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

Education and training framework – Modules and Learning Outcomes for Function B

Modules from Function A&D course:

Module 1: National legislation [National - Core]
Module 2: Ethics, animal welfare and the Three Rs (level 1) [Core]
Module 3.1: Basic and appropriate biology – species specific (theory) [Core]
Module 4: Animal care, health and management – species specific (theory) [Core]
Module 5: Recognition of pain, suffering and distress – species specific [Core]
Module 6.1: Humane methods of killing (theory) [Core]
Module 7: Minimally invasive procedures without anaesthesia – species specific (Theory)
[Function Specific for Functions A and B]
Module 20: Anaesthesia for minor procedures
[Additional Task Specific Module for Functions A and B as required]
Module 21: Advanced anaesthesia for surgical or prolonged procedures
[Additional Task Specific Module]
Module 22: Principles of surgery
[Additional Task Specific Module for Functions A and B as required]

Module 9: Ethics, animal welfare and the Three Rs (level 2) [Function Specific for Function B]

This module provides guidance and information to enable individuals designing procedures and projects (Function B of Article 23) to look, in detail, at different aspects of ethics and the Three Rs and to apply the principles learned to the ethical and welfare issues raised by the use of animals in scientific procedures within their own programme of work.

The purpose of this module is to address the fact that those designing procedures should command a deeper and broader understanding of the general issues. Thus, the main difference between level 1 and level 2 Modules on "Ethics, animal welfare that the Three Rs" is not necessarily the topics to be covered (which have not been repeated here) but rather that some of them are addressed in more detail and with a greater expectation for the Learning O outcome itself. For example, at level 1 there are elements the trainee should know and be able to describe, which at level 2 the trainee should have a more detailed understanding and be able to discuss. 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:

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.

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.
3. 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.
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 minimised, and benefits maximised.
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.
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.
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.

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 Explain how to access expert help in the design of an experiment and the interpretation of experimental results.

Module 11: Design of procedures and projects (level 2) [Function Specific for Function B]

This module provides a relevant level of understanding of the national and international legal and regulatory framework within which projects are constructed and managed, and of their legal responsibilities.

The trainee must be able to identify, understand and respond appropriately to the ethical and welfare issues raised by the use of animals in scientific procedures generally, and specifically within their own programme of work. These have been addressed in Module 2.

The trainee should be able to develop, direct and control a programme of work in order to achieve its stated objectives, while ensuring compliance with the terms and conditions of any regulation governing the project. This includes implementation of the Three R's through out the programme of work. Learning outcomes relating to Reduction are addressed in Module 2.

Learning Outcomes

Trainee should be able to:

(i)   Leagal issues
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 (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).
2. List the key purposes of other relevant EU and international legislation and associated guidelines that impact on the welfare and use of animals. Thisincludes 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 practices
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.
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 experiments.
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.

6. Describe situations when pilot experiments may be necessary.
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.
8. Explain the importance of rigorous scientific technique and the requirements of assured quality standards such as GLP
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
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. Explain the importance of literature and internet searches, discussion with colleagues and with relevant professional bodies in identifying opportunities for applying each 'R'
12. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.
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).
14. Describe examples of alternative methods and research strategies that replace, avoid or complement the use of animals in different types of research programme.
15. 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.
16. Define and apply appropriate humane end-points; establish suitable criteria to identify when the humane endpoint has been reached
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
18. Define the requirements for, and controls on, re-homing of animals; identify any relevant re-homing guidelines

(iv)   Responsibilities
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