

Regulation of GM-Animals in Argentina

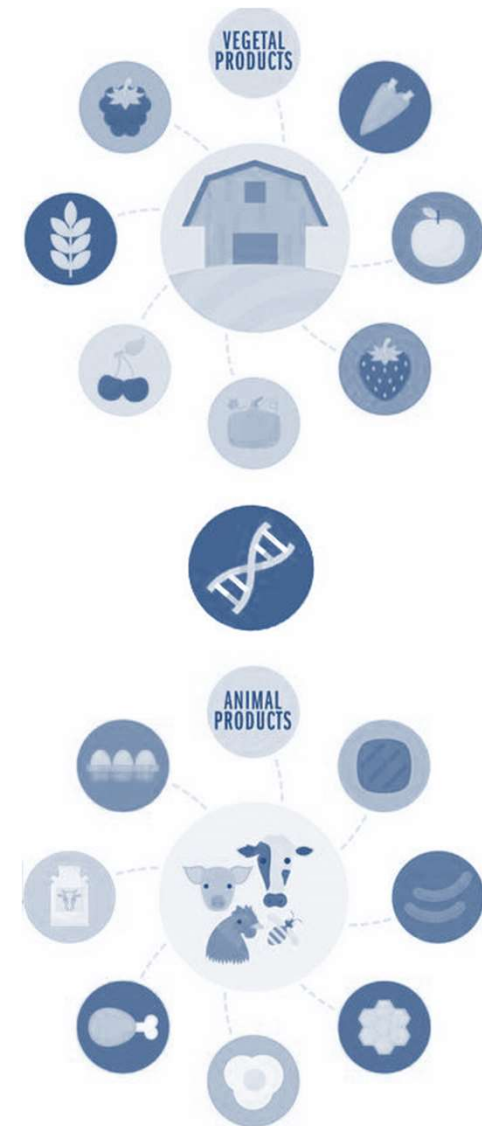
Yanina Petracca, Ph.D.

Head of GM-Animal Unit
Directorate of Biotechnology
Argentine Ministry of AgroIndustry



REGULATORY FRAMEWORK IN ARGENTINA •

- » **Enforced since 1991** at the Federal Level & within the scope of the **Ministry of AgroIndustry**.
- » Regulation of activities involving **GMOs of AG use**.
- » The main goal of the regulation is to **ensure that GMOs are safe** for the **agro-ecosystem** and for **food & feed** and that they are **beneficial to our farmers** (impacts on domestic production & int'l trade).
- » Activities with **GMOs are regulated** and demand **prior written authorization** by the Secretary of Added Value.



TYPES OF AUTHORIZATIONS •

Confined release:

- ✓ **All types** of GMOs, including GM Animals.



Commercial release (deregulation):

- ✓ **Only GM crops** (no GM microorganisms or animals yet!).

Activities **may begin only after proper authorization** is granted.

CONFINED RELEASE OF GMA •

As per **Resolution 57/03**, Argentina currently regulates the **confined release of GMA of agricultural interest** (for experimental purposes).

- ✓ **Tests in Lab Animal facilities.**
- ✓ **Trials in Confined Environments.**
(e.g. land-based aquaculture systems, corrals, aviaries, barns, pens).



Authorizations are granted **upon fulfilment** of specific **regulatory requirements** by the applicants.

CONFINED RELEASE OF GMA •

Applicants **must fill out & submit a Form** and attest to the truth of the information submitted.

Applicants must inform:



- ✓ **Applicant's** and/or Legal representative's **ID**.
- ✓ Characteristics of the **non-GMA & potential receiving environment**.
- ✓ Description of the **genetic modification** & genetic engineering **techniques applied** to obtain it.
- ✓ Phenotypic **changes in the GMA** (intended- unintended) comparing with the non-modified recipient.
- ✓ Activities conducted, **biosafety conditions** & risk mitigation measures in the trial.

WHICH AGENCIES ENFORCE GMA REGULATORY FRAMEWORK?



A number of federal **agencies** take part in the **risk assessment & oversight of the activities** involving GMA.

Ministry of AgroIndustry



Secretary of
Agriculture,
Livestock & Fisheries



Directorate of
Biotechnology

National Advisory
Commission on
Agricultural Biotechnology
(CONABIA)



National Service of
Agrifood Health and
Quality (SENASA).

Decentralized agency

Enviro-RA

RA process

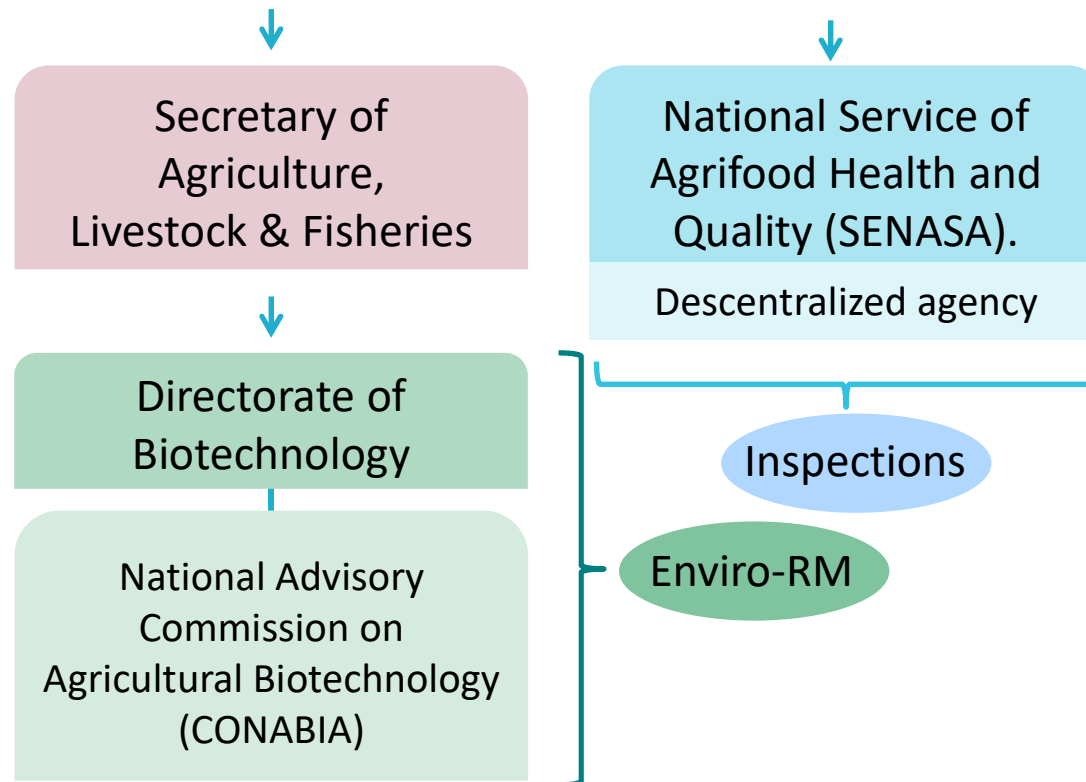
- » The **DB & CONABIA** assess applications focusing on **confinement conditions**.
- » RA follows a **case-by-case & a science-based** approach.
- » CONABIA submits a **report** on the “**advisability**” of **granting** (or denying) an authorization.
- » Based on this report, the **Secretary grants (or not)** the authorization.

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Ministry of AgroIndustry



Upon authorization

- » **SENASA verifies** the fulfillment of the **biosafety conditions** by means of periodic on-site inspections.
- » SENASA also oversees issues **animal health & welfare, requirements** for the import of animals and **quarantine conditions**.
- » During the trial, **applicants must submit periodic reports** to the DB & CONABIA on the **activities done** and/or on **events that might impact biosafety**.

CASE STUDIES IN ARGENTINA •

Since 2005, we have received **17 applications** for generating & conducting confined trials with **GMA**.

Biopharming

GM cattle expressing *human Growth Hormone* in mammary glands.



Functional
Foods

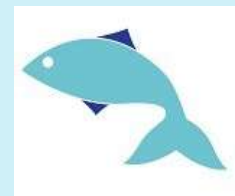
GM cattle that express:

- ✓ *llama Nanoantibodies* against Rotavirus in the milk (gastrointestinal infections).
- ✓ *human lysozyme* and *lactoferrin* in the milk (antifungal, antibacterial and antiviral functions).



Aquaculture

Growth-enhanced AquAdvantage Salmon reared in land-based facilities.



NEW CHALLENGES, NEW REGULATIONS •

There have been **huge advances in the animal biotechnology field** since 2003, when our current regulation on GMA was enforced.



- » **2016:** we have worked on the **revision of our regulations for GMA confined releases** taking into account: Previous experience + new technologies available.
- » Last year, CONABIA **submitted a proposal** for the enforcement of **new GMA regulations** to the competent authorities on June, 16th, whose **approval is still pending**.

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NEW CHALLENGES, NEW REGULATIONS •

The organisms generated by the use of the **genome editing techniques** pose **new challenges** to most of the existing regulatory frameworks.

- » **2015:** In Argentina, a **new regulation** was enforced to address **plant products** obtained by **new breeding techniques**.

Resolution 173/15 sets out the steps to follow to determine **in which cases** a crop produced by new plant breeding techniques (**NPBT**), **does NOT fall under GMO rules and regulations**.

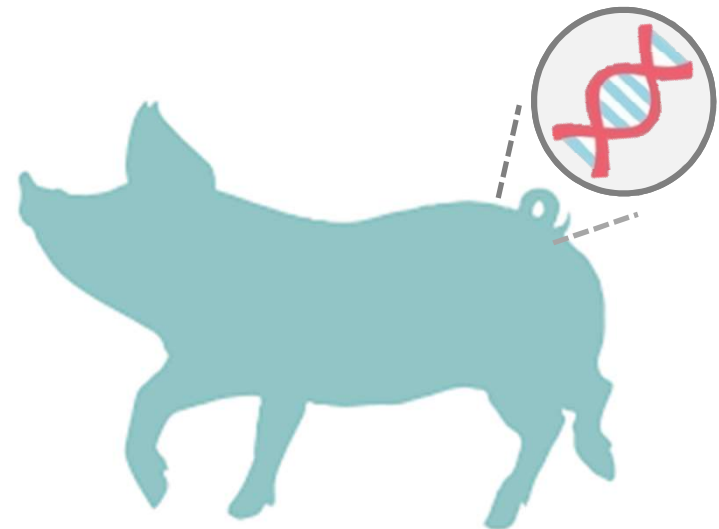


NEW CHALLENGES, NEW REGULATIONS •

- » **2016:** Directorate of Biotechnology & CONABIA discussed the manner to **address animal products** developed by use of **genome editing techniques**.

We recommended to follow an **approach similar** to the one adopted for **plants**.

- » The **suggested regulatory criteria** for addressing **Genome-edited Animals** was **included** in the proposal for **new GMA regulations**.



HOW TO ADDRESS GE ANIMALS •

GE animal: Applicant's previous consultation

↓
CONABIA

↓
Is there a new combination of genetic material?

NO

Non
GMO

GE animal does not fall under GMA Regulations

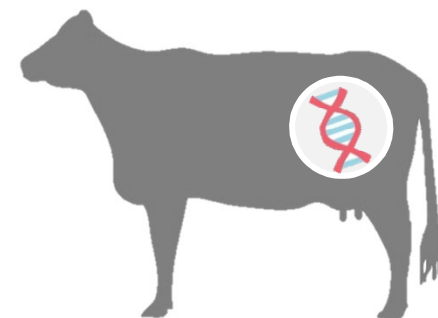
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» Applicant shall request CONABIA to establish **whether the animal produced by genome editing techniques**, bears a **new combination of genetic material** (GMO definition).

What is a new combination of genetic material?



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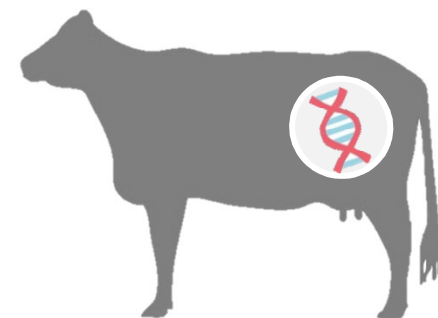
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DEFINITION: A genetic change shall be regarded as a **new combination of genetic material** when the assessment establishes that **one or more genes** or DNA sequences that are a part of a defined genetic construct **have been inserted jointly & stably into the animal genome.**



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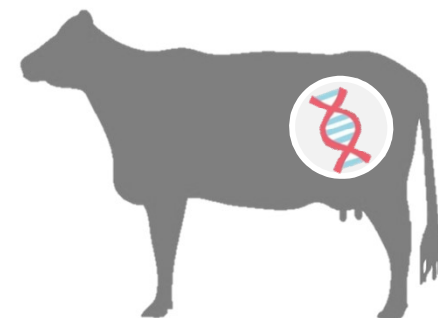
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» For the assessment, the applicant must submit to CONABIA data on:

- ✓ The **methodology** used to **produce** the GE animal.
- ✓ The **new trait** or characteristic introduced.
- ✓ The **genetic changes** present in the **final product**.



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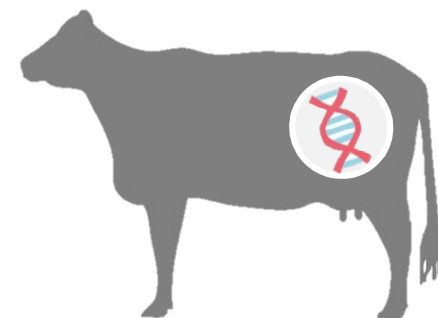
GMO

GE animal falls under GMA Regulations

» CONABIA will determine **if the final product has a new combination of genetic material.**

X **If it does not**, the Applicant will be informed that the GE animal **does not fall under GM-Animal Regulations.**

✓ **Otherwise**, the GE Animal product will have to go through the regulatory process.



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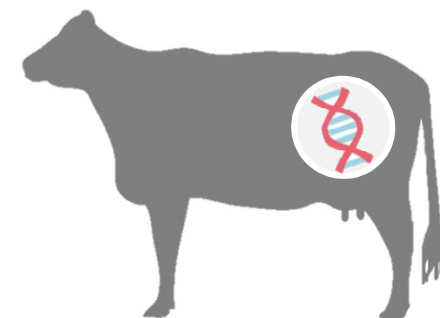
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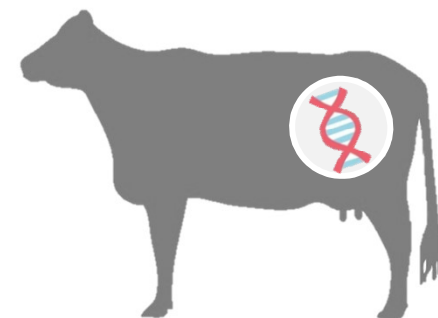
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» **CONABIA may recommend** the authorities the adoption of **follow-up or monitoring measures** for an individual genome-edited animal not regarded as GMO **based on its features and/or novelty.**

HOW TO ADDRESS GE ANIMALS •



- » **2016:** First authorization for the **generation of GE cattle** under confined conditions.
- » **2017:** Risk assessment of **new applications** involving the generation of other GE animals.



If the proposed **new regulations are approved** in the near future, it will be possible for developers to request the CONABIA to **establish whether the genome edited animal**, they have already produced, falls under **GMA Regulations**.

FUTURE CHALLENGES



No Applications for the commercial release of GMA have been submitted in Argentina.

- » We will work on **new regulations** in anticipation of such applications in the near future.
- » **Risk assessment** should be **focused on** the **environmental, feed & food and economic impacts** and shall be carried out by **different federal agencies** in order to ensure proper expert analysis.





**THANK YOU VERY MUCH FOR YOUR
ATTENTION!**

ypetra@magyp.gob.ar

yaninapetracca@gmail.com

The abovementioned presentation represents my expert opinion on the matters therein and those not necessarily represent the ones of the Argentine Government.

Photos of Argentina by: Yann Arthus-Bertrand