

# **PREMASUR- MERCOSUR'S REGIONAL PLATAFORM FOR ALTERNATIVE METHODS TO ANIMAL EXPERIMENTATION**

**Pan-American Conference for Alternative Methods  
August 23-24, 2018**

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Ministry of Industry, Foreign Trade  
and Services

*The National Institute of Metrology, Quality and Technology (Inmetro) was created by law in December, 1973, to support Brazilian enterprises, to increase their productivity and the quality of goods and services.*

PROVIDE CONFIDENCE TO THE  
SOCIETY CONCERNING  
MEASUREMENTS AND PRODUCTS

PROMOTING HARMONIZATION IN  
CONSUMPTION RELATIONS, INOVATION  
AND COMPETITIVENESS

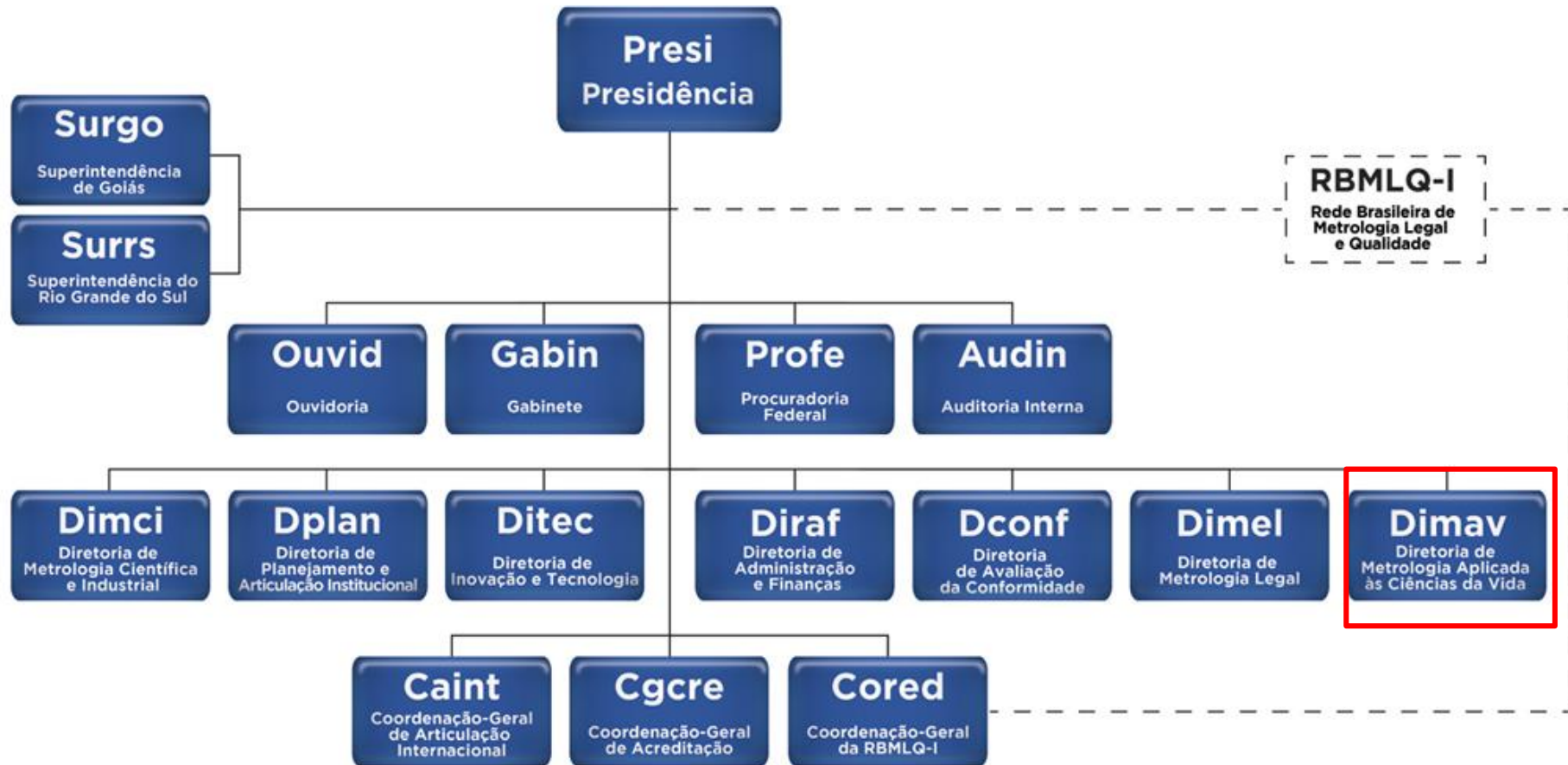
through:

METROLOGY and CONFORMITY  
ASSESSMENT

## Inmetro's Main Activities

- ❖ Scientific and Industrial Metrology;
- ❖ Legal Metrology;
- ❖ Conformity Assessment Regulations;
- ❖ Accreditation of Laboratories and Certification Bodies;
- ❖ GLP Monitoring Authority;
- ❖ WTO/TBT Enquiry Point.
- ❖ Market Surveillance/Consumer information





**Dimav**

**Life Sciences Metrology**

**Lamav**

**Microscopy**

*Optical,  
electronic,  
High throughput*

**Lamic**

**Microbiology**

*identification,  
quantification,  
preservation*

**Labio**

**Cell culture**

*Authentication  
Tissue-equivalents  
in vitro toxicology*

**Lamac**

**Macromolecules**

*DNA, carbohydrate  
and protein  
analysis*

**Lqbio**

**Small biological  
molecule  
analysis**

**Pharma  
scale-up**





The National Network of Alternative Methods - RENAMA  
Was created by  
Ministry of Science, Technology, Innovation and Communication -  
MCTIC, is supervised by a Steering Committee.

2012



I - promote the **implementation, development and validation** of alternative methods to the use of animals;

II - to promote the adoption of alternative methods to the use of animals in teaching and research activities;

III - to stimulate the implantation of alternative methods to the use of animals **through technical training and implementation of validated methodologies**;

IV - periodically monitor the performance of the associated laboratories through **interlaboratory comparisons**;

V - to promote the quality of the tests using the development of certified chemical and biological reference materials, where applicable;

VI - to encourage the implementation of the laboratory quality system and the principles of good laboratory practice (**GLP**);

VII - to **disseminate knowledge** in the theme of alternative methods to the use of animals;

VIII - offer, within the Network's laboratories, services for toxicological tests using alternative methodologies to the use of animals.



**ASSOCIATED LABS: 39**  
**CENTRAL LABS: 3**







**Initiative of the Ministry of Science, Technology, Innovation and Communication (MCTIC), Brazil**

**Proposed and Approved in Specialized Meeting of Science and Technology (RECyT - Reunião Especializada em Ciência e Tecnologia (RECyT))  
2016**

### **Objectives:**

**To insert the theme “Alternative Methods” in MERCOSUR and to promote the creation of a laboratorial infrastructure and specialized human resources capable of implementing alternative methods to animal testing in their respective countries.**

- I. To stimulate the adoption of validated alternative methods;**
- II. To promote the qualification and training of qualified human resources;**
- III. To promote research, development and validation of new alternative methods**
- IV. To promote laboratorial competence in MERCOSUR.**



➤ **CONCEA** – National Council for the Control of Animal Experimentation

- ***Normative Resolution no. 18/2014***
- ***Normative resolution no. 31/2016***

- ✓ **Skin Corrosion/Irritation: OECD TG 430, 431, 435, and 439;**
- ✓ Eye Corrosion: **OECD TG 437**, 438, and 460;
- ✓ Phototoxicity: **OECD TG 432**;
- ✓ Skin Absorption: **OECD TG 428**;
- ✓ Skin Sensitisation: OECD TG 429, 442A, and 442B;
- ✓ Acute Toxicity: OECD TG 420, 423, 425, and 129\*;
- ✓ Genotoxicity: **OECD TG 487** Eye Irritation/non classified: **OECD TG 491, and 492**;
- ✓ Skin Sensitisation: **OECD TG 442C, and 442D**;
- ✓ Reproduction/Developmental Toxicity: OECD TG 421, and 422\*;
- ✓ Bacterial Endotoxin Test: Evaluation of pyrogenic contamination in injectable products



## THEORETICAL – PRATICAL COURSES 40h

❖ **IN VITRO** METHODOLOGY DETERMINED BY CONCEA (RN 18 e 31)

❖ RENAMA's Specialists (**Associates and Centrals**)

✓ Programing 60% practical 40% theoretical

<b>15 VAGAS</b>	<b>Membros plenos</b>	 Argentina (1991)	 Brasil (1991)	 Paraguai (1991)	 Uruguai (1991)	 Venezuela (2012) (suspensa)
	<b>Estados associados</b>	 Chile (1996)	 Bolivia (1996) (em processo de adesão)	 Peru (2003)	 Colômbia (2004)	 Equador (2004)
	<b>Estados observadores</b>	 Nova Zelândia (2010) <sup>[66]</sup>			 México ( <i>Não disponível</i> )	



# THEORETICAL – PRATICAL COURSES

## 40h

### ❖ Lecture Material (PPT, SOPs, etc)

MERCADO COMUM DO SUL  
REUNIÃO ESPECIALIZADA DE CIÊNCIA E  
TECNOLOGIA

REPÚBLICA FEDERATIVA DO BRASIL  
MINISTÉRIO DA CIÊNCIA, TECNOLOGIA,  
INOVAÇÕES E COMUNICAÇÕES

**PLATAFORMA REGIONAL DE MÉTODOS ALTERNATIVOS DO MERCOSUL**

Certificamos que **Ricardo Sergio Couto de Almeida** participou do curso teórico-prático "Métodos in vitro para avaliação do potencial genotóxico de substâncias químicas", realizado no Instituto Nacional de Controle de Qualidade em Saúde – INCQS / FIOCRUZ, no Rio de Janeiro-RJ, no período de 31 de outubro a 04 de novembro de 2016.

Luciene Bottenhuit López Balottin  
Coordenadora do Projeto

Luiz Henrique M. do Canto Pereira  
Coordenador da CPB/RECYT/Mercosul  
Brasil

Isabella Fernandes Delgado  
Coordenadora do Curso

os Alternativos ao Uso de Animais de Experimentação no MERCOSUL

ção do potencial genotóxico de substâncias químicas

jado

PROGRAMA

**ÁULAS PRÁTICAS**

1. Ensaio Cometa: preparação de lâminas com agerose
2. Planejando os ensaios Mm vitro. Prática Sistema teste (CHO-K1): Observação ao microscópio (morfologia esperada), Impresãoção, planejamento para o ensaio
3. Ensaio Cometa: Teste com células de sangue humano; tratamento mutagênico in vitro; preparação das lâminas; teste das preparações
4. Ensaio Mm vitro: Preparo da substância teste. Tratamento com extrato de fígado de rato. Exposição do sistema teste às substâncias de interesse
5. Ensaio Cometa: tratamento alcalino e eletrofose; neutralização e secagem das lâminas
6. Ensaio de Mm vitro, tratamento com colchicina e preparação das lâminas
7. Ensaio Cometa: coloração e avaliação microscópica
8. Ensaio Mm vitro: coloração e análise das lâminas
9. Interpretação de resultados e elaboração de relatório.

Carga horária: 40 horas

PLATAFORMA REGIONAL DE MÉTODOS ALTERNATIVOS AO USO DE ANIMAIS DE EXPERIMENTAÇÃO DO MERCOSUL - PReMASUL

Ministério da Ciência, Tecnologia, Inovações e Comunicações

[TÍTULO DO DOCUMENTO]

PROGRAMA

DIA 1 (8h)

8h00-8h30	Boas-vindas, apresentação do curso e participantes.
8h30-9h00	Módulo teórico - Métodos Alternativos
	Módulo teórico
	CITOTOXICIDADE: Toxicidade aguda em ensaios com animais existentes; a Citotoxicidade (OECD GD 129) : métodos limitações, controles internos de resultados esperados.

CURSO XX/2017 – [Título do Curso]

TÍTULO DO DOCUMENTO

Página 1/2

1. **Objetivo**  
Definir o objetivo do documento
2. **Siglas**
3. **Termos**
4. **Reagentes e soluções**
5. **Materiais e equipamentos**
6. **Considerações iniciais**
7. **Limitações**
8. **Princípio do método**

Clique para

**PLATAFORMA REGIONAL DE MÉTODOS ALTERNATIVOS AO USO DE ANIMAIS DE EXPERIMENTAÇÃO DO MERCOSUL - PReMASUL**

Ministério da Ciência, Tecnologia, Inovações e Comunicações

Coordenador(a) Curso

## PREMASUR CALENDAR

I - OECD TG 487	FIOCRUZ	10/2016
II - OECD GD 129 & OECD TG 432	INMETRO	01/2017
III - HET-CAM & OECD TG 437	INMETRO	04/2017
IV - OECD TG 439	Boticário	05/2017
V - <i>ALTERNATIVE METHODS TO ANIMAL EXPERIMENTATION AND REGULATORY ACCEPTANCE</i>	FIOCRUZ	06/2017
VI - OECD TG 428	UFPE	09/2017
VII - TG OECD 491 & OECD TG 492	LN BIO	10/2017
VIII – TG OECD 442C & 442D	UFG	11/2017
IX - OECD TG 487	UFCSPA	05/2018
X- OECD TG 439	PASTEUR- UR	05/2018
XI – OECD TG 428	UFPE	09/2018
XII -TG OECD 491 & OECD TG 492	LN BIO	10/2018
XIII - TG OECD 442C & 442D	UFG	11/2018

## **COURSE 01 - NOV/2016**

**Title: Theoretical-practical course for the use of alternative methods to animal use for evaluation of genotoxic potential of chemical substances.**

**Coordination: Instituto Nacional de Controle de Qualidade em Saúde – INCQS / FIOCRUZ**

**Location: Rio de Janeiro – RJ.**

**168 candidates**

**7 Brazilians**

**1 Argentine**

**1 Paraguayan**

**9 Participants**



## **COURSE 02 - JAN/2017**

**Title: Theoretical-practical course for alternative methods that use Balb 3T3 guidelines as a test system: citotoxicity according to GD129 OECD and phototoxicity according to TG 432 OECD .**

**Coordination: Instituto Nacional de Metrologia, Qualidade e Tecnologia (Inmetro)**

**Location: Duque de Caxias-RJ.**

**58 candidates**

**13 Brazilians**

**13 participants**



## **COURSE 03 - APR/2017**

**Title: Theoretical-practical course for alternative methods to the animal use for the evaluation of the potential to ocular reaction and corrosion of chemical substances.**

**Coordination: Instituto Nacional de Metrologia, Qualidade e Tecnologia (Inmetro)**

**Location: Duque de Caxias-RJ.**

**39 candidates**

**9 Brazilians**

**9 participants**





## **COURSE 04 - MAY/2017**

**Title: Theoretical-practical course of alternative methods that use human skin as a test system: method OECD TG431 – in vitro Dermic Corrosion, method OECD TG 439 – in vitro cutaneous reaction test, and method OECD TG 428 – in vitro cutaneous absorption method.**

**Coordination: Grupo O Boticário**

**Location: São José dos Pinhais, PR.**

**81 Candidates**

**11 Brazilians**

**2 Argentines**

**13 Participants**



## COURSE 05 - JUN/2017

Title: *Validation of alternative methods to animal use and regulatory acceptance.*

Coordination: Instituto Nacional de Controle de Qualidade em Saúde – INCQS / Fiocruz & Instituto Nacional de Metrologia, Qualidade e Tecnologia (Inmetro).

Location: Brasília, DF.

47 Candidates

24 Brazilians

1 Argentine

25 Participants



## **COURSE 06 - SEP/2017**

**Title: OECD TG 428 Method (Cutaneous absorption *in vitro* method)**

**Coordination: Laboratório de Métodos Alternativos do Núcleo de Desenvolvimento Farmacêutico e Cosméticos da Universidade Federal de Pernambuco (NUDFAC/UFPE).  
Location: Recife, PE.**

**49 Candidates**

**7 Brazilians**

**1 Argentine**

**8 Participants**



## **COURSE 07 - OCT/2017**

**Title: Evaluation methods of the ocular reaction and corrosion potential that utilize a *in vitro* cornea model (OECD TG 491 & OECD TG 492).**

**Coordination: Laboratório Nacional de Biociências (LNBIO)**

**Location: Campinas, SP.**

**15 candidates**

**8 Brazilians**

**1 Argentine**

**9 Participants**



## **COURSE 08 - NOV/2017**

**Title: Innovative approaches for the evaluation of potential for dermic sensibilization from chemical products.**

**Coordination: Laboratório de Farmacologia e Toxicologia Celular/ Faculdade de Farmácia - Universidade Federal de Goiás.**

**Location: Goiânia, GO**

**17 Candidates**

**8 Brazilians**

**8 Participantes**



## **CURSO 09 - MAY/2018**

**Title: Use of alternative methods to the animal use for the evaluation of genotoxic potential of chemical substances – *in vitro* evaluation of Micronucleus OECD 48.**

**Coordination: Universidade Federal de de Ciências da Saúde de Porto Alegre.**

**Location: Porto Alegre , RS**

**80 Candidates**

**13 Brazilians**

**13 Participants**



## COURSE 10 - MAY/2018

Title: Alternative methods to animal use for experimentation: *In vitro* evaluation of the skin irritation (TG 439) and sensabilization (TG442E).

Coordination: L'ORÉAL Research & Innovation & Institut Pasteur Montevideo

Location: Montevideo, Uruguay

81 Candidates

2 Brazilians

9 Uruguayans

3 Argentines

14 Participants





## NEXT STEPS (2018-2019)

**2018 TRAINING RN 18 & 31 CONCEA**

**2019 WORKSHOP + TRAININGS**

**635** Candidates

**102** Brazilians

**9** Uruguayans

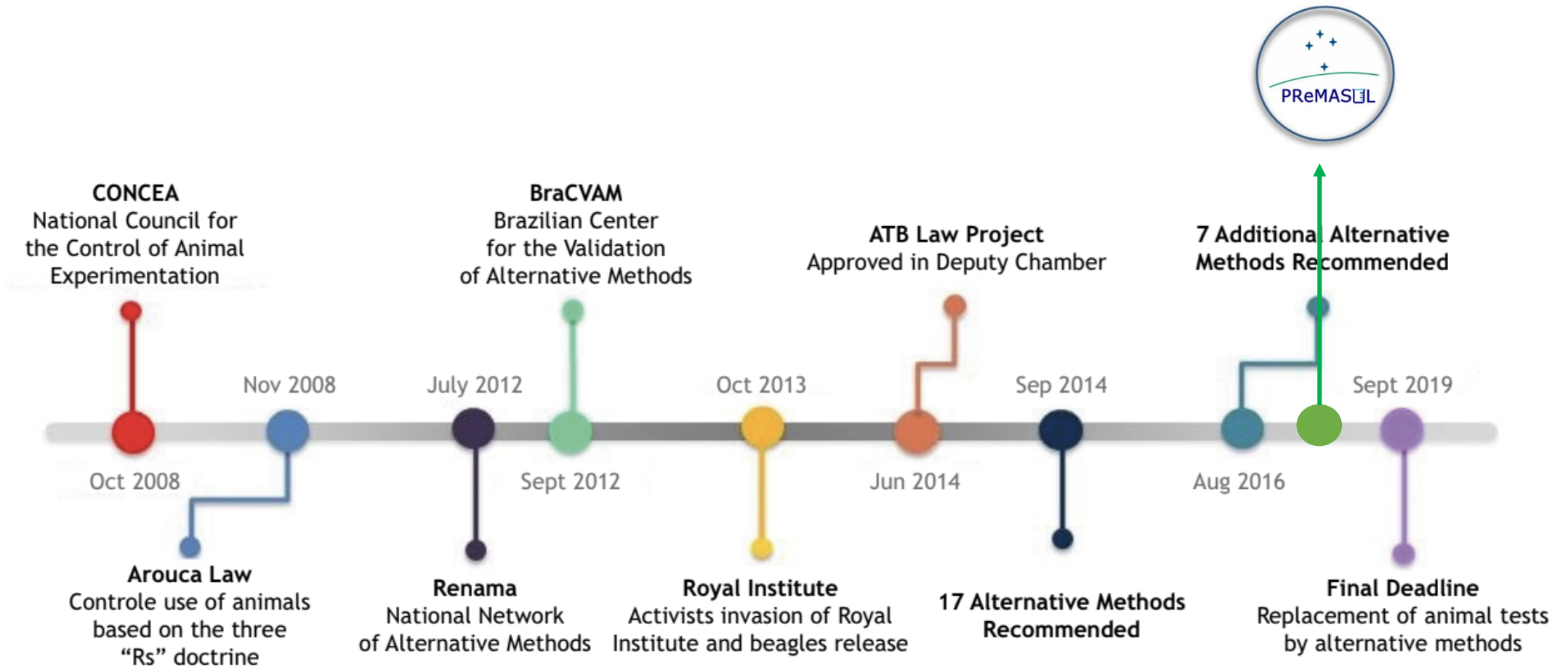
**9** Argentines

**1** Paraguayan

**121** Participants







**Figure 1.** Regulatory evolution related to the control of animal experimentation and alternative methods recognition in Brazil. Since the creation of Concea in 2008, Brazil had significant regulatory advances and its counting down to ban animal testing for several endpoints on September 2019.

De Vecchi et al ,2018

September 2019 !!

**Thank you!**



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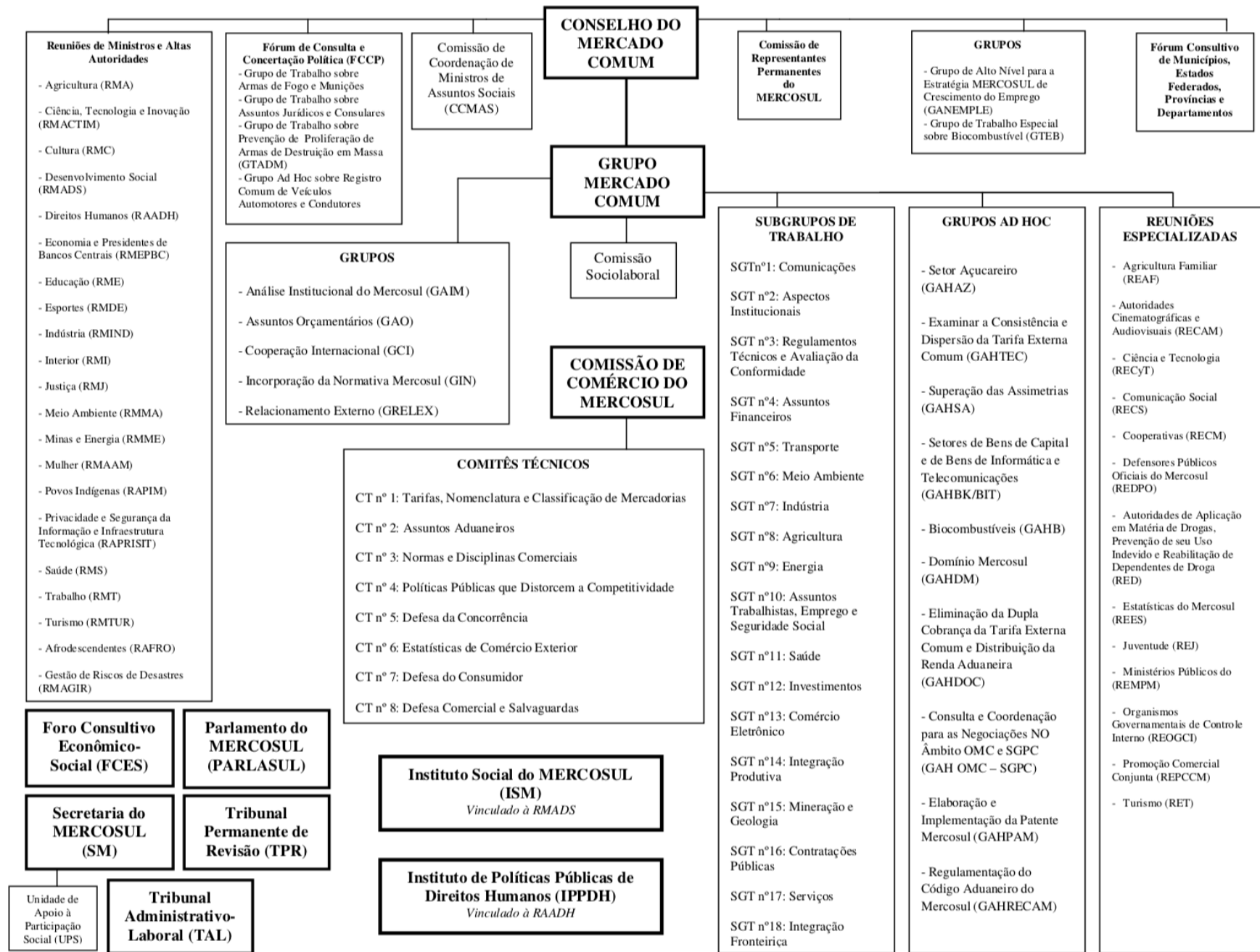
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**[Lbbalottin@gmail.com](mailto:Lbbalottin@gmail.com)**



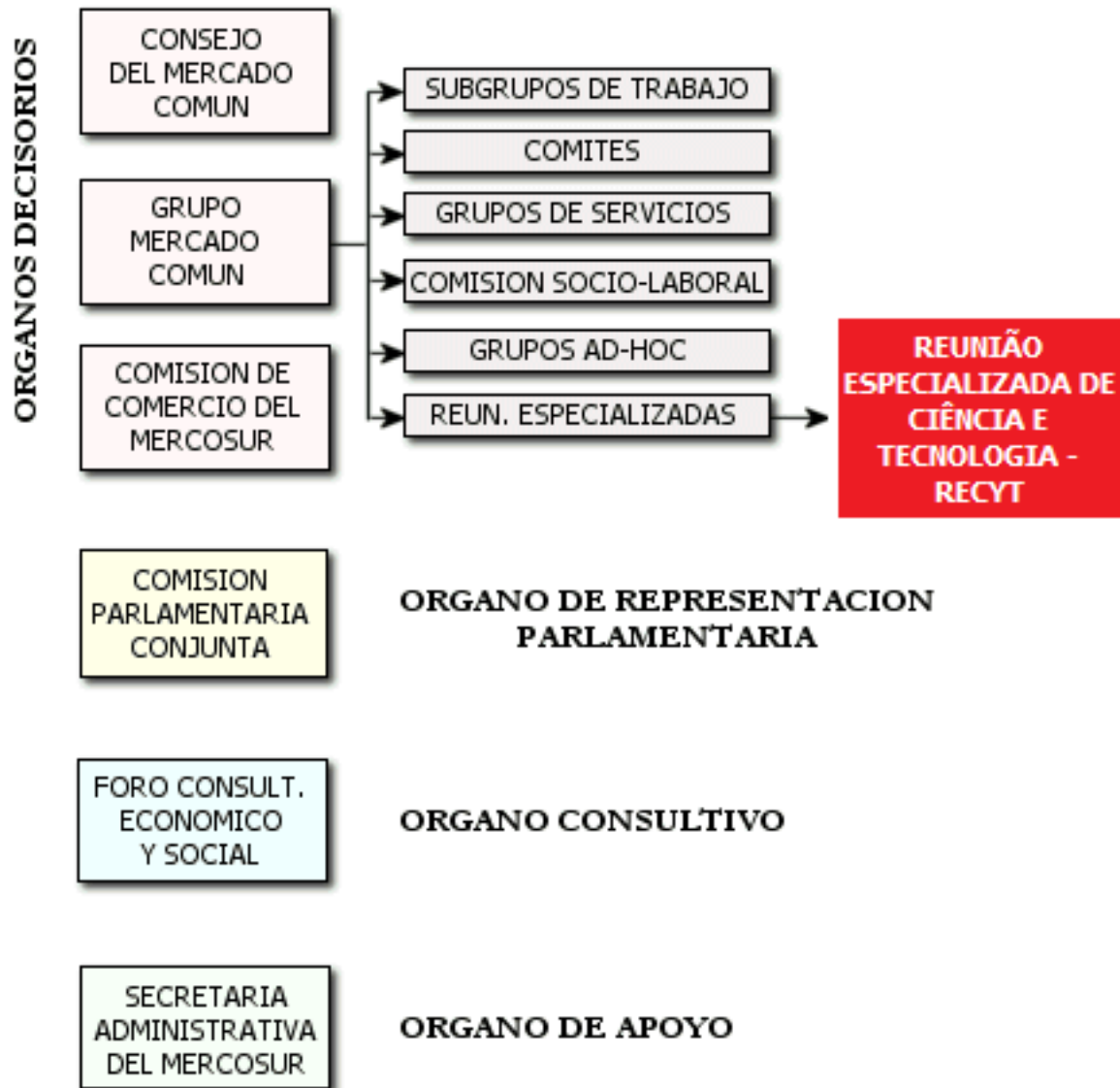


Figura 04 – Fluxo de funcionamento reuniões RECYT

