

# Challenges for the implementation of Directive 2010/63/EU

Oscar Dignoes Torres-Quevedo  
ceeba@marm.es

Animal Welfare Unit  
Ministry for Environmental, Rural and Marine Affairs,  
Spain

<http://www.remanet.net/>

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# Structure of the presentation

Analysis of Directive 2010/63/EU, focusing on the 3 Rs and on alternative approaches

1. Whereas introducing the Directive (Desiderata)
2. Specific articles of the Directive

# 1. Whereas introducing the Directive (Desiderata)

- 14 out of a total of 56 “Whereas” directly or indirectly address the principle of 3Rs with special attention to the alternative methods

Whereas: 10, 11, 12, 13, 14, 27, 31, 38, 39, 42, 46, 47, 48 and 49

- Important step towards achieving the final goal of full replacement on procedures on live animals (W 10).
- The principles of the 3 Rs should be considered systematically when implementing the directive (W 11)
- Alternative methods are top hierarchy in implementing 3Rs (W 11)

## 2. Specific articles of the Directive

- 17 out of 66 articles directly or indirectly regulate, or at least address, the principle of 3Rs and the alternative approaches

Articles: 1, 4, 13, 18, 20, 23, 27, 37, 38, 39, 43, 46, 47, 48, 49, 54, 58

- A. Obligation to use alternative methods
- B. Requisites on users, projects & personell
- C. Promotion, Facilitation & Dissemination
- D. Transparency and Information
- E. Development & Validation
- F. Networking
- G. The Future: Review of the Directive

## A. Obligation to use alternative methods

- **No procedure shall be used** if a scientifically satisfactory alternative method or testing strategy is available (art. 4)
- **No procedure shall be carried out** if an alternative method or testing strategy for obtaining the result sought is recognised under EU legislation (art. 13)
- **No procedure shall be duplicated** in a MS if there are already data available which have been obtained in other MS by procedures recognised under EU legislation, with some exceptions (art. 46)

## B. Requisites

- Each user
  - Must be authorised (art. 20)
  - Must designate a responsible person (art. 20)
  - Must establish an Animal Welfare Body (art, 26 and 27)
- Each project
  - Must be evaluated (art. 38)
  - Must be authorised (art. 36 and 37 and Annex VI)
- Some projects
  - May undergo a retrospective assesment (art, 39)
- Personell: must be competent (art. 23 and annex V)



## C. Promotion, Facilitation & Dissemination

- Programs for sharing organs and tissues of killed animals (art. 18)
- Animal-Welfare Body (art. 27.b): advisory
- MS shall ensure promotion and dissemination at national level (art. 47.3.)

## D. Transparency and Information

- Publication of non-technical project summaries (art. 43)
  - Including a demonstration of compliance with 3Rs
- Statistical reporting (art. 54)
  - Useful as benchmarks for measuring progress
  - Essential information source on trends
  - Harmonized generation and collation of data

## D. Development & Validation

- ECVAM as EURL for alternative methods (art. 48 and Annex VII)
- European Commission and MS shall contribute to the development and validation of alternative approaches (art. 47)
- Including in the areas of basic and applied research and regulatory testing (annex VII)

## E. Networking: Pooling Experience, expertise and resources

- Network of National Contact points (art. 59 and 47)  
For the implementation of the directive (general)
- Network of National Committees (art. 49)  
Exchange of information and operations of AWB and share best practices within the EU
- NETVAL: A network of laboratories for the development and validation of Alternative methods under ECVAM's impulse and guidance as EURL (art. 47.2 and 47.3)
- Network of National PARERE Contact points (art. 47.5)

## F. The Future

- The Directive will be reviewed in 2017, in order to allow its adaptation to new possibilities on the implementation of 3Rs due to scientific development, with special emphasis on replacement (art. 58)
- The Commission, MS and stakeholders shall conduct periodic thematic reviews of the 3Rs (art. 58)

This directive is not an end-point,  
it is not destination,  
but rather another step  
on the long and winding road  
towards the final goal  
of full implementation of the 3 Rs

## This is not the end

- **It is up to us,**
  - administration
  - scientific community
  - NGOs
  - and the rest of the stakeholders
- **To pool efforts and resources....**

This is the end.

**THANK YOU  
FOR YOUR  
ATTENTION**

**Oscar Dignoes**