



Regulatory Framework and Harmonisation on the Care and Use of Animals in Research

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Director Europe & Latin America

ESLAV Course, KI Stockholm, 25 June 2018

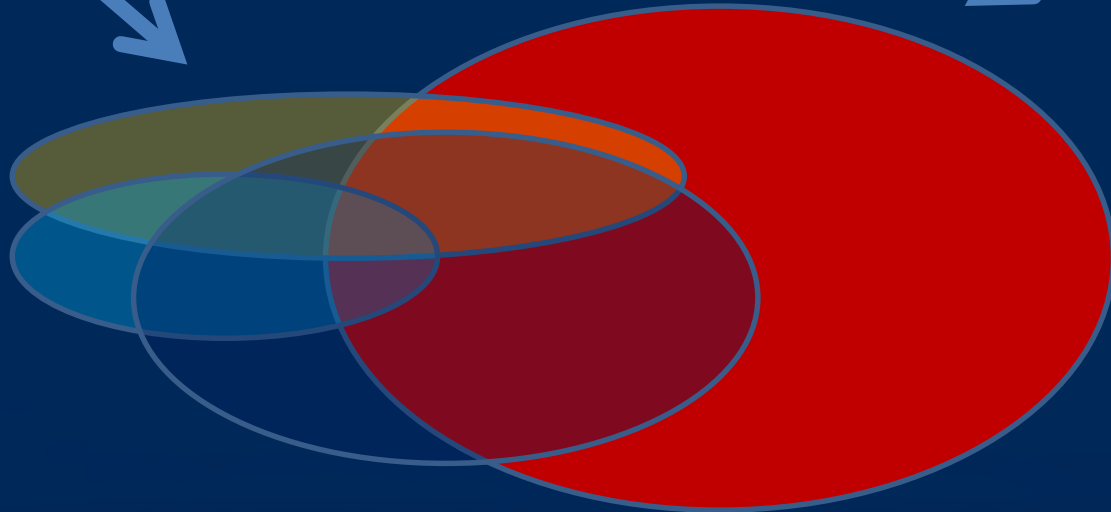




Professional
Guidelines
Recommendations



Legal
Standards



Science/
Best practice
Standards



The Principles...

- **The Three Rs of Russel & Burch (1959)**

Replacement, Reduction, Refinement

- **The Five Freedoms of Brambel (1965)**

From Hunger and Thirst

From Discomfort

From pain, injury, or disease

To express (most) normal behaviour

From fear and distress



...Internationally accepted (1):

- **Council of Europe ETS 123 (1986)**

Three Rs (not explicitly) but across the articles

- **U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (1985)**

Three Rs (not explicitly) but across the principles



...Internationally accepted (2):

- Directive 2010/63/EU (2010)

Article 4 (Three Rs), and across entire document

- Guide for the Care and Use of Laboratory Animals 8th edition
(NAS, 2011)

pp. 4-5 (The Three Rs)



...Internationally accepted (3):

- **World Organization for Animal Health (OIE)(2012)**

Terrestrial Code Chapter 7.1. (Five Freedoms + Three Rs)

Terrestrial Code Chapter 7.8.3.: Three Rs

- **CIOMS-ICLAS International Guiding Principles for Biomedical Research Involving Animals (2012)**

Principle iii): Adoption of the principle of the Three Rs



...Internationally accepted (4):

CCAC

AALAS

FELASA

FESAHANCCAL

AFLAS

FESSACAL

ANZCCART



Requirements on programme areas





But different implementation, why?

- Tradition
- Politics
- Financial implications
- Resources
- Pragmatism
- Culture
- Religion
- Need to be different? (and of course, the best)



USDA

PHS (NIH)

Animal Welfare Act
Rats, mice and birds?

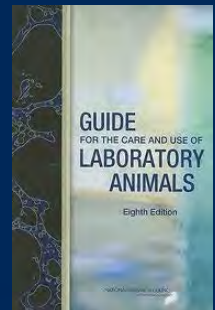
PHS Policy

Animal Welfare Regulations

Animal Welfare Assurance

APHIS Inspections

OLAW - Guide

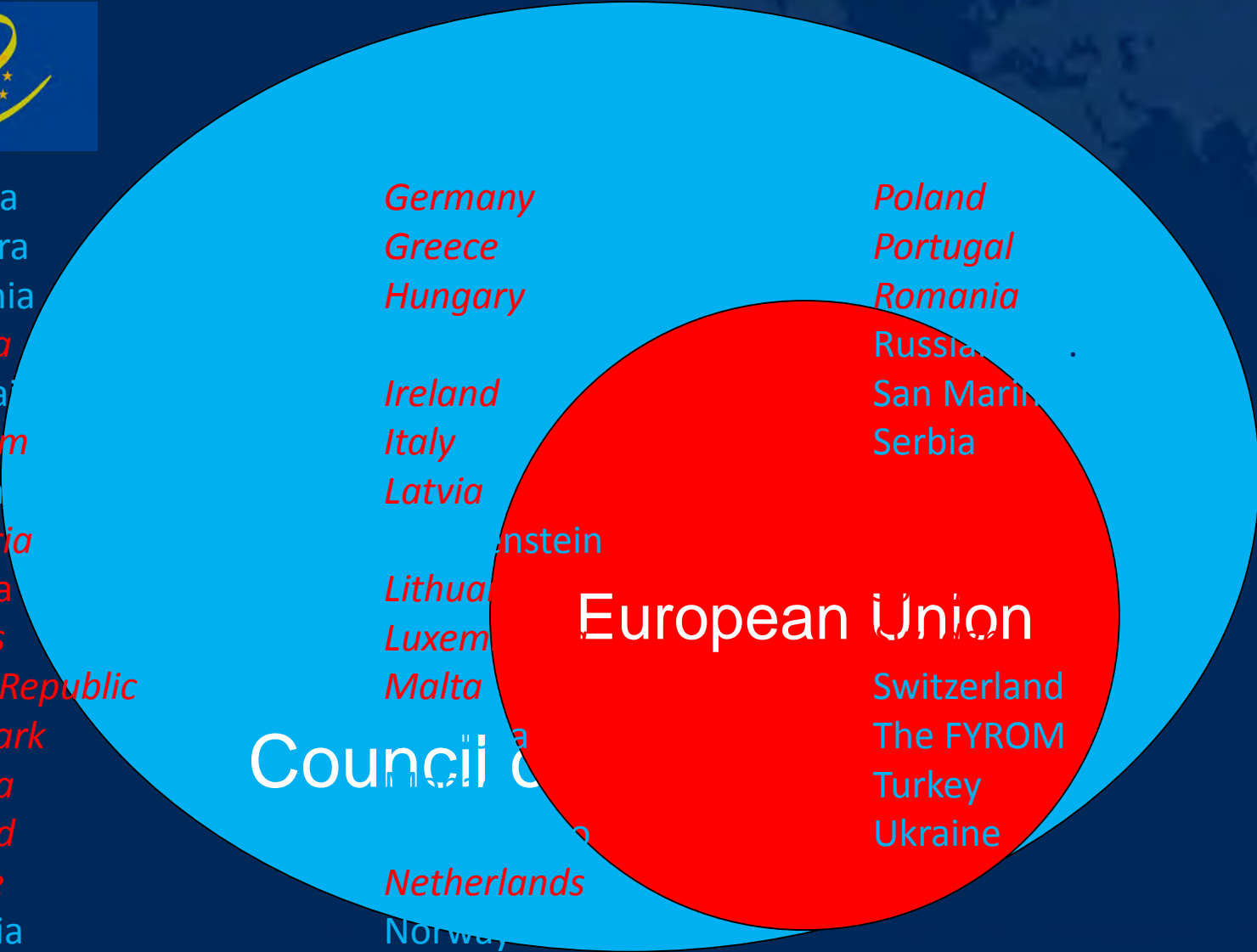




Albania
 Andorra
 Armenia
 Austria
 Azerbaijan
 Belgium
 Bosnia
 Bulgaria
 Croatia
 Cyprus
 Czech Republic
 Denmark
 Estonia
 Finland
 France
 Georgia

Germany
 Greece
 Hungary
 Ireland
 Italy
 Latvia
 Liechtenstein
 Lithuania
 Luxembourg
 Malta
 Netherlands
 Norway

Poland
 Portugal
 Romania
 Russia
 San Marino
 Serbia
 Switzerland
 The FYROM
 Turkey
 Ukraine





- Council of Europe

- Inter-governmental
- No legislative power
- Seeks voluntary cooperation
- Recommendations, Agreements and Conventions (ETS 123)

- European Union

- Supra-national
- Policy-making and legislative powers
- Delegation of sovereignty by MSs
- Regulations and Directives (2010/63/EU)



ETS 123

Appendix A (Guidelines for Accommodation and Care of Animals)



Revised 2006

Recommendation of European Commission (2007)



Part of it

Annex III of Directive 2010/63/EU (cage sizes, mandatory)



ETS 123 Appendix A "Should"



Directive 2010/63/EU "Shall"



Same legislation across Europe? No...



EU Member States Legislation



Individual Responsibilities

- Person responsible for ensuring compliance with the provisions of this Directive
- Responsible for overseeing the welfare and care of the animals in the establishment
- Responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence
- Designated veterinarian (or a suitably qualified expert)

- Institutional Official
- Attending veterinarian





Ethical Review Process & Oversight

- Protocol/Project evaluation
- Follow up of approved protocols/projects
- On going review of animal care and use
- Advice on 3Rs matters
- Establish/Review SOPs
- Periodic review of program areas
- Periodic review of facilities



Ethical Review and Oversight Bodies

Government



Different body(ies)

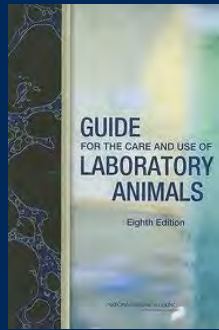
- Composition
- Functions
- Authority
- Independence

Institution

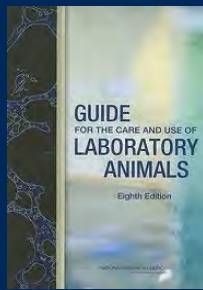


External



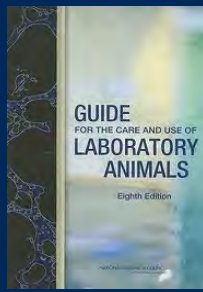


The *IACUC* (or institutional equivalent) is responsible for assessment and oversight of the institution's Program components and facilities. It should have sufficient authority and resources (e.g., staff, training, computers and related equipment) to fulfill this responsibility. (p. 14-15)



Composition IACUC

- a **Doctor of Veterinary Medicine** either certified (e.g., by ACLAM, ECLAM, JCLAM, KCLAM) or with training and experience in laboratory animal science and medicine or in the use of the species at the institution
- at least one **practicing scientist experienced** in research involving animals
- at least one member from a **nonscientific background**, drawn from inside or outside the institution
- at least one **public member** to represent general community interests in the proper care and use of animals.



Functions IACUC

- Review and approval of proposed animal use
- regular inspection of facilities and animal use areas
- regular review of the program
- ongoing assessment of animal care and use
- Mechanism for animal Welfare concerns



Directive 2010/63/EU

Art. 26: Animal Welfare Body

...each breeder, supplier and user sets up an animal-welfare body.

Composition (Art. 26)

The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal-welfare body shall also receive input from the designated veterinarian.



AWB functions – Art. 27

- (a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
- (b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
- (c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
- (d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and
- (e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.



Project Authorisation

Art. 36:

- projects are **not carried out without prior authorisation** from the competent authority
- no project is carried out unless a **favourable project evaluation** by the competent authority has been received



Project Evaluation

Art. 38:

No required composition evaluation body, but **EXPERTISE**

- (a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;
- (b) experimental design, including statistics where appropriate;
- (c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;
- (d) animal husbandry and care, in relation to the species that are intended to be used.



Project Evaluation

Art. 59:

Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body:

- (a) has the expertise and infrastructure required to carry out the tasks; and
- (b) is free of any conflict of interests as regards the performance of the tasks.

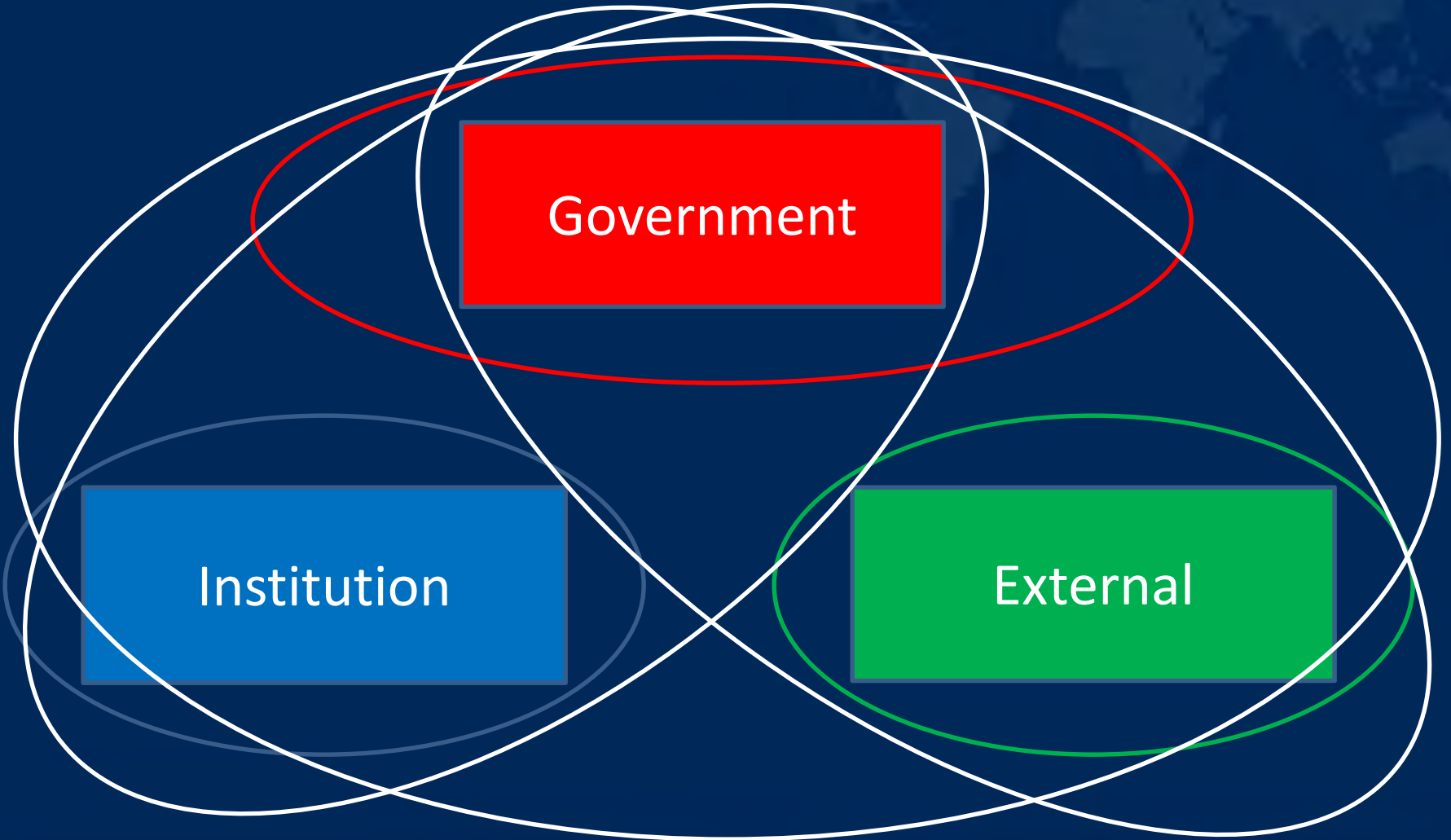


Approaches to animal research project evaluation in Europe after implementation of Directive 2010/63/EU

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Cornelia Exner, PhD⁴ & Martje Fentener van Vlissingen, DVM, PhD, DipECLAM⁵*



Project Evaluation



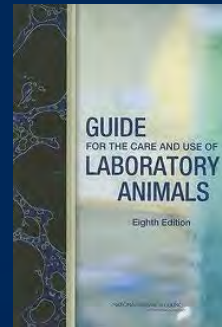


Ethical (protocol-project) Review



“The project evaluation shall consist in particular of the following:
... an assessment of the compliance of the project with the requirement of replacement, reduction and refinement; (art. 38)
... a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment...” (Art. 38)

“...the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns. By considering opportunities for refinement, the use of appropriate nonanimal alternatives, and the use of fewer animals, both the institution and the principal investigator (PI) can begin to address their shared obligations for humane animal care and use” (p.27)





Solutions Ethical Review Process

PERFORMANCE STANDARDS

- Expertise
- Resources
- Responsibility
- Authority
- Independence, impartiality
- Participation
- Evidence deliberations
- Transparency



Solutions Ethical Review Process

From Principle X CIOMS-ICLAS Guiding Principles

While implementation of these **Principles may vary from country to country** according to cultural, economic, religious, and social factors, **a system of animal use oversight that verifies commitment to the Principles should be implemented** in each country. This system should include **a mechanism for authorization** (such as licensing or registering of institutions, scientist, and/or projects) **and oversight** which may be assessed **at the institutional, regional, and/or national level.**



Solutions Ethical Review Process

From the AAALAC EU Program Description template:

Irrespective of whether the programmatic oversight is carried out by just one body or is delegated to several bodies (e.g., protocol review to an Ethics Committee either internal or external, to an Institutional Animal Care and Use Committee, and/or to the Competent Authority; oversight of animal care and welfare and promotion of the 3Rs to an Animal Welfare Body; occupational health and safety to the Occupational Health Unit, etc.), it must be described, through the next questions, how the comprehensive programmatic oversight is implemented, including the responsibility, functions and authority of the body/bodies involved.



Performance Based Approach

- Is there an effective evaluation of research proposals?
- Do all animals used for research, teaching or testing belong to an approved protocol and are they provided effective oversight?
- Is animal use being conducted in accordance with the approved proposals?
- Are there appropriate institutional policies and are they followed?



Performance Based Approach

- Is there a routine and effective evaluation of the animal care and use program?
- Are the key institutional representatives (e.g., the Institutional Official) informed of the outcome of the ethical review/oversight process?
- Are corrective actions taken when/if deviations are identified?
- Do all personnel involved in the process have the appropriate training and competence?



LAS Education & Training



- Legislation
 - Professional Guidelines/ Recommendations
 - Training Providers
- 
- Competence of Personnel (learning outcomes)



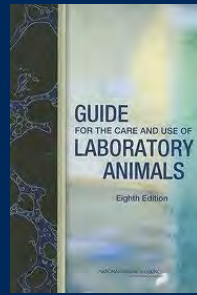
AWA/AWRs (USDA)

“Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment” (AWA)

“Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility’s responsibilities” (AWRs). Training should include:

- use of humane methods of animal maintenance and experimentation; the concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress; the proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility; and methods whereby deficiencies in animal care and treatment can be reported (AWRs)

IACUC: recommendations to the IO on training of personnel

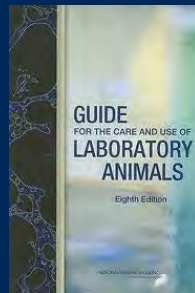


“All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science...” “...number and qualifications... depend on several factors...”

Veterinary and Other Professional Staff. Veterinarians providing clinical and/or Program oversight and support must have the experience, training, and expertise necessary to appropriately evaluate the health and wellbeing of the species used in the context of the animal use at the institution.”. “Continuing education...”

“*Animal Care Personnel* caring for animals should be appropriately trained and the institution should provide for formal and/or on-the-job training...”

“According to program scope...”



“The institution should provide appropriate education and training to members of *research teams...*”

“Training should be tailored to the particular needs of research groups; however, all research groups should receive training in animal care and use legislation, IACUC function, ethics of animal use and the concepts of the Three Rs, methods for reporting concerns about animal use, occupational health and safety issues pertaining to animal use, animal handling, aseptic surgical technique, anesthesia and analgesia, euthanasia, and other subjects, as required by statute. Continuing education programs should be offered to reinforce training and provide updates that reflect changes in technology, legislation, and other relevant areas. Frequency of training opportunities should ensure that all animal users have adequate training before beginning animal work.”

“It is the institution’s responsibility to ensure that **IACUC members** are provided with training opportunities...” “Ongoing opportunities to enhance their understanding of animal care and use in science should also be provided.”



Beijing (BAOLA): Personnel must obtain a “Position Qualification Certificate of the Laboratory Animal Practitioners.”

CALAS: Standard TB/CALAS 00001-2016, six categories: ALAT, LAT, and LATG, managers [MAR], senior MAR [SMAR]), assistant laboratory animal veterinarian [ALAV], laboratory animal veterinarian [LAV], senior LAV [SLAV], junior laboratory animal researcher [JLAR], laboratory animal researcher [LAR], and senior LAR [SLAR], laboratory animal associate support practitioner (LASP), and laboratory animal phased practitioner (LAPP).



CPCSEA Guidelines

“Initial in-house training of staff at all levels is essential. A few weeks must be spent on the training of the newly recruited staff...” (animal care staff)



Canadian Council on Animal Care *in science*
Conseil canadien de protection des animaux *en science*

CCAC Guidelines on: Training of Personnel Working with Animals in Science

“Institutions must establish a means of assessing the competency of individuals prior to permitting them to carry out any procedures related to the care and/or use of animals. Until personnel have had their competency assessed and been found to be competent to perform the relevant tasks or procedures, any work with animals should be carefully supervised. ” (G.2)

“Access to training must be offered on a regular basis to ensure that all personnel working with animals possess the necessary knowledge, skills and competency to perform their required tasks prior to commencement of any work involving animals. ” (G.5)



Canadian Council on Animal Care *in science*
Conseil canadien de protection des animaux *en science*

CCAC Guidelines on: Training of Personnel Working with Animals in Science

“Institutions are responsible for providing evidence that all personnel working with animals have the appropriate knowledge, skills and competency to perform their required tasks.” (G.6)

Syllabus for Animal Users (Appendix 1): Core topics + knowledge streams



Continuing Education



Australian code for the care and use of animals for scientific purposes

Competent: the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments.

1.29 People who care for and use animals must ensure that procedures are performed competently, and

- (i) be competent for the procedure they perform, or
- (ii) be under the direct supervision of a person who is competent to perform the procedure.



Australian code for the care and use of animals for scientific purposes

2.18 (ii) (institutional responsibility) providing adequate resources for appropriate education, training, and assessment of competence of investigators, and certification of such competence to the satisfaction of the AEC.

2.44 (v) (investigator responsibility) undertake education and training, and competency assessment, in accordance with institutional and AEC policies and procedures

2.1.5 (1)(a) (Guidelines approved by AEC) how the competence of people involved in the care and use of animals will be assessed and ensured

Competency applied at all levels: animal care, husbandry, procedures, monitoring, wellbeing, health, AEC review, investigators, managers...



Directive 2010/63/EU

Art. 23 Competence of Personnel. The staff shall be adequately educated and trained before they perform any of the following functions:

- (a) carrying out procedures on animals;
- (b) designing procedures and projects;
- (c) taking care of animals; or
- (d) killing animals.

Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions...



ANNEX V

LIST OF ELEMENTS REFERRED TO IN ARTICLE 23(3)

1. National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes.
2. Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes.
3. Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration.
4. Animal behaviour, husbandry and enrichment.
5. Species-specific methods of handling and procedures, where appropriate.
6. Animal health management and hygiene.
7. Recognition of species-specific distress, pain and suffering of most common laboratory species.
8. Anaesthesia, pain relieving methods and killing.
9. Use of humane end-points.
10. Requirement of replacement, reduction and refinement.
11. Design of procedures and projects, where appropriate.



Directive 2010/63/EU

Art. 24 Specific requirements for personnel. Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall:

(c) be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.



Harmonization

“Adjustment of differences and inconsistencies among different measurements, methods, procedures, schedules, specifications, or systems to make them ~~uniform~~ or mutually compatible”
(*Business Dictionary*)



http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf

National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes

A working document on the development of a common education and training framework to fulfil the requirements under the Directive

- Replacing consensus document of 18-19 September 2013 -

Brussels, 19-20 February 2014

EU guidance is developed to respond to a need for harmonisation and a common framework to ensure competence and to facilitate free movement of personnel. It is important to note that the outcome is on the basis of general agreement and not binding. It is left to each Member State to interpret whether and how this general guidance is to be implemented.



http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf



Modular Training + Learning Outcomes

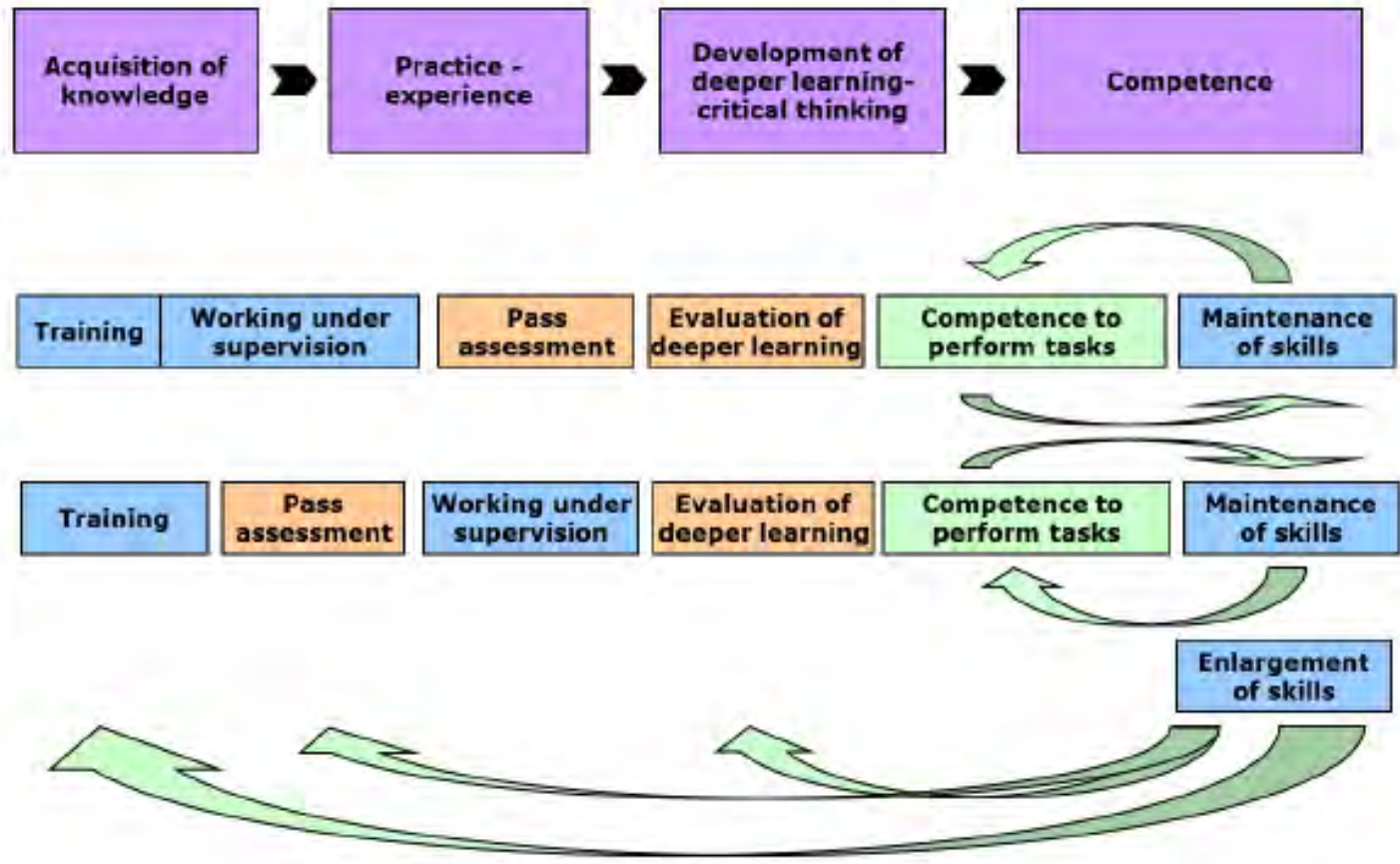
“Training alone does not deliver competence”

“Only after individuals have been assessed as competent, should they work without supervision.”

“The objective of the initial training is the attainment of basic knowledge and/or understanding with the concept that a deeper understanding of the knowledge base as well as proficiency in skills should have developed and be expected by the time competence is assessed. “



http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endors ed_E-T.pdf





http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf

The Modular Training structure and **Learning Outcomes** approach is **flexible**. The learning outcomes deal with output rather than processes and help to define the skills and knowledge that module participants should be able to demonstrate by the time these learning outcomes are assessed. Learning outcomes are the specific intentions of a training programme or module, written in specific terms. They **describe what a student should know, understand, or be able to do at the end of that module**.

These do not represent a course syllabus or a list of topics to be covered. Training providers are free to build course content, training materials and delivery methods which will deliver all of the learning outcomes for each selected module in a manner which meets their national/local/institutional and/or individual/group requirements.



http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf

Core module = a compulsory module for all functions and with the same Learning Outcomes

Function specific (prerequisite) module = a compulsory module for (a) specific function(s)

Task specific module = a recommended module to enable staff to carry out (a) specific task(s)

National module = includes national/regional transposing legislation and any other legislation relevant to the use of animals for scientific purposes (e.g. transport, CITES, waste, GM)

Course = a programme, containing one or more Modules, designed to meet the training needs of individuals identified in the Directive



http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf



Assessment of Learning Outcomes

Mechanisms for Supervision and Assessment of Competence

- 4** – Supervisor present when the procedure takes place providing direct supervision and advice
- 3** – Supervisor aware when procedures are taking place and available for rapid intervention if required (i.e. in the vicinity of the procedure)
- 2** – Supervisor aware when procedures are taking place and available to attend to provide advice if required (i.e. in the vicinity of the establishment)
- 1** – Supervisor aware when procedures are taking place and available for discussion to provide advice if necessary (e.g. by telephone)
- 0** – No supervision required

http://www.lasa.co.uk/LASA_GP_Supervision_&_Competence_2013_final.pdf



http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf

“Ideally, the person who assesses competence should not be the same person as that who trained but this may be difficult for highly specialized skills and in small establishments.”

“The assessor should observe and evaluate the trainee performing the procedures to assess practical competence.”

Continuing Professional Development (CPD)

<http://www.felasa.eu/recommendations/guidelines/guidelines-for-continuing-education-for-persons-involved-in-animal-experime/>).



Program Description

“Describe *how* the IACUC/OB provides oversight and evaluates the effectiveness of training programs and the assessment of personnel competencies. Describe how training is documented.”

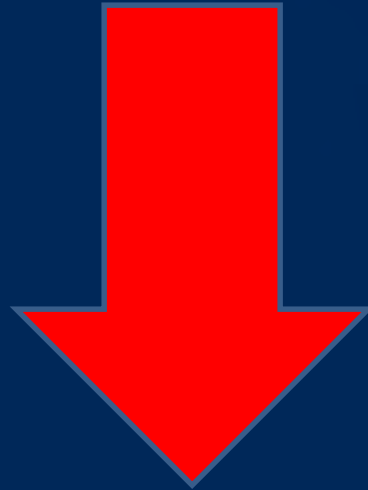
“Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.”

“Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including: who determines that personnel are qualified and trained for surgical procedures”

“Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). ”



Education and Training



Supervision

Competence
(learning outcomes)



DV in Directive 2010/63/EU

“veterinarian” appears 5 times in articles:

- Art. 25 Designated Veterinarian: “Member States shall ensure that each breeder, supplier and user has a **designated veterinarian** with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.”



DV in Directive 2010/63/EU

- Art. 9 Animals taken from the wild: “Any animal found, at or after capture, to be injured or in poor health shall be examined by a **veterinarian** or another competent person...”
- Art.17.2: End of the procedure: “At the end of a procedure, a decision to keep an animal alive shall be taken by a **veterinarian** or by another competent person. ”
- Art.26.2: Animal Welfare Body: “The animal welfare body shall also receive input from the **designated veterinarian** or the expert referred to in Article 25. ”

DV in Directive



And some “veterinary” as part of the DV role:

- Art. 16.1.d Reuse: “it is in accordance with **veterinary advice**, taking into account the lifetime experience of the animal.”... 16.2: “...after a veterinary examination of the animal, the competent authority may allow reuse...in a procedure entailing severe pain, distress...”
- Art. 31.2: Information on dogs, cats and non-human primates: “The file shall be established at birth or as soon as possible thereafter and shall cover any relevant reproductive, **veterinary and social information** on the individual animal and the projects in which it has been used. ” “In the case of rehoming, relevant **veterinary care and social information** from the individual history file referred to in paragraph 2 shall accompany the animal. ”



DV in Directive

More “veterinary” as part of the DV role:

- Art. 38.3.c Project evaluation: expertise on “veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;”
- Some in Annex III “in consultation with veterinary staff” concerning exceptions to housing standards



DV in Directive

Summary:

- There must be a Designated Veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert
- Advisory role in certain matters
- Input in Animal Welfare Body

Missing something?

- Defined Authority
- Details on Veterinary care program areas
- Exclusiveness



Legal requirements
Directive 2010/63/EU

Institutional Commitment
Professional
Recommendations



Advisory role

Good institutional
veterinary care
programme on the
ground



WORKING GROUP REPORT

Guidelines for the veterinary care of laboratory animals: report of the FELASA/ECLAM/ESLAV Joint Working Group on Veterinary Care

Members of the Joint Working Group on Veterinary Care:
Hanna-Marja Voipio* (Convenor), **P Baneux[†]** (USA), **I A Gomez de Segura[‡]** (Spain), **J Hau[§]** (Denmark) and **S Wolfensohn[¶]** (UK)

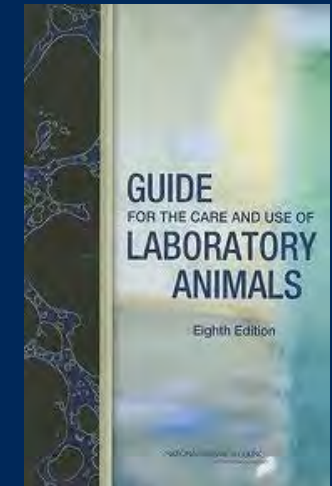
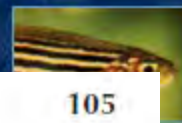
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Laboratory Animals (2008) 42, 1–11

4 VETERINARY CARE

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Guide for the Care and Use of Laboratory Animals Eighth Edition (2011), National Research Council



Working Party Report

ESLAV/ECLAM/LAVA/EVERI recommendations for the roles, responsibilities and training of the laboratory animal veterinarian and the designated veterinarian under Directive 2010/63/EU

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Laboratory Animals (2015) 49(2), 89-99



FELASA/ECLAM/ESLAV

“A veterinarian’s **primary responsibilities** are defined by their own **professional regulatory bodies**, but in this area of work there are **further opportunities** for contribution, which will assist in safeguarding the health and welfare of animals used in research.”

“...a laboratory animal veterinarian **must obtain specific education, training and competencies...**”



FELASA/ECLAM/ESLAV – vet care

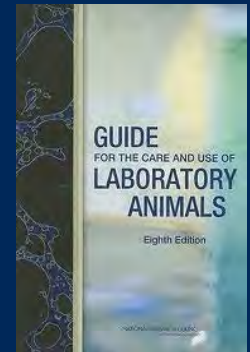
- Introduction of animals
- Quarantine
- Health monitoring programme
- Veterinary records
- Clinical evaluation, diagnosis, and treatment (and emergency)
- Anaesthesia, analgesia, surgical techniques, perioperative care
- Euthanasia
- Control of drugs
- Training of researchers on experimental procedures
- Ethical review process and project design
- Culture of Care
- Regular visits/inspections to facilities
- Occupational health and safety



Guide – chapter 4 – vet care

“The primary focus of the veterinarian is to **oversee the well-being and clinical care of animals** used in research, testing, teaching, and production. This responsibility extends to monitoring and promoting animal well-being **at all times** during animal use and during all phases of the animal’s life.”

“The **veterinary care program** is the responsibility of the attending veterinarian (AV), who is certified or has training or experience in laboratory animal science and medicine or is otherwise **qualified in the care of the species being used.**”

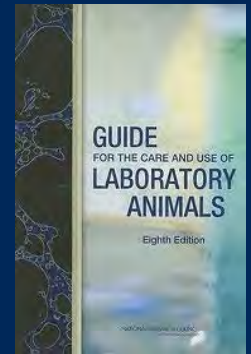




Guide – chapter 4 – vet care

“An adequate veterinary care program consists of assessment of animal well-being and effective management of

- animal procurement and transportation
- preventive medicine (including quarantine, animal biosecurity, and surveillance)
- clinical disease, disability, or related health issues
- protocol-associated disease, disability, and other sequelae
- surgery and perioperative care
- pain and distress
- anesthesia and analgesia
- euthanasia



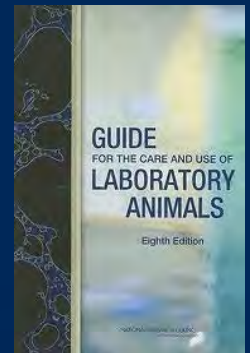
Specific recommendations



Guide – chapter 4 – vet care

The Attending Veterinarian

“The *attending veterinarian* (AV) is **responsible** for the **health and wellbeing** of all laboratory animals used at the institution. The institution must provide the AV with sufficient **authority**, including **access** to all animals, and **resources** to manage the program of veterinary care.”





AAALAC Position Statement

<http://www.aaalac.org/accreditation/positionstatements.cfm#vetcare>

- “...the veterinarian must have sufficient **authority**, as provided by the institution, to ...”
- “The Attending Veterinarian must have adequate **resources** to manage the overall program of veterinary care.”
- “...must have **experience, training, and expertise** necessary to appropriately evaluate the health and well-being of the species used...”



AAALAC Position Statement

<http://www.aaalac.org/accreditation/positionstatements.cfm#vetcare>

- “There must be **timely provision** of veterinary medical care, and **emergency** veterinary care must be available at all times”
- “The Attending Veterinarian must have **oversight** of additional aspects of the veterinary care program, such as...”
- “If there is no full-time Attending Veterinarian on-site, there must be a designated person who is responsible for **daily animal care...**”



ESLAV/ECLAM/LAVA/EVERI - DV

“The role and responsibilities of the DV include the development, **implementation and continuing review of an adequate programme for veterinary care** at establishments breeding and/or using animals for scientific purposes. The programme should be tailored to the needs of the establishment and **based on the Directive’s requirements, other legislations, and current guidelines in laboratory animal medicine**. Postgraduate laboratory animal veterinary training should include a basic **task-specific training** module for DVs to complement veterinary competences from graduation, and **continuing professional development** on the basis of a gap analysis.”



ESLAV/ECLAM/LAVA/EVERI - DV

Table 1. Current roles and responsibilities of respondents to an ESLAV-ECLAM survey run between April and June 2012 on the role of veterinarians under Directive 2010/63/EU.

Activities	Respondents (%)
Ethical committee	87% participating
Facility management	85% participating
Health monitoring	60% responsible, 94% participating
Research project	85% responsible, 52% involved
Occupational health and safety	68% involved or responsible
Compliance with legislation	56% responsible, 33% involved
Training of other persons	88% responsible or involved



ESLAV/ECLAM/LAVA/EVERI - DV

Elements of a veterinary care programme

- movement of animals
- husbandry and care
- assessment of well-being
- disease control and management
- use of medicines
- recognition and alleviation of pain, suffering and distress
- animal models
- surgical and non-surgical interventions
- anaesthesia and analgesia
- euthanasia
- 3Rs
- routine visits

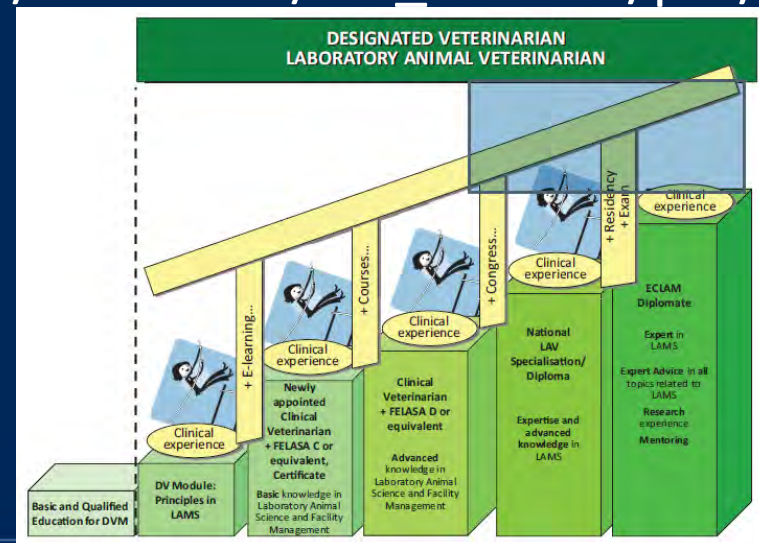


ESLAV/ECLAM/LAVA/EVERI - DV

Training/education/competence

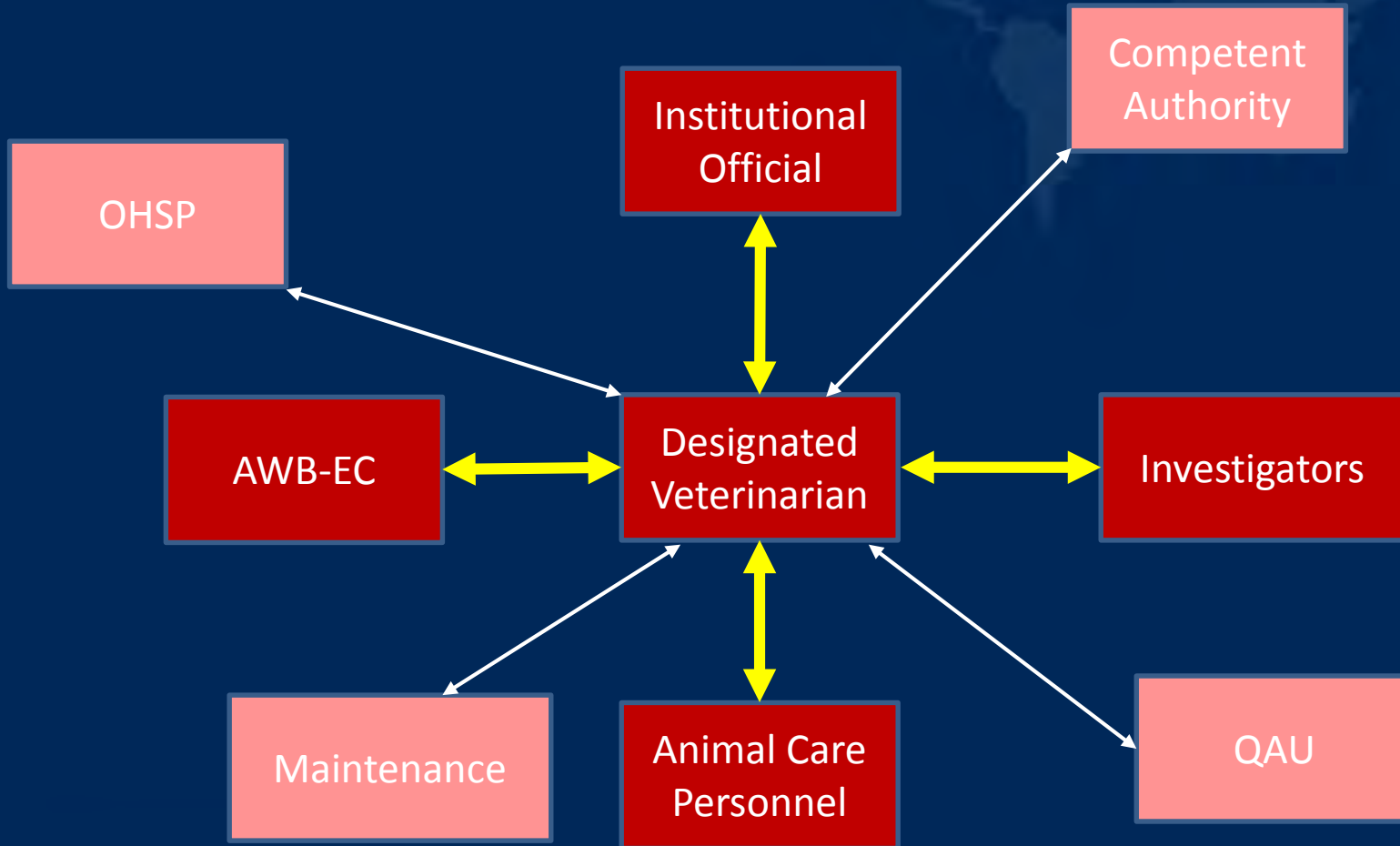
According to the European Commission working document on the development of a common education and training framework to fulfil the requirements under the Directive

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf



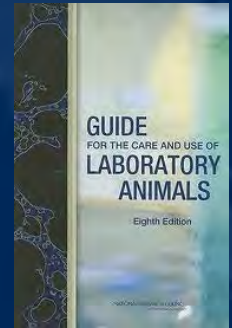


Responsibilities - Organization





Positive Combination



- Follow an order (concept of a programme)
- Get the best of each one, while complying with legislation
- Strengthen similarities
- Performance standards to address differences
- Complete with additional specific literature
- Help International collaboration and harmonisation

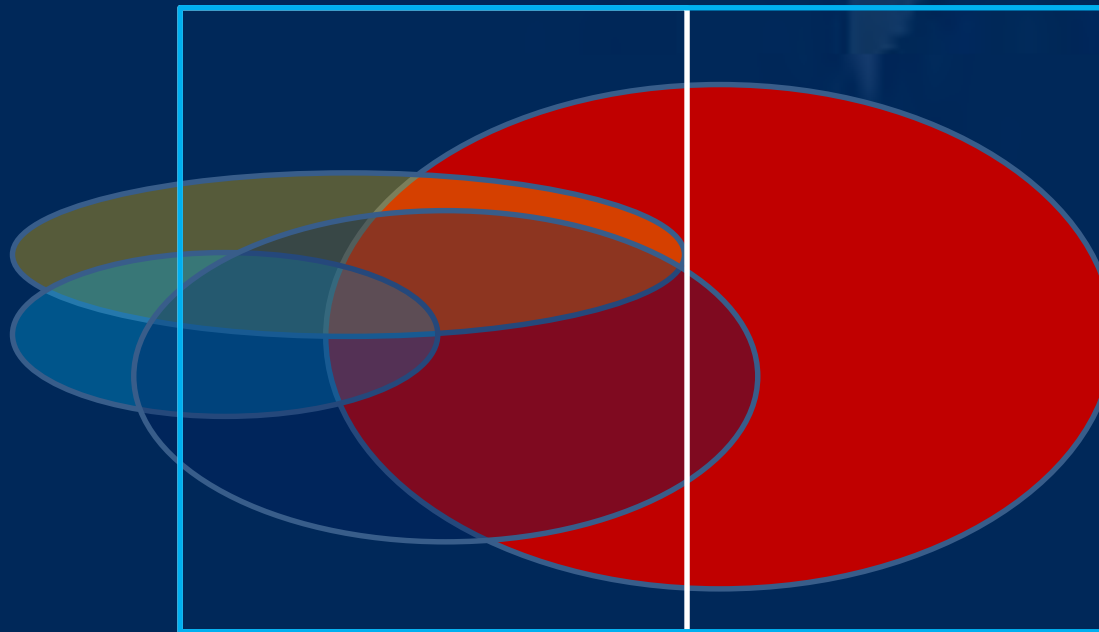
Solutions



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Standards



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