Directive 2010/63/EU

Project evaluation – importance of a coherent and consistent approach

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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

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

- 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

Project evaluators
- Named person for AW
- Designated veterinarian

Experimental design? Reduction of bias?

Use of humane end-points, observational strategy?

Origin of animals & training?

Refinement during procedures?

Dissemination of results?
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 manner
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!