

## Standards of accommodation and care for animals used in scientific procedures in Europe

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### Abstract:

The regulation of the use of animals for experimental and other scientific purposes and the determination of minimum required standards of animal care and accommodation within Europe is generally informed by recommendations and conventions at the level of the Council of Europe (CoE) and by legislation within the European Union (EU). Each signatory party (CoE) and Member State (EU) is expected to use these "European" recommendations to inform standards in their own country.

The United Kingdom (UK) has implemented these recommendations within the Animals (Scientific Procedures) Act and the related Codes of Practice for the Housing and Care of Animals used in Scientific Procedures, and in Designated Breeding and Supplying Establishments.

Provisions are made in the UK Codes of Practice for the housing and environment of the animals including sections on the construction of animal holding rooms and rooms where procedures are conducted, staffing and provision of veterinary services. Also included are recommendations for the environment in which animals are kept, including for example temperature, relative humidity, noise and lighting.

There are also sections on animal care and health which provides guidance on the animal accommodation (cage/enclosure), including minimum sizes and stocking densities.

In 1997, the Council of Europe determined that, in view of the advancements in knowledge on laboratory animal housing and care practices since the relevant convention (ETS123) was adopted in 1986, a review should be made of these recommendations. Following a lengthy process involving the key stakeholder organizations and input from many technical experts, new recommendations were agreed within the Council of Europe in June 1996 and these entered into force in the signatory countries in June 2007.

The European Union adopted a Recommendation in June 2007 to align the EU legislation (Directive EC86/609) with the revised Council of Europe guidelines.

**Keywords:** legislation, Europe, care, accommodation

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### Introduction:

The care and accommodation provisions for animals undergoing scientific procedures in Europe are generally informed by the technical Annex/Appendix attached to the European Directive 86/609 EC (Annex II) and the European Convention ETS123 (Appendix A) regarding the protection of animals used for experimental and other scientific purposes. These technical documents provide additional guidance to member countries on the interpretation of Articles contained within the Directive/Convention which set out the basic principles for care provision.

Within the UK, Codes of Practice have been issued which set standards for the care of animals undergoing scientific procedures and for the breeding and care of the main laboratory animal species bred for subsequent use.

In June 2007, following ten years of discussion, revised technical Appendices were introduced, which

will have a significant impact on the care and use of laboratory animals for scientific purposes within Europe.

This paper will provide a brief description of the legislative framework within the UK, the main provisions on care and accommodation within the Convention ETS 123 and Directive 86/609, the background and procedures for change to the technical Appendix to ETS123 and some examples of the key changes which have been adopted.

### United Kingdom (UK) legislation

The Animals (Scientific Procedures) Act 1986 came into force on 1 January 1987 and makes provision for the protection of animals used for experimental or other scientific purposes in the United Kingdom. It replaced the Cruelty to Animals Act 1876 and implements the requirements of the European Directive 86/609/EEC.

The Act regulates experiments and other scientific procedures that may cause pain, suffering, distress or lasting harm to protected animals (all vertebrates plus a single invertebrate species, *Octopus vulgaris*). Under the Act, two kinds of licence are required: the procedures must be part of a programme of work authorised by a Project Licence and any person carrying out regulated procedures must possess a Personal Licence.

Project licences will only be issued if the likely benefits (to man, animals or the environment) outweigh the costs to the animals involved and if there are no alternatives which replace animal use, reduce the number of animals needed or refine the experimental design to minimise suffering.

Applicants for personal and project licences have to satisfactorily complete accredited training programmes.

With a few exceptions such as fieldwork, any establishment where regulated procedures are carried out must also be covered by a Certificate of Designation, held by an individual occupying a position of authority. Under the terms of the 1986 Act, project licences are granted for a maximum of 5 years and personal licences must be reviewed at least every 5 years.

In 2006, there were around 14,500 Personal Licence Holders, 2800 Project Licences and 213 licensed establishments.

Certificate of Designation holders are required to nominate one or more Named Animal Care & Welfare Officers (NACWOs) to be responsible for the day to day care of the animals; and one or more Named Veterinary Surgeons, or another suitably qualified person, to be responsible for providing advice on animal health and welfare.

Codes of Practice have been issued for the housing and care of animals used in scientific procedures, and for animals held in designated breeding and supplying establishments. It is expected that the standards of accommodation and care within these establishments meet or surpass the minimum provisions of these codes.

These Codes of Practice contain sections on Housing and Environment, Animal Care and Health and on Humane Killing of animals.

The Housing and Environment section covers aspects of facility security, room lay-out and construction, provision of procedures area, service and support facilities, technical staffing and training, provision of veterinary services, and expectations on the environment and environmental controls. The importance of maintaining suitable environmental controls, including temperature, relative humidity, ventilation, lighting, noise, on animal health and welfare and scientific outcomes is emphasised.

Animal Care and Health covers issues such as

transport, acclimatisation and quarantine, enclosure dimensions, including flooring and provision of nesting/bedding material, food and water provision, exercise, and handling.

The Humane Killing section provides information on suitable killing methods, both physical and chemical, for the common laboratory species.

The "breeding" Code of Practice provides additional guidelines on the special needs of breeding animals, and has specific guidance on each of the commonly used species.

Members of the Animals (Scientific Procedures) Inspectorate carry out visits, mainly without notice, to establishments designated under the Act to determine whether scientific work is authorised, to inspect the premises and to check that the terms and conditions of licences issued under the Act are being observed. In 2006, around 2300 visits were made.

Further details of the UK legislative system and on the Codes of Practice can be found at :- <http://scienceandresearch.homeoffice.gov.uk/animal-research/>.

### **Council of Europe Convention ETS123**

The Council of Europe (CoE), which currently has 46 member states, was established in 1949 to promote international cooperation. The general aims are to protect human rights, to promote awareness and encourage the development of Europe's cultural identity and diversity, to seek solutions to problems facing European society (for example environmental protection and human cloning), and to promote democratic stability in Europe by backing political, legislative and constitutional reform. The main Council instrument is the Convention—an agreement to impose common standards and practices that are binding only on the member states that choose to sign and ratify. However, there are no legal penalties for failing to comply with Conventions.

In 1986 the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes was opened for signature, and this entered into force in 1991.

The provisions of this Convention cover areas such as care and accommodation, conduct of experiments, humane killing, authorisation procedures, control of breeding or supplying and user establishments, education and training, and collection of statistical information.

Article 5 of the Convention states that any animal used or intended for use in a procedure shall be provided with accommodation, an environment, at least a minimum degree of freedom of movement, food, water and care, appropriate to its health and well-being. Any restriction on the extent to which an animal can satisfy its physiological and ethological needs shall be limited as far as practicable. In the

implementation of this provision, regard should be paid to the guidelines for accommodation and care of animals set out in Appendix A to the Convention. The environmental conditions in which animals are bred, kept or used shall be checked daily. The well-being and state of health of animals shall be observed sufficiently closely and frequently to prevent pain or avoidable suffering, distress or lasting harm. Each Party shall determine arrangements to ensure that any defect or suffering discovered is corrected as quickly as possible.

The Convention provides for Multilateral Consultations of the Parties at least every five years, to examine the application of the Convention and the advisability of revising it or extending any of its provisions according to changed circumstances and new scientific evidence. The Multilateral Consultations are prepared by a working party. Multilateral Consultations were held in 1992, 1993, 1997 and 2006.

Further information on the Convention can be found at [http://www.coe.int/T/E/Legal\\_affairs/Legal\\_co-operation/Biological\\_safety\\_use\\_of\\_animals/Laboratory\\_animals/](http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Biological_safety_use_of_animals/Laboratory_animals/).

### **European Union**

In contrast to the Council of Europe, the European Union (EU) is focused on economic and political union. Primarily through Directives and Regulations, member countries are obliged to adopt common policies and approaches toward these ends. In 2007 the number of countries in the EU increased to 27. The European Commission monitors transposition and implementation, and noncompliance is dealt with through legal proceedings in the European Courts.

The EU is a member of the Council of Europe and it seeks to represent EU countries on relevant issues within the Council of Europe.

Directive 86/609/EEC aims at harmonising national provisions covering the welfare of animals used for experimental and scientific purposes. The Directive includes measures related to the use of experimental animals such as their housing and care, requirements for the authorisation of persons and establishments and the minimisation of pain, suffering and distress of these animals. Annex II to the Directive is very similar to Appendix A to ETS 123 and, as with the Convention, offers guidance to the Member States on the interpretation of Article 5 of the Directive which includes the obligation to ensure that all experimental animals shall be provided with housing, an environment, at least some freedom of movement, food, water and care which are appropriate to their health and well-being, and that any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited to the absolute minimum.

In June 2007, Commission Recommendation 2007/526 EC replaced the existing Annex II guidance, with new guidelines aligned to the revised Council of Europe guidelines (Appendix A of Convention ETS 123), on accommodation and care of laboratory animals.

### **Revision to Appendix A**

At the 1997 Multilateral Consultation a resolution on the accommodation and care of animals was adopted which contained supplementary guidance, based on developments in housing and care practices since the Convention was introduced in 1986. At the same meeting, it was agreed that, as scientific knowledge and experience had progressed since adoption of ETS123 in 1986, a Working Party should be convened to consider the revision of Appendix A.

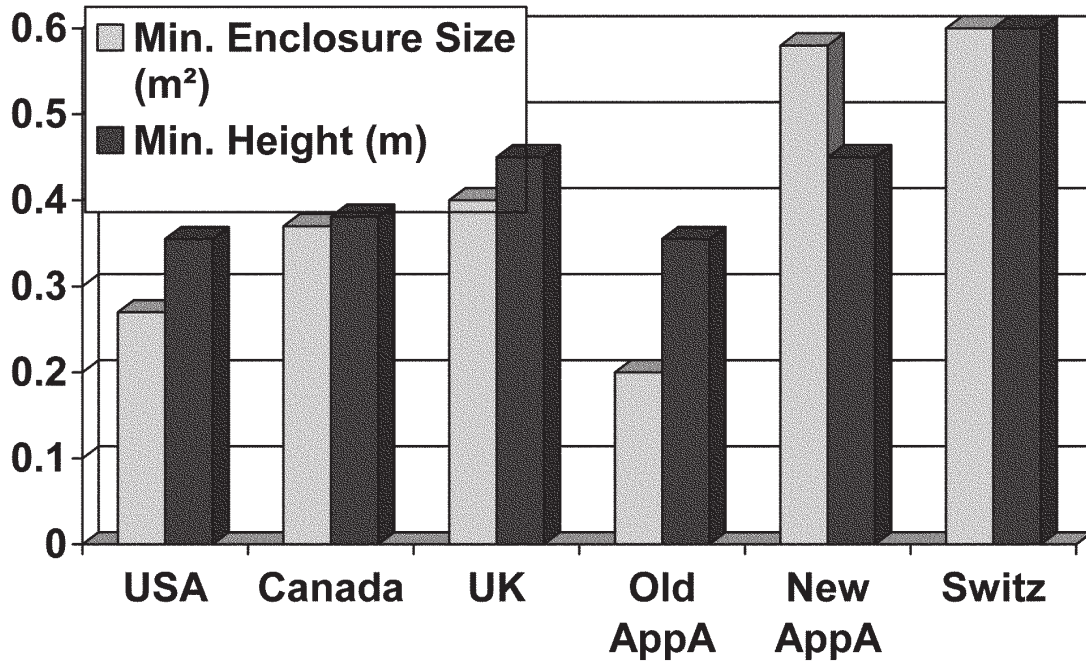
The revision of Appendix A began in 1998 and was concluded at a Multilateral Consultation in June 2006.

Organisations who attend the Meetings of the Parties were invited to nominate experts to contribute to discussions on the revision of Appendix A.

The first meeting of the Working Party was held in January 1999 in Strasbourg. Representatives from the Member States were invited together with representatives from the key stakeholder organisations involved with the care and use of animals in scientific procedures. Small Expert Groups were subsequently convened to prepare proposals for the common laboratory species, which would supplement the guidance contained in the general section of Appendix A. Initially, additional guidance from the experts was requested on rodents, rabbits, dogs, cats and non-human primates. Subsequently, the Working Party agreed that guidance on additional species should be included and additional expert groups were established to produce proposals for the commonly used farm species, mini-pigs, birds, reptiles, amphibia and fish.

In addition to their proposals for changes to Appendix A, the Expert Groups provided background material and justification for any proposed changes to existing text. These documents are posted at the Council of Europe web-site. The initial remit from the Working Party to the Expert Groups was that changes should only be proposed where there is scientific evidence that welfare will be enhanced, and that due consideration should be given to any impact such changes may have on scientific objectives. Perhaps not unexpectedly, it proved difficult in some circumstances to produce compelling scientific evidence for change, simply because many basic behavioural studies have not been done. In such circumstances, it was accepted that the recommendations could be made based on the practical experiences of the experts having consideration of current practices.

Table 1. - Comparisons of Minimum Enclosure Sizes - 3.5kg Rabbit



Note – For the Revised Appendix A and the Swiss Guidelines the enclosure size can include the shelf area where provided.; USA – ILAR Guidelines ; Canada – CCAC Guidelines

#### Convention ETS 123 Appendix A (adopted June 2006)

The revised document has two main sections, a general section, applicable to all animals, and a species-specific section which gives recommendations for all the commonly used laboratory species, including provisions for farm animals, birds, amphibia, reptiles and fish.

The general section acknowledges that although there are often highly conflicting interests between the scientific requirements and the needs of the animal, the basic physiological and ethological needs of the animals (freedom of movement, social contact, meaningful activity, nutrition, water) should be restricted only for the minimum necessary period of time and degree.

The importance of good communication between scientists and animal care staff is emphasised to ensure that any compromise to animal welfare is minimised to a level consistent with the scientific objectives of the study.

As a minimum, animals should be socially housed wherever possible, and be provided with an adequately complex environment to allow the animals to express a wide behavioural repertoire.

The promotion of social housing and encouragement towards a complex environment has resulted in significant increases in minimum enclosure sizes. The proposed new dimensions should provide an improved environment for the animals, and eliminate the welfare problems associated with some

of the existing standards, for example the skeletal damage found in rabbits housed for long periods in small cages (1, 2). Table 1 provides a comparison of the minimum enclosure size and heights for an adult rabbit between the old and revised Appendix A, together with some comparisons of housing codes from other countries.

Similar increases in enclosure sizes for other species have been incorporated in the revised document, for example the minimum enclosure size for an adult beagle has increased from 2.8m<sup>2</sup> to 4m<sup>2</sup>, and for an adult cynomolgus monkey from 0.7m<sup>2</sup> to 2m<sup>2</sup> (with the minimum height also increasing from 85cm to 180cm). Changes have also been made to minimum space allowances for animals kept in groups, and for some classes /ages of animals this will significantly reduce holding capacity – for example the minimum floor area per animal for rats > 600g increases from 350cm<sup>2</sup> to 600cm<sup>2</sup>.

FELASA has published a "EUROGUIDE" (3) which provides a concise "user- friendly" version of the revised Appendix A, and includes the key housing and care requirements for each laboratory animal species together with the Tables of enclosure dimensions and stocking densities.

#### Revision to European Directive EC/86/609

The European Commission is presently undertaking a revision of EC/86/609. This process has been in progress for a number of years and a draft document is expected shortly. The main aims of the revision are

to achieve a significant improvement in the welfare of animals undergoing scientific procedures, and to promote a level playing throughout Europe for those undertaking research on animals. The commission has sought advice from a number of experts and has undertaken a public consultation. Among the main issues under consideration are the scope of the Directive, for example should certain invertebrates or immature forms be afforded protection, the sourcing and justification for use of non-human primates, a severity/benefit assessment of animal use, controls on re-use of animals, humane methods of killing and purpose-breeding for scientific use.

One issue of significant relevance to standards of accommodation and care which has been raised during discussions on the revision is a proposal to incorporate the requirements in Annex II (which is broadly the equivalent of Appendix A of ETS123) as minimum standards (at present the Annex only provides guidance/information to Member States on the interpretation of Article 5).

#### **Summary:**

A recent comprehensive review of accommodation and care practices has recently resulted in changes to the technical appendices to the main European legislation relating to the use of animals for scientific purposes. These changes are expected to improve the welfare of animals used and the quality of science generated.

Further changes can be anticipated within Europe when the outcome of the present revision of the relevant European Directive is known.

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