Modules art. 23.2.b function:
designing procedures and projects;

Core

Module 1: Legislation

This module provides a relevant level of understanding of the national and international legal and regulatory framework within which projects involving animals are constructed and managed and of the legal responsibilities of the people involved, i.e. those carrying out procedures on animals; designing procedures and projects; taking care of animals; or killing animals, and may cover other relevant legislation.

Learning outcomes

Trainees should be able to:

1.1. Mention 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. Name and describe related animal welfare legislation.
1.3. Have detailed knowledge of 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 (Function B staff) 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).
1.4. Name 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.
1.5. Describe the authorisation that is needed before acting as user, breeder or supplier of laboratory animals and especially the authorisation required for projects and where applicable individuals.
1.6. Indicate sources of information and support that are available (regarding national legislation).
1.7. Describe the role of the personnel mentioned in Article 24, 25 and 26, and their statutory duties and other responsibilities under the National Legislation (see also 1.9).
1.8. Describe the roles and responsibilities of the local animal welfare bodies and the national committee for the protection of animals used for scientific purposes.
1.9. Indicate who is responsible for compliance at an establishment and how this responsibility may be exercised.
1.10. Describe when a procedure becomes regulated under National legislation (minimum threshold of pain, suffering, distress or lasting harm).
1.11. Specify who bears primary responsibility for the animals undergoing procedures.

1.12. Name which species, including respective stages of development that are included in the scope of the Directive / National law.
1.13. 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.
1.14. Describe the legislative controls over the killing of animals bred or used for scientific Procedures

Module 2: Ethics, animal welfare and the Three Rs

This module provides guidance and information to enable individuals working with animals to identify, understand and respond appropriately, to the ethical and welfare issues raised by the use of animals in scientific procedures generally and, where appropriate, within their own programme of work. It provides information to enable individuals to understand and to apply the basic principles of the Three Rs. This module also prepares individuals so that they are able to keep themselves informed in order to continuously apply the Three Rs to their work as new methods and approaches evolve.

Learning Outcomes

Trainees should be able to:

2.1. Be aware of the differing views, within society, relating to the scientific uses of animals and recognise the need to respect these.
2.2. Recognise the responsibility of humans when working with research animals and recognise the importance of having a respectful and humane attitude towards working with animals in research.
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. Recognise 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 minimise the harm, maximise benefits and 3) promote good animal welfare practices.
2.6. 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.
2.7. 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.
2.8. Recognise 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.
2.9. 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 minimised, and benefits maximised.

2.10. 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.
2.11. 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.
2.12. Understand the importance of disseminating information that will promote understanding of ethical issues, good animal welfare, good science and application of the Three Rs.
2.13. Describe and discuss the importance of the Three Rs as a guiding principle in the use of animals in scientific procedures.
2.14. Demonstrate a comprehensive understanding of the principles of replacement, reduction and refinement, and of how these ensure good science and good animal welfare.
2.15. Explain the importance of literature and internet searches, discussion with colleagues and with relevant professional bodies in identifying opportunities for applying each 'R'
2.16. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.
2.17. Be aware of the different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. Systematic reviews, meta-analysis) and of how and where to apply these.
2.18. Describe examples of alternative methods and research strategies that replace, avoid or complement the use of animals in different types of research programme.
2.19. Identify, assess and minimise 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.
2.20. Define and apply appropriate humane end-points; establish suitable criteria to identify when the humane endpoint has been reached
2.21. 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
2.22. Be aware of the requirements for, and controls on, re-homing of animals; identify any relevant re-homing guidelines.
2.23. Understand the Five Freedoms and how these apply to laboratory species
2.24. Describe the concept of harms to animals including avoidable and unavoidable suffering, direct, contingent and cumulative suffering
2.25. Describe the severity classification system, and give examples of each category. Describe cumulative severity and the effect this may have on the severity classification.
2.26. Describe the regulations regarding re-use of animals.
2.27. Describe the importance of good animal welfare including its effect on scientific outcomes as well as for societal and moral reasons.
2.28. Understand the need for a culture of care and the individual's role in contributing to this.
2.29. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.

Module 3: Basic and appropriate biology

This module provides an introduction to the basic principles of animal behaviour, care, biology and husbandry. It incorporates information in relation to anatomy and physiological features, including reproduction, behaviour and routine animal husbandry and enrichment practices. It is not intended to provide more than the minimum background information which is needed for someone to be able to begin work under supervision.

Learning Outcomes

Trainees should be able to:

3.1. Recognize and describe life events that have the potential to cause suffering including sourcing, transport, housing, husbandry, handling and procedures (on a basic level).
3.2. 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.
3.3. When relevant to the species, recognise that there are different strains, and that these can have different characteristics which can affect both welfare and science.
3.4. Understand the importance to maintain and interpret accurate, comprehensive records of animals held in the animal facility, including the wellbeing of the animals

Module 4: Animal care, health and management

This module provides information on various aspects of animal health, care and management including, environmental controls, husbandry practices, diet, health status and disease. It also includes relevant basic learning outcomes relating to personal health and zoonosis.

Learning Outcomes

Trainees should be able to:

4.1. Describe suitable routines and husbandry practices for the maintenance, care and welfare for a range of animals used in research, to include small laboratory species and large animal species where appropriate.

4.2. Describe in general suitable environmental and housing conditions for laboratory animals, how conditions are monitored and identify the consequences for the animal resulting from inappropriate environmental conditions.

4.3. Recognise that changes to or disruption of circadian or photoperiod can effect animals.

4.4. Describe, in general, the biological consequences of acclimatisation, habituation and training

4.5. Describe how the animal facility is organized to maintain an appropriate health status for the animals and the scientific procedures.

4.6. Describe how to provide water and an appropriate diet for laboratory animals including the sourcing, storage and presentation of suitable foodstuffs and water

4.7. Describe the methods, and demonstrate an understanding of appropriate, safe and humane handling, sexing and restraint of one or more named species for common scientific procedures.

4.8. Name different methods for marking individual animals and state an advantages and disadvantage for each method.

4.9. recognise potential disease risks in the animal facility, including specific predisposing factors which may be relevant. Name methods available for maintaining appropriate health status (including use of barriers, different containment levels use of sentinels as relevant to the species).

4.10. Describe appropriate breeding programmes

4.11. Describe how genetically altered animals can be used for scientific research and the importance of monitoring such animals very carefully.

4.12. List the correct procedures for ensuring health, welfare and care of animals during their transport.

4.13. Describe potential human health hazards associated with contact with laboratory animals (including allergy, injury, infection, zoonosis) and how these can be prevented.

Module 5: Recognition of pain, suffering and distress

This module prepares individuals to be able to identify normal condition and behaviour of experimental animals and enable them to differentiate between a normal animal and one which is showing signs of pain, suffering or distress which could be a result of factors including environment, husbandry or the effect of experimental protocols. It will also provide information regarding severity classifications, cumulative severity and the use of humane endpoints.

Learning Outcomes

Trainees should be able to:

5.1. Recognise normal or desirable behaviour and appearance of the individuals in the context of species, environment and physiological status.

5.2. Recognise abnormal behaviour and signs of discomfort, pain, suffering, or distress, as well as signs of positive well-being and principles of how pain, suffering and distress can be managed.

5.3. Distinguish factors to be considered and methods available for assessing and recording the welfare of animals e.g. score sheets.

5.4. Describe what a humane end point is. Identify criteria to be used to set humane endpoints.

5.5. Define action to be taken when a humane endpoint is reached and consider possible options for refining methods to finish at an earlier endpoint.

5.6. 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.

5.7. Describe the circumstances when anaesthesia or analgesia may be necessary to minimise pain, suffering, distress or lasting harm

Module 6: Humane methods of killing

This module provides theoretical information on the principles of humane killing and the need to have someone available, at all times, who is able to kill an animal quickly and humanely if required.

Learning Outcomes

Trainees should be able to:

6.1. Describe the principles of humane killing (e.g. what constitutes 'a good death')

6.2. Describe the different methods by which the relevant animals are allowed to be killed, and the influence different methods can have on scientific outcomes.

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

Module 10: Design of procedures and projects

This module comprises information about experimental design concepts, possible causes and elimination of bias, statistical analysis and information about where expertise can be found to assist with procedure, design, planning and the interpretation of results.

Learning Outcomes

Trainees should be able to:

10.1. Describe the concepts of fidelity and discrimination.

10.2. Explain the concept of variability, its causes and methods to reduce variability (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 randomisation, blind trials and possible actions when randomisation and blinding are not possible).

10.4. Understand the concept of experimental unit and recognise 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. Explain the different types of formal experimental designs (e.g. completely randomised, randomised 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.

(ii) Good scientific practice

10.9. Describe and explain the relevance of obtaining a reliable overview of already performed animal studies by synthesis of evidence methods like systematic reviews and meta-analysis.

10.10. 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.

10.11. Explain the understanding of the need to take expert advice and use appropriate statistical methods, recognise causes of biological variability, and ensure consistency between experiments7.

10.12. 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.

10.13. Explain how good welfare can promote good science: e.g. explain how the failure to attend to biological and behavioural needs may affect the outcome of procedures.

10.14. Explain 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.

10.15. Describe situations when pilot experiments may be necessary.

10.16. 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

10.17. Explain the importance of rigorous scientific technique and the requirements of assured quality standards such as GLP.

10.18. Explain the importance of publication of the study results irrespective of the outcome and describe the key issues to be reported when using live animals in research.

(iv) Responsibilities

10.19. Explain the need to be aware of local arrangements relating to project licence 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

Module 20: Anaesthesia for minor procedures

This module provides guidance and information to individuals who, during their work with animals, will need to apply sedation or short-term anaesthesia for a brief period and mild pain level procedure. The objectives of this module are:

- to introduce the course candidates to the administration of anaesthetics to laboratory animals;
- to discuss anaesthesia under the following broad headings (pre anaesthetic considerations; effects of anaesthetic agents; anaesthetic administration; regional/local/ general anaesthesia; anaesthetic emergencies; recovery from anaesthesia);
- to provide information on the effects of drugs used during anaesthesia;
- to consider the potential adverse effects of anaesthesia and on recovery;
- to discuss anaesthetic emergencies and their treatment and
- to identify when anaesthesia may compromise science.

The Learning Outcomes aim to give the minimum knowledge necessary for the appropriate and safe application of such a sedation or brief anaesthesia, with simple induction, basic maintenance for the purpose of performing minor procedures such as illustrated defined below:

- Simple induction process (e.g. chamber induction or simple IP administration, no requirement for endotracheal intubation) and
- Basic “hands on” and “observational” monitoring of anaesthetic depth; maintenance is anticipated to be uncomplicated at a stable anaesthetic depth and maintenance rate.
- Brief duration (up to about 15 minutes in a rodent species
- maintenance of anaesthesia for imaging
- if the anaesthesia is expected to last longer than this, the trainee would require further modules, see Module 10 below)”.
- use for minor procedures only - non-invasive / superficial procedures only (skin level, no access to body cavities unless terminal anaesthesia is used), superficial venous access and taking a blood sample, identification using SC microchip or, tail tipping (limited biopsy of tip of tail), anaesthesia for restraint.
- no pain or short / minor pain level,
- no high-risk or sensitive animal

Learning Outcomes

Trainees should be able to:

20.1. Define sedation, local and general anaesthesia

20.2. Identify the three components of the triad of anaesthesia and understand that different anaesthetic agents produce these to different degrees.

20.3. Define balanced anaesthesia and indicate that this is best achieved by using drugs in combinations to achieve all components of the anaesthetic triad to an acceptable degree

20.4. Relate why and when sedation or anaesthesia might be used for restraint.

20.5. Identify the factors to be considered in pre-anaesthetic evaluation of animals - how to perform a basic health check, consider physiological or pathological status of the model they are working with and how these may influence the choice of anaesthetic agent.

20.6. Discuss the relative merits / drawbacks and principles of selection of different agents and their application, including calculation of doses, in relevant species, including injectable and volatile agents (or dissolved agents in the case of aquatic species), including local anaesthesia regimes

20.7. Indicate the importance of minimising stress prior to anaesthesia in reducing the likelihood of complications due to anaesthesia.

20.8. Recognise when premedication is beneficial to incorporate into an anaesthetic regime.

20.9. Recall the correct set-up, operation and maintenance of anaesthetic equipment appropriate to the species concerned.

20.10. Evaluate and appreciate the different levels and planes of anaesthesia (voluntary excitement, involuntary excitement, surgical anaesthesia (light, medium & deep), excessively deep).

20.11. List the factors indicating that an animal is suitably anaesthetized (stable and of appropriate depth) to enable procedures to be undertaken and what actions should be taken if an adverse event occurs. This will include basic “hands on” and “observational” anaesthetic monitoring techniques, including assessment of reflexes appropriate for species.

20.12. Describe methods of optimising post anaesthetic recovery (e.g. heat blankets, analgesia, reversal agents, access to food and water, environmental conditions) to ensure a smooth and rapid recovery from anaesthesia.

20.13. Recall an understanding of safe / good working practices with regard to use, storage and disposal of anaesthetic and analgesic agents.

Module 22: Principles of surgery

This module covers principles of pre-operative animal assessment and care, preparations for surgery including equipment preparation and aseptic technique and the principles of successful surgery.

The module provides information about possible complications, post-operative care and monitoring along with details of the healing process.

It also covers more practical elements for example the demonstration of commonly used instruments and provide an opportunity for trainees to practice some of the practical aspects of surgical technique, such as methods of suturing, using appropriate non-animal models.

Learning Outcomes

Trainees should be able to:

22.1. Explain the relevance and need for pre-operative assessment and, where appropriate, conditioning.

22.2. Identify sources of reference for good surgical practice

22.3. Describe the process of tissue healing and relate to this to the importance of asepsis and hygienic practices, wound creation, the principles of tissue handling and selection of a suitable surgical approach

22.4. Discuss possible causes of delayed or impaired wound healing or other post-surgical complications and describe ways in which these can be avoided or, if they occur, treated

22.5. Recall in general terms how personnel, animals, instruments and equipment should be prepared for aseptic surgery

22.6. Recall the principles of successful surgery (e.g. Halstead's principles) and indicate how to achieve these

22.7. Recall the characteristics of different, commonly-used instruments, suture materials and needles

22.8. Distinguish the importance of good technique in accessing surgical sites, handling tissues and repairing incisions

22.9. Recall the characteristics of different suture patterns and their applicability to different situations

22.10. Demonstrate how to place a suture correctly

22.11. Describe common post-surgical complications and their causes

22.12. Relate the principles of post-surgical care and monitoring

22.13. Describe the planning of surgical procedures and discuss the competencies required of all personnel involved

22.14. Distinguish particular aspects of care appropriate for animals before, during and after surgical or any other potentially painful intervention