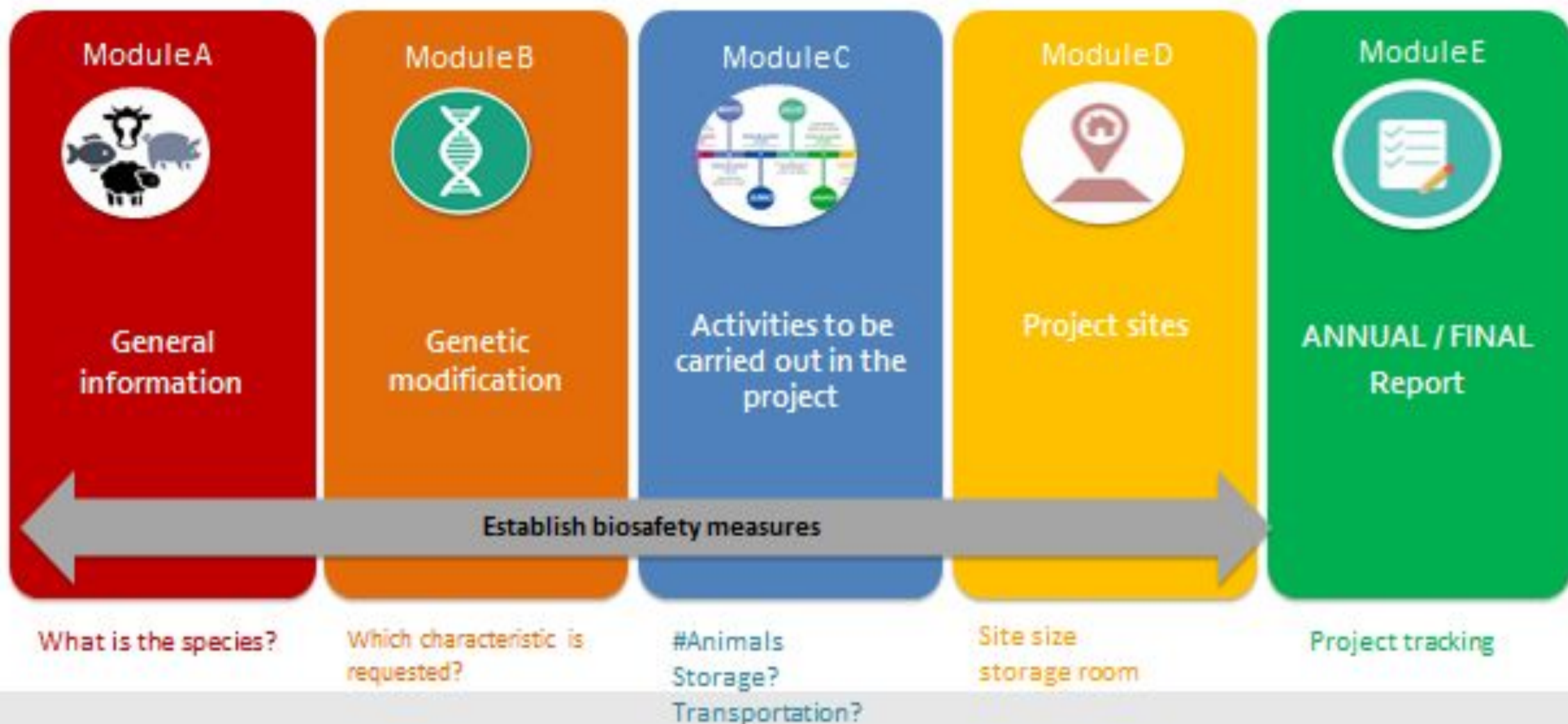
Animal regulations cover...



From....



to...



Phase 1
(Regulation)

Fishes

Growth hormone

Consumption

Cows and sheep

Difference in the
composition of milk:

Biopharmacy or
consumption

- Growth hormone
- Antibodies (rotavirus)
- Proteins

Sheep

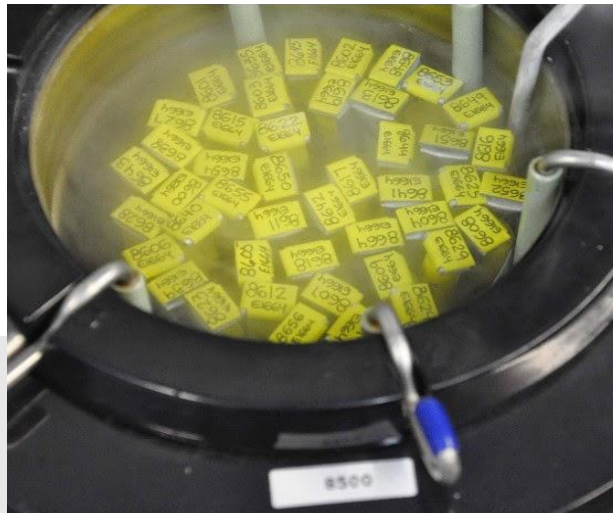
GFP Expression

Research

Bovine



Bovine
Milk: human growth hormone
Trial test: 2005- today



Phase 2
(Desregulation)

CONABIA: environmental risk

SENASA: Food Aptitude

SsMA: International Markets

ENVIRONMENTAL Risk Assessment (Commercial Approval)



Species receiver

Characteristic sought is a "risk" for the agroecosystem?

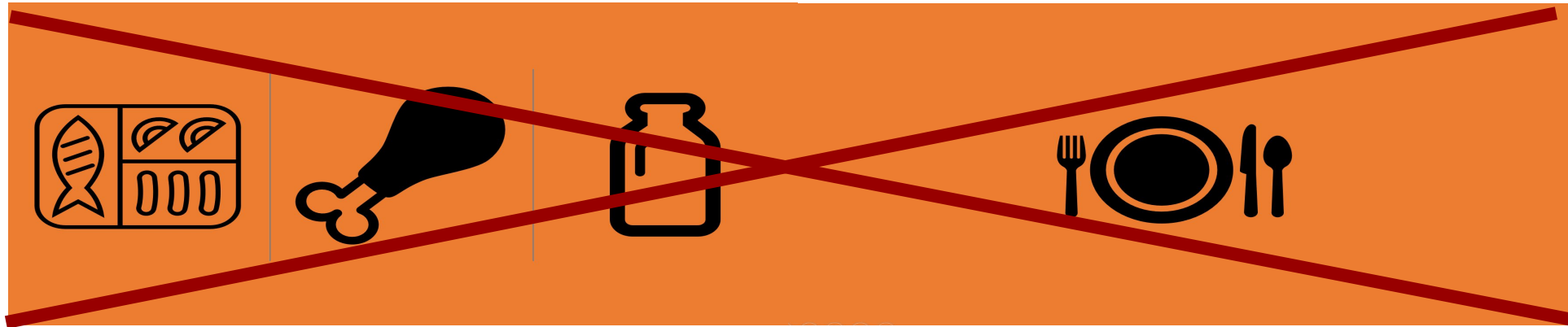
detection techniques Specific

Interaction with other species. Relevance in the food chain of other species?

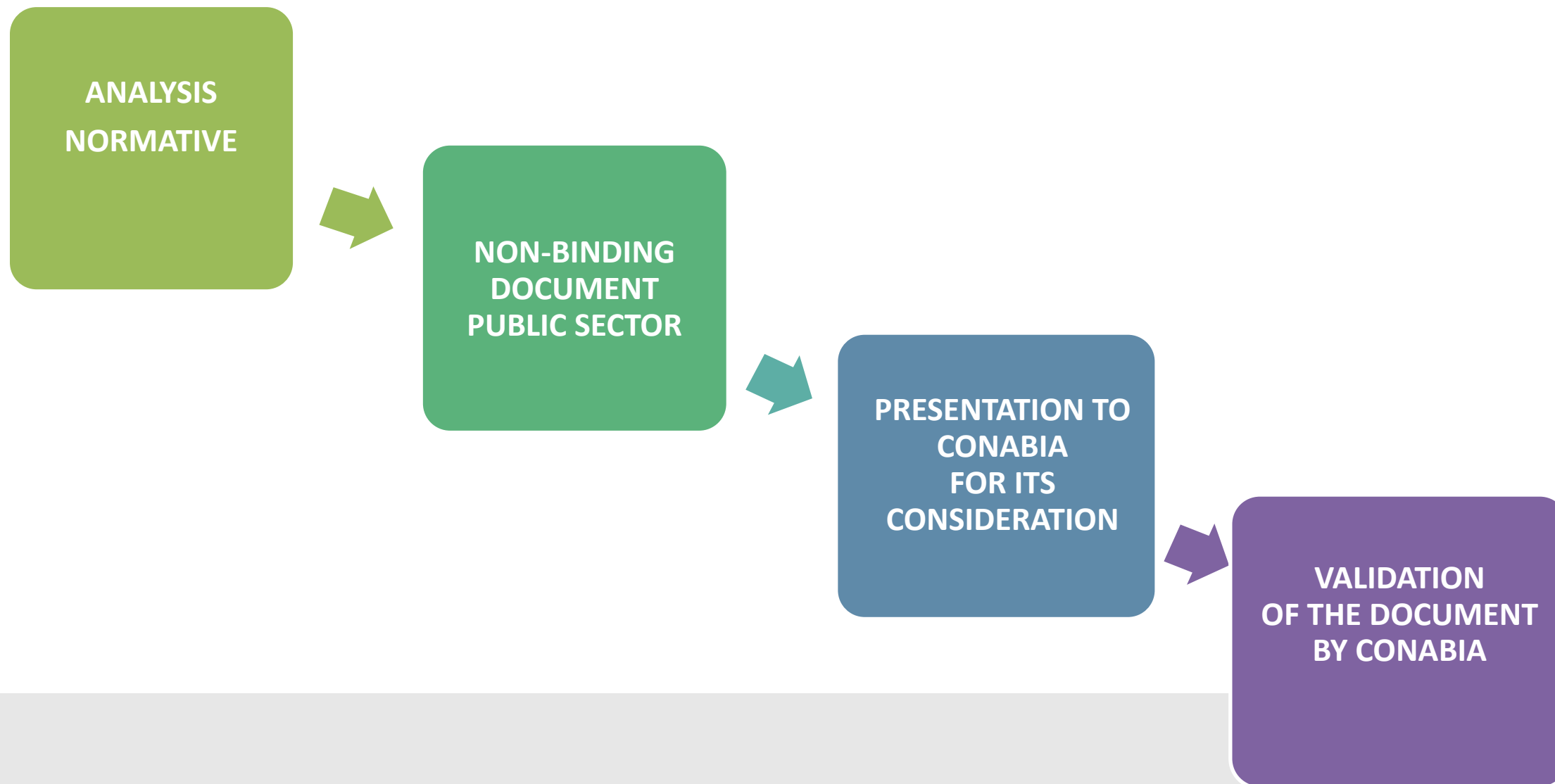
Use of gmo animal Consumption Production

Phase 2 (Desregulation)

There are no GM animals in Argentina approved for use, consumption or commercialization

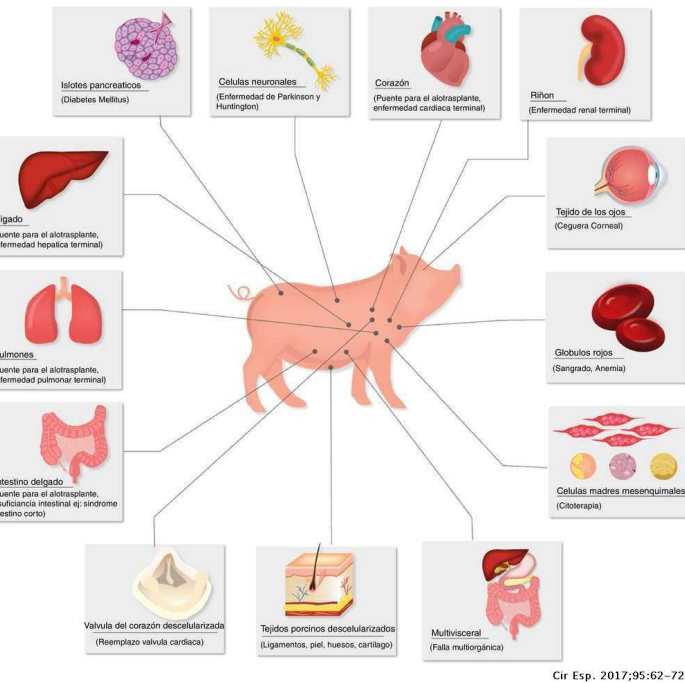


REGULATION UPDATE



GM insects

- **Adequacy of the GM animal regulations for GM insects for agricultural use or impact.**



Cir Esp. 2017;95:62-72

Xenotransplantation

- **Regulatory circuit analysis for the development of GM pigs for human organ transplantation.**

LINKS

Coordination of Innovation and Biotechnology

<https://www.argentina.gob.ar/agricultura/bioeconomia/biotecnologia>

Normatives, Regulations and Forms

<https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/solicitudes-conabia>



Ministerio de Agricultura,
Ganadería y Pesca
Argentina