Directive 2010/63/EU on the protection of animals used for scientific purposes

Education and training framework – Modules and Learning Outcomes for Functions A and D

Module 1: National legislation [National - Core]

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. 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.
2. Identify and describe related animal welfare legislation.
3. 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.
4. List sources of information and support that are available (regarding national legislation).
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.
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.
7. Indicate who is responsible for compliance at an establishment and how this responsibility may be exercised (e.g. through the local AWB).
8. Describe when a procedure becomes regulated under National legislation (minimum threshold of pain, suffering, distress or lasting harm).
9. Indicate who bears primary responsibility for the animals undergoing procedures.
10. List which species, including respective stages of development that are included in the scope of the Directive / National law.
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.
12. Describe the legislative controls over the killing of animals bred or used for scientific procedures

Module 2: Ethics, animal welfare and the Three Rs (level 1) [Core]

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.

Learning Outcomes

Trainees should be able to:

1. Describe the differing views, within society, relating to the scientific uses of animals and recognise the need to respect these.
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.
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.
4. Recognise that compliance with ethical principles may contribute to the long-term trust and acceptance in scientific research from the general public.
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.
6. Describe and discuss the importance of the Three Rs as a guiding principle in the use of animals in scientific procedures.
7. Explain the Five Freedoms and how these apply to laboratory species
8. Describe the concept of harms to animals including avoidable and unavoidable suffering, direct, contingent and cumulative suffering
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.
10. Describe the regulations regarding re-use of animals.
11. Describe the importance of good animal welfare including its effect on scientific outcomes as well as for societal and moral reasons.
12. Describe the need for a culture of care and the individual's role in contributing to this.
13. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.
14. Be aware of different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. Systematic reviews, meta-analysis).

Module 3.1: Basic and appropriate biology – species specific (theory) [Core]

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.

Following this module practical training, under supervision, should provide each individual with the expertise and skills needed for them to carry out their particular function. Practical training requirements will, inevitably, differ according to function.

Learning Outcomes

Trainees should be able to:

1. Describe basic anatomy, physiology, reproduction and behaviour of the relevant species.
2. Recognise and describe life events that have the potential to cause suffering including sourcing, transport, housing, husbandry, handling and procedures (on a basic level).
3. Indicate 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.
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.
5. Describe the dietary requirements of the relevant animal species and explain how these can be met.
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.
7. 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.
8. When relevant to the species, recognise that alterations to the genome can affect the phenotype in unexpected and subtle ways, and the importance of monitoring such animals very carefully.
9. Maintain and interpret accurate, comprehensive records of animals held in the animal facility, including the wellbeing of the animals

Module 3.2: Basic and appropriate biology – species specific (practical) [Function Specific for Functions A, C and D]

1. Be able to approach, handle/pick up and restrain an animal and return it to its cage/pen in a calm, confident and empathetic manner such that the animal is not distressed or caused harm.

Module 4: Animal care, health and management – species specific (theory) [Core]

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 zoonoses.

Learning Outcomes

Trainees should be able to:

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.
2. Describe suitable environmental and housing conditions for laboratory animals, how conditions are monitored and identify the consequences for the animal resulting from inappropriate environmental conditions.
3. Recognise that changes to or disruption of circadian or photoperiod can effect animals.
4. Describe the biological consequences of acclimatisation, habituation and training
5. Describe how the animal facility is organized to maintain an appropriate health status for the animals and the scientific procedures.
6. Describe how to provide water and an appropriate diet for laboratory animals including the sourcing, storage and presentation of suitable foodstuffs and water
7. List 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.
8. Name different methods for marking individual animals and state an advantages and disadvantage for each method.
9. List 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).
10. Describe appropriate breeding programmes
11. Describe how genetically altered animals can be used for scientific research and the importance of monitoring such animals very carefully.
12. List the correct procedures for ensuring health, welfare and care of animals during their transport.
13. List 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 – species specific [Core]

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:

1. Recognise normal or desirable behaviour and appearance of the individuals in the context of species, environment and physiological status.
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.
3. Discuss factors to be considered and methods available for assessing and recording the welfare of animals e.g. score sheets.
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. 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.
6. Describe the circumstances when anaesthesia or analgesia may be necessary to minimise pain, suffering, distress or lasting harm.

Module 6: Humane methods of killing

6.1: Humane methods of killing (theory) [Core]

This module provides 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. The module will include information and descriptions of the different methods available, details of the species for which these methods are suitable and information to help trainees compare the methods permitted and determine how to select the most appropriate method.

Learning Outcomes

Trainees should be able to:

1. Describe the principles of humane killing (e.g. what constitutes 'a good death')
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.
3. Explain why someone competent to kill animals should be available at all times (whether care staff or person carrying out procedures)

6.2: Humane methods of killing (skills) [Function Specific for Functions D, and Additional Task Specific Module for Functions A and C as required]

This module provides practical training to reflect the information and principles delivered in module 6.1 and will involve practical training in the appropriate methods for the species and suitable methods of confirming death.

Learning Outcomes

Trainees should be able to:

1. Proficiently and humanely carry out euthanasia using appropriate techniques on relevant species of laboratory animals.
2. Demonstrate how death is confirmed and how cadavers should be processed or otherwise disposed of.

Module 7: Minimally invasive procedures without anaesthesia –species specific (Theory) [Function Specific for Functions A and B]

This module provides an introduction to the theory relating to minor procedures. It provides information about appropriate methods of handling and restraint and describes appropriate techniques for injection, dosing and sampling relevant to the species. It should provide information sufficient for individuals to understand what will be required of them before they go on to trained in the practical aspects of these skills whilst under supervision.

Learning Outcomes

Trainees should be able to:

1. Describe appropriate methods and principles to be followed when handling animals (including methods of manual restraint and use of restricted environments).
2. Describe the biological impact of procedures and restrain t on physiology.
3. Describe refinement opportunities for procedures and restraint e.g. through training (using positive re-enforcement), habituation and socialisation of animals.
4. Describe techniques/procedures including, for example, injection, sampling and dosing techniques (routes/volumes/frequency), dietary modification, gavage, tissue biopsy, behavioural tests, use of metabolic cages.
5. Describe how to perform minor techniques and relate appropriate sample volumes and sampling frequencies for the relevant species.
6. Describe the need for rigour and consistency in conducting scientific procedures and the correct recording and handling of samples.
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.
8. Recognize that refinement is an on-going process and know where to find relevant, up-to-date, information.
9. Describe the biological consequences of transport, acclimatization, husbandry conditions and experimental procedures on the species concerned and describe how these can be minimised.

Module 8: Minimally invasive procedures without anaesthesia – species specific (skills) [Function Specific for Function A]

This module delivers practical elements of training relevant to Module 7. Practical training for minor procedures can be taught through a number of methods using different tools which are available and designed for the purpose (this is likely to include synthetic animal models and the use of cadavers).

The module should be designed in such a way that it will enable the trainee to attain a level of proficiency such that, when commencing work under supervision, s/he should cause no pain, suffering, distress or lasting harm to the animal.

Learning Outcomes

Trainees should be able to:

1. Select and explain the best methods for common procedures (such as blood sampling and application of substances) including route/volume/ frequency as appropriate.
2. Demonstrate that s/he can handle and restrain the animal in the best position for the technique.
3. Perform minor techniques under supervision, in a manner that does not inflict unnecessary pain, suffering, distress or lasting harm.

Module 10: Design of procedures and projects (level 1) [Function Specific for Function B and Additional for Function A (as required)]

This module is a pre-requisite for people who will be designing projects (Function B) but it is also be beneficial for scientists who have some involvement in designing the procedures that they carry-out (Function A). The 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:

1. Describe the concepts of fidelity and discrimination (e.g. as discussed by Russell and Burch and others).
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).
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).
4. Identify the experimental unit and recognise issues of non-independence (pseudo-replication).
5. Describe the variables affecting significance, including the meaning of statistical power and "p-values".
6. Identify formal ways of determining of sample size (power analysis or the resource equation method).
7. List the different types of formal experimental designs (e.g. completely randomised, randomised block, repeated measures [within subject], Latin square and factorial experimental designs).
8. Explain how to access expert help in the design of an experiment and the interpretation of experimental results.

Module 20: Anaesthesia for minor procedures [Additional Task Specific Module for Functions A and B as required]

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.
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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:

1. Define sedation, local and general anaesthesia
2. Identify the three components of the triad of anaesthesia and understand that different anaesthetic agents produce these to different degrees.
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
4. Relate why and when sedation or anaesthesia might be used for restraint.

5. List 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.
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
7. Indicate the importance of minimising stress prior to anaesthesia in reducing the likelihood of complications due to anaesthesia.
8. Recognise when premedication is beneficial to incorporate into an anaesthetic regime.
9. Describe and demonstrate the correct set-up, operation and maintenance of anaesthetic equipment appropriate to the species concerned.
10. Evaluate and appreciate the different levels and planes of anaesthesia (voluntary excitement, involuntary excitement, surgical anaesthesia (light, medium & deep), excessively deep).
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 "observation al" anaesthetic monitoring techniques, including assessment of reflexes appropriate for species.
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.
13. Demonstrate an understanding of safe / good working practices with regard to use, storage and disposal of anaesthetic and analgesic agents.

Module 21: Advanced anaesthesia for surgical or prolonged procedures [Additional Task Specific Module]

This module is linked, but not exclusively, to the "surgery" module (22). "Surgical procedures" include all procedures not defined as "Minor procedures" in the Preamble to Module 20. Prolonged is defined as any duration greater than 15 minutes, which may require additional or continuous dosing (including anaesthesia for imaging).

This module also discusses the alleviation of pain during painful procedures such as surgery, through the use of anaesthetic and analgesic drugs. Anaesthesia is also used for producing muscle relaxation, suppressing reflexes, and producing loss of consciousness for purposes other than prevention of pain perception. For example, anaesthesia is required for MRI, CT scans and other minimally invasive imaging modalities.

Because of the wide variability of laboratory animal species and strains, as well as anaesthetic agents, an appropriate anaesthetic regimen should be developed in consultation with a veterinarian.

If not used for restraint alone, the need to use an anaesthetic to perform a procedure implies that the procedure would be painful for an awake animal. In addition, there may be some residual pain after the animal recovers from the anaesthetic and analgesics should be used. Some drugs described here appear in both the anaesthesia and surgery modules.

Learning Outcomes

Trainees should be able to:

1. Relate why and when anaesthesia might be used, including additional factors relevant for long term anaesthesia.
2. Relate the need for and list the factors to be considered in pre-anaesthetic evaluation of animals, including acclimatisation.
3. Discuss the use of pre-anaesthetic agents and analgesics as part of a balanced anaesthetic regime.
4. Indicate that a range of drugs are commonly used for premedication and the induction and maintenance of anaesthesia in relevant laboratory species, and identify where to get advice on the different drug available and their use.
5. Describe how an animal's concurrent pathology may require specific anaesthetic regimen, monitoring or nursing care.
6. Indicate types of agents used for the induction and maintenance of general anaesthesia, their advantages and disadvantages and when each might be used.
7. Describe how anaesthetic agents interact to produce the three components of the anaesthetic triad to different degrees, and how balanced anaesthesia might be best achieved by using combinations.
8. Demonstrate a sufficient understanding of anaesthetic agents having a low analgesic effect, potentially requesting the use of an additional analgesia.

9. List the factors to be considered when monitoring anaesthesia both for anaesthetic depth and physiological stability. Indicate how to determine that an animal is sufficiently deeply anaesthetised to enable painful procedures to be undertaken, and what action should be taken if an adverse event occurs.
10. List methods which can used to assist monitoring of anaesthesia (e.g. ECG, BP, Urine output, Oxygen saturation, CO_2) and how these can be monitored.
11. Monitor anaesthetic depth and the animals' vital signs, using both clinical signs, and electronic apparatus if appropriate.
12. Describe and demonstrate the correct set-up, operation and maintenance of anaesthetic and monitoring equipment appropriate to the species concerned.
13. Demonstrate competence in maintaining and interpreting records of pre-and post-anaesthetic induction and whilst an animal is anaesthetised, as well as in managing the animal care adequately.
14. Indicate the problems that may occur during anaesthesia and understand how to avoid these, or manage them if they occur.
15. Demonstrate an understanding of mechanical ventilation.
16. Describe methods to optimise post anaesthetic recovery to ensure a smooth and rapid recovery from anaesthesia, as in Basic Module but with additional methods required, including analgesia and fluid replacement, for animals having undergone lengthy anaesthesia of surgical procedure.
17. Consider the consequences of anaesthesia and the surgical procedures on recovery.
18. Appreciate how the choice of anaesthetic agent will determine the rate of recovery and describe how duration and quality of anaesthesia governs the rate of recovery.
19. Describe the problems that can arise (in the post-operative period), and indicate how to avoid these, or manage them if they occur.
20. Discuss how to integrate a program of pain management into an overall scheme of perioperative care.
21. Indicate some of the problems associated with pain recognition and pain management in animals.
22. Demonstrate a sufficiently detailed understanding of analgesics to be able to administer safely, including routes of administration and potential adverse effects.
23. Demonstrate an understanding of safe / good working practices with regard to use, storage and disposal of anaesthetic and analgesic agents.

Module 22: Principles of surgery [Additional Task Specific Module for Functions A and B as required]

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:

1. Explain the relevance and need for pre-operative assessment and, where appropriate, conditioning.
2. Identify sources of reference for good surgical practice
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
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
5. Describe in general terms how personnel, animals, instruments and equipment should be prepared for aseptic surgery
6. List the principles of successful surgery (e.g. Halstead's principles) and indicate how to achieve these
7. Describe the characteristics of different, commonly-used instruments, suture materials and needles
8. Relate the importance of good technique in accessing surgical sites, handling tissues and repairing incisions
9. Indicate the characteristics of different suture patterns and their applicability to different situations
10. Demonstrate how to place a suture correctly
11. Describe common post-surgical complications and their causes
12. Relate the principles of post-surgical care and monitoring
13. Describe the planning of surgical procedures and discuss the competencies required of all personnel involved
14. Demonstrate competence in surgical techniques, including ablations and incisions and their closure by methods appropriate to the tissue concerned
15. Describe particular aspects of care appropriate for animals before, during and after surgical or any other potentially painful intervention