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Assessable learning outcomes for the EU Education and Training Framework core and Function A specific modules: Report of an ETPLAS WORKING Group

Ismene A Dontas[1], Kenneth Applebee[2], Martje Fentener van Vlissingen[3], Viola Galligioni[4], Katerina Marinou[5], Kathy Ryder[6], Johannes Schenkel[7], Jan-Bas Prins[8,9], Anne-Dominique Degryse[10] and David I Lewis[11]

Abstract

Article 23(2) of the European Union Directive 2010/63/EU, which regulates welfare provisions for animals used for scientific purposes, requires that staff involved in the care and use of animals for scientific purposes be adequately educated and trained before they undertake any such work. However, the nature and extent of such training is not stipulated in the Directive. To facilitate Member States in fulfilling their education and training obligations, the European Commission developed a common Education and Training Framework, which was endorsed by the Member States Competent Authorities. An Education & Training Platform for Laboratory Animal Science (ETPLAS) Working Group was recently established to develop further guidance to the Learning Outcomes in the Framework, with the objective to clarify the levels of knowledge and understanding required by trainees, and to provide the criteria by which these Learning Outcomes should be assessed. Using the Framework document as a starting point, assessment criteria for the Learning Outcomes of the modules required for Function A persons (carrying out procedures on animals) for rats, mice and zebrafish were created with sufficient detail to enable trainees, providers and assessors to appreciate the level of knowledge, understanding and skills required to pass each module. Adoption and utilization of this document by training providers and accrediting or approving bodies will harmonize introductory education and training for those involved in the care and use of animals for scientific purposes within the European Union, promote mutual recognition of training within and between Member States and therefore free movement of personnel.

Keywords

Assessment, assessment criteria, Directive 2010/63/EU, education, learning outcomes, training, mice, rats, zebrafish

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[1]Laboratory for Research of the Musculoskeletal System, School of Medicine, National & Kapodistrian University of Athens, Greece
[2]Applebee Advisory Ltd, UK
[3]Erasmus Laboratory Animal Science Centre, Erasmus University Medical Centre, The Netherlands
[4]Comparative Medicine Unit, Trinity College Dublin, Ireland
[5]Ministry of Rural Development and Food, Greece
[6]Home Office, Dundee, UK
[7]German Cancer Research Centre and Institute of Physiology and Pathophysiology, University of Heidelberg, FR Germany
[8]Biological Research Facility, The Francis Crick Institute, UK
[9]Leiden University Medical Centre, The Netherlands
[10]Domaine de Mirabel, France
[11]School of Biomedical Sciences, Faculty of Biological Sciences, University of Leeds, UK

Corresponding author:
Ismene A Dontas, National and Kapodistrian University of Athens, Faculty of Medicine, 26 Athanasiou Diakou Street, Kifissia, Athens, 14561 Greece.
Email: idontas@med.uoa.gr

Introduction

The European Union (EU) Directive 2010/63/EU[1] provides legislative framework for the protection and welfare of animals used for scientific purposes. It has three principal objectives: (a) to enhance the efficient functioning of the EU internal market and the competitiveness of research and industry in the EU; (b) to ensure high standards of research animal welfare; (c) to improve transparency to the general public on the use of animals for scientific purposes.

Critical to the realization of these objectives is to ensure that all personnel involved in the care and use of research animals are appropriately educated, trained and competent to fulfil their respective functions. Article 23(2) of the Directive[1] requires that 'staff shall be adequately educated and trained before they perform any of the following functions'. Whilst the Directive does not stipulate how Member States ensure appropriate provision of education and training, the European Commission (EC) developed a common Education and Training Framework,[2] which was endorsed by the Member States Competent Authorities, to facilitate them in fulfilling their obligations.

The developed Framework describes the education, training, supervision, competence and continuing professional development of the four Functions set out in the Directive, based on a modular training structure. It includes compulsory ('Core') and Function specific modules, each module comprising a set of Learning Outcomes. Core modules are compulsory to all four functions whereas Function specific modules are compulsory for a specific Function.[2] The Learning Outcomes define the minimum knowledge and skills trainees should possess on completion of the required modules for their respective Function. Adoption and use of this Framework by education and training providers across the EU promotes the harmonization of training provision to a common standard or level of knowledge and understanding. This in turn facilitates mutual recognition of provision within and between Member States, and therefore promotes the free movement of personnel.

To promote the Framework to prospective, new or existing providers, the Education & Training Platform for Laboratory Animal Science[3] (ETPLAS) was established. ETPLAS functions as an information sharing and communication portal to facilitate the sharing of information and good practice in education and training in research animal sciences between Member States, accrediting or approval bodies, education and training providers and employers.[4] It seeks to encourage consistency of content, assessment and outcomes across modules, and between education and training providers, critical for mutual recognition and acceptance of provision.

The Framework provides an outline of the required introductory education, training and assessment provision. However, the underlying Learning Outcomes were not written using assessable verbs (verbs that enable the Learning Outcomes to be assessed objectively and by electronic means), and thereby posing difficulties for their assessment in their current format. These difficulties include an incomplete set of assessment criteria; the suggested assessment tools cannot be justified pedagogically, and only few exemplars of good assessments are provided. To address these issues, ETPLAS was awarded an EU Parliament Pilot grant to undertake the following: (1) development of guidance for producing assessment criteria for the Learning Outcomes; (2) development of a database of assessment criteria for core and Function A specific modules; (3) establishment of a questions database; (4) establishment of a database of assessments of common practical tasks; (5) establishment of a suitable IT platform. In 2019, Working Groups were established to fulfil objectives 1-5.

Development of assessable Learning Outcomes and guidance on assessment tools for theory modules

The ETPLAS Working Group tasked with the development of guidance, assessable Learning Outcomes and assessment criteria comprised the authors of this paper. Learning Outcomes have been expanded by creating assessment criteria with sufficient detail to enable trainees, providers and assessors to appreciate the level of knowledge, understanding and skills required to pass each module. Assessment criteria for core modules 2, 3.1, 4, 5 and 6.1, as well as Function A (persons carrying out procedures on animals)[2] specific and species specific modules 3.2, 7 and 8 for rats and mice have been developed. Zebrafish specific assessment criteria are provided as Supplementary Material online (Appendix A). Criteria for module 1 (National Legislation) have not been included, as legislative requirements may differ between and within Member States. Minor amendments (indicated in footnotes in the tables) have been made to some Learning Outcomes in the original Framework document, as the Working Group considered these as needing additional clarification or being beyond the scope required for introductory courses.

In the tables below of the Learning Outcomes for each of the aforementioned modules, each assessment criterion assesses an individual element of a composite Learning Outcome, includes assessable verbs in

accordance with Bloom's taxonomy of educational objectives,[5] and is capable of being marked objectively using electronic or digital tools. Objective marking is where the answer can only be either right or wrong, it does not require interpretation by the assessor (subjective marking), thereby providing a robust means of assessing the level of knowledge and understanding of the trainee, free of bias introduced by the assessor. Guidance on appropriate assessment tools and exemplars of different formats of questions are provided as Supplementary Material (Appendix B). These include, but are not limited to: multiple choice questions (with single or multiple correct answers), extended matching questions, missing words, drag and drop, and 'label a diagram'.[6–8] Open comment question formats, requiring written text answers, have been specifically excluded, as they cannot be marked electronically and have been shown to discriminate against those being examined in their non-native language or students with learning challenges.

Modules, Learning Outcomes and assessment criteria – Core modules

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 (LOs): the trainees should be able to:

Learning Outcome 2.1 Describe the differing views, within society, relating to the scientific uses of animals and recognize the need to respect these.	**Assessment criteria pertaining to LO 2.1:** The candidate should have retained the information that they have been taught and be able to: 1. Relate opinions as voiced collectively or individually by • animal protection societies • patient support societies • establishments and researchers • industry, including pharma, biotech and food • people with personal, cultural or religious beliefs; 2. Recognize the fundamental right of freedom of speech; 3. Recall different perspectives which enable an individual to determine their own opinion on the use of animals for scientific purposes; 4. Explain how different perspectives drive forward advancements in animal welfare, legislation and science.
Learning Outcome 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.	**Assessment criteria pertaining to LO 2.2:** The candidate should be able to: 1. Identify examples of how animals depend on humans for their welfare throughout their lifetime; 2. Recognize that working with animals is a privilege and not a right; 3. Explain how collaboration with others will promote animal welfare and therefore contribute to a culture of care.
Learning Outcome 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.	**Assessment criteria pertaining to LO 2.3:** The candidate should have retained the information that they have been taught and be able to: 1. Identify the harms and benefits in their proposed work; 2. Explain how their behaviour and actions can impact on the welfare of the animals and scientific outcomes; 3. Describe additional harms from other 'contingent' factors (e.g. keeping in captivity, transport, ill health).
Learning Outcome 2.4 Recognize that compliance with ethical principles may contribute to the long-term	**Assessment criteria pertaining to LO 2.4:** The candidate should be able to: 1. Recognize that public acceptance of animal studies is dependent on the application of the Three Rs and having

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trust and acceptance in scientific research from the general public.	gone through robust ethical review processes; 2. Describe the purpose and content of a Non-Technical Summary (NTS); 3. Relate how public availability of NTSs contributes to transparency and public trust; 4. Explain how retrospective review and its dissemination contribute to transparency and public trust; 5. Identify examples of how openness builds public trust.
Learning Outcome 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 harms[a] and (3) promoting good animal welfare practices.	**Assessment criteria pertaining to LO 2.5:** The candidate should have retained the information that they had been taught and be able to: 1. State the legal requirements for a harm/benefit assessment (as in Article 38) and provide examples of what this means in practice. For example: • identify the potential harms for animals (physical and psychological) that should be taken into account in a study outline • identify examples of the permitted purposes for which animals can be used • understand the process of harm/benefit analysis • identify individuals and/or committees that are tasked to conduct a harm/benefit assessment; 2. Recall that: • the Three Rs have to be applied • the objectives of the project cannot be achieved without the use of animals • the harms caused are justified by the expected outcome • the project authorization will only be granted by the competent authority for projects where benefits exceed harms • additional harms may appear and should be managed appropriately; 3. Identify examples of how animal welfare may be improved.
Learning Outcome 2.6 Describe and discuss the importance of the Three Rs as a guiding principle in the use of animals in scientific procedures.	**Assessment criteria pertaining to LO 2.6:** The candidate should be able to: 1. Name and define each of the Three Rs; 2. Identify examples of each of the Three Rs; 3. Provide an explanation how each may be applied to optimize the number of animals used and to minimize animal suffering.
Learning Outcome 2.7 Explain the Five Freedoms and how these apply to animals used for scientific purposes.	**Assessment criteria pertaining to LO 2.7:** The candidate should have retained the information that they have been taught and be able to: 1. Identify the Five Freedoms; 2. Identify an example for each of these which may be impacted by scientific procedures; 3. Identify an example for each of these which may impact on animal welfare; 4. Explain how, and to what extent, the housing, care, husbandry and use of animals in establishments may compromise the Five Freedoms; 5. Recall how guidance on housing, care and husbandry are continually evolving.

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Learning Outcome 2.8 Describe the concept of harms to animals including avoidable and unavoidable suffering, direct, contingent and cumulative suffering.	**Assessment criteria pertaining to LO 2.8:** The candidate should be able to: 1. Define harms to animals in terms of potential animal suffering; 2. Discriminate between avoidable and unavoidable suffering in examples provided; 3. Discriminate between direct suffering (inherent to the procedure) and contingent suffering in examples provided; 4. Explain the concept of cumulative suffering; 5. Identify factors which can modulate cumulative suffering.
Learning Outcome 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.	**Assessment criteria pertaining to LO 2.9:** The candidate should be able to: 1. Define the four severity categories; 2. Classify the severity of procedures using given examples; 3. Classify the severity of combined procedures using a given example in which cumulative severity has occurred.
Learning Outcome 2.10 Describe the regulations regarding re-use of animals.	**Assessment criteria pertaining to LO 2.10:** The candidate should be able to: 1. Define re-use and explain why re-use can in some circumstances be appropriate; 2. Identify the legal restrictions to re-use in given examples; 3. Identify whether single use or re-use has occurred in given examples; 4. Recognize from examples provided that multistep procedures for a single purpose is single use; 5. Discriminate correctly when the experimental use of an animal with harmful phenotype is not considered re-use; 6. Relate that genetically altered animals are to be reported in some countries as regulated procedures even in the absence of harmful phenotype and/or scientific use.
Learning Outcome 2.11 Describe the importance of good animal welfare including its effect on scientific outcomes as well as for societal and moral reasons.	**Assessment criteria pertaining to LO 2.11:** The candidate should be able to: 1. Provide examples of where animal welfare can alter the reproducibility and reliability of data from animal studies; 2. Provide examples of where inappropriate animal welfare can impact on the physiological and/or psychological wellbeing of the animal; 3. Demonstrate knowledge of the outcomes of surveys of public opinion on animal experimentation including the conditional acceptors; 4. Recognize cases where public acceptance of animal studies is conditional that good practice in animal welfare is being implemented at all times; 5. Provide examples of organizations that promote openness and transparency regarding animal care and use; 6. Recognize the moral obligation of individuals to implement good practice in animal welfare at all times and how using animals for research is a privilege.
Learning Outcome 2.12 Describe the need for a culture of care and the individual's role in contributing to this.	**Assessment criteria pertaining to LO 2.12:** The candidate should be able to: 1. Explain the concept of a 'Culture of Care' and its importance;

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	2. Provide examples of how an individual (irrespective of role or function) can contribute to the development and enhancement of a Culture of Care within their establishment; 3. Reflect on where a lack of, or a limited, Culture of Care within an establishment can lead to harms or distress to research animals.
Learning Outcome 2.13 Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.	**Assessment criteria pertaining to LO 2.13:** The candidate should be able to name the information sources within establishments (e.g. animal welfare bodies), nationally (e.g. national committees) and globally (e.g. websites, journals) for information on ethics, animal welfare, alternatives to animal experimentation and the Three Rs.
Learning Outcome 2.14 Be aware of different search tools[b], methods of search and advanced methods of analysis[c] (e.g. systematic reviews, meta-analyses).	**Assessment criteria pertaining to LO 2.14:** The candidate should be able to: 1. Recall examples of relevant search tools/repositories/databases for information on research animal studies, animal welfare, alternative methods to animal experimentation and the Three Rs; 2. Explain the principles and purpose of a systematic review and a meta-analysis; 3. Recognize how these methodologies may be utilized to critically evaluate and interpret information from multiple sources.

[a]The words 'and maximize the benefits' have been removed from the original E&T Framework document as being beyond the scope of this Guidance for introductory courses.
[b]The parentheses existing in the original E&T Framework document (e.g. EURL ECVAM Search Guide, Go3Rs) have been removed as the examples were not search tools but repositories and databases which have been included in assessment criterion 2.14.1.
[c]The wording of the original E&T Framework document has been revised in order to be consistent with the examples of the methods of analysis in parentheses.

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: the trainees should be able to:

Learning Outcome 3.1.1 Describe basic anatomy, physiology, reproduction and behaviour of the relevant species.	**Assessment criteria pertaining to LO 3.1.1:** The candidate should be able to: 1. Identify key anatomical features, organs and structures according to life stages; 2. Describe breeding strategies, gestation periods and requirements for successful rearing of offspring; 3. Explain key physiological features, behaviours and environmental interactions in a research environment.
Learning Outcome 3.1.2 Recognize and describe factors[a] that have the potential to cause suffering, including sourcing, transport, housing, husbandry, handling and procedures (on a basic level).	**Assessment criteria pertaining to LO 3.1.2:** The candidate should be able to identify stressors, throughout life, that have the potential to cause long-lasting suffering to research animals and explain why.

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Learning Outcome 3.1.3 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.	**Assessment criteria pertaining to LO 3.1.3:** The candidate should be able to: 1. Relate that good welfare contributes to good science, reproducibility and reliability of data from animal studies; 2. Recall examples of how poor animal welfare can affect biological and/or behavioural parameters, and adversely change the scientific outcomes.
Learning Outcome 3.1.4 Indicate how husbandry and care may influence experimental outcome and the number of animals needed[b].	**Assessment criteria pertaining to LO 3.1.4:** The candidate should be able to correctly identify scenarios where husbandry and care may influence: 1. Experimental outcome; 2. Experimental design, including animal numbers and the need to randomize.
Learning Outcome 3.1.5 Describe the nutritional[c] requirements of the relevant animal species and explain how these can be met.	**Assessment criteria pertaining to LO 3.1.5:** The candidate should be able to: 1. Identify the nutritional requirements of the relevant species; 2. Match nutritional requirements to appropriate life stages; 3. Identify examples of how nutritional requirements can be met in specific experimental paradigms; 4. Identify from examples provided where nutrition can influence scientific outcomes.
Learning Outcome 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.	**Assessment criteria pertaining to LO 3.1.6:** The candidate should be able to: 1. Recognize the importance of providing an enriched environment appropriate to both the species and the science; 2. Identify species specific enrichments which give opportunities for research animals to express their natural behaviour; 3. Identify the benefits of social housing in compatible groups.
Learning Outcome 3.1.7 When relevant to the species, recognize that there are different strains, and that these can have different characteristics which can affect both welfare and science.	**Assessment criteria pertaining to LO 3.1.7:** The candidate should have retained the knowledge to: 1. Identify examples of different strains and sub-strains which have different characteristics and explain how these can affect both welfare and science; 2. Recognize that the characteristics of a strain may differ between suppliers and may change over generations; 3. Recognize that traits may have greater variance in outbred than in inbred animals; 4. Identify examples of the behavioural and physiological differences that the two sexes may have within the same (sub) strain.
Learning Outcome 3.1.8 When relevant to the species, recognize that alterations to the genome can affect the phenotype in unexpected and subtle ways, and the importance of monitoring such animals very carefully.	**Assessment criteria pertaining to LO 3.1.8:** The candidate should: 1. Recognize that both spontaneous and intended alterations to the genome can affect the phenotype, which may be subtle; 2. Recall that additional measures for phenotyping and monitoring of animals with harmful mutations and/or genetically altered animals may be required; 3. Identify genotyping and phenotyping resources and tools.

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Learning Outcome 3.1.9 Maintain and interpret accurate, comprehensive records of animals held in the animal facility, including the wellbeing of the animals.	**Assessment criteria pertaining to LO 3.1.9:** The candidate should be able to: 1. Discriminate between high quality, accurate and comprehensive records of research animals and lower quality examples; 2. Relate how this information can be utilized to support the management and wellbeing of the research animals.

[a]The words 'life events' in the original E&T Framework document have been replaced by 'factors', as 'life events' depict long-lasting impacts and as an expression, lack clarity.
[b]The examples provided in the original E&T Framework document have been consistently removed throughout this Guidance.
[c]'Dietary' has been replaced by 'nutritional' as the former does not encompass the animals' full needs.

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 zoonosis.

Learning Outcomes: the trainees should be able to:

Learning Outcome 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.	**Assessment criteria pertaining to LO 4.1:** The candidate should be able to select appropriate protocols and practices for the husbandry, maintenance, care and welfare for relevant species in their research environment.
Learning Outcome 4.2 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.	**Assessment criteria pertaining to LO 4.2:** The candidate should be able to: 1. Describe suitable housing conditions for laboratory animals; 2. Recall the legal minimum requirements for housing and sources of information which describe the required environmental conditions; 3. Identify examples of impacts for the animal resulting from inappropriate environmental conditions.
Learning Outcome 4.3 Recognize that changes to or disruption of circadian or photoperiod can affect animals.	**Assessment criteria pertaining to LO 4.3:** The candidate should be able to: 1. Recognize the importance of the circadian rhythms on the physiology, function and wellbeing of the relevant species; 2. Identify changes in, or disruption of, circadian rhythms and/or the photoperiod that can affect the physiology and wellbeing of the research animal; 3. Recognize that even brief disruptions can have a significant, negative impact.
Learning Outcome 4.4 Describe the biological consequences of acclimatization, habituation and training.	**Assessment criteria pertaining to LO 4.4:** The candidate should be able to: 1. Recall the physiological and behavioural consequences that acclimatization, habituation and training can have in the relevant species; 2. Identify good practice in achieving acclimatization, habituation and training.
Learning Outcome 4.5 Describe how the establishment[a] is organized to maintain an appropriate health status for the animals and the scientific procedures.	**Assessment criteria pertaining to LO 4.5:** The candidate should be able to: 1. Recall the principles of animal health monitoring and how these may vary between facilities and containment levels; 2. Select appropriate biosecurity measures for a higher health status facility; 3. Recall the principles of quarantine for newly acquired animals;

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	4. Identify relevant tasks which are the responsibilities of key individuals.
Learning Outcome 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.	**Assessment criteria pertaining to LO 4.6:** The candidate should be able to: 1. Identify how to adequately provide and present safe water and diet, appropriate to the species; 2. Recognize the importance of appropriate sourcing and storage of water and diet; 3. Identify circumstances when restrictions of water or food supply might be appropriate to the needs of the species or the science; 4. Recognize the legal requirements for the provision of food and water and describe how exemptions on these requirements can be requested.
Learning Outcome 4.7 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.	**Assessment criteria pertaining to LO 4.7:** The candidate should be able to: 1. Identify from examples provided at least one good practice method for the appropriate, safe and humane handling and restraint of the relevant species; 2. Identify from examples provided how scientific procedures may influence handling; 3. Discriminate between external sexual characteristics in male and female animals.
Learning Outcome 4.8 Name different methods for marking individual animals and state the advantages and disadvantages[b] for each method.	**Assessment criteria pertaining to LO 4.8:** The candidate should be able to: 1. Identify current good practice for permanently marking individual animals; 2. Identify the advantages and disadvantages of potential methods of permanently marking the relevant species according to welfare consequences and scientific requirement; 3. Recognize the legal requirement to apply the least harmful method appropriate to the species, life stage and intended use.
Learning Outcome 4.9 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 and use of sentinels as relevant to the species).	**Assessment criteria pertaining to LO 4.9:** The candidate should be able to: 1. Identify examples of at least two diseases which may occur in the relevant species and the relevance of them to scientific use; 2. Identify predisposing factors in the relevant species which increase potential risks to animal health and wellbeing in the animal facility; 3. Correctly match terminology with descriptions of methods for maintaining appropriate health status.
Learning Outcome 4.10 Describe appropriate breeding programmes.	**Assessment criteria pertaining to LO 4.10:** The candidate should be able to recall appropriate breeding practices relevant to the species.
Learning Outcome 4.11 Describe how genetically altered animals can be used for scientific research and the importance of monitoring such animals very carefully.	**Assessment criteria pertaining to LO 4.11:** The candidate should be able to: 1. Identify examples of genetically altered animals and how they can be used for scientific research; 2. Identify specific additional measures for phenotyping and monitoring of animals with defined harmful mutations and/or genetic alterations to ensure early detection of welfare harms.
Learning Outcome 4.12 List the correct procedures for ensuring health, welfare and care of animals during their transport.	**Assessment criteria pertaining to LO 4.12:** The candidate should be able to identify the multiple factors (legally required and good practice), relevant to the species, which ensure the health, welfare and care of animals during their transport.

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Learning Outcome 4.13 List potential human health hazards associated with contact with laboratory animals (including allergy, injury, infection, zoonosis) and how these can be prevented.	**Assessment criteria pertaining to LO 4.13:** The candidate should be able to identify the potential human health risks associated with contact with research animals and how these can be prevented or managed.

[a]'Animal facility' in the original E&T Framework document has been replaced by 'establishment' to include all possible environments or contexts.
[b]Revised from the original E&T Framework document to plural.

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: the trainees should be able to:

Learning Outcome 5.1 Recognize normal or desirable appearance and behaviour[a] of the individuals, as well as signs of positive well-being[b], in the context of species, environment and physiological status.	**Assessment criteria pertaining to LO 5.1:** The candidate should have retained the information that they have been taught and be able to: 1. Recognize the normal appearance and behaviour of relevant species in a research environment; 2. Recall defined signs of positive well-being appropriate to the species.
Learning Outcome 5.2 Recognize abnormal behaviour and signs of discomfort, pain, suffering or distress[c], and principles of how pain, suffering and distress can be managed.	**Assessment criteria pertaining to LO 5.2:** The candidate should have retained the information that they have been taught and be able to: 1. Recognize abnormal behaviour and defined signs of discomfort, pain, suffering or distress of relevant species in a research environment; 2. Identify the advantages of using defined welfare terms and name at least one relevant source; 3. Identify examples of how pain, suffering and/or distress can be prevented or managed.
Learning Outcome 5.3 Discuss factors to be considered and methods available for assessing and recording the welfare of animals, e.g., score sheets.	**Assessment criteria pertaining to LO 5.3:** The candidate should be able to: 1. Identify the persons responsible for welfare monitoring and assessment under legislation and within the establishment; 2. Describe different methodologies by which aspects of welfare can be appropriately assessed, recorded and reported.
Learning Outcome 5.4 Describe what a humane endpoint 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.	**Assessment criteria pertaining to LO 5.4:** The candidate should be able to: 1. Define what is meant by a humane endpoint; 2. Discriminate between a humane and a scientific endpoint; 3. Identify humane endpoints in specific scenarios; 4. Identify possible actions to be taken when criteria for a humane endpoint are or will be reached in specific scenarios; 5. Recognize that procedures can be refined to achieve meaningful scientific outcomes before the pre-defined humane endpoints are reached.
Learning Outcome 5.5 Describe the severity classifications included in the Directive and give examples of each	**Assessment criteria pertaining to LO 5.5:** The candidate should be able to: 1. Define the four severity categories;

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category; explain cumulative suffering[d] and the effect this may have on the severity classification.	2. Classify the severity of procedures using given examples; 3. Explain the concept of cumulative suffering; 4. Classify the severity of combined procedures using a given example in which cumulative suffering has occurred.
Learning Outcome 5.6 Describe the circumstances when analgesia or anaesthesia[e] may be necessary to minimize pain[f].	**Assessment criteria pertaining to LO 5.6:** The candidate should be able to: 1. Identify examples of circumstances where analgesia or anaesthesia are indicated to prevent pain; 2. Recall that there may be physiological and pharmacological interactions between analgesics and anaesthetics; 3. Recognize that in certain procedures or models, the administration of specific analgesics may be incompatible with the scientific objectives.

[a]Change of sequence from original E&T Framework document because this is the logical sequence of monitoring.
[b]Addition to original E&T Framework document, moved from LO 5.2, because it is required to know what is normal before recognizing what is abnormal.
[c]The words 'as well as signs of positive well-being' in the original E&T Framework document have been moved to LO 5.1.
[d]The word 'severity' in the original E&T Framework document has been replaced by 'suffering', as the Directive refers to cumulative suffering (Annex VIII, section II).
[e]Change of sequence from the original E&T Framework document.
[f]The words 'suffering, distress or lasting harm' in the original E&T Framework document have been removed from here. The use of analgesia or anaesthesia to ameliorate suffering, distress or lasting harm is undesirable for welfare reasons and should not be encouraged. Their effects are temporary and may mask conditions that require relief. Furthermore, the application of analgesia or anaesthesia is time-limited. Recognition and management of pain, suffering and distress is addressed under LO 5.2.

Module 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: the trainees should be able to:

Learning Outcome 6.1.1 Describe the principles of humane killing (e.g. what constitutes 'a good death').	**Assessment criteria pertaining to LO 6.1.1:** The candidate should be able to identify the principles of humane killing.
Learning Outcome 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.	**Assessment criteria pertaining to LO 6.1.2:** The candidate should be able to: 1. Recall that only a limited list of specified methods of humane killing of research animals is permitted by legislation; 2. Recognize there are different methods for specific species and/or ages/weights; 3. Identify appropriate methods for a given species and/or ages/weights; 4. Recognize that the method selected must be compatible with the scientific objectives; 5. Recognize that in addition to humane killing, confirmation of death is mandatory; 6. Identify at least one appropriate method for confirming death in the relevant species and/or age/weight.
Learning Outcome 6.1.3 Explain why someone competent to kill animals should be available[a] (whether care staff or person carrying out procedures).	**Assessment criteria pertaining to LO 6.1.3:** The candidate should be able to explain the advantages and necessity of having someone trained and competent to kill animals who should be readily available.

[a]The words 'at all times' in the original E&T Framework document have been removed because the Directive does not state this requirement.

Modules, Learning Outcomes and assessment criteria – Function A specific Modules

In addition to the Core Modules, to meet the minimum training needs for a specific function,[2] Function specific Modules are required. For Function A persons (carrying out procedures on animals), the following Function A specific Modules need to be delivered and assessed.

Module 3.2: Basic and appropriate biology – species specific (practical) (function specific for Functions A, C and D)

Learning Outcomes: the trainees should be able to:

Learning Outcome 3.2.1 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.	**Assessment criteria pertaining to LO 3.2.1:** The candidate should be able to: 1. Demonstrate the currently accepted good practice in handling, picking up and restraining method appropriate to the species; 2. Select an appropriate method for the animal's species, age, health status and behavioural response, taking into account the study's scientific aims; 3. Perform a restraining technique while displaying a calm, confident and empathetic manner, with minimal distress or harm caused to the animal.

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 be* trained in the practical aspects of these skills whilst under supervision.

*Addition to original E&T Framework document.

Learning Outcomes: the trainees should be able to:

Learning Outcome 7.1 Describe appropriate principles and methods[a] to be followed when handling animals (including methods of manual restraint and use of restricted environments).	**Assessment criteria pertaining to LO 7.1:** The candidate should be able to: 1. Explain the importance of gentle and safe practices for handling animals; 2. Recognize that animals will adapt to regular handling practices; 3. Select methods for manual restraint and the application of restricted environments which are proportional to the purpose; 4. Identify proper handling practices including some adequate methods for manual restraint and the application of restricted environments.
Learning Outcome 7.2 Describe the biological impact of procedures and restraint on physiology.	**Assessment criteria pertaining to LO 7.2:** The candidate should be able to: 1. Explain that procedures and restraint will provoke physiological and psychological responses in the animal which may also impact on experimental parameters;

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	2. Explain that physiological and psychological responses to procedures and restraint will last some time beyond the actual event; 3. Explain that procedures and restraint can exceed the adaptive capacities of the animal, especially when repeated, and then may cause chronic stress responses which are pathological, impact on the quality of life of the animal and may significantly affect the experimental outcomes.
Learning Outcome 7.3 Describe refinement opportunities for procedures and restraint, for example, through training (using positive reinforcement[b]), habituation and socialization of animals.	**Assessment criteria pertaining to LO 7.3:** The candidate should be able to: 1. Explain how proper handling practices can contribute to refinement of the scientific procedures; 2. Explain the need and describe options for refinement when restraining an animal; 3. Apply known strategies to train an animal for specific procedures and describe the principles of positive reinforcement; 4. Relate the importance of habituation of an animal to its physiological and psychological homeostasis; 5. Explain the social needs of an animal and recall strategies to minimize social distress.
Learning Outcome 7.4 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.	**Assessment criteria pertaining to LO 7.4:** The candidate should be able to: 1. Describe the commonly used approaches and procedures of administration of test substances, drugs or modified diets; 2. Describe the common routes of withdrawal of bodily fluids and tissues samples; 3. Identify and apply relevant sources of information, including on injection volumes, frequencies, vehicles, withdrawal of bodily fluids or tissue samples; 4. Explain the advantages and disadvantages of the use of behavioural tests and metabolic cages, and the potential impact on the animal; 5. Identify options for refinement of the techniques applied.
Learning Outcome 7.5 Describe how to perform minor techniques and relate appropriate sample volumes and sampling frequencies for the relevant species.	**Assessment criteria pertaining to LO 7.5:** The candidate should be able to: 1. Relate that maximum sampling volumes are determined by sampling volume, frequency, age and body weight in the appropriate species; 2. Recall the physiological factors underlying recovery from minor procedures.
Learning Outcome 7.6 Describe the need for rigour and consistency in conducting scientific procedures and the correct recording and handling of samples.	**Assessment criteria pertaining to LO 7.6:** The candidate should be able to: 1. Identify factors which may affect the reproducibility of scientific experiments; 2. Recall the need for consistency in the conduct of experimental procedures; 3. Identify options for accurate recording of experimental parameters; 4. Recall how sample quality depends on appropriate identification, handling and storage.

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Learning Outcome 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.	**Assessment criteria pertaining to LO 7.7:** The candidate should be able to: 1. Explain severity classifications and how the severity of a procedure can be assessed (prospective/actual/retrospective severity); 2. Describe good practice in the assessment of animal welfare; 3. Recall ameliorative actions required in instances where animals deviate from expected adverse effects.
Learning Outcome 7.8 Recognize that refinement is an on-going process and know where to find relevant, up-to-date, information.	**Assessment criteria pertaining to LO 7.8:** The candidate should be able to: 1. Explain that refinement is an on-going process; 2. Identify relevant sources of information that drive this process; 3. Recall that Named Persons are valuable sources of information and are specifically tasked to provide this information; 4. Recall that Continuing Professional Development is required in the Directive and should include science and welfare.
Learning Outcome 7.9 Describe the biological consequences of transport, acclimatization and husbandry conditions[c] on the species concerned and describe how these can be minimized.	**Assessment criteria pertaining to LO 7.9:** The candidate should be able to: 1. Describe the physiological consequences of transport and new environments; 2. Recall the need for an appropriate period of acclimatization and quarantine.

[a]Change of sequence to original E&T Framework document, as principles have to be understood before being applied in practice.
[b]Typo corrected.
[c]The words 'and experimental procedures' have been deleted from the original E&T Framework document as these have been covered previously.

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 surrogate materials,** 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.

**Addition to original E&T Framework document to encompass alternative skills training materials

Learning Outcomes: the trainees should be able to:

Learning Outcome 8.1 Select and explain the best methods for common procedures (such as blood sampling and application of substances) including route/volume/frequency as appropriate.	**Assessment criteria pertaining to LO 8.1:** The candidate should have retained the information that they have been taught and be able to: 1. Demonstrate good practice for administration of substances and the withdrawal of bodily fluids, appropriate for the species' age, health status and the study's scientific aims; 2. Recall that there are welfare and scientific limits to these sampling and administration practices and sources of this information; 3. Explain the physiological consequences of exceeding these limits.

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Learning Outcome 8.2 Demonstrate that s/he can handle and restrain the animal in the best position for the technique.	**Assessment criteria pertaining to LO 8.2:** The candidate should be able to: 1. Demonstrate good practice in the handling and restraint of an animal, appropriate to the species, age and the procedure to be carried out; 2. Explain why a specific restraining method is the most appropriate for the procedure to be carried out.
Learning Outcome 8.3 Perform minor techniques under supervision, in a manner that does not inflict unnecessary pain, suffering, distress or lasting harm.	**Assessment criteria pertaining to LO 8.3:** *The following assessment criteria and approaches to provision of training must comply with the national regulations, that is, in some Member States no live animals will be used to perform regulated procedures (for training purposes) before authorizations are granted, but cadavers or models may be used.* The candidate should have retained the information that they have been taught and be able to: 1. Demonstrate good practice in preparing for and performing minor procedures; 2. Recall the need for appropriate risk management to minimize all possible harms to animals and humans, prior to performing minimally invasive procedures without anaesthesia; 3. Recall the potential consequences on animal health and wellbeing of inappropriate conduct of the demonstrated minor procedure(s).

Implementation and next steps

This document builds on the EC Education and Training Framework,[2] providing guidance on the level of knowledge and understanding required to achieve the Framework Learning Outcomes. Some of the original Learning Outcomes have been revised in order to better portray the desired educational objectives; the rationale of these revisions is explained in the tables' footnotes. We have produced assessment criteria for all the Learning Outcomes of the modules required for Function A persons, with wording that permits the evaluation of the knowledge acquired by objectively assessable examination methods. The user community could choose to add to this suggested provision, determine themselves where to give greater focus, and choose the most appropriate educational method, means of delivery and method of assessment.

The course should cover all Learning Outcomes of the required modules, ensuring that trainees have been provided with all the required knowledge. However, the assessment at the end of the course will, by necessity, access only a restricted number of these. The Learning Outcomes which are assessed should be chosen at random, varying between each time the assessment test is presented, and should collectively cover all modules being examined. A successful independent assessment should give reassurance that the trainee is ready to begin using animals for scientific purposes under supervision.

In developing assessments for these Learning Outcomes, providers and accrediting or approving bodies should consider the following: whether or not to hold examinations as open (can bring resources/information with them) or closed book (no resources/information permitted); standardized formats of questions; a balanced sample of assessed Learning Outcomes; provide extra time for non-native speakers to complete the assessment; supervised or unsupervised examinations, all of which have been shown to influence the marks awarded to those taking the assessment.[6-8] In addition, consideration should be given to the pass mark for the assessment based on its complexity rather than selection of an arbitrary pass mark, and re-assessment options (including feedback, support and timelines) in the case of failure.

It should be noted that the assessment criteria for each respective Learning Outcome have been developed so as to be capable of assessing individual elements of a composite Learning Outcome, and that their marking can be conducted electronically, provided questions are designed appropriately. Electronic marking is objective, that is, not open to interpretation by the assessor, and therefore is more robust than subjective marking.[8] Exemplars of objective question formats that test both knowledge and understanding are

provided as Supplementary information in Appendix B. The ETPLAS Working Group recommend the use of these formats as they are inclusive, they do not discriminate against those being examined in their non-native language or students with learning challenges.

Harmonization of all of the features discussed in this paper by training providers and recognition of their value and importance to promote equivalent standards between courses by accrediting or approving bodies will provide a tool for mutual recognition of training within and between Member States and more widely to other nations, and therefore promote free movement of personnel.

This document provides guidance to implement the Learning Outcomes from the Framework document[2] for introductory Function A courses and describes assessment criteria that can be used for their examination. On successful completion of these courses, trainees will have the minimum level of knowledge and understanding required, under the Directive, to carry out procedures on research animals under supervision. This should be followed by further education and training for those who continue to be involved with the care and use of animals for scientific purposes. As an individual's career progresses, opportunities should be sought for additional education and training (continuous professional development) to deepen knowledge and understanding, as well as broadening the scope of what is learnt to accommodate developments in science and/or welfare, or enhanced leadership responsibilities or a new role within the establishment.

This programme of work is being further developed by two additional ETPLAS working groups: WG3, who are developing a database of assessment tools, and WG4, who are developing a database of assessments of common practical tasks. All of the above will be available via the ETPLAS website.[3]

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ORCID iDs

Ismene A Dontas https://orcid.org/0000-0002-2440-0119
Kenneth Applebee https://orcid.org/0000-0002-7714-215X
Viola Galligioni https://orcid.org/0000-0002-6894-3318
Johannes Schenkel https://orcid.org/0000-0002-3326-1130
Jan-Bas Prins https://orcid.org/0000-0002-1831-8522
David I Lewis https://orcid.org/0000-0003-3014-3427

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Résumé

L' article 23(2), de la directive 2010/63/UE de l'Union européenne, qui réglemente les dispositions relatives au bien-être des animaux utilisés à des fins scientifiques, exige que le personnel chargé des soins et de l'utilisation des animaux à des fins scientifiques soit correctement formé avant d'entreprendre de tels travaux. La nature et l'étendue de cette formation ne sont toutefois pas précisées dans la directive. Afin de faciliter le respect, par les États membres, de leurs obligations en matière d'éducation et de formation, la

Commission européenne a élaboré un cadre commun d'éducation et de formation, qui a été approuvé par les autorités compétentes des États membres.

Un groupe de travail de la plateforme d'éducation et de formation sur les animaux de laboratoire (ETPLAS) a récemment été créé afin d'élaborer des directives supplémentaires concernant les résultats d'apprentissage dans ce cadre commun, afin de préciser les niveaux de connaissances et de compréhension requis par les apprentis et de fournir les critères d'évaluation de ces résultats d'apprentissage. En utilisant le document-cadre comme point de départ, les critères d'évaluation des résultats d'apprentissage des modules requis pour le personnel de la fonction A (effectuant des procédures sur les animaux) pour les rats, les souris et les poissons-zèbres ont été créés avec suffisamment de détails pour permettre aux apprentis, aux fournisseurs et aux évaluateurs d'apprécier le niveau de connaissances, de compréhension et de compétences requises pour réussir chaque module.

L'adoption et l'utilisation de ce document par les prestataires de formation et les organismes d'accréditation ou d'approbation harmoniseront l'enseignement et la formation de base des personnes impliquées dans le soin et l'utilisation des animaux à des fins scientifiques au sein de l'Union européenne, permettra de promouvoir la reconnaissance mutuelle de la formation au sein des États membres et donc la libre circulation du personnel.

Abstract

Artikel 23(2) der Richtlinie 2010/63/EU der Europäischen Union, die die Tierschutzbestimmungen für zu wissenschaftlichen Zwecken verwendete Tiere regelt, schreibt vor, dass mit der Pflege und Verwendung von Tieren für wissenschaftliche Zwecke befasstes Personal angemessen ausgebildet und geschult werden muss, bevor es solche Arbeiten ausführt. Art und Umfang einer solchen Ausbildung sind jedoch in der Richtlinie nicht festgelegt. Um den Mitgliedstaaten die Erfüllung ihrer Aus- und Fortbildungsverpflichtungen zu erleichtern, hat die Europäische Kommission einen gemeinsamen Ausbildungs- und Schulungsrahmen entwickelt, der von den zuständigen Behörden der Mitgliedstaaten gebilligt wurde.

Vor kurzem wurde eine Arbeitsgruppe der Education & Training Platform for Laboratory Animal Science (ETPLAS) eingerichtet, um weitere Orientierungshilfe zu den Lernergebnissen im Rahmenwerk zu entwickeln, mit dem Ziel, die von den Auszubildenden benötigten Wissens- und Kenntnisstufen zu präzisieren und die Kriterien bereitzustellen, nach denen diese Lernergebnisse bewertet werden sollten. Unter Verwendung des Rahmendokuments als Ausgangspunkt wurden Bewertungskriterien für die Lernergebnisse der Module, die für Personen der Funktion A (Durchführung von Verfahren an Tieren) für Ratten, Mäuse und Zebrafische erforderlich sind, ausreichend detailliert erstellt, um Auszubildende, Anbieter und Prüfer in die Lage zu versetzen, den Wissensstand, das Verständnis und die Fähigkeiten einzuschätzen, die für eine erfolgreiche Absolvierung der einzelnen Module erforderlich sind. Die Einführung und Nutzung dieses Dokuments durch Ausbildungsanbieter und Akkreditierungs- oder Zulassungsstellen wird Erstausbildung und Fortbildung für diejenigen, die mit der Pflege und Verwendung von Tieren für wissenschaftliche Zwecke innerhalb der Europäischen Union befasst sind, harmonisieren und die gegenseitige Anerkennung der Ausbildung innerhalb und zwischen den Mitgliedstaaten und damit die Freizügigkeit des Personals fördern.

Resumen

El artículo 23(2) de la Directiva de la Unión Europea 2010/63/UE, que regula las disposiciones de bienestar para animales utilizados para fines científicos, dicta que el personal involucrado en el cuidado y uso de animales para fines científicos deben estar debidamente formados y entrenados antes de realizar dicho trabajo. Sin embargo, la naturaleza y el alcance de dicha formación no se estipulan en la Directiva. Para ayudar a los Estados Miembros a cumplir con sus obligaciones en cuanto a formación y educación, la Comisión Europea creó un Marco de Educación y Formación, el cual fue adoptado por las Autoridades Competentes de los Estados Miembros.

Recientemente se creó un grupo de trabajo para una Plataforma de Educación y Formación para la Ciencia de Animales de Laboratorio (ETPLAS) a fin de desarrollar las directrices de los resultados de aprendizaje en el Marco, con el objetivo de aclarar los niveles de conocimiento y entendimiento requeridos por parte de los aprendices, así como para ofrecer los criterios a seguir durante la evaluación de estos Resultados de

Aprendizaje. Utilizando el documento del Marco como punto de partida, se crearon con suficiente detalle los criterios de evaluación para los Resultados de Aprendizaje de los módulos requeridos para las personas en el módulo de Función A (que realizan procedimientos con animales: ratas, roedores y peces cebra) a fin de permitir a los aprendices, proveedores y evaluadores apreciar el nivel de conocimiento, entendimiento y pericia requerido para aprobar cada módulo.

La adopción y utilización de este documento por los proveedores de formación y los organismos de acreditación y autorización armonizará una formación y educación de introducción para aquellas personas involucradas en el cuidado y uso de animales para fines científicos dentro de la Unión Europea, y fomentará el reconocimiento mutuo de la formación dentro y entre los Estados Miembros y, por tanto, el libre movimiento del personal.