

Ending Cosmetic Animal Testing & Trade in Brazil and Worldwide



HUMANE SOCIETY
INTERNATIONAL

BE 
CRUELTY
FREE

About



HUMANE SOCIETY
INTERNATIONAL

- **Expert team**

Toxicology, ecotoxicology, pharmacology, regulatory science, endocrinology, biochemistry, neuroscience, law, etc.

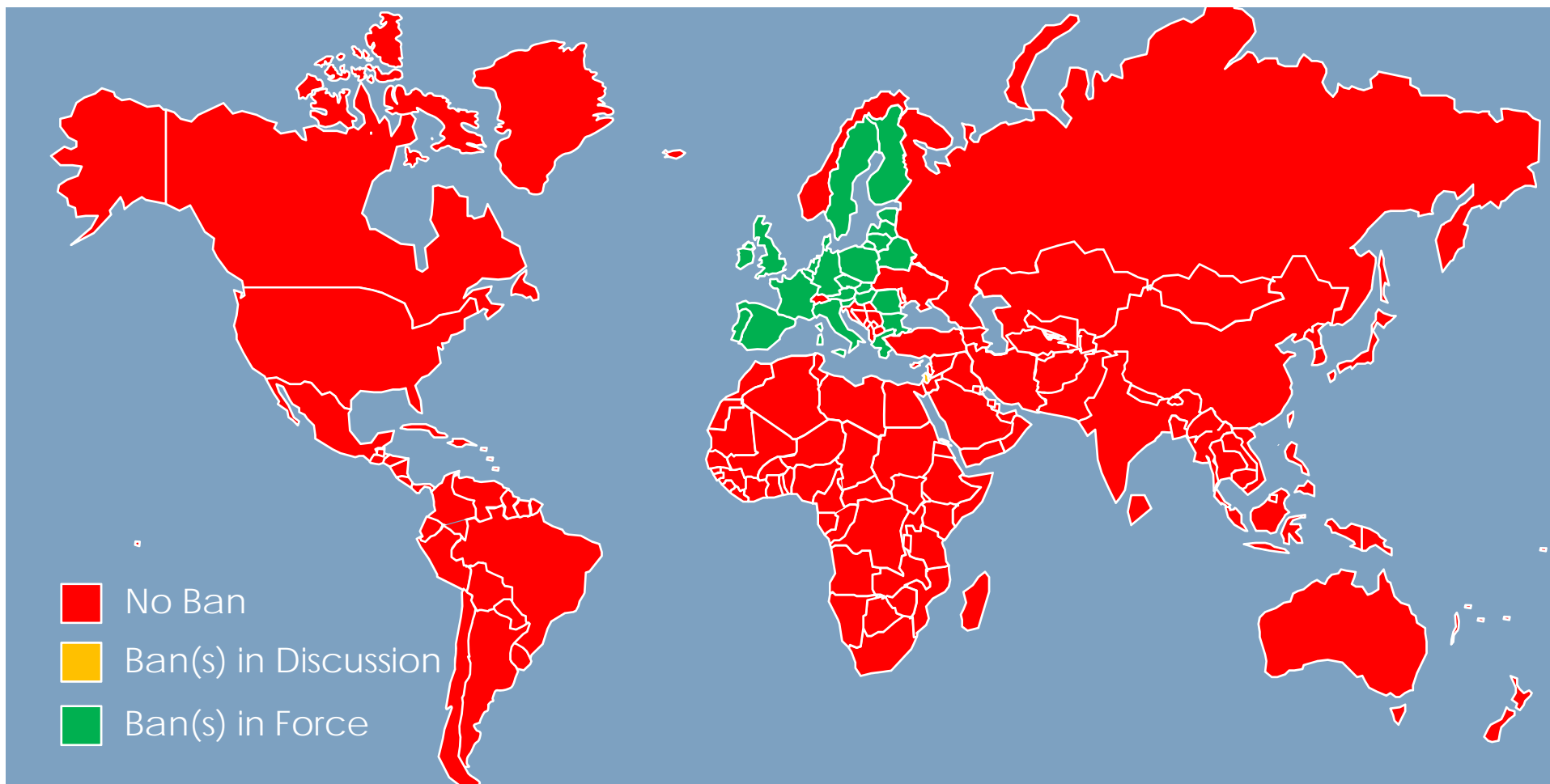
- **Global presence**

Brazil, United States, Canada, Mexico, Central America, European Union, India, Japan, South Korea, Viet Nam, Australia, Africa and beyond

- **Approach**

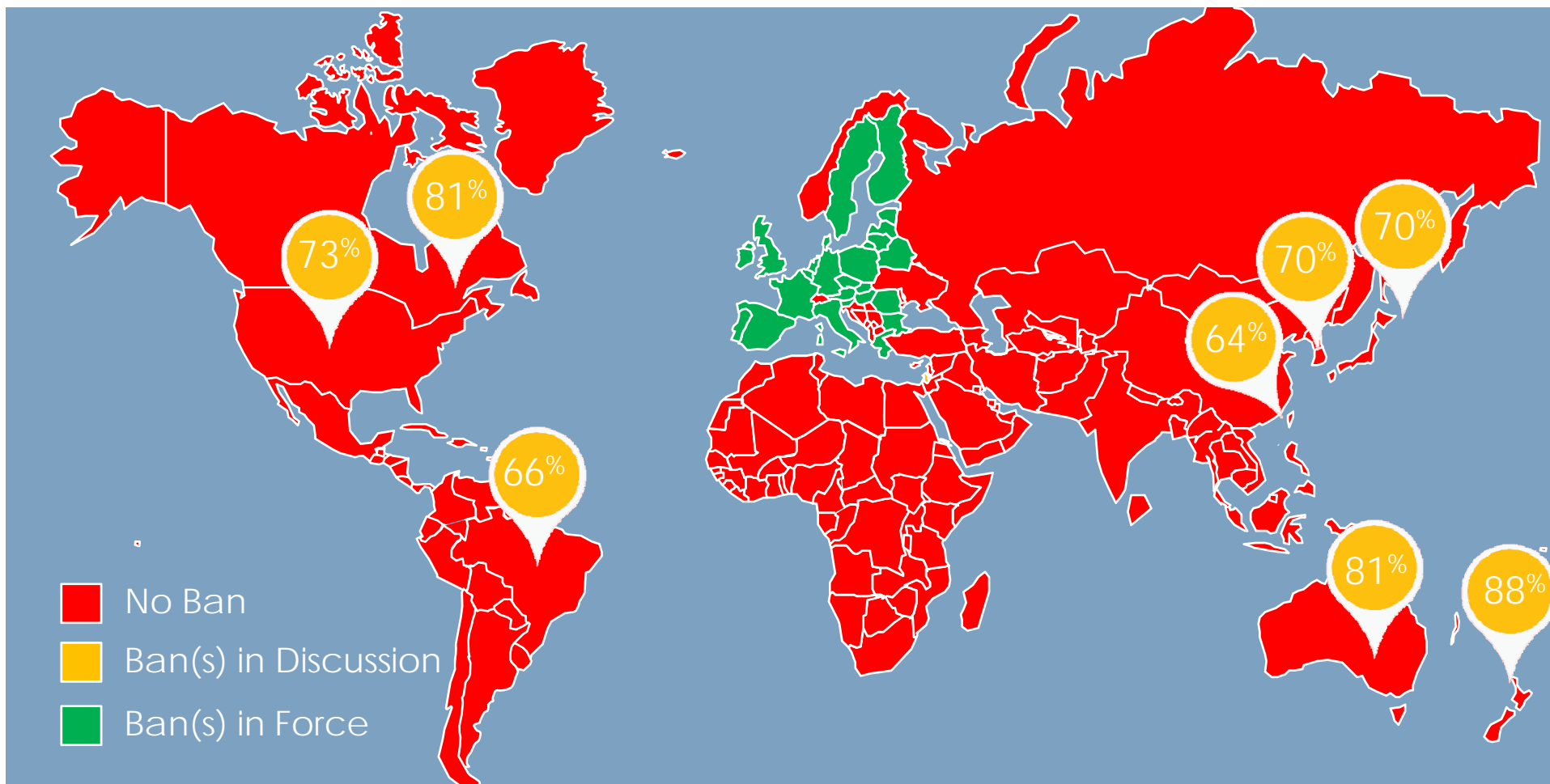
Working with policy makers, regulators, companies, scientists, and other stakeholders to build partnerships for progress

*HSI is the leading
international NGO
working to advance
non-animal testing
& health research
worldwide*



2012: before HSI's global campaign

EU ban on cosmetic animal testing; sales ban uncertain



Polling by HSI & partners

Public support for cosmetic
animal testing ban

The global cruelty-free revolution



2013

- EU – sales ban
- Israel – sales ban
- India – test ban
- **Brazil – PLC 70/2014**

2014

- India – import ban
- **Brazil – São Paulo & Mato Grosso do Sul state test bans**
- China – ends mandatory animal testing for some domestically produced cosmetics

2015

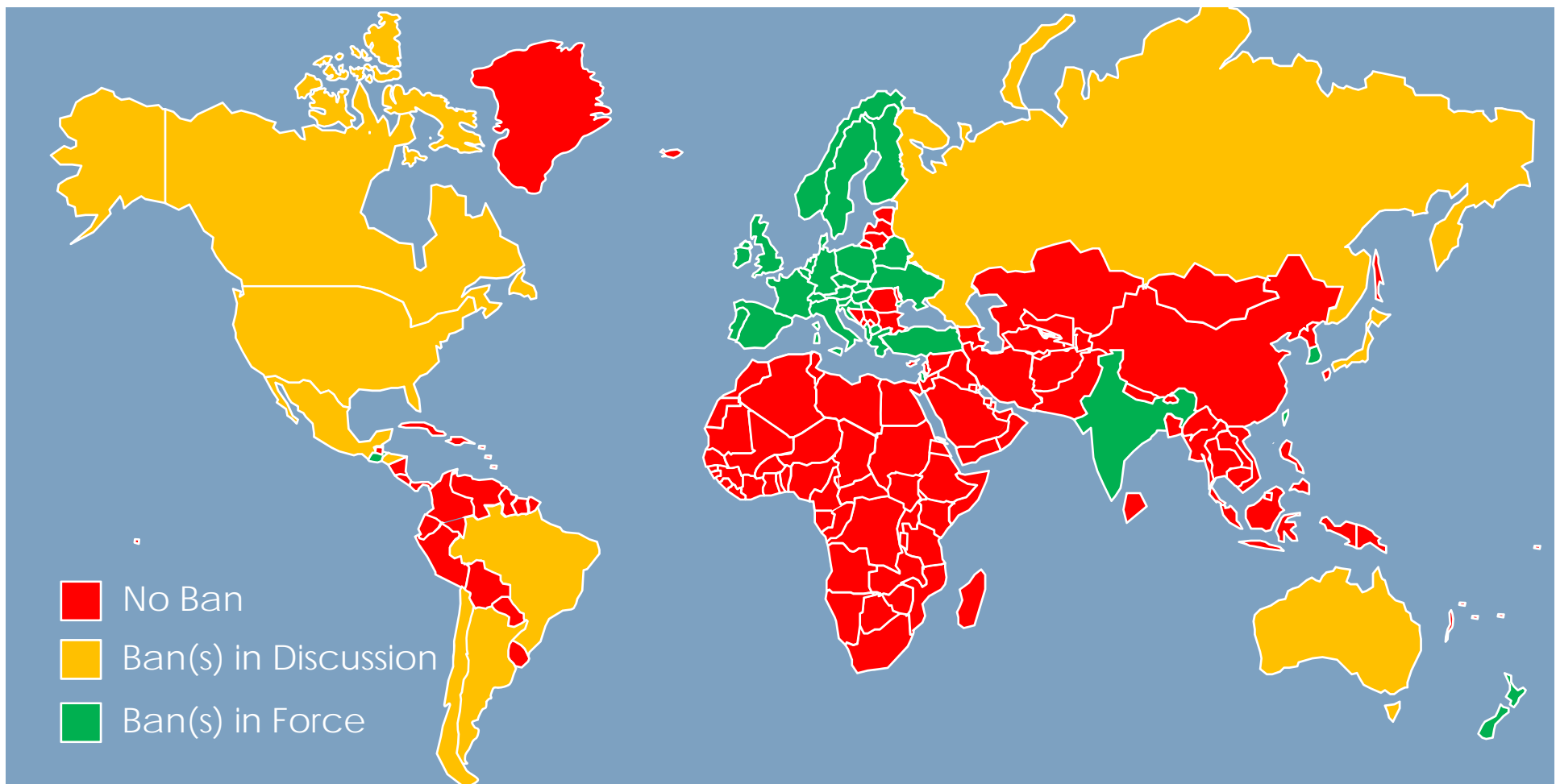
- New Zealand – test ban
- South Korea – sales ban (dependent on available alternative methods)
- Turkey – mandatory alternatives
- **Brazil – Paraná & Amazonas state test bans**

2016

- Taiwan – test ban
- Switzerland – test ban
- **Brazil – Pará state test ban**

2017

- Switzerland – sales ban
- Guatemala – test ban
- **Brazil – Senate CCT unanimously endorses amendments to PLC 70/2014**
- Australia – promises to implement dual test + sales ban



2017: after campaigning by HSI and others

37 national testing/trade bans;
10+ others in development



>600 beauty brands produce safe
new products without animal testing



'Responsible innovation'



1. Choose from among **thousands of existing ingredients** with established toxicity profiles and **history of safe use**
2. Evaluate new product formulations using modern **non-animal methods** (calculation, computer modeling, cell tests)
3. Avoid new-to-the-world chemical ingredients (subject to new animal testing under chemical laws)
4. Avoid ingredients with known health concerns that may be subject to further animal testing

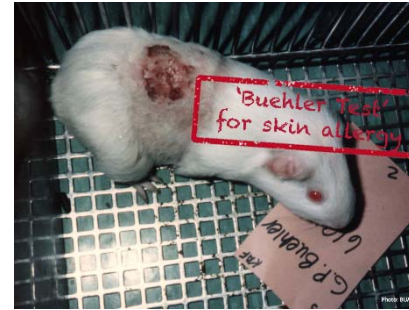
Animal tests = last century's science

1920s

1940s

1960s

2017



We embrace new technology in
virtually every part of lives...

PAST...

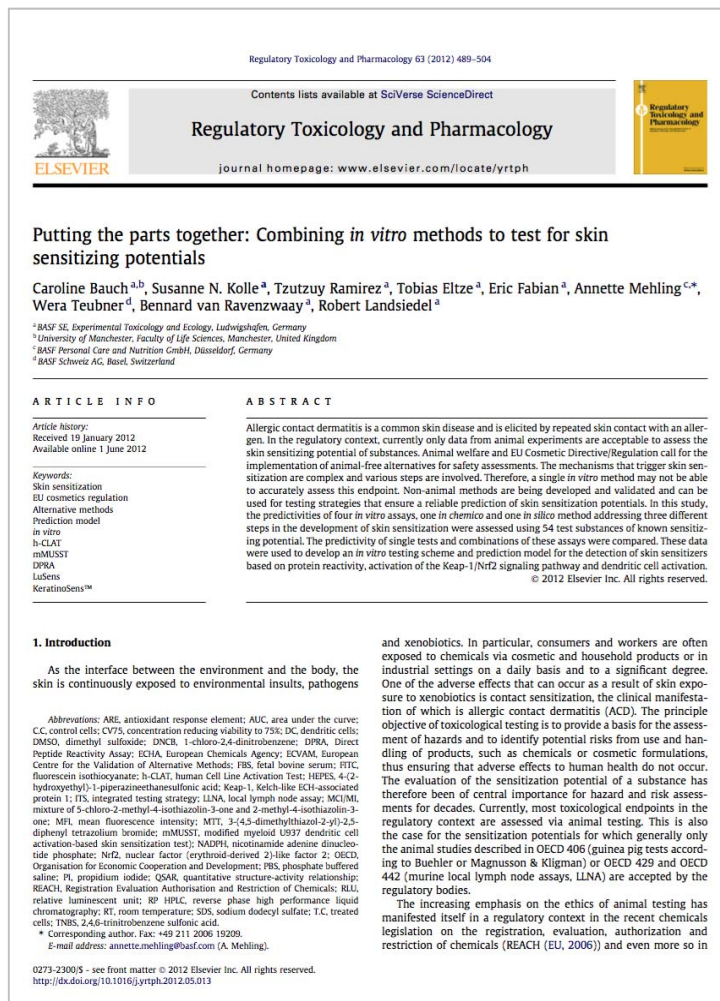


PRESENT...



... so why is cosmetic safety still assessed
using tests that are 50-90 years old?

Modern non-animal methods are more predictive, e.g. skin allergy



Compared to human

Accuracy

Animal test

Mouse LLNA

84%

Individual non-animal tests

DPRA

87%

LuSens

82%

MUSST

85%

h-CLAT

78%

Combinations of non-animal tests (1 out of 2 is positive)

DPRA + LuSENS

85%

DPRA + MUSST

81%

DPRA + h-CLAT

83%

LuSens + Musst

80%

LuSens + h-CLAT

82%

Non-animal (2 out of 3) approach

DPRA + LuSens + MUSST

94%

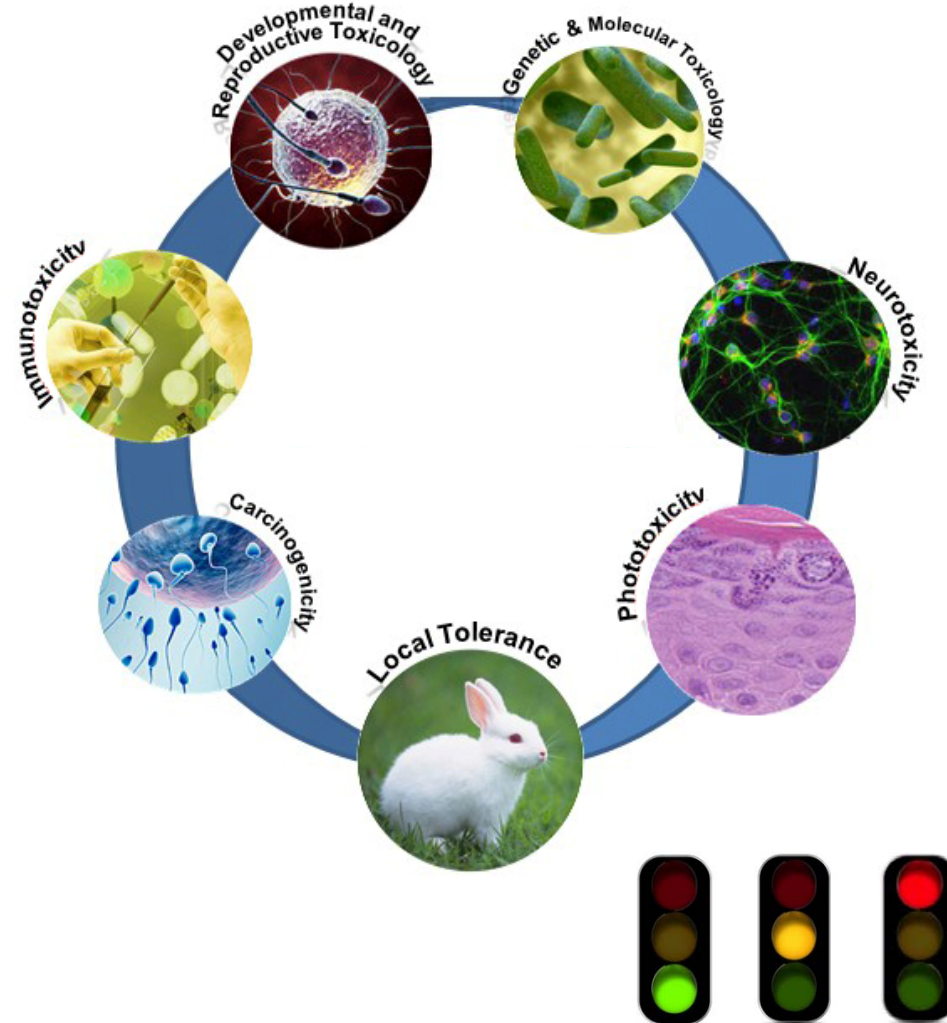
Non-animal replacement methods*

Health area	Test method (OECD guideline; year)	CONCEA	ANVISA
Skin corrosion	- Reconstructed human epithelium (TG 431; 2004)	2014	2015
	- CORROSITEX™ (TG 435; 2006)	2014	2015
Skin irritation	- Reconstructed human epithelium (TG 439; 2013)	2014	2015
Eye irritation	- BCOP (TG 437; 2013)	2014	2015
	- ICE (TG 438; 2013)	2014	2015
	- Fluorescein leakage (TG 460; 2014)	2014	2015
	- Short time exposure (TG 491; 2015)	2016	-
	- EpiOcular™ (TG 492; 2015)	2016	-
Skin allergy	- DPRA (TG 442C; 2015)	2016	-
	- KeratinoSens (TG 442D; 2015)	2016	-
	- h-CLAT (TG 442E; 2016)	-	-
Skin absorption	- Human post-surgical skin (TG 428; 2004)	2014	2015
Acute oral toxicity	- Starting dose guidance (GD 129; 2010)	2014	2015

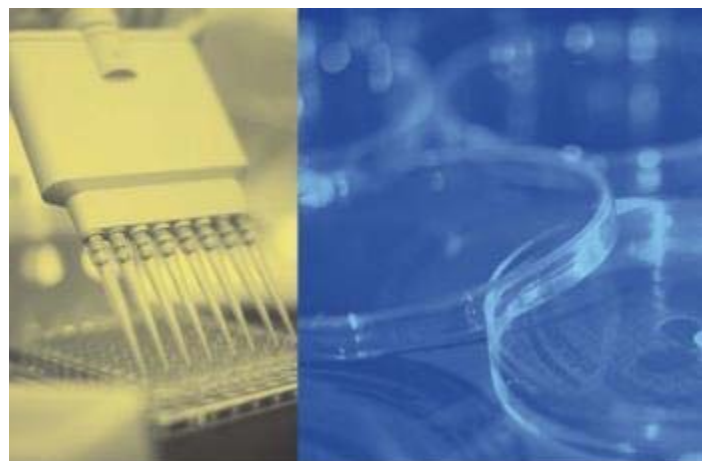
* When used as part of an integrated approach to testing and assessment (IATA)

Replacement status of health areas relevant to cosmetic safety

1. Physico-chemical properties
2. Skin and eye irritation
3. Skin allergy
4. Photo-induced toxicity
5. Mutagenicity / genotoxicity
6. Acute toxicity (if oral $LD_{50} > 2000$ mg/kg)
7. Toxicokinetics (ADME)
8. Carcinogenicity
9. Repeated dose toxicity
10. Reproductive toxicity
11. Human data



U.S. National Academy of Sciences vision of '21st century toxicology'



**TOXICITY TESTING IN THE 21ST CENTURY
A VISION AND A STRATEGY**



“envision[s] a not-so-distant future in which virtually all routine toxicity testing would be conducted in human cells or cell lines *in vitro*”

“Animal testing won’t disappear overnight, but the agencies’ work signals the beginning of the end.”

Elias Zerhouni, M.D.
Former Director
National Institutes of Health



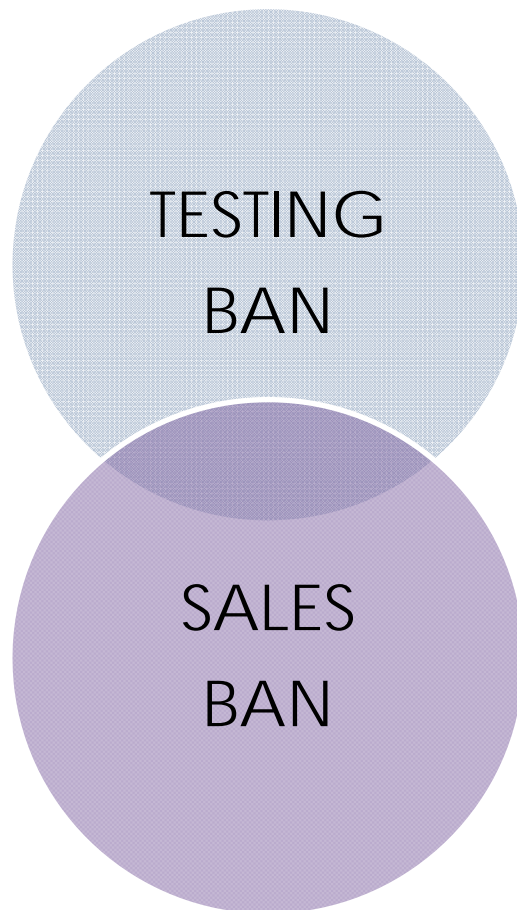
Projected doubling in size of the *in vitro* testing market in 10 years

“The global *in vitro* toxicology testing market is expected to reach USD 27.36 billion by 2021 from USD 14.15 billion in 2016...

“Opposition to animal testing, new & promising technologies, increasing R&D to detect toxicity at early stages ... are the primary growth drivers.”

<http://military-technologies.net/2017/01/13/in-vitro-toxicology-testing-market-worth-27-36-billion-usd-by-2021/>

Understanding the proposed bans



Testing ban needed to prevent new animal testing for cosmetic products and ingredients *in Brazil*

However, a test ban alone *cannot* prevent:

- New animal testing in Brazil claimed to be for '*non-cosmetic*' purposes (e.g., chemicals)
- New cosmetic animal testing *in other countries* and import of these products or ingredients into Brazil

Sales ban needed to prevent cosmetic products or ingredients newly tested on animals in another part of the world from undermining Brazilian testing restrictions

Testing and sales bans support one another, ensuring equal treatment for domestic and foreign companies

Legislative history in Brazil

2013 - Chamber Bill 6602/2013 by Deputy Ricardo Izar to modify Lei Nº 11.794/2008 ('Arouca law') establishing procedures for the scientific use of animals; articles 14 (prohibitions), 17 and 18 (penalties)

2014 - Bill moves to Senate; renumbered PLC Nº 70/2014*

2015-16 - Report amending PLC Nº 70/2014 prepared by Sen. Cristovam Buarque for Comissão de Ciência e Tecnologia (CCT) but never voted

2017 - Report amending PLC Nº 70/2014 prepared by Sen. Randolfe Rodrigues and endorsed unanimously by CCT*
- Bill moves to Senate Comissão de Meio Ambiente (CMA); rapporteur Sen. Jorge Vania

Official legal documents in Portuguese available online at:

- **Lei Nº 11.794/2008:** http://www.planalto.gov.br/ccivil_03/_ato2007-2010/2008/lei/l11794.htm
- **PLC Nº 70/2014:** <https://legis.senado.leg.br/sdleg-getter/documento?dm=4768742&disposition=inline>
- **CCT report:** <https://legis.senado.leg.br/sdleg-getter/documento?dm=5130821>

Importance of CCT amendments

TESTING
BAN

PLC N° 70/2014

Paragraph 7 The use any kind of animals in *teaching, research* and laboratory testing activities aimed at the development and production of cosmetics, personal care products and perfumes *for ingredients with known effects and known to be safe* for human use or *for cosmetic finished products* as defined by the regulation of the National Sanitary Surveillance Agency is forbidden.

CCT Amendments 2017

§ 11. The use of animals of any kind is prohibited in *tests* of personal hygiene *products*, cosmetics and perfumes, including tests aimed at evaluating their efficacy or safety.

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This Law shall enter into force after three years from the date of its publication.

In relation to finished products, the prohibitions contained in this law are *effective immediately*.

Importance of CCT amendments

TESTING
BAN

PLC N° 70/2014

Paragraph 8 In the case of ingredients with *unknown effects*, the prohibition referred to in paragraph 7 will be applied in a period of *up to 5 years following the recognition of alternative techniques* capable of proving the safety for human use.

CCT Amendments 2017

§ 12. The use of animals of any kind in tests of ingredients that compose or may be made into personal hygiene products, cosmetics and perfumes, including tests intended to evaluate their efficacy or safety, shall be prohibited.

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This Law shall enter into force *after three years from the date of its publication*.

The prohibition on the marketing of personal hygiene products, cosmetics and perfumes, as well as the ingredients that make them, that have been tested on animals do not affect the products and substances tested until the end of the period included in the caput.

Importance of CCT amendments

PLC N° 70/2014

No equivalent text

SALES
BAN

CCT Amendments 2017

§ 13. The trade in personal hygiene products, cosmetics and perfumes, as well as their ingredients, which have been tested on animals, are prohibited.

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This Law shall enter into force *after three years from the date of its publication*.

The prohibition on the marketing of personal hygiene products, cosmetics and perfumes, as well as the ingredients that make them, that have been tested on animals do not affect the products and substances tested until the end of the period included in the caput.

Importance of CCT amendments

ALTERNATIVE
METHOD
ADOPTION

PLC Nº 70/2014

Paragraph 9 Internationally recognized alternative techniques will be accepted by the Brazilian authorities on a priority basis.

CCT Amendments 2017

§ 14. Internationally recognized alternative techniques will be accepted by the Brazilian authorities on a priority basis.

Importance of CCT amendments

PLC N° 70/2014

No equivalent text

DEROGATION

CCT Amendments 2017

§ 15. The national health regulatory authority, which is preceded by public consultation with civil society *in exceptional circumstances, where serious concerns arise as to the safety of a cosmetic ingredient*, may derogate from the prohibitions set out in the preceding paragraphs if the following conditions were simultaneously satisfied:

- a) it is an ingredient *widely used on the market and can not be replaced* by another capable of performing a similar function;
- b) To detect a *specific human health problem* related to the ingredient, in a reasoned manner;
- c) There is *no alternative method* capable of meeting the testing requirements.

Conclusions

- CONCEA has declared: *“The tests are already carried out with alternative methods in Brazil and abroad. Therefore, the ban would not change the established scenario.”*
- More than 1,300 cosmetic companies (more than half the Brazilian beauty industry) are established in states where all cosmetic tests on animals are forbidden
 - **No negative economic effect of bans reported in these states**
- 37 national cosmetic animal testing/trade bans already in place and 10+ more under development
 - **Brazilian bans would help guard against future trade disruption with current and future export markets**

Our ask

**We urge the CMA to endorse
all amendments to PLC N°
70/2014 proposed by the CCT,
without further changes**



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Obrigado!

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