

Alternative methods in Argentina: regulation, legislation and opportunities for the incorporation of new methodologies



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Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.



European
Commission

Law for animal experimentation

BRAZIL - Law 11,794 (2008)

Also known as the Arouca Law, that regulates the procedures for scientific animals use



URUGUAY Law No. 18,611 (2009)

Use of animals in scientific research activities and teaching



2017- ARGENTINA – A proposal for new legislation was introduced in the congress. It has the approval of one Congress chamber.

Law for the protection of experimentation animals used with scientific and educational purposes.

- ✓ Creation of the National Commission of Animal Experimentation (Conadea)
- ✓ Institutional committees for the care and use of experimental or laboratory animals (CICUAL)
- ✓ Registration and qualification of animal facilities
- ✓ 3Rs application
- ✓ Replace the use of animals whenever possible by **alternative methods**

Cosmetics and household products annual registration

Resolution GMC (Common Market Group) MERCOSUR

Cosmetics (MERCOSUR GMC N° 07/05)

Grade I: initially not evaluation required

Grade II: evaluation required.

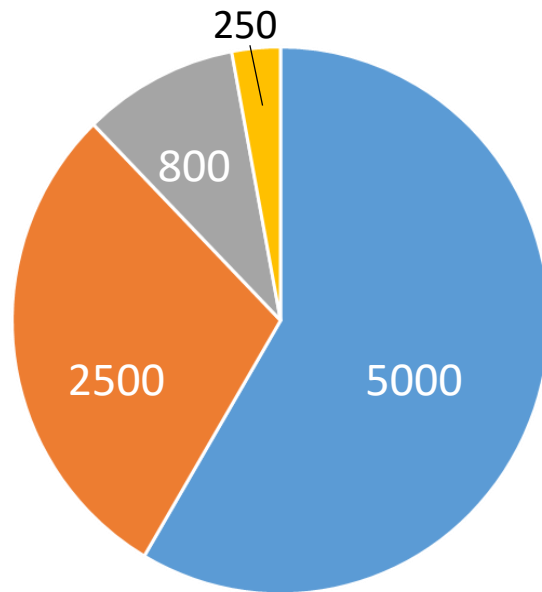
- ✓ Skin irritation (children's products, creams and facial gels, hair colorations, sunscreens, insect repellents)
- ✓ Ocular irritation (products applied in the eye area and children's products)
- ✓ Skin sensitization (products with hypoallergenic label)
- ✓ Phototoxicity (suntan products, mosquito repellents and baby and child colonies)
- ✓ Clinically (states dermatologically/ophtalmologically tested)

Household products (MERCOSUR GMC N.° 50/06)

Risk I: do not require evaluation (detergents, laundry soap)

Risk II: evaluation required (disinfectant, plaguicides and antimicrobial action)

- ✓ Oral toxicity
- ✓ Dermal Toxicity
- ✓ Inhalation toxicity
- ✓ Skin and eye irritation
- ✓ Skin sensitization
- Mutagenicity, teratogenicity and carcinogenicity
- Oral chronic toxicity



■ Cosmetics G I ■ Cosmetics G II
■ Home use R I ■ Home use R II

Without considering drugs and medical devices !



Destination of pesticides produced in Argentina:

- 1° MERCOSUR countries
- 2° Asian and African countries
- 3° European countries and North America

Resolution 350/99: "Procedures Manual for the Registration of Pesticides Products in the Argentine Republic".

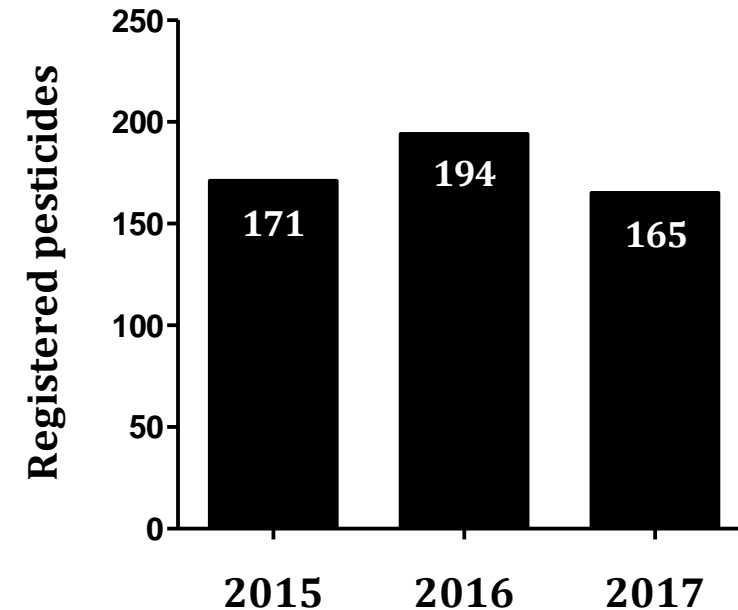
Acute toxicity requirements for the registration of active and formulated products:

- ✓ Oral toxicity
- ✓ Dermal Toxicity
- ✓ Inhalation toxicity
- ✓ Skin and eye irritation
- ✓ Skin sensitization

OECD Guidelines

- Mutagenicity, teratogenicity and carcinogenicity
- Ecotoxicity

SENASA



Estimation of the animal number used per year in Argentina for the registration of cosmetics, households and pesticides

Toxicity	Cosmetics		Households		Pesticides	
	Min	Max	Min	Max	Min	Max
Oral	-	-	2.500	5.000	1.700	3.400
Dermal	-	-	2.500	5.000	1.700	3.400
Inhalatory	-	-	2.500	5.000	1700	3.400
Skin irritation	5.000	7.500	500	750	340	680
Eye irritation	5.000	7.500	500	750	340	680
Skin sensitization	62.500	125.000	6.250	12.500	4.250	8.500
Total	72.500	140.000	14.750	29.000	10.030	20.060

Approximately 97.300 – 190.000



Argentinian companies that provides services of safety and hazard assays:

- 15 laboratories for cosmetics and household testing on animals (ANMAT registered)
- 2 cosmetics testing on human beings (ANMAT)
- 5 agrochemical and chemical industries testing on animals (SENASA)

> **No alternative methods used**

Producing / importing establishments:

- 450 cosmetics (ANMAT)
- 400 households (ANMAT)
- 65 agrochemicals (CIAFA)

Compliance GLP - OECD



TRAINING





Ministry of Science and Technology



Ministerio de
Ciencia, Tecnología
e Innovación Productiva
Presidencia de la Nación

Technology Platform
Preclinical trials



- Laboratory of transgenic animals – INGEBI



- Laboratory of experimental animals
LAE - UNLP



- Laboratory of Clinic and Preclinic
Pharmacology - UBA



INSTITUTO *de*
FARMACOLOGÍA

First laboratory in Argentina dedicated to the incorporation of Alternative Methods with Governmental funding



1° Incorporation of methodologies internationally accepted

2° Development of new methodologies

3° Safety assessment and hazard classification assays for:

- ✓ Cosmetics
- ✓ Households
- ✓ Medical devices
- ✓ Pesticides
- ✓ Drugs

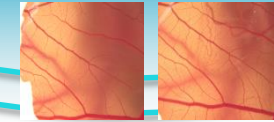
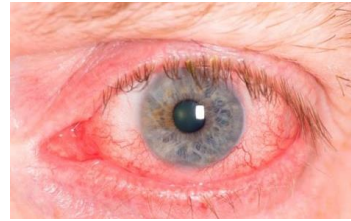


4° Training courses:

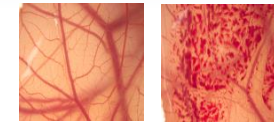
- ✓ To introduce available methodology
- ✓ Practical training on alternative methods



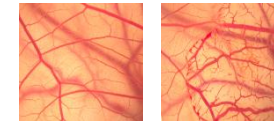
Eye irritation and corrosion



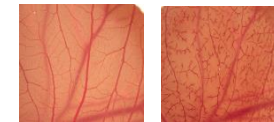
Saline
No Irritante



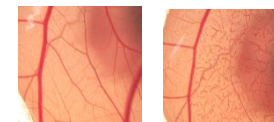
0,1 N NaOH
Irritante Severo



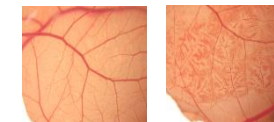
Imidazol
Irritante Severo



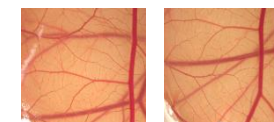
5% Texapon ASV
Irritante Severo



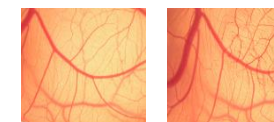
1% SDS
Irritante Severo



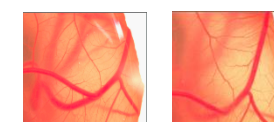
Shampoo 1
Irritante Moderado



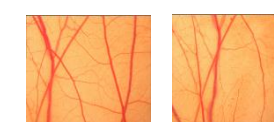
Agua Micelar.
No Irritante



Serum Parpados 1.
Irritante Moderado



Herbicida a base de Glifosato.
Irritante Leve



Herbicida a base de Glifosato.
Irritante Moderado

Time 0 and 300 seg.

HET-CAM: The hen's egg chorioallantoic membrane test

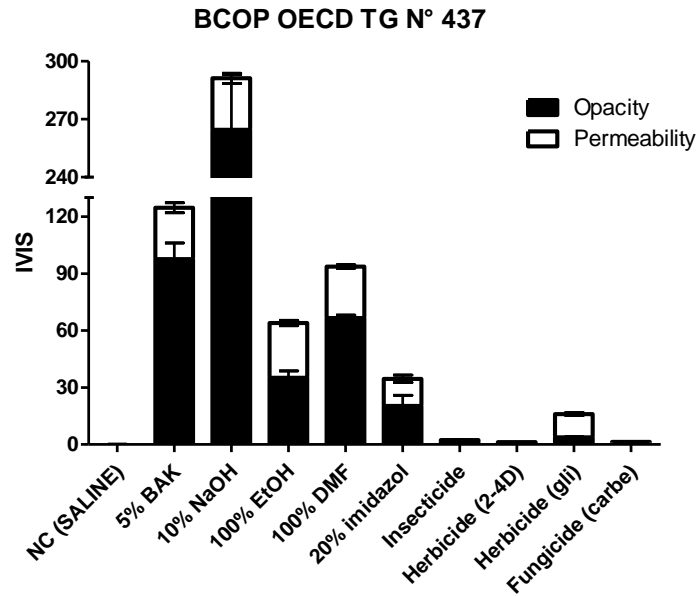
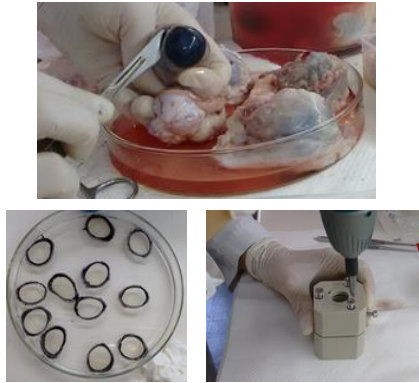
	Características	n	IS	Clasificación
1	Solución Fisiológica	15	0	No irritante
2	Hidroxido de Sodio 0,1 N	10	20	Irritante severo
3	Cloruro de Benzalconio (BAK 0,5 %)	5	11,7	Irritante severo
4	Imidazol solido	4	19	Irritante severo
5	Imidazol saturado	4	19	Irritante severo
6	Texapon ASV 5%	4	12	Irritante severo
7	SDS 1%	8	15	Irritante severo
8	Acido Acetico	2	12	Irritante severo
9	Shampoo 1	5	8	Irritante Moderado
10	Agua Micelar	5	0	No irritante
11	Shampoo 2	4	8	Irritante Moderado
12	Locion Facial	4	0	No irritante
13	Serum Parpados 1	4	8	Irritante Moderado
14	Crema Parpados	4	0	No irritante
15	Serum 1	6	8	Irritante Moderado
16	Serum 2	5	0,8	No irritante
17	Serum Parpados 2	4	0,25	No irritante
18	Contorno de Ojos	6	0,17	No irritante
19	Insecticida Acaricida Sistemico (Dimetoato)	4	8	Irritante Moderado
20	Acaricida/ Insecticida (Avermectina)	4	0,75	No irritante
21	Acaricida/ Insecticida (Aceite mineral parafinico)	4	0	No irritante
22	Insecticida Sistemico (Imidacloprid)	4	0	No irritante
23	Insecticida/ Orugicida (Lambdacialotrina9)	4	0,75	No irritante
24	Fungicida Sistemico (Carbedazim)	3	2,67	Irritante Leve
25	Fungicida (Captan)	4	0	No irritante
26	Fungicida Sistemico (Triazol)	4	1,75	Irritante Leve
27	Hormigüicida (Cipermetrina)	4	0,75	No irritante
28	Fitorregulador (Folcisteina)	4	0	No irritante
29	Herbicida (2-4)	4	1,25	Irritante Leve
30	Herbicida (Glifosato)	4	8	Irritante Moderado

Products approved and used
in Argentina

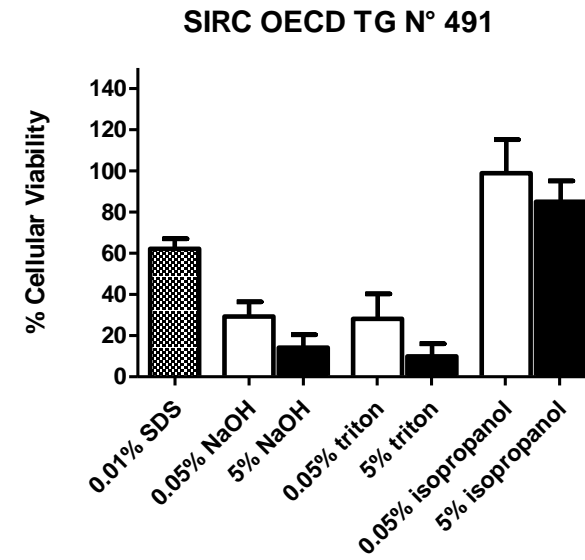
cosmetics



Bovine Corneal Opacity and Permeability Test

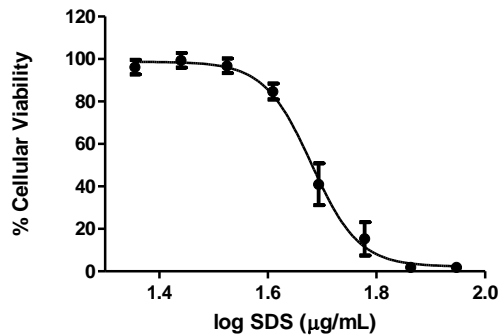


Short Time Exposure In Vitro Test

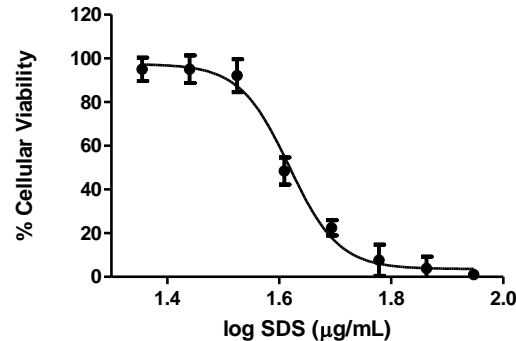


Cytotoxicity test to estimate starting doses for acute oral systemic toxicity

3T3 cells
OECD No. 129



3T3 cells
NIH No. 01- 4500



Phototoxicity test NRU 3T3 (OECD TG 432)



Short term → Skin sensitization

Events that should occur to implement alternative methods in Argentina:

- ✓ Approval of the Law for the protection of experimentation animals
- ✓ Creation of a validation center for alternative methods
- ✓ Show proficiency on the methodologies
- ✓ Acceptance by regulatory organism



- ✓ First PREMASUL course in Argentina 2019
- ✓ Consolidate the implementation of alternative methods as a regional policy
- ✓ Harmonize the legislation and the methodologies to be used within the MERCOSUR taking Brazil as a local model.

**III CONGRESO
LATINOAMERICANO
DE MÉTODOS ALTERNATIVOS
AL USO DE ANIMALES DE
EXPERIMENTACIÓN**
EN EDUCACIÓN, INVESTIGACIÓN
E INDUSTRIA



Reducir, Refinar y Reemplazar:
nuestra responsabilidad y compromiso.

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Thanks for your attention



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