

FELASA 2015 Recommendations for the Accreditation of Education and Training Courses in Laboratory Animal Science

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Note of institutions of authors - Appendix 4

Summary

This document is addressed to Course Organisers with current, or intention to apply for, FELASA accreditation for the education and training of personnel involved in animal experimentation. It describes how the revised FELASA accreditation addresses both the letter and the spirit of the new Directive 2010/63/EU and the related EC Guidelines (European Commission, 2014), whilst maintaining the high standard of training quality, which has become the recognised hallmark of FELASA accredited courses. The main changes include:

The Four EU Functions: FELASA now accredits courses that fulfil the requirements of Functions A, B, C and D as defined by EU Directive, Article 23, as well as for designated veterinarians and specialists in laboratory animal science (EU Directive, Articles 24, 25 & 26).

Modularity and Mobility: Cohesive courses, rather than single modules, are accredited, but flexibility and mobility for a researcher is possible: a person can start his/her training with one training provider and complete other modules with another. The Course Organiser of each accredited course will deliver a FELASA certificate relating exclusively to the successfully completed programme.

Accreditation Process: The FELASA scheme is based on the following two-stage process:

1. Review of full course documentation provided by the applicant can lead to FELASA Accreditation.
2. FELASA Accreditation is confirmed by an on-site course audit.

Continuation of accreditation requires revalidation every five years for courses delivered over a period lasting less than one year. Renewal is required each 10 years for courses delivered over a period greater than one year.

How to cite this document

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Updates

In order to maintain high quality training whilst responding to a changing European landscape, this paper is maintained as a living document on the FELASA website and will be updated whenever relevant. This document replaces the one published in 2002 (FELASA, 2002).

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Please check on the FELASA website (www.felasa.eu) under the accreditation board section for the current version.

Contact for further enquiries and detailed documentation: secretariat@felasa.eu

Purpose of this document and background

Article 23 of the Directive on the Protection of Animals Used for Scientific Purposes 2010/63/EU recognises the importance of education and training of all persons involved with the breeding, supplying and use of laboratory animals. Annex V of the Directive identifies a list of topics to be included in education and training and the National Competent Authorities endorse a working document proposing a common education and training framework that has been endorsed by (European Commission, 2014).

Article 23 of the Directive recognises competence of personnel required to carry out four functions, designated A, B, C, and D. These four functions however differ from the categories used previously by the Council of Europe and by FELASA since the 1990s (see Appendix 1). Thus the FELASA accreditation scheme needed to be adapted to address functions A to D as defined by 2010/63/EU (art. 23, al 2) and their associated learning outcomes. In addition to these four functions, FELASA accreditation will also be available to the education and training of what we define as specialists in laboratory animal science (Specialist in LAS) - a person who may be involved in tasks described in article 24, 25 and 26 (fulfilling specific requirements for the welfare and care of animals, for the education and training of personnel or any other requirement for the education and training of the designated veterinarian).

Principles and process for Accreditation by FELASA

The Expert Working Group established by the Commission recommended a modular approach to the development of competencies, with defined learning outcomes (European Commission, 2014 and see Appendix 3). It acknowledged that the objective of initial training is to instil basic knowledge and/or understanding and is only the first step of the learning process. It involves a program of work/study leading to specific learning outcomes, which provide basic understanding and skills appropriate to the function.

Satisfactory completion of this initial training is followed by work with animals under supervision, leading to deeper understanding (Figure 1). This second level of training promotes the necessary *in vivo* competences for caring for and working with experimental animals in a fully responsible way and in accordance with the 'Three Rs'. This may be developed further with a programme of Continuous Professional Development (CPD).

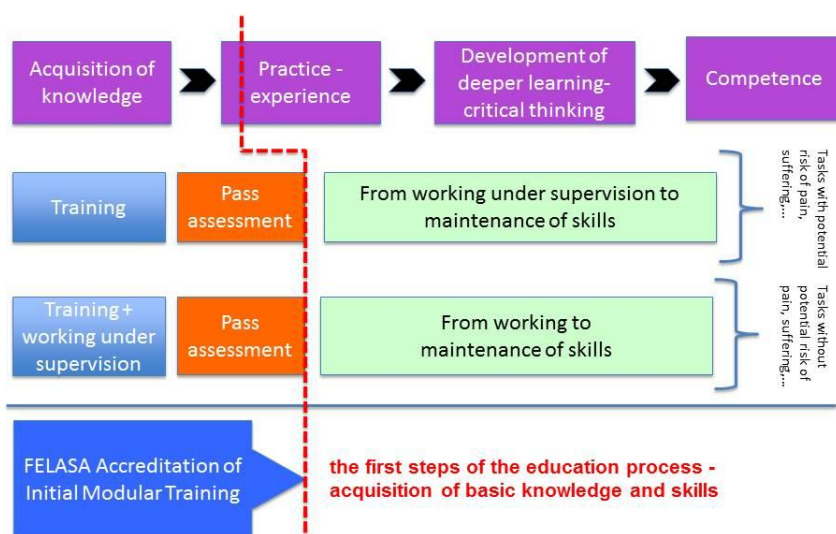
The EU Expert Working Group also recommended that persons performing one of the functions A, B, C or D during which there is a likelihood of causing pain, suffering, distress or lasting harm, should have completed relevant training prior to working under supervision (European Commission, 2014). In other cases, the trainee could begin working under supervision before the relevant modules have been satisfactorily completed (European Commission, 2014).

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Responsibility for correct performance of tasks always remains with the supervisor until training has been completed and the requisite competence demonstrated. Guidelines for supervision requirements are available (*e.g.* LASA 2010).

These new requirements are reflected in different approaches to the assessment of satisfactory training and attainment of competence. The FELASA accreditation scheme addresses the first steps of the education process - acquisition of basic knowledge and skills - that is concluded by an examination (Figure 1) and ensures their international recognition as a benchmark of high quality.

Figure 1: The steps of the EU education process that FELASA accredits (European Commission, 2014)



The new FELASA Accreditation scheme

Functions: Advantages of modularity in tailoring course to match specific needs of personnel

FELASA accreditation is available for courses that develop initial training leading to competency in each of the four functions identified in the Directive. Moreover, the scheme is also available for designated veterinarians and specialists in laboratory animal science (EU Directive, Articles 24, 25 & 26)

Because of its modular structure, the EU education scheme allows competence to develop by following a variety of courses tailored to the needs of the participants. A brief description of the modules can be found in Appendix 3.

Table 1 gives a summary of the different types of modules that participants must or can attend for EU Function A to D defined under article 23 and illustrates how courses can be organized to provide an educational program that covers several functions at once. It is important to remember that the course should be relevant to the species chosen.

Table 1

EU ID	Module Description	EU Function				Species
		C	D ¹	A	B	
1	National Legislation	C	C	C	C	
2	Ethics, Animal Welfare and the Three Rs (level 1)	C	C	C	C	
3.1	Basic and Appropriate Biology	C	C	C	C	X
4	Animal Care, Health and Management	C	C	C	C	X
5	Recognition of Pain, Suffering and Distress	C	C	C	C	X
6.1	Humane Methods of Killing	C	C	C	C	X
3.2	Basic and Appropriate Biology - Skills	F	F	F		X
7	Minimally Invasive Procedures Without Anesthesia			F	F	X
8	Minimally Invasive Procedures Without Anesthesia - Skills			F		X
9	Ethics, Animal Welfare and the Three Rs (level 2)				F	
10	Design of procedures and projects (level 1)			T	F	
11	Design of procedures and projects (level 2)				F	
6.2	Humane methods of killing – Skills	T	F	T		X
20	Anaesthesia for Minor Procedures			T	T	
21	Advanced Anaesthesia for Surgical and Prolonged Procedures			T	T	
22	Principles of Surgery			T	T	
23	Advanced Animal Husbandry, Care and Enrichment Practices	T				

EU Function A: carrying out procedures on animals

EU Function B: designing procedures and projects

EU Function C: taking care of animals

EU Function D: killing animals

¹ Module 6.3 is a stand-alone module for EU Function D (not mentioned here)

C: Core modules: modules that are required for all functions, F: function specific (prerequisite) modules, T: Task specific modules: modules that are relevant to specific tasks within a function. X: Species specific.

Level 1: At this level the trainee should describe and explain the subjects taught.

Level 2: At this level the trainee should show detailed understanding and be able to critically evaluate the subjects taught.

The simplest course structure is the EU Function C for person taking care of animals. It comprises six core modules and one function specific module (Module 3.2).

The addition of the two modules on minimally invasive procedures without anaesthesia (Modules 7 and 8: theory and skills) leads to a course covering requirements for EU Function A (person carrying out procedures on animals) in addition to EU Function C.

The EU Directive and particularly the EC paper (European Commission, 2014) allow tailoring of training that may be required by specific tasks within a function. This is the role of the additional task-specific modules (Table 1). Note that Module 10 (on experimental design) is a function-specific module of EU Function B (i.e. compulsory) but can be included in an EU Function A curriculum (i.e. task specific); this choice could, for example, be specifically delivered to PhD students starting their own research under supervision of the principal investigator.

EU Function B can be seen as a stand-alone course that is entirely theoretical and does not need to provide skill training with the aid of live animals. However, it is easy to conceive, as a way of example, that a course organiser may propose a programme combining both the required elements for EU Functions A (persons carrying out animal experiments) and B (persons responsible for designing experiments). Thus a person aiming for EU Function B could decide to also attend the additional elements required for EU Function A. The benefit of such combined training would be that such a person would better able to appreciate the practicalities of performing procedures and

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adoption of best practices in their design and integration within projects than would a person with only EU Function B education. A course based on such a unified programme would deliver FELASA accredited certificates for EU Functions A or B for persons who have successfully completed the relevant parts of the programme, or certificates for those who have completed both.

If only EU Function B courses are given, it is still possible to cover the requirements of EU Function C by adding Module 3.2 to the EU Function B course.

EU Function D (the carrying out of euthanasia) is recognised as a separate function under the EU Directive. A stand-alone module (6.3) can fulfil the training requirement for those who only carry out euthanasia. In practice however, this function is likely to go alongside others such as caring for animals (EU Function C) or carrying out experiments (EU Function A). Indeed, it is straightforward in this case to add Module 6.2 to those of EU Function A or C to fulfil the training requirements of EU Function D (Table 1).

Accreditation: Modules vs Function

The amended FELASA accreditation scheme is based on the modules set out in the document endorsed by the National Competent Authorities (European Commission, 2014 – see Appendix 3) but for these to be accredited they must be part of a broader accredited programme fulfilling the requirement of specific functions. Thus a FELASA accredited programme will consist of at least a) the “Core Modules”, b) the modules that are prerequisite to that function (see “Function specific Modules (prerequisite)” – Table 1 and Appendix 3), c) for at least one species or a group of species. These constitute the minimum modules that need to be covered before a course can be accepted for FELASA accreditation. Course organisers can also seek accreditation for “Additional Modules” (see Table 1 / Appendix 3) as part of those functions. Indeed we anticipate that many institutions may want to cover some “Task Specific Modules” such as the Anaesthesia for Minor Procedures module for example to meet the needs of many research workers.

Within this function-orientated framework, course organisers will be able to deliver certificates for one or more of the constituent modules in order to facilitate movement of personnel (see Mobility below).

Mobility of students and FELASA accredited course attendance

The FELASA accreditation scheme accredits courses or training programmes, not persons. The rules governing the accreditation of individuals are, of course, the responsibility of relevant competent authorities, not of FELASA. But in order to facilitate access to training as well as mobility, students intending to undertake training for a specific function will be able to attend part of a FELASA accredited course in one institution and complete their training by taking another course in a different institution. Organisers of FELASA accredited courses will be able to deliver a FELASA Certificate for the specific modules completed by the student. As stated above, the modules must be part of a general accredited programme for at least one function.

Entry qualifications

When a course covers several functions, entry qualification criteria must be satisfied, especially if a course includes EU Function A and B because Article 23/2 of EU Directive states specific requirement for EU Function B. As a rule of thumb, entry qualifications should always be those relevant to the highest function (i.e. in the increasing order from EU Function C, to D, A, B and other requirements linked to Art. 24, 25, & 26) that the course aims for.

Certificate content

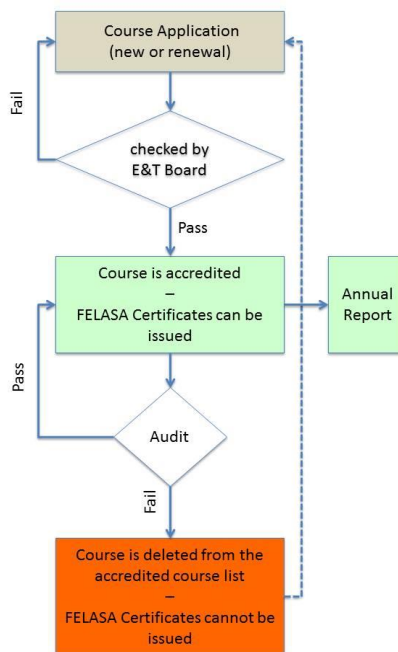
With the previous system of education and training, the certificate had to specify the FELASA category course, the name of the accredited trainer, and incorporate the FELASA logo.

Under the new scheme for education and training, the certificate with the FELASA logo should also identify the FELASA accredited course but also accurately describe the course content. Table 1 shows the high diversity of courses that can be designed. This diversity needs to be made explicit in the certificate design. These listed elements will facilitate acceptance by the competent authorities and ensure mobility of people.

The revised FELASA Accreditation Process

In order to combine flexibility of training and speed of process the FELASA Accreditation scheme will be based on a two-stage approach based on verification of course quality (Figure 2; Appendix 2 for definitions).

Figure 2: The FELASA Education and Training Accreditation Process



1) FELASA Accreditation based on written submission

The FELASA Accreditation scheme is voluntary and course organisers seeking accreditation are required to complete an application form obtainable from the FELASA Secretariat.

This form seeks information about the applicant and the institution where the course is held. It asks confirmation that the course has been run in its present form previously at least once, the frequency with which it is held, the number of students and admission qualifications when appropriate (for example the requisite competence of education in a scientific discipline for EU Function B), whether the use of living animals has been authorised by competent authorities and whether the course is recognised as part of a formal educational programme. Applicants provide information about course structure, syllabus and learning outcomes, arrangements for practical classes, the way in which knowledge and competency are assessed and the results of those assessments retrospectively. Finally, the credentials of teaching staff must be provided along with details of how students are enabled to comment on the quality of the learning experience.

On the basis of this written submission, the FELASA Accreditation Board for Education and Training verifies that the training delivered meets the requirements of the relevant EU function (European Commission, 2014), reviews the mix of teaching methodology, the use made of supporting materials such as course notes and recommended reading and ensures that the objectives of the course conform with relevant national laws, recommendations and guidelines. Consideration is also given to the method of student assessment, the range and depth of evaluation of learning outcomes and the way in which practical skills are assessed. Course organisers must have implemented a mechanism by which students can reflect and report on their learning experience, and must provide examples of course evaluation to provide reassurance that the course is balanced, effective and worthwhile. It is considered impracticable to ask course organisers to provide copies of all examination papers, all student evaluation results and all teaching materials, so the assessment is primarily based on evaluation of the written submission.

On the basis of the information provided being satisfactory, the course will be given accreditation.

2) FELASA Accreditation confirmed by audit

Since the E&T Board implemented a programme of course audits in 2006, it has become apparent that assessment of course quality based only on written evidence may lack robustness and can on some occasions be misleading. In view of this, the E&T Board audits all courses (whilst they are running) and this enables unbiased information about the quality of the student-learning environment to be obtained at first-hand.

The audit comprises a visit by two members of the FELASA Accreditation Board for Education and Training, who request documentary materials before the visit and also submit a list of materials that they wish to examine during the audit. The latter includes copies of examination papers and written student course evaluations as well as notes of meetings held by teachers, records of course attendance, copies of course materials provided to the students, checklists including teaching aids and those used for practical training, and a list of certificates issued. In addition to review of these documents, the auditors also attend theory and/or practical sessions included in the accredited programme (both wherever possible). The auditors also speak to students who have completed training, the supervisors of students who recently completed training, students and teachers of the current course and others responsible for course organisation and delivery.

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At the end of the audit visit, the auditors prepare a report which is submitted to the E&T Board and forms the basis for a decision as to whether the course is deemed satisfactory, should be modified to take account of some concerns, or whether major changes to delivery are necessary.

The E&T Board regards the audit process as the most reliable method of establishing the quality of the student learning experience, and hence it is the basis for confirming FELASA Accreditation.

The E&T Board will maintain an up-to-date list of programmes that have been FELASA accredited and this will be a public document published on the FELASA web page (www.felasa.eu) subject to agreement by course organisers.

Appeal procedure

In the event of an application for accreditation being rejected by the E&T Board, an applicant will have the right to appeal against the decision by addressing a request to the FELASA Executive Committee (EC) within 10 days after receiving written notification of that rejection. If an EC member has a conflict of interest, he or she will be excluded from the discussions and decisions.

Review of application and documentation

Confidentiality

The FELASA Accreditation process is conducted and maintained in strict confidence. No member of the E&T Board shall disclose details of any application to any person who is not a member of the FELASA Accreditation Board for Education and Training. Only the Chairperson of the E&T Board is authorised to contact the applicant during the review process.

External expertise

Should a member of the E&T Board feel that any issue arising from the submission by the Applicant is not within the area of his/her professional competence, the Chairperson may authorise consultation with a corresponding liaison member, who will be provided only with such information as is necessary to resolve the area of uncertainty. The Liaison member will also be obliged to maintain strict confidence.

FELASA Audit

The E&T Board reserves the right to conduct audits, other than those involved in the accreditation process, subject to provision of at least 10 days advance notice.

Requirements for maintaining FELASA Accreditation

Accreditation for programmes of training delivered over a period lasting less than one year will normally be valid for five years. Courses for Function A, B, C and D will certainly fall in this category. For courses lasting over a year, accreditation will normally be valid for ten years. Example may be found for courses for laboratory animal specialists.

Organisers of each programme of training and education that has been accredited by FELASA must submit an annual report, confirming adherence to conditions specified on the application or providing explanations for any deviations; further details and a template for this are available from the FELASA secretariat.

Failure to submit a report without due reason and by the due date will lead to automatic termination of FELASA Accreditation.

Significant unauthorised deviation of content from the programme approved, understaffing for course delivery, inappropriate content or teaching methodology, concerns about animal welfare, occupational health issues, *etc.*, could be sufficient cause for withdrawal of FELASA Accreditation.

It is expected that course organisers will continuously evaluate the content, teaching methodology, *etc.* of the programme and, where appropriate, introduce modifications to improve the quality of the learning experience in light of experience and comments from participants. In many cases new ideas should be evaluated by introduction on a trial basis, assessed by teachers and participants and reported in the next annual report.

If it is proposed to introduce major changes to a FELASA Accredited programme, a detailed proposal should be submitted to the Chair of the E&T Board before these are implemented, so that the E&T Board can give them prior consideration and, if appropriate, approval. This requirement refers to changes of course structure and/or delivery process and is independent of the obligation to submit an annual progress report.

If the E&T Board decides to withdraw FELASA Accreditation previously awarded, this decision will be communicated to those responsible for the programme and to the Institution. Appeal against the decision should be lodged within 10 days to the FELASA Executive Committee.

Renewal

FELASA Accreditation will lapse at the end of each accreditation period. If continued Accreditation is required, Course Organizers must submit, at least six months before the existing accreditation expires, a new application in accordance with the requirements for FELASA Accreditation. During the renewal process the course will be entitled to retain its status of FELASA Accreditation.

If the first or the renewal audit reveals major problems leading potentially to the cancelling of the accreditation, the E&T board will decide whether the application is rejected or, if satisfactory changes have been implemented, accreditation may be restored. A second audit will then confirm accreditation of the course if the changes have addressed the shortcomings (Figure 2).

Fees

The FELASA Accreditation programme is a non-profit making venture, but is required to be financially self-supporting. In addition to this a modest income may be produced to support FELASA education activities or to waive or reduce accreditation fees of courses held in case of hardship. Applications for accreditation will be processed only after an application fee has been received; this application fee (<http://www.felasa.eu/accreditation-boards/accreditation-board-for-education-and-training1/>) is independent of the number of courses given annually and is non-refundable, irrespective of the outcome of the accreditation application. The E&T Board will propose a scale of fees annually to the FELASA Board of Management.

For Courses given in European countries with constituent member association of FELASA, the fees for FELASA Accreditation include the cost of the audit. The cost of renewing accreditation will be the same as for initial accreditation. In case the audit reveals major failures in the course quality and a second audit needs to be done, the costs of the second audit are covered by the course organizer.

For Courses offered in countries that are not represented in FELASA, the fee for accreditation or renewal is identical to that for European courses but does not include the cost of the audit, which will be levied as an additional invoice.

Members of the E&T Board will not receive remuneration, but will be reimbursed for any direct costs incurred by secretarial requirements or travel and subsistence. The E&T Board will prepare an annual budget for approval by the FELASA EC.

Accreditation by FELASA Accreditation Board for Education and Training in the future

The current E&T Board accreditation scheme addresses only the initial stage of the EU education process (Figure 1). Supervision, deeper learning and critical thinking, assessment of competences and CPD may be considered for accreditation at a later stage.

Accreditation in accordance with the process and requirements described above may also be considered for programmes already recognised by other well-established non-European bodies in laboratory animal science, on the basis that the FELASA Accreditation Board for Education and Training considers that such programmes will lead to the development of assured, comparable competences for similar functions.

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Appendix 1: The FELASA “Categories” and Directive “Functions”: an historical reminder

Three out of the four former FELASA categories (Council of Europe, 1986, 1993; FELASA 1995, 1999, 2000 and 2010) correspond roughly to three of the functions defined in the Directive 2010/63/EU (Table 2) although some additional adjustments are clearly needed, *e.g.* learning outcomes instead of syllabus, recommendations for FELASA Category A0 do not match the current Directive proposals for Function C.

Table 2. Comparison of FELASA Categories and the functions identified in Directive 2010/63/EU.

FELASA Category	Task	Directive EU Function
A	Persons taking care of animals	C (may include D)
B	Persons carrying out animal experiments	A (may include C/D)
C	Persons responsible for directing animal experiments	B (may include A/C/D)
D	Specialists in LAS	Refer to Art. 24, 25, 26
NE ¹	Persons killing animals	D

¹NE: Not existing in the FELASA category system

FELASA Category D does not map directly into one of the four Directive functions. However it may be applicable partly to “*persons overseeing the welfare and care of the animals, ensuring adequate information specific to the species housed available to the staff, and ensuring that the staff has the required competences*” (Article 24), to “*designated veterinarians with expertise in laboratory animals medicine*” (Article 25) and to “*persons responsible for the welfare and care of the animals*” (Article 26).

References to Appendix 1

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Appendix 2: Definitions

A course: A training programme consisting of *modules designed to provide the education and training needs of personnel dedicated to a specific function*. It may or may not have been endorsed/accredited by a National or Regional Authority or a Laboratory Animal Science Association.

FELASA Accreditation: The status of a training program that has undergone approval, based on a written application detailing the structure, content of the course and learning outcomes and submitted to and approved by the FELASA E&T Board; this may be announced officially as such on the FELASA website as “FELASA Accredited”.

After fulfilment of the requirements for FELASA Accreditation, an on-site audit of the course is carried out in the first year after accreditation. In case of negative outcome of the audit, FELASA accreditation is withdrawn and the course is deleted from the list of FELASA accredited courses. FELASA certificates cannot be issued anymore.

A quality control system is in place to maintain accreditation. Periodic renewal is required to maintain FELASA Accreditation status. Accreditation is given to a program, a team and specified location/s of a course. An accreditation contract is to be signed between FELASA and the Institution that will issue the training certificates.

FELASA accredited courses provide a FELASA certificate to every participant who fulfilled the requirements to enter and to attend the course and who passed the examination. There is only one kind of FELASA accredited certificate delivered.

Appendix 3: Modules considered as minimum training necessary before persons are allowed to carry out a Function (A to D)

These have been endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes (see EC, 2014, February 19&20, for explanation and details of learning outcomes).

Core Modules - Functions A, B, C & D

1. National Legislation
- 2 Ethics, Animal Welfare and the Three Rs (level 1)
- 3.1 Basic and Appropriate Biology – Species Specific (theory)
- 4 Animal Care, Health and Management – Species Specific (theory)
- 5 Recognition of Pain, Suffering and Distress - Species Specific
- 6.1 Humane Methods of Killing (theory)

Function Specific (Prerequisite) Modules - Function A: carrying out procedures on animals

- 3.2 Basic and Appropriate Biology – Species Specific (practical)
- 7 Minimally Invasive Procedures Without Anaesthesia – Species Specific (theory)
- 8 Minimally Invasive Procedures Without Anaesthesia – Species Specific (skills)

Function Specific (Prerequisite) Modules - Function B: designing procedures and projects

- 7 Minimally Invasive Procedures Without Anaesthesia – Species Specific (theory)
- 9 Ethics, Animal Welfare and the Three Rs (level 2)
- 10 Design of procedures and project (level 1)
- 11 Design of procedures and project (level 2)

Function Specific (Prerequisite) Modules - Function C: Function C: taking care of animals

- 3.2 Basic and Appropriate Biology – Species Specific (practical)

Function Specific (Prerequisite) Modules - Function D: killing animals

- 3.2 Basic and Appropriate Biology – Species Specific (practical)
- 6.2 Humane Methods of Killing (skills)

Alternatively

- 6.3 Stand-alone Module for Function D (only)

Additional Task Specific Modules

- 20 Anaesthesia for Minor Procedures
- 21 Advanced anaesthesia for surgical or prolonged procedures
- 22 Principles of Surgery
- 23 Advanced animal husbandry, care and enrichment practices
- 24 Designated Veterinarian
- 25 Project Evaluator

Other Additional Modules

- 50 Introduction to the local environment (establishment) for persons taking specific roles under the Directive
- 51 Information provision and retrieval

Appendix 4: Institutions of authors

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