



Nationaal Comité
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The role of the Animal Welfare Bodies (AWB) and Competent Authorities

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The role of the Animal Welfare Bodies (AWB) and Competent Authorities

- Project authorisation – the landscape
- Competent Authority
- Animal Welfare Body
- National Committee
- Requirements
- How to facilitate?



Project evaluation - Competent Authority

Recital 39

- 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.
- 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.



Project evaluation - Competent Authority

Article 36

- Member States shall ensure,..., that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the authorisation.
- Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.



Project evaluation - Competent Authority

Article 38

1. The project evaluation shall verify that the project meets the following criteria:
 - a) the project is justified from a scientific or educational point of view or required by law;
 - b) the purposes of the project justify the use of animals; and
 - c) the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.



Project evaluation - Competent Authority

Article 38

2. The project evaluation shall consist in particular of the following:
 - a) an evaluation of the objectives, the predicted scientific benefits or educational value;
 - b) an assessment of the compliance of the project with the 3Rs;
 - c) an assessment and assignment of the classification of the severity of procedures;
 - d) a harm-benefit analysis of the project;
 - e) an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and
 - f) a determination as to whether and when the project should be assessed retrospectively.



National committees for the protection of animals used for scientific purposes

Recital 48

There is a need to ensure a **coherent approach to project evaluation and review strategies** at national level. Member States should establish national committees for the protection of animals used for scientific purposes to give advice to the competent authorities and animal-welfare bodies in order to promote the principles of replacement, reduction and refinement.

A **network** of national committees should play a role in the exchange of best practice at the level of the Union.



National committees for the protection of animals used for scientific purposes

Article 49

Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

The national committees shall exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union.



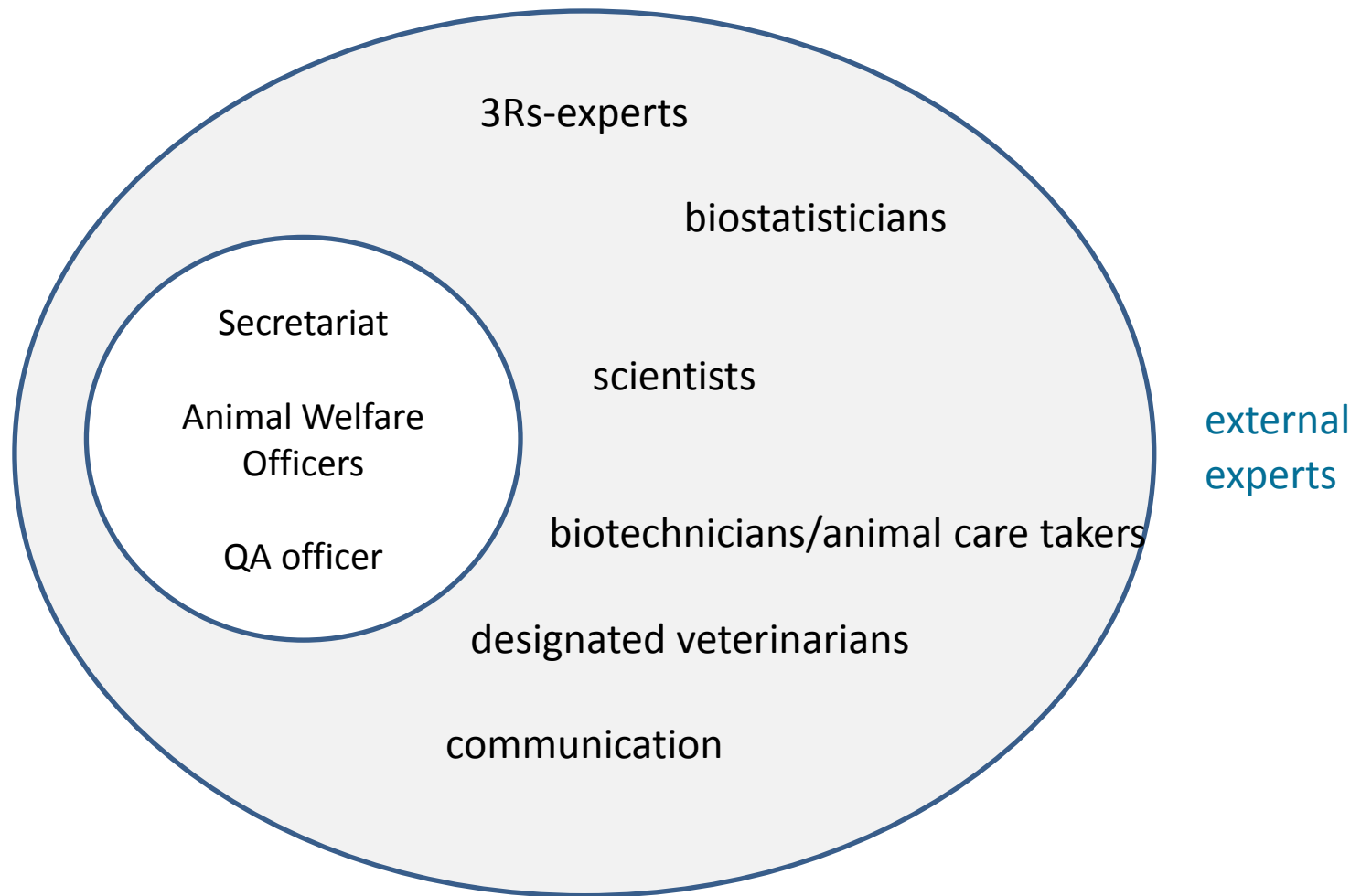
Animal Welfare Bodies

Article 26

- Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body
- The animal-welfare body shall include at least:
 - › Person(s) responsible for the welfare and care of the animals
 - › a scientific member
 - › input from the designated veterinarian



Composition of the Animal Welfare Bodies





Tasks of the Animal Welfare Bodies

Article 27

The AWB shall, as a minimum, carry out the following tasks:

- advise staff on: welfare, acquisition, accommodation, care and use;
- advise staff on the application of 3Rs, and keep it informed of technical and scientific developments;
- establish and review internal operational processes: monitoring, reporting and follow-up in relation to the welfare of animals housed or used;
- follow the development and outcome of projects
- advise on rehoming schemes



Animal Welfare Bodies also

- Advice on best practices
- Contribute to training and education
- Provide a critical forum for: review of applications, day-to-day application of the 3rs,
- Develop internal policies
- Promote and facilitate tissue sharing and avoidance of surplus animals
- dissemination of information on 3Rs, animal welfare, interdisciplinary initiatives, etc.
- Foster a culture of care
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competent authority

scientists

biotechnicians

applicants

establishment licence holder

animal caretakers

AWB

veterinarians

national committee

3R experts

biostatistician

AEC

students

public



Animal Welfare Bodies – licence applications

- Is the application complete
- All the information needed for a proper justification
- Experimental design
- Justification on specific issues
- Inclusion of best practices
- Considering the 3Rs
- Acceptability of the research from a local view





Licence applications – starting point

- Continue on a track based on former choices
- Need for a documented argumentation for every project/experiment and the design of it
- In order to:
 - › enhance quality of research questions and experimental design,
 - › prevent unnecessary repetition,
 - › contribute to transparency





Synthesis of Evidence

- Encourage the application of a documented SoE in the design of a research project that considers the use of laboratory animals
- Assessors of projects involving animal procedures should critically assess the application of SoEs during in the assessment of projects.
- SoE should facilitate decision-making in by assessors



Synthesis of Evidence – what is needed?

- Maximum access to the results of scientific research
- Open access
- Negative results
- Data bases
- Data sharing
- Tools, education and training, facilitation





Synthesis of Evidence – how could AWBs facilitate?

- Organize/facilitate access to information (*journals, databases, online resources, .*)
- Act as a consulting service
- Share best practices
- Be an intermediary between disciplines
- Establish an open communication framework
- Organize/facilitate training courses on SoE
- Stimulate publishing according to the ARRIVE guidelines
- Organize critical mass for the internal review of a licence application



Synthesis of Evidence – how could CA facilitate?

Make available information on:

- Criteria used to assess the substantiation of the need for an animal experiment
- Applicable 3R methods
- Valid arguments for justification on specific issues

- Give information on in vitro methods used in previous steps and its limitations for the next steps