



Caring for animals aiming for better science

EU GUIDANCE ON THE IMPLEMENTATION OF DIRECTIVE 2010/63/EU ON PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

PROJECT EVALUATION

LEGAL REQUIREMENTS – PROJECT EVALUATION (PE)

As per recital 39 and Article 38 of the Directive 2010/63/EU, “it is essential, both on moral and scientific grounds, to ensure that *each use of an animal is carefully evaluated as to the scientific or educational validity, usefulness and relevance of the expected result of that use. The likely harm to the animal should be balanced against the expected benefits of the project.*”

“Therefore, an impartial project evaluation independent of those involved in the study should be carried out as part of the authorisation process of projects involving the use of live animals. Effective implementation of a project evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge”

INFORMATION IN PROJECT APPLICATION

There needs to be a mechanism for ensuring provision of sufficient good quality information, with evidence that the applicant has considered and understood all the relevant issues, to facilitate a well-informed harm-benefit analysis.

An application for a project authorisation shall include a project proposal, non-technical project summary and specific information as set out in Annex VI of the Directive. (see box)

The Directive also requires specific justification for the use of certain types or sources of animal, methods of killing other than those listed in Annex IV, and for work that is carried outside a user establishment.

All information included should be correct, complete, current and relevant and be presented in sufficient detail to facilitate an effective evaluation of the harms and benefits of the project.

ANNEX VI

LIST OF ELEMENTS REFERRED TO IN ARTICLE 37(1)(C)

1. Relevance and justification of the following:
 - (a) use of animals including their origin, estimated numbers, species and life stages;
 - (b) procedures.
2. Application of methods to replace, reduce and refine the use of animals in procedures.
3. The planned use of anaesthesia, analgesia and other pain relieving methods.
4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.
5. Use of humane end-points.
6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.
7. Reuse of animals and the accumulative effect thereof on the animals.
8. The proposed severity classification of procedures.
9. Avoidance of unjustified duplication of procedures where appropriate.
10. Housing, husbandry and care conditions for the animals.
11. Methods of killing.
12. Competence of persons involved in the project.

KEY FACTORS NECESSARY FOR AN EFFECTIVE PROJECT EVALUATION PROCESS

1. Availability of suitable expertise – scientific; veterinary; experimental design; husbandry & care
2. Impartiality – lack of conflict of interest
3. Proportionality
4. Consistency
5. Efficiency
6. Transparency of the process
7. Access to an independent appeals process
8. Detailed understanding of context of and criteria for PE, in particular harm
9. Sufficient resources
10. Knowledge of local culture and practices

PERFORMING A PROJECT EVALUATION

Requires assessment of scientific justification, ensures application of the Three Rs and that harms to the animals are justified by the expected outcomes taking into account ethical considerations.

BENEFITS (WHAT, WHO, HOW, WHEN)

There should be an expectation and confirmation in the application that the project will contribute new knowledge, and that there is no unjustified duplication of animal use.

IDENTIFICATION OF DIRECT AND INDIRECT BENEFITS

- **What** will be the benefits of the work?
- **Who** will benefit from the work?
- **How** will they benefit – impact?
- **When** (where possible) will the benefits be achieved?

Although not always possible, some quantitative/qualitative estimate of the impact of the research is helpful to evaluators – for example the number of persons/animals affected and the level of improvement which can be expected if the project is successful.

HARMS

The assessment of harms during PE has to consider the impact on all animals planned for use in the project – prospective severity classification of procedures is based on the highest severity anticipated for a single animal – however, this effect may only be expected in 1/100 animals or could be expected 90/100 animals, significantly affecting the overall welfare “costs”. It is important therefore to know what the predicted severity is for all animals used on the procedure, taking into account the methods used to minimise adverse effects.

The key issues which need to be included in consideration of harms include:

- Procedures being applied to animals;
 - o Frequency/duration of procedures;
 - o Likelihood of adverse effects;
 - o Severity level and methodology to minimise severity;
 - o Monitoring regime; welfare assessment protocols;
 - o Humane end-points and triggers for interventions;
- Species/strain/age of animals being used;
- Number of animals;
- Fate of animals;
 - o Death – intrinsic value of animal; “quality” of death impacts on animal’s experience and on severity;
 - o Criteria for re-use or rehoming;
- Contingent harms – husbandry and care practices; transportation.

LIKELIHOOD OF SUCCESS

Many factors can influence the potential of a project to achieve the predicted benefits and these need to be given due consideration in the analysis of the project. These include e.g.:

- realistic objectives (SMART – Specific; Measurable; Achievable; Realistic; Timely);
- scientific soundness;
- adequately resourced (financial, appropriate facilities, personnel – scientific and care staff);
- experience/track record in field and in specific area of planned work;
- clearly defined plan of work – choice of methods/design/species/animal model;
- feedback from retrospective assessment of previous projects from the applicant/research group should increasingly facilitate determination of likelihood of success.

HARM – BENEFIT ANALYSIS

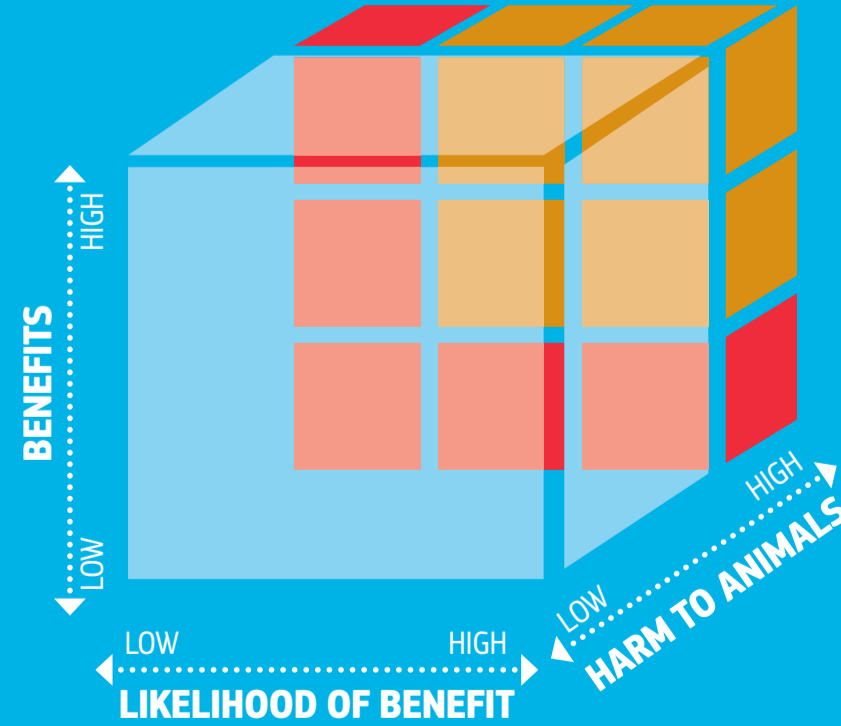
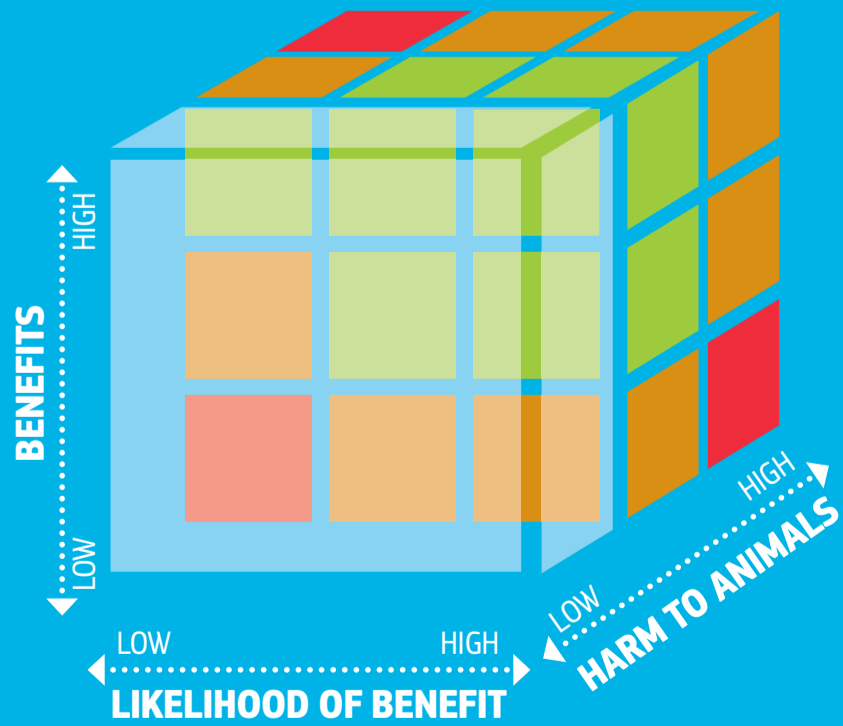
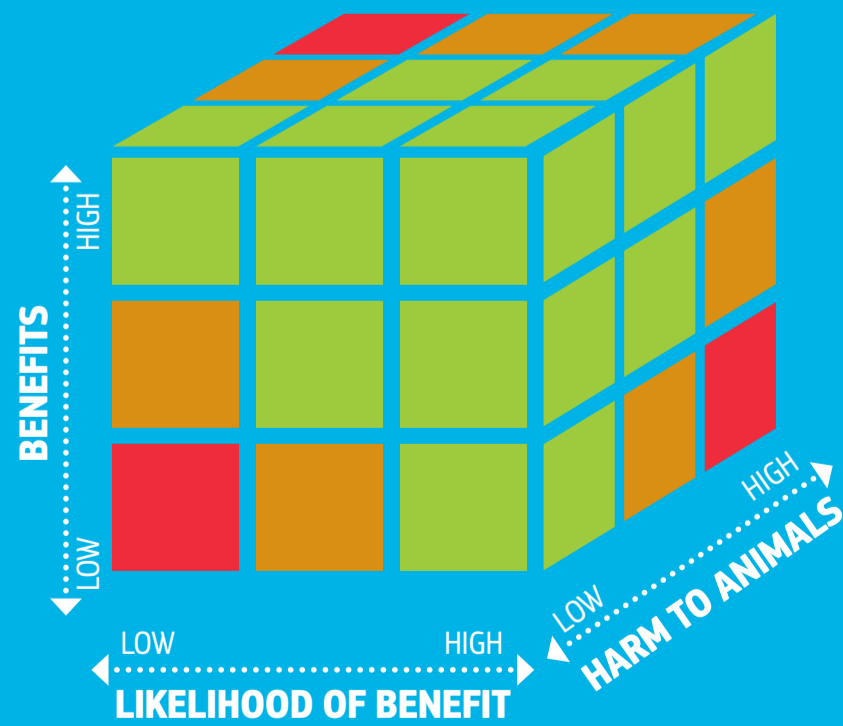
The weighing of harms against benefits is not a simple decision-making process and requires carefully consideration. For well-informed judgements to be made all relevant information must be available to those undertaking the PE.

$$\text{Justification} = \frac{\text{Importance of objectives} \times \text{Probability of achievement}}{\text{Harms to animals}}$$

A thorough understanding of these three areas is essential to enable an informed decision to be reached.

A number of “models” have been used to inform the process, the Bateson cube (1986) is used by some as a simple matrix to assist the process. This algorithm suggests that the level of suffering should be linked to the importance of research (potential benefits) and the likelihood of the benefit being achieved. Where high welfare cost is linked to low importance research with low likelihood of any benefit, the use of animals for such work should not be permitted.

A revised “Cube” was developed by the Expert Working Group using colours to indicate which applications would require most scrutiny with regard to a harm/benefit analysis. The colours reflect a relationship between the level of harms, degree of benefits and likelihood of success. Where the intersection of the variables is shaded green it is likely that a favourable harm-benefit analysis will result from the project evaluation. In contrast, it is likely that much more detailed considerations will be needed for the amber and red shaded cubes.



MODIFIED
BATESON CUBE

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

(Bateson, P. When to experiment on animals. New Scientist, 109 (1986) p 30-32)



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