

# REGULATORY HARMONIZATION AND GLOBAL TRADE

## Panel: Impact of Differential Regulatory Approaches and Asynchrony on the use of Livestock Cloning

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Preparing Markets for New Animal Product Opportunities  
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# STANDPOINT

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Biotechnology practitioner also working in human AC  
Developer, Owner of land and animals, private funding  
Short history about New Millennium achievements  
“Toolbox”: MOET, IVF and Cloning

# 2002: MOET

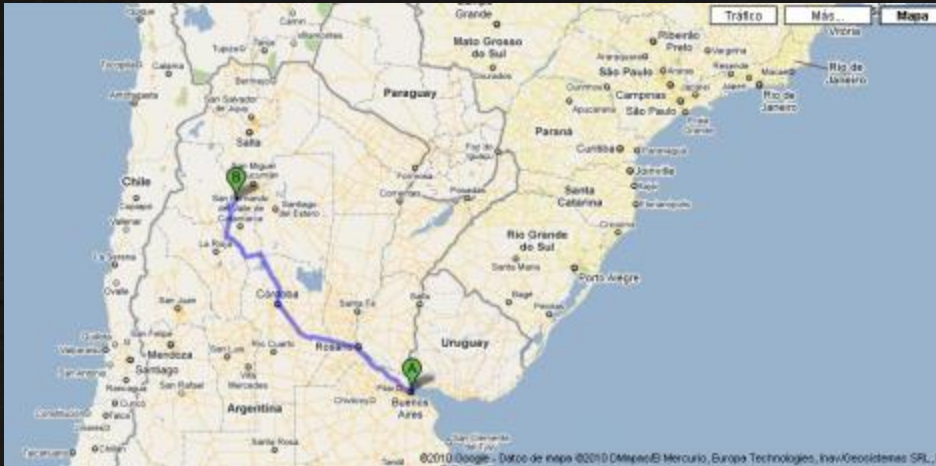


- Province of Formosa
- Firstly with Boer Goats and then with Dorper Sheeps
- 50-100 receptors each month
- Still ongoing with the same species, now including also bovines.





# Interaction with local producers of goat farming



- 2007
- Las Palmitas, Departamento La Paz, Catamarca
- Andalgalá, Catamarca
- La Rioja, Provincia de La Rioja



# 2007: IVF

- Germinal Biotech in Marcos Paz, Buenos Aires
- To generate IVEP embryos
- Boer, Dorper and Bovine sps.
- Holstein oocytes + Gir sperm → Gir-Holstein IVP embryos.
- 2013: Vittrification of surplus embryos





# 2010: first births by cloning (SCNT)



# GERMINAL CLONING RESULTS

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TOTAL SPECIES	4
BREEDS	8 3 OVINES, 3 BOVINES, 1 GOAT, 1 SWINE
TOTAL INDIVIDUALS PRODUCED	22
SURVIVAL	15 (68%)

# GERMINAL CLONING RESULTS

YEAR	SPECIES	BREED	BORN	ALIVE	%
2010	Goat	Boer	2	2	100
2010	Swine	Yorkshire	3	3	100
2010	Sheep	Santa Ines	2	1	50
2010	Sheep	Dorper	4	1	25
2011	Bovine	Bradford	1	1	100
2011	Sheep	Santa Ines	2	1	50
2012	Sheep	Texel	3	1	33
2013	Sheep	Dorper	1	1	100
2014	Bovine	Girolando	2	2	100
2014	Bovine	Holstein	2	2	100
TOTAL	4	8	22	15	68





## BOER GOATS

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Two, born in March 2010 from skin fibroblasts obtained from an animal belonging to the New Millennium Farm.



Both are alive and its semen is routinely used to produce IVF embryos.



# YORKSHIRE SWINES

Three Yorkshire swines born in July 2010 from skin cells obtained from an animal belonging to the New Milenium Farm.



## GERMINAL BIOTECH CLONACION DE CERDOS



Germinal Biotech es un Laboratorio dedicado a la excelencia en Biotecnología Reproductiva. El objetivo primario es la multiplicación exponencial de ejemplares ovinos y caprinos de la más alta aptitud carnícera, a través de uso de biotecnologías de reproducción asistida (BRA). Siguiendo este objetivo, el laboratorio en Marcos Paz, Buenos Aires, logró clonar con éxito cabras Boer y ovejas Dropper de alta genética.

La clonación de cerdos se realizó en el laboratorio del 12 de Marzo al 17 de Abril del 2010. Participaron en este intenso trabajo, los técnicos de Germinal Biotech y capacitados especialistas extranjeros. En Julio de 2010 se produjeron los nacimientos exitosos



### Primera clonación de cerdos

Más recientemente hemos incorporado la transferencia nuclear o, como se la refiere más comúnmente, clonación a cerdos.



  
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# YORKSHIRE SWINES

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First time in Latin America.  
10 transfers – 3 calves born.

*One of them was sent to a farm in  
Angola, during a presidential trip  
with a delegation of businessmen.*





## TEXEL SHEEPS

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Three Texel Sheeps born in 2012 from skin cells obtained from an animal belonging to the “La Juntada” Farm.

# SANTA INES SHEEPS

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Four Santa Ines Sheeps: two born in 2010 and two in 2011, all from skin cells obtained from an animal belonging to the New Milenium Farm.

One of them (a male) is on site in perfect condition, which semen is used to produce IVF embryos.

One female died after giving birth.

*The third animal (a female) was sent to Angola during a presidential trip with a delegation of businessmen.*





# BLACK HEADED DORPER SHEEPS

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Four Black Headed Dorper Sheep born in March 2010 from skin cells obtained from animal B005 belonging to the New Millennium Shack.

One Black Headed Dorper Sheep born in 2013 from skin cells obtained from animal B005 belonging to the New Milenium Shack. His semen is routinely used to produce IVF embryos.



# BOVINES

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Bradford

Holstein

Girolando (Gir-Holstein)



# BRADFORD

A bull originated from skin cells born in April 2011.

There are over 500 semen straws from this animal that are used routinely to produce IVF embryos.

## GERMINAL BIOTECH Cloning Technology SUCCESSFULLY CLONES A FAMOUS BULL



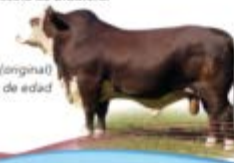
El clon Pascual con 5 días de edad.



El 22 de abril del 2011 nació en Germinal Biotech un ternero Bradford llamado "Pascual". El evento fue un hito importante en la historia de nuestro laboratorio ya que se convirtió en el primer grupo en producir con éxito clones vivos de cuatro especies diferentes de animales de granja (cabras, ovejas, cerdos y ahora, vacunos).

El ternero es una copia genética del toro "Kachapé" de 11 años de edad, que es considerado por muchos como el mejor toro en la historia de la raza Bradford en la Argentina, y fue producido utilizando la tecnología de transferencia nuclear de células somáticas por el personal profesional de Germinal Biotech. Kachapé es famoso por la altísima consistencia en la producción de carne de su progenie, según lo medido en miles de hijos e hijas producidos hasta la fecha. La producción de su réplica genética por tecnología de clonación permitirá ampliar su vida reproductiva, a pesar de la avanzada edad del "original". Esto permitirá prolongar las contribuciones de Kachapé al mejoramiento genético de la industria de Bradford.

El toro "Kachapé" (original) de 11 años de edad



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# HOLSTEIN

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Two Holstein females originated from skin cells obtained from a cow belonging to an establishment in Buenos Aires Province, born in July 2014.





## GIROLANDO



Two Girolando females from skin cells obtained from a cow belonging to the New Millennium Farm, born in January and March 2014.

# ORIGINAL REGULATORY FRAMEWORK INITIAL SCENARIO

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To develop a productive model in a frontier region of Argentina, under particular local environment and state legislation.

Easy access to very simple tech to develop MOET.

Local market of meat products.

Open a second lab close to Bs As to develop IVF.

Use of MOET and IVF products to sustained the develop of cloning technology.

Investment in cloning for a potential future use, without actual benefit apart from the learning of the different techniques.

# PRESENT SCENARIO

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- There is a cloning record or experience in our country: polo horses, for example
- There is some development in certain areas of technology
- It's interesting to local and foreign developers



# PRESENT REGULATORY FRAMEWORK

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	USA	UK	EU	Arg	Brazil
GLOBAL TRADE	NONE	Is regulated through a combination of EU and national legislation.	Proposals to prohibit the commercial cloning of animals for food production (including semen)	NONE	NONE
REMARKS	it would be impossible to ensure full traceability	Donor animals, surrogate mothers and clones themselves would be subject to welfare requirements	Cloning for now is so expensive that its use for food production isn't viable	it would be impossible to ensure full traceability	it would be impossible to ensure full traceability

# PRESENT REGULATORY FRAMEWORK OR SCENARIO

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- The need of patents could be a future concern
- Difficulties to the access of chemicals due to present customs regulations
- Potential difficulties to put products out of Argentina
- EU regulations on food products that exceed the local legislation
- Regulations on animal cloning products
- Some difficulties in the access to new technology



# HUMAN IMPACT ON THE BIOSPHERE IS NOW REALIZED IN INCREASINGLY NOVEL WAYS

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- Breaching boundaries between species
- Creating novel forms and functions
- Integrating the living and the non-living
- Some of these ends through the purposeful manipulation of DNA itself,
- We can now not only “read” but “write” DNA letters
- giving rise to the field of synthetic biology.

# SIX SECTORS OF POTENTIAL TRANSFORMATION HAVE BEEN IDENTIFIED

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- Bioenergy
- Agriculture and food production
- Environmental protection and remediation
- Consumer products
- Chemicals
- Human health



# THE FUTURE OF SYNTHETIC BIOLOGY

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- Positive view: “Many of the major global problems, such as famine, disease and energy shortages, have potential solutions in the world of engineered cells”
- Catastrophic view: “The purposed use of synthetic microbes in the production of the next generation of fuels, medicines and industrial chemicals may massively increase human impact on biodiversity”

# RISKS

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- Risk of bioterror or bioerror (release of synthetic organisms into the environment)
- Genetically modified crops have become quite popular with farmers in many countries.



	Animal Biotech	Synthetic Biology	Human Assisted Fertilization
TIME FRAME	1950	1985	1978
MAIN METHODOLOGIES	MOET, IVF, Cloning	DNA reading and writing	IVF, Vitrification, PGD, embryo selection
MAIN PRODUCTS	Faster production of selected breeds	Faster selection of desired traits  New species	Human beings
USE IN FOOD	+++++	Potential	NA
GLOBALITY	+++	+++++	None ICSI: 0.08%

# LESSONS LEARNED

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- Private initiative vs government or official research entities
- Need to be properly informed before starting
- Progress is running faster than we can run
- We now have a broader understanding or perspective





## ***Leadership***

Miguel Mellano  
Julio Mellano



### ***Administration***

Pablo Mellano  
Andres Meltzas

### ***IVF/Cloning Lab***

Federico Mellano  
Marcelo Albornoz  
Claudio Bisioli

### ***Veterinary Team***

Claudio Colato  
Juan Ignacio Mellano

### ***Formosa***

Cesar Núñez

