



European Union Reference Laboratory for alternatives to animal testing

Chapter 1



Elisabet Berggren, Joint Research Centre, European Commission
Swaccs course *Regulatory Toxicology II: European and International Perspectives*,
23 January 2024

Joint Research Centre

Our purpose

The JRC provides independent, evidence-based knowledge and science, supporting EU policies to positively impact society.





Directive 2010/63/EU on the protection of animals used for scientific purposes



European Union Reference Laboratory for alternatives to animal testing

mandate under the Directive:

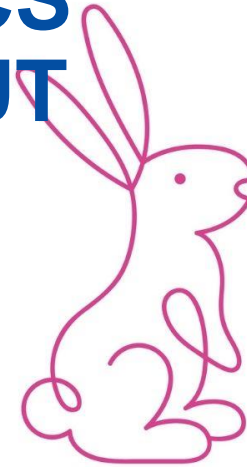
- research & evaluation
- validation
- dissemination
- promotion



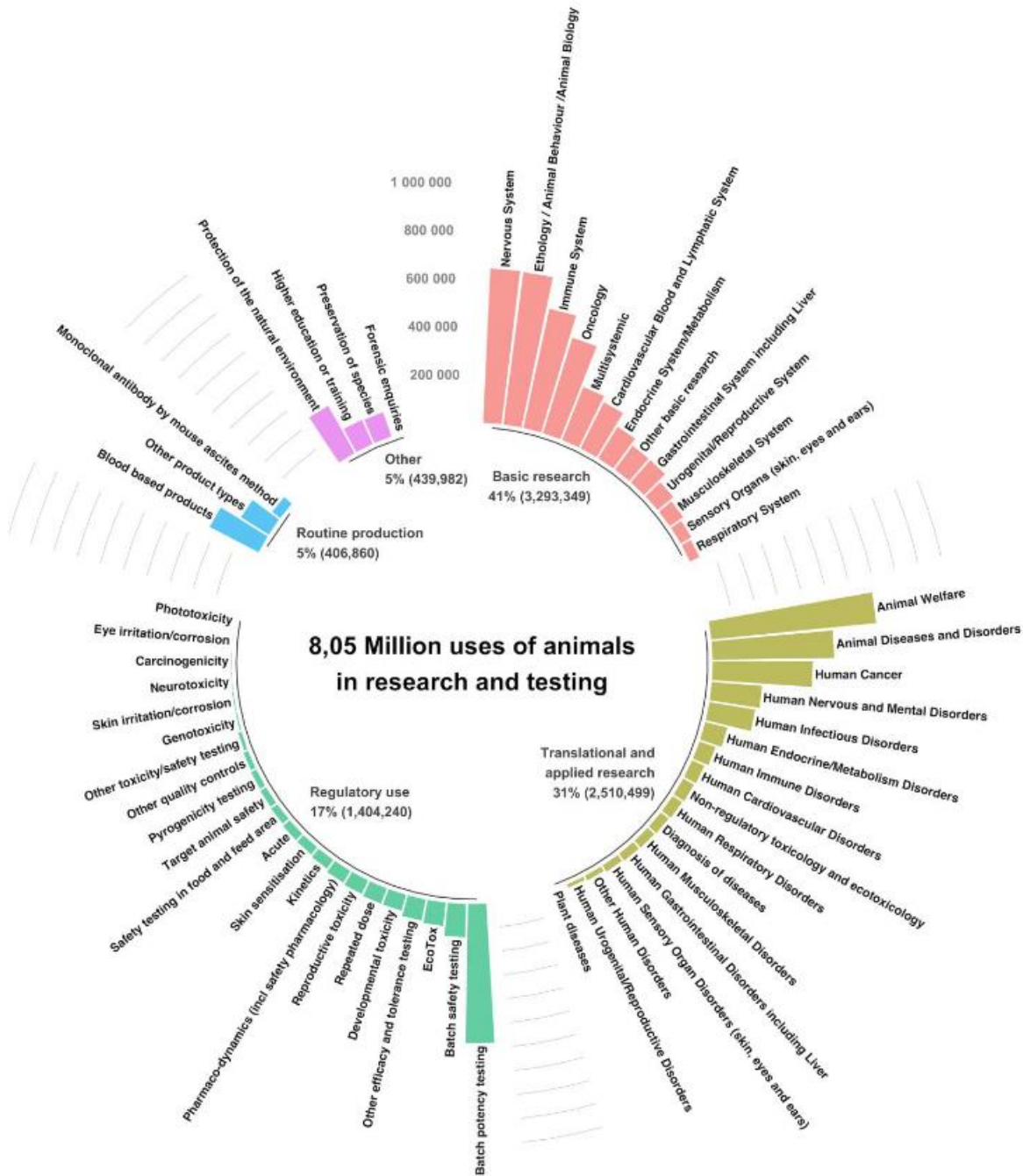
What are we doing at ECVAM?
Watch what my colleague Raffaella is doing
(<https://audiovisual.ec.europa.eu/en/video/I-230374?language=EN>)

European Citizens' Initiative (ECI) **SAVE CRUELTY FREE COSMETICS - COMMIT TO A EUROPE WITHOUT ANIMAL TESTING**

- ECI started in 2012
- 1,000,000 signatures requested
- Up to date 10 successful initiatives out of 107
- 2 on stopping animal testing



Save
Cruelty Free
Cosmetics

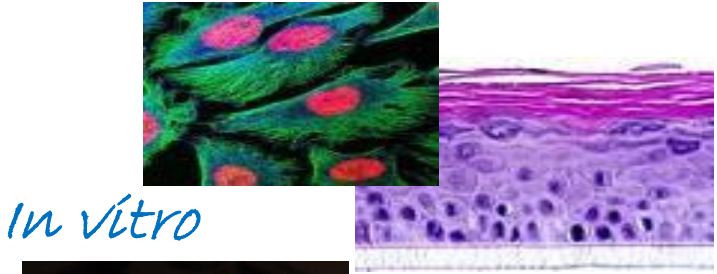


Directive 2010/63/EU on the protection of animals used for scientific purposes

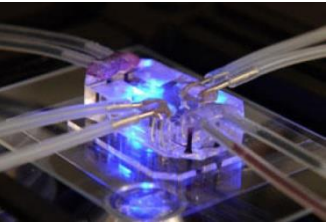
Caring for animals
**aiming for better
science**



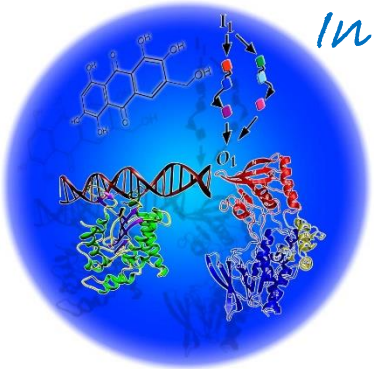
New Approach Methods (NAMs)



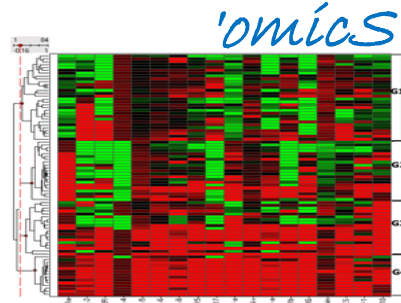
In vitro



The human biology tool box



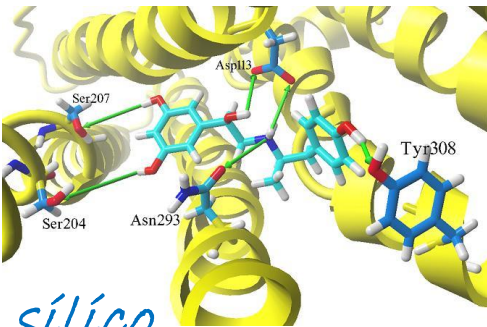
In chemico



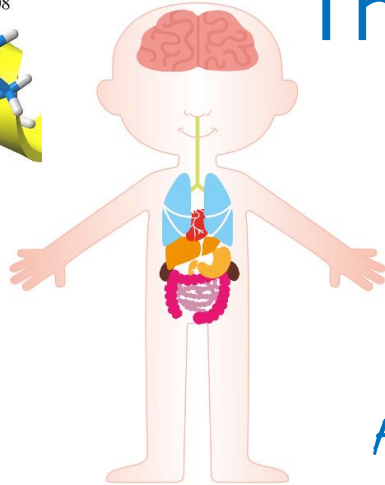
'omics



High Throughput Screening



In silico



Biokinetics



Human Biomonitoring

Existing data explored by AI



Non-animal models in Biomedical research

European Commission

Advanced Non-animal Models in Biomedical Research
Respiratory Tract Diseases

284 models

simple cell cultures
3D cell cultures
immortalized cells
in vitro
in vivo

EUR 30334 EN

European Commission

Advanced Non-animal Models in Biomedical Research
Breast Cancer

935 models

immortalized cells
3D cell cultures
in vitro
in vivo

EUR 30335 EN

European Commission

Advanced Non-animal Models in Biomedical Research
Neurodegenerative Diseases

568 models

simple cell cultures
3D cell cultures
in vitro
in vivo

EUR 30336 EN

European Commission

Advanced Non-animal Models in Biomedical Research
Immuno-oncology

542 models

immortalized cells
3D cell cultures
in vitro
in vivo

EUR 30337 EN

European Commission

Advanced Non-animal Models in Biomedical Research
Immunogenicity testing for advanced therapy medicinal products

88 models

Primary cell cultures
immortalized cells
3D cell cultures
in vitro
in vivo

EUR 30338 EN

European Commission

Advanced Non-animal Models in Biomedical Research
Cardiovascular diseases

449 models

in silico
in vitro with cells
in vitro without cells

EUR 30339 EN

European Commission

Advanced Non-animal Models in Biomedical Research
Autoimmune diseases

183 models

human primary cells
stem cells
immortalized cells

EUR 30340 EN

Knowledge-base of models collected and freely available in the [JRC Data Catalogue](#)

Chemicals Management within the EU



Regulation 1907/2006 on registration, evaluation, authorisation and restriction of chemical substances
'REACH'

Regulation 1107/2009 on the placing of **Plant Protection Products** on the market

Regulation 528/2012 on authorisation of **Biocidal** active ingredients and **Products**

Regulation 1272/2008 on classification, labelling and packaging of chemical substances and mixtures **'CLP'**

Directive 2001/82/EC on **Veterinary Medicinal Products**

Directive 2001/83/EC on **Human Medicinal Products**

Regulation 1223/2009 on **Cosmetic Products**

Directive 2004/37/EC on **carcinogens, mutagens or reprotoxic substances at work**

Directive 2009/48/EC on the **safety of toys**

EU
chemicals
acquis:
>40
pieces of
legislation

THE ECOSYSTEM OF CHEMICALS LEGISLATION

Vertical legislation:



Horizontal legislation:

CLP - all chemicals on the market (no information requirements)

REACH

Registration & Evaluation > 1 tonnes
(information on systemic health effects +
chemical safety report > 10 tonnes)
Authorisation & Restriction based on concern

Downstream legislation



Scientific opinion

ESAC

EURL ECVAM Scientific Advisory Committee

Advice from regulators

PARERE

Preliminary Assessment of Regulatory Relevance

Stakeholder dialogue

ESTAF

EURL ECVAM Stakeholder Forum

Global partnership

ICATM

Intern. Cooperation on Alternative Test Methods

Validation support

EU-NETVAL

EU Network of Laboratories for the Validation of Alternative Methods



The European Partnership for Alternative Approaches to Animal Testing



Collaboration = Larger Impact

International Cooperation on Alternative Test Method



Health Canada



NICEATM-ICCVAM



BraCVAM



EURL ECVAM



KoCVAM



JaCVAM



化学品の分類および表示に関する世界調和システム (GHS) 改訂7版

Harmonized System of Classification and Labelling of Chemicals (GHS) Seventh revised edition





€60 Million,
3 Projects,
5 Years (2021-2026)



Animal-free Safety assessment of chemicals: Project cluster for Implementation of novel Strategies



RISK [:::]
HUNT3R

Partnership for the Assessment of Risks from Chemicals



€400 Million,
200 partners,
7 Years (2021-2028)



Three Rs in Education

- Guidance on how to introduce the Three Rs in education programmes and curricula
- Awareness & training for Schools, High Schools and Universities
- Three Rs teaching resources



The Three Rs MOOCs



Thank you



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