

WC6 Follow-up Symposium

**“Regulation for Animal Experiments Based on 3Rs and,
Assessment and Accreditation for Laboratory Animal Care”**

The Science Council of Japan

Japanese Society for Alternatives to Animal Experiments

22 (Fri.) – 23 (Sat.) February, 2008

Roppongi Hills Mori Tower 49F and 51F

General Information

Organized by: Science Council of Japan

<http://www.scj.go.jp/>

Japanese Society for Alternatives to Animal Experiments

<http://wwwsoc.nii.ac.jp/jsaae/>

Date: 22 (Fri.) – 23 (Sat.) February, 2008

Venue: Roppongi Hills Mori Tower 49F and 51F
Roppongi Hills Mori Tower Academyhills 49
6-10-1 Roppongi, Minato-ku, Tokyo 106-6155, Japan
TEL : 03-6406-6220
URL : <http://www.academyhills.com/>

Access: Tokyo Metro H Hibiya Line H04 Roppongi Station
0 min. walk from Exit 1C (Direct link to concourse)

Toei Subway E Oedo Line E23 Roppongi Station
4 min. walk from Exit 3

Fri. 22 Feb.	Symposium Welcome Reception	Conference Room 6 (49F) Roppongi Hills Club (51F)
Sat. 23 Feb.	Symposium Reception	Tower Hall (49F) Library Café (49F)

Program

Fri. 22 February, 2008

- 15:00 - 17:00 Symposium
18:00 - 20:00 Welcome Reception

Sat. 23 February, 2008

- 10:00 - 10:10 Opening remarks Yasuo Ohno (National Institute of Health Sciences)
Makoto Asashima (Science Council of Japan)

Part I A regulation trend inside and outside this country

- 【Chair】** Hajime Kojima (National Institute of Health Sciences),
Masaharu Akita (Kamakura Women's University)
- 10:10 - 10:30 *Revision of the Act on Welfare and Management of Animals and Guidelines for proper handling of Laboratory Animals*
A. Ueda (Ministry of the Environment)
- 10:30 - 10:50 The guideline of the animal experiment in the Ministry of Health, Labour and Welfare
10:50 - 11:30 *Accreditation and Inspection of Animal Experiments according to Current Legal Requirements in the USA*
A. Rowan (The Humane Society of the United States)
- 11:30 - 12:10 *Accreditation and Inspection of Animal Experiments According to Current Legal Requirements in Eu Countries*
H. Spielmann (Freie Univ. Berlin)

12:10 - 13:30 Lunch Break

Part II The on-site correspondence and third person certification

- 【Chair】** Yasuo Ohno (National Institute of Health Sciences)
Noriho Tanaka (Hatano Research Institute, Food and Drug Safety Center)
- 13:30 - 14:00 *Guidelines for Proper Conduct of Animal Experiments by the Science Council of Japan*
H. Karaki (Science Council of Japan)
- 14:00 - 14:20 *The Current Status for Inspection of Animal Experiment conducted in National Institute of Health Sciences*
Y. Kodama (National Institute of Health Sciences)
- 14:20 - 14:40 *AAALAC International accreditation in Japan*
T. M. Kurosawa (Osaka University)
- 14:40 - 15:00 *Learning from the accreditation of AAALAC International*
T. Agui (Hokkaido University)
- 15:00 - 15:20 *The Assessment and Accreditation Laboratory Animal Care plan by Japan Health Science foundation*
Y. Sasaki (Japan Health Science foundation)
- 15:20 - 15:40 *Coffee Break*
- 15:40 - 17:25 **Panel Discussion “Regulation for Animal Experimentation”**
【Chair】 Makoto Hayashi (National Institute of Health Sciences),
Chizuko Yamaguchi (Japan Animal Welfare Society)
- 【Panelist】** Animal welfare organizations
Hiroimi Kamekura (JAVA), Asako Araki (ALIVE)
Keiko Yamazaki (The Japanese Coalition for Animal Welfare)
Japanese Society for Alternatives to Animal Experiments
Hiroyoshi Ninomiya (Azabu University)
- 17:25 - 17:30 Closing Remarks
President, Japanese Society for Alternatives to Animal Experiments
- 18:00 - 20:00 Reception (at Library Café)

Abstracts

Revision of the Act on Welfare and Management of Animals and Guidelines for proper handling of Laboratory Animals

Akihiro Ueda

Director, Animal Welfare and Management Office, Policy and Coordination Division,
Nature Conservation Bureau, Ministry of the Environment

1. Revision of the Act on Welfare and Management of Animals

Today, Animal especially pets such as dogs and cats are an important part of a spiritually rich lifestyle in Japan.

Unfortunately, however, all of us have heard stories of behaviors that have become social problems; namely, animal cruelty and abandonment, and animal sales by unscrupulous business dealers. Furthermore, the numbers of public nuisances such as noise and bad smell caused by bad-manner pet owners or pet owners who own large numbers of pets and accidents caused by animals have increased.

Given these circumstances, the Act on Welfare and Management of Animals (Enacted in 1973, 1st Revision 1999) was revised in June 2005 to further promote the welfare and appropriate management of animals.

Main key points are related to 3R's (Replacement, Reduction, Refinement) for Laboratory Animal, Animal relating business etc.

2. Guidelines for proper handling of Laboratory Animals and related issue

While the supply of animals for scientific purposes is an essential part of scientific advancement and technical development, efforts must be made to handle such animals appropriately by remembering that they are living beings. They must therefore be treated with consideration for their physiology, ecology, and habits, and with a sense of gratitude.

Ministry of the Environment has established Guideline raising and keeping of Laboratory animals in 2006. Other ministry and Science council of Japan also set specific guidelines.

In Japan, Each laboratory set and observes on voluntary basis.

ACCREDITATION AND INSPECTION OF ANIMAL EXPERIMENTS ACCORDING TO CURRENT LEGAL REQUIREMENTS IN THE USA

ANDREW N ROWAN

Humane Society of the United States, 2100 L Street NW, Washington, DC 20037, USA
phone +1-301-548-7770 ; fax +1-301-548-77268 ; e-mail: arowan@erols.com

The protection of laboratory animals and the oversight of research in the USA are divided among a number of government and private entities. These include the U.S. Department of Agriculture (the Animal Welfare Act), the Public Health Service (the PHS Policy on Humane Care and Use of Laboratory Animals), a few individual states and various private entities (e.g. AAALAC International, PRIMR, SCAW, CAAT) who either run private certification schemes or who are involved mainly in education. The basic approach relies on “enforced self-regulation” via a local institutional committee. These committees are either mandated by the Animal Welfare Act for regulated institutions or required if one wishes to receive funding from the Public Health Service. The talk will review the various elements of these animal research oversight mechanisms and comment on how well they are functioning.

ACCREDITATION AND INSPECTION OF ANIMAL EXPERIMENTS ACCORDING TO CURRENT LEGAL REQUIREMENTS IN EU COUNTRIES

HORST SPIELMANN, Federal Institute for Risk Assessment (BfR), Centre for Alternative Methods to Animal Experiments (ZEBET), Berlin; Freie Universität Berlin (Free University Berlin), and Alternative Congress Trust (ACT) Germany, Berlin, Germany

phone +49-30-8412-2270 ; fax +49-30-8412-2958 ; e-mail: horst.spielmann@bfr.bund.de

The protection and welfare of animals is a wide area covered by a considerable number of pieces of EU Community legislation. Areas include wildlife, animals in zoos, farm animals, animals in transport and, last but not least, animals used in scientific experiments. The latter are covered by **Directive 86/609/EEC “On the Protection of Animals used for experimental and other scientific Purposes”**. Animal experimentation, be it for the development of new chemicals or medicines, for physiological studies, for studying environmental effects or for testing new food additives, has to be carried out in compliance with Directive 86/609/EEC. This EU Directive is currently under revision.

The European Commission has adopted on 18 June 2007 **Recommendation 2007/526/EC “On Guidelines for the Accommodation and Care of Animals used for experimental and other scientific Purposes**. The Recommendation will align EU legislation with the revised **Council of Europe Guidelines (Appendix A of Convention ETS 123) “On Accommodation and Care of Laboratory Animals”**. This Recommendation reflects the current best practice and the latest scientific knowledge on good husbandry and care of experimental animals. It assists Member States in the implementation of Article 5 of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

Directive 86/609/EEC and Recommendation 2007/526/EC are defining the conditions for authorisation of experimental projects conducted on experimental animals, the authorisation and inspection of establishments, where animal experiments are being conducted, the authorisation of persons carrying out procedures using animals and being responsible for directing or designing procedures and projects.

Authorisation of projects, establishments and persons dealing with experimental animals and inspections are key elements of the legal framework for the protection of experimental animals in EU Member States. Another important element is the ethical evaluation of projects comprising of an assessment of the scientific aims, incorporation of the “Three Rs”, assigned severity classes and harm-benefit analysis.

All establishments shall have installations and equipment suited to the species of animals housed and/or to the performance of the procedures conducted. Their design, construction and method of functioning shall ensure that the procedures are performed as effectively as possible in the line with the principles of refinement, reduction and replacement. Each establishment shall have sufficient trained staff, including a minimum of persons responsible on site for the welfare and care of the animals bred, kept or used in the establishment, an animal welfare officer and a person responsible for the functioning and maintenance of the

equipment used on the animals. According to the EU legislation the position of an animal welfare officer (NACWO Notified Animal Care and Welfare Officer) has for the first time been introduced in most EU Members States. Education and training of personnel should follow recommendations of FELASA (Federation of European Laboratory Animal Sciences Associations), which is focusing on the following groups with different levels of academic background and responsibilities, e.g. animal care staff, personnel responsible for performing procedures on animals, scientists directing the project and animal welfare officers (in the UK veterinary surgeons).

National Competent Authorities (CA) will provide authorisation to an establishment after evaluation of the application. After authorisation of an establishment the CA should ensure the establishment act according to EU legislation thus keeping it's authorisation rightfully. The National CA will visit to verify at least once per year that breeding, supplying and user establishments comply with the recommendations of the general provisions and the species specific provisions of the EU Directive and its annexes. Unannounced inspections are encouraged.

Guidelines for Proper Conduct of Animal Experiments
by the Science Council of Japan

Hideaki Karaki

The Second (Life Science) Department, The Science Council of Japan

In 2004, the Science Council of Japan issued a proposal entitled “Promotion of public understanding of animal experimentation”. On receipt of this proposal, the Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labor and Welfare compiled basic policies for the conduct of animal experimentation and requested the Science Council of Japan (SCJ) to prepare detailed guidelines to serve as a reference material or a model when research institutions compile their own specifications for animal experimentation, and SCJ submitted the guidelines in 2006.

The Current Status for Inspection of Animal Experiment conducted
in National Institute of Health Sciences.

Yukio KODAMA
NIHS

Based on Animal Experimentation Guideline in the Ministry of Health, Labor and Welfare, “Regulation of The Animal Care and Use in National Institute of Health Sciences” was established. Animal Experiment Committee approves the animal experiments conducted in National Institute of Health Sciences in the light of the regulation. In order to perform appropriate inspections, Guideline of Inspection for Animal Experiment is established, 156 experiments having been approved as of January, 2008. Several members from 14 committeemen selected from 20 research divisions are appointed each experiment, they passing judgment within 3 weeks. The experimental protocol consists of 3 parts; Part I describes careers of researchers, aim of the study and the experimental procedures. Part II describes species and number of animals examined, and the way of handling animals. Part III describes policies for care and management of experimental animals.

AAALAC International accreditation in Japan

Tsutomu Miki Kurosawa, DVM, M.Phil, Ph.D, DVCS, DJCLAM
The Institute of Experimental Animal Sciences, Osaka University Medical School

The final goal of Refinement is the alleviation of pain and distress. This might be completed with the systematic approach rather than the theoretical preparation of rules and documents for laboratory animal welfare.

In Japan, the alleviation of pain and distress is thought to be achieved by the establishment of ACUC which reviews experimental protocols. The president of the research organization is responsible for the proper conduct of animal experimentation with adequate manpower and facility and the consequence of this program should be reported publicly. However, for example, the alleviation of pain and distress is almost impossible without the expert as a ACUC member in laboratory animal anesthesia. The early recognition of distress of animals cannot be achieved without well trained technicians.

In advanced countries, the third party's inspections and recognition of laboratory animal care program are conducted to assure the proper conduct of animal experimentation in research organizations. AAALAC which used to be one of committees of AALAS was independently founded in 1964. It has become an international organization. The European and Pacific Rim offices have been established and it accredits laboratory animal care program as AAALAC International. The accreditation is made with the site visit by Ad Hoc consultants and councils.

There were not any accredited organizations in Japan after the first Ad Hoc consultant was nominated more than ten years ago while there were many organizations accredited in Asian countries. Three year ago, Ina research Inc. has been accredited as a first accredited organization in Japan. Since then there are 5 Organizations fully accredited including Hokkaido University Veterinary School which is the first academic organization with accreditation in Japan. The increase in number of accredited academic organization will be expected for laboratory animal welfare.

Learning from the accreditation of AAALAC International

Takashi Agui, DVM, Ph.D, DJCLAM
Laboratory of Laboratory Animal Science and Medicine
Department of Disease Control, Graduate School of Veterinary Medicine,
Hokkaido University

AAALAC International is one of the NPOs, which accredits the Institution, of which laboratory animal care and use program is appropriate. More than 730 Institutions in 30 countries have been accredited by AAALAC International. Accreditation is achieved through peer-review if the Institutional care and use program follows the ILAR's (Institution for Laboratory Animal Research) Guide (for the Care and Use of Laboratory Animals). The School of Veterinary Medicine, Hokkaido University achieved full accreditation on October 26, 2007. Because this is the first case for Japanese Universities, I will state the process and significance of the accreditation in this lecture.

On the other hand, the Japanese Animal Welfare Act was revised in 2005, and the Guidelines were issued from the Science Council of Japan (SCJ) and the Ministry of Education, Culture, Sports, Science and Technology-Japan (Monkasho), respectively in 2006. Especially Monkasho's Guideline demands that the Institutional self-regulation should be achieved under the leadership of the President of the Institution, not by each division of the Institution as before. Based on this Guideline, Hokkaido University organized the Institutional Animal Care and Use Committee (IACUC) and established the Regulation concerning Laboratory Animal Care and Use Program in April, 2007. The regulation of Hokkaido University and the direction and peer-review by the IACUC are all based on the SCJ Guideline.

This situation requests us in the School of Veterinary Medicine to deal with the double standard, that is, "AAALAC and ILAR's Guide" versus "Regulation of Hokkaido University and the SCJ Guideline". Due to the double standard, however, we could find some inappropriate issues and demerits in the Japanese system, which will be introduced with some proposals in this lecture.

The Assessment and Accreditation Laboratory Animal Care plan
by Japan Health Science foundation

Yayoi SASAKI

Executive Director, Japan Health Science foundation

The Ministry of Health, Labour and Welfare notified "Guide for the Care and Use of Laboratory Animals in the jurisdiction organization of the Ministry of Health, Labour and Welfare" in June, 2006. It requests that animal experiments conducted institutions comply with it and voluntary management for Care and Use of Laboratory Animals.

Japan Health Science foundation is advancing the preparation for the third party evaluation business concerning adaptability to "Guide for the Care and Use of Laboratory Animals in the jurisdiction organization of the Ministry of Health, Labour and Welfare" under the cooperation of Japan Pharmaceutical Manufacturers Association.

Concretely, the committee for the preparation is set up in November, 2007, and discuss the name, the purpose, the criterion, the checklist, the submitting material, and the management, etc. The business are scheduled to start at the spring of 2008.

Can A Third-Party Accreditation System Save Animals?

February 23, 2008

NPO Japan Anti-Vivisection Association
Director Hiromi Kamekura

JAVA is a citizen's group established in 1986 that opposes animal testing and seeks abolition of animal experiments. In 1997, JAVA became a supporting member of the Japanese Society for Alternative to Animal Experiments.

Together with other major animal protection groups in Europe, Canada and the United States, we have set up ICAPO (International Council on Animal Protection in OECD Programmes) and ICAPPP(International Council on Animal Protection in Pharmaceutical Programmes) .

“Supporting animal experiments” and “seeking reduction and abolition of animal testing” are completely contradictory to each other and therefore cannot be carried out at the same time.

At the symposium, we are going to verify the third-party accreditation systems which have already been adopted in European countries and the United States, and show how the systems have actually been working. Based upon this careful study, we are strongly against the introduction of a third-party accreditation system that has no time limit for abolition of animal testing and could be controlled by researchers.

The 3R's and Consumer Responsibility: Developing the Educated Consumer

The Japanese Coalition for Animal Welfare

Keiko Yamazaki

The concept of the 3R's has been the focus of much attention now for many years. In recent years, the concept has even been introduced in the wording of the Animal Welfare Law of Japan. However, there is still a large obstacle which stands in the way of its implementation on a wider scale. That, put very simply, is the motivation of those in R and D. Needless to say, the call for higher moral standards, the need to adhere to the ever increasing trend in society to respect life, etc., are but a few of the numerous factors now emerging in society that necessitate the reorganization of strategies for utilizing animals in research experiments. But one of the main factors influencing the social behavior of human kind is economics. Especially, in the field of R+D in the private corporate sector, the economic factor is just as important as the ethics and animal welfare factors. This in turn means that consumer trends must be considered. In the field of preventive medicine, the concept of appropriate knowledge and information being of equal importance as vaccination has been growing in recent years. But this concept can apply, in fact, to any field. During the WC6 in August, 2007, the author presented a paper on how feedback on a Human Animal Relations lecture series based on rational and objective analysis of information, presented to a population of young adults (university, vocational college) clarified the fact that many perspectives held by the general public are based on misinformation. An interim analysis of approximately 400 individual feed backs showed animal experiments to be ranked among the top 5 items reported as "opinion changed after information." If the consumer can be properly educated the concept of the 3R's has the potential of becoming a powerful marketing tool. Just as the words "environmentally friendly" gives added value to a product, the 3R's will certainly appeal to the intelligent consumer. But in order for this to work, the seeds must first be sowed, i.e. the critical work of increasing not emotional but intellectual consumers must be undertaken.