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



ANIMAL WELFARE BODIES AND
NATIONAL COMMITTEES

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

A working document on Animal Welfare Bodies and National Committees to fulfil the requirements under the Directive

Brussels, 9-10 October 2014

The Commission established an Expert Working Group (EWG) to prepare guidance on Animal Welfare Bodies and National Committees to fulfil the requirements under Articles 26, 27 and 49 of Directive 2010/63/EU on the protection of animals used for scientific purposes. All Member States and main stakeholder organisations were invited to nominate experts to participate in the work. The EWG met on 11-12 June 2014.

The objectives of the EWG were to develop guidance and principles of good practice with respect to the requirements of the Directive for Animal Welfare Bodies and National Committees to facilitate the implementation of the Directive.

This document is the result of the work of the EWG meetings, 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 9-10 October 2014.

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.

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Introduction

The objective of this document is to provide information to all those involved in the oversight of and in the care and use of animals used in scientific procedures on how the requirements of the Directive with regard to the structure and function of the Animal Welfare Body (AWB) (Articles 26 and 27) and the National Committee (Article 49) may be met.

The Directive states that animal welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. One of the mechanisms of the Directive to achieve this aim is the creation of an AWB in each establishment (with potential exemption for small establishments which may fulfil the tasks of an AWB in other ways). AWBs provide internal oversight and guidance on the day-to-day application of the Three Rs, monitors the work in progress and reviews the outcomes of the work, and may have a positive role in the preparation of a project proposal.

It is important for public confidence and to ensure a level playing field for all those involved in matters related to the acquisition, breeding, accommodation, care and use of animals within each Member State, that there is a coherent approach to project evaluation and the application of the Three Rs. Member States should have the necessary structures and tools to deliver these objectives, utilising the National Committee as appropriate.

Both the AWBs and the National Committees play a fundamental role in establishing and maintaining an appropriate climate of care, often called in practice, and subsequently referred to in this document as, a "culture of care", among the animal user community.

Although the AWB may have input to the project application process, the evaluation of projects is an entirely separate requirement under the Directive. Guidance on Project Evaluation and Retrospective Assessment was developed by an earlier EWG and this was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU at their meeting of September 2013¹. This guidance document is not intended to replicate or reproduce information contained in the Project Evaluation and Retrospective Assessment Guidance document.

¹ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf

Animal Welfare Body

Recital 31

"Animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Breeders, suppliers and users should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. The advice given by the animal-welfare body should be properly documented and open to scrutiny during inspections."

Article 26 – Animal-welfare body

- "1. Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body.*
- 2. The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals*
and, in the case of a user, a scientific member. The animal- welfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25.
- 3. Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means."*

Article 27 - Tasks of the animal-welfare body

- "1. The animal-welfare body shall, as a minimum, carry out the following tasks:*
 - (a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;*
 - (b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;*
 - (c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;*
 - (d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and*
 - (e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.*

2. Member States shall ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least 3 years.

The records shall be made available to the competent authority upon request."

National Committees

Recital 48

"There is a need to ensure a coherent approach to project evaluation and review strategies at national level. Member States should establish national committees for the protection of animals used for scientific purposes to give advice to the competent authorities and animal-welfare bodies in order to promote the principles of replacement, reduction and refinement. A network of national committees should play a role in the exchange of best practice at the level of the Union."

Article 49 - National committees for the protection of animals used for scientific purposes

"1. Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

2. The national committees referred to in paragraph 1 shall exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union."

Animal Welfare Bodies

Benefits of an effective Animal Welfare Body

An effective AWB has many benefits for both animals and science and for the staff working with animals. It provides assurance to the establishment by

- improving animal welfare – including improvements in housing, husbandry, breeding, care and use practices;
- taking a lead role in promoting animal welfare and the responsible care and use of animals bred, held or used for scientific procedures including advising on planned work and work in progress;
- provides advice on good practice and ensures it is implemented as appropriate;
- provides a critical forum to ensure day-to-day application of the Three Rs;
- provides motivation and support for animal welfare and the Three Rs;

- provides advice on the project application process, in particular promotion of the Three Rs, with continued input as projects develop;
- is a main point of contact for any conflicts between animal welfare and science;
- improves link and communication between scientists and animal care takers/technicians;
- influences management to ensure suitable resources to allow delivery of good science and welfare are made available;
- provides for effective liaison with National Committee;
- promotes Laboratory Animal Science - through communication with external stakeholder environment;
- improves public confidence in the quality of scientific work and care provided at establishments;
- fosters a good culture of care;
- improves the quality of science.

Structure, composition and competencies required of Animal Welfare Bodies

The minimum tasks of the AWB set out in the Directive cover a wide range of technical, scientific and management topics, which require input from personnel with a wide range of knowledge, expertise and experience. The minimum membership stated in Article 26 consists of the person(s) responsible for animal welfare and care, and, in the case of user establishments, a scientific member, with input from the designated veterinarian².

Structure

There are many factors which may influence the optimal structure of the AWB including:

- nature of the establishment (breeder, supplier, user);
- size of the establishments including number and complexity of animal units, and number of staff;
- area of research;
- number and type of projects and procedures;
- species and number of animals used;
- institutional structure and organisation – e.g. multiple sites at different locations;
- management style and structure;
- institutional commitment (e.g. allocation of resources);

² Term "designated veterinarian" when mentioned in this document refers to both "designated veterinarian" and "a suitably qualified expert where more appropriate" as per Article 25 of the Directive.

- institutional culture of care – which can vary dependent on the nature of the establishment, for example, academic versus industry, and public versus private sector;
- additional missions and tasks assigned to the AWB within the establishment.

In large complex establishments, the tasks of the AWB are often broken down into smaller components achieved through specialised, focused sub-groups (e.g. an environmental enrichment sub-group), reporting back to a main AWB.

Core competencies

To enable delivery of the tasks and realisation of the full benefits of an effective AWB, the membership should include input from personnel with an adequate level of knowledge, understanding and expertise in a number of key areas. The required competencies can vary according to the specific issues under consideration by the AWB at any point in time, and co-option of additional expertise may be necessary from time to time.

User establishments

- relevant legislation;
- animal ethology, husbandry, care, health and welfare of all the species within an establishment including enrichment practices;
- each of the Three Rs relevant to work within the establishment
 - Replacement alternatives;
 - Reduction through appropriate experimental design and statistical input; efficient breeding programmes;
 - Refinement ensuring that consideration is given to the application of refinement principles throughout the lifetime of animals used in breeding and/or scientific procedures, including methods for alleviation of pain, suffering and distress (e.g. anaesthesia, analgesia) and determination of humane end-points;
- welfare assessment (including recognition of pain, suffering and distress);
- humane killing;
- all of the procedures and animal models used at the establishment;
- the scientific disciplines in which research is undertaken at the establishment.

Additional expertise which can improve the effectiveness of the AWB include:

- communication/interpersonal skills (including presentational, leadership, influencing, organisational, understanding of collective responsibility);
- educational skills;
- quality assurance/auditing skills, where applicable.

Breeding and supplying establishments

In comparison with user establishments, breeding and supplying establishments carry out a more limited range of activities. Therefore, the core competences required can be less extensive. However, the following are considered essential:

- relevant legislation;
- animal husbandry, care, health and welfare of all the species (including genetically altered animals, where appropriate) within an establishment including enrichment practices;
- the Three Rs, in particular Refinement and Reduction, in the context of their application throughout the lifetime of animals used in breeding procedures;
- welfare assessment (including recognition and alleviation of pain, suffering and distress), defined intervention strategies for breeding and health issues, and humane killing;
- expertise in breeding practices.

Composition – involving a wider membership

In view of the extensive knowledge requirements, a broader membership than the minimum required by Article 26 would generally be needed, the exception possibly being in very small establishments with few animals and/or a narrow range of scientific projects/procedures.

The membership should be sufficiently flexible to ensure all aspects are covered – in the case of scientific input, this may vary depending on the scientific issues under discussion. Consideration may be given to a structured use of external networks and experts to supplement the core AWB membership on an ad hoc basis.

Although the membership of the AWB does not require a veterinarian, their input is required under the Directive as it is considered to be very valuable. Therefore a number of Member States have mandated their formal inclusion in their AWBs.

Independent members (from within the establishment or from elsewhere) are also considered important as a means to incorporate broader views and to promote transparency. There are several categories of such members. They may be experts from a relevant field (such as animal behaviour or replacement technology), from a different scientific discipline, or may be completely ‘lay’. They may either be independent of the establishment, or of the science, or of both.

Benefits of a wider membership include

- advice is available on a wider range of scientific, Three Rs, welfare and technical issues - leading to improvements in both animal welfare and science and identification of opportunities for replacing animals, reducing suffering and refining procedures;
- support for specific activities can be shared out e.g. into sub-groups to maximise use of resources and staff time;

- a pool of scientific members from which to select can overcome any conflicts of interest within particular areas of research;
- more members result in access to a wider contacts base (both within and external to the establishment);
- it facilitates developing awareness of, and support for, the AWBs role within the establishment;
- involvement of independent members will bring in a fresh perspective and contribute to openness and transparency and to challenge of the “status quo”;
- representation from senior management can ensure support for the AWB across the establishment;
- a ‘critical mass’ of experts is available, which will provide greater opportunity to debate good practice issues and identify further opportunities to implement the Three Rs.

Challenges of a wider membership include

- strain on resources (time, people, money);
- efficiency may suffer – it may be more difficult or take longer to reach decisions, with more people – and perspectives - involved, in particular in large complex organisations;
- maintaining the balance of different competencies within the AWB membership;
- dilution of responsibility (“someone else will do it”);
- maintaining balanced input from animal care and scientific staff;
- maintaining confidentiality.

Each establishment should determine a suitable size and structure having regard for the complexity of the establishment and the skills required, taking into consideration the potential benefits as well as challenges. These determinations should result in an “optimum size”, which facilitates full delivery of the objectives of the AWB. It should ensure an effective overview of the care and use of animals and buy-in from all staff, and contribute positively towards welfare improvements, effective implementation of the Three Rs and better science.

Meeting the Animal Welfare Body requirements in small breeders, users and suppliers

There is no definition in the Directive of what constitutes a “small” establishment. Two Member States have provided a definition for such establishments – one is an establishment with fewer than 10 staff, the other having fewer than 5 staff and using fewer than 50 animals per year.

In many Member States, all establishments, irrespective of size, are expected to comply with the requirements of Articles 26 and 27 through the establishment of AWBs.

However, in those Member States where small breeders, suppliers and users are allowed to fulfil the tasks of the AWB by other means, the specified tasks must be achieved even where there is no formal AWB in place in line with Article 27 of the Directive.

One of the main challenges in smaller establishments is to provide all the skills and competencies necessary to deliver an effective AWB. Such establishments often turn to external resources to fill any gaps.

External input can broaden the knowledge base, as small establishments can be at a greater risk of failing to remain current with respect to developments in the laboratory animal science field.

Such external input can take the form of:

- using outside experts for specific skills on a case by case basis, in particular on detailed aspects of science;
- pooling resources with other smaller facilities;
- utilising AWBs of larger establishments.

It is important that the tasks are focused and proportionate to meet the local needs.

Some small establishments, in particular where there are similarities e.g. work on farm species, have combined resources and have developed shared AWB tasks.

Dealing effectively with potential conflicts of interest can be challenging, especially when resources are shared between facilities.

The designated veterinarian possesses many of the necessary skills and can contribute in fulfilling the tasks effectively.

Delivering the tasks of the Animal Welfare Body

Each AWB should develop effective terms of reference, ensuring clarity on the roles and responsibilities, and level of authority to all those in the establishment.

These should be endorsed and visibly supported by the management within the Establishment. It is important that all staff are made aware of the existence and role of the AWB, and that they are encouraged to contribute suggestions, and bring matters of concern, to its attention. Such information can be delivered in induction training material for new staff.

An effective communication framework is necessary (often developed in concert with the person responsible for information (Article 24(1)(b)) to ensure efficient dissemination of information within and, as appropriate to other scientists/organisations outside the establishment.

Guidance on delivering the AWB's five key tasks is given below.

i. Advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use

The AWB should be the forum at which new or revised practices relating to the care and use of animals can be considered and endorsed. The AWB may develop tailored practices

in-house taking into account information from a variety of internal and external sources such as new publications, attendance at continued professional development (CPD) events and contacts with other scientists/establishments.

- **Developing local policies and standards including SOPs (standard operating procedures)**

The AWB often reviews and endorses internal standards and practices for aspects of care and use and suggests updates as new knowledge and improved practices become available. For example, it can set out guidance on: the most refined methods for administration and sampling (e.g. volumes, routes) for the species used; severity assessment; management of adverse effects including harmful genetically altered (GA) phenotypes; environmental enrichment, socialisation and habituation strategies; the use of animals in the wild.

The AWB may develop advice on how to deal with exceptions to standard practices (e.g. any requirement for single housing) and how any such exceptions are followed up to assess the impact on the animals.

It may also consider elements linked to transport (e.g. suitability of transporters, climate issues, local establishment issues) and in particular those issues not picked up by other pieces of legislation which, may impact negatively on animal welfare.

- **Dissemination of information on standards and policies within the establishment**

The AWB has a significant role, often in combination with the person responsible for ensuring access to information (Article 24(1)(b)), to ensure that staff are kept well informed of the establishment's requirements regarding welfare, care and use practices, and that such practices are implemented. Improvements or changes in Three R practices need to be drawn to the attention of relevant personnel in a timely manner, and followed up to assess the impact of such changes.

Consideration may also be given to the establishment of an external scientific advisory board that meets at least once a year to consider welfare, use and care practices and the effectiveness of the AWB.

Standing agenda items (e.g. health reports from the designated veterinarian) are considered useful to help disseminate information on new developments to improve the health and welfare of animals in the establishment.

Issues which may be considered include: source of animals, health status, avoidance of surplus animals and promotion of organ/tissue sharing.

ii. Advise the staff on the application of the requirement of replacement, reduction and refinement, and keep them informed of technical and scientific developments concerning the application of those requirements

The AWB can approach this task in a number of ways, for example by

- development of, and input to guidance on application of the Three Rs for inclusion in the Education and Training Framework, including CPD for the establishment;
- identification and dissemination of good practice on the Three Rs e.g. improvement of experimental design and optimisation of group sizes;
- establishment of processes to recognise and reward Three R initiatives and the implementation of these in practice;
- interdisciplinary initiatives in the area of the Three Rs e.g. workshops bringing together *in vivo* and *in vitro* practitioners/experts to explore Three R possibilities;
- internal discussion and analysis to identify areas for future prioritisation for development of Three Rs solutions within the establishment;
- actively encouraging scientists, technicians and care staff to work together to develop and implement refinements;
- ensuring Reduction and Replacement are specifically addressed as well as Refinement – members with expertise in experimental design and developments in alternatives can provide effective contributions on these issues;
- creation of a Three Rs culture within the establishment – for further information, an example of how this may be approached can be found at the NC3Rs³ web-site⁴.

iii. Establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment

The mechanisms adopted to meet these requirements will vary significantly depending on the size of the establishment and the nature and complexity of the work being carried out.

All breeders, suppliers and users should have quality control procedures in place and recorded. These should include the definition, scope and duties of the AWB within the establishment, and the related principles and practices, including procedures for recording, reporting, and managing relevant issues, including mechanisms for preventing recurrence of any problems which arise. The inclusion of specific animal welfare reviews should be considered in these procedures (what/when/how/frequency/reporting and feedback need to be considered).

There may be other management practices in place focusing on operational processes independent from the AWB. However, AWBs should be aware of any that impact on the welfare, care and use of animals. They should ask to receive relevant reports from such processes and be encouraged to input to and provide feedback on them.

³ National Centre for the Replacement, Refinement & Reduction of Animals in Research (UK)

⁴ An institutional framework for the Three Rs <http://www.nc3rs.org.uk/institutional-framework-3rs>

The following suggestions are for mechanisms that will help in establishing and reviewing internal processes. These have worked successfully in establishments, but their applicability will depend on the nature of establishment and no one establishment is likely to have all of them in place:

- formal internal Quality Assurance audits during projects/procedures which may involve input from the AWB;
- specific AWB projects/procedures audits;
- systems for tracking audit findings and responses;
- a Standard Operating Procedure (SOP) on how non-compliance or welfare concerns found during audits are handled, recorded and reported;
- external client audits;
- AWB animal housing facility reviews with input and feedback to scientific and care staff to help promote a good culture of care;
- setting up of an (anonymous) reporting line to enable anyone to report animal welfare concerns outside of their direct management reporting line;
- periodic internal reviews of specific issues, for example, minimising animal surplus, reviewing anticipated versus actual severity and how often humane endpoints are reached;
- reviewing the effectiveness of the systems in place to ensure that animals are adequately monitored, for example, the day-to-day monitoring of individual animals cage-side, observing behaviour and clinical signs and recording these using ‘score sheets’.

For example, EU Guidance Document on a Severity Assessment Framework⁵ recognises that it is good practice to adopt a ‘team approach’ to setting out and implementing a welfare assessment protocol for each study. It also recommends that AWBs play a role in defining protocols for actual severity assessment, to help ensure consistency. A verification process, in which judgements made by different people are compared, is also cited as helping to promote consistent use of the system;

- Inviting external experts to review internal systems and/or animal facilities;
- Processes to report and log welfare issues and if necessary escalate concerns
 - Procedures to track issues and ensure they have been followed up and resolved
 - Ability to use the record keeping system to monitor trends/ recurrence of issues
 - Ensure a specific individual is identified as responsible for tracking and monitoring issues;
- System for internal follow-up of formal competent authority inspections.

⁵ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/severity/en.pdf

iv. Follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement

The AWB can impact positively at all stages of a project, from the early planning, through the formal application process, monitoring of work in progress, and during follow up on project completion.

Input at the project planning and application stage can afford opportunities to improve the quality of applications, ensure that the Three Rs have been implemented and determine whether or not there are suitable facilities and expertise for the work to be conducted within the establishment. Further information and suggestions may be found at "Guiding Principles on Good Practice for Ethical Review Processes"⁶. AWBs can also contribute in a similar way to submissions for project amendments.

It is helpful for the AWB to receive reports after pilot studies for new areas of work where there are some uncertainties over the effects of the procedures on the animals.

Mid-term project reviews, in particular for projects of longer duration, can be used to ensure that the work is on track and that any further opportunities for implementation of the Three Rs are taken.

Internal end-of-project assessment/reports give good opportunities to assess the actual impact on the animals against those predicted, and to determine whether additional Three Rs opportunities can be identified for dissemination. See EU Guidance on Project Evaluation and Retrospective Assessment⁷.

Further approaches which can be utilised by an AWB include

- The AWB can require a system for reporting of any unexpected adverse effects or deaths, or where projected numbers are likely to be exceeded;
- AWBs in consultation with project holders can tailor-make monitoring programmes for animals under-going procedures (see also the EU Working Document on a Severity Assessment Framework – referenced above) which contain:
 - the frequency of monitoring events based on the proposed severity of procedures (defining specific critical steps during the procedure)
 - the training required for individuals monitoring animals (ensures ability to recognise normal/abnormal animal behaviours in context of procedures being applied);
 - a checklist or template of welfare indicators to be evaluated during the monitoring process (e.g. a formal scoring system of welfare, indicators clearly setting out humane end-points);
 - a template for reviewing/discussing findings with the responsible researcher;
 - a template for use at the end of the project to feedback to the AWB;

⁶ <http://www.lasa.co.uk/PDF/GP-ERPJuly2010printFINAL.pdf>

⁷ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf

- The AWB can utilise already available information (for example that included in research grant applications) on animal use to reduce duplication of effort;
- The AWB can establish processes to ensure all relevant staff are aware of AWB practices regarding project oversight, including when information is required and in what format and from whom. It can also establish processes for raising and dealing with concerns (whistle-blowing).

v. Advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed

Although rehoming is permitted under the terms of the Directive (Article 19), it should only take place when specific conditions can be met, namely that

- (a) the state of health of the animal allows it;
- (b) there is no danger to public health, animal health or the environment;
- (c) appropriate measures have been taken to safeguard the well-being of the animal.

There should be national (Member State) guidance in place complemented by local (AWB) guidance on rehoming as this may help minimise undue delays should an opportunity to rehome arise.

The AWB guidance should set out clearly the establishment's conditions to be met. This should include information on:

- Circumstances under which an animal might be rehomed;
- How the animal has been identified as a candidate for rehoming and how its welfare will be maintained/enhanced by inclusion in a rehoming programme;
- Veterinary input necessary to the process and any follow up required;
- Details of health/use/preventive medicine programme as necessary;
- Details of the proposed socialization programme (to be agreed with suitable experts);
- The criteria on which to assess the suitability of a new owner/environment;
- Defined responsibilities and the related declaration templates for new owners;
- Details of any follow up programme;
- Agreed documentation to accompany the animal;
- How to provide ongoing advice, where necessary, to the new owners (e.g. through a named contact person);
- Identification of potential new owners (N.B. collaboration with animal charities, with expertise in rehoming schemes, has proved successful);

A LASA publication provides further recommendations for rehoming of dogs⁸.

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<http://www.lasa.co.uk/PDF/LASA%20Guidance%20on%20the%20Rehoming%20of%20Laboratory%20Dogs.pdf>

Other tasks to which the Animal Welfare Body may contribute

The central role of the AWB in an establishment coupled with the good overview it should have on matters relating to animal welfare, care and use provides a prime opportunity to assist in other related tasks for the benefit of both animal welfare and science should resources permit. Further tasks suggested where AWBs can usefully contribute to welfare and care practices within an establishment include:

- Contributing to the education and training framework and its content within the establishment; liaison with the person responsible for training and competence (Article 24(1)(c)) to ensure that the training and CPD provision remains current and appropriate - the AWB can help to identify issues for updates or refresher training e.g. on anaesthesia;
- Considering the implementation of related legislation such as on live animal transport and biosafety;
- Contributing to the development and implementation of the establishment's communication strategy on animal use – both internal and external;
- Contributing to the prioritisation of resource allocations within establishments.

Fostering a Culture of Care

Ensuring an appropriate culture of care is in everyone's interests, as it will promote improved animal welfare and therefore enhanced scientific outcomes, and give all those involved in the establishment confidence that delivering high quality animal care and use practices is an important priority.

Simply having animal facilities and resources which meet the requirements of the legislation will not ensure that appropriate animal welfare, care and use practices will automatically follow. All those involved in the care and use of animals should be committed to the Three Rs principles and demonstrate a caring and respectful attitude towards the animals bred or used for scientific procedures. Without an appropriate culture of care within an establishment, it is unlikely that welfare and scientific outcomes will be optimised.

The key factors which blend together to foster the appropriate culture of care within an establishment include:

- Appropriate behaviour and attitude towards animal research from all key personnel is of critical importance. Management should be knowledgeable of animal care and use issues with a commitment to provide high animal welfare standards; staff who work diligently, accept individual responsibility at all levels, and are willing to take the initiative to resolve problems should any arise. In summary, an attitude that is not based on complying with the rules alone but on an individual's positive and proactive mind-set and approach to animal welfare and humane science;

- A corporate expectation of high standards with respect to the legal, welfare, Three Rs and ethical aspects of the use of animals, operated and endorsed at all levels throughout the establishment; The establishment will maintain animal facilities to a high standard, and have established policies on animal welfare. Animals will be provided with good veterinary and technical care by well trained staff;
- Shared responsibility (without loss of individual responsibility) towards animal care, welfare and use;
- A pro-active approach towards improving standards, rather than merely reacting to problems when they arise;
- Effective communication throughout the establishment on animal welfare, care and use issues and the relation of these to good science;
- The importance of compliance is understood and effected;
- Those with specified roles know their responsibility and tasks;
- Empowered care staff and veterinarians - Animal care and technical staff are respected and listened to and their roles and work are supported throughout the establishment;
- All voices and concerns are heard and dealt with positively. Personnel at all levels throughout the organisation should be encouraged to raise issues of concern (i.e. there should be a “no blame culture”), and good interaction and communication between researchers and animal care staff should also be encouraged.

How can a good culture of care be developed?

Although, the culture of care should permeate throughout all levels of the establishment, it is essential that senior staff should take the lead, and visibly demonstrate their commitment to, and support for, a good culture of care within the establishment.

Selection of staff utilising tailored recruitment processes which assist recognition of the desired traits. These processes should preferably apply to selection of all those involved in the care and use of animals.

Management should acknowledge and appreciate efforts of staff to promote an effective culture of care, for example as part of staff appraisal criteria or by developing award programmes for Three R initiatives.

Expectations of the establishment with regard to welfare and care practices should be communicated to all personnel, not just those directly involved with animal care and use. These should be further emphasised and expanded in the induction and ongoing training programmes for all those using and caring for animals.

Encourage development of formal and informal communication channels between researchers and care and technical staff for mutual benefit with respect to science and animal

welfare. Encourage links with outside establishments to develop and share good practices, for example inviting in guest lecturers or arranging exchange visits for staff.

Role of Animal Welfare Body in promoting a good Culture of Care

The AWB is in ideal position to drive the culture of care, and should demonstrate effective leadership in this area. The AWB should ensure, in collaboration with senior management, that there are appropriate structures in place to promote a suitable culture of care, and that these are kept under review to ensure the outcomes are delivered effectively.

All relevant staff should be aware of the role of the AWB and be encouraged to contribute ideas and initiatives to further develop good practices.

The AWB should deliver a collaborative, collegiate and non-confrontational approach whilst maintaining authority and achieving implementation of advice

Further suggestions to assist the AWB in achieving a good culture of care:

- Encourage scientists to work with (and value the contribution of) animal care staff;
- Provide information on the role and functions of the AWB for new staff and encourage their contributions;
- Provide for on-going involvement of project holders in the AWB;
- Provide the opportunity and encouragement for any staff member to raise issues with, and to attend AWB meetings;
- Communicate with all staff (presentations/newsletters/web page) and spread the word about the Three Rs, welfare improvements, policy changes, roles of care staff, training persons and veterinarians, and the AWB itself.

Achieving an effective Animal Welfare Body

The legislation requires each breeder, supplier and user to set up an AWB. Significant welfare and scientific benefits can accrue where the role and tasks are delivered effectively. However there are challenges to ensuring effectiveness which have to be addressed.

The key critical elements necessary to achieve an effective AWB are:

Resource

The establishment needs to ensure that there are sufficient resources made available – this includes personnel being given sufficient time to devote to AWB functions, facilities for meetings and administrative support.

Members need to be given the time to attend to AWB duties, including meetings, actions and follow-ups, and dealing with issues between meetings.

Personnel /Competencies

- Members, including the chair, need to have personal qualities that invite technical/scientific respect;
- Independence of members concerning the AWB role, who are free from conflicts of interest during discussions and review of projects;
- Motivated individuals (preferably volunteers) who support the aims of AWBs.
- Links with key named responsible persons under the Directive (Articles 20(2), 24(1), 25, 40(2)(b)) – alternatively these could be included in a wider AWB membership or network;
- AWB members should receive appropriate individual induction training and CPD;
- Sufficient authority delegated to and visible management support for the AWB - with close links and communication with senior management and strategically placed in the establishment organogram;
- Establishments should have clear and established mechanisms to ensure AWB advice is taken and that the AWB has authority to carry through any recommendations impacting on animal welfare in order to enforce their decisions with users. Advice by AWB should be respected, accepted, implemented and followed up.

Structure

Ensure appropriate structure proportionate to the complexity of the establishment

Communication/visibility within organisation

The operational processes and working modalities, including the goals and priorities (e.g. policies, SOPs), of the AWB should be known to relevant staff as should meetings planned and scheduled with agendas, recording of actions and follow up.

Establishment of clear communication channels (formal and informal) is very important

- **within the establishment:** mechanisms should be in place to deliver the relevant information to the correct people in a timely manner. The advice should be properly focussed and targeted to the correct audience. For example:
 - Advice on environmental enrichment for mice should be targeted at all those breeding, caring for, or using mice in an establishment;
 - Advice on refining a commonly used technique (e.g. blood sampling from a peripheral vein) should be targeted at all research teams within the institution who are using the technique;
 - Advice on a technique or model specific to a particular project should be targeted at the research team involved with that project (e.g. the project holder designing the experiments, staff carrying out the procedure/s, veterinarians and animal care staff advising on endpoints and monitoring the animals).

For dissemination of advice, internal web-sites are considered helpful, but should be allied with individual notification by e-mail, or in a regular update, such as an establishment/AWB newsletter.

- **outside the establishment:** for example between the AWB and National Committee and other AWBs.
- **with the competent authority** responsible for project evaluation: depending on the local set up, and where appropriate, this could include interactions to ensure appropriate quality of information in project applications, and in retrospective assessments access to relevant information for all AWB members (including journals, databases etc).

Challenges and possible solutions to achieving an effective AWB

Challenges	Possible Solutions
Insufficient resource/authority/management support - with no effective authority to deal with non-co-operative individuals, or to have advice accepted, or inadequate resource to deliver recommendations.	<p>A heightened awareness within senior management of the key roles and responsibilities of AWB can be conveyed through encouragement/support from competent authority</p> <p>Through feedback on inspections (under Article 34) ; Published guidance on role/expectations of AWBs and Establishments e.g. Compliance; Good culture of care; Adequate composition and skills; Regular meetings; Effectively dealing with problems; Appropriate education and training</p>
Lack of knowledge/understanding of role of AWB; Insufficient in-house expertise; Personnel reluctant to volunteer for AWB role; concerns over conflict of interest	<p>Acknowledgement of importance of role on AWB by management; inclusion of discussion on AWB roles in induction programmes and periodic appraisals.</p> <p>Training and CPD for members of AWB</p> <p>Careful consideration of competencies needed (knowledge, skills and personal competencies) and a selection process for AWB members based on these.</p> <p>Gap-analysis of skills required, and support to seek external expertise as necessary</p> <p>Avoidance of conflict is essential: needs to be given proper consideration and process put in place to avoid this</p>
Poor, unstructured communications from AWB	Support for effective information strategy; develop close links and support for person(s) responsible for information

<p>Not being able to speak freely</p>	<p>All personnel should be encouraged to raise issues of concern, without fear of reprisals. An institutional culture of intolerance of bullying should be developed to facilitate freedom to speak out and address problems.</p> <p>The chairperson should take care to ensure that all members of the AWB are empowered to actively contribute at the meetings.</p>
<p>AWB not taken seriously; Advice not taken or implemented</p>	<p>Proper empowerment of AWB – advice should be taken, unless compelling reasons not to do so.</p> <p>Defining appropriate structures: establishment specific/tailor-made to establishment needs</p> <p>Avoidance of unnecessary bureaucracy: keeping activities appropriate to the establishment; use of existing tools; combination of formal and informal recording</p> <p>Sufficient authority but without losing the 'advisory' role and need to balance these.</p> <p>Maintaining consistency and continuity: overlapping membership terms may help here</p> <p>Obtaining feedback on the given advice: review impact of advice</p>

National Committees

Article 49 and Recital 48 of the Directive describes the requirements for the establishment of National Committees for the protection of animals used for scientific purposes in each Member State. National Committees should advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals and ensure sharing of good practice.

National Committees should facilitate a coherent approach to project evaluation as well as play an important role in the exchange of good practice on the operation of AWBs and project evaluation within the Member State and at the level of the Union.

Although several Member States had a National Committee prior to Directive 2010/63/EU, their functions differed significantly. These committees generally responded to requests from the competent authority, often relating to aspects of the legislation, or in the development of new policies, for example on genetically altered (GA) animals, or to advise on particular types of work e.g. severe procedures in non-human primates. None had significant interaction with local AWBs.

In many Member States, at the time of writing (summer 2014), National Committees are still in the very early stages of development, and even those which existed previously are undergoing some restructuring to meet the requirements of the new directive.

Benefits of an effective National Committee

- Promotes an appropriate level of coherence and consistency on matters relating to the care and use of animals within Member State, directly with AWBs or, as appropriate within the Member State, through regional structures – and within EU;
- Promotes consistency of the conduct of project evaluations within Member State - in particular in those countries where two or more bodies carry out the evaluation;
- Provides good co-ordination within each Member State of advice/information on animal care and use to and between AWBs;
- Creates an effective network of communications with AWBs;
- Provides independent input to animal welfare policies and practice in the field of care and use of animals for scientific purposes;
- Can contribute in the develop of guidance on the implementation of national law;
- Can facilitate discussion on care and use of animals in scientific procedures among relevant stakeholders;
- Can provide a central repository for and effective dissemination of contemporary good practice at national level.

Additional benefits noted, dependent on national structure and applicable national legislation:

- Provides an oversight role in the provision of training in the Member State;

- Can assist the competent authority in effective communication on the use of animals for scientific purposes with general public.

Composition and structures of the National Committees

Composition of Committee

In some Member States, the composition of the National Committee is described in national legislation.

Membership should be well-balanced to promote credibility and confidence among researchers, welfare and care groups and the general public. The necessary competencies include animal welfare, animal behaviour, species expertise, veterinary expertise, ethics, science, alternatives (all Three Rs), experimental design, legislation including regulatory/safety evaluation and animal protection.

Members should be appointed primarily on the basis of the skills and competencies, and perspectives which they can bring to the committee. Whatever their background, the members should be independent in the performance of their functions, and the committee and its members should not be subject to the direction of any other person or organisation in the performance of their duties.

All members should have a good understanding of the legislation and the roles and responsibilities of the National Committee. Depending on the background of individuals, some induction training may be required.

Structure/working practices

Although the work of the National Committee should be independent and impartial, there are generally close links with the competent authority (who may provide administrative support and be involved either as members or observers).

The structure needs to be well co-ordinated in order to ensure that all establishments within the Member State are included within the working plans/communication strategy for the committee. This will be a particular challenge where there are a number of regional structures in place below the national committee.

To facilitate progress with the promotion of a coherent approach to project evaluation, close liaison with the competent authority responsible for carrying out the project evaluation and granting the project authorisation would be beneficial.

What do Animal Welfare Bodies expect of a National Committee?

National Committees are expected to advise AWBs on matters relating to the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of good practice across all establishments.

To meet these obligations there will need to be effective communication between the National Committee and all AWBs, with dissemination of information and sharing of good practice on relevant topics, such as, for example the structure and function of AWBs and developments in animal welfare and the Three Rs.

Other factors to which National Committees may give consideration to achieve the expectations of AWBs are:

- Development of Frequently Asked Questions (FAQs) and guidance on common issues raised by AWBs;
- Development of a forum to exchange information - use of modern IT tools can assist with this;
- Development of general guidance and/or organisation of workshops on common issues raised by AWBs;
- Development of a system of direct (and targeted) communication with relevant senior management, such as the head of institute, to establish or re-enforce the position, role and importance of AWBs e.g. through periodic newsletters;
- Maintenance of an awareness of on-going initiatives in relation to animal care and use, channelling relevant information to AWBs. The National Committee may act as an information hub for online resources and contacts with other players such as, for example, Three Rs Centres, PARERE⁹, EU NETVAL¹⁰, training providers, Laboratory Animal Science Associations;
- Provision of an advice service on areas of difficulty for AWBs e.g. how to consider animal use in areas which are not under project authorisation or on research being carried out by EU scientists in facilities outside the EU (which may not operate to EU standards, and may therefore represent a reputational risk to their home establishments).

Delivering the tasks of a National Committee

The Directive specifies a number of objectives for the National Committee. However, these are very general and therefore guidance could be beneficial as to how these may be delivered in practice.

Core tasks (Article 49)

- Provision of liaison point and support to AWBs;
- Promotion of the Three Rs in the context of advising AWB/competent authority(/ies);
- Provision of advice to competent authorities (preferably both pro- and reactively);
- Dissemination of good practice;

⁹ <https://eurl-ecvam.jrc.ec.europa.eu/about-ecvam/scientific-advice-stakeholders-networks/parere>

¹⁰ <https://eurl-ecvam.jrc.ec.europa.eu/eu-netval>

- Exchange of information on the approach to project evaluation to facilitate a coherent and harmonised approach at national level;
- Provision of guidance on specific topics in the areas of acquisition, breeding, accommodation, care and use of animals;
- Sharing information with other National Committees.

Additional/optional tasks for consideration

- Informing public debate on the use of animals for scientific purposes;
- Providing opinion on draft legislation/guidance;
- Providing suggestions for future research areas and topics relating to animal care and use;
- Providing scientific opinions/expertise on request;
- Advising on the implementation of the Education and Training Framework within the Member State;
- National arrangements following transposition of the Directive may provide for additional tasks – for example, provision of advice on particular types of projects or advice on appeals over project authorisation decisions.

Delivering the core tasks of the National Committee

i. Advice to Animal Welfare Bodies

Each Member State needs to facilitate access for their National Committee to all AWBs within the Member State.

National Committees should correspond with AWBs/National Contact Points to enquire what advice/guidance/communication links would be helpful.

Visits to establishments can help the members of the National Committee become better informed on issues relating to the use and care of animals in scientific procedures, and provide further opportunities to identify issues on which advice would be desirable.

To discharge effectively their advisory role, National Committees need an effective communication strategy which could involve for example:

- meetings with the competent authorities (especially when a number of competent authorities are involved);
- meetings with AWB representatives;
- establishing an AWB network to facilitate communication to/from/and among AWBs.

The National Committee may also

- Endorse and disseminate useful guidance material;
- Develop an information portal and discussion forum for AWBs;
- As necessary, co-opt additional experts/create expert working groups to develop advice on particular issues identified by AWBs (e.g. on assessment of severity).

Ideally, there should be mechanisms in place to determine the effectiveness of the National Committee and its advice, including from Competent Authorities and AWBs.

ii. Sharing best practice in project evaluation

This task will be very dependent on the structures for project evaluation in place within each Member State. Whether or not each National Committee could contribute towards promoting a coherent approach to project evaluation will depend on a number of factors including the number, complexity and range of projects, and the regulations and guidance in place within each Member State.

Among the options available to National Committees to progress this task are, national legislation permitting, to:

- Develop/endorse guidance on project evaluation – this may include guidance to applicants to promote improved submissions;
- Collaborate with those conducting project evaluation e.g. through observer status at meetings. This would be intended to inform those involved in the process – not to become involved in the individual application process;
- Review samples of projects/project evaluations;
- Review performance of the MS on authorisation times for projects (in line with Article 41); gather feedback on the authorisation process from applicants.

Consistency may be further promoted by appropriate training of applicants and project evaluators, and by regular reviews of the outcomes of PE. The National Committee may consider and/or review the content of such training and any guidance available to applicants/evaluators.

iii. Role of National Committee in promoting a good culture of care

The National Committee may contribute in a number of ways by:

- Organisation of a national forum to allow sharing of good practice;
- Ensuring sharing of good practices through the establishment of a national framework to collect, store and disseminate information on good practices;
- Promoting the importance and relevance of a good culture of care to good scientific and animal welfare outcomes;
- Making AWBs aware of, and supporting their role as, the promoter of a good culture of care;
- Utilising the benefits of personal contacts and interactions, in contrast to impersonal 'newsletters' to emphasise the importance of good culture of care.

iv. Promoting consistency at national level

The National Committee can contribute by:

- Contributing to the development, and active distribution of agreed charters/codes of conduct/guidance for carrying out project evaluation, AWB tasks/work, retrospective assessment and non-technical project summaries;
- Contributing to a common framework and standards within the education and training framework.

Dissemination of information from the National Committee of the advice given is deemed helpful as well as feedback from competent authorities and AWBs as to how the advice was followed up, and how effective it proved in practice.

Ensuring an effective National Committee

Member States should ensure National Committees

- have sufficient time and resources to meet expectations;
- have sufficient expertise – membership is often undertaken on a voluntary basis;
- retain continuity of National Committee membership by the use of rotation/overlap of in/out-going members;
- keep up to date on developments on the care and use of laboratory animals.

Facilitating information exchange at EU level

A framework and appropriate tools for information exchange among National Committees (EU National Committees' Network) should be developed.

To assist in this task a restricted discussion forum for National Committee Chairpersons, or nominated representatives, could be created (such as CIRCABC) to disseminate and share information on national activities and policies.

A list of contacts/chairpersons of National Committees should be prepared to assist communication. Meetings of the chairpersons of the National Committees (or their nominees) from each Member State should be established, to facilitate the sharing of experiences and good practices.

National Contact Point meetings should have a standing agenda item on National Committee updates, to follow the development of National Committees and to discuss issues of concern.

Meetings of National Committees should exchange good practices on specific issues as well as develop guidance on issues of common concern.

National Committees should meet and contribute at international meetings on science/animal welfare, to further promote and develop work of National Committees.

Sharing of national reports, including summaries of progress, is considered good practice where these are available.

