



Directive 2010/63/EU

**Project evaluation – importance of a
coherent and consistent approach**

Importance of a coherent and consistent approach to Project Evaluation



- *Why a consistent approach to PE*
- *Influencing factors*
- *Conclusions*

Systematic Project Evaluation (Article 38)



- ✓ *Evaluate the aims and objectives*
- ✓ *Assess application of the Three Rs – Annex VI*
- ✓ *Assess and assign severity classification of the procedures – Annex VIII*
- ✓ *Carry out a harm-benefit analysis of the project*

Systematic Project Evaluation (Article 38)



...continued

- ✓ *Assess justifications for requesting exemptions*
- ✓ *Determine the need for a retrospective assessment of the project*

The objectives of a systematic Project Evaluation



- *Systematic implementation of the Three Rs*
- *Efficient and effective project evaluation process*
 - **Administrative burden to minimum**
 - **No PE shopping**

Systematic Project Evaluation ensures that



- *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*
- *Benefits are expected to outweigh the harms taking into account ethical considerations*

Directive review findings 2017



- *Concerns re time taken to obtain project authorisation*
- *Despite guidance, applicants found it difficult to submit the necessary "correct and complete" information to the CA and*
- *Requirements vary significantly between MS*
- *Suggested lack of (numbers and experienced) staff at competent authority to deal with applications*

Directive review findings 2017



***Inconsistency of the PE process** was highlighted, in particular, where multiple competent authorities (up to 125) and review groups were involved within MS, and between MS with different processes*

Why consistency in PE must be addressed



- *Inconsistencies within and between MS*
- *Non-level playing field for users*
- *Systematic application of the Three Rs questionable*
- *Risk of wasted resources and delayed science*

Importance of a coherent and consistent approach to Project Evaluation



- *Why a consistent approach to PE*
- *Influencing factors*
- *Conclusions*

Factors influencing consistency



- *Information requirements*
- *Evaluation process*
- *Training / Expertise of Evaluators*

Information Requirements

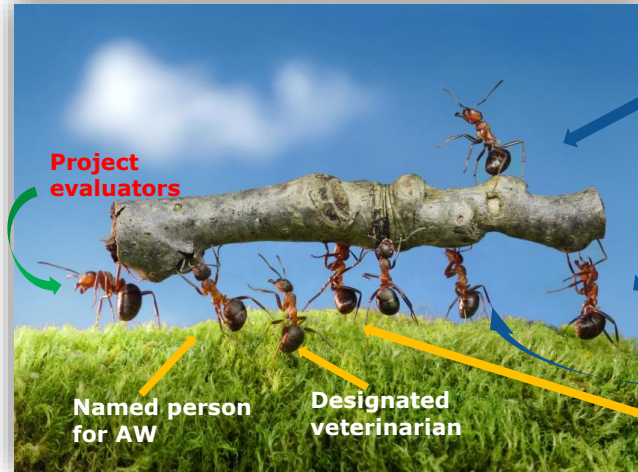


- *"Procedure vs Project"*
- *Simple vs Complex*
- *Ensuring a "complete & correct" application*
- ***Level of detail***
- ***MSI ! (MS Specific Information requirement)***

Implementing existing Three Rs – Project Evaluation



- Justification for the animal models?
- How were alternatives searched?
- Experimental design? Reduction of bias?
- Use of humane end-points, observational strategy?
- Origin of animals & training?
- Refinement during procedures?
- Dissemination of results?



Named person responsible
for establishment compliance

Named person responsible
for project compliance

Named person responsible
for staff competence

Competent staff

- ~~✓ Pain relief, anaesthesia?~~
- ~~✓ AW and care procedures respect legal requirements?~~
- ~~✓ Properly educated and trained, competent staff?~~
- ~~✓ Compliant housing, appropriate to the species?~~

Promoting correct information



Inter alia through

- *Project template*
- *Guidance on completion of template*
- *Provision of examples*
- *Include application structure/content in training*



Evaluation Process

- *PE was new to many MS*
- *Number of Competent Authorities for PE: 1-125*
- *Significantly differing structures developed*
 - *National - 18*
 - *Regional - 6*
 - *Local - 4*

Factors influencing consistency



- *Information requirements*
- *Evaluation process*
- ***Expertise/training of evaluators***

Project Evaluation (Article 38)



- *The Competent Authority shall consider expertise in*
 - ***Relevant scientific use***
 - ***Experimental design***
 - ***Veterinary practice***
 - ***Animal husbandry & care***
- *Evaluation to be performed in an impartial manne*



Training / Expertise of evaluators

- *Difficulties in securing sufficient experienced evaluators (non-availability/costs) – in particular in certain areas of science, or in smaller MS*
- *Training for Project Evaluators delivered by 6/28 MS*
 - ***EP Pilot to deliver open access, eLearning module for project evaluation (end 2020)***

Promoting consistency in the EU



- *Twice yearly MS meetings*
- *EU Guidance on PE/RA -in 23 languages*
- *EP grant – eLearning module for Project Evaluators (available by end 2020)*
- *EU Publication of NTS / RA from July 2021*

Promoting consistency in MSs



- ***Review of projects (evaluations) within and across competent authorities, where applicable***
- *Role of national authorities – development and review of requirements, processes, guidance, templates*
- *Role of National Committees, where applicable*

Take action – everyone wins!



National authority:

- **Review information requirements**: essential for harm-benefit assessment or duplication of tasks?
- **Review processes**; identify and remove duplication
- Provide **sufficient resources** (expertise, tools, training)

Take action – everyone wins!



Competent authority for PE:

- *Review information requirements and processes*
- **Engage in dialogue** where not optimum
- **Require** sufficient expertise, **request** training

User:

- **Engage in dialogue** where issues identified



More information at:

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

***Thank you
for your attention!***