



Directive 2010/63/EU

**Moving forward with the Three Rs in
the EU**

Copenhagen, Denmark
11 October, 2015

Susanna Louhimies
DG Environment, European Commission



Moving forward with the Three Rs in the EU

- *Background to the Directive and the Three Rs*
- *Two legs of the Three Rs in the Directive*
 - **Striving for new alternative approaches**
 - **Implementing the Three Rs today**
- *Calling for a new culture*



Background to revision

- *Animal welfare - high priority for EU citizens*
- *Strong animal welfare lobby*
- *Contradictory objectives including inter alia:*
 - *Increasing concern for environment*
 - *New and existing chemicals*
 - *Emerging concerns (e.g. nano, endocrine disruptors)*
 - *New diseases and aging population*



Background to revision

- *No longer responded to advancements in science*
- *New scientific knowledge on animal welfare*
- *Ethical considerations have evolved since 1980s*

*As a consequence, national legislation resulted
in widening gap in standards in Europe*



Objectives

- *Significant increase in animal welfare*
- *Level playing field for industry and academia*
- *Active promotion and implementation of the Three Rs principle*



Governing principles

- *Ultimate goal full replacement*
- *Acknowledgment that animals, including non-human primates, are still needed today*
- *Principle of the Three Rs govern all breeding, use and care of animals for scientific purposes*



Main differences and the 3Rs

- ***Explicitly spells out the Three Rs:***
e.g. Recitals 10-13; Articles 1, 4, 13
- *Ensuring that **Refinement is not limited to scientific procedures** but also relevant in relation to care, accommodation and breeding of animals*
- *The development, validation and use of alternative approaches **a clear legal requirement***



Article 1

"Subject matter and scope"

1. This Directive establishes measures for the protection of animals used for scientific or educational purposes

To that end, it lays down rules on the following:

(a) the **replacement** and **reduction** of the use of animals in procedures and the **refinement** of the breeding, accommodation, care and use of animals in procedures; ..."



Three Rs and the Directive

- *Three Rs central in project **planning**, evaluation, **during** the course of the project and **after***
- *Significant **new tools for** the development, validation and uptake of alternative approaches to progress towards the ultimate goal of full replacement*



Moving forward with the Three Rs in the EU

- *Background to the Directive and the Three Rs*
- *Two legs of the Three Rs in the Directive*
 - **Striving for new alternative approaches**
 - **Implementing the Three Rs today**
- *Calling for a new culture*

New tools for alternatives

- Commission obligations



- **Contribute** to the development and validation of alternative approaches
- Obtain **international acceptance** of alternative approaches
- Formally establishing the Union Reference Laboratory, **EURL ECVAM**

New tools for alternatives

- Member State obligations



- **Contribute** to the development and validation of alternative approaches
- **Promote** and **disseminate** information on alternative approaches **at national level**



EURL-ECVAM – Article 48

The Union Reference Laboratory for alternatives tasks described in Annex VII

- (a) coordinate and promote the development and use of alternatives including in the areas of **basic and applied research** and regulatory testing;
- (b) **coordinate the validation of alternatives in the EU;**
- (c) focal point for the exchange of information;
- (d) set up and maintain database and information systems on alternative approaches and their development;
- (e) promoting dialogue between all stakeholders

New tools for alternatives

- Member State obligations



- *MS shall assist the Commission in identifying and nominating **suitable specialised** and qualified **laboratories** to carry out validation studies, **EU-NETVAL***
- *MS shall appoint a single point of contact for **assessment of regulatory relevance, PARERE***



Moving alternatives forward

- *EUROL ECVAM on clear legal basis*
- *Key collaborators and partners established:*
 - *Internal: PARERE, EU NETVAL, **ESAC** and **ESTAF***
 - *International : ICATM, OECD, ICH etc*
- *Strategic change from a passive to active co-ordinator for alternative approaches*

EURL ECVAM Strategies

- ✓ *address different regulatory needs*
 - ✓ *review the progress made*
 - ✓ *identify gaps and opportunities*
 - ✓ *outline actions to deliver solutions with Three Rs impact*
- *Specific calls for assays/methods*

<http://publications.jrc.ec.europa.eu/>



JRC SCIENTIFIC AND POLICY REPORTS

EURL ECVAM Strategy for Replacement
of Animal Testing for Skin Sensitisation
Hazard Identification and Classification



JRC SCIENTIFIC AND POLICY REPORTS

EURL ECVAM Strategy to Avoid and
Reduce Animal Use in Genotoxicity Testing

Raffaella Corvi, Federico Madin,
Andrew Worth and Maurice Whelan
2013



Promoting alternatives

EURL ECVAM Search Guide



Second edition of the EURL ECVAM Search Guide now available

— filed under: [EURL ECVAM](#), [alternatives to animal test](#), [ECVAM](#)

Good search practice on alternatives to animal testing

Encouraged by the success of the first edition in 2012, the Joint Research Centre has re-published an entirely updated version of the EURL ECVAM Search Guide.

The **second edition** of the Guide has specifically been developed to support untrained database users in finding high quality information on alternatives to animal testing (strategies and methods) from the wide range of sources available on the web.

The Guide provides examples of search procedures, suggested search terms and user guidance. It includes descriptions of relevant resources and thesauri. A check list is offered (the "seven golden steps") to allow for searches in a structured and systematic way and to document them - a basic step in preparing a research project in biomedical sciences and toxicology.


Target users are scientists, national authorities involved in animal protection and ethical committees verifying that all possible alternatives have been considered before conducting animal experiments.

Free copies can be obtained from the EU Bookshop: [EURL ECVAM Search Guide](#)

See also the dedicated EU Bookshop page [on Facebook](#)

[More info on EURL ECVAM](#)



Contact Name 

guidance
searches



— Send this — Print this —

Moving forward with the Three Rs in the EU



- *Background to the Directive and the Three Rs*
- *Two legs of the Three Rs in the Directive*
 - **Striving for new alternative approaches**
 - **Implementing the Three Rs today**
- *Calling for a new culture*



Key elements

- *Authorisation of establishments and projects*
- ***Systematic project (ethical) evaluation***
- *Binding standards for housing and care*
- ***Animal Welfare Body*** in each establishment
- *Increased transparency and enforcement with risk based inspections*



Succeeding with the Three Rs

- *Availability of information to replace, reduce and refine*
- *From imposed to self-motivated reflection on opportunities for Three Rs*
- *A need for dissemination, communication and collaboration*



Finding the Three Rs

- *Named person for the Welfare of Animals*
- *Named person for the information on the species housed and used*
- *Animal Welfare Body*
- *Designated Veterinarian*
- *Named person responsible for each Project*
- *Named person for compliance of the establishment*



Finding the Three Rs

- *National Committee to share best practice and facilitate the operation of Animal Welfare Bodies*
- *The role of Three Rs centers*
 - *No specific mandate*
 - *Collaboration initiated by EURL ECVAM*
 - *Can a strategic approach be found?*



European
Commission

Home

About us

Policies ▾

Funding ▾

Legal compliance ▾

News & outreach ▾



Animals used for scientific purposes

Legislation and implementation ▶

The "Three Rs" and alternative approaches ▾

Replacement, Reduction and Refinement – the "Three Rs" ▶

Validation, acceptance and use ▶

EU activities to advance alternatives

Member State activities to advance alternatives

Finding and distributing information on alternatives

Key resources

[Search Tools](#)

Databases

Portals and web-sites

Journals

Other resources and organisations

Animals used for scientific purposes



Search Tools

- [EURL ECVAM Search Guide \(the Guide\)](#) – The Guide is particularly helpful to inexperienced database users. It represents a useful resource where comprehensive searches for alternatives are required as part of authorisation processes for animal experiments and where regulatory requirements mandate the application of the Three Rs. The Guide provides examples of search procedures and user guidance to facilitate the location of the desired information on Three Rs alternatives; it also includes an inventory of relevant resources, contains a check list (the seven golden steps) to allow for searches in a structured and systematic manner, moreover, search principles, suggested search terms etc. Free copies of the handbook or a pdf version are available from the [EU Bookshop](#).
- [Go3R](#) – is a free of charge 'semantic' search engine making use of underlying expert knowledge on 3Rs methods to systematically retrieve Three Rs-relevant information. Currently, the semantic Go3R tool searches in the databases PubMed and TOXNET. Additionally, Go3R allows searching the entire World Wide Web using a Google search with automatic higher ranking of 3Rs relevant websites. Results of PubMed and TOXNET searches are presented to the user together with a dynamic table of contents highlighting 3Rs information and allowing to quickly restrict vast search results to relevant documents. The Go3R expert knowledge covers the entire scientific domain of alternatives to animal testing in all biomedical disciplines, but has a special focus on regulatory toxicity testing.
- [Search.norecopa.no](#) is a search engine for Norecopa's four **databases**: [3R Guide](#), [NORINA](#), [TextBase](#) and [Classic AVs](#). The search engine takes into consideration the words which have been entered by the user; an index of all the words in the databases; a list of synonyms constructed specifically for these databases; an "auto-complete" function which suggests search terms based on the search engine's own dictionary; algorithms which prioritise or suppress words depending on their relevance; Boolean operators, which the user can edit and "fuzzy logic" (words resembling those entered by the user). The user can limit the search to one or more of Norecopa's four databases, or to one or more of a variety of search fields and scientific disciplines.

Last updated: 26/10/2015 | [Top](#)

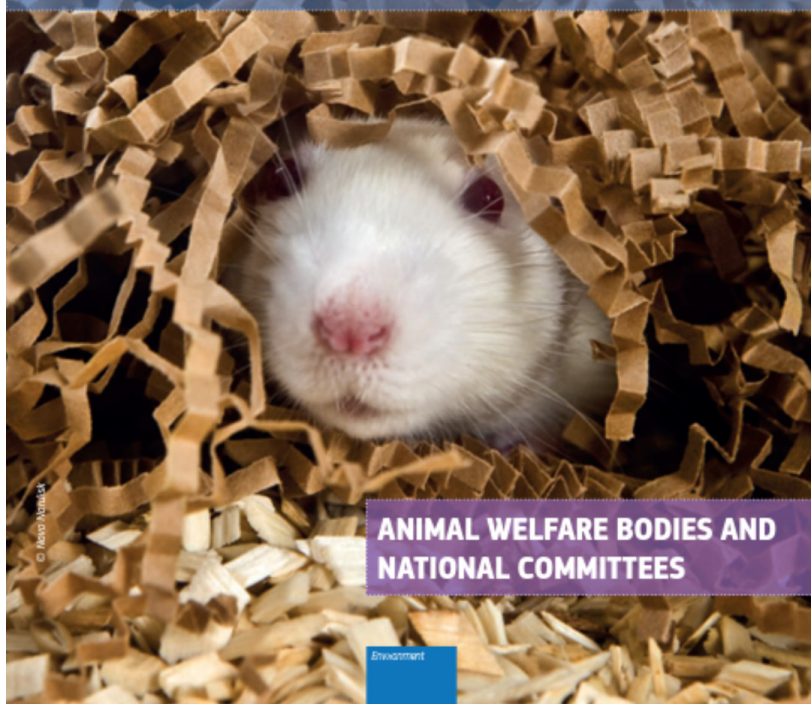


European
Commission



Caring for animals aiming for better science

DIRECTIVE 2010/63/EU
ON PROTECTION OF ANIMALS USED
FOR SCIENTIFIC PURPOSES



ANIMAL WELFARE BODIES AND
NATIONAL COMMITTEES

Environment



Caring for animals aiming for better science

DIRECTIVE 2010/63/EU
ON PROTECTION OF ANIMALS USED
FOR SCIENTIFIC PURPOSES



SEVERITY ASSESSMENT
FRAMEWORK

Environment

ING

ND
SMENT



Moving forward with the Three Rs in the EU

- *Background to the Directive and the Three Rs*
- *Two legs of the Three Rs in the Directive*
 - **Striving for new alternative approaches**
 - **Implementing the Three Rs today**
- *Calling for a new culture*



However..

*"Simply meeting the legislative requirements will **not** ensure appropriate welfare, care and use practices"*

- Requires **commitment**
- Commitment enabled through **institutional support**
- Institutional support facilitated via **regulatory support**



Culture of Care - strategy

- *Compliance with laws and regulations*
- *An **explicit action plan** by the **management***
 - *building blocks*
 - *resources*
 - *institutional support*
 - *setting example*
- *Implementation*
- *Monitoring, feedback and follow up*

Culture of care – attitude



"... EVEN better!"

"... STILL higher!"

Many faces of Culture of Care



- *Willingness for initiative*
- *Individual responsibility and empowerment*
- *Improving standards vs reacting to problems*
- *Management acknowledgement*
- *Award and recognition programmes*
- *Inspector's role...*



Three Rs stem from CoC

- *Improvements in housing*
 - e.g. igloos for metabolic cages
- *Non-acceptance of repeated problems*
 - e.g. dermatitis in mice
- *Project design - e.g. openness to employ new techniques to replace standard practice, willingness to receive team input*

New Directive, new cultures..



Change of mindset

- *bringing Three Rs alive through commitment, openness and team approach*
- *But...is the legal framework and the right Culture of Care enough?*



Facts..

- *Fish belong to the group of cold-blooded species*
- *Brain is isolated from the main lymphatic immune-system of the body*

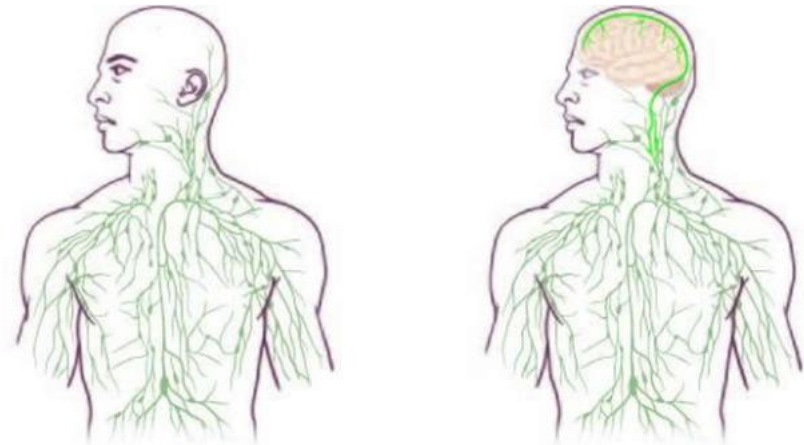
....?



***Meet Opah,
the warm-blooded fish!***

***"Time to rewrite the
biology books!"***

new lymphatic system map



Culture of **Challenge**



Challenge – the path for discovery

Researcher

- **Right questions?**
- **Right disciplines?**
- **Right models?**
- **Beyond obvious?**

- **Refinement..**

Culture of **Challenge**



Refined questions on refinement:

- *Isolation*
 - **visual, olfactory, acoustic contact?**
- *Reduced space*
 - **alternative enrichment?**
- *Use of analgesia, ...*

Culture of **Challenge**



Competent Authority

- **Project evaluation**
 - Training/expertise
 - Competence
 - Support
- **Authority**

Culture of **Challenge**



*Animal technicians, animal caretakers,
veterinarians*

- **Practices, standard techniques**
- **'Status quo' e.g. repeated problems**
- ***Authority***

Building Culture of Challenge



**on a solid foundation
of Culture of Care**



Conclusions

- *Legal framework and necessary networks in place to strive for new alternative approaches – **take part***
- *From aspiration to practical, continued implementation of the Three Rs*
- *Three Rs is **everyone's responsibility***
- *Time to roll out **Culture of Challenge**
- for the benefit of science and animals*

A full-page background image showing two divers in a dark underwater cave. The scene is dimly lit with blue and green light filtering through the water. One diver is in the foreground, silhouetted against the light, holding a camera. Another diver is further back, also silhouetted. The cave walls are rocky and uneven. Bubbles are visible rising from the divers. The overall mood is mysterious and adventurous.

Go find your Opah

*with compassion
and care!*

Thank you for your attention!

More information at:

**[http://ec.europa.eu/
animals-in-science](http://ec.europa.eu/animals-in-science)**

