

Directive 2010/63/EU

Webinar – Policy making to bring the Three Rs alive

Policy making to bring the Three Rs alive



- *Facts and figures – putting the topic in context*
- *Short journey through the history of the Three Rs and animal welfare in Europe*
- *Discussing pros and cons of legislation*
- *Legislation in the EU*
- *Influencing policy making*

Numbers of animals in the EU



- ***Farm animals***

2,000 million chickens/hens

300 million cows, pigs, sheep

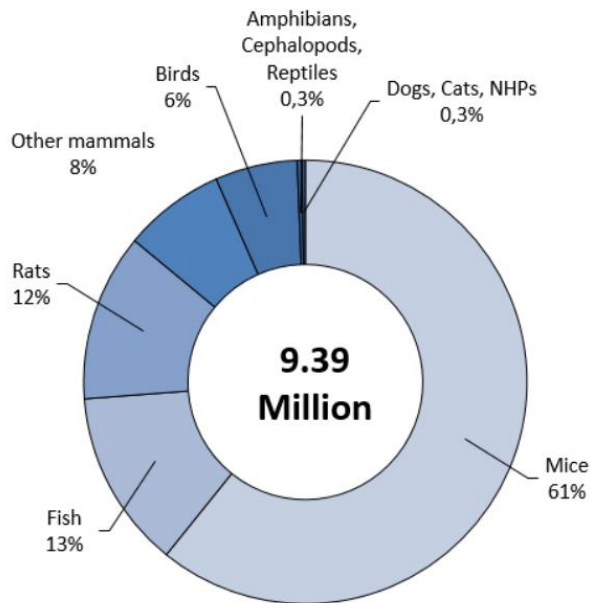
- ***Pet animals***

120 million dogs and cats

- ***Animals used in science***

10 million

Animals used in science in the EU in 2017



Mice, rats, fish and birds together 92%

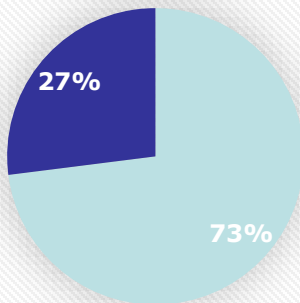
Of those genetically altered:

- 64% of zebra fish and
- 38% of mice

*1.28M animals used for the **creation and maintenance of genetically altered** animal lines*

Total of 10.67M animals

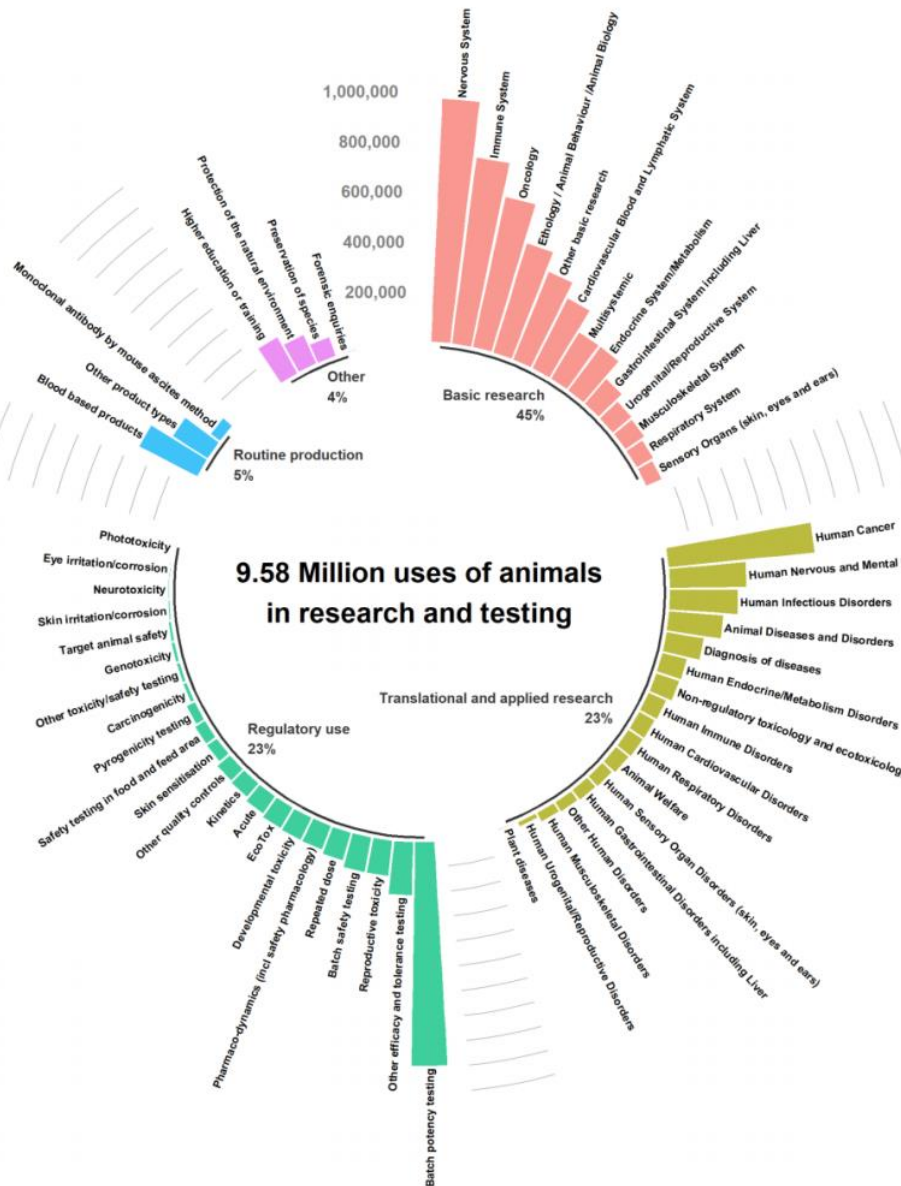
Genetic status



■ Not genetically altered ■ Genetically altered



Animals used in science in the EU in 2017

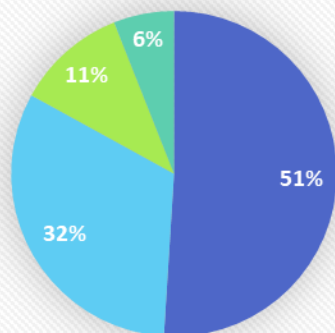


- Basic and applied research together 68%
- 23% to satisfy legislative requirements e.g. chemicals, pharmaceuticals safety testing

Animals used in science in the EU in 2017



Actual experienced severity



■ Mild ■ Moderate ■ Severe ■ Non-recovery

- *Most animals experience only **mild impact** from e.g. an injection, blood sampling*
- **Moderate:** e.g. surgery under a general anesthesia
- **Severe:** e.g. toxicity testing or potency testing of a vaccine
- **Non-recovery:** animal only experiences the administration of an anesthetic

Statistics on the use of animals for scientific purposes in the EU:

https://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm

Animal use in science around the world



Some published statistics:

- *EU 10M*
- *Switzerland: <600K*
- *Norway: 1.68M – including large fish studies*
- *Canada: 3.8M*
- *USA: <800K (excluding mice, rats, fish and birds)*
 - *total estimated between 12-23M*
 - *Non-human primates 75,825 (versus 8,235 in the EU)*
- *South Korea: 3.7M*
- *China: ?*

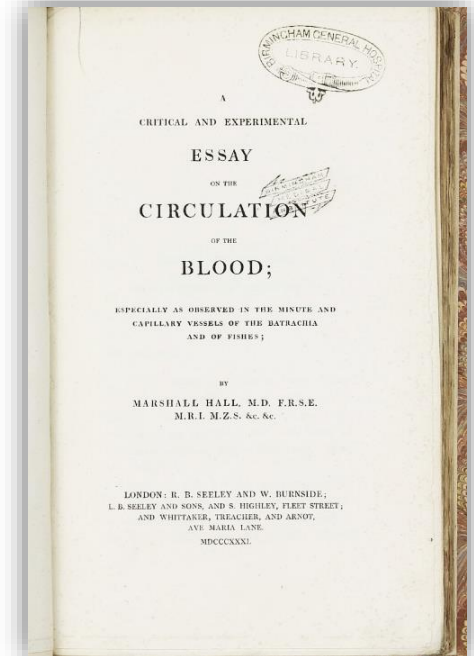
Policy making to bring the Three Rs alive



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- *Short journey through the history of the Three Rs and animal welfare in Europe*
- *Discussing pros and cons of legislation*
- *Legislation in the EU and in the global context*
- *Influencing policy making*

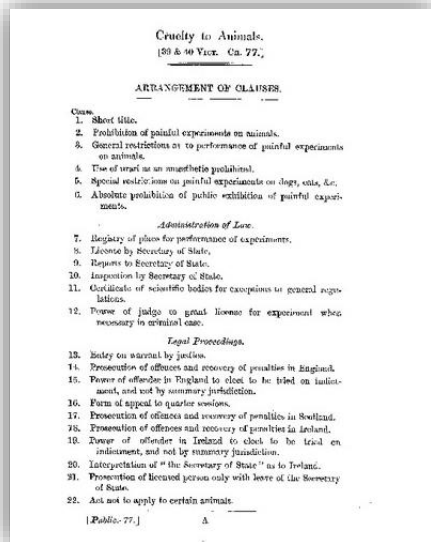
Three Rs and AW through European history

- 1831 Marshall Hall plants the seeds for the principle of the Three Rs



Source:
<https://www.milestone-books.de/>

- 1876 first legislation on animal welfare
“Cruelty to animals Act” in the UK



Source: <https://www.legislation.gov.uk>

Three Rs and AW through European history



- **1959 - William Russell and Rex Burch** published a paper "The Principles of Humane Experimental Technique" introducing the Three Rs

Available at : <https://caat.jhsph.edu/principles/the-principles-of-humane-experimental-technique>

- 1986 - Council of Europe Convention ETS 123
- **1986 – Adoption of Directive 86/609/EEC** on the protection of experimental animals

Other EU legislation on animal welfare standards



- *Protection of Animals during transport*
- *Protection of animals at the time of slaughter or killing*
- *Keeping of wild animals in zoos*
- *Trapping of animals*
- *Trade in seal products*

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Laws or codes of practice and guidance?



- *Flexibility – inflexibility?*
- *Promotes voluntary initiatives – forces action?*
- *Standards ensure level playing field?*
- *Standards discourage to go beyond?*
- *Enforcement?*

➤ **Suggestion for student work:**
Prepare a debate on pros and cons of legislation to promote the Three Rs using examples from different countries and regions e.g. EU, Japan, USA taking into account cultural differences



From policy to legislation

*Legislative **process***

- *Brings together relevant stakeholders*
- *Keeps the momentum, often expanding to a wider societal dialogue*
- *Continued focus during the process draws attention also to other related subjects*
- *Mutual learning and identification of common ground between different interest groups*



From policy to legislation

- *Best policies work with **a mix of tools**: legal framework, complementary guidance and voluntary initiatives*
- *Legislation is by default **a compromise** between **different, competing interests** – in this case the protection of humans, animals and the environment*
- ***"Avalanche effect"** once set in motion other policies need to take it into account and build on*

➤ **Suggestion for student work:**

Prepare a co-decision debate on a legislative proposal on a topic related to animal use, divide students into groups to prepare and debate

- the Council (MS interests e.g. local industry)
- the Parliament (constituents/voters)
- various stakeholder lobby groups
- the Commission (to moderate the debate)
- (patients/pharma industry/NGOs/research organisations/animal breeders..)

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Legislative powers in the EU

- *Legal base is needed in the Treaty on the Functioning of the EU (TFEU) for EU to act*
- ***No legal base to legislate animal welfare***
- *Article 13 of the TFEU:*

"In formulating and implementing the Union's agriculture, fisheries, transport, **internal market**, research and technological development and space **policies**, the Union and the Member States shall, since **animals are sentient beings, pay full regard to the welfare requirements of animals**, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage."

Legislation revised in 2010



Directive 86/609/EEC revised in 2010:

- *Ultimate goal to replace all use of animals*
- *Acknowledging that animals are still needed today*
- *Recognising that animals have intrinsic value in themselves which must be respected*
- *The principle of the Three Rs is the key to more humane and better science*



Aims of the Directive

- ***Harmonisation of legislation** to obtain level playing field to promote competitiveness and innovation*
- *Improve **animal welfare** standards and the **uptake of the Three Rs** (Replacement, Reduction, Refinement)*
- *Improve **transparency***

Directive 2010/63/EU explained in one sentence



*In the EU, **live vertebrate animals** and **cephalopods** can **only** be used for **specified scientific purposes***

- once the **project** is **authorised**
- by a **competent authority**
- having **evaluated** that **harms are justified by the expected benefits** taking into account **ethical considerations**, and
- the work is carried out by **trained and competent staff**,
- according to the **rules and conditions** set by the Directive,
- in a **regularly inspected** and **authorised establishment**
- in compliance with **housing and care standards** and with
- mandatory **persons** and **structures** for **animal health & welfare**.



Three Rs in the Directive

- *Full **Replacement** is the ultimate goal*
- *Three Rs is **a legal obligation** in **all interaction** with animals, also when **not** in a project*
- ***Refinement** extended to apply **beyond use***
- *New tools and structures for the development and validation of **new alternative methods***



Legislation breathing life into the Three Rs

- **Replacement**

- **Project planning** (*scientists, Animal Welfare Bodies (AWB)*)
- **Project evaluation** (*competent authorities*)
- New alternatives **during** the life cycle of a project (*project leaders, AWB, inspectors*)

- **Reduction**

- **Project planning:** *experimental design, statistical design*
- **Project evaluation**
- **During** the project
- **Breeding:** *animals bred and not used in scientific procedures*

Animals bred and not used for scientific purposes

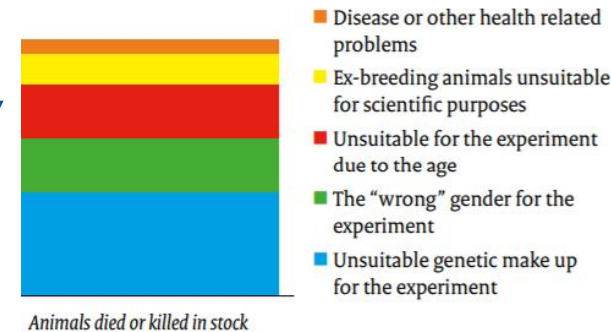


- *By law, animals need to be purpose bred*
- *Together with the statistical reports, there is a total transparency in animal numbers in the EU*
- *Snapshot every 5 years*
- *In 2017 in the EU: 12,597,816 animals bred but not used*

Animals bred and not 'used'

Main reasons:

- *Breeding animals*
- *Animals killed for scientific use – e.g. collection of organs/tissues for the development of alternatives*
- *Narrow specifications required for studies e.g. weight/age range/sex*
- *Breeding of genetically altered animals: some animals will not carry the desired gene*



Source: Dutch National Committee

Legislation breathing life into the Three Rs



- **Refinement**

- **Project application:** humane end-points, techniques, pain relief, sourcing, housing and care etc (scientists, AWB)
- **Project evaluation** (competent authority)
- **During** the project (all staff, inspectors)
- Before, after and in between projects; breeding practices e.g., genotyping

Refinement of care and accommodation



Laws in EU require, inter alia,

- *Standards for appropriate accommodation and care*
- *Social housing where appropriate to species*
- *Enrichment*
- *Appropriate habituation and training programmes for animals to collaborate*

Refinement of accommodation and care

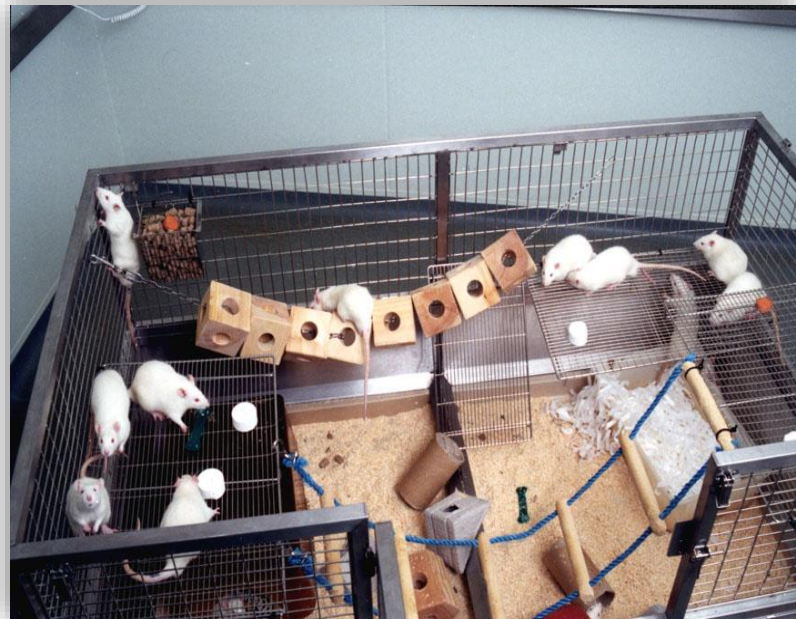


*Housing: "Animals, except those which are naturally solitary, shall be **socially housed in stable groups** of **compatible individuals**. ... "*

*Enrichment : "All animals shall be provided with space of sufficient complexity to **allow expression of a wide range of normal behaviour**. They shall be given a **degree of control and choice over their environment** to reduce stress-induced behaviour. Establishments shall have **appropriate enrichment techniques** in place, to extend the range of activities available to the animals and increase their coping activities including **physical exercise, foraging, manipulative** and **cognitive activities**, as appropriate to the species. Environmental enrichment in animal enclosures shall be adapted to the species and individual needs of the animals concerned. The enrichment strategies in establishments shall be **regularly reviewed and updated**.*

Rodents

- *Social housing*
- *Secure areas*
- *Interactive inclusions*



Non-human primates

- *Social housing*
- *Environmental complexity*
- *Foraging*
- *Training*



Enrichment – not only about the environment



*Enrichment explained [US perspective] – EU laws already
oblige enrichment since the 2010 Directive:*

<https://www.youtube.com/watch?v=GB5BSzPsLsw>

The EPAA partners grant 2 types of awards to scientists and laboratory technicians, whose work has brought an outstanding contribution to the development and implementation of alternatives to animal testing: The EPAA Science Prize and the EPAA Refinement Prize, alternating from year to year. In addition, the EPAA partners yearly provide several grants to students or young scientists to help them participate in major scientific conferences relevant to the 3Rs. For current open calls please see below.



The European Partnership
for Alternative Approaches to Animal Testing

Refinement Prize

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is proud to announce the winner of its [2019 refinement prize](#). The 2019 prize was given to Yvonne Ambrecht of the Veterinary University of Hannover for her outstanding work on the 'Effect of positive conditioning on stress induced heart rate increase in sheep used in a research and veterinary education facility'.

See the [refinement prize ceremony](#) and read the [research abstract](#).

➤ **Suggestion for student work:**
**Creative brainstorming on how
the lives of different species
used in labs could be enriched**



Not only about the environment - implementing Culture of Care

Mouse handling web-page with video tutorial:

<https://www.nc3rs.org.uk/how-to-pick-up-a-mouse>

Rat tickling explained:

<https://www.youtube.com/watch?v=cjhiKvE3g4Y>

<https://www.youtube.com/watch?v=uFz8DGnJOqo>

Clicker training for laboratory animals:

[https://www.researchgate.net/publication/314275980_Introducing_Clicker_Training
as a Cognitive Enrichment for Laboratory Mice](https://www.researchgate.net/publication/314275980_Introducing_Clicker_Training_as_a_Cognitive_Enrichment_for_Laboratory_Mice)

[http://www.altex.ch/resources/477479
_So776rensen21.pdf](http://www.altex.ch/resources/477479_So776rensen21.pdf)

➤ **Suggestion for student work:**
Take a rat tickling training course at
http://storage.googleapis.com/ecourses/Rat%20Tickling%20Course%20Open/story_html5.html



Refinement resources

More about refinement of housing and care:

- Housing of animals:
<https://www.nc3rs.org.uk/results-search/all/housing>
<https://www.novonordisk.com/research-and-development/bioethics/animal-ethics/responsible-use-of-animals.html>
[https://www.novonordisk.com/content/dam/Denmark/HQ/r-and-d/documents/Bioethics Animal%20research%20UK Dec%202015.pdf](https://www.novonordisk.com/content/dam/Denmark/HQ/r-and-d/documents/Bioethics_Animal%20research%20UK_Dec%202015.pdf)
- Accommodation, care and enrichment of non-human primates:
<https://www.nc3rs.org.uk/housing-and-husbandry-non-human-primates>
https://www.youtube.com/watch?time_continue=3&v=804BsSuMbYc
- The use of non-human primates:
<https://www.youtube.com/watch?v=w1rPP7BM0MA&feature=youtu.be>
- Positive enforcement training:
<https://www.nc3rs.org.uk/training-animals>

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*"**PETA's***) **mission** is to get the **animal rights** message out to as many people as possible..*

*..sometimes **necessary to shake people up** in order **to initiate** discussion, debate, questioning of the status quo, and, of course, **action**.*

*..we try to make our actions.. **controversial***

*thereby **grabbing headlines**.. spreading the message.. to thousands - sometimes to millions of people."*

*) *People for the Ethical Treatment of Animals*



Source:
<https://www.crueltyfreeinternational.org/>

EU Reports Reveal Catalogue of Suffering: More Than 20 Million Animals Languished in Laboratories

Posted by [Margarita S](#) on February 5, 2020 | [Permalink](#)

New figures published by the European Commission reveal that cruel and archaic experiments are rampant across the EU. In 2017, **9.39 million** mice, rats, fish, dogs, and other animals were used for the first time in cruel experiments and other scientific procedures.

The creation and breeding of animals with debilitating genetic modifications accounted for an additional **1.28 million** individuals. The UK was the most prolific user of animals in the EU, using an appalling **2.51 animals** in laboratories.



RECENT



Order PETA's 'Fur Free' Enamel Pin



Giant 'Celery' 'Stalks' Politicians With Vegan Message



Victory! Plans for Monstrous Chicken Farm in Lincolnshire Are Rejected



Pigs on UK 'High-Welfare' Farm Filmed Eating Each Other Alive



'Feline' Good: 'Drag Race' Star Scaredy Kat Keeps Paws Off Cruel Fashion

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Pro-Test

standing up for science



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FACTS

Without animal research, medicine as we know it today wouldn't exist. Animal research has enabled us to find treatments for cancer, antibiotics for infections, vaccines to prevent some of the most deadly and debilitating viruses and surgery for injuries, illnesses and deformities. For more information, please click on one of the above links. To go into the issues in further depth, Understanding Animal Research offers an [unparalleled database](#) of hard facts to counter the junk science of anti-vivisectionists.

[Understanding Animal Research](#) have developed a new booklet entitled [<>](#) which outlines many important advances developed through the use of animal research, as well as explaining the importance of such techniques in the future. This booklet can be viewed or downloaded from our website [here](#).

Pro-

Against ?

Fifty Shades of Grey



Pro-



Polarisation

Over simplification



- *Scrutinise 'Q&As' and 'fact' claims*
 - **Origin – reliability of the source, up-to-date, supporting facts (not only social media multiplication), ...**
- *Over simplification and selective choice of topics to gain public interest*
- *Complexity of issues overlooked*



Animal testing is unnecessary? Animal testing is necessary?

- <https://speakingofresearch.com/facts/faq-about-animal-research/>
- <https://www.crueltyfreeinternational.org/why-we-do-it/arguments-against-animal-testing>
- <http://www.understandinganimalresearch.org.uk/animals/faqs/>
- <https://www.hsi.org/news-media/about/>
- <http://www.animalresearch.info/en/resources/faqs/>
- <https://www.aerzte-gegen-tierversuche.de/en/resources/46-why-animal-experiments-are-not-necessary>
- <http://www.understandinganimalresearch.org.uk/contact-us/science-action-network/forty-reasons-why-we-need-animals-in-research/>
- <https://speakingofresearch.com/extremism-undone/bad-science/>
- <https://animal-testing.procon.org/>
(see also 'Teachers' corner')

N.B. Important to note that some sites make reference to the US (not EU) regulatory system

➤ **Suggestions for student work:**

- Analyse and identify exaggerated claims
- Group debate on the necessity and usefulness of animal testing

Case study: Cosmetics testing



Source: HSI



Source: PETA

- *A topic that people can relate to*
- *Active campaigns in early 1990s*
- *Animal testing for cosmetic products and their ingredients **banned in the EU since 2009***

Impact?

- *In 2008, 1,967 of the total of 12,001,022 animals were used for cosmetics testing = **< 0.02%***

➤ **Suggestion for student work:**
Elaborate on topics of animal use that are easy to relate to. Discuss how to engage public in animal use areas that are highly scientific but use a lot of animals or result in high suffering.

Issues of high public concern



- *Use of highly sensitive species: **non-human primates, dogs, cats***
- ***Genetic alteration** (gene-editing) of animals*

Over simplification – Case study: air transport



Topic: air transport of animals for science

- *Easy for the general public to relate to*
- *Potential financial impact on operators*
- *Logic: If animals are no longer imported into EU, animal use will stop*

N.B. Example on the next slide is not from the EU, however, the topic is equally valid. Species most often imported into the EU include non-human primates, hamsters, dogs and cats

Over simplification



Tell Air France to stop transporting monkeys

Air France continues to transport monkeys for cruel research despite other airlines saying no.

While holidaymakers flying Air France enjoy their flights in comfort, they are totally unaware of the cruelty that might be just below their feet. Monkeys, torn from their families are imprisoned in small wooden crates, suffering in the dark and noisy cargo hold - destined for the laboratory.

Please use our form below to contact Air France and tell them to end this cruelty. Urge them to join many of the world's leading airlines that refuse to accept these cargoes of cruelty.

Feel free to edit the message to make it more personal.

Mr Franck Turner
Air France

Stop transporting monkeys for research

Dear Mr Franck Turner,

I am shocked to learn, from Cruelty Free International, that Air France is transporting monkeys from the holiday island of Mauritius to Europe and the USA, to be used in experiments in which they will suffer and most likely die.

I find it unacceptable that these highly intelligent and sensitive animals should be packed in small wooden crates and shipped on cargo in the



Airlines that do – and don't – transport monkeys for animal experiments



Find out which airlines do transport monkeys for research - and which ones refuse to



Thanks to our long-running campaign, many of the world's major passenger airlines refuse to transport monkeys for animal research.

Source:

<https://www.crueltyfreeinternational.org/airlines>



Over simplification

- *Non-human primates imported from Mauritius (country of origin) to Singapore (user)*
- ***Flying time 7:10 hours***
- *Airlines between Mauritius and Singapore no longer transport animals for research*

Impact?

- *New routing: Mauritius - Paris (11:45 hrs), transit in Paris (9 hrs), Paris - Singapore (12:45 hrs)
= **total transport time 33:30 hrs** (almost five fold)*
- *Additional risk from multiple transfers of transport cages*



Killing myths

- *EU law does not require the use of alternatives*
 - > Authorities **cannot authorise animal use** if an alternative, non-animal method, exists
- *Stolen and/or stray dogs and cats are used in experiments*
 - > Dogs and cats **must be purpose-bred by law**
 - > Good **science can only be done** on animals with **known background** (health/genetics)
- *Scientists prefer using animals*
 - > Scientists prefer using tools that do not cause suffering
 - > The use of **alternatives** is often **cheaper and faster**



Killing myths

- *Most animals go through severe suffering and die as a consequence of the tests*
 - > **over half (51%) experience only 'mild'** impact, equivalent to an introduction of a needle
 - > **death** as the end-point **must be avoided by law** and suffering ended at an earlier stage
 - > some animals are re-used when not detrimental to their welfare in order to reduce overall numbers; some animals are returned to their habitat (e.g. wild animals)
 - > legislation in the EU provides a possibility to **re-home retired laboratory animals** such as dogs, cats, rabbits

Future challenges and opportunities



- **Ultimate goal full Replacement** – target efforts to progress replacement, reduction and refinement
- **New alternative technologies** e.g. organoids, organs-on-a-chip, AI, machine learning, big data, 3D printed tissues, gene-editing tools
- **Emerging health risk** e.g. corona virus, antibiotic resistant bacteria, aging population, nano-materials, environmental pollution etc.

Indicative trend before and after the adoption of Directive 2010/63/EU



Numbers of <u>animals</u> used in research, testing, routine production and E&T	2008*) (EU27)	2011*) (EU27)	2015 (EU28)	2016 (EU28)	2017 (EU28)
	12.001.022	11.481.521	9.590.379	9.817.946	9.388.162
Change from 2008		-4,3%	-20,1%	-18,2%	-21,8%

***) Data under the previous legislation, Directive 86/609/EEC**

Conclusions and take home messages



Take home messages - 1

*The topic of animal testing is **not** black and white.
Learn to separate facts from fiction!*





Take home messages - 2

Issues are complex. Good policy requires carefully balancing of contradictory objectives – take time to understand the views of others.

Take home messages - 3



*Use the **entire tool box**
of **investigative
methods** combining
those most appropriate to
your specific question.*

***Question your
questions!***

***Think outside
the box!***

Take home messages - 4

*The use of animals in science is a **privilege, not a right.***

*Responsible use implements the **Three Rs in all interaction with animals.***





Further resources

EU web-sites:

Legislation: <http://ec.europa.eu/animals-in-science>

Three Rs resources:

https://ec.europa.eu/environment/chemicals/lab_animals/3r/alternative_en.htm

EU Reference Laboratory for alternatives to animal testing, EURL ECVAM:

<https://ec.europa.eu/jrc/en/eurl/ecvam>

Other resources:

<https://science.rspca.org.uk/sciencegroup/researchanimals/implementing3rs>

<https://www.nc3rs.org.uk/3rs-resources>

<https://norecopa.no/>

... and plenty more!

Thank you for your attention!

More information at:

<http://ec.europa.eu/animals-in-science>

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