



# Directive 2010/63/EU

On protection of animals  
used for scientific purposes

- Implementing the Three Rs through the Directive
- Keys aspects of Project Evaluation



# Implementing the Three Rs through the Directive

- *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**
- *Project Evaluation – how it should look like*
- *Calling for a new culture*





## Background to revision

- *Old Dir 86/609/EEC 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 of 2010/63/EU

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



# 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***







## 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***





# 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

Reffaela Corvi, Federico Madia,  
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](#)

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## Where are we today?



**Busy working together**





# Implementing the Three Rs today

- *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*





## The objectives of a systematic Project Evaluation (Art.38)

- *Animals are used only when properly justified*
- *Assurance that no alternatives are available*
- *The minimum numbers of animals are used*
- *The procedures cause the least pain, suffering, distress or lasting harm*
- *Expected benefits must outweigh the harms taking into account ethical considerations*

# Common problems with the content

➤ *Too little*



➤ *Too much*



➤ *Too old*







# Information provision for Project Evaluation (PE)

*The quality of information submitted for the PE is a **crucial prerequisite** for an efficient and accurate project evaluation. It has to be*

- *Correct*
- *Complete*
- *Current*
- *Relevant*



## The level of detail **may vary** based on, e.g.

- *Type of project (e.g. regulatory work, basic research, education)*
- *Species and numbers of animals and their level of sentience*
- *Scale of project, complexity, novelty (e.g. pilot studies)*
- *Duration of project*
- *Expected severity of the procedures in the project*



## The level of detail that **should not vary**, e.g.

- *Application of the **Three Rs** (e.g. refinement, use of humane end-points and pain relief, housing and care practices)*
- *Individual procedures and how the related **severity classification** translates to the numbers of animals involved*



## 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**

*\* add creativity, collaboration, courage,...!*



## Culture of care – attitude



*"... EVEN better!"*

*"... STILL higher!"*



# 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 **Challenge**

*Challenge – the path  
for discovery*

*Researcher*

- Right questions?
- Right disciplines?
- Right models?
- Beyond obvious?
- Refinement..

*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**

## *Animal technicians, animal caretakers, veterinarians*

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







## 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*



*Thank you for  
your attention!*

*More information at:*

[http://ec.europa.eu/  
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