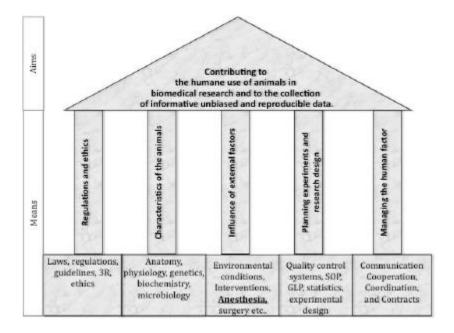
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LAS is a multidisciplinary branch of science, contributing to the <u>humane use of animals</u> in biomedical research and to the collection of informative unbiased and reproducible data



#### **National legislation**

- 1.1. Identify and describe the national and EU laws and guidance which regulate the scientific use of animals and in particular the activities of those carrying out scientific procedures involving them.
- 1.2. Identify and describe related animal welfare legislation.
- 1.3 Describe the authorization that is needed before acting as user, breeder or supplier of laboratory animals and especially the authorization required for projects and where applicable individuals.
- 1.4. List sources of information and support that are available (regarding national legislation).
- 1.5. Describe the role of the personnel mentioned in Article 24, 25 and 26, and their statutory duties and other responsibilities under the National Legislation.
- 1.6. Describe the roles and responsibilities of the local animal welfare bodies and the national committee for the protection of animals used for scientific purposes.
- 1.7. Indicate who is responsible for compliance at an establishment and how this responsibility may be exercised (e.g. through the local AWB).
- 1.8. Describe when a procedure becomes regulated under National legislation (minimum threshold of pain, suffering, distress or lasting harm).
- 1.9. Indicate who bears primary responsibility for the animals undergoing procedures.
- 1.10. List which species, including respective stages of development that are included in the scope of the Directive / National law.
- 1.11. Indicate the circumstances in which animals under the scope of the Directive should be humanely killed or removed from the study to receive veterinary treatment.
- 1.12. Describe the legislative controls over the killing of animals bred or used for scientific procedures.

#### Ethics, animal welfare and the Three Rs

- 2.1. Describe the differing views, within society, relating to the scientific uses of animals and recognize the need to respect these.
- 2.2. Describe the responsibility of humans when working with research animals and recognize the importance of having a respectful and humane attitude towards working with animals in research.
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- 2.3. Identify ethical and animal welfare issues in their own work and be aware and able to reflect on the consequences of their own actions.
- 2.4. Recognize that compliance with ethical principles may contribute to the long-term trust and acceptance in scientific research from the general public.
- 2.5. Describe how the law is based on an ethical framework which requires 1) weighing the harms and benefits of projects (the harm/benefit assessment) 2) applying the Three Rs to minimize the harm, maximize benefits and 3) promote good animal welfare practices.
- 2.6. Describe and discuss the importance of the ThreeRs as a guiding principle in the use of animals in scientific procedures.
- 2.7. Explain the Five Freedoms and how these apply to laboratory species
- 2.8. Describe the concept of harms to animals including avoidable and unavoidable suffering, direct, contingent and cumulative suffering
- 2.9. Describe the severity classification system, and give examples of each category. Describe cumulative severity and the effect this may have on the severity classification.
- 2.10. Describe the regulations regarding re-use of animals.
- 2.11. Describe the importance of good animal welfare including its effect on scientific outcomes as well as for societal and moral reasons.
- 2.12. Describe the need for a culture of care and the individual's role in contributing to this.
- 2.13. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.
- 2.14. Be aware of different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. s
- +ystematic reviews, meta-analysis).
- 3.1.3. Indicate how good welfare can promote good science: e.g. explain how the failure to attend to biological and behavioral needs may affect the outcome of procedures.
- 3.1.4. Indicate how husbandry and care may influence experimental outcome and the number of animals needed e.g. example where the place in the room influences the outcome, hence randomisation.
- 3.1.6. Describe the importance of providing an enriched environment (appropriate to both the species and the science) including social housing and opportunities for exercise, resting and sleeping.
- 3.1.9. Maintain and interpret accurate, comprehensive records of animals held in the animal facility, including the wellbeing of the animals
- 5.4. Describe what a humane end point is. Identify criteria to be used to set humane endpoints. Define action to be taken when a humane endpoint is reached and consider possible options for refining methods to finish at an earlier endpoint.
- 5.5. Describe the severity classifications included in the Directive and give examples of each category; explain cumulative severity and the effect this may have on the severity classification.
- 5.6. Describe the circumstances when anesthesia or analgesia may be necessary to minimize pain, suffering, distress or lasting harm

### **Humane methods of killing (theory)**

- 6.1.1. Describe the principles of humane killing (e.g. what constitutes 'a good death')
- 6.1.2. Describe the different methods by which the relevant animals are allowed to be killed, the influence different methods can have on scientific outcomes, and how to select the most appropriate method.

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6.1.3. Explain why someone competent to kill animals should be available at all times (whether care staff or person carrying out procedures)

## Minimally invasive procedures without anesthesia

- 7.1. Describe appropriate methods and principles to be followed when handling animals (including methods of manual restraint and use of restricted environments).
- 7.2. Describe the biological impact of procedures and restraint on physiology.
- 7.3. Describe refinement opportunities for procedures and restraint e.g. through training (using positive re-enforcement), habituation and socialization of animals.
- 7.4. Describe techniques/procedures including, for example, injection, sampling and dosing techniques (routes/volumes/frequency), dietary modification, gavage, tissue biopsy, behavioral tests, use of metabolic cages.
- 7.5. Describe how to perform minor techniques and relate appropriate sample volumes and sampling frequencies for the relevant species.
- 7.6. Describe the need for rigour and consistency in conducting scientific procedures and the correct recording and handling of samples.
- 7.7. Describe appropriate methods for the assessment of the welfare of animals with respect to the severity of procedures and know what appropriate action to take.
- 7.8. Recognize that refinement is an on-going process and know where to find relevant, up-to date, Information.
- 7.9. Describe the biological consequences of transport, acclimatization, husbandry conditions and experimental procedures on the species concerned and describe how these can be minimized.

#### Ethics, animal welfare and the Three Rs

- 9.1. Understand that there is a broad range of ethical, welfare and scientific perspectives on the use of animals in scientific procedures, and that thinking on all of these matters evolves over time and is influenced by culture and context.
- 9.2. Understand that this means there is need for *on-going* critical evaluation of the justification for using animals and of implementation of the Three Rs at all stages of the life of a project.
- 9.3. Recognize that there are ethical limits to what it is considered permissible to do under the Directive and that even within these legal constraints, there are also likely to be national and institutional differences in this respect.
- 9.4. Explain that legislation requires that the justification for programmes of work is assessed by weighing potential adverse effects on the animals against the likely benefits; that harms to animals must be minimized, and benefits maximized.

- 9.5. Understand and provide the information necessary to enable a robust harm/benefit assessment to be performed; and explain why they personally consider that the potential benefits outweigh the likely adverse effects.
- 9.6. Understand the need to communicate appropriate information to a wider public audience, and be able to prepare an appropriate non-technical project summary to facilitate this.
- 9.7. Describe the importance of disseminating information that will promote understanding of ethical issues, good animal welfare, good science and application of the Three Rs.

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### Design of procedures and projects (level 1)

- 10.1. Describe the concepts of fidelity and discrimination (e.g. as discussed by Russell and Burch and others).
- 10.2. Explain the concept of variability, its causes and methods of reducing it (uses and limitations of isogenic strains, outbred stocks, genetically modified strains, sourcing, stress and the value of habituation, clinical or sub-clinical infections, and basic biology).
- 10.3. Describe possible causes of bias and ways of alleviating it (e.g. formal randomization, blind trials and possible actions when randomization and blinding are not possible).
- 10.4. Identify the experimental unit and recognize issues of non-independence (pseudo replication).
- 10.5. Describe the variables affecting significance, including the meaning of statistical power and "p-values".
- 10.6. Identify formal ways of determining of sample size (power analysis or the resource equation method).
- 10.7. List the different types of formal experimental designs (e.g. completely randomized, randomized block, repeated measures [within subject], Latin square and factorial experimental designs).
- 10.8. Explain how to access expert help in the design of an experiment and the interpretation of experimental results

### Design of procedures and projects

#### **Legal issues**

- 11.1. Describe in detail the main components of the national legislation regulating the scientific use of animals; in particular, explain the legal responsibilities of those designing procedures and projects and those of other persons with statutory responsibilities under the national legislation (e.g. the person responsible for compliance, veterinarian, animal care staff, training officers).
- 11.2. List the key purposes of other relevant EU and international legislation and associated guidelines that impact on the welfare and use of animals. This includes Directive 2010/63/EU and legislation/guidelines relating to: veterinary care, animal health, animal welfare, genetic modification of animals, animal transport, quarantine, Health & Safety, wildlife and conservation.

# (ii) Good scientific practice

- 11.3. Describe the principles of a good scientific strategy that are necessary to achieve robust results, including the need for definition of clear and unambiguous hypotheses, good experimental design, experimental measures and analysis of results. Provide examples of the consequences of failing to implement sound scientific strategy.
- 11.4. Demonstrate an understanding of the need to take expert advice and use appropriate statistical methods, recognise causes of biological variability, and ensure consistency between

Learning objectives group <u>B: persons that plan and design experiments in animals</u> and <u>A: performing procedures</u>

experiments11.

- 11.5. Discuss the importance of being able to justify on both scientific and ethical grounds, the decision to use living animals, including the choice of models, their origins, estimated numbers and life stages. Describe the scientific, ethical and welfare factors influencing the choice of an appropriate animal or non-animal model.
- 11.6. Describe situations when pilot experiments may be necessary.
- 11.7. Explain the need to be up to date with developments in laboratory animal science and technology so as to ensure good science and animal welfare
- 11.8. Explain the importance of rigorous scientific technique and the requirements of assured quality standards such as GLP.
- 11.9. Explain the importance of dissemination of the study results irrespective of the outcome and describe the key issues to be reported when using live animals in research e.g. ARRIVE guidelines.

#### (iii) Implementing the Three Rs

- 11.10. Demonstrate a comprehensive understanding of the principles of replacement, reduction and refinement, and of how these ensure good science and good animal welfare.
- 11.11. Explain the importance of literature and internet searches, discussion with colleagues and with relevant professional bodies in identifying opportunities for applying each 'R'
- 11.12. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.
- 11.13. Explain how to use different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. systematic reviews, meta-analysis).
- 11.14. Describe examples of alternative methods and research strategies that replace, avoid or complement the use of animals in different types of research programme.
- 11.15. Identify, assess and minimize all of the welfare costs to animals throughout the animals' lifetime (including adverse effects relating to sourcing, transport, housing, husbandry, handling, procedures and humane killing); Explain and give examples of welfare assessment protocols.
- 11.16. Define and apply appropriate humane end-points; establish suitable criteria to identify when the humane endpoint has been reached
- 11.17. Describe possible conflicts between Refinement and Reduction (e.g.in the case of re-use) and the factors that need to be considered to resolve this conflict
- 11.18. Define the requirements for, and controls on, re-homing of animals; identify any relevant re-homing guidelines

## (iv) Responsibilities

11.19. Explain the need to be aware of local arrangements relating to project license management, e.g. procedures for ordering animals, accommodation standards, disposal of animals, safe working practices and security, and the actions to take in the event of unexpected problems arising with any of these.

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