

Panel discussion: Differential Impact of Regulatory Approaches and Asynchrony of Livestock Cloning



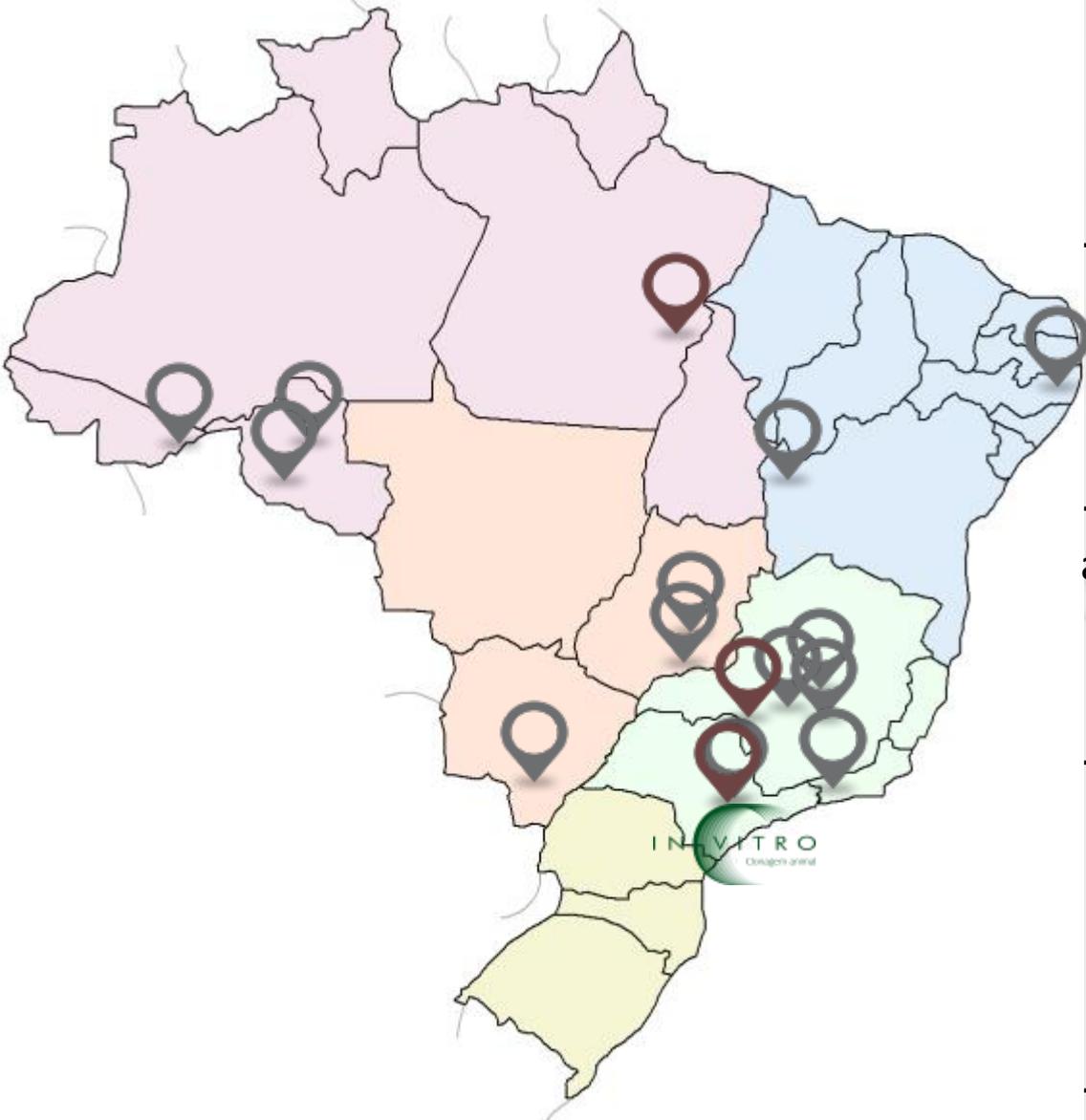
IN VITRO

Clonagem animal

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In Vitro Brasil Clonagem Animal SA

August 18th 2014





In Vitro Brasil Clonagem Animal

→ Founded (2005) in Mogi Mirim Brazil

→ Production of bovine, equine clones as well as equine ICSI.

→ Produced over :
→ 150 bovine clones
→ 3 equine clones
→ 2 equine ICSI.

→ Projects R&D

Brazilian Cloning Market

Bovine

- World leader in exportation of beef
- Export 2 million metric tons/year
 - US 1.4 million metric tons
 - Australia 1 million metric tons
- 23 million head milking breeds
- Potential for 40-60 clones/year

Equine

- Market of 7.5 billion
- 3.2 billion in direct and indirect employment (ALMEIDA; SILVA, 2010; IBGE, 2010)
- Embryo transfer 43% of all worldwide
 - Argentina (29%)
 - USA (19%)
- Potential for 10-20 clones/year

Regulation of Cloning in Brazil



SENADO FEDERAL PROJETO DE LEI DO SENADO Nº 73, DE 2007

Regulamenta as atividades de pesquisa, produção, importação, liberação no ambiente e comercialização de clones de mamíferos, exceto humanos, peixes, anfíbios, répteis e aves.

→ Importation of cloned non-human mammals

→ Production of non-human mammalian, fish, amphibians, reptiles and bird, clones

→ Domestic

→ Wild

→ Transgenic

→ Penalties

→ Fees and Jail time

Current Regulation of cloning in Brazil

MAPA

Ministério da Agricultura, Pecuária e Abastecimento
(Ministry of Agriculture, Livestock and Food Supply)

Importation of cloned animals- reported to MAPA for any animal importation

Laboratory- needs certification from MAPA for animal production
→ CQnBIO for transgenic animal production

Breed association registration

→ Drafts regulations for registration and sends to MAPA for approval.

Food supply

→ Milk and Beef inspection **SIF** Serviço de Inspeção Federal
(Federal Inspection Service)

Regulation of cloning in Brazil

Bovine

Breed Association regulations; ABCZ

MARCAÇÃO DE PRODUTOS PROVENIENTES DA TÉCNICA DE TRANSFERÊNCIA NUCLEAR

ONDE SE LÊ A MÃE
NO RGN COMUM



ORELHA DIREITA
Tatuagem do
Registro Genealógico do
Doador Nuclear



RGN CONVENCIONAL

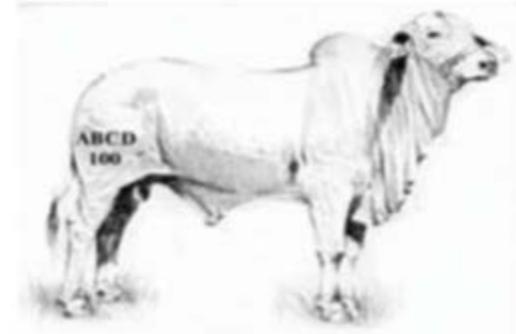
ORELHA ESQUERDA
Tatuagem da série
alfabética do criador e do número
de Registro Genealógico
de Nascimento do Produto.



- Use same breed oocytes (Mitochondria)
- 125 clones registered
- 42 from InVitroBrasil Clonagem Animal

PERNA DIREITA

Marcação a fogo, até a desmama, com a série do criador e o número correspondente ao seu RGN, exatamente como um produto convencional



PERNA ESQUERDA

Marcação a fogo, até a desmama, com o registro do doador nuclear sobreposto pela sigla "TN".



Images used with permission from Jose Olavo Jr

Regulation of cloning in Brazil; Equine

Breed Association regulations;

Mangalarga Paulista (A.B.C.C.R.Mangalarga)

→ So far the only breed association which registers clones

→ Specific situations for cloning to be registered:

- 1. Original animal is no longer alive**
- 2. Original animal cannot reproduce (castrated)**
- 3. The clone cannot participate in competitions**
- 4. The clone can only be used for reproductive purposes**

International cloning market for Brazil (Clones made in Brazil for exportation)

Bovine

→ Exportation of live bovine to US and EU restricted

→ Meat exportation to:

- Russia
- Japan
- Korea
- Hong Kong
- Egypt
- Iran
- EU - 27

Equine

→ Same regulations as horses produced by other means

→ Meat exportation to:

- France
- Italy
- Japan
- Belgium
- Russia
- Vietnam

Gia malva, J 2012 Restrictions in Export Markets for Brazilian and U. S. Beef

Potential challenges observed in the international cloning market.

1. Regulation of Process (EU) vs regulation of the Final Product (USA)

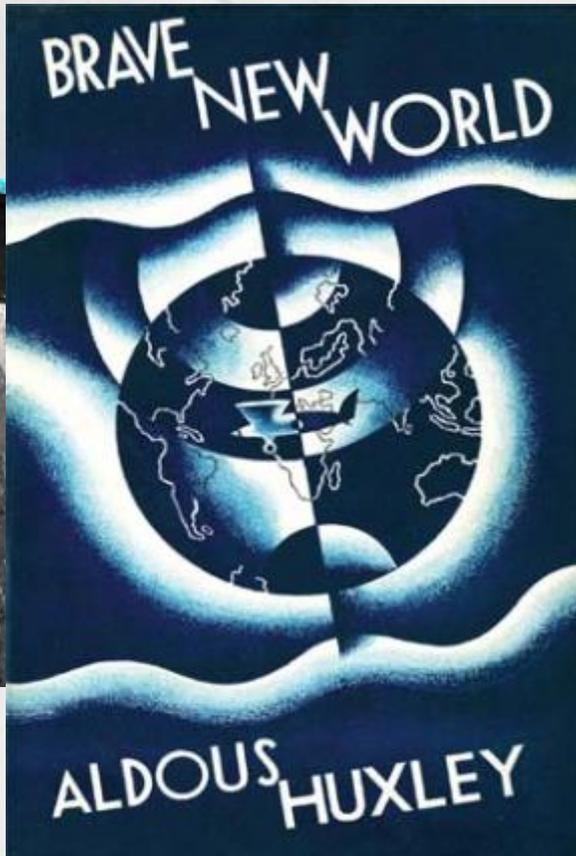
→ Exportation of Brazilian meat requiring labeling as to method of reproduction?

2. Exportation destination of animals produced by cloning will determine the use of the animal.

3. How will inspectors be able to independently verify if the product or animal imported was made by cloning?

How do we move forward from here?

→ Regulation with education



Animal Cloning: A Risk Assessment

Center for Veterinary Medicine
U. S. Food and Drug Administration
Department of Health and Human Services
7500 Standish Place
Rockville, MD 20855

1/8/2008



FDA

Education through public engagement



Thank you for your attention!



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