comissão técnica nacional
CTNBio
de biossegurança

Regulators building public trust

The example of CTNBio

Brazil

Maria L. Z. Dagli / Luiz Sergio Camargo

CTNBIO, Brazil

Animal Biotech Workshop

November 2020

comissão técnica nacional
CTNBio
de biossegurança

What is the CTNBio?

CTNBio is a multidisciplinary collegiate body, created by the Law No. 11.105, of March 24th, 2005, whose purposeses are :

- ✓Provides **technical advisory support** and advice to the Federal Government in the formulation, updating and implementation of the National Biosafety Policy on GMO.

- ✓Establishes 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.

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Law nº 11.105, dated March 24th, 2005

"Biosafety Law"

Purpose and Scope

- ✓ **Protection of human, animal and plant life and environment**
- ✓ **It covers research activities and commercial use**
- ✓ **Meets monthly**
- ✓ **Case by case analysis**

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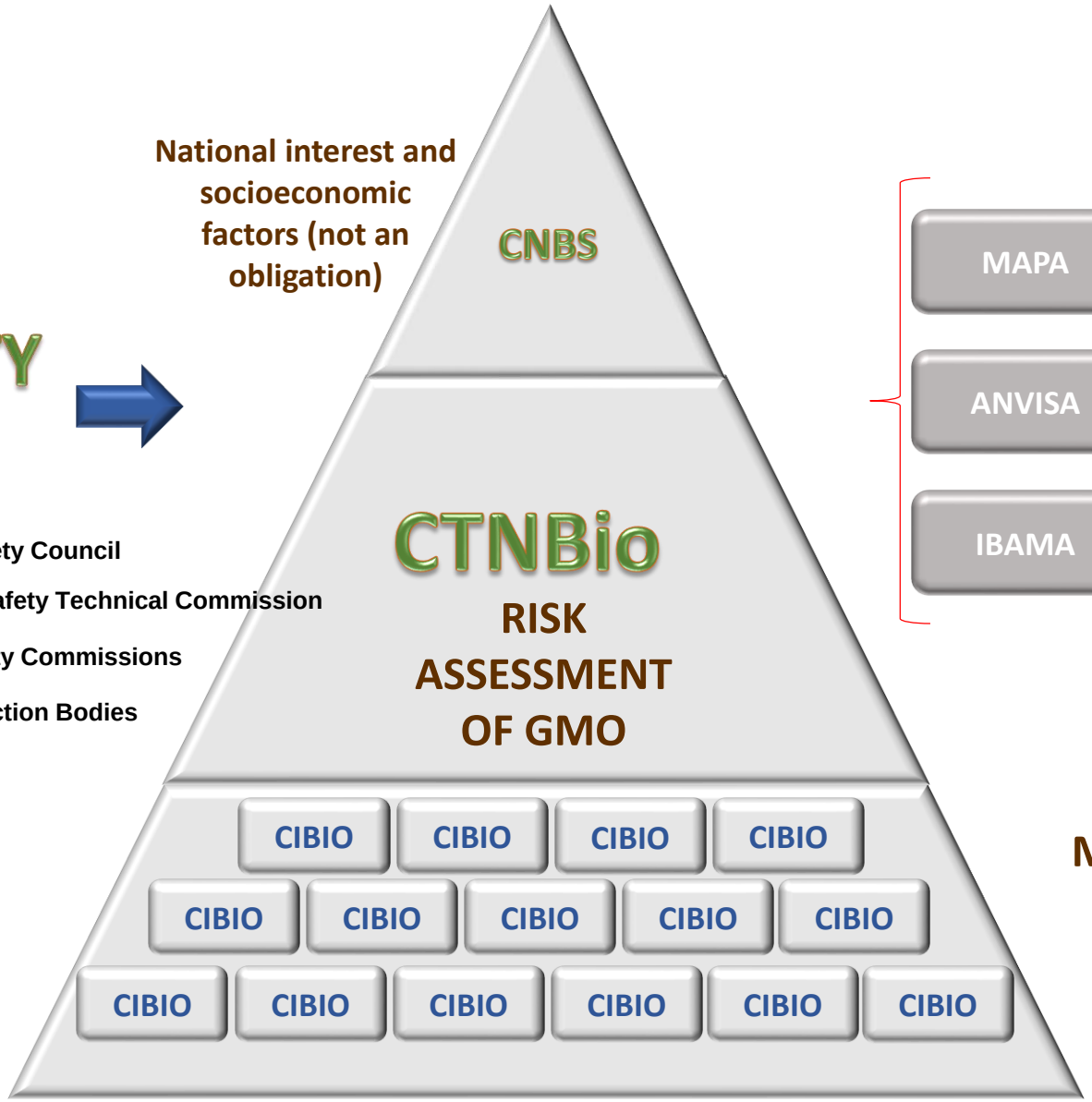
BIOSAFETY LAW

- CNBS=National Biosafety Council
- CTNBIO=National Biosafety Technical Commission
- CIBIO=Internal Biosafety Commissions
- Registration and Inspection Bodies



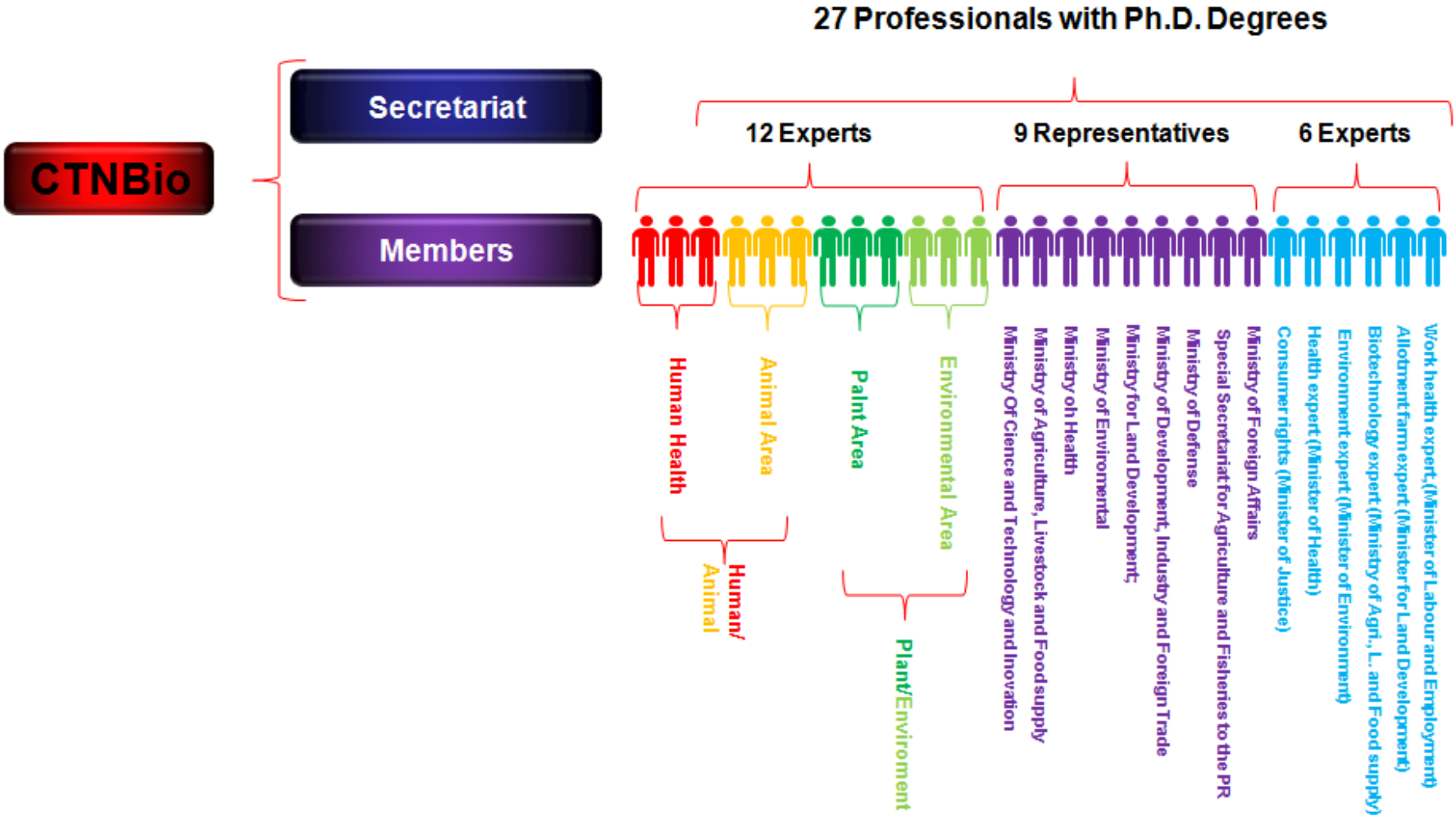
REGISTRATION AND INSPECTION

- MAPA — Agriculture
- ANVISA — Human Health
- IBAMA — Environmental

Maintenance of biosafety

comissão técnica nacional
CTNBio
de biossegurança

Composition of The National Biosafety Technical Commission (CTNBio)



Source: CTNBio (http://www.ctnbio.gov.br/)

HOW DOES CTNBIO FOSTER PUBLIC CONFIDENCE/TRUST?

comissão técnica nacional
CTNBio
de biossegurança

TRANSPARENCY

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).

TRANSPARENCY OF CTNBIO

CTNBIO webpage

all agendas, minutes and activities are available to the public

Comissão Técnica Nacional de

Biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES

Avisos

INSCRIÇÕES PARA A 237ª REUNIÃO ORDINÁRIA DA CTNBIO - DEZEMBRO DE 2020

A Comissão Técnica Nacional de Biossegurança - CTNBio realizará, em caráter ordinário, sua 237ª Reunião Ordinária, no dia 03 de dezembro do corrente ano, por meio da modalidade virtual de "webconferência". Com vistas a possibilitar a participação de pessoas externas à Comissão, estamos...

Visualizar »

Destaques

EDITAL DE CONSULTA PÚBLICA Nº 2 DE 2020

O PRESIDENTE DA CTNBIO, no uso de suas atribuições legais, considerando a deliberação da Comissão Técnica Nacional de Biossegurança na 232ª Reunião Ordinária, resolve submeter a proposta...

TRANSPARENCY OF CTNBIO

CTNBIO monthly meetings

are opened to public attendance

-registration needed-

Comissão Técnica Nacional de

Biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES

INSTITUCIONAL

- A CTNBio
- Secretaria Executiva
- Processo de OGM
- Reuniões
  - Atas
  - Pautas
  - Deliberações
  - Calendários das Reuniões
- Relatórios Anuais
- Audiência Pública

Avisos

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TRANSPARENCY OF CTNBIO

Normative Resolutions of CTNBIO
PUBLIC CONSULTATIONS

(Ex. RN 2 – RN 18)

TRANSPARENCY OF CTNBIO

New Products that are under evaluation
to **commercial release**

PUBLIC AUDIENCE

Fundação Padre Anchieta é parcialmente ou totalmente financiada pelo governo do Estado de São Paulo. Wikipedia

#JTCultura

Liberação do trigo transgênico é pauta em audiência no Ministério da Ciência, Tecnologia e Inovação

Audiência Pública - Trigo Geneticamente Modificado - CTNBio

274 assistindo agora • Stream iniciado há 104 minutos

91 4 COMPARTILHAR SALVAR

Ministério da Ciência, Tecnologia e Inovações
33,3 mil inscritos

INSCREVER-SE

Principais mensagens

Lenilce Santos Fora transgênico

Francisco C. Siliprandi Kuwer "ausência de evidencia não é evidencia da ausência"

Marcelo Lima dos Santos O alimento seguro, a saúde pública, o meio ambiente.... estamos precificando a vida! Não aos OGMs!!!

Eliane Borges Não ao trigo transgênico.

Valério Pillar Os argumentos da empresa interesada na liberação apenas evidenciam ausência de precaução.

Pedro Jesus Muito bom Nodari!! QUeremos Agroecologia, e não queremos venenos!!

Albanise Pfeifer Coelho Não ao trigo transgênico!

Gabriel B Fernandes Parabéns, professor Nodari. Viva Andrés Carrasco!

Pedro Jesus NÃO AO TRIGO TRANSGÊNICO

Vivi Excelente apresentação professor Nodari!

Maria Dagli
Diga algo...

0/200

OCULTAR CHAT

Próximo REPRODUÇÃO AUTOMÁTICA

Reconhecimento Facial com Microcontroladores e...
Ministério da Ciência, Tecnologia...
19 assistindo

Drought resistant wheat

TRANSPARENCY OF CTNBIO

Transparency

regarding the scientific community

regular CIBIO meetings

“ENCIBIO”

TRANSPARENCY OF CTNBIO

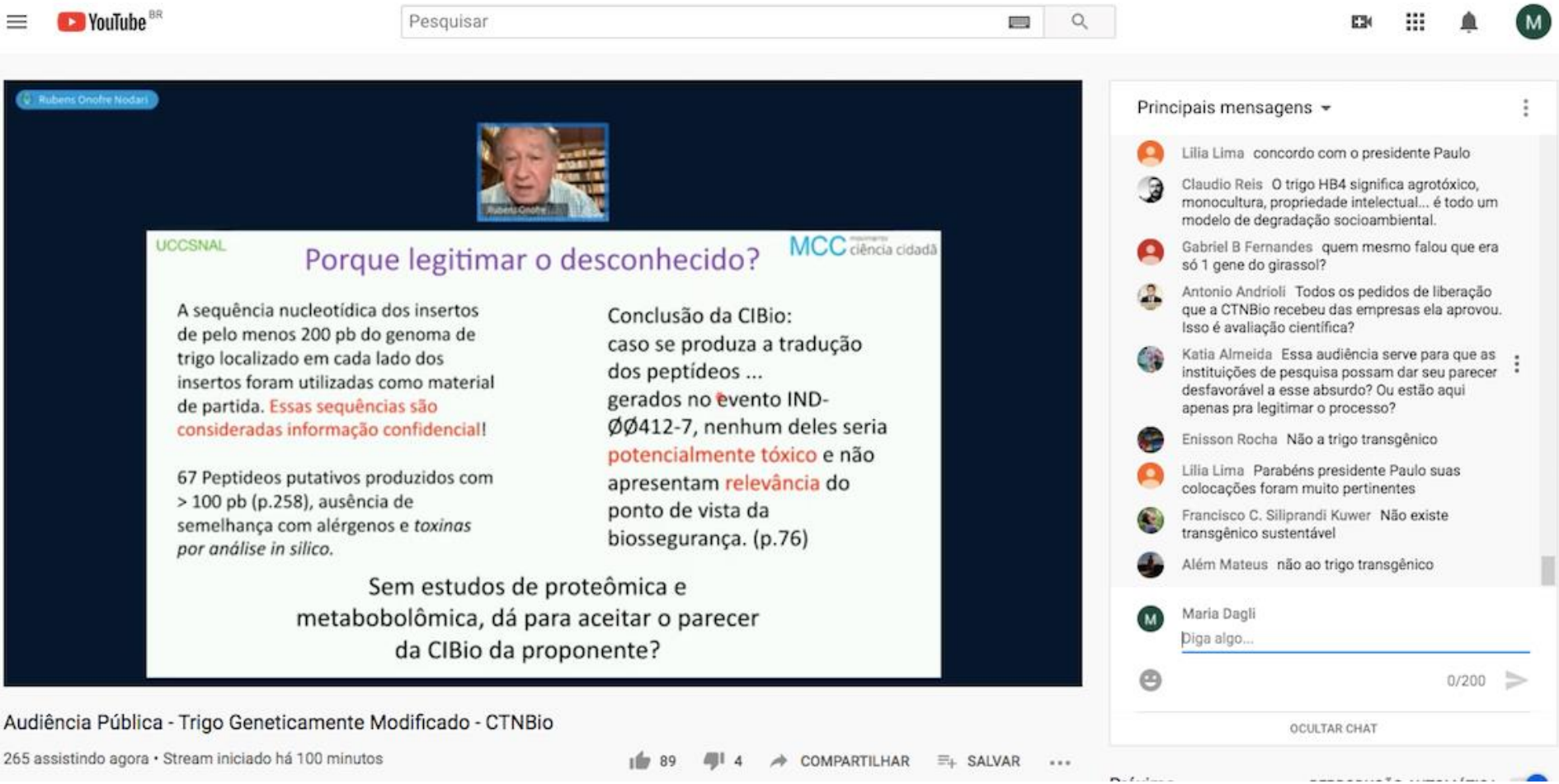
Transparency

regarding the general public

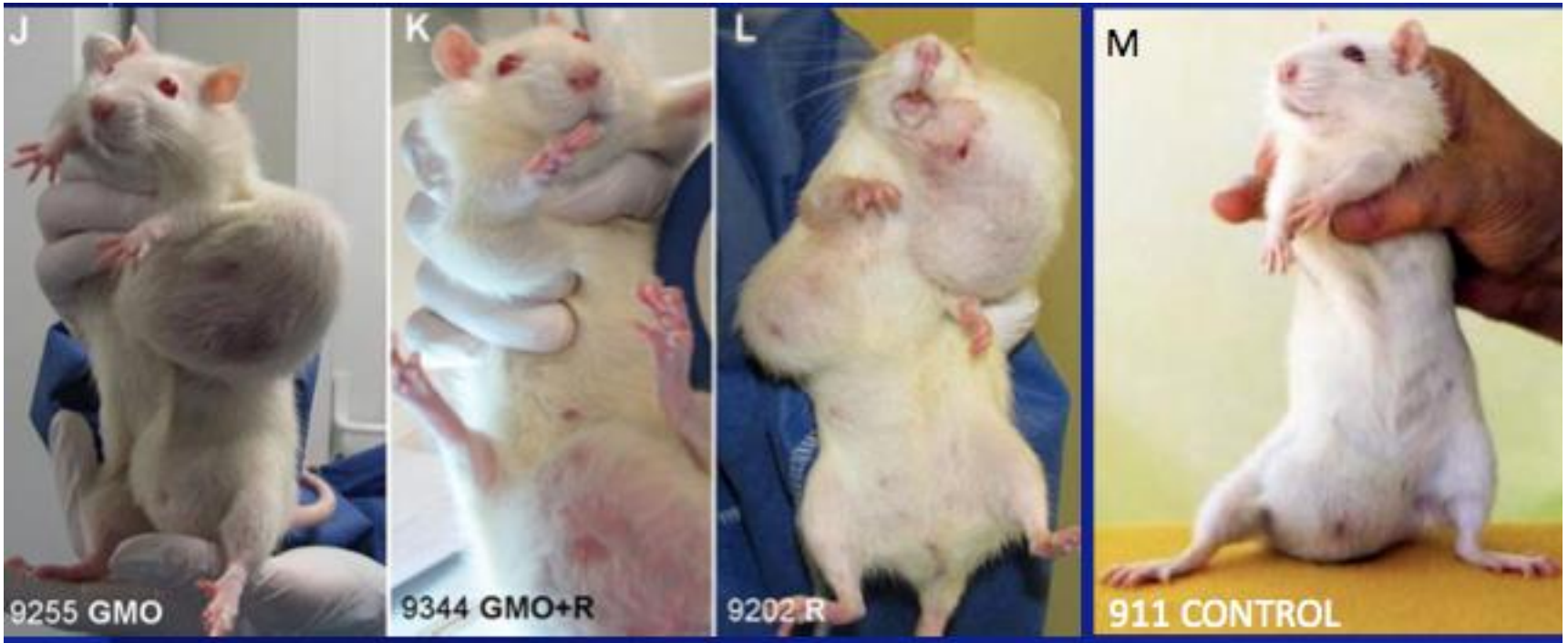
CTNBIO presidency and members are frequently invited to talk about GMO, gene edition, new products that are released for commercialization

(TV, radio, journals, etc.)

IS TRANSPARENCY ENOUGH TO BUILD PUBLIC TRUST?


YouTube BR
Pesquisar
Rubens Onofre Nodari
UCCSNAL
Porque legitimar o desconhecido?
MCC movimento ciência cidadã
A sequência nucleotídica dos insertos de pelo menos 200 pb do genoma de trigo localizado em cada lado dos insertos foram utilizadas como material de partida. Essas sequências são consideradas informação confidencial!
67 Peptideos putativos produzidos com > 100 pb (p.258), ausência de semelhança com alérgenos e toxinas por análise in silico.
Conclusão da CIBio:
caso se produza a tradução dos peptídeos ...
gerados no evento IND-ØØ412-7, nenhum deles seria potencialmente tóxico e não apresentam relevância do ponto de vista da biossegurança. (p.76)
Sem estudos de proteômica e metabobolômica, dá para aceitar o parecer da CIBio da proponente?
Audiência Pública - Trigo Geneticamente Modificado - CTNBio
265 assistindo agora • Stream iniciado há 100 minutos
89
4
COMPARTILHAR
SALVAR
Principais mensagens
Lilia Lima concordo com o presidente Paulo
Claudio Reis O trigo HB4 significa agrotóxico, monocultura, propriedade intelectual... é todo um modelo de degradação socioambiental.
Gabriel B Fernandes quem mesmo falou que era só 1 gene do girassol?
Antonio Andrioli Todos os pedidos de liberação que a CTNBio recebeu das empresas ela aprovou. Isso é avaliação científica?
Katia Almeida Essa audiência serve para que as instituições de pesquisa possam dar seu parecer desfavorável a esse absurdo? Ou estão aqui apenas pra legitimar o processo?
Enisson Rocha Não a trigo transgênico
Lilia Lima Parabéns presidente Paulo suas colocações foram muito pertinentes
Francisco C. Siliprandi Kuwer Não existe transgênico sustentável
Além Mateus não ao trigo transgênico
Maria Dagli
Diga algo...
0/200
OCULTAR CHAT

Seralini
et al., 2012



Food and Chemical Toxicology 50 (2012) 4221–4231

Contents lists available at SciVerse ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize

Gilles-Eric Séralini [a,*], Emilie Clair [a], Robin Mesnage [a], Steeve Gress [a], Nicolas De[illegible]rge [a], Manuela Malatesta [b], Didier Hennequin [c], Joël Spiroux de Vendômois [a]

[a] University of Caen, Institute of Biology, CRIIGEN and Risk Pole, MRSH-CNRS, EA 2608, Esplanade de la Paix, Caen Cedex [illegible]032, Franc[illegible]
[b] University of Verona, Department of Neurological, Neuropsychological, Morphological and Motor Sciences, Verona 37[illegible], Italy
[c] University of Caen, UR ABTE, EA 4651, Bd Maréchal Juin, Caen Cedex 14032, France

ARTICLE INFO

Article history:
Received 11 April 2012
Accepted 2 August 2012
Available online 19 September 2012

Keywords:
GMO
Roundup
NK603
Rat
Glyphosate-based herbicides
Endocrine disrupting effects

ABSTRACT

The health effects of a Roundup-t[illegible] genetically [illegible]dified maize (from 11% in the diet), cultivated with or without Roundup, and [illegible]undup alone (from 0.[illegible]ppb in water), were studied 2 years in rats. In females, all treated groups die[illegible]2–3 times more than controls, and more rapidly. This difference was visible in 3 male groups fed GMO[illegible] All results we[illegible] hormone and sex dependent, and the pathological profiles were comparable. Female[illegible]veloped lar[illegible] mammary tumors almost always more often than and before controls, the pituitary wa[illegible]e second[illegible]ost disabled organ; the sex hormonal balance was modified by GMO and [illegible]p treatme[illegible] treated males, liver congestions and necrosis were 2.5–5.5 times higher. This p[illegible]thologi[illegible]s confirmed by optic and transmission electron microscopy. Marked and severe kidney nep[illegible]ropa[illegible]es w[illegible] also generally 1.3–2.3 greater. Males presented 4 times more large palpable t[illegible]ors than a[illegible]ols which occurred up to 600 days earlier. Biochemistry data confirmed very signifi[illegible]t kid[illegible]y chron[illegible] deficiencies; for all treatments and both sexes, 76% of the altered parameters


Liver (M)
9129 C
9129 C
8892 GMO
9135 GMO+R
8899 R
Kidney (M)
F
G
H
I
F'
I'
9528 C
8892 GMO
8891GMO+R
9118 R
9528 C
Mammary glands (F)
J
K
L
J'
K'
L'
9255 GMO
9344 GMO+R
9202 R
9255 GMO
9202 R
M 8787 C
N 9255 GMO
O 9344 GMO+R
P 9202 R

SCIENTIFIC REPORTS
natureresearch

OPEN

Transgenic *Aedes aegypti* Mosquitoes Transfer Genes into a Natural Population

Received: 11 February 2019
Accepted: 29 August 2019
Published online: 10 September 2019

Benjamin R. Evans[1], Panayiota Kotsakiozi[1], Andre Luis Costa-da-Silva[2,3], Rafaella Sayuri Ioshino[2,3], Luiza Garziera[3], Michele C. Pedrosa[2,3,4], Aldo Malavasi[4], Jair F. Virginio[4], Margareth L. Capurro[2,3] & Jeffrey R. Powell[1]

In an attempt to control the mosquito-borne diseases yellow fever, dengue, chikungunya, and Zika fevers, a strain of transgenically modified *Aedes aegypti* mosquitoes containing a dominant lethal gene has been developed by a commercial company, Oxitec Ltd. If lethality is complete, releasing this strain should only reduce population size and not affect the genetics of the target populations. Approximately 450 thousand males of this strain were released each week for 27 months in Jacobina, Bahia, Brazil. We genotyped the release strain and the target Jacobina population before releases began for >21,000 single nucleotide polymorphisms (SNPs). Genetic sampling from the target population six, 12, and 27–30 months after releases commenced provides clear evidence that portions of the transgenic strain genome have been incorporated into the target population. Evidently, rare viable hybrid offspring between the release strain and the Jacobina population are sufficiently robust to be able to reproduce in nature. The release strain was developed using a strain originally from Cuba, then outcrossed to a Mexican population. Thus, Jacobina *Ae. aegypti* are now a mix of three populations. It is unclear how this may affect disease transmission or affect other efforts to control these dangerous vectors. These results highlight the importance of having in place a genetic monitoring program during such releases to detect un-anticipated outcomes.

Mosquito-borne diseases take a tremendous toll on human health and economies especially in Third World countries. Effective vaccines and drugs are available for only a few so the major means of controlling these diseases is to control the mosquitoes that transmit them. As traditional methods of control, such as insecticides, have become less effective and acceptable, alternative methods have been sought[1]. Methods based on genetic manipulations are among the most appealing and actively pursued[2]. One such genetic-based program has involved releasing a

Notícias

Carta da Presidência da CTNBio sobre o artigo publicado na Scientific Reports referente a mosquitos transgênicos

« Back

TECHNICAL NOTE FROM CTNBio'S PRESIDENT AND VICE PRESIDENT (National Technical Commission of Biosafety) regarding the recently published article in Scientific Reports entitled: Transgenic Aedes aegypti Mosquitoes Transfer Genes into a Natural Population, Evans et al. Scientific Reports, Vol 9, Article number: 13047 (2019).

CTNBio is a technical and scientific Commission created by the Brazilian Biosafety Law 11.105, in March 23, 2005. The CTNBio is composed by 54 scientist bearing PhD title, and meets 10 times a year in Brasilia in order to analyze, on a case by case basis, the safety of genetically modified organisms for human and animal health, plants and the environment. The process is robust and transparent, so that documents used in the analysis and all the decisions are published in CTNBio's homepage (http://www.ctnbio.mctic.gov.br).
CTNBio analyzes projects in contention, the planned releases in the environment and the commercial releases of GMO.
After the analysis of the article in Scientific Reports entitled: Transgenic Aedes aegypti Mosquitoes Transfer Genes into a Natural Population, Evans et al. Scientific Reports, Vol 9, Article number: 13047 (2019) by members of the CTNBio, population genetics specialists and technology developers from universities and companies, with the objective of controlling disease-causing vectors of high relevance to Brazilian Public Health, CTNBio raises the following considerations in relation to the above mentioned Article published in a renowned international journal in the scientific area.

1. From the methodological point of view the authors used a very robust, high performance SNPs array with number of markers and appropriate analysis, as well as gene introgression in mosquito populations;

2. The genetic background of the Oxitec's strain OX513A originated from the crossing of two other highly susceptible to insecticides strains from Cuba and Mexico, precisely to minimize its persistence in the environment. The Brazilian strains do not present high sensitivity to insecticides, due to the long-term use of chemical agents to control the mosquito that transmits diseases of high relevance to the Public Health;

http://ctnbio.mctic.gov.br/en/noticias1/-/asset_publisher/XmL81XricRmS/content/carta-da-presidencia-da-ctnbio-sobre-o-artigo-publicado-na-scientific-reports-referente-a-mosquitos-transgenicos?redirect=/en/inicio&

We are hereby contacting the Editors of the Scientific Reports journal to clarify the rigorous criteria used by CTNBio, based on scientific data and experiments, which guide all the technicalscientific decisions made by this Biosafety Committee in Brazil.

Finally, it is important to highlight that all experimental work and commercial use of this technology, which is on the frontier of knowledge in Brazil and in the world and, implies in risks and uncertainties is under a permanent analysis and surveillance by CTNBio with total transparence with the facts. This is what CTNBio has always done and will continue to do in order to make its decisions.

Sincerely,

Maria Sueli Felipe
CTNBio President

Maria Lucia Zaidan Dagli
CTNBio Vice President

SCIENTIFIC REPORTS
natureresearch

OPEN

Editorial Expression of Concern: Transgenic *Aedes aegypti* Mosquitoes Transfer Genes into a Natural Population

Published online: 24 March 2020

Benjamin R. Evans, Panayiota Kotsakiozi, Andre Luis Costa-da-Silva, Rafaella Sayuri Ioshino, Luiza Garziera, Michele C. Pedrosa, Aldo Malavasi, Jair F. Virginio, Margareth L. Capurro & Jeffrey R. Powell

Addendum to: *Scientific Reports* https://doi.org/10.1038/s41598-019-49660-6, published online 10 September 2019

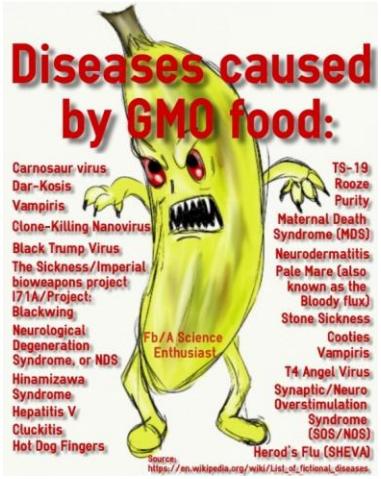
The Editors are issuing an Editorial Expression of Concern for this Article.

Shortly after publication of this Article in September 2019, the Editors were alerted to concerns regarding the interpretation of the data and some of the conclusions. Specific concerns include:

- the title does not make it clear that the authors only examined genomes of specimens that lacked the transgenes and sampled during the release period;
- the Abstract and Introduction use language which is not justified given the evidence present in the peer reviewed literature and the data presented in this Article. No sampling for this study was conducted more than a few weeks after the release program, and as such there is no evidence in the Article to establish whether the non-transgenic, introgressed sequences from the released strain remained in the population over time. Furthermore, previous work from some of the authors (Reference 6 in the Article) showed that over time, the transgene is lost from the population, but the Article does not disclose this information;
- in the Discussion, the authors claim that because of the distinct genetic backgrounds of different mosquito populations (two used to create OX513A mosquitoes, and one local population), the existing population in Jakobina is more robust than the original wild population due to hybrid vigour. There are no data in the Article to support this point; furthermore, data included in the Article indicate that a number of hybrid individuals rapidly declined post-release;
- the conclusion of the Article highlighting "the importance of having in place a genetic monitoring program during such releases" could be misunderstood to mean that such program was not in place. The Mosquito release program in Jakobina is monitored by the Brazilian regulator, the National Technical Commission of Biosafety (CTNBio).

When contacted about these issues, some of the authors indicated that they had not approved the final version that was submitted for publication.

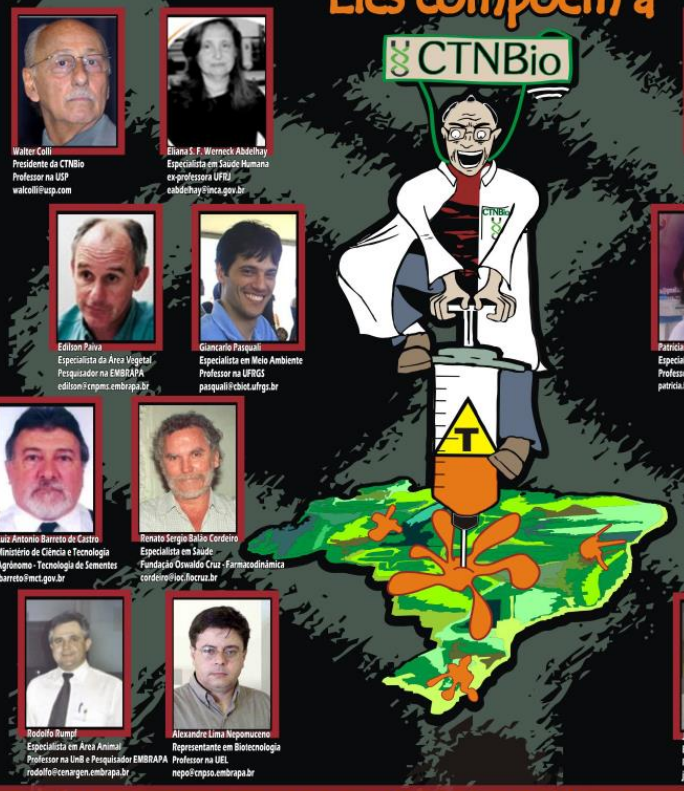
World GMO Madness



Estes são Doutores favoráveis aos

TRANSGÊNICOS

Eles compõem a CTNBio



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"O que vemos na prática cotidiana da CTNBio são votos pré-concebidos e uma série de artimanhas obscurantistas no sentido de considerar as questões de biossegurança como dificuldades ao avanço da biotecnologia. A razão colocada em jogo na CTNBio é a racionalidade de mercado..."

Dra. Lia Giraldo, em sua Carta de Desligamento da CTNBio (17/05/07)

CTNBIO - COMISSÃO TÉCNICA NACIONAL DE BIOSEGURANÇA

Por um Brasil Livre de Transgênicos

Mais Informações "Campanha Brasil Livre de Transgênicos"

www.feab.org.br

www.abeef.cib.net

FEAB

ABEEF - UNE

ADRIANO MACHADO/AE

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


DILMA,
veneno no meu
prato não.
GREENPEACE
DILMA,
veneno no meu
prato não.
GREENPEACE
GREENPEACE


NÃO QUEREMOS


NÃO QUEREMOS +
TRANSGÊNICOS

government
trust
public
political
attitudes
service
performance
administrators
nations
citizens
institutions
citizen
likely
efficacy
people
trusting
perceptions
competence
social
individual
trustworthiness
research
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correlates
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However
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number
reforms
state
dimension
question
questions
relationship
process
support
following
commitment
agree
binary
satisfaction
Bouckaert
Christensen
hypothesis
greater
attributes
education
effectiveness
respondent
corruption
used
democratic
capital
among
examine
important
system
study
Laegreid
Van
analysis
administration
others
federal
found

Thank you!

Questions?

mlzdagli@usp.br