European Commission

Caring for animals

aiming for better science

DIRECTIVE 2010/63/EU ON PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

© Novo Nordisk

EDUCATION AND TRAINING FRAMEWORK

Environment

National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes

A working document on the development of a common education and training framework to fulfil the requirements under the Directive

- Replacing consensus document of 18-19 September 2013 -

Brussels, 19-20 February 2014

The Commission established an Expert Working Group (EWG) to develop a common education and training framework for the EU to fulfil the requirements under Articles 23, and 24 of Directive 2010/63/EU on the protection of animals used for scientific purposes. All Members States and main stakeholder organisations were invited to nominate experts to participate in the work. The EWG met on 22 - 23 February and 19-20 September 2012, and 3-4 July 2013.

The objectives of the EWG were to develop a common framework to facilitate meeting the requirements for competence of all those involved in use and care of animals for scientific purposes and free movement of personnel.

This document is the result of the work of the EWG meetings (including those on Project Evaluation/Retrospective Assessment[1] and Inspection and Enforcement[2]), discussions with the Member States as well as legal input from the Commission. It was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU at their meeting of 19-20 February 2014 with the exception of Appendix V[3].

Disclaimer:

The following is intended as guidance to assist the Member States and others affected by Directive 2010/63/EU on the protection of animals used for scientific purposes to arrive at a common understanding of the provisions contained in the Directive and to facilitate its implementation. All comments should be considered within the context of this Directive 2010/63/EU. It provides some suggestions on how the requirements of the Directive may be met. The content of the document does not impose additional obligations beyond those laid out in the Directive.

Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority.

[1] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf
[2] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/inspections/en.pdf
[3] All contents are fully supported, however, national competence issues prevent formal endorsement of Annex V related to training of Inspectors by the National Competent Authorities for Directive 2010/63/EU.

The table of contents:

Legal background - Article 23 of Directive 2010/63/EU[4]

Competence of personnel

1. Member States shall ensure that each breeder, supplier and user has sufficient staff on site.

2. The staff shall be adequately educated and trained before they perform any of the following functions:

(a) carrying out procedures on animals;

(b) designing procedures and projects;

(c) taking care of animals; or

(d) killing animals.

Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.

Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.

3. Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.

4. Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2).

The education and training framework objectives and structure

EU guidance is developed to respond to a need for harmonisation and a common framework to ensure competence and to facilitate free movement of personnel. It is important to note that the outcome is on the basis of general agreement and not binding. It is left to each Member State to interpret whether and how this general guidance is to be implemented.

However, any agreement at EU level on general principles will also assist those developing training courses to work towards common, acceptable standards. This in return should result

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0063:EN:NOT

in a wider offering of available training courses to promote the aims of availability, accessibility and affordability.

The framework includes consideration of the training, supervision, competence assessment and continuing training requirements of persons carrying out procedures, taking care of animals, killing animals and of those responsible for the design of procedures and projects.

The common education and training framework facilitates and **assures the competence of all persons involved** in the use, care and breeding of animals for scientific procedures, and assists the **free movement of personnel.**

The training framework should meet the following objectives and be

- flexible;
- available and accessible;
- affordable and
- of agreed quality.

The Educational Process under Directive 2010/63/EU

There are many different ways by which training, supervision and competence can be delivered. The objective was to develop a framework within the EU which would assure the competence of staff caring for or using animals in procedures, and facilitate the free movement of personnel within EU. The proposed framework is based on a Modular Training structure with a focus on Learning Outcomes.

Training alone does not deliver competence.

The Learning Outcome approach with appropriate assessment provides confidence that the trainee has achieved a suitable level of understanding to meet the learning criteria.

A period of supervision will generally be necessary, to re-enforce understanding and to ensure the tasks/duties/procedures are conducted to an appropriate standard, with interventions as necessary by the supervisor(s) to ensure this is attained.

Only after individuals have been assessed as competent, should they work without supervision. By this time, those deemed competent should have attained a deeper understanding of the task.

Competence should be subject to review.

The time taken to achieve individual Learning Outcomes and to complete Modular Training will vary considerably, depending on the individual, the method of teaching and assessment.

Duration of the supervision period and time taken until competence is attained will also vary, for example due to the frequency/availability of the task being performed, technical complexity, and ability of the individual.

It is therefore not desirable to specify any time limits for teaching or supervision periods.

The objective of the initial training is the attainment of basic knowledge and/or understanding with the concept that a deeper understanding of the knowledge base as well as proficiency in skills should have developed and be expected by the time competence is assessed.

This approach should reflect what happens in practice – after completion of an initial training Module the expectation is that the student will have a basic understanding of the issues, but during the period of supervision this understanding will continue to improve, such that by the time competence is achieved a much deeper understanding of the task being undertaken can be expected. These differences will be reflected in the different standards of assessment for training completion and attainment of competence.

Training should be a considered as a continuous process, through the initial Modular Training, to a period of working under supervision until such time as competence is attained. Individuals shall maintain competence through a process of continuing education (Continuing Professional Development – CPD).

Understanding Article 23(2) requirements

Article 23(2) of Directive 2010/63/EU states that *"The staff shall be adequately educated and trained before they perform any of the following functions…"*

When performing one of the functions and **there is a likelihood of causing** pain, suffering, distress or lasting harm, **the relevant training modules should be completed prior to** working under supervision.

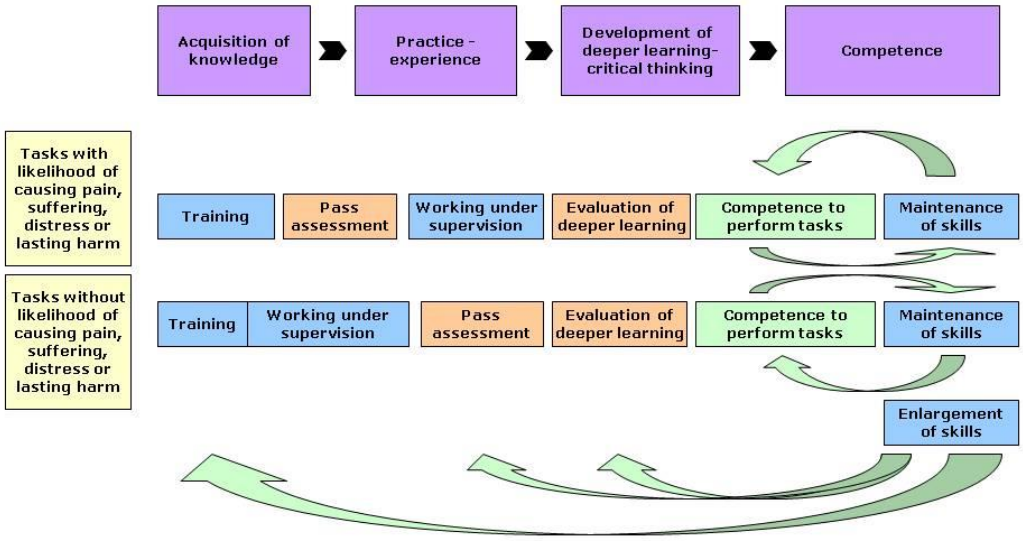
If this is not the case, the trainee could begin working under supervision before the relevant modules are satisfactorily completed.

The responsibility for the correct performance of the task remains with the supervisor in all cases until such time the training is completed and the requisite competence demonstrated.

The process

On the basis of the above, the suggested process is laid out below:

EDUCATIONAL LEARNING PROCESS
UNDER DIRECTIVE 2010/63/EU



To achieve the desired outcomes of appropriate training standards and free movement of personnel, sufficiently detailed Learning Outcomes for the Modular Training are required, together with an agreed understanding of assessment criteria. Training should be subject to quality assurance oversight.

A European platform at which information on education and training can be exchanged is proposed.

Academic qualifications for functions (a), (b), (c) and (d)

With the focus on competence, on the basis of training modules which fulfil the agreed quality criteria and are assessed in a consistent manner, passing successfully the required modules infers a level of schooling and maturity sufficient for these functions.

Functions (a), (c) and (d) should not require any specific educational qualifications.

Individuals responsible for designing procedures and projects under function (b) should normally hold an academic degree or equivalent in an appropriate scientific discipline. This will be important to ensure such individuals are able to apply the Three Rs effectively in the design of the procedures and projects and make appropriate ethical and scientific judgments.

There may be some individuals who are recognised as qualified to perform any of the tasks identified in Article 23 of Directive 2010/63/EU prior to its entry into force for whom recognition should be continued.

It should be noted that Article 40(2)(b) describes no educational requirements for the persons responsible for the overall implementation of the project. However, it is important for both science and welfare reasons, and to ensure compliance, that the persons understand the role and have sufficient knowledge on the care and use of animals to effectively fulfil the role.

PART A

Modular Training and Learning Outcomes

The Modular Training structure and Learning Outcomes approach is flexible. The learning outcomes deal with output rather than processes and help to define the skills and knowledge that module participants should be able to demonstrate by the time these learning outcomes are assessed. Learning outcomes are the specific intentions of a training programme or module, written in specific terms. They describe what a student should know, understand, or be able to do at the end of that module.

These *do not* represent a course syllabus or a list of topics to be covered. Training providers are free to build course content, training materials and delivery methods which will deliver all of the learning outcomes for each selected module in a manner which meets their national/local/institutional and/or individual/group requirements.

It needs to be acknowledged that the achievement of practical Learning Outcomes may be separate from theoretical/knowledge based learning outcomes. The assessment of Learning Outcomes on *practical skills* should ensure that with the acquired skill level the trainee can proceed to working under supervision with no increased risk to animal welfare. The proficiency in skills will be developed during working under supervision. However, the period and level of supervision will vary due to *inter alia* the complexity of the task, its frequency and previous experience of the trainee.

In cases where there is no risk of causing pain, distress, suffering or lasting harm to the animals, the trainee can proceed to work under supervision before achieving the Learning Outcomes.

However, in all other cases, Learning Outcomes need to be attained in line with the agreed pass criteria before proceeding to work under supervision. The Learning Outcome approach should allow the achievement of an acceptable level of understanding of the subject to ensure that no unnecessary pain, suffering, distress or lasting harm is inflicted when working under supervision.

Quality criteria for a training module

- Sufficiently detailed learning outcomes;
    - Theoretical knowledge to be gained;
    - Practical skills to be obtained;
- Defined assessment;
- Pass-fail criteria.

Terminology used

The training should be based on a modular structure. The modules fall into different categories

- compulsory to all functions as stated in Article 23(2) (including National Legislation Module);
- required only for (a) specific function(s);
- additional modules for facilitating learning specialised skills as well as lifelong learning, (e.g. Surgery Module).

Function = one of the four functions provided in Article 23(2)[5]

Task = tasks identified e.g. in Articles 24 (responsible for care and welfare etc.), 25 (designated veterinarian) and 38 (project evaluation)

Core module = a compulsory module for all functions and with the same Learning Outcomes

Function specific (prerequisite) module = a compulsory module for (a) specific function(s)

Task specific module = a recommended module to enable staff to carry out (a) specific task(s)

National module = includes national/regional transposing legislation and any other legislation relevant to the use of animals for scientific purposes (e.g. transport, CITES, waste, GM)

Course = a programme, containing one or more Modules, designed to meet the training needs of individuals identified in the Directive

Specialisation for species

Some of the training modules will be species (group of species) specific.

The initial training module needs to be **completed fully** for a specific species or a group of species.

Skills expansion to further species will require **demonstration of attainment of Learning Outcomes** for the new species within the same module.

[5] (a) carrying out procedures on animals; (b) designing procedures and projects; (c) taking care of animals; or (d) killing animals.

However, it may not always be necessary to repeat all the elements of the initial training module for the new species as there may be common elements of content between the species which do not require to be repeated.

Exemptions to Modular Training for functions (a), (b), (c) and (d)

Exemptions from modular training may be permissible, and will be dependent on the information provided on previous training and expertise. The principles on which such exemptions are given should be transparent and available to all.

Approval of training exemptions could either be made by the Competent Authority (CA) or, where clearly defined criteria have been made available to the establishment by the CA, this may be approved at the local establishment level (by person responsible for training (Article 24(1)(c)), with any such exemptions recorded and available for inspection by the CA).

As a matter of good practice, irrespective of the training history, any new arrival at an establishment should have training and competence reviewed before the individual is permitted to work unsupervised.

Some form of mutual recognition at least within EU of approved training courses is needed to facilitate movement of personnel.

Principles for Exemption

"Grandfathering in" should be accepted for training in Functions a-d – that is, if individuals are already trained and experienced in their areas of work, there is no requirement for additional training (except where the individual wishes to develop in new areas e.g. new species), although there remains the requirement to maintain competence and undertake appropriate CPD.

For individuals who have not been working with or caring for animals in scientific procedures for a significant period of time (in any event if exceeding 5 years), these individuals, should be required to satisfactorily complete appropriate training before re-commencing to work.

There should be no exemption to the requirement for training in Member State legislation – completion of the legislation module training is generally expected.

However, rarely, in circumstances where specialist input on a particular procedure is required, and where the individual will have n*o formal responsibility for the welfare and care of the animals, and is performing under supervision of experienced care staff, an introduction to the legislation, in particular the role and responsibilities of the individual, may be considered appropriate.*

Applications for exemption should contain all relevant training and previous experience, such that these may be mapped/matched to Member State training requirements.

Member State should identify and publicise information on any standard exemption criteria.

Training Modules with the respective Learning Outcomes

Appendix I contains the developed Training Modules covering all Core and Function Specific (prerequisite) Modules. In addition, a number of Task Specific and other Additional Modules were developed to support the development of appropriate training courses.

Assessment of Learning Outcomes

As there are many different ways that LOs may be assessed, it is impractical to develop fixed pass/fail and assessment criteria for each Module. Therefore, **assessment criteria should be developed by the course provider for each LO within a module covered by the proposed course.**

While different means, such as multiple choice (MC), written/oral examination, online exams or examination of practical skills can be used to assess and individuals learning performance, some considerations should be taken into account when preparing the assessment criteria:

Assessment/pass-fail criteria

It should

- Be objective and transparent;
- Be comprehensible and clear without ambiguity;
- Have clear pass-fail criteria;
- Provide reliable results;
- Ensure students have achieved an acceptable level of understanding of the subject – suitable to proceed to working under supervision, such that no unnecessary pain, suffering, distress or lasting harm is inflicted;
- Identify, where appropriate, critical elements that cannot be failed.

Assessment should have appropriate oversight / invigilation. Course attendance requirement should be set in accordance with Learning Outcomes; some parts may require full attendance.

Methods of assessment should be economically viable and available

Consideration needs to be given on whether or not there should be a maximum number of attempts which can be made to achieve the appropriate standards.

Illustrative examples of assessment of Learning Outcomes are included in Appendix II.

Mechanisms for Supervision and Assessment of Competence

Satisfactory completion of a Training Course and attainment of Learning Outcomes are important steps, but these must be followed by a period of appropriate supervision (unless competence is satisfactorily attained **and assessed** during the training course), until the requisite competence has been attained, and before the initial educational process can be considered to have been completed.

Good supervision can re-enforce and enhance learning outcomes, but equally inappropriate supervision can have negative consequences, occasionally promulgating out-of–date or simply poor practices.

Qualities required of a good supervisor

The selection of the right individuals as supervisors is crucial. Practical training and supervision should be carried out by a person whose qualities include:

- has appropriate and up to date knowledge and is skilled and competent in the procedures,
- has sufficient seniority to command respect and be authoritative with regard to their knowledge and experience
- is able to impart skills and knowledge to others (requisite teaching skills)
- understands the reasons why training and supervision are important
- has good interpersonal skills
- is committed to implementing the spirit of the legislation as well as the letter of the law

For complex procedures more than one supervisor may be required, for example where both surgical and anaesthetic skills are needed.

The supervision process

Each User, Breeder and Supplier should ensure that there is a robust framework within which training and supervision can take place, with clear standards that define competence in knowledge-based and practical skills.

Achieving consistency in all of these processes is essential.

Each trainee should have:

- a formal training plan outlining their personal objectives and the practical and knowledge-based skills s/he requires;
- a clear idea of the criteria for competence in each skill;
- records of training and competence;
- regular reviews of training, competence and their personal development plan.

A trainee's development should be clearly documented by progression in training records. Equally, the level of supervision should be traceable in the training records.

The level of supervision can be divided in five stages:

4 – Supervisor present when the procedure takes place providing direct supervision and advice
3 – Supervisor aware when procedures are taking place and available for rapid intervention if required (i.e. in the vicinity of the procedure)
2 – Supervisor aware when procedures are taking place and available to attend to provide advice if required (i.e. in the vicinity of the establishment)
1 – Supervisor aware when procedures are taking place and available for discussion to provide advice if necessary (e.g. by telephone)
0 – No supervision required

The UK Laboratory Animal Science Association has produced guiding principles on the supervision requirements for persons carrying out procedures (personal licence holders) which can be found at:
http://www.lasa.co.uk/LASA_GP_Supervision_&_Competence_2013_final.pdf

Assessment of competence

Ideally, the person who assesses competence should not be the same person as that who trained but this may be difficult for highly specialized skills and in small establishments.

Trainees should understand what standards/pass/fail criteria will be applied to their assessment.

The assessment of competence should preferably take place at the trainee's normal working environment. **The assessor should observe and evaluate the trainee performing the procedures to assess practical competence.**

It is also important for all establishments to have a mechanism in place to ensure that incompetence / poor practice in any member of staff is recognised and reported to allow appropriate remedial action to be taken.

Illustrative examples of assessment of competence are included in Appendix III.

Review/maintenance of competence

This should be considered as an on-going process and there should be some oversight within the facility to ensure that acceptable standards are maintained.

Where procedures are performed intermittently/rarely and/or individuals have not performed procedures for some time, consideration should be given to provision of additional supervision. Similarly, problems being encountered or the introduction of a new or amended procedure should trigger a review of competence.

Continuing Professional Development (CPD)

Meeting requirements of Articles 23 and 2 with regard to continuous training and maintenance of competence

Article 23(3) requires that staff shall maintain competence through a process of continuing education (Continuing Professional Development - CPD). This process shall be overseen by the person responsible for training, identified in Article 24(1)(c). This requirement is intended to ensure that all those involved in the use and care of animals remain competent and up-to-date on new developments in the field.

FELASA[6] has proposed guidelines for continuing education for all persons involved in the care and use of animals for scientific purposes experiments. The system is based on the award of credits, of which 50% must be achieved by attendance at endorsed activities which have been subject to scrutiny by a professional body. The other 50% can be achieved from activities which are recognised by the employer. Further details are given on the web site:

> http://www.felasa.eu/recommendations/guidelines/guidelines-for-continuing-education-for-persons-involved-in-animal-experime/).

It is important that whatever process is established the training is mutually recognized and that the records are transferable. It is also essential that at least some of the CPD is directly relevant to the field of (Laboratory) Animal Science.

Recording of Training and Supervision

Training records should reflect the level of training and level of competence to allow skills transfer across the EU. Currently there is a high variability in types of records being kept and in the control of record keeping from centralised facility to individual. The culture and/or compliance history of the establishment influences record keeping. GLP establishments usually have good records of training which may require little / no change. Accurate records are an essential part of all training schemes and should incorporate professional education and relevant competencies acquired prior to present employment.

Records should be detailed down to the procedure level and be species specific. They should identify the level of supervision required, attainment of initial competence as well as the level of competence to allow the person to supervise and train others.

A common approach in the way training and attained competences are recorded will facilitate movement of personnel. An example of a common Record Template is included in Appendix IV.

[6] The Federation of European Laboratory Animal Science Associations

PART B

Approval / Accreditation of Courses

There needs to be a system of Approval / Accreditation for Training Courses to assure confidence in the quality of training and assessments being provided. Training courses may cover one or more Modules.

Glossary of terms

Quality assurance

The maintenance of a desired level of quality in a service or product – should be undertaken by Module Providers and, where applicable, will form part of an accreditation process.

Accreditation

Process in which certification of competency, authority, or credibility is presented.

Mutual recognition

Agreement between two organisations (e.g. Member State Competent Authorities) to recognise each other's processes or programmes. Mutual recognition may between higher education institutions, quality or accrediting agencies or professional bodies.

Benefits of having an approval/accreditation system for Training Courses

1. Facilitates free movement of personnel;
2. Enhances Animal Welfare;
3. Improves quality of science using live animals.

How should a Training Course be approved / accredited?

Accreditation is a continuing two-way process which is reliant on good communication between all parties. The accreditation process should include

- Written submissions
- Discussions between course providers and assessors
- Visit to course
- Course accreditation/approval should be reviewed at least 5 yearly and if any significant changes to delivery, content or assessment are proposed
- Ensure training is delivered to the agreed standard.

Information requirements for the Course Approval / Accreditation

Any approval/accreditation process should specify clearly to course providers what information on course content, delivery and assessment should be provided. There should be appropriate expertise available to assess the submitted information. The information should cover *inter alia*

- Applicant and institution
- Information on trainers and their qualifications/experience
- Full content of the syllabus for the Module(s) and the associated Learning Outcomes
- Course materials and the way it will be taught which will include course hand-outs, pre course reading, teaching aids, practical/theoretical.
- If practical elements included – how are these taught and assessed.
- Information on use (and justification for use) of live animals
- Description of facilities where the course is taking place
- Timetable and information about the type of teaching in each session
- Communication with students
- If distance learning, what methods will be used and how to ensure independent assessments
- Ratio of trainees to lecturers in both theory and practical elements (1 to 4 suggested as maximum for practical training)
- Desirable that the trainer is not the assessor (or ensure clear distinction between training and assessment)
- How the course is going to be evaluated - Assessment; Feedback
- Assessment of Satisfactory Completion - methods, pass/fail criteria, critical elements not to be failed
- Certification (two languages, mother tongue and English (annex) would be preferred to promote free movement – certificate should have basic content included for information
- Module provider should maintain records of participants, pass/fail and feedback.
- Submission is always best to have too much information rather than too little, but this can be managed by Information Request Form from approver/accreditor
- Attendance requirements to be included as applicable (this allows the attitude of student to be better assessed e.g. ethics discussion).
- Minimum of two courses to be held prior to approval/accreditation. (**N.B.** Provisions should be in place for course attendees when a course fails to meet the standards.)
- Information to the accrediting body on attendance and pass/fail and frequency of the course - not published but held by the accrediting bodies. Feedback should be made available to Competent Authorities on request.

Principles for an Approval / Accreditation Process

1. Independence from the training provider/organization;
2. Should be proportionate and affordable;
3. Sustainable and consistent standards;
4. Builds confidence with trainees, trainers and Member States;
5. Competent assessors.

Responsibilities of those approving / accrediting courses

The main responsibilities of approving / accrediting bodies are to:

- **offer advice and information** to prospective course providers;
- **approve/ accredit courses** which respond to the agreed quality criteria;
- **ensure consistency of content and outcomes** across modules;
- **ensure compliance** with declared objectives and procedures in relation to the delivery of training and **assessment the set Learning Outcomes**;
- **apply and review the mechanisms** for monitoring the successful outcome of training and assessment.

Framework for mutual acceptance

Principles for a mutual Approval / Accreditation framework are required as the **basis for mutual acceptance** of training carried elsewhere.

There are many different approaches employed currently within EU to "approve" training courses – these are not always managed by Member State authorities, nor is there any common system to obtain "approval" by a Member State.

To meet obligations under Article 23, Member States are obliged to ensure that staff are appropriately trained – there is therefore a need for Member States to indicate satisfaction over training provision – whether delivered locally, regionally, nationally or internationally.

Confidence in training standards and outcomes is required, but trust and improved communications will need to be established to deliver mutual recognition between Member States.

A forum for exchanging information and a central repository of course availability/content are desirable, and mechanisms/resources available to ensure information remains current.

All courses should have some form of independent oversight/approval, and this should apply also to local in-house training courses.

The system to promote mutual recognition and quality of training at an EU level should be cost effective with minimal administrative burden. As there is no specific funding available for this purpose, the potential benefits would need to be sufficiently attractive to secure funds from Member States and user community. The European Commission cannot co-ordinate this task as it falls outside its direct area of competence, however, it **can facilitate** with e.g. organisation of Expert Working Groups on specific subjects in relation to the implementation of the requirements of the Directive and provide E&T related information on its web-site.

Proposal for an EU Platform and Information Portal on Education & Training

An EU Platform should be established for a modular training framework to enable information sharing and communication between:

- Approval / Accrediting Bodies
- Course Providers
- Member State authorities

This EU Platform would conduct business electronically, and meet by audio / video conferencing 2-3 times/year. It should be made up from balanced representation of Member States, Approval / Accrediting Bodies, Course Providers. The purpose of this EU Platform would be to:

1. Establish criteria for Approval / Accrediting Bodies;
2. Recognise and maintain a list of Approval /Accrediting Bodies and courses;
3. Maintain criteria for modules and evolve these as required;
4. Share information on standards for supervision and assessment;
5. Share information on standards and templates for recording training and assessment;
6. Provide contact details for liaison.

The above is not an exhaustive list and agreement would need to be reached as to the specific purpose(s) and functions of the EU Platform.

There should be no conflict of interest or direct control by any member of the EU Platform and its purpose would be simply to serve as a means of sharing of information and best practice, and to develop an understanding of the training and education in each Member State, thus building confidence and promoting mutual recognition of training delivery.

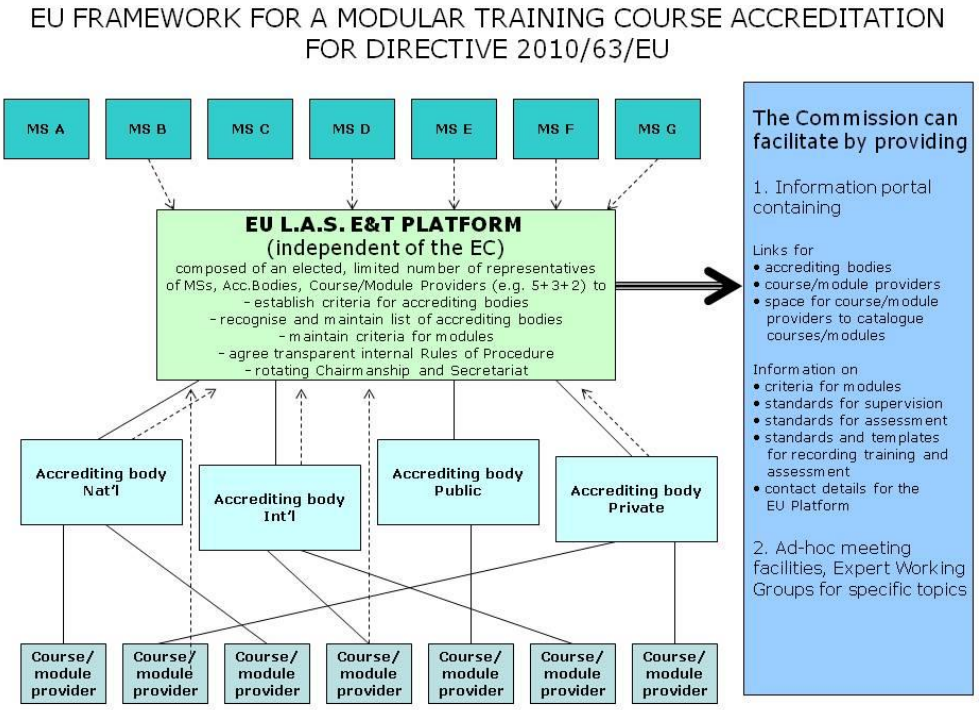
The above will require drivers to move this forward and prepare terms of reference for the information portal.

This EU Platform is not intended to add bureaucracy or to exercise any means of control over the approval / accrediting processes and mechanisms, or to provide any unfair advantage to any individual or organization that participates. It is simply there to facilitate and inform.

The aims are

- To develop and build on mutual trust and confidence in each Member States training mechanisms across the EU;
- To deliver the objective of free movement of personnel;
- To share training resources;
- To review modules where required and agree new modules and
- To provide a point of contact for course information for trainees, and course providers.

This will be an evolving process.



PART C

Roles, tasks and training for functions in Articles 24 and 25

Additional guidance has been prepared to assist those performing functions under Articles 24 and 25 to better understand the roles and also to provide suggestions for training for those persons fulfilling these functions.

In addition, a desirable profile is suggested for each of the functions to further illustrate the needs of the role. However, it is acknowledged that priorities will differ dependent on the needs of the individual establishment. Similarly, the person's educational background, previously completed training and work experience may justify exemptions or part exemptions from the recommended training. For example, the person responsible for the care and welfare of animals could be exempted from module 23 in circumstances where information is provided of suitable prior training or qualifications for example in aquatics or agricultural animals.

Person(s) responsible for overseeing the welfare and care of animals in Article 24(1)(a)

This role will often be fulfilled by an experienced care person/senior animal technologist, although the designated veterinarian may occasionally assume this role. There could be one or more persons, named, each with clearly defined areas of responsibilities.

The individual should be able to provide independent advice on welfare and care of all animals within the establishment to minimise suffering and optimise welfare of animals being bred, kept for use or used in the establishment.

The individual is expected to be actively involved on a daily basis in safeguarding the welfare of animals within the establishment, should have managerial authority enabling them to establish and maintain high standards of husbandry and care, meeting the standards set out in Annex III of the Directive and to champion a culture of care amongst both husbandry and scientific staff. Institutional support and structure is required, especially when advice of the person responsible for care is challenged.

The individual should be pro-active, working as appropriate with the designated veterinarian, to promote implementation of refinements in animal husbandry, care and use, and contribute actively to the work of the Animal Welfare Body.

The role can play an important part in improving the quality of the scientific outcomes.

A simple acronym describing the role was suggested – ICARE - **I**nstitutional **C**are and **A**nimal welfare **RE**sponsible (person).

Summary of main tasks

- Establish an overarching system for continuous care of the animal;
    - Ensure animals are checked daily;

    - Establish an information-decision chain and make it known to all relevant personnel;
    - Ensure there is available expertise to recognise any variation from the normal health and behaviour of the animals;
- Input to the Animal Welfare Body (AWB) including advice on refinement of procedures and other aspects that impact on the lifetime experience of the animals;
- Develop a good understanding and working partnership, with the Designated Veterinarian (DV);
- Develop and maintain high standards of husbandry and care appropriate to the species used;
    - Ensure the welfare and husbandry requirements of the species housed at the establishment are met;
    - Ensure the caging or housing needs for different group sizes, optimum environmental conditions including enrichment opportunities and nutritional requirements are met;
    - Ensure the physiological and biological needs of the species are fulfilled;
- Champion the principles of culture of care among staff of all levels.

Suggested profile

- Should have "personal authority" deriving from their background, experience, knowledge and confidence;
    - Ability to discuss “at the same level” with the scientist to ensure animal welfare issues are understood and addressed;
- Communication and diplomacy skills;
    - Understand the importance of effective communication and ability to impart information in the appropriate format and level;
    - Ability to work collectively and collaboratively, with the DV, AWB, and scientists: e.g. to introduce and implement an improved enrichment program;
    - Effective written and oral communication skills;
- Good judgement – being able to balance scientific and welfare needs;
- Independence from scientific research projects as far as possible.

Initial training

All persons responsible for overseeing the welfare and care of animals should have received appropriate training. Where a combination of the developed training modules is used,

Module 9 should be included as this module requires a deeper appreciation of the Three Rs and good scientific practice.

Training and experience should therefore include:

- All Core Modules;
- Function specific Modules for function A (3.2, 7 and 8) and Modules 9 and 23;
- Module 50 - "Introduction to the local environment (establishment)";
- Development of sufficient understanding of scientific procedures to enable informed interactions with scientists;
- Development and maintenance of appropriate record keeping systems.

Continued Professional Development (CPD)

- Maintaining knowledge of standards of housing and care of species for which they have responsibilities;
- Further develop skill set on roles and responsibilities;
    - understand the specificities of their role, how to handle their responsibilities and manage interactions/communications with animal care staff and scientists;
- Keep up to date with developments in Three Rs, communication and management.

Person(s) responsible for ensuring information is available on the species housed in the establishment in Article 24(1)(b)

The person(s) responsible for this role would have to ensure that a range of relevant information is made available, to those who need it, and that the information is kept up-to-date as far as possible.

This would include all manner of information on the species housed and used relating to a varied range of subjects such as:

- information relating to the species used in the establishment;
- animal care and husbandry;
- animal welfare and the Three Rs;
- EU and national legislation, guidance and local rules/information;
- external information and publications which deliver relevant guiding principles for good practice in a particular aspect or area of work (FELASA guiding principles documents for example);
- information regarding new initiatives, technical and practical advancements and good practice in a relevant field of research and in relation to the species concerned.

In large establishments it will be difficult for any one person to be aware of all the issues in all areas of science. Ensuring that the most relevant information is available to all will require an appropriate network within the establishment to ensure that all relevant information is

collected and disseminated appropriately. The individual(s) responsible may concentrate on specific areas e.g. animal husbandry and care; particular animal models, or one individual may act as a central co-ordinator within the establishment.

It has been suggested that the Animal Welfare Body may contribute to the task, to assist in the identification of relevant information and co-ordinate dissemination to the correct individuals.

It is essential that the relevant individuals are appropriately trained in information search and retrieval, and have access to the relevant information sources.

This function is sometimes linked to that of the person responsible for overseeing welfare, but the person does not need to be expert in all areas of science – rather have good networking ability.

Summary of main tasks

- maintaining contacts for information sharing (e.g. with the National Competent Authority, various specialist interest groups including, specialist research groups, professional bodies, FELASA and national LAS associations, Three Rs and animal welfare organisations);
- searching for and disseminating current information (new Three Rs initiatives in a particular scientific field for example);
- maintaining local contact details based on function, type of role (Article 23(2)(a-d)), research interests etc. in order to circulate information effectively i.e. directed to those individuals who would benefit (avoiding a copy-to-all approach which would carry the risk of information being ignored);
- distributing information pro-actively, as appropriate, to individuals and groups of staff/students;
- assisting, as appropriate or as requested, persons in charge of projects in securing the necessary information relevant to their project;
- be able to provide guidance on where and how to search for relevant information.

This role should not work in isolation but in co-operation with other roles and in particular complementary to the work of the AWB to achieve the aims established in Article 27(1)(b). A system should be established within which facilitates all staff having access to the relevant information e.g. "3Rs information Centre" to perform their tasks, whether care staff or scientists.

Suggested profile

- Good communication skills;
- Trained in accessing/finding and distributing relevant information to relevant users/recipients;
- Ability to select and target information relevant to the individual persons needing it (avoiding "information overload").

Initial training

Training should include searches for information and strategies for dissemination:

- LO 2.13: Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs;
- LO 51.1: Be aware of different search tools (e.g. Go3Rs, EURL ECVAM Search Guide) and methods of search (e.g. Systematic reviews, meta-analysis);
- LO 51.2: Explain the importance of dissemination of study results irrespective of the outcome and describe the key issues to be reported when using live animals in research e.g. ARRIVE guidelines;
- Module 50 - "Introduction to the local environment (establishment)".

Continued Professional Development (CPD)

- Communication;
- Information resources.

Person(s) responsible for education, competence and CPD of staff in Article 24(1)(c)

This role may be a stand-alone defined position within a large establishment, but often the role will be undertaken by different persons, and, can also be undertaken in combination with other roles. Where more than one person is tasked with this role it is important that they all work to the same principles and standards, and oversight of this role should therefore be maintained at establishment level, rather than at the level of an individual research group or department.

The person will generally be involved in the coordination of training and ensuring that supervision, competence assessment and continued professional development are undertaken and recorded, rather than being directly involved in delivery or assessment of training or competence. They could not, in most cases, be directly responsible for the day-to-day training of each individual so certain practical responsibilities would have to be delegated to experienced practitioners who, themselves, should be able to train and/or to supervise the necessary techniques.

The person responsible for training and competence should have sufficient authority in order to influence others and to be able to make decisions on training issues.

Summary of main tasks

The person responsible for training and competence should oversee the following tasks:

- setting and monitoring the required standards for the institution for training, supervision, competence and CPD for each of the functions in Article 23(2)(a–d);

- communicating requirements/expectations (for example identified training needs to all staff concerned and ensuring that staff are aware of their individual responsibilities to train/supervise and/or to be trained and supervised, until competent, as appropriate to their expertise and their function;
- communicating to trainers;
- identifying appropriate training (modules, species and specific techniques) of recognised quality;
- identifying and disseminating opportunities/ activities for education, training and CPD;
- identifying possible trainers for specialist procedures/techniques;
- developing local requirements for training records to be used throughout the establishment; ensuring that mechanisms are in place to identify new training needs;
- establishing mechanisms to identify any refresher training requirements as they arise (which may be triggered in a number of ways, for example procedure not been used for a prolonged period, poor surgical results);
- checking and verifying training records when individuals transfer from other establishments and identifying any new training which might be required;
- receipt and checking of training records/certificates;
- consideration of requests for exemptions from training and, as appropriate, in agreement with CA determined criteria;
- ensuring that all records are complete, accurate and up-to-date;
- working with colleagues locally and further afield to develop a consistent local/ national/EU approach to training/supervision/competence and to the content and detail needed for individual training records (to ensure that these are meaningful across and beyond the institution) to facilitate the transfer of staff;
- ensuring that competence is maintained.

Involvement in training/supervision/assessment

This will depend on the nature of the person's role within the establishment and may vary. If this role is solely a management/administrative role then direct involvement in training/supervision/assessment will be less likely. However, where the tasks associated with the role are delegated (i.e. where the personnel involved have other active duties as project designer/manager, member of the animal care staff or designated veterinarian) then direct contribution to training/supervision/assessment is likely. In each case this will be subject to the background, expertise and competence of the individual/s concerned and their day-to-day work. Whilst the person responsible for training and competence may or may not be directly involved in the provision of training they should oversee the process of training, supervision, competence and CPD within the establishment which would include making sure that training is taking place, that standards are acceptable and that a consistent approach is being adopted and delivered by and for all staff.

Suggested profile

Personal skills

- Good communication skills;
- Good management and organization skills (data management);
- Good judgmental abilities.

Knowledge based skills (all considered essential)

- Extensive understanding of the regulatory system and legislation;
- Knowledge of Ethics and the Three Rs;
- Basic understanding of the research process;
- Detailed knowledge of institutional policies and research programs;
- Thorough knowledge and understanding of relevant educational and training requirements (both national and international/EU);
- Knowledge of available training;
- Understanding of management of confidential data, including legal obligations.

Initial training

Training will vary significantly depending on whether person is actively involved in delivery of training, supervision or competence assessment.

For those involved in the coordination, confirmation and recording of training an understanding of the legislative requirements is necessary.

As a minimum

- Module 1 - "National legislation";
- Module 2 - "Ethics, animal welfare and the Three Rs" (level 1);
- Module 50 - "Introduction to the local environment (establishment)".

Continued Professional Development (CPD)

- Remain current on laboratory animal training and new methodologies;
- Knowledge of the EU platform for Education, Training and competences;
- Basic understanding of teaching principles.

Person(s) carrying out project evaluation in Article 38

Those involved in project evaluation should have access to training in the process, in particular on how the objectives of the project, the application of the Three Rs and the assessment of severity classification should be evaluated, and on how the harm-benefit analysis should be undertaken.

Although there are different structures in place for meeting the requirements of Article 38, training for all those involved would be beneficial to promote transparency and consistency in the evaluation process. The training should address the context, the principles and the criteria of a project evaluation to allow the evaluators to formulate impartial and justified opinions. Project evaluation also requires careful consideration of the effectiveness of the application of the Three Rs within the project.

It is important that those carrying out the PE have a good understanding of the expected harms to the animals and the proposed benefits of the research, as the harm-benefit assessment is a central element of the authorisation process. In terms of assessing harms, it follows that an ability to perform a well-informed and consistent assessment of severity is an essential element of the process. Training should include information on the various systems available to assist the process, and how these can be applied in practice.

Considerations on the requirements for retrospective assessment of projects and how amendments to project applications are dealt with should also be part of this training.

Initial training

- Module 1 – "National legislation";
- Modules 2 and 9 - "Ethics, animal welfare and the Three Rs" (levels 1 and 2);
- Module 25 - "Project Evaluators".

Designated Veterinarian in Article 25

Under the Directive, each breeder supplier, and user establishments should have a Designated Veterinarian (DV) with expertise in Laboratory Animal Medicine, charged with advisory duties in relation to the well-being and treatment of animals. The role of the DV extends beyond advice on disease or health issues, and is an integral part of the development of continued improvement of scientific practices, in particular with respect to refinements in model design, clinical monitoring, and a culture of care.

In case a “suitably qualified expert where more appropriate” (than a veterinarian) is to be charged with “advisory duties in relation to the well-being and treatment of the animals”, this person will already have the necessary technical and zoological expertise relevant to the species concerned. They should be able to demonstrate a holistic approach to ensuring health, husbandry, treatment and welfare of the animals under their care. In addition they should undertake such training as necessary to be able to deliver the role effectively. This is likely at the very least to include training in legislation, ethics and the Three Rs.

Summary of main tasks

Establish a programme of veterinary care and collaboration with the AWB to deliver

- Provision of advice and veterinary services regarding choice of species and strains (including GA animals), transport, import and export of animals;

- Provision of advice regarding animal acquisition, husbandry, housing and care;
- Surveillance of the health status, prevention, detection, treatment and control of diseases (including zoonoses) and disaster planning in case of outbreaks;
- Contribution to the work of the Animal Welfare Body (AWB) on matters of animal health and welfare and the implementation of the Three Rs;
- Input and advice to the researchers, the person(s) responsible for the project and the AWB on animal use models, experimental design (as appropriate), implementation of the Three Rs and severity assessment of procedures;
- Recognition and management of adverse events impacting the health or welfare of animals, whether associated with an experimental protocol or not;
- Provision of advice and recommendations for non-surgical and surgical interventions;
- Provision of advice and guidance for the anaesthesia, analgesia, post-operative care and alleviation of pain, suffering and distress in relation to experimental protocols;
- Assessment of the well-being of animals and recognition of severity classification;
- Establishment and maintenance of adequate clinical observation sheets;
- Keeping of accurate veterinary records;
- Provision of advice and guidelines regarding implementation of humane endpoints and euthanasia practices;
- Veterinary examination and advice and decision taking regarding:
  - keeping an animal alive at the end of procedures (Article 17);
  - animals taken from the wild that are found in poor health (Article 9);
  - re-use of animal (Article 16) and the related aspects to be taken into account;
  - re-homing of animals (Article 19) and the related aspects to be taken into account.

A veterinarian may also provide useful expert input on project evaluation.

Involvement in training/supervision/assessment

A veterinarian may also provide useful expert input in evaluating whether an adequate training programme is in place regarding:

- Embedding of a culture of care in the overall training program;
- Handling and care of laboratory animals;
- Handling and care during procedures;
- Clinical observation and their correct recording;
- Non-surgical and surgical interventions in the species concerned;
- Euthanasia practices.

Initial training

Veterinarians have a strong background in animal health, disease, welfare and hygiene. However, it is recognised that the field of Laboratory Animal Medicine and Science

represents a focused area of veterinary expertise and that additional post-graduate veterinary training is therefore needed to fulfil the roles and responsibilities of the DV.

The general appreciation of **animal care, health and management** (Module 4), r**ecognition of pain, suffering and distress** (Module 5), and **anaesthesia, analgesia and surgery (**Modules 20-22) are all part of normal professional veterinary training. Species specific specialisation (e.g. non-human primates, avian, fish, cephalopods) can be dealt with as and when required following a gap analysis and as part of CPD. This is not a pre-requisite for initial DV training.

However, core competencies should include appropriate knowledge of the European and National legal environment under which they will be required to work.

Veterinarians should have adequate core competencies that are specific to the relevant species or to groups of species (and related practices) e.g. in the field of Laboratory Animal Medicine and Science, including relevant competencies that are not included in the normal veterinary curriculum.

The exact definition of additional training needs will depend on the activities of the establishment (e.g. species involved and type of activities, e.g. breeder/supplier vs. user).

A modular approach to this necessary additional training will maximize the efficiency of training through customization, and will ensure that competencies are tailored to the needs of the establishment and the veterinarian.

Core competences should preferably be gained prior to starting a DV assignment, or as soon as possible thereafter.

The DV should have completed training in the following modules:

- Module 1 - "National legislation" with additional Learning Outcomes as described in Module 24 (24.1 - 24.5);
- Module 9 - "Ethics, animal welfare and the Three Rs" (level 2) with additional Learning Outcomes as described in Module 24 (24.6 - 24.12);
- Module 10 – "Design of procedures and projects";
- Module 50 - "Introduction to the local environment";
- Module 24 - "Designated Veterinarian".

CPD

DVs should be responsible for their own continuing development relevant to their work in order to maintain and develop their competencies. DVs should also refer to national veterinary Regulatory Authorities for minimum CPD requirements in the country where they work.

A variety of modalities could count towards CPD, such as conferences, literature, formal courses, site visits, internships, congresses, or interaction with colleagues. In some circumstances depending on personal choice, CPD could be integrated into a career

development path leading to additional qualifications such as a Certificate in Laboratory Animal Medicine (e.g. CertLAS in the UK), a national Diploma in Laboratory Animal Medicine (e.g. Fachtierarzt für Versuchstiere in Germany) or an ECLAM (European College of Laboratory Animal Medicine) Diploma.

DVs are responsible for maintaining records of their CPD.

Use of live animals for the purposes of education and training

It may be useful to separate and define what is meant by education versus training since they may entail different concerns over animal use: education could be interpreted principally to refer to the imparting of general principles (e.g. in anaesthesia) to gain knowledge whereas training could refer mainly to the teaching of practical skills[7].

The use of live animals for education and training purposes which may cause the animals pain, suffering, distress or lasting harm (as defined in Article 3(1)) will require project authorisation.

The extent to which animal use is permitted varies considerably among Member States, and quite diverse views are expressed, for example from routine use in acquisition of skills to exceptional use under very specific circumstances.

However, in all circumstances, there should be a considered and structured approach towards the use of animals in education and training. The use of alternative strategies should be fully explored and specific objectives and defined benefits be presented in any request for the use of live animals.

Where the use of live animals can be justified and project authorisation secured, often other limitations are used to minimise numbers or suffering, for example limiting severity to mild; re-use of animals under non-recovery anaesthesia.

The differing views on the use of animals in training has resulted in occasions when scientists from one Member State which limits animal use in education and training have attended courses in other Member States specifically to attend courses which use animals to develop manual skills; one example cited was to develop embryo transfer skills as part of a GA programme.

Ideally, within the EU, there should be a common understanding on the circumstances under which live animals are required for education and training, and similar outcomes to requests for such animal use.

It is important to note in this context that with the adoption of the Directive it is considered acceptable to allow the use of animals for the purposes of higher education, and training for

[7] Article 5(f) of Directive 2010/63/EU describes training "*for the acquisition, maintenance or improvement of vocational skills"*

the acquisition, maintenance or improvement of vocational skills in the EU. Therefore, the present discussion focuses not on whether but on what circumstances under which animal use is justified.

Justification for the use of live animals in education

The use of live animals for the purposes of education divides views. In many Member States, the use of animals for this purpose has been in decline for many years. If education without the use of live animals is achievable in some institutes (e.g. many medical schools) the question beckons why this would not be achievable elsewhere. Furthermore, the development and availability of new alternative teaching methods/strategies continue to increase rapidly in this area.

The applicant needs to set out in detail the context in which animals are necessary, explain the alternatives which have been considered and why these have been rejected, the specific educational objectives to be obtained and how the applicant will determine if these are met.

The applicant should also explain why observations and use of data from on-going scientific procedures within the establishment could not be used to demonstrate the principles.

Examples of educational benefits to consider when assessing project proposals for educational purposes include

- a need to understand and learn variability of responses in live subjects;
- contextual learning in specific scientific environment;
- opportunities for students to be 'exposed' as basis to form a view on the issue.

Justification for the use of live animals in training

The use of live animals for the purposes of training of vocational skills was discussed separately.

In contrast to the use of animals in education, their use in training could be more readily justified.

Training using live animals should be restricted to those individuals who are at a stage in their career development where animal use is considered necessary – for those who will

- work with animals;
- use animals in scientific projects and
- require the use of animals to develop surgical skills for clinical purposes.

Project applications and evaluations for the use of animals in education and training

All applications for the use of live animals in education and training require careful consideration to ensure that animal use is essential to meet the education or training objectives, and that no other alternate strategy would suffice.

Wherever the use of animals is proposed, the application should explain how the animals fit into the overall education or training programme. The Consensus Document on Project Evaluation and Retrospective Assessment[8] includes a number of pre-formulated questions for building a project application template to invite the necessary information.

In general a tiered approach is used, using non-animal alternatives, cadaver work and finally live animals.

[8] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf

1. No animal use

    - Theory;
    - Demonstration of procedures/techniques (or physiological responses) by the use of e.g. pictures, videos, interactive audio-visual tools;
    - Observation of a competent person performing the procedure live as part of an existing study;
    - Practice of technical/practical skills on "simulators".

2. Use of cadavers

3. Use of live animals

    a. Non-recovery (anaesthetised) animals

        - Use of the animal for more than one technique is recommended since the harms for the animal are the same.

    b. Use of conscious animals

        - If the procedure will not influence experimental outcome, or significantly affect severity, training could be done on animals within an existing study;
        - Training should always begin with teaching of the appropriate handling techniques to the species in question.

In the development of manual skills, trainees should only progress to the use of live animals, having demonstrated appropriate aptitude in simulator and cadaver work.

The tiered approach should be part of a systematic assessment when project evaluation is carried out for educational/training purposes. Consideration should also be given to

- the type of trainees – the skills needed, and an indication that these will be used;

- the provenance of the animals to be used e.g. surplus stock animals; animals from completed studies, which have not yet been euthanized.

It is acknowledged, however, that a person will not be fully competent until sufficient direct experience on the performance of the procedure is gained. Therefore, an appropriate structure for supervision and competence assessment needs to be assured to ensure no unnecessary pain, suffering, distress or lasting harm is caused to the animals as experience is gained.

Acceptable "harms" within an education or training

The severity of procedures should be restricted to "non – recovery" or "mild".

However, it is recognised that rare, well justified exceptions could be accepted to this general principle.

Examples of such exceptions include

- a surgeon training for the implantation of a device where it could be important to evaluate the success during the recovery phase ;
- preparation of educational material to replace future live animal use.

The assessment of exceptions should always be carried out on a case-by-case basis with due consideration to the harms, benefits and the educational value of the proposed work.

Due to the fact that in the area of education and training animals are often used on multiple occasions, particular attention should be paid to the cumulative effects of techniques considered to be 'lower than or 'below threshold' which when used in combination or on more than one occasion (multiple) may lead to a 'higher' or above 'minimum threshold' severity when repeated.

The importance of and availability of competent supervision cannot be over-emphasised and these aspects should be specifically addressed and evaluated in proposals for projects using live animals for educational and training purposes.

Transition from "training" to "working under supervision"

One of the main arguments for using live animals for training is to ensure that when procedures are carried out by individuals, these should be performed competently with no adverse impact on the scientific outcome due to poor technique.

This is not the case for all studies, for example, blood harvesting for in-vitro studies, where although the scientific outcome may not be adversely affected, there remains the potential for adverse welfare consequences.

As individuals will vary in the time taken to attain competence, no hard and fast rules can be set out to determine, for example, how many animals need to be used for training purposes before undertaking scientific procedures under supervision. This further emphasises the importance of having a well-integrated training, supervision and competence assessment programme. Individuals should only undertake scientific procedures for the first time under supervision, after some informed consideration by the supervisor on the individual's ability and the potential impact of poor technique on the science and animal welfare.

Appendix I
Modules and the related Learning Outcomes

Part 1: Modular structure

This document is intended to provide guidance to Member States and all those involved in the care and use of animals under 2010/63/EU on the minimum recommended training requirements under EU Directive 2010/63/EU (Article 23 and Annex V). It is intended to enable the development of an Education and Training framework, within the EU, which will include practical competencies, training and Continuing Professional Development (CPD) to ensure the competence of staff and to facilitate the free movement of personnel within and between Member States.

The approach adopted here of a **modular structure** and the associated **Learning Outcomes** recognises that training should be correlated with needs. It is important to note that this document deals with output rather than processes and is not intended to be prescriptive. Trainers can be flexible in the selection of course content, training materials and delivery methods which will deliver the learning outcomes in a manner which meets their national/local/institutional and/or individual/group requirements. Trainers are able to use their discretion when incorporating additional information to deliver training specific to individual needs.

1) Modular Structure

The modules presented here include all those considered as the **minimum training** necessary before persons are allowed to carry out a Function (A to D)[9], and some Additional modules required to perform specific tasks, for example surgery. It is acknowledged that in some cases, as detailed below, training will have an element of practical training that will be carried out under supervision. Finally, all modules can be delivered separately but it is intended that course organisers can combine individual modules to deliver courses suited to a particular function or specific training needs.

The modules (see table below) can be grouped into three categories:

1. Core Modules represent the basic theoretical training for all personnel performing any of the Functions A-D of Article 23. Completion of all Core Modules is compulsory for function A, B and C, D (in the case of function D an alternative specific tailor-made course has been developed as an option [see below]). This includes Module 1 covering national legislation.

2. Function Specific (Prerequisite) Modules are required, in addition to the core modules to meet the minimum training needs for a specific function.

[9] Article 23(1) functions: A = person carrying out procedures on animals; B = person designing procedures and projects; C = person taking care of animals; C = person killing animals

Training for Function D (killing animals) may be achieved by completing the required Core and Function Specific Modules or by completing an alternative tailor-made module that combines the relevant necessary learning outcomes from the respective Core and Function specific modules (module 6.3 in table below).

3. Additional and Task Specific Modules - Following the principle of correlating training to requirements, additional, "as required", task specific modules address the fact that some, but not all, persons carrying out a function will need some essential additional training before performing out a category of tasks or procedures. The task-specific modules described here refer to training that is required for broad categories of tasks (e.g. advanced anaesthesia for surgical procedures, see Module 21 below) but also covering other tasks specified in the Directive such as in Articles 24, 25 and 38.

Species Specific Training: after successful completion of the initial training module for a species/group of species, skills expansion to further species will require demonstration of attainment of learning outcomes for the new species within the same module. However, it may not be necessary to repeat all elements of the initial training module for the new species to achieve the learning outcomes required for the additional species. Module providers will be able to exercise discretion in determining which of the learning outcomes will be required for the new species as these will have to be assessed on a case by case basis.

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

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

7	Minimally invasive procedures without anaesthesia – species specific (theory)
9	Ethics, animal welfare and the Three Rs (level 2)
10	Design of procedures and projects (level 1)
11	Design of procedures and projects (level 2)

Function Specific (Prerequisite) Modules - Function C

3.2	Basic and appropriate biology – species specific (practical)

Function Specific (Prerequisite) Modules - Function D

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

Part 2: Learning Outcomes

Learning Outcomes, expressed in terms of measurable verbs (see Annex) help to define the knowledge and skills that course participants should be able to demonstrate by the time these learning outcomes are assessed.

Firstly, it was felt that a reasonably detailed list will be helpful to course organisers, but re-iterate that these are not meant to be prescriptive.

Secondly, the measurable verbs used in this document, whilst helpful in describing the range of relevant topics, are mostly written at the simple level of "knowledge" and "comprehension". There is a strong argument however that modern teaching should go beyond that whenever possible and encourage critical thinking (e.g. evaluation; see hierarchy of measurable verbs in Annex). Thus we encourage course organisers to promote "deep learning", already from the initial training, rather than just recalling facts or mimicking actions whenever possible (see Annex for some examples).

It is acknowledged that the achievement of practical learning outcomes may be separate from theoretical/knowledge based learning outcomes. In cases where there is no risk of causing pain, distress, suffering or lasting harm to the animals, the trainee can proceed to work under supervision before being assessed for having achieved the Learning Outcomes. Because scientific procedures carry the risk of causing pain, suffering, distress or lasting harm only animal care and husbandry tasks (Function C) should be done under supervision, before achieving the Learning Outcomes.

In all other cases, learning outcomes of a module need to be attained *in line with the agreed pass criteria*, as set by the course provider, before the person commences work under supervision. This should lead to an acceptable level of understanding of the subject which will ensure that no unnecessary pain, suffering, distress or lasting harm is inflicted when working under supervision.

It is important to note that the attainment of these learning outcomes does not mean that the trainee has achieved practical competence. Competence and competencies[10] are achieved through practical application of the acquired knowledge and experience gained through working. Competencies are assessed separately from learning outcomes.

Part 3: Modules

The following numbering has been used for the modules in order to allow insertion of new modules as these are developed:

1 – 19	- Core and Function Specific Modules for functions under Article 23
20 – 49	- Task and Additional skill related Modules
50 and above	- Other Additional Modules

[10] **Competence**: the combination of knowledge, skills and behaviour used to improve performance (a broad concept, taking into account skills, knowledge and experience);
Competency: the ability of an individual to perform a task properly (much narrower, activity- or task- based in focus)

LIST OF MODULES

1	National legislation	**C**
2	Ethics, animal welfare and the Three Rs (level 1)	**C**
3.1	Basic and appropriate biology – species specific (theory)	**C**
3.2	Basic and appropriate biology – species specific (practical)	**F**
4	Animal care, health and management – species specific (theory)	**C**
5	Recognition of pain, suffering and distress - species specific	**C**
6.1	Humane methods of killing (theory)	**C**
6.2	Humane methods of killing (skills)	**F**
6.3	Humane methods of killing - Alternative stand-alone Module for Function D	**F**
7	Minimally invasive procedures without anaesthesia – species specific (theory)	**F**
8	Minimally invasive procedures without anaesthesia – species specific (skills)	**F**
9	Ethics, animal welfare and the Three Rs (level 2)	**F**
10	Design of procedures and projects (level 1)	**F**
11	Design of procedures and projects (level 2)	**F**

20	Anaesthesia for minor procedures	**T**
21	Advanced anaesthesia for surgical or prolonged procedures	**T**
22	Principles of surgery	**T**
23	Advanced animal husbandry, care and enrichment practices	**T**
24	Designated Veterinarian	**T**
25	Project Evaluator	**T**

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

Module 1: National legislation [National - Core]

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

Learning outcomes

Trainees should be able to:

1.1. Identify and describe the national and EU laws and guidance which regulate the scientific use of animals and in particular the activities of those carrying out scientific procedures involving them.

1.2. Identify and describe related animal welfare legislation.

1.3 Describe the authorisation that is needed before acting as user, breeder or supplier of laboratory animals and especially the authorisation required for projects and where applicable individuals.

1.4. List sources of information and support that are available (regarding national legislation).

1.5. Describe the role of the personnel mentioned in Article 24, 25 and 26, and their statutory duties and other responsibilities under the National Legislation.

1.6. Describe the roles and responsibilities of the local animal welfare bodies and the national committee for the protection of animals used for scientific purposes.

1.7. Indicate who is responsible for compliance at an establishment and how this responsibility may be exercised (e.g. through the local AWB).

1.8. Describe when a procedure becomes regulated under National legislation (minimum threshold of pain, suffering, distress or lasting harm).

1.9. Indicate who bears primary responsibility for the animals undergoing procedures.

1.10. List which species, including respective stages of development that are included in the scope of the Directive / National law.

1.11. Indicate the circumstances in which animals under the scope of the Directive should be humanely killed or removed from the study to receive veterinary treatment.

1.12. Describe the legislative controls over the killing of animals bred or used for scientific procedures

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

This module provides guidance and information to enable individuals working with animals to identify, understand and respond appropriately, to the ethical and welfare issues raised by the use of animals in scientific procedures generally and, where appropriate, within their own programme of work. It provides information to enable individuals to understand and to apply the basic principles of the Three Rs.

Learning Outcomes

Trainees should be able to:

2.1. Describe the differing views, within society, relating to the scientific uses of animals and recognise the need to respect these.

2.2. Describe the responsibility of humans when working with research animals and recognise the importance of having a respectful and humane attitude towards working with animals in research.

2.3. Identify ethical and animal welfare issues in their own work and be aware and able to reflect on the consequences of their own actions.

2.4. Recognise that compliance with ethical principles may contribute to the long-term trust and acceptance in scientific research from the general public.

2.5. Describe how the law is based on an ethical framework which requires 1) weighing the harms and benefits of projects (the harm/benefit assessment) 2) applying the Three Rs to minimise the harm, maximise benefits and 3) promote good animal welfare practices.

2.6. Describe and discuss the importance of the ThreeRs as a guiding principle in the use of animals in scientific procedures.

2.7. Explain the Five Freedoms and how these apply to laboratory species

2.8. Describe the concept of harms to animals including avoidable and unavoidable suffering, direct, contingent and cumulative suffering

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.

2.10. Describe the regulations regarding re-use of animals.

2.11. Describe the importance of good animal welfare including its effect on scientific outcomes as well as for societal and moral reasons.

2.12. Describe the need for a culture of care and the individual's role in contributing to this.

2.13. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.

2.14. Be aware of different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. Systematic reviews, meta analysis).

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

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

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

Learning Outcomes

Trainees should be able to:

3.1.1. Describe basic anatomy, physiology, reproduction and behaviour of the relevant species.

3.1.2. Recognize and describe life events that have the potential to cause suffering including sourcing, transport, housing, husbandry, handling and procedures (on a basic level).

3.1.3. 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.

3.1.4. Indicate how husbandry and care may influence experimental outcome and the number of animals needed e.g. example where the place in the room influences the outcome, hence randomisation.

3.1.5. Describe the dietary requirements of the relevant animal species and explain how these can be met.

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.

3.1.7. When relevant to the species, recognise that there are different strains, and that these can have different characteristics which can affect both welfare and science.

3.1.8. When relevant to the species, recognise that alterations to the genome can affect the phenotype in unexpected and subtle ways, and the importance of monitoring such animals very carefully.

3.1.9. Maintain and interpret accurate, comprehensive records of animals held in the animal facility, including the wellbeing of the animals

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

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.

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

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

Learning Outcomes

Trainees should be able to:

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

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

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

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

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

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

4.7. 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.

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

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 use of sentinels as relevant to the species).

4.10. Describe appropriate breeding programmes

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

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

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

Module 5: Recognition of pain, suffering and distress – species specific [Core]

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

Learning Outcomes

Trainees should be able to:

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

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

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

5.4. Describe what a humane end point is. Identify criteria to be used to set humane endpoints. Define action to be taken when a humane endpoint is reached and consider possible options for refining methods to finish at an earlier endpoint.

5.5. Describe the severity classifications included in the Directive and give examples of each category; explain cumulative severity and the effect this may have on the severity classification.

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

Module 6: Humane methods of killing

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

This module provides information on the principles of humane killing and the need to have someone available, at all times, who is able to kill an animal quickly and humanely if required. The module will include information and descriptions of the different methods available, details of the species for which these methods are suitable and information to help trainees compare the methods permitted and determine how to select the most appropriate method.

Learning Outcomes

Trainees should be able to:

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

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.

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

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

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

Learning Outcomes

Trainees should be able to:

6.2.1. Proficiently and humanely carry out euthanasia using appropriate techniques on relevant species of laboratory animals

6.2.2. Demonstrate how death is confirmed and how cadavers should be processed or otherwise disposed of.

6.3: Humane methods of killing - Alternative stand-alone Module for those who only perform Function D

This module has been designed for those who only perform Function D and is a pre-requisite for this Function which can be delivered in place of a number of other modules for anyone who will only be involved in the humane killing of animals. This module combines Learning Outcomes from the modules relating to legislation, ethics and the Three Rs with practical animal handling, safe working practices and the theory and practical elements of the humane killing modules.

Learning Outcomes

Trainees should be able to:

(i) Legislation, Three Rs and ethics (i.e. subset of Modules 1 and 2)

6.3.1. Describe the regulatory framework for the scientific use of animals and in particular controls relating to the conduct of humane killing and confirming death – including role of named persons and the Animal Welfare Body

6.3.2. Recognize differing societal views about the scientific use and humane killing of animals

6.3.3. Have an understanding of the ethical principles underlying the use of animals and of their own role in contributing to the 'culture of care'

6.3.4. Relate ways in which the Three Rs can be applied to the humane killing of animals

(ii) Species specific Handling (i.e. subset of Module 3)

6.3.5. Demonstrate appropriate techniques for the safe and competent handling of relevant species. 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. Explain the importance of transporting animals correctly and safely

6.3.6. Describe the normal and abnormal behaviour and the behavioural requirements of relevant species and be able to recognise and discuss strategies for minimising and responding to occurrences of pain, suffering and distress

6.3.7. Describe in outline the basic biological and husbandry needs of relevant species

(iii) Safe working practices

6.3.8. Discuss the importance of correct storage and handling of chemical agents used for humane killing and maintaining hygiene in the workplace

6.3.9. Describe the correct procedures to deal with accidental exposure or spillage

6.3.10. Describe the basic hygiene rules and relate these to the workplace

6.3.11. Relate the importance of correct disposal of different categories of waste (clinical waste, hazardous waste and normal waste) and describe appropriate strategies

6.3.12. Explain how engineering solutions combined with personal protection equipment can minimise exposure to laboratory animal allergens preventing sensitisation

6.3.13. Identify clinical symptoms commonly associated with allergy to laboratory animals

6.3.14. Describe what is meant by zoonosis, and explain why contact with different species (in particular non-human primates) constitutes a potential human health hazard.

(iv) Species specific humane killing (modules 6.1 + 6.2)

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

6.3.16. Describe the different methods by which the relevant animals are allowed to be killed, the influence different methods can have on scientific outcomes, if relevant, and how to select the most appropriate method.

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

6.3.18. Proficiently and humanely carry out euthanasia using appropriate of techniques on relevant species of laboratory animals

6.3.19. Demonstrate how death is confirmed and how cadavers should be processed or otherwise disposed of.

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

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

Learning Outcomes

Trainees should be able to:

7.1. Describe appropriate methods and principles to be followed when handling animals (including methods of manual restraint and use of restricted environments).

7.2. Describe the biological impact of procedures and restraint on physiology.

7.3. Describe refinement opportunities for procedures and restraint e.g. through training (using positive re-enforcement), habituation and socialisation of animals.

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.

7.5. Describe how to perform minor techniques and relate appropriate sample volumes and sampling frequencies for the relevant species.

7.6. Describe the need for rigour and consistency in conducting scientific procedures and the correct recording and handling of samples.

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.

7.8. Recognize that refinement is an on-going process and know where to find relevant, up-to-date, information.

7.9. Describe the biological consequences of transport, acclimatization, husbandry conditions and experimental procedures on the species concerned and describe how these can be minimised.

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

This module delivers practical elements of training relevant to Module 7. Practical training for minor procedures can be taught through a number of methods using different tools which are available and designed for the purpose (this is likely to include synthetic animal models and the use of cadavers). The module should be designed in such a way that it will enable the trainee to attain a level of proficiency such that, when commencing work under supervision, s/he should cause no pain, suffering, distress or lasting harm to the animal.

Learning Outcomes

Trainees should be able to:

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.

8.2. Demonstrate that s/he can handle and restrain the animal in the best position for the technique.

8.3. Perform minor techniques under supervision, in a manner that does not inflict unnecessary pain, suffering, distress or lasting harm.

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

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

The purpose of this module is to address the fact that those designing procedures should command a deeper and broader understanding of the general issues. Thus, the main difference between level 1 and level 2 Modules on "Ethics, animal welfare that the Three Rs" is not necessarily the topics to be covered (which have not been repeated here) but rather that some of them are addressed in more detail and with a greater expectation for the Learning Outcome itself. For example at level 1 there are elements the trainee should know and be able to describe, which at level 2 the trainee should have a more detailed understanding and be able to discuss. This module also prepares individuals so that they are able to keep themselves informed in order to continuously apply the Three Rs to their work as new methods and approaches evolve.

Learning Outcomes

Trainees should be able to:

9.1. Understand that there is a broad range of ethical, welfare and scientific perspectives on the use of animals in scientific procedures, and that thinking on all of these matters evolves over time and is influenced by culture and context.

9.2. Understand that this means there is need for *on-going* critical evaluation of the justification for using animals and of implementation of the Three Rs at all stages of the life of a project.

9.3. Recognise that there are ethical limits to what it is considered permissible to do under the Directive and that even within these legal constraints, there are also likely to be national and institutional differences in this respect.

9.4. Explain that legislation requires that the justification for programmes of work is assessed by weighing potential adverse effects on the animals against the likely benefits; that harms to animals must be minimised, and benefits maximised.

9.5. Understand and provide the information necessary to enable a robust harm/benefit assessment to be performed; and explain why they personally consider that the potential benefits outweigh the likely adverse effects.

9.6. Understand the need to communicate appropriate information to a wider public audience, and be able to prepare an appropriate non-technical project summary to facilitate this.

9.7. Describe the importance of disseminating information that will promote understanding of ethical issues, good animal welfare, good science and application of the Three Rs.

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

This module is a pre-requisite for people who will be designing projects (Function B) but it is also be beneficial for scientists who have some involvement in designing the procedures that they carry-out (Function A). The module comprises information about experimental design concepts, possible causes and elimination of bias, statistical analysis and information about where expertise can be found to assist with procedure, design, planning and the interpretation of results.

Learning Outcomes

Trainees should be able to:

10.1. Describe the concepts of fidelity and discrimination (e.g. as discussed by Russell and Burch and others).

10.2. Explain the concept of variability, its causes and methods of reducing it (uses and limitations of isogenic strains, outbred stocks, genetically modified strains, sourcing, stress and the value of habituation, clinical or sub-clinical infections, and basic biology).

10.3. Describe possible causes of bias and ways of alleviating it (e.g. formal randomisation, blind trials and possible actions when randomisation and blinding are not possible).

10.4. Identify the experimental unit and recognise issues of non-independence (pseudo-replication).

10.5. Describe the variables affecting significance, including the meaning of statistical power and "p-values".

10.6. Identify formal ways of determining of sample size (power analysis or the resource equation method).

10.7. List the different types of formal experimental designs (e.g. completely randomised, randomised block, repeated measures [within subject], Latin square and factorial experimental designs).

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

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

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

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

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

Learning Outcomes

Trainee should be able to:

(i) Legal issues

11.1. Describe in detail the main components of the national legislation regulating the scientific use of animals; in particular, explain the legal responsibilities of those designing procedures and projects (Function B staff) and those of other persons with statutory responsibilities under the national legislation (e.g. the person responsible for compliance, veterinarian, animal care staff, training officers).

11.2. List the key purposes of other relevant EU and international legislation and associated guidelines that impact on the welfare and use of animals. This includes Directive 2010/63/EU and legislation/guidelines relating to: veterinary care, animal health, animal welfare, genetic modification of animals, animal transport, quarantine, Health & Safety, wildlife and conservation.

(ii) Good scientific practice

11.3. Describe the principles of a good scientific strategy that are necessary to achieve robust results, including the need for definition of clear and unambiguous hypotheses, good experimental design, experimental measures and analysis of results. Provide examples of the consequences of failing to implement sound scientific strategy.

11.4. Demonstrate an understanding of the need to take expert advice and use appropriate statistical methods, recognise causes of biological variability, and ensure consistency between experiments.

11.5. Discuss the importance of being able to justify on both scientific and ethical grounds, the decision to use living animals, including the choice of models, their origins, estimated numbers and life stages. Describe the scientific, ethical and welfare factors influencing the choice of an appropriate animal or non-animal model.

11.6. Describe situations when pilot experiments may be necessary.

11.7. Explain the need to be up to date with developments in laboratory animal science and technology so as to ensure good science and animal welfare

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

11.9. Explain the importance of dissemination of the study results irrespective of the outcome and describe the key issues to be reported when using live animals in research e.g. ARRIVE guidelines.

(iii) Implementing the Three Rs

11.10. Demonstrate a comprehensive understanding of the principles of replacement, reduction and refinement, and of how these ensure good science and good animal welfare.

11.11. Explain the importance of literature and internet searches, discussion with colleagues and with relevant professional bodies in identifying opportunities for applying each 'R'

11.12. Describe relevant sources of information relating to ethics, animal welfare and the implementation of the Three Rs.

11.13. Explain how to use different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. Systematic reviews, meta-analysis).

11.14. Describe examples of alternative methods and research strategies that replace, avoid or complement the use of animals in different types of research programme.

11.15. Identify, assess and minimise all of the welfare costs to animals throughout the animals' lifetime (including adverse effects relating to sourcing, transport, housing, husbandry, handling, procedures and humane killing); Explain and give examples of welfare assessment protocols.

11.16. Define and apply appropriate humane end-points; establish suitable criteria to identify when the humane endpoint has been reached

11.17. Describe possible conflicts between Refinement and Reduction (e.g.in the case of re-use) and the factors that need to be considered to resolve this conflict

11.18. Define the requirements for, and controls on, re-homing of animals; identify any relevant re-homing guidelines

(iv) Responsibilities

11.19. Explain the need to be aware of local arrangements relating to project licence management, e.g. procedures for ordering animals, accommodation standards, disposal of animals, safe working practices and security, and the actions to take in the event of unexpected problems arising with any of these

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

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

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

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

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

Learning Outcomes

Trainees should be able to:

20.1. Define sedation, local and general anaesthesia

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

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

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

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

20.6. Discuss the relative merits / drawbacks and principles of selection of different agents and their application, including calculation of doses, in relevant species, including injectable and

volatile agents (or dissolved agents in the case of aquatic species), including local anaesthesia regimes

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

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

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

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

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

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

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

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

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

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

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

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

Learning Outcomes

Trainees should be able to:

21.1. Relate why and when anaesthesia might be used, including additional factors relevant for long term anaesthesia.

21.2. Relate the need for and list the factors to be considered in pre-anaesthetic evaluation of animals, including acclimatisation.

21.3. Discuss the use of pre-anaesthetic agents and analgesics as part of a balanced anaesthetic regime.

21.4. Indicate that a range of drugs are commonly used for premedication and the induction and maintenance of anaesthesia in relevant laboratory species, and identify where to get advice on the different drug available and their use.

21.5. Describe how an animal's concurrent pathology may require specific anaesthetic regimen, monitoring or nursing care.

21.6. Indicate types of agents used for the induction and maintenance of general anaesthesia, their advantages and disadvantages and when each might be used.

21.7. Describe how anaesthetic agents interact to produce the three components of the anaesthetic triad to different degrees, and how balanced anaesthesia might be best achieved by using combinations.

21.8. Demonstrate a sufficient understanding of anaesthetic agents having a low analgesic effect, potentially requesting the use of an additional analgesia.

21.9. List the factors to be considered when monitoring anaesthesia both for anaesthetic depth and physiological stability. Indicate how to determine that an animal is sufficiently deeply

anaesthetised to enable painful procedures to be undertaken, and what action should be taken if an adverse event occurs.

21.10. List methods which can used to assist monitoring of anaesthesia (e.g. ECG, BP, Urine output, Oxygen saturation, CO2) and how these can be monitored.

21.11. Monitor anaesthetic depth and the animals' vital signs, using both clinical signs, and electronic apparatus if appropriate.

21.12. Describe and demonstrate the correct set-up, operation and maintenance of anaesthetic and monitoring equipment appropriate to the species concerned.

21.13. Demonstrate competence in maintaining and interpreting records of pre- and post-anaesthetic induction and whilst an animal is anaesthetised, as well as in managing the animal care adequately

21.14. Indicate the problems that may occur during anaesthesia, and understand how to avoid these, or manage them if they occur.

21.15. Demonstrate an understanding of mechanical ventilation.

21.16. Describe methods to optimise post anaesthetic recovery to ensure a smooth and rapid recovery from anaesthesia, as in Basic Module but with additional methods required, including analgesia and fluid replacement, for animals having undergone lengthy anaesthesia of surgical procedure.

21.17. Consider the consequences of anaesthesia and the surgical procedures on recovery.

21.18. Appreciate how the choice of anaesthetic agent will determine the rate of recovery and describe how duration and quality of anaesthesia governs the rate of recovery.

21.19. Describe the problems that can arise (in the post-operative period), and indicate how to avoid these, or manage them if they occur.

21.20. Discuss how to integrate a program of pain management into an overall scheme of perioperative care.

21.21. Indicate some of the problems associated with pain recognition and pain management in animals.

21.22. Demonstrate a sufficiently detailed understanding of analgesics to be able to administer safely, including routes of administration and potential adverse effects.

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

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

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

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

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

Learning Outcomes

Trainees should be able to:

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

22.2. Identify sources of reference for good surgical practice

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

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

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

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

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

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

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

22.10. Demonstrate how to place a suture correctly

22.11. Describe common post-surgical complications and their causes

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

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

22.14. Demonstrate competence in surgical techniques, including ablations and incisions and their closure by methods appropriate to the tissue concerned

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

Module 23: Advanced animal husbandry, care and enrichment practices
[Additional Task Specific for Function C]

This module delivers a more in-depth knowledge of animal care practices aimed at Function C and those taking the responsibility as the named person responsible for the welfare and care of the animals in an establishment.

Learning Outcomes

Trainees should be able to:

(i) Demonstrate a thorough understanding of how animal welfare is maintained in the animal unit

23.1. Describe how environmental conditions may need to be varied according to the species, age, and life stage or specific care conditions (e.g. peri-operative care, immuno-deficient animals, genetically altered strains).

23.2. Discuss the possible effects of an uncontrolled environment on animal welfare and experimental results.

23.3. Discuss how environmental enrichment is achieved.

23.4. Explain how the Three Rs contribute to the continuous improvement of welfare, husbandry and enrichment practices.

(ii) Know suitable environmental conditions for laboratory animals and how they are monitored

23.5. Describe suitable environmental conditions and enrichment for the relevant animal species and how these conditions are monitored.

23.6. Be able to use environmental measure equipment, read charts, graphs or tables generated by environmental monitoring equipment and evaluate potential problems.

(iii) Explain how the organisation of the animal facility maintains an appropriate health status for the animals and the scientific procedures.

23.7. Describe suitable routines and housing conditions or laboratory animals housed for different scientific purposes.

23.8. Explain how routines and housing conditions may change given specified conditions.

23.9. Evaluate the use of barriers in controlling the animals' health status.

(iv) Identify potential disease risks in the animal facility

23.10. Describe a health-screening programme suitable for the animals in their care.

23.11. Discuss potential sources of disease in the animal facility.

23.12. Recognise examples of laboratory animal parasites.

23.13. Describe the life cycle of some common laboratory animal disease organisms.

(v) Evaluate methods for minimising the risks from potential disease organisms

23.14. Explain methods for minimising the risk from disease organisms.

23.15. Apply suitable disease control methods under specified conditions.

(vi) Devise appropriate breeding programmes for laboratory animals given specified conditions

23.16. Summarise the basic breeding data of common laboratory animals

23.17. Describe in detail suitable breeding programmes for named species under specified conditions

23.18. Select suitable future breeding stock

(vii) Evaluate methods for determining oestrus, checking mating has taken place and confirming pregnancy in a range of laboratory species

23.19. List methods for determining oestrus, mating and confirming pregnancy in laboratory animals and evaluate their effectiveness.

(viii) Analyse breeding performance

23.20. Analyse breeding cards/data to describe the breeding performance of a breeding group.

23.21. Describe any identified problems and suggest appropriate remedial actions.

(ix) Explain the use and problems associated with genetically altered animals [where appropriate to the species concerned]

23.22. Explain how genetically altered animals are used for research purposes.

23.23. Describe the potential problems associated with the use of genetically altered animals.

23.24. Describe methods for producing genetically altered animals.

(x) Know procedures for the safe and legal transportation of animals

23.25. Identify the key pieces of legislation controlling the transportation of animals.

23.26. Describe the procedures, equipment, legislative responsibilities and responsible persons in transport of animals.

23.27. Explain how health status & animal welfare standards are maintained throughout the transport.

(xi) Accurately apply the legislation that governs the use of research animals

23.28. Summarise the key aspects of the legislation protecting laboratory animals.

23.29. Discuss how the legislation controls the use of animals for scientific purposes.

Module 24: Designated Veterinarian
[Additional Task Specific Module]

This module provides basic guidance and information for the veterinarian at the entry Designated Veterinarian (DV) level. As applies to all veterinarians, DVs are expected to develop and enhance their skills through continuing professional development, and for the DV, specific courses relevant to their area of work are available in various Member States. Other training opportunities could be developed as needed for veterinarians to complete their expertise as DV, depending on the programme of the establishment (e.g. involvement in training/supervision/assessment; media communication on responsible use of animals in science; species-specific husbandry and veterinary care).

This module focuses on the principles of veterinary management of animal health and welfare for animals maintained, bred and/or used for scientific purposes ensuring that the DV understands the role of the vet in the research environment according to professional obligations, in addition to the description of the role in the Directive.

There may be elements of training that can be exempted on the basis of a gap-analysis of the individual's previous educational background and experience.

The objectives of this module are to:

- cover the basic principles of (rather than species-specific) components of a programme of veterinary care specifically in relation to the care and use of animals for research, which are:
    - Movement of animals and its implications
    - Animal care, health and management
    - Assessment of well-being
    - Recognition and alleviation of pain, suffering and distress
    - Relevance of the choice of animal models
    - Design of procedures and projects
    - Implementation of the Three Rs
    - Use of medicines
    - Surgical and non-surgical interventions
    - Anaesthesia and analgesia
    - Euthanasia
    - Occupational health and safety (zoonosis, allergies, etc.)

- consider the importance of routine veterinary visits and factors enabling the determination of an adequate frequency for the visits;
- discuss the balance between animal treatment and the need to ensure valid scientific results;
- appreciate how to identify ethical issues associated with biomedical research;
- consider the role of the vet in advising on choice of animal model and model refinement;
- discuss the role of the vet in advising on the implementation of humane end-points;
- discuss the principles of management of veterinary communications and decisions;
- review the opportunities to gather further veterinary information in Laboratory animal medicine and science.

Learning Outcomes

The trainees should be able to:

(i) Legislation

24.1. Summarise the statutory duties and professional requirements of the DV

24.2. Compare the roles, responsibilities and interactions of those working under the Directive within an establishment and explain the legal composition and the role of Animal Welfare Body

24.3. Explain the role of the veterinarian in directing prescription, order, storage and dispensing and disposal of medicines for animals maintained at authorised establishments and used in procedures

24.4. Describe the role of the DV in the import and export, and transport of laboratory animals

24.5. Outline legislative controls on the creation and use of Genetically Altered Animals

(ii) Ethics, Animal Welfare and the Three Rs

24.6. Define the Three Rs principles and provide examples of application of each to a breeding/supplier/user establishment; in particular, discuss the alleviation of pain and potentially lasting harm

24.7. Justify the importance of good animal health and welfare (with regards to the scientific outcomes and societal or moral reason) and recognise the relationship between health and welfare and scientific validity

24.8. Identify sources of information relating to ethics, animal welfare and veterinary information enabling the implementation of the Three Rs

24.9. Explain the need for a culture of care and the individual's role in contributing to this

24.10. Explain how the DV can contribute to the dissemination of information that will promote understanding of ethical issues, good animal welfare, good science and application of the Three Rs

24.11. Identify the criteria used in making a harm-benefit analysis and be able to apply them

24.12. Identify the role of the DV in advising on choice of animal model and model refinement

(iii) Animal Care, Health and Management

24.13. Relate the purposes of a routine animal house visit and how to deal with issues arising

24.14. Outline the preparation required for routine visits

24.15. Formulate the information to be included in health records and reports to the animal care staff and others

24.16. Summarise basic principles of disease surveillance, prevention and management in laboratory animals and the principles of health monitoring schemes, including information on relevant microorganisms infecting laboratory animals such as their classification, the potential impact on research and animal health, their zoonotic potential, their prevention, diagnosis, treatment and eradication, as well as the clinical appearance, aetiology and pathology of common laboratory animal diseases

24.17. Outline the requirements for health screening, e.g. FELASA guidelines

24.18. Outline appropriate management and control strategies for biosecurity and disease outbreak in laboratory animals

24.19. Describe an overview of the principles of laboratory animal husbandry, outlining the main principles of cage/enclosure design and construction and the advantages and disadvantages of different types of caging system

24.20. Explain the principles relating to the choice of appropriate environmental conditions and types of environmental enrichment used for laboratory animals

24.21. Describe the different methods by which the relevant animals are allowed to be killed, the influence different methods can have on scientific outcomes and on how to select the most appropriate method

24.22. Outline the principles of hygiene/disinfection/sterilisation that apply to the laboratory animal facility including the parameters influencing water quality, how to check for water quality and how to interpret results

24.23. Demonstrate an awareness of the main hazards that may be encountered in a laboratory animal facility and the role of the DV in minimizing the risks

24.24. Describe key biological characteristics and features of relevant species and recognize factors that may impact their care or use as laboratory animal

24.25. Discuss the creation and use of genetically altered animals in research including common types of GA animals and uses in research and different ways to create and evaluate GA animals, as well as how these are designated according to international guidelines for nomenclature

(iv) Anaesthesia, analgesia, surgery

24.26. Demonstrate adequate knowledge of the management of anaesthesia, analgesia and surgery in the context of animals used for scientific purposes

24.27. Relate the factors influencing choice of anaesthetic protocols in different situations

24.28. Describe the specific issues arising from experimental surgery and identify the role of the DV in relation to experimental surgery

(v) The principles of veterinary communications

24.29. Define strategies for effective communication and explain how these promote animal welfare and good science

24.30. Review the opportunities to gather further veterinary information in laboratory animal medicine and science

Module 25: Project Evaluator
[Additional Task Specific Module]

This module provides guidance and information to enable individuals involved in project evaluation to understand the context, the principles and the criteria of project evaluation and to develop a consistent approach of project evaluation and to formulate well-informed, impartial and justified opinions.

This module should be completed by anyone carrying out project evaluation, irrespective of their individual background and knowledge (e.g. science, techniques, veterinary medicine, ethics, the Three Rs, animal welfare, laypersons). It focuses on common training needs for all those involved in project evaluation. Those include in particular training in how the objectives of the project, the application of the Three Rs and the assessment of severity classification should be evaluated, and how the harm-benefit analysis should be undertaken. Considerations on the requirements for retrospective assessment of projects and how amendments are dealt with are also included

Learning Outcomes

Trainees should be able to:

(i) Understand EU and National legislation and in particular the obligations of PE and the principles for PE, as well as their roles and responsibilities, rights and duties, particularly as concerns conflict of interest

25.1. Describe the legal requirements underlying the PE process and discuss the distinction between project evaluation and authorisation

25.2. Describe the range of expertise required and issues of impartiality, confidentiality and conflict(s) of interest

25.3. Appreciate the importance of a transparent project evaluation process

25.4. List the different purposes of procedures (as listed in Article 5) and illustrate by some examples

(ii) Ethical and welfare issues

25.5. Analyse the ethical and welfare issues related to the use of animals in scientific procedures, and soundly appreciate the importance of the implementation of the Three Rs in all scientific research

(iii) Harm-benefit analysis

25.6. Discuss how to contribute to the harm-benefit analysis of a project, including understanding of the process and significance of the outcome of a harm-benefit analysis

25.7. Define the Three Rs and give a realistic and relevant example of each of the Three Rs covering scientific areas of animal use including regulatory testing

25.8. List the criteria to consider when identifying the potential harm to the animals

25.9. Identify potential sources of pain, suffering, distress and lasting harm

25.10. Describe methods to prevent or ameliorate suffering

25.11. Explain the severity classification and be able to classify procedures with consistency (using case-studies), taking into account specific considerations for animals that are physiologically compromised, such as genetically modified animals, where relevant

25.12. Describe the concepts of direct and contingent suffering

25.13. Describe factors to be considered in assessing cumulative suffering

25.14. Interpret the proposed/expected benefits of the project. Explain and discuss the essential information needed in the project application to enable consideration of the relevance of the proposed work in relation to current knowledge and/or the subject (or legal requirements) to be addressed

25.15. Assessment of the likelihood of success. List the criteria to consider when assessing the likelihood of success of a project

(iv) Sources of Information

25.16. Describe sources of information related to availability and relevance of other (non-animal) methods, e.g. replacement methods, data obtained from clinical studies

25.17. Describe the benefits of a "project evaluation check list"

(v) Methods of harm-benefit assessment

25.18. Recognize the various systems available to assist the process of project evaluation and how these can be applied in practice

25.19. Compare and discuss different approaches and tools to weigh and comparatively analyse harms and benefits of a project

(vi) Outcomes of project evaluation

25.20. Describe the legal basis of why project evaluation needs to formulate a well-informed, valid and timely decision on a project and the need to justify any additional recommendations

25.21. Describe the principles and approaches to ensure consistency in judgment and outcome of evaluation, to guarantee confidentiality, competence and ensure impartiality for each project evaluated

25.22. List the arguments for reaching a decision and which should be documented in the decision

(vii) Retrospective assessment

25.23. Describe legal requirements for retrospective assessment (RA) of projects (requirements and principles for identifying projects subject to RA) and other factors impacting on the selection of projects for RA

25.24. Describe the process of RA

25.25. Discuss possible outcomes of RA and how they may impact on future practices

Local module 50: Introduction to the local environment (establishment) for persons taking specific roles under the Directive (e.g. under Articles 24, 25 and 38)
[Other Additional Module]

This Module provides the necessary understanding of the local structure, key roles and their related tasks as well as appreciation as to how these contribute to the welfare of animals, good science, implementation of the Three Rs, and the establishment of the culture of care.

Learning Outcomes

Trainees should be able to:

50.1. Discuss how the scope and the spirit of the Directive 2010/63/EU and other legislation and guidelines pertain to the care and use of animals for scientific purposes in your establishment.

50.2. Describe the local organogram and your role within it.

50.3. Distinguish the roles, responsibilities and interactions of those working under the Directive within the establishment, namely those listed under Article 20, 24, 25 and 40.

50.4. Relate the tasks of the Animal Welfare Body and describe your role in contributing to these tasks.

50.5. Analyse ways in which your role can contribute towards the promotion and implementation and dissemination of the Three Rs at your establishment.

50.6. Discuss the importance of proactive approach to, and mechanisms of communication, as a tool to promote the Three Rs and the culture of care.

Module 51: Information provision and retrieval
[Other Additional Module]

This Module provides an introduction to the retrieval, handling and dissemination of information, and their importance in the context of implementation of the Three Rs.

Learning Outcomes

Trainees should be able to:

LO 2.13. Describe relevant sources of information relating to legislation, ethics, animal welfare and the implementation of the Three Rs.

51.1. Be aware/Explain *[adjust measurable verb according to the level]* how to use different search tools (e.g. EURL ECVAM Search Guide, Go3Rs) and methods of search (e.g. Systematic reviews, meta analysis).

51.2. Explain the importance of dissemination of study results irrespective of the outcome and describe the key issues to be reported when using live animals in research e.g. ARRIVE guidelines.

Part 4: Learning Outcomes, Measurable verbs and Critical Thinking

Competence	Increasing level of "Critical Thinking" Skills →					
	Knowledge	**Comprehension**	**Application**	**Analysis**	**Synthesis**	**Evaluation**
Measurable verbs / Question cues	list, define, tell, describe, identify, show, label, collect, examine, tabulate, quote, name, who, when, where, etc.	summarize, describe, interpret, contrast, predict, associate, distinguish, estimate, differentiate, discuss, extend	apply, demonstrate, calculate, complete, illustrate, show, solve, examine, modify, relate, change, classify, experiment, discover	analyze, separate, order, explain, connect, classify, arrange, divide, compare, select, explain, infer	combine, integrate, modify, rearrange, substitute, plan, create, design, invent, what if?, compose, formulate, prepare, generalize rewrite	assess, decide, rank, grade, test, measure, recommend, convince, select, judge, explain, discriminate support, conclude, compare, summarize
Skills Demonstrated	observation and recall of information knowledge of dates, events, places knowledge of major ideas mastery of subject matter	understanding information grasp meaning translate knowledge into new context interpret facts, compare, contrast order, group, infer causes predict consequences	use information use methods, concepts, theories in new situations solve problems using required skills or knowledge	seeing patterns organization of parts recognition of hidden meanings identification of components	use old ideas to create new ones generalize from given facts relate knowledge from several areas predict, draw conclusion	compare and discriminate between ideas assess value of theories, presentations make choices based on reasoned argument verify value of evidence recognize subjectivity

Redrawn from www.coun.uvic.ca/learning/exams/blooms-taxonomy.html

Bloom, B. S (Ed.) (1956) Taxonomy of educational objectives: the classification of educational goals; Handbook I:The Cognitive Domain New York, Toronto: Longmans, Green,

Anderson, L.W & Krathwohl, D.R. (Eds) (2001) *Taxonomy for Learning, Teaching and Assessing: A Revision of Bloom's Taxonomy of Educational Objectives* New York: Addison-Wesley. London: Longman

A useful application of the revised taxonomy for writing instructional objectives is at:

http://oregonstate.edu/instruct/coursedev/models/id/taxonomy/#table

In defining desired Learning Outcomes, it can be useful to think in terms of "measurable verbs" that indicate explicitly what the student must do in order to demonstrate learning. Benjamin Bloom (1956) created a taxonomy of measurable verbs to help describe and classify observable knowledge, skills, attitudes, behaviours and abilities.

The table above provides a hierarchy of verbs within the cognitive domain (and the range of skills demonstrated) that describe level of thinking in order of increasing complexity. This hierarchy is based on the premise that there are levels of observable (and therefore assessable) actions that indicate the cognitive processes happening in the brain.

As mentioned at the start of this document, the Learning Outcomes here are mostly written at the simple level of "knowledge" and "comprehension". But in accordance with modern teaching, course organisers are encouraged to go beyond these levels whenever possible, and promote deep learning / critical thinking rather than just recalling facts or mimicking actions. Below are some examples that put this in context of the modules, from the Ethical Module to the more practical-orientated Surgery module

Ethics Module

Be able to:

(Knowledge)

- **Identify** ethical and animal welfare issues in their proposed own work

(Critical Thinking)

- **Rank** ethical and animal welfare issues in their proposed own work

Assessment choices: for example: after listing the major known animal welfare issues, delegates asked to rate the importance of each issue in their own proposed work. For further development, delegates could estimate impact these issues may have on the outcomes of their proposed work- impact on wider society?

Surgery Module, as an example of something much more practical:

Be able to:

(Knowledge)

- **Describe** the characteristics of different, commonly-used instruments, suture materials and needles

(Critical Thinking)

- **Choose** appropriate instruments, suture materials and needles for commonly-used procedures

Assessment choices: images on a test paper (which would you use/in what context etc.) or imaginary scenarios/word problems (provide the species and the surgical procedure—which instruments would they choose and why?)

(Knowledge)

- **Indicate** the characteristics of different suture patterns and their applicability to different situations

(Critical Thinking)

- **Assess** the characteristics of different suture patterns and **evaluate** their applicability to different situations

[i.e. rather than about listing, this is about making a judgment and justifying it]

Assessment choices: identify different suture patterns, state the pros and cons each pattern. Give scenario *and* a choice of suture, ask delegates to evaluate the decision

(Knowledge)

- **Describe** common post-surgical complications and their causes

(Critical Thinking)

- **Interpret** common post-surgical complications and conclude their causes

Assessment choices: Give delegates a list of pathologies, so that they can identify those caused by common post-surgical complications and the delegates must draw a conclusion as to the cause.

(Knowledge)

- **Demonstrate** how to place a suture correctly

(Critical Thinking)

- **Appraise** how to place a suture correctly

[i.e. rather than just "mimicking "this focusses on the greater understanding of the factors that are important/or not in the suturing technique]

Assessment choices: have delegates working in pairs during practical session- have each give feedback on the strengths and weaknesses of suturing technique of the other (peer feedback). Have delegates compare their suture to the suture of the tutor —measure or rate their technique against this exemplar.

Appendix II
Illustrative examples of assessment criteria for Learning Outcomes

1. Introduction

This document/section sets out guidance for the development of assessment criteria; acknowledged standards of judgment, principles for assessment and the means by which a course accreditor/provider/assessor will determine whether a student has acquired and attained the knowledge and/or skills required to achieve an acceptable performance standard in the learning outcomes set out in the training modules.

The guidance is not meant to be prescriptive. The assessment of learning outcomes may already be regulated by other means in the individual member states, for example if the modules are part of, or integrated in, already existing educational structures, such as university or vocational schools. However, the guidance should help new module providers and assessors, particularly in situations where no previous training and assessment programmes exist. Wider adoption of these guiding principles should also contribute to the development of mutual recognition of training between member states.

The criteria, and methods of assessing standard of performance (e.g. through written exam, discussion work or observation), will depend on the nature of the particular learning outcome. It is important, initially, to define pass/fail standards for a particular learning outcome.

If individual learning outcomes are repeated in modules at different levels (for example in level 1 and 2 'ethics, animal welfare and the Three Rs') increased proficiency is expected, between the two levels. This is reflected in the wording used in the assessment criteria (see Annex: Learning Outcomes, Measurable Verbs and Critical Thinking). At a basic level students should, for example, be able to 'list' or 'describe' the facts that they have been taught. At the higher level 2, they should be able to 'discuss' and 'evaluate' the issues (demonstrating deeper learning/critical thinking). Assessment criteria should be as objective as possible and consistent between course providers and accreditors and, ideally, between member states.

1.1 Examples of Assessment Criteria

Assessment criteria need to be developed for all of the proposed earning outcomes and some examples are provided as a starting point in the tables below. The criteria should accurately reflect the standard of performance required; they should be as objective as possible, unambiguous, provide reliable results and be easy to use.

Criteria for knowledge based learning outcomes need to be developed. For many of the training modules, this amounts to an assessment of whether the student has retained and can clearly reiterate the information that they have been 'taught', for example with respect to aspects of legislation (see table 1, bullet point one). However, some knowledge based learning outcomes require a greater level of understanding of the issues and **an ability to**

relate the knowledge to the student's individual role or responsibilities and the assessment criteria need to reflect this (see table 1, bullet point two).

The development of assessment criteria and methods of assessment for learning outcomes that cover issues that require **'deeper understanding and thinking'** may call for more consideration, in particular where, as in the case of ethics modules 2 and 12, the modules cover similar topics but at two levels, 'basic' and 'higher'. The assessment criteria need to reflect the different levels. An example is given in table 2.

It is important to point out that it should often be possible to develop assessment criteria for a group of learning outcomes, particularly where a number of learning outcomes can be combined into a related sequence. This approach would be preferable to having separate assessment criteria for each of the learning outcomes and can be applied to theoretical as well as practical learning outcomes. (For example see table 3).

For **practical skills**, the easiest approach to developing objective assessment criteria is to break a specific procedure or technique down into its individual components covering, for example, both the theory and practical elements (e.g. handling, restraint, asepsis, pre and post- operative care, euthanasia, experimental outcomes and data quality) each of which can then be assessed.

1.2 Pass/Fail Criteria

No definite pass/fail criteria for the individual modules have been suggested as these will depend on course delivery, specific content and in some cases pre-existing requirements/limitations (e.g. university, national). However, in all cases, the trainer needs to have established the standard of performance that is required and the trainee needs to understand this.

Most educational programmes deem study outcome to be sufficient if the student has achieved a pass-mark of 50% or has otherwise demonstrated an acceptable level of understanding. However, in areas which demand a high level of factual knowledge (for example legislation) and where failure could subsequently result in animal welfare problems (e.g. a failure to recognise adverse effects or to maintain sufficient anaesthesia during surgery) a higher pass mark (for example 70 to 75%) is recommended.

1.3 Responsibility for assessment of trainees

It is important to be clear about who is responsible for 'signing off' the trainee as having reached an acceptable standard in their training, and for the assessor to have sufficient knowledge and authority to pass or fail students. With respect to practical skills, it is essential that someone is given the ultimate responsibility for observing an individual carrying out a procedure/husbandry task and verifying that it is being done in a competent way.

All those concerned need to understand that assessors will only sign people off as trained and competent if they are confident that the required standards have been achieved.

Examples of assessment criteria for knowledge-based learning outcomes have been provided in the following tables:

Table 1: Assessment criteria for a knowledge based learning outcome
Module 1: Legislation

Table 2: Assessment criteria for an ethics learning outcome
Module 2 and Module 12: Ethics, Animal Welfare and the Three Rs

Tables 3-4: Assessment criteria for anaesthesia knowledge-based outcomes
Module 9: Anaesthesia for minor procedures
Module 10: Anaesthesia for surgical or prolonged procedures

EXAMPLES OF ASSESSMENT CRITERIA FOR LEARNING OUTCOMES

Table 1: Assessment criteria for a knowledge based learning outcome

***Assessment will test for**: basic understanding of 2010/63/EU and the resulting national legislation relating to animal research*

Module 1: National legislation	
Learning outcome	**Assessment criteria**
Explain the roles and responsibilities of national committees and local animal welfare bodies	The candidate should have retained the information that s/he had been taught and be able to: • list the key roles and responsibilities of the local animal welfare body (in the level of detail as set out in article 27 of the Directive) • demonstrate an understanding of these roles and responsibilities by correctly stating how the student believes the animal welfare body affects their own roles, responsibilities and day to day activities • list the key roles and responsibilities of the country's national committee (e.g. in the level of detail set out in article 49 of the Directive)

Table 2: Assessment criteria for ethics learning outcomes

Assessment will test for: *basic understanding of issues underlying animal research. Student will understand concepts relating to animal experimentation and welfare.*

Module 2: Ethics, Animal Welfare and the Rs (level 1)	
Learning outcome	**Assessment criteria**
Explain that the law is based on a framework which requires weighing the harms and benefits of projects, applying the Three Rs to minimise harms and maximise benefits, and promote animal welfare	The candidate should have retained the information that s/he had been taught and be able to: • state the legal requirements for a harm/benefit assessment (as in article 38) and what this means in practice. For example, list the potential harms for animals (physical and psychological) that should be taken into account; list the permitted purposes for which animals can be used; demonstrate an understanding of the principles of how harms and benefits are weighed • state how this relates to the legal process of project authorisation • state what the Three Rs are and give examples of how they can reduce harms, increase benefits and improve animal welfare
Module 12: Ethics, Animal Welfare and the Three Rs (level 2)	
Assessment will test for: Reflection on issues underlying animal experimentation. Student will be able to explain and discuss concepts relating to animal experimentation and welfare.	
Learning outcome	**Assessment criteria**
Explain that the legislation requires that the justification for programmes of work is assessed by weighing potential adverse effects on the animals against the likely benefits; that harms to animals must be minimised and benefits maximised	The candidate should be able to answer the questions set out for level 1, but should also be able to: • *discuss* the concept of 'justification' for animal use, recognising that there are different perspectives on what constitutes a justifiable harm and benefit and on the weight that different harms and benefits should be given • describe the harms and benefits in their own proposed work and explain how they assess and weigh these • provide examples of how they would integrate the Three Rs into their own area of work

Table 3: Assessment criteria for anaesthesia knowledge-based outcomes

***Assessment will test for**: Understanding of anaesthetic properties of commonly used anaesthetic agents, influence of anaesthetic agents on the animal & scientific outcome, choice of route and whether methods other than anaesthesia are available.*

Module 9: Anaesthesia for minor procedures ***Basic knowledge***	
Learning outcome	**Assessment criteria**
Relate why and when sedation might be used for restraint of a mouse	The candidate will be able to: • State the difference between physical and chemical restraint • State two scenarios when sedation might be required to restrain a mouse • For one of these scenarios, state two advantages and two disadvantages of using sedation for restraint
Learning outcome	**Assessment criteria**
Discuss the relative merits and drawbacks of different anaesthetic agents and their application for a 15-minute anaesthesia of a mouse	The candidate will be able to demonstrate that s/he can: • Name one injectable and one inhaled anaesthetic agent suitable for mice • Describe and comment on the method of administration of an injectable anaesthetic with respect to route, dose volume (including requirement for dilution as necessary) • Describe and comment on the method of administration of a volatile anaesthetic with respect to route, carrier gas and inspired percentage • Compare the characteristics of an injectable and inhaled agent with respect to onset, duration and recovery from anaesthesia • Comment on the possible effect on a study of different anaesthetic agents • Comment on the health and safety implications of using some commonly-used anaesthetic agents

Table 4: Assessment criteria for anaesthesia knowledge-based outcomes - continued

Module 10: Anaesthesia for surgical or prolonged procedures *Basic knowledge*	
Learning outcome	**Assessment criteria**
Know how to monitor a mouse under anaesthesia for a surgical procedure from induction to recovery	The candidate will be able to: • State the clinical signs that indicate that the mouse is suitable for anaesthesia, with respect to factors such as age, any previous procedures, pre-existing pathology. • State the clinical signs that indicate anaesthesia in a mouse, such as respiration rate and quality, evoked reflexes • State what depth of anaesthesia is required for a surgical procedure and what factors would indicate this. • List the signs used to monitor anaesthetic depth and which are most important • Suggest some equipment that might be helpful in monitoring anaesthesia • Be able to record vital signs, such as heart rate, respiration rate, body temperature on an anaesthetic record sheet • Know what clinical signs indicate an anaesthetic emergency and what actions to take • Discuss what are the most relevant clinical signs and physiological parameters that should be measured during anaesthesia and how this can be achieved • Evaluate the changes in clinical signs during anaesthesia that may indicate changing level of anaesthesia • Discuss reasons why level of anaesthesia may change during a procedure, whether or not this causes a problem, and what action should be taken to remedy changes • Explain the consequences of changes in vital signs, such as blood pressure, oxygen saturation, or body temperature for the mouse • Discuss the advantages and disadvantages of using monitoring equipment, such as PulseOximeter, ECG, compared to manual examination of the mouse • Explain the clinical signs that indicate a good recovery from anaesthesia and what action to take if recovery is not as expected. • Evaluate the anaesthetic protocol used with respect to the study and the Three Rs

Appendix III
Illustrative examples of Competence Assessment

Assessment of Competence should

1. include a clear description and explanation of the standards expected
2. reflect the complete procedure (planning, execution, control of outcome)
3. have a time frame in which the procedure can be realistically executed (including e.g. planning of the procedure, workspace preparation and documentation)

Assessment criteria for a practical skill: blood sampling from a conscious rabbit

***Assessment will test for**: Knowledge of indicators of good/poor health or any sign of pain and distress in the animal, knowledge of the influence of restraint on laboratory animals, different routes of blood sampling sites and where appropriate choice of method, sample volumes and sampling frequencies, (as well as effect of "time of day" on sampling).*

Module 7 and 8: Minimally invasive procedures	
Learning outcome	**Assessment criteria**
The trainee should be able to successfully take a blood sample from a *conscious* rabbit without causing the animal undue distress	S/he should be able to demonstrate to the assessor that s/he: • can recognise the normal demeanour and appearance of a healthy rabbit and signs of ill-health, pain or distress in the species • has determined that appropriate authorities exist for the proposed procedures • can pick up, handle and restrain a rabbit in a way that the animal is supported and does not indicate distress • has knowledge of blood volumes, blood sampling routes and techniques suitable for rabbits so that the least invasive, most appropriate is selected • can select and prepare equipment (e.g. correct needle size, clippers/scissors, surgical swabs) • can prepare the sampling site with minimal distress to the animal and collect blood successfully without causing adverse effects (pain, haematoma, bleeding) • knows how to provide appropriate aftercare, including methods for haemostasis and to provide for expected and unexpected events (e.g. can decide on appropriate monitoring intervals) • knows (and can recognise) the adverse effects to look for and how and when to deal with these, and is aware of the need to contact veterinarian or other "designated" person for assistance. • knows how to handle blood samples to ensure adequate labelling and thorough mixing • knows how to keep appropriate records (e.g. cage labels, other procedural records)

Assessment criteria for a practical skill – Anaesthesia

***Assessment will test for**: Choice and understanding of anaesthetic properties, be knowledgeable of influence of anaesthetic agent on laboratory animal and scientific outcome, choice of method as proposed in the procedure*

Module 9: Anaesthesia for minor procedures	
Learning outcome	**Assessment criteria**
The trainee should be able successfully to induce, maintain and recover a mouse from brief (10mins) anaesthesia in a mouse	The trainee should be able to: • Determine that they appropriate legal authorities exist in order to perform the procedure • Know the effects of anaesthesia on the mouse and possible effects on the scientific study • Demonstrate handling the mouse with empathy and appropriate care, such that it is not distressed • Assess the health and well-being of the mouse, such that it is suitable for anaesthesia. Demonstrate obtaining and recording bodyweight. • State an anaesthetic suitable for the species and duration of the procedure • Demonstrate correct setup and safe use of anaesthetic equipment and anaesthetic agents. • Knows proper dosage/concentration and can calculate dose/volumes in case of injectable anaesthetics • Demonstrate correct induction technique (eg induction chamber, injection) • Explain/Name methods of assessing anaesthetic depth and demonstrate one method that can be used, for example, to show that the mouse is sufficiently anaesthetised for the procedure to be performed. Know how to monitor basic physiological functions and demonstrate measurement of respiration rate. • Discuss the possible adverse effects of anaesthesia, such as hypothermia, and describe the steps taken to avoid these. • State what emergency situations may arise and how to manage these. • Demonstrate recovering the mouse from anaesthesia and discuss the clinical signs that indicate good or poor recovery. • Explain after-care of the mouse, including any special nursing care required. • Correctly update records, such as: cage label, unit daybook, medicine and other procedural records.

Module 10: Anaesthesia for surgical or prolonged procedures	
Learning outcome	**Assessment criteria**
The trainee should be able successfully to induce, maintain and recover a mouse from anaesthesia for an invasive surgical procedure	The trainee should be able to: • Determine that there is an appropriate legal authorisation to perform the procedure. • State how the concept of "Refinement" applies to anaesthesia for a surgical procedure. • Relate the effects an anaesthetic agent may have on the mouse and how this may influence the study. • Demonstrate handling the mouse with care, such that it is not distressed • Assess the health and well-being of the mouse. Discuss the effects that previous Procedures or existing pathology may have with regard to suitability for anaesthesia. Demonstrate obtaining and recording bodyweight. • Knows proper dosage/concentration and can calculate dose/volumes in case of injectable anaesthetics • State/Know an anaesthetic suitable for the species and duration of the procedure (may have taken veterinary advice in advance). • Discuss analgesia for the procedure, including choice of agent, route of administration to cause minimal stress to the animal, followed by assessment for effectiveness. • Demonstrate correct setup and safe use of anaesthetic equipment and anaesthetic agents. • Demonstrate correct induction technique (e.g. induction chamber, injection) • Discuss methods of assessing anaesthetic depth for surgery and demonstrate one method that can be used to show that the mouse is insensible to a painful stimulus. • Demonstrate understanding of monitoring basic physiological functions and vital signs, using clinical signs and/or monitoring apparatus such as pulse oximeter. • Discuss the possible adverse effects of anaesthesia, such as hypothermia, and the steps taken to avoid these. • Discuss what emergency situations may arise and how to manage these. • Demonstrate recovering the mouse from anaesthesia and discuss the clinical signs that indicate good or poor recovery. • Discuss after-care of the mouse, including any special nursing care required, such as fluid replacement. • Describe the clinical signs associated with pain and state a suitable system for monitoring post-operatively. • Correctly update records, such as: cage label, unit daybook, medicine and other procedural records. • Discuss interpretation of records in determining the success of the anaesthetic and quality of recovery.

Example of an examination for a practical skill illustrating how each component can be marked

For each task, there will be a set of criteria against which the student will be assessed and a score allocated

A maximum score can only be achieved if the trainee works independently and can describe and explain the task without inquiry by the examiner. The more he/she has to be asked the lower the achieved overall result.

Assignment 1

Euthanasia and removal of tissues

Your task is to euthanize a conscious mouse by cervical dislocation and to dissect the spleen and the left kidney for further analysis. Choose proper technique in line with animal welfare requirements.

Task :	**Percentage** [11]	**Percentage achieved**	To standard[12] **YES - NO**
Preparation of work space	5		□ □
Safe and humane handling of the animal – removing the animal from the cage/pen and transporting to procedure room +*	15		□ □
Safe and humane restraint *	15		□ □
Safe and humane euthanasia and confirmation of death*	30		□ □
Dissection of organs	10		□ □
Record keeping	10		□ □
Cleaning of work space and tools used	5		□ □
Disinfection	5		□ □
Dispose of cadaver	5		□ □
Total	100%		
Comments			

Tasks marked with asterisks must be passed

[11] Percentages are suggestions only. They may vary according to task and focus of evaluation.
[12] Trainee needs at least 6/7 checkmarks. Euthanasia must be performed competently.

Assignment 2

Intra-peritoneal injection

A hamster shall receive a dose of 100/mg/kg BW of substance X i.p. The concentration of substance X is 20mg/ml. Calculate the correct dose and inject the appropriate dose/amount i.p.

Level of expectation:	**Percentage** [13]	**Percentage achieved**
Preparation of work space (15%):		
Use of antiseptic hand rubs & antiseptics application solution		
Selection of the appropriate size of cannula/ needle/ syringe		
Carrying out the procedure (60 %)		
Safe and humane handling of the animal – removing the animal from the cage/pen, transporting to procedure room and return *		
Evaluation of health status		
Measure and record body weight		
Calculation of dose & appropriate volume (15%)		
Filling syringe (air bubbles? volume?)		
Disinfection of injection site	YES NO	
Proper placement of needle, injection of material, and needle withdrawal *	YES NO	
After completion of procedure (10%)		
Cleaning of work space		
Documentation of procedure		
Overall safe working practice for animals & operator		
Total	100%	
Comments		

Tasks marked with asterisks must be passed

[13] Percentages are suggestions only. They may vary according to task and focus of evaluation.

Appendix IV
Training Record Template

AIMS

The aim is to provide a template to record training, core skills and competency which can be utilised throughout Europe. This would provide a level of reassurance regarding the skills and competency of individuals, facilitate mutual recognition throughout Europe to allow staff movement and safeguard animal welfare. The person(s) responsible for ensuring that staff are trained and supervised until competent (Article 24(1)(c)) has/have an important role in ensuring that suitable records are maintained. The templates below are not intended to be prescriptive or exhaustive. It remains the responsibility of the competent authority to determine the mechanisms for recording training and competencies.

Rationale and explanations for EU Training Record Templates

1. The template contains three defined training record sections: initial modular training, training records during skills development, and an external training and CPD section to cover courses, conferences etc. An example is also included of a general training section to cover other non- Directive related areas, such as Health and Safety and Security.
2. A training record is often accompanied by a CV, job description and responsibilities.
3. There are three levels of training/competency: trainee who is "under supervision", "trained and competent" and "trainer for others".
4. A trainee's development should be clearly documented by progression in training records. Equally, the level of supervision should be traceable in the training records.
5. The trainer signatory can be any identified competent trainer. An authorised trainer list can be helpful for trainees.
6. A regular review of training is helpful to consider training development and future needs. Changes to Roles should require a training review to ensure training and competence is achieved for new responsibilities.
7. The trainee should sign and initial to confirm identification in the training record and other documents.
8. The exact module, technique, species involved should be a defined clearly by providing as a separate entry in the training log.

Note in reference to current competent staff and trainers: rather than complete the whole section of the training record for each defined module, the person responsible for training will sign off once on the relevant page to confirm the member of staff is considered competent and/or has historical records to confirm this.

Name: _____ Date Commenced: _____ Signature _____ Initials _____/_____/_____

1. Record of Module Training

Module	Core / Function-specific / Additional	Species	Training Provider	Date of Training (Start)	Date of Training (End)	Confirmed by (Name/title/signature)

Form No.:

Issue Date:

2. Procedures/Skills

Procedure	Species	Trainee under supervision				Competence Achieved			Trainer Status Achieved		
		Date	Level of super-vision	Trainee (initials)	Trainer (initials)	Date	Trainee (initials)	Trainer (initials)	Date	Trainee (initials)	Trainer (initials)

4 – Supervisor present when the procedure takes place providing direct supervision and advice

3 – Supervisor aware when procedures are taking place and available for rapid intervention if required (i.e. in the vicinity of the procedure)

2 – Supervisor aware when procedures are taking place and available to attend to provide advice if required (i.e. in the vicinity of the establishment)

1 – Supervisor aware when procedures are taking place and available for discussion to provide advice if necessary (e.g. by telephone)

0 – No supervision required

Form No.:

Issue Date:

3. CPD and External Training

Training	Internal Review		
	Date	Trainee (initials)	Trainer (initials)
Description and date(s) of course and outcome/certification achieved			

Form No.:

Issue Date:

4. General Training Modules (e.g. Health and Safety; Security)

Training Requirement (internal)	Trainee under supervision			Competence Achieved			Trainer Status Achieved		
	Date	Trainee (initials)	Trainer (initials)	Date	Trainee (initials)	Trainer (initials)	Date	Trainee (initials)	Trainer (initials)

Form No.:

Issue Date:

Appendix V
Recommendations for Person(s) carrying out inspections under Article 34

This Appendix contains Expert Working Group suggestions for a suitable profile for an Inspector and for training in this role. National Competent Authorities for this Directive fully support the aims and contents of these suggestions. However, as the competence for education and training rests primarily with the Member States coupled with the fact that formal competencies on inspection and enforcement differ between Member States, the National Competent Authorities for this Directive are not in a position to formally endorse this particular appendix. It is, however, important that this information is made widely available as its contents can facilitate and provide guidance on a suitable profile and the training of inspectors.

Person(s) carrying out inspections under Article 34

Article 34 requires that competent authorities carry out regular inspections of all breeder, supplier and user establishments, to verify compliance with the requirements of the Directive.

Inspectors may come from different backgrounds, both within and between Member States. As a consequence, their training needs are likely to differ, depending on their previous training and experience in the area of scientific research.

It is acknowledged that all training will not necessarily be completed prior to starting work as an Inspector, where appropriate supervision and support is provided.

Recommended Profile

In order to verify the requirements of the Directive, Inspectors must have a detailed knowledge and a good understanding of the relevant legislation and any relevant national policies. They should understand the different roles and responsibilities of personnel involved, and the basis of and detail required within authorisations for establishments.

Inspectors should have a good understanding of animal welfare, animal breeding and accommodation and care practices.

For inspections within user establishments, to enable verification that the Three Rs, are being implemented as far as possible within the projects being inspected, Inspectors should have a good understanding of project and experimental design, and the content of project authorisations for the establishments being inspected.

This role can be fulfilled by persons with a good understanding of the care and use of animals in scientific procedures, in particular the application of the Three Rs. These can be veterinarians. Biologists or other personnel with appropriate training and expertise in medical, biomedical or

biological sciences can also fulfil this role. Inspectors should have broad, detailed experience in science and scientific methods, experimental design and expertise in, and / or a keen interest in optimising, animal health and welfare.

Inspectors should be proactive and promote improved practice in animal care and use and development and maintenance of a good culture of care. Inspectors may be able to encourage collaboration among key players working within establishments. Team-working among Inspectors will facilitate the dissemination of knowledge and sharing of experiences and will promote consistency.

Inspectors should have "personal authority" deriving from their background, experience and knowledge. Effective interpersonal skills, including oral and written communication is beneficial.

Inspectors should be trained to identify conflicts of interest and how to avoid these. This will allow inspections to be independent and increase public confidence in the regulatory oversight.

Initial training

The training for inspectors should be devised for each individual taking into account the required role having regard for the way in which the Directive is implemented in the MS in question, and previous education, training and experience. Where the role is fulfilled by a qualified veterinarian–with significant experience in the field of animal research, it is likely that the Learning Outcomes of some of the modules will already have been achieved. In such circumstances, following a gap-analysis of the learning outcomes, he/she may be exempted from any of the modules, or from parts of the Inspector Module.

All inspectors should perform a gap analysis of the following modules and review their related Learning Outcomes to ensure that all relevant skills and knowledge are acquired:

- Modules 1 - 3.1
- Modules 4 - 6.1
- Modules 7, 9 - 11
- Modules 20, 23
- Module 51
- Any additional modules such as 21 and 22 when part of the remit of their inspections.

The core training to ensure understanding of the Inspector's role and the requirements of Guidance Document on Inspections and Enforcement http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/inspections/en.pdf are covered in:

- Inspector Module

Unlike for other roles, a number of LOs neither forms a part of inspector's tasks nor responsibilities. Instead they should deliver sufficient **level of understanding to allow compliance to be confirmed**. This should be reflected in their assessment and their training records.

CPD

Inspectors should keep up to date with current best practice in science and animal care and husbandry and the Three Rs by having a formal Continuous Professional Development (CPD) programme.

Inspector Module

This module provides all the necessary elements of the inspection process required by Article 34, and is intended for those who have a very good understanding of the care and use of animals in scientific procedures and the legislation covering such use. It requires a detailed understanding of the legislative requirements for inspection and enforcement, and includes guidance and principles on the design, conduct, and reporting of inspections.

Learning Outcomes

Trainee should be able to:

(i) Understand legislative requirements on care and use of animals in research

Insp.1 Appreciate the ethical issues related to the use of animals in ongoing and / or completed scientific procedures (as case studies)

Insp.2 Show how the concepts of the Three Rs are enshrined within the national legislation implementing European Directive 2010/63/EU. Show a detailed understanding of the principles, and practical implementation of, replacement, reduction and refinement (the Three Rs) in animal care and breeding practices and in on-going and / or completed scientific research projects, in particular

i. show understanding of the potential for implementing refinements through good knowledge of the species being used, good 'welfare assessment', and effective control of adverse effects using clear and valid scientific, welfare and/ or humane end-points
ii. describe how training, good animal accommodation, husbandry and handling arrangements and application of appropriate endpoints can contribute to implementing the Three Rs and improve the quality of science

Insp.3. Discriminate between experimental procedures for animals, and veterinary practice, husbandry and non-experimental procedures

Insp.4. Explain the correct apportioning of projects to purposes of scientific procedures (Article 5)

Insp.5. Describe the grounds for exemption from the requirements to use purpose bred animals of the species listed in Annex 1

Insp.6. Compare the roles, responsibilities and interactions of those working under the Directive within an establishment

Insp.7. Explain the legal composition and the role of Animal Welfare Body

Insp.8. Describe the conditions/requirements for setting free and re-homing of animals

(ii) Understand the principles and practice of inspection

Insp.9. Demonstrate how the detailed controls specified within the legislation apply to inspection

Insp.10. Describe the legal requirements of inspection and other related functions (information gathering, management and dissemination, discussion of Three Rs, continuity, advice to user community and competent authority)

Insp.11. Explain the duties and responsibilities of inspectors including neutrality and probity (honesty, integrity, appropriate conduct, etc.) and the interaction between inspectors and other responsible persons/bodies such as Animal Welfare Body

Insp.12. Describe what an effective inspection should entail (http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/inspections/en.pdf) e.g. approach to inspection, need for liaison/rapport, compliance/non-compliance detection role

Insp.13. Describe the principles of risk analysis, legal requirements for inspection frequency, unannounced versus announced inspections, required standards of performance and assess risk

Insp.14. Describe the key sources of advice and additional knowledge for the inspector on legislation, policy, working practices and case histories

Insp.15. Indicate the required standards of communication (including written reports) to competent authority and stakeholders, and record storage requirements

Insp.16. Describe how to access project proposals, evaluations and authorisations and how to plan an inspection based on this information

Insp.17. Explain how the requirements for marking or identifying animals can be met and how to determine when these have not been met

Insp.18. Describe methods of humane killing of animals used under this legislation and explain how these are permitted

Insp.19. Describe the severity assessment framework including cumulative severity, and the responsibilities of all those involved in having an impact on ameliorating suffering and reducing severity from project conception to completion

Insp.20. Explain prospective assignment of severity and actual severity and the purposes of such assessments

Insp.21. Correctly assign severity classification to samples of animals being bred (GA) and / or used for scientific purpose according to Annex VIII and the EU severity assessment framework document (http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/severity/en.pdf)

Insp.22. Describe appropriate practical methods of assessing welfare and how these can be used to reduce suffering in line with achieving the scientific objectives during inspections of scientific work in progress

Insp.23. Discriminate between re-use and continued use and explain the situations when re-use may be legally authorised

Insp.24. Explain the basis for the collection of annual statistics on animal use in procedures (Article 54 and the related Commission Implementing Decision)

Insp.25. Describe the penalties (e.g. offences and infringements, compliance advice/notices) arrangements for suspension / withdrawal of authorisation and explain how these are reported to the Competent Authorit(y)/(ies) concerned and dealt with

(iii) Appreciate differences in types of designated establishments and animal units, and in the management of animal facilities

Insp.26. Explain the legal requirements for an establishment authorisation

Insp.27. Indicate the sort(s) of animal work likely to be found at each type of establishment

Insp.28. Relate the types of animal holding areas and their main features

Insp.29. Describe the strategies used for maintaining differing levels of biosecurity and precautions to be taken by an inspector to avoid spreading animal pathogens or allergens

Insp.30. Describe strategies involved for minimising animal surplus / over-breeding of animals, including genetically altered animals

Insp.31. Describe strategies for facilitating the sharing or organs and tissues from animals

Insp.32. Indicate the considerations for transport of animals between sites (including national and international transport)

Insp.33. Describe special considerations and methods to be used in inspection of particular types of establishment and projects (e.g. regulatory toxicology projects, work in the wild)

Insp.34. Discuss the care and accommodation requirements of Annex III for each of the relevant laboratory animal species, and explain the potential welfare and scientific consequences where their husbandry and welfare needs are not met

Insp.35. Appreciate the special considerations required for the care and use of certain animals (e.g. non-human primates, animals taken from the wild, stray/feral animals of domestic species and endangered species)

i. discuss the reasons for these groups receiving special consideration and the rationale required for exemptions
ii. identify the parts of the legislation on usage of certain species and exemptions
iii. describe the conditions under which the use of these species is authorised or exemptions granted

(iv) Medicines

Insp.36. Describe good practice in the use of medicines within establishments

(v) Understand the principles of training and assessment

Insp.37. Identify the recommendations for training of personnel as outlined in "A working document on the development of a common education and training framework to fulfil the requirements under the Directive" (along with any additional national or local requirements)

Insp.38. Explain the minimum requirements for records of training and competence and CPD of personnel and describe how these may be reviewed during the inspection process

Insp.39. Describe circumstances in which discretionary exemptions from specific training modules or elements may be permitted

(vi) Understand the principles and methods by which assessment and authorisation of programmes of work are undertaken

Insp.40. Describe the principles of the harm-benefit analysis

Insp.41. Describe the requirements for implementation of the Three Rs within a project

i. indicate sources of information on methods which either fully or partially replace, reduce or refine the use of animals
ii. show understanding of the scope for reduction of animal use through clear experimental strategy, good design, valid analysis and comprehensive reporting of animal studies

Insp.42. Explain how projects are authorised

Insp.43. Correctly determine in on-going and / or completed work, scientific projects which do not comply with project authorisation in relation to using / having used the most refined protocol and earliest humane endpoints consistent with achieving the scientific objectives

(vii) Understand the role of the Inspector as communicator, promoter of good practices and the Three Rs

Insp.44. Discuss the concept of culture of care

Insp.45. List issues which contribute to a good culture of care (a proactive approach to the Three Rs, clear mechanisms for communication between all staff which are used effectively, effective collaboration among key players)

Insp.46. Describe methods which can be used to promote better quality science and reporting (e.g. the use of ARRIVE guidelines)

Insp.47. Explain the benefits of a consistent and pro-active inspection system