

Retrospective Assessment

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Requirements of Directive 2010/63/EU

1. Retrospective review

Article 27 – tasks of animal welfare body

“The animal welfare body shall, as a minimum, carry out the following tasks:

1.(d) follow the development & outcome of projects, taking into account the effect on the animals used & identify & advise as regards elements that further contribute to the 3Rs”

2. Retrospective assessment

Article 39 – retrospective assessment

3. Review

Article 58 – Review

“The Commission shall review this Directive by 10 November 2017...”
and

“...in consultation with Member States and stakeholders, conduct periodic thematic reviews of the 3Rs...”

Requirements of Directive 2010/63/EU

Article 39 – Retrospective Assessment

1. *“Member States shall ensure that, when determined in accordance with Article 38 (2)(f) (Project Evaluation), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:*

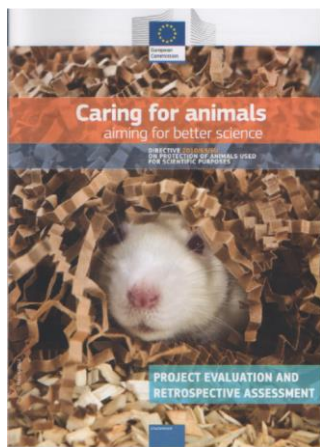
- a) *Whether the objectives of the project were achieved*
- b) *The harm inflicted on animals, including the numbers and species of animals used and the **severity** of the procedures*
- c) *Any elements that may contribute to the further implementation of the requirements of replacement, reduction and refinement”*

Requirements of Directive 2010/63/EU

Article 39 – Retrospective Assessment

2. *“All projects using non-human primates and projects involving procedures classified as ‘severe’, including those referred to in Article 15(2) (safeguard clause), shall undergo a retrospective assessment.*

Member States may, by way of derogation, exempt projects involving only procedures classified as ‘mild or ‘non-recovery’ from the requirement for a retrospective assessment.”



Retrospective assessment and review [in](#)

RSPCA and LASA, 2015, **Guiding principles on good practice for Animal Welfare and Ethical Review Bodies**. A report by the RSPCA Research Animals department and LASA Ethics & Training Section. (M. Jennings ed.)

The value of looking back: Improving Science & Welfare through Retrospective Review (2007). M. Jennings, B. Howard & M. Berdoy

www.lasa.co.uk/publications.html

Benefits of retrospective assessment

- Opportunity to review outcome of project against objectives set and, when applicable, reasons where not achieved
- Comparison of actual versus predicted harms
- Comparison of actual numbers of animals used versus estimates and consideration of reasons for variation
- Opportunities to identify future refinement possibilities
- Opportunity, should something go wrong during study, to analyse reasons thereof and learn from these
- Allows competent authority to review effectiveness of project evaluation/harm benefit analysis
- Increased transparency & accountability when published

Factors to determine if retrospective assessment should be carried out

In addition to severe projects & those involving NHPs, project evaluation could decide to include retrospective assessment for:

- Introduction of new models or research areas
- Significant uncertainties in outcomes or effects on animals e.g. creation & breeding of certain GA lines
- Regulatory studies on new classes of compound
- Projects whose purpose is education & training
- Continuation of a project where severity exceeded that predicted

Timing of retrospective assessment

Determined at project evaluation stage based on:

- Case-by-case but as soon as practicable following completion of project
- When performed a considerable time after project completion, mechanisms must be in place to secure information for retrospective assessment
- At termination of pilot studies if these precede more extensive work
- At key milestones or annually in long-term projects e.g. annually in a 5 year project

Information gathering for retrospective assessment

- Primary responsibility lies with user but some oversight by person responsible for overall implementation of project
- Flexibility in the process as described for periodic feedback
- Proportionality in the detail – degree of sentience, severity of procedures, experience of applicant
- Input from all relevant persons including those responsible for animal care and welfare
- A template is helpful to specify information (see later slides)
- Feedback to researcher in order to introduce improvements/changes for future studies

Information requirements – Achievements

- Explain briefly how & to what extent the objectives set out in application have been met
- Provide information if there have been other significant findings
- Where appropriate, provide reasons why objectives not been attained
- Describe the benefits that have accrued from the work to date and if further benefits are expected

Information requirements – Animal use & Severity

- Give details of animal numbers and species used together with severity experienced (on individual animal basis)
- Provide an explanation for any differences to those estimated in the application

Information requirements – Implementation of the 3Rs

Replacement

- Identify any developments in the relevant scientific field that might replace some or all of the use of animals

Reduction

- Revisit the experimental design to enable further reduction in predicted animal use
- Review the appropriateness of the model
- Review statistical analysis (too many/too few)

Information requirements – Implementation of the 3Rs

Refinement

- List refinements introduced to reduce harm to the animals
- Identify any further reduction to the harms
- Identify further refinements to the procedure (e.g. surgery, administration routes)
- Review animal monitoring regimes for improvement
- Review score sheets/welfare protocols for improvement
- Review appropriateness of humane end-points
- Review appropriateness of euthanasia methods

Outcomes from retrospective assessment

1. Feedback to research group

- Issues raised by assessment process including suggestions for future improvements and recommendations to disseminate key information

2. Dissemination of information on use of animals & 3Rs (+/-)

- Within establishment
- Promotion of publications, presentations by researcher/user
- Role of National Committee (Article 49) in sharing best practice by identification, collation and publication of key issues arising from RAs

Outcomes from retrospective assessment

3. Updated information on non-technical project summaries

- Updating of the non-technical summary will provide greater transparency on actual harms and benefits related to the use of animals in scientific procedures (Article 43)

Factors for success

1. Make it a positive & constructive experience

- Make the process and objectives clear
- Make staff aware of how it benefits them, their science and animal welfare
- Be inclusive of all relevant staff
- Include information in local training courses/CPD
- Focus on discussion and outputs not filling in forms
- Provide feedback, including concerns and any remedial action taken

Factors for success

2. Create a workable process – one size does not fit all

- Be flexible with timing and plan at the outset
- Prioritise projects for review – those with higher severity, larger numbers, new models
- Keep documentation to a minimum – identify inputs and how it will be provided
- Be clear who is involved – it may not need a whole committee
- Focus on outputs and how to move things forward

Factors for success

3. Ensure it is properly resourced

- Make it an integral part of project management and team meetings
- Combine with other activities e.g. review by grant-awarding body, preparing papers for publication, submission of amendments
- Involve senior management so they see the value