

# Food animals versus public health applications

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# Common applications of Genetically modified animals

- Basic research ( mice and rats)
- Xenotransplantation (GM KO pigs for alpha-galactosyl transferase gene)
- Bioreactors
- Pets, aquarium fishes
- **Food animals**

# Commercial approvals in Brazil

## Corn (19)

T25 – Liberty Link

MON 810 - YieldGard

Bt11

NK 603 - Roundup Ready 2

GA21

TC 1507 - Herculex

MIR162 - Viptera

MON 810 x NK603 – YieldGard/RR2

Bt11 x GA21

MON 89034 – YieldGard VT Pro

TC1507 x NK603

MON 89034 x NK 603 – YieldGard VT Pro

Bt 11 x MIR 162 x GA21

MON 88017 - YieldGard VT Rootworm/RR2

MON 89034 x TC 1507 x NK 603

TC 1507 x MON 810 x NK 603

TC 1507 x MON 810

MON 89034 x MON 88017

TC1507 x DAS-59122-7

## Mosquito (1)

OX513A – Oxitec

## Cotton (12)

MON 531 - Bolgard I

LLCOTTON25 – Liberty Link

MON 1445 – Roundup Ready

281-24-236/3006-210-23 Widestrike

MON 15985 - Bolgard II

MON 531 x MON 1445

GHB 614 – GlyTol

GHB 119 x T 304-40 – TwinLink

MON 88913

GlyTol x TwinLink

GlyTol x LibertyLink

MON 15985 X MON 88913

## Soybean (5)

GTS-40-3-2 – Roundup Ready

BSP-CV127-9 - Cultivance

A-2704-12 - Liberty Link

A 5547-127 – Liberty Link

MON 87701 x MON 89788 – Intacta RR2 PRO™

## Common Bean (1)

EMBRAPA 5.1

## Vaccines (17)

VAXXITEK MD/IBD

RECOMBITEK

SUVAXYN PCV2

PORCILIS CIRCUMVENT

IGELVAC CIRCOFLEX

POULVAC *E. COLI*

VECTORMUNE FP-MG+AE

VECTORMUNE FP-MG

VECTORMUNE HVT-NDV

VECTORMUNE HVT-IBD

POULVAC ST

INNOVAX

VECTORMUNE FP-LT

VERTORMUNE FP-LT+AE

INNOVAX ND

PROTEQFLU

PROTECFLU TE

## Microrganisms (4)

Levedura – Cepa Y1979

Levedura – Cepa Y5056

Microalga – Cepa S2014

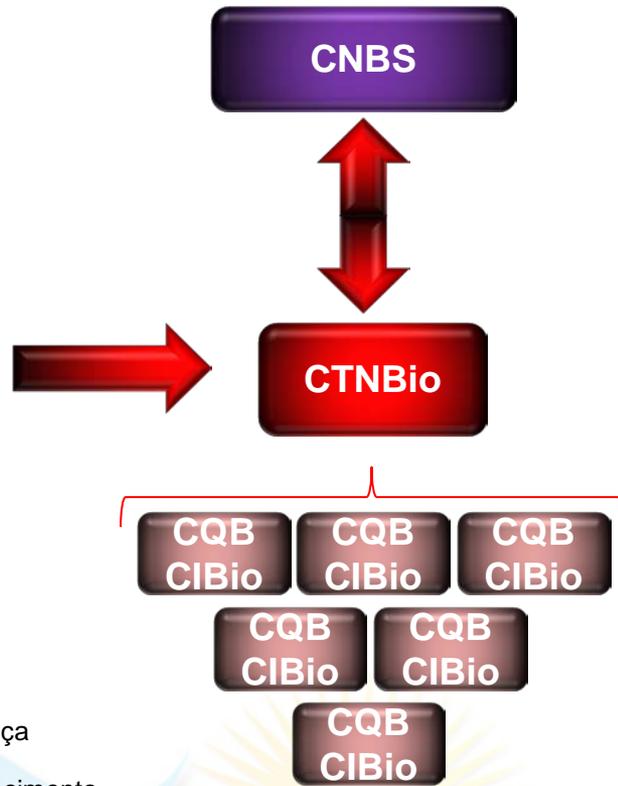
Levedura - Cepa RN1016

yeasts

# Brazilian system of Biosafety

## Regulatory organs

Biosafety Law (11.105)



-  Conselho Nacional de Biossegurança
-  Comissão Técnica Nacional de Biossegurança
-  Ministério da Agricultura, Pecuária e Abastecimento
-  Agência Nacional de Vigilância Sanitária
-  Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis
-  Ministério da Pesca e Agricultura
-  Comissão Interna de Biossegurança

CTNBio



Ministério da Agricultura, Pecuária e Abastecimento





BUSCA:

MENU

- CTNBio
- CIBio
- Comunicados CIBio
- Gestão Administrativa
- Legislações
- Legislation
- Documentos
- Aprovações Comerciais
- Commercial Approvals
- Eventos
- Outros Links
- Orgãos de Fiscalização
- Fale Conosco
- Audiência Pública - Eucalipto
- Requerimento de Cópias e Pedido de Vistas
- Posição da CTNBio sobre os trabalhos de Séralini com milho transgênico - CTNBio position about Séralini report transgenic corn
- Comunicado aos Presidentes das CIBios
- VIII Congresso Brasileiro de

NOTÍCIAS

- 20/06/2014 19:31:00  
Projeto de lei define novas regras para acesso ao patrimônio genético
- 17/06/2014 10:16:00  
LNCC realiza 7ª Escola de Modelagem Molecular em Sistemas Biológicos
- 05/06/2014 16:35:00  
CTNBio aprova vacina contra circovirose suína e discute eucalipto
- 29/05/2014 10:00:00  
Brasil e Reino Unido definem estudos em biodiversidade e bioeconomia

**AUDIÊNCIA PÚBLICA EUCALIPTO - Faça aqui a sua inscrição**

**AVISO IMPORTANTE:** A CTNBio solicita que as inscrições efetuadas entre as 10:00h e as 16:00h do dia 04 de agosto de 2014, via formulário em nosso site, sejam refeitas.

[Acesse a PAUTA da 174ª REUNIÃO ORDINÁRIA, de 31 de julho de 2014.](#)

[Confira os LOCAIS das REUNIÕES setoriais e plenária de 30 e 31 de julho de 2014.](#)

- CTNBio is a multidisciplinary collegiate body, created by Law No. 11.105, of March 24, 2005, whose purpose is to provide technical advisory support and advice to the Federal Government in the formulation, updating and implementation of the National Biosafety Policy on GMOs and as the establishment of technical safety standards and technical reports **relating to the protection of human health, living organisms and the environment**, for activities involving the construction, experimentation, cultivation, handling, transporting, marketing, consumption, storage, release and disposal GMOs and derivatives.

# CNBS

- I – Ministro de Estado Chefe da Casa Civil da Presidência da República, que o presidirá;
- II – Ministro de Estado da Ciência e Tecnologia;
- III – Ministro de Estado do Desenvolvimento Agrário;
- IV – Ministro de Estado da Agricultura, Pecuária e Abastecimento;
- V – Ministro de Estado da Justiça;
- VI – Ministro de Estado da Saúde;
- VII – Ministro de Estado do Meio Ambiente;
- VIII – Ministro de Estado do Desenvolvimento, Indústria e Comércio Exterior;
- IX – Ministro de Estado das Relações Exteriores;
- X – Ministro de Estado da Defesa;
- XI – Secretário Especial de Aquicultura e Pesca da Presidência da República.

# CTNBio – 54 members

(27 members and 27 alternate members)

3 specialists of human health

3 specialists of animal health

3 specialists of vegetal area

3 specialists of environmental area

1 representative of Ministry of Science and Technology

1 representative of the Ministry of Agriculture, Livestock and Supplies (MAPA)

1 representative of the Ministry of Health

1 representative of the Ministry of Environment

1 representative of the Ministry of Agriculture Development

1 representative of the Ministry of Development, Industry and Foreign Commerce

1 representative of the Ministry of Defense

1 representative of the Ministry of External Relationship

1 representative of the Ministry of Fishing and Waterculture

1 specialist in Familiar Agriculture

1 specialist in Biotechnology

1 specialist in Consumer Defense

1 Specialist in environment

1 specialist in worker 's health

1 specialist in the health area.

# CTNBio

- 2 separate sectors
  - Human/animal
  - Vegetal/environmental
- 1 plenary session
- 2 day meetings every month in Brasilia

# CTNBio

- Does not evaluate only the product, but performs a broader evaluation of the laboratory that produces that GMO, the people working there, the biosafety level, and the biosafety conditions.
- **CASE BY CASE ANALYSIS**
  - PROJETS
  - PLANNED RELEASES
  - COMMERCIAL RELEASES (evaluated by 4 sectors: human, animal vegetal and environmental)

# CTNBio

- **Normative Resolution No. 06 of November 6, 2008.**
- Provides on rules for the planned release to the environment of Genetically Modified Organisms (GMO) of **plant origin and their derivatives.**

# CTNBio

- **NORMATIVE RESOLUTION Nº 7, of April 27, 2009.**
- Provides on rules for **planned release into the environment of Risk Class I Genetically Modified Microorganisms (GMM) and Genetically Modified Animals (GMA<sub>n</sub>)** and their derivatives.

- ANNEX I
- APPLICATION FOR PLANNED RELEASE OF GENETICALLY MODIFIED MICROORGANISMS OR GENETICALLY MODIFIED ANIMALS AND THEIR DERIVATIVES  
**INFORMATION ON THE APPLYING INSTITUTION**
  1. Name of Institution in Charge;
  2. Address for contact with CIBio;
  3. Name, title and address of the Person Legally in Charge and the Chief Technician;
  4. CIBio opinion, including comments on the ability of the Chief Technician to manage the works, adequacy of experimental plan contained in the proposal, selection of location and emergency security plan;
  5. Statement for the purpose that “The information contained in this document is, to the best of my knowledge, complete, accurate and true”. (name and signature of the Person Legally in Charge, and date);
  6. CIBio endorsing statement: “CIBio has assessed and endorses this proposal” (name, date and signature of the President of CIBio); and
  7. Name and signature of the Person Legally in Charge, and date.

- ANNEX II  
INFORMATION ON THE GMM or GMAn
  1. Information on the **species of Genetically Modified Microorganism or Genetically Modified Animal to be released** (include, as appropriate, scientific name, subspecies, lineage, etc.);
  2. Information on genetic modifications introduced and their consequences;
  3. Information on vector used and methodology of transformation;
  4. Description of exogenous DNA/RNA sequence, indicating the regulating elements that may be present;
  5. Indication of one or more markers (phenotypic, cytogenetic or molecular) that enable identification of the GMM or GMAn;
  6. Information on number of proceedings approved by CTNBio of which the current proposal is a sequel;
  7. Description of genetic characteristics of the GMM or GMAn that may affect their survival in the environment;
  8. Information on measures taken to contain gene flow;
  9. Description on how survival of the GMM or GMAn will be monitored at the location of the planned release;
  10. Information on whether the release relates to GMM or GMAn, as well as type of derivative, its composition, degradability, possible toxic or allergenic effect.

- ANNEX III

**INFORMATION ON THE PLANNED RELEASE OF THE GMM OR GMAn AND THEIR DERIVATIVES**

1. Title of proposal;
2. Purpose of the proposal;
3. Address of the proposed location where the planned release is to be conducted;
4. Procedures for transporting the GMM or GMAn and their derivatives to the location of the planned release, indicating their origin;
5. Experimental protocol for the planned release and monitoring during the experiment – include biosafety and discarding procedures, information on the size of the total area of GMM or GMAn and their derivatives planned release;
6. Information on the date foreseen for starting the planned release;
7. Information on the date foreseen for the completion of the planned release;
8. Description of supervision procedures for the area of planned release and safety procedures to be conducted by the persons in charge;
9. CIBio shall make a list of individuals in charge for developing the experiment and describe the training given to staff members, together with a letter informing the installation of the experiment;
10. Information on whether there will be or not a transfer or sending of material for analysis or storage by another unit and what will the destination be;
11. Information on whether the planned release is likely to affect the characteristics or abundance of other species, and how this will be monitored;
12. In case the GMM or GMAn and their derivatives remain in the environment after the planned release experiment, inform: length in time and possible consequences, and the monitoring to be conducted; and
13. Measures to be taken to remove the GMM or GMAn and their derivatives in case of any evident threat occurs during the planned release experiment.

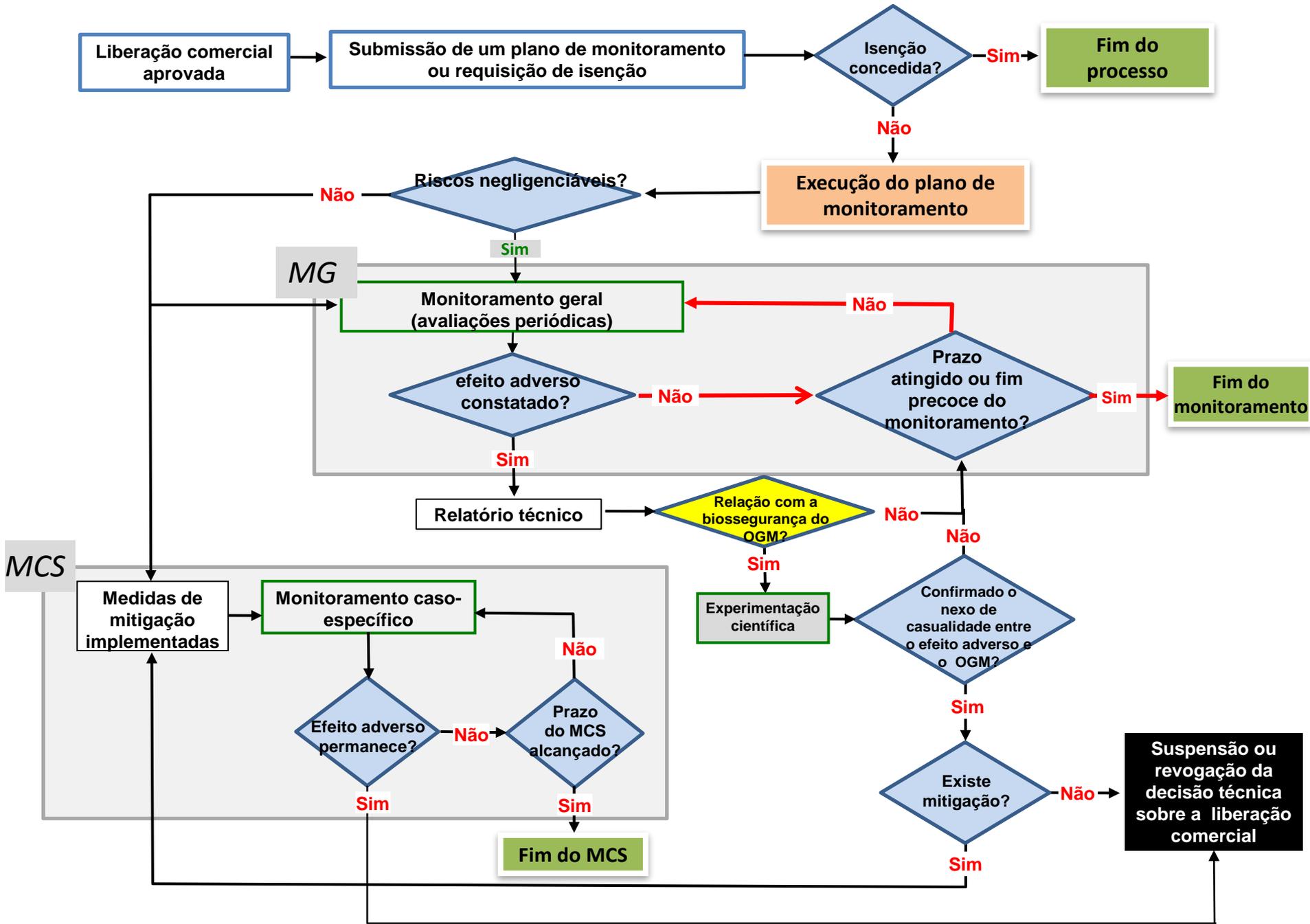
- ANNEX IV

**MAPS AND SKETCHES FOR THE PLANNED RELEASE INTO THE ENVIRONMENT OF A GMM OR GMA<sub>n</sub> AND THEIR DERIVATIVES**

1. Name of Municipality and State;
2. Name of property and property's owner;
3. Full address of the property, telephone, fax and electronic address;
4. Sketch, indicating the name of the main highway of access to the property, reference to the nearest city identifying the entrance to the property, kilometer of reference for entering the property and secondary/feeder road;
5. Map of the area accredited by CQB, including:
  - Map size and scale used. Inform cartographic (nominal and graphic) scale, orientation by compass card and by geographic and topographic coordinates, as the case may be, of the experimental area.
  - Indication of any existing improvements;
  - Identification of boundaries of CQB accredited area;
  - Identification of permanent protection areas and legal reserve;
  - Indication of water bodies (rivers, rivulets, natural and artificial lakes, dams);
6. Location of the experiment, including geographic coordinates, within the area accredited by CQB. In case it proves necessary to change the location, within the same area accredited by CQB and under CTNBio rules, the applicant shall inform the exact location within fifteen (15) days from the establishment of the experiment.

# CTNBio

- **Post-commercial release monitoring system.**
- **Normative Resolution nº 9, of December 2, 2011**
- Makes provisions on rules for genetically modified organisms postcommercial release monitoring.
- All commercial releases must be approved by the CNBS.



# GM FOOD ANIMAL SAFETY

- WHAT SHOULD WE BE AFRAID OF?
  - NEW PROTEIN AFFECT ANY IMPORTANT CELLULAR PATHWAY?
  - IS THE FINAL PRODUCT TOXIC? AT WHICH DOSE?
  - ALLERGIES?
  - HORMONES? ENDOCRINE DISRUPTORS?

# TO TEST OR NOT TO TEST?

- FDA says no.
- 3”R”s – reduce, replace and refine the use of animals.
- HARMONIZATION

# No Long-term Feeding Toxicities on the Health Status in Rats Fed with Cloned Korean Native Beef Cattle (Hanwoo) Meat

NAM-JIN LEE<sup>1,2</sup>, BYOUNG-CHUL YANG<sup>3</sup>, GI-SUN IM<sup>3</sup>, SUNG-SOO LEE<sup>3</sup>, HWAN-HOO SEONG<sup>3</sup>, JIN-KI PARK<sup>3</sup>,  
WON-KYONG CHANG<sup>3</sup>, JONG-KOO KANG<sup>1,2</sup>, AND SEONGSOO HWANG<sup>3</sup>

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Chungbuk, Republic of Korea*

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<sup>3</sup>*Animal Biotechnology Division, National Institute of Animal Science, Gyeonggi-do, Republic of Korea*

## ABSTRACT

This study was designed to undertake a risk assessment to identify the health status of rats fed with somatic cell nuclear transfer (SCNT)-cloned Korean native beef cattle (Hanwoo) meat for 26 weeks. The rats were randomly divided into 5 groups, each consisting of 12 male ( $142.6 \pm 5.23$  g) and 12 female ( $113.7 \pm 6.31$  g) rats each. The animals were fed commercial pellets (control), pellets containing 5% (N-5) and 10% (N-10) of normal cattle meat, and diets containing 5% (C-5) and 10% (C-10) of cloned cattle meat. The mortality; clinical signs; body weight; food consumption; urinary, hematology, blood biochemistry, and histopathological analyses; and absolute and relative organ weights were analyzed and compared. During the 26-week test period, health status-related factors of the rats fed on cloned Hanwoo meat were found to have no test substance-related toxicities. The only difference was the increased uterus weight in female C-10 rats as compared to their counterparts counterparts ( $p <$

## **CTNBio: rigor and transparency on GMO biosafety assessment in Brazil**

Flavio Finardi Filho\*

Science applied to agriculture has been increasing the food offer for many years, thus reducing the need to find new farming areas. In Brazil, the truth of such statement is proven by the fact that in the past 20 years the production volume increased by over 100%, while the total growing area increased only by 25%. In the period, the Brazilian primary sector became one of the most competitive, innovative agriculture in the world. Together with other methods, biotechnology made management easier and increased productivity. Most Brazilian cotton, maize and soy is genetically modified (GM) and helps the country to strengthen its farming industry.

The transgenic safety assessments follow international standards defined by the World Health Organization (WHO) and by the Food and Agriculture Organization of the United Nations (FAO/UN), institutions that already support GM food, as many others, such as the Pontifical Academy of Sciences. In Brazil, GMOs approved are submitted to toxicological, allergenic, nutritional and environmental testing that go through the National Technical Biosafety Committee (CTNBio), group connected to the Science, Technology and Innovation Ministry (MCTI).



**TENSÃO** - Reunião da CTNBio foi acompanhada por 50 integrantes do MST; contra liberação, membros da comissão saíram em protesto



# CONCEA – National Council for the Control of Animal Experimentation

- Arouca Law 11.794, October 8<sup>th</sup>, 2008.
- “ The creation and use of animals for research and teaching in all national territory obey the criteria established in this law”.
- 3 “R” s
- CEUA – Comission of Ethics in the Use of Animals.

## Ministério da Ciência, Tecnologia e Inovação

Temas



### Conselho Nacional de Controle de Experimentação Animal - CONCEA

- >> Consulta CEUA - Projetos
- >> Instituições Credenciadas no CONCEA
- >> O CONCEA
- >> Extratos de Pareceres Técnicos de Solicitações de Credenciamento - publicados no DOU
- >> Cadastro das Instituições de Uso Científico de Animais - CIUCA
- >> Relatório Anual de Atividades -

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## Conselho Nacional de Controle de Experimentação Animal - CONCEA



O Conselho Nacional de Controle de Experimentação Animal (CONCEA) é órgão integrante do Ministério da Ciência e Tecnologia, constituindo-se em instância colegiada multidisciplinar de caráter normativo, consultivo, deliberativo e recursal. Dentre as suas competências destacam-se a formulação de normas relativas à utilização humanitária de animais com finalidade de ensino e pesquisa científica, bem como estabelecer procedimentos para instalação e funcionamento de centros de criação, de

biotérios e de laboratórios de experimentação animal. O Conselho é responsável também pelo credenciamento das instituições que desenvolvam atividades nesta área, além de administrar o cadastro de protocolos experimentais ou pedagógicos aplicáveis aos procedimentos de ensino e projetos de pesquisa científica realizados ou em andamento no País.



## Proteção à Saúde

Agrotóxicos e Toxicologia

Alimentos

Cosméticos

Derivados do Tabaco

Insumos Farmacêuticos

Laboratórios

Medicamentos

Portos, Aeroportos e Fronteiras

Produtos para a Saúde

Saneantes

Sangue, Tecidos e Órgãos

Serviços de Saúde



### Anvisa autorizou 37 pedidos de importação do Canabidiol

A Anvisa já autorizou até o momento 37 dos 54 pedidos de importação dos medicamentos a base do CBD encaminhados à Agência, a partir de abril do corrente ano.

+ VER MAIS

### Consulta Produtos



Tire suas dúvidas sobre produtos e empresas.

ACESSE AQUI

### Notificação - Notivisa



Relate aqui problemas encontrados no uso dos produtos sob vigilância sanitária.

ACESSE AQUI

**Talidomida**  
Apoio, informação e orientação

**CURSO DE MANIPULADORES DE ALIMENTOS**  
JÁ DISPONÍVEL

**Acesso à Informação**

**Petições aguardando análise**

**CATEGORIZAÇÃO DOS SERVIÇOS DE ALIMENTAÇÃO**

Pós - Comercialização / Pós - Uso

Destaque

Notícias

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1 ||

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**CARTA DE SERVIÇOS AO CIDADÃO**



**METEOROLOGIA**

### ESCOAMENTO

Exportação de soja aumenta em 6 milhões de toneladas

Foto: Sérgio Furtado



### METEOROLOGIA

Tempo seco e quente

### AGROPAUTA

## Serviços e Sistemas

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# ***Conclusion***

CTNBio will analyze the GM animals for FOOD according to the Brazilian Biosafety Law and Decree, and the Normative Resolutions.

As the BIOSAFETY process is ROBUST, it will guarantee the safety of humans (public health), animals, vegetables, and the environment.

Thanks!