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Theme Topic on "Unraveling Animal Welfare"

Japanese Policy on Animal Welfare: An Instructive Example for Scientific Animal Experimentation

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Abstract

Takahashi-Omoe H, Omoe K. Japanese Policy on Animal Welfare: An Instructive Example for Scientific Animal Experimentation. ARBS Annu Rev Biomed Sci 2008;10:T63-T78. Animal use for scientific purposes, 'animal experimentation', is conducible to scientific development, protecting human health, civilized way of life and so on; however, animal use for human advantage is controversial. Despite of the heated discussion on the rights and wrongs of animal experimentation, animals have been used for research, testing and education in many nations under management systems for the appropriate use of animals from both scientific and ethical viewpoints. Previous efforts to achieve a delicate balance between the scientific rationale and animal protection involve the welfare of animals in scientific procedures. In Japan, each institution where animal experimentation is conducted independently regulates its use of animals under the Ministry's fundamental guidelines, without legal binding force. The management systems are so-called 'self-regulated' or 'self-motivated' management and they are unique, a departure from those in other nations, and fit Japanese religions, traditions and regulatory and administrative frameworks of science and technology. However, several tasks for the management systems for further animal experimentation have become apparent, in response to the new mode of the experimentation developed by the progress of science, technology and animal welfare issues. Here, we describe the current management systems and the future tasks for animal experimentation in Japan. This attempt will provide material for further discussion about animal experimentation and contribute to build an international consensus about animal welfare in scientific procedures.

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1. Introduction - Gap in Management of Animal Experimentation among Nations

Animal use for scientific purposes, 'animal experimentation', is conducible to scientific development, protecting human health, civilized way of life and so on; however, animal use for human advantage is controversial. Despite of the heated discussion on the rights and wrongs of experimentation, animals have been used for research, testing and education in many nations under management systems for the appropriate use of animals from both scientific and ethical viewpoints. Previous efforts to achieve a delicate balance between the scientific rationale and animal protection involve the welfare of animals in scientific procedures.

The management systems of animal experimentation vary among nations, some based on legislation on the protection of animals used for experimental and other scientific purposes (Directive 86/609) (European Union) (Council of the European Communities, 1986); others on peer review or other forms of non-legislated overseeing (Canada) (Canadian Council on Animal Care, 2008), and yet others on a combination of legislated and non-legislated overseeing (United States) (US Department of Agriculture, 1998; Institute for Laboratory Animal Research, 1996; Office of Laboratory Animal Welfare, 2002). In Japan, each institution where animal experimentation is conducted (hereinafter, institution) independently regulates its use of animals under the Ministry's fundamental guidelines, without legal binding force. The management systems are so-called 'self-regulated' or 'self-motivated management' (Omoe, 2006; Takahashi-Omoe & Omoe, 2007). In all nations, the management systems for animal experimentation are based on the international basic principles of humane experimental techniques for laboratory animals, the 'three Rs' tenet of replacement, reduction, and refinement of animal usage (Russell & Burch, 1992) or the 'five Rs' of the 3Rs plus responsibility and review (hereinafter, 3Rs or 5Rs). The 3Rs or 5Rs are currently recognized as the measures for animal welfare in scientific procedures and are applied to animal experimentation around the world.

As described above, Japan has regulated animal experimentation based on self-motivated management systems. These management systems have continued without any critical problems; however, they have acquired a reputation for being opaque by other nations. Unfortunately, Japan has long been misunderstood to not have consistent management systems for animal experimentation. This misunderstanding seems to have been resolved by enforcing the Ministry's fundamental guidelines for animal experimentation in 2006 (Ministry of Education, Culture, Sports, Science and Technology, 2006); however, it should be kept in mind that Japan has long managed experimentation without any severe

mishaps, even before introducing the Ministry's fundamental guidelines. Japan has a policy of promoting self-motivated management systems for animal experimentation without strict laws and regulations and treats the Ministry's fundamental guidelines as a measure for executing these systems.

In this report, we introduce Japan's management systems for animal experimentation in order to provide material for further discussion about animal use in scientific procedures. This report describes how the Japanese concept of animal experimentation is different from other nations and reflects the religions, traditions and regulatory and administrative frameworks of science and technology in Japan. Additionally, the status of animal experimentation conducted in Japan is described, focusing on the number of laboratory animals used. We hope that this report will be valuable to reconsider the significance of animal experimentation and contribute to build an international consensus on animal welfare in scientific procedures.

2. Legislation Process for Animal Experimentation in Japan

2.1. Concept for treatment and management of animals

In the course of establishing a concept for the treatment and management of animals, Japanese included their religions, traditions and regulatory and administrative frameworks of science and technology, and adopted the ideas and actions of other nations. Generally, it is considered that Japanese ideas of the relationship between humans and animals have been affected by Buddhism, which has been tightly linked with 'animism' and has been adopted in Japan (Ministry of the Environment, 2004). These features are described below.

    a. Guilt for killing and wounding animals, which is based on the tradition of 'ahimsa';

    b. The idea that humans and animals are equal from the viewpoint of existence, which is based on the tradition that Buddha's soul dwells in all earthly things;

    c. The idea that human life is linked to animal life, which is based on the tradition of transmigration (samsara).

As described above, Japanese embrace the idea of transmigration between humans and animals; however, they consider that humans and animals are not ranked equally and that humans are always dominant over animals. This people-centered idea is symbolized by the Japanese thought that humans might descend downward (transmigrate) to a lower form of being, such as an animal, if they commit many wrongful acts.

The above ideas, influenced by Buddhism, have been perpetuated among the Japanese and have affected their emotional response to animals. Based on these ideas, the Japanese justifies the use and killing of animals for their advantage and holds memorial services for sacrificed animals, incorporating methods to reduce their feelings of guilt about animal use. This established practice has also been introduced into animal experimentation; for example, most Japanese institutions where experimentation is performed currently hold voluntary memorial services for laboratory animals every year.

The legislation for animal experimentation has been established according to the above ideas and by adjusting the related regulations to prevent abuse, for protection, humane treatment and management of animals.

2.2. Legislation to prevent animal abuse

The concept for the treatment and management of animals was first applied in Japan for livestock as horses and cows (Ministry of the Environment, 2004). Over time, this concept became the norm in Japanese society. The first legislation relevant to the treatment and management of animals was the 'Law to Punish Criminal Offenses' enacted in 1908. The law prevented the physical abuse of livestock visible to the public. Nevertheless, the original purpose of the law was to protect human feelings from the brutal spectacle, not to protect animals themselves. After implementing this law, the House of Councilors and the Japan Association for Animal Protection tried to establish a law for animal protection, but failed (Table 1).

Table 1. History of the development of management systems regarding animal care, use and management.

Year	Regulations stipulated or submitted as drafts	Remarks
1951	Law for the Prevention of Cruelty to Animals	Formulated by the House of Councilors, but not executed*
1963	Wildlife Protection and Hunting Act	The 'Hunting Act' stipulated in 1895 was amended and renamed
1965	Law for the Prevention of Cruelty to Animals	Formulated by Japan Association for Animal Protection , but not executed*
1966	Law for the Protection and Control of Animals	Formulated by the House of Councilors and the related organizations, but not executed*
1973	Law for the Protection and Control of Animals	Formulated by the initiative of the lawmakers
1980	Standards Relating to the Care and Management of Laboratory Animals	Formulated by the Prime Minister's Office.
1987	Notification 'Animal Experimentation in Universities and Similar Institutions'	Notified by the Ministry of Education (currently, Ministry of Education, Culture, Sports, Science and Technology)
1995	Notification 'Guidelines on the Disposal of Animals'	Notified by the Prime Minister's Office
1999	Law for Humane Treatment and Management of Animals	The law stipulated in 1973 was amended and renamed
2006	Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain	The standards stipulated in 1980 were amended and renamed by the Ministry of the Environment
2006	Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology	Formulated by the Ministry of Education, Culture, Sports, Science and Technology
2006	Basic Policies for the Conduct of Animal Experimentation in the Ministry of Health, Labour and Welfare	Formulated by the Ministry of Health, Labour and Welfare
2006	Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Research Institutions under the Jurisdiction of the Ministry of Agriculture, Forestry and Fisheries	Formulated by the Ministry of Agriculture, Forestry and Fisheries
2006	Guidelines for Proper Conduct of Animal Experiments	Formulated by the Science Council of Japan
2006	Fundamental National Policy on Animal Treatment	Formulated by the Ministry of the Environment

This chronological table is based on our interpretation of data from the Ministry of the Environment, 2004. These laws and regulations, except for the ones marked with *, were implemented.

2.3. Legislation for protection, humane treatment and management of animals

The catalyst for promoting the protection, humane treatment and management of animals was the 'Law for the Protection and Management of Animals' established in 1973 (Table 1) (Cabinet Secretariat, 2008). After being amended twice, in 1999 and 2005, and renamed the 'Law for the Humane Treatment and Management of Animals' (Law No. 50, June 2005), the law was firmly established and disseminated the Japanese concept for the humane treatment and management of animals. This law is comparable to various animal welfare acts formulated by other nations.

The 'Law for the Humane Treatment and Management of Animals' consists of 2 items: to 'give rise to a general environment of humane treatment of animals and contribute to the cultivation of respect for life, feeling of fellowship and peace through the treatment of animals', and to 'prevent violation of our life, body and belongings by animals' (Article 1 of the law 2005). The law phrases animals as

'animate things' and requires Japanese nationals not to kill, injure or distress them unnecessarily, and to treat them appropriately with due consideration of the coexistence of humans and animals and animal behavior (Article 2). According to the law, all animals relating to humans are covered by humane treatment and the management systems for selling, keeping, lending, training and showing animals.

2.4. Rules and regulations for managing animal experimentation

The above 'Law for the Humane Treatment and Management of Animals' also stipulates the basic principles for animal experimentation in Japan. The law defines animal experimentation as the 'Utilization of animals for education, testing, research and development, manufacture of biological products, or other scientific purposes' and requires the humane treatment of animals based on the 3Rs (Article 41 of the law 2005).

Under the 'Law for the Humane Treatment and Management of Animals', the 'Fundamental National Policy on Animal Treatment' (Ministry of the Environment, No.140, October 2006) was stipulated in 2006 to disseminate the concept of the law throughout Japan (Ministry of the Environment, 2006). The policy clearly specifies the Japanese concept of animal welfare as described below.

> "We are beings that live by using other living beings and sacrificing their life; therefore, we should not deny that we have to use and sacrifice animals for our survival and should gravely accept animal use in our life as a natural act in the order of life. However, we must not trivialize the lives of animals or use animals unnecessarily. It is necessary to cultivate respect for life, feeling of fellowship, and peace in our society, as described in the purpose of the 'Law for the Humane Treatment and Management of Animals', to pay respect to the lives of animals and treat animals humanely".

This description in the National Policy, encompassing animal welfare, is generally applicable to all Japanese people. The concept also offers a rationale for conducting animal experimentation in Japan.

3. Current Management Systems for Animal Experimentation in Japan

3.1. System overview

As described above, the principles for animal experimentation in Japan are shown in the 'Law for the Humane Treatment and Management of Animals' and the related national policy. Meanwhile, the code of conduct for experimentation is based on two kinds of regulations; the standards and guidelines referring to 'animals', as the 'Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain' (Ministry of the Environment, Notification No.88, April 2006), and guidelines on 'experimentation', as the 'Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities' (formulated independently by the following three ministries in 2006: the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Agriculture, Forestry and Fisheries, hereafter the fundamental guidelines) (Ministry of Education, Culture, Sports, Science and Technology, 2006; Ministry of Health, Labour and Welfare, 2006; Ministry of Agriculture, Forestry and Fisheries, 2006) and the 'Guidelines for Proper Conduct of Animal Experiments' formulated by the Science Council of Japan (June 2006, hereafter the practical guidelines) (Science Council of Japan, 2006) (Fig. 1). The law, policy, standards and guidelines have a basic role in the conduct of animal experimentation; however, they can not legally restrict experimentation. The Japanese management of animal experimentation is based on a system strongly reflecting the responsibility of each institution and animal experimenter, such as researchers in the

institution; therefore, the Japanese system involves a so-called 'self-motivated management' or 'self-regulation' of animal experimentation. The details of the management system in each institution are shown in 3.2. and 3.3.
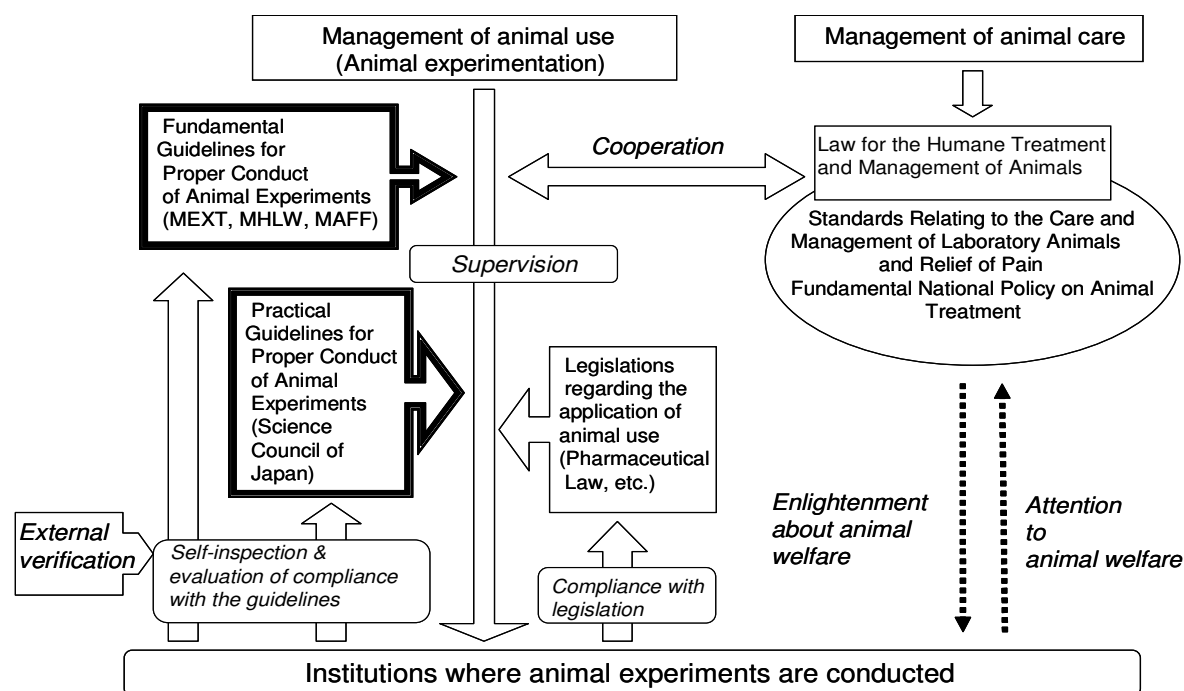

Figure 1. Framework of the management systems for animal experimentation in Japan.

Depending on the purpose of experimentation, it may be subject to several laws, such as the 'Pharmaceutical Law' that regulates animal testing for medicines, and the ministerial ordinance for experimentation using genetically modified animals under the 'Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms' (Law No.97, June 2003) (Japan Biosafety Clearing House, 2003), which was formulated to ensure the precise and straightforward implementation of the Cartagena Protocol on Biosafety that Japan ratified in November 2003 (Convention on Biological Diversity, 2000). However, these have been not integrated into a single comprehensive law with overall control of animal experimentation in Japan. The overall picture of the related legislation is shown in Fig. 2.

3.2. National guidelines

As described in 3.1., there are two kinds of guidelines specific to animal experimentation in Japan: the fundamental guidelines formulated by the related ministries and the practical guidelines by the Science Council of Japan. The former fundamental guidelines have a central role in managing animal experimentation. Although the guidelines are formulated and managed independently by 3 ministries, the basic policy is common, as a matter of course. The fundamental guidelines were formulated independently by these ministries because they can work out details of their content, depending on the variety of purposes of animal experimentation. In the fundamental guidelines, animal experimentation is defined as described below.

'Animal experiments and related activities are necessary and unavoidable for gaining scientific insight into the biological activities of living organisms, but they must be performed properly, taking into consideration the welfare of animals' (preamble to the guidelines). The guidelines therefore require experiments to have a fine balance between the scientific rationale and animal welfare.
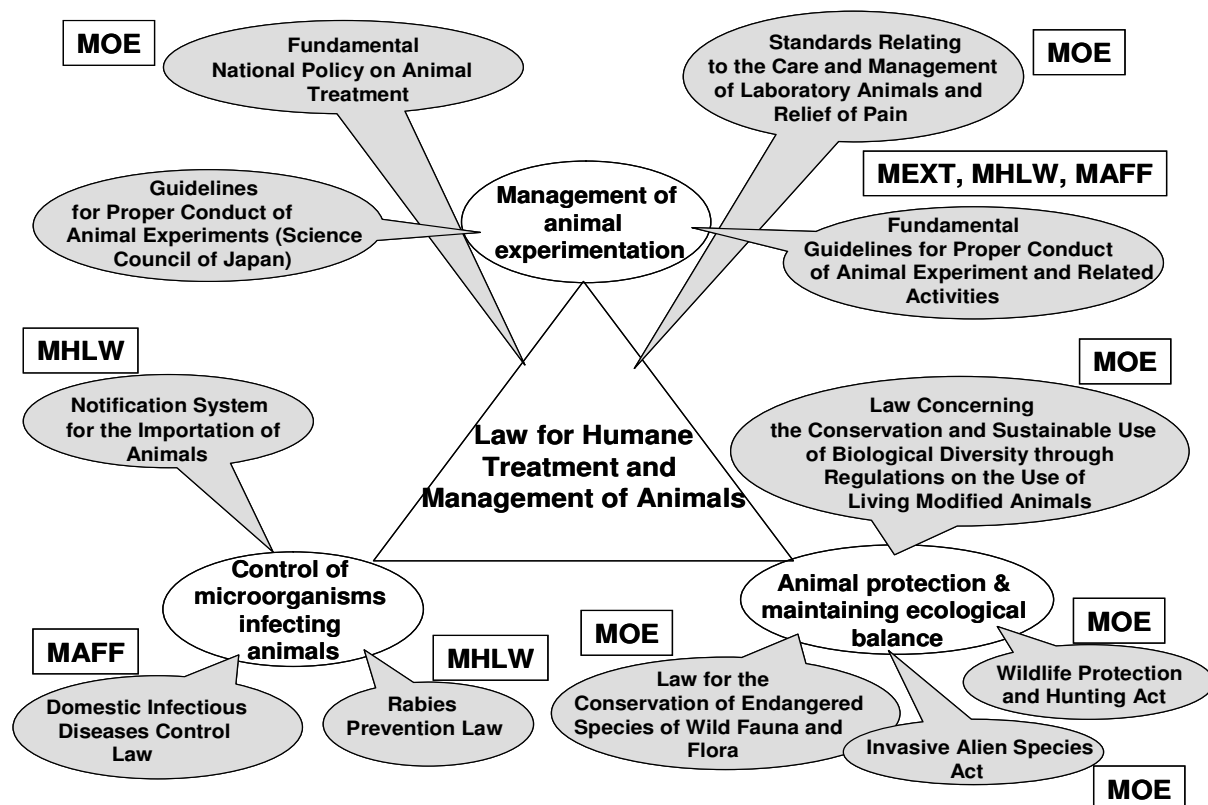
Figure 2. Overall picture of Japanese legislations regarding animal care and use. MEXT: Ministry of Education, Culture, Sports, Science and Technology; MHLW: Ministry of Health, Labour and Welfare; MAFF: Ministry of Agriculture, Forestry and Fisheries; MOE: Ministry of the Environment.

The guidelines define the framework for self-motivated management systems of animal experimentation by each institution, which involves living mammalian, avian and reptilian species, but not amphibians, fish and dead animals. The framework of the guidelines consists of the responsibilities of the director of each institution, including the establishment of institutional regulations and the approval of protocols for each animal experiment, etc. (Article 2 in the guidelines by the Ministry of Education, Culture, Sports, Science and Technology, 2006), the establishment of an institutional animal care and use committee (Article 3, as above), special attention to the conduct of animal experimentation (Article 4, as above), the rearing and maintenance of laboratory animals (Article 5, as above), and the provisions of education and training relating to animal experimentation, self-inspections and evaluation of compliance with the guidelines, external verification of the results of the self-inspections and self-evaluations, and public disclosure of information regarding the conduct of animal experimentation.

The latter practical guidelines formulated by the Science Council of Japan maintain consistency with the above fundamental guidelines and serve as reference material and a model when institutions compile their own specifications for animal experimentation according to the Ministry's fundamental guidelines. The details of the guidelines are shown in the document by the Science Council of Japan, 2006.

3.3. Institutional regulations

The above fundamental and practical guidelines for animal experimentation have set out the basic concept for compliance in every institution. Under these guidelines, the director of each institution sets out unique internal regulations to manage their own experimentation (hereafter, institutional regulations), introducing useful foreign references such as the 'Categories of Biomedical Experiments Based on Increasing Ethical Concerns for Non-human Species' formulated by the Scientists Center for Animal Welfare (SCAW) (Orlans *et al.*, 1987), which improves animal experimentation from the viewpoint of 'Refinement' in the 3Rs. Almost all institutions have their own regulations and have revised them according to the fundamental and practical guidelines, if needed. The overall view of the institutional regulations is shown in Fig. 3 and an example of the regulations is available on the web of the Japanese Association of Laboratory Animal Facilities of National University Corporations (Japanese Association of Laboratory Animal Facilities of National University Corporations, 2008a).
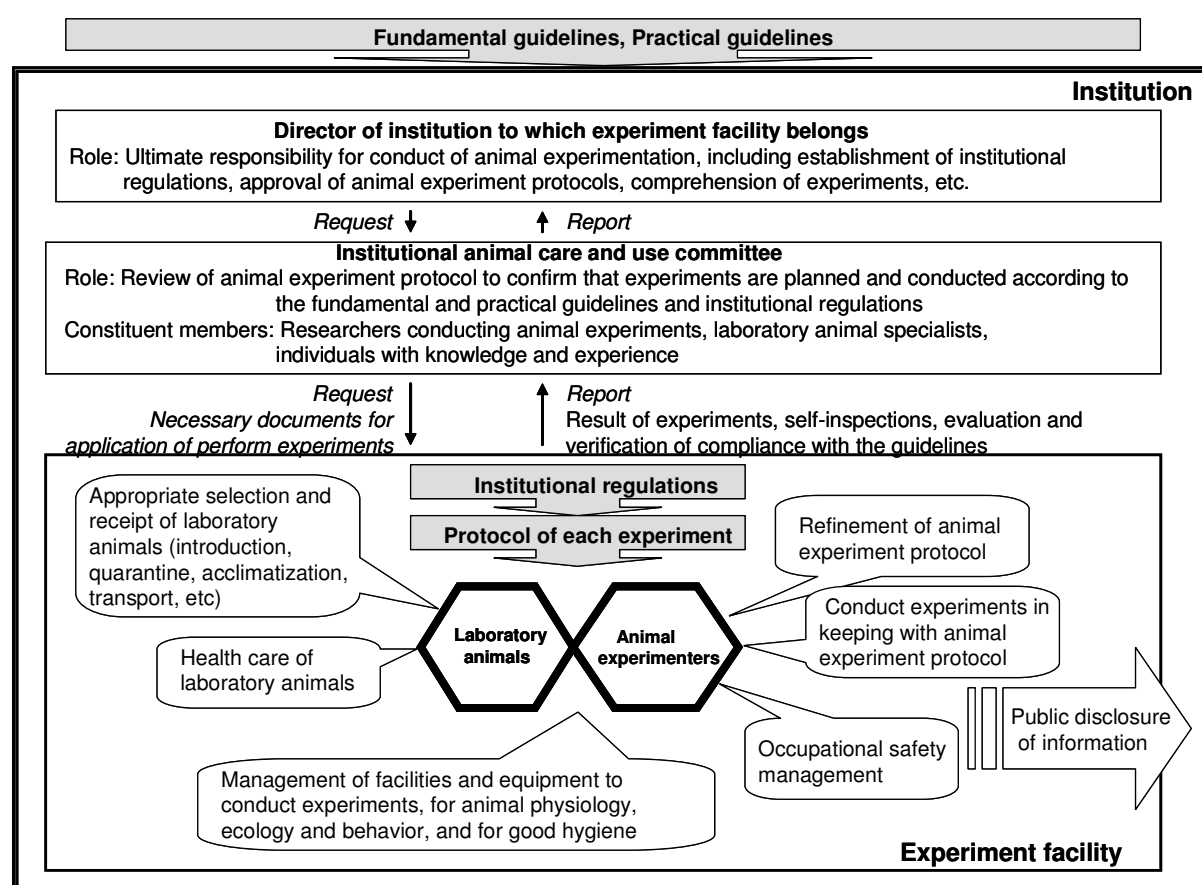

Figure 3. Overall picture of the management of animal experimentation at each institution under the fundamental and practical guidelines in Japan.

3.4. External verification

As described in 3.2., the fundamental and practical guidelines require all institutions to undergo external verification of the results of self-inspection and self-evaluation of their animal experimentation. Before implementing the guidelines, verification specific to animal experimentation was not standardized in Japan, except for being assessed by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) (Association for Assessment and Accreditation of Laboratory Animal Care International, 2008). In addition to AAALAC Interna-

tional, the Japanese Society for Laboratory Animal Resources (Japanese Society for Laboratory Animal Resources, 2008), the Japanese Association of Laboratory Animal Facilities of National University Corporations (Japanese Association of Laboratory Animal Facilities of National University Corporations, 2008b) and of the Public and Private Universities (Japanese Association of Laboratory Animal Facilities of Public and Private Universities, 2008), and the Japan Health Sciences Foundation (Japan Health Sciences Foundation, 2008) are currently assigned to verify the results of self-inspection and self-evaluation of animal experimentation and related activities such as laboratory animal breeding. The base and coverage of the verification system are listed in Table 2 and an overall view of the verification system is shown in Fig. 4.

Table 2. External verification systems for animal experimentation in Japan.

Organizations	Base for verification*	Coverage for verification	Remarks
Domestic organizations			
Japanese Society for Laboratory Animal Resources (JSLAR)	Charter of Laboratory Animal Welfare (JSLAR, revision December 2006), Guidelines for Animal Welfare in Laboratory Animal Breeding Facilities (JSLAR, revision December 2006)	Animal breeding facilities, testing facilities	Pilot survey on the facilities has been conducted since 2004
Japanese Association of Laboratory Animal Facilities of National University Corporations (JALAN) and Japanese Association of Laboratory Animal Facilities of Public and Private Universities (JALAP)	Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutes Under the Jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) (MEXT Notice No.71, June 2006)	Universities affiliated with JALAN and JALAP	Cross-validation among corporations is planned
Center for Accreditation of Laboratory Animal Care and Use, Japan Health Science Foundation	Basic Policies for the Conduct of Animal Experimentation in the Ministry of Health, Labour and Welfare (MHLW) (MHLW, Notice, June 2006)	Institutes under the jurisdiction of MHLW	Systems for accreditation have been used since 2008
International organization			
Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)	Guide for the Care and Use of Laboratory Animals (NRC1996), and wide range of other publications regarding animal care and use in various countries	Animal care and use programs of universities, hospitals, government agencies, pharmaceutical and biotechnology companies, and other types of research institutions	Seven institutions have been accredited (open information on the web in October 2008*)

*Accredited organizations. http://www.aaalac.org/accreditedorgs/aaalacprgms.cfm (October 3, 2008).
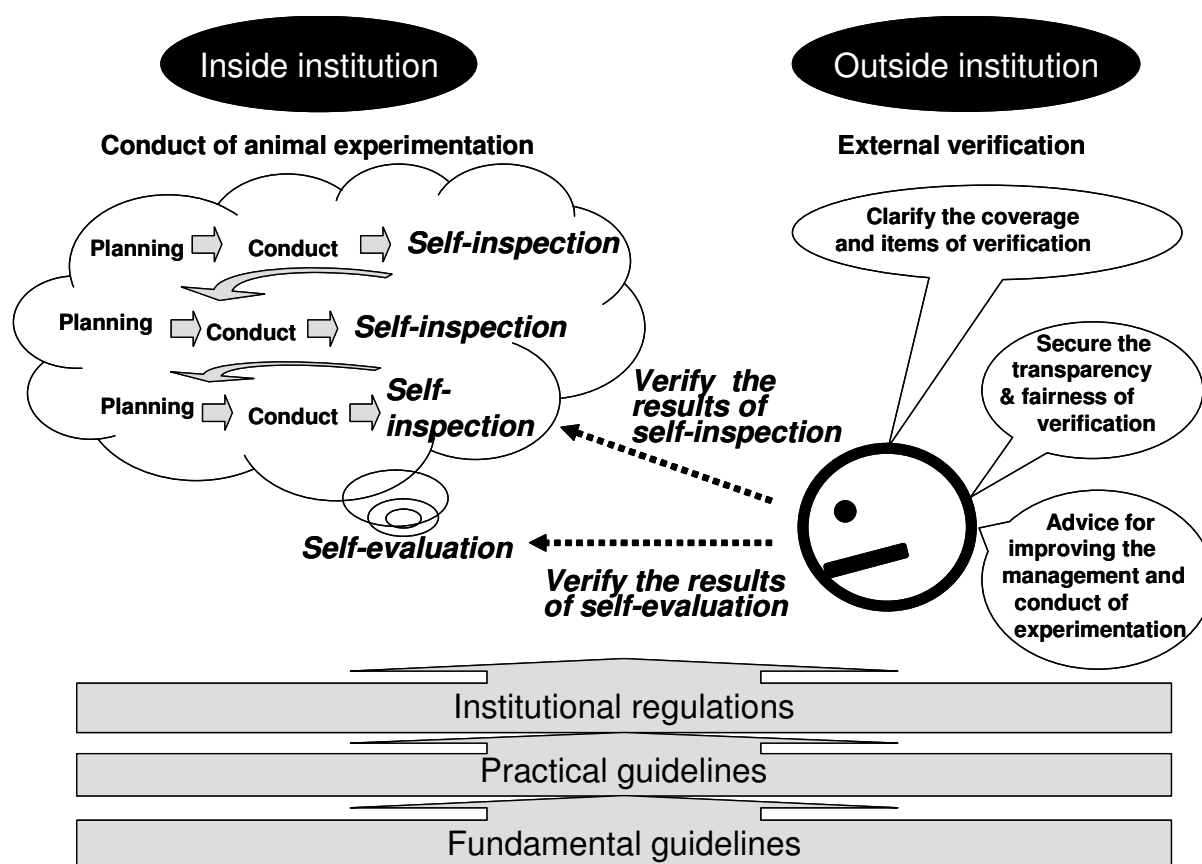
Figure 4. Procedure for self-inspection, self-evaluation and external verification of animal experimentation in Japan.

4. Status of Animal Experimentation in Japan - Number of Laboratory Animals Used

Understanding the number of laboratory animals used is very useful for grasping the statement of conduct of animal experimentation; however, in Japan, the number of animals used has not been surveyed fully because Japanese regulations do not require a report of the number, in contrast to the UK, US and Canada where the number is reported according to legal regulations.

The survey of animal use in Japan is based on voluntary questionnaires organized by the Japanese Association for Laboratory Animal Science (hereinafter, JALAS) (JALAS, 2008), which targets the number of animals and species used in various universities and research institutes, including national and foundation institutes, and companies. The survey has been performed 12 times since fiscal year (FY) 1973 and the collection rate has been over 50%, although the questionnaires are voluntary. For example, in FY 1995 to 2001, the survey targeted 884 to 910 research facilities, resulting in a collection rate of 57–69%. The total number of animals used was 10,850,652 to 9,380,935, and it decreased slightly each year. Mice were used most (7,364,185 in FY 1995, 6,935,376 in FY 1998 and 6,081,511 in FY 2001), and the number of genetically modified mice significantly increased (762 in FY 1995 to 2,744 in FY 2001). Genetically modified mice have been used to research various diseases, and the increase in the number of these animals reflects the research progress. Detailed data of the survey are shown in our previous report (Takahashi-Omoe & Omoe, 2007) and reports by JALAS (1998, 2001, 2003).

Since FY 2004, the above survey has focused on animals used after breeding in experimental facilities (JALAS, 2007). The survey is considered to be effective for grasping the current status of animal use, including genetically modified animals, because the development and usage of animals

tend to occur in the same experimental facility. The collection rate of the survey in 2004 was much higher than in previous surveys (75.6%, replies from 413 of 546 facilities in which animals were bred and used for experimentation). The survey revealed that 1,221,649 animals were used for experiments after breeding, and 42.8% were genetically modified in FY 2004. The disaggregated data are shown in Fig. 5.
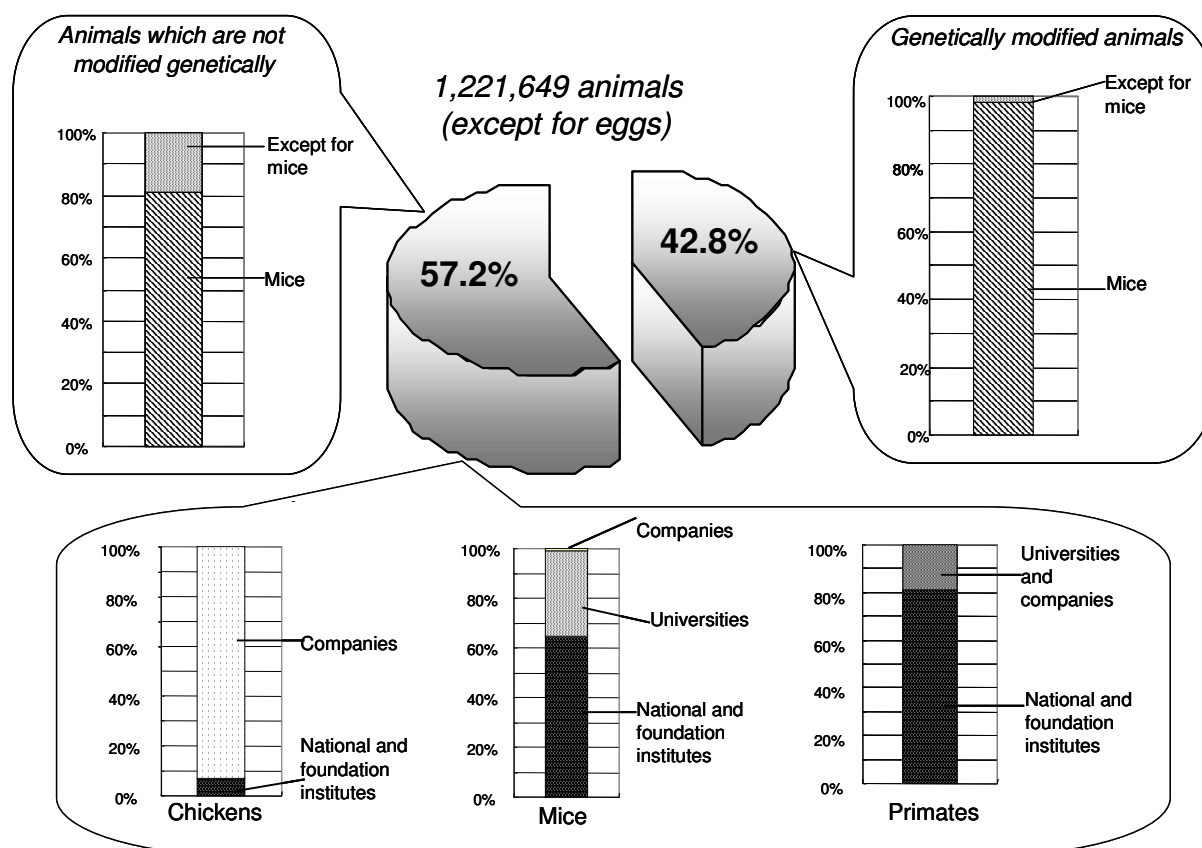

Figure 5. Number of animals used in experimentation in fiscal year 2004 in Japan.

5. Perspective for Further Animal Experimentation in Japan - Future Conduct

Thus far, we have introduced the characteristics of management systems for animal experimentation and the status of its conduct in Japan where animal experimentation has been performed at each institution by self-motivated management, which is led by not only legislation to prevent abuse, for protection, humane treatment and management of animals, but also by religion, tradition and so on. Currently in Japan, animal experimentation has been handled as 'necessary and unavoidable actions for gaining scientific insight into the biological activities of living organisms', as specified in the Ministry's fundamental guidelines, and it has been conducted depending on its appropriateness from scientific viewpoints and animal welfare (Ministry of Education, Culture, Sports, Science and Technology, 2006).

Recently, animal experimentation has increased the diversification of its purposes, methods and goals. It is applied to analyze and resolve complex biological processes, such as the higher functions of the central nervous system, intercellular crosstalk, to develop medical technologies, and so on. As an example of effective use of the experimentation in Japan, a new therapeutic method for liver cirrhosis

has been demonstrated in rat models of the disease (Sato *et al.,* 2008). In addition to the above contributions, experimentation has played an important role in recovering from a worldwide health crisis, as shown when severe acute respiratory syndrome (SARS) virus was firstly identified by experiments using cynomolgus macaques (Kuiken *et al*., 2003; World Health Organization, 2003). Given that animal experimentation has contributed enormously to our knowledge and that alternative methods, such as *in vitro* toxicity testing, have not been fully developed, we might have no choice but to depend on the benefits of animal experimentation for the foreseeable future.

The Japanese management system for animal experimentation compares favorably with that of other nations. In fact, Japanese studies involving animal experimentation have been accepted by international journals because they have scientific value and ensure animal welfare. Given such a situation, the management system has not seemed to have any critical problems until now. However, several of the tasks described below will be necessary to conduct experimentation in the near future because the mode of animal experimentation will change depending on the development of science and technology and our awareness of animal welfare.

5.1. Revision of the current management systems

As described above, animal experimentation has been conducted without critical problems under self-motivated management systems driven by each institution in Japan, and these systems have been maintained or strengthened by the Ministry's fundamental and practical guidelines. The requirements of the guidelines shown in 3.2 seem to be mostly fulfilled by each institution; however, countermeasures against new animal experimentation should be developed to be closely geared to experimentation that will become more sophisticated and diverse in the future. Studies on genetic disorders using genetically modified animals, studies on brain functions using non-human primates, studies on emerging infectious diseases using specific animal models, and studies on heteroplastic transplantation, etc. require new forms of experimentation and management systems in Japan will need to be developed further. Moreover, the systems for external verification of animal experimentation and public disclosure of information about experimentation should be advanced because the systems are developing or are different among institutions in Japan. Fig. 6 illustrates an example of the requirements for conducing further experimentation, focusing on current Japanese legislation.

Additionally, the current management systems for animal experimentation should be revised because the 'Law for the Humane Treatment and Management of Animals' will be amended in 2011 and new regulations, such as more stringent management of laboratory animal care and use, might be introduced. In parallel with discussing necessary amendments of the law, the current management systems for animal experimentation should be reviewed.

5.2. International harmonization

International harmonization of the guidance for animal experimentation has become more important than previously because science and technology have become global, requiring higher quality and more appropriate research and development involving animal experimentation in order to be internationally accepted from both scientific and ethical standpoints. Regarding the variation of management systems for animal experimentation among nations (Demers *et al*., 2006; Omoe, 2006), the term 'harmonization of the guidance for animal experimentation' might be interpreted as meaning 'harmonization of the benchmark for the welfare of animals used for scientific purposes', not 'establishment of one worldwide set of regulations for experimentation'. Seen in this light, all nations, in which animal experimentation is conducted, including Japan, should make an effort to establish a climate for harmonization, while respecting each other's religions, traditions and previous legislation.

In addition to the above work on filling the gaps in each nation's management system for animal experimentation, there have been international efforts to use universal performance standards for animal testing. Examples of international collaboration include the program for testing chemicals by the Organization for Economic Cooperation and Development (OECD) (Organization for Economic Cooperation and Development, 2008) and the International Conference on Harmonization of Technical
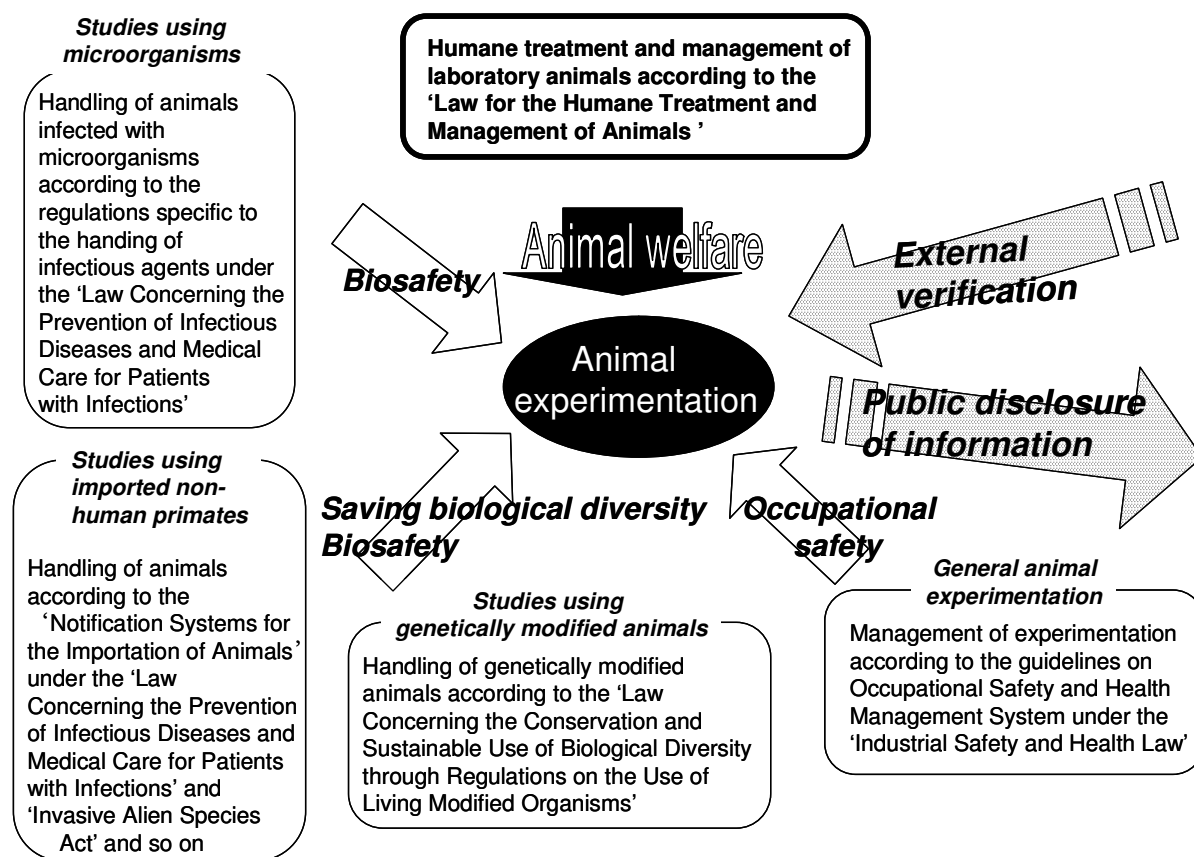
Figure 6. Examples of the requirements for further management of animal experimentation in Japan.

Requirements for Registration of Pharmaceuticals for Human Use (ICH) (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2008) and for Registration of Veterinary Medicinal Products (VICH) (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, 2008). These instances of international collaboration are reducing unnecessary duplication of studies involving animals and link directly to the development of alternative methods based on the 3 Rs or 5 Rs and the promotion of animal welfare in scientific procedures. Japan, as a member nation of these programs, has actively participated in the planning and should implement these measures.

6. Concluding Remarks

Japan has set up self-motivated management systems for animal experimentation without strict laws and regulations. These systems are unique, a departure from those in the EU, US and Canada, and are appropriate for Japanese religions, traditions and regulatory and administrative frameworks of science and technology. These management systems will continue; however, operation of the systems will be revised through trial and error, depending on the domestic and international environment. In order to implement appropriate animal care, use and management in future scientific procedures, not only animal experimenters but also people who benefit from animal experimentation must develop common perceptions of animal welfare through discussion because it is difficult to uniformly assess animal experimentation from the standpoint of animal welfare in the current situation, although experimentation can be assessed scientifically. From this regard, we hope that our report will be helpful to build consensus about animal welfare in scientific procedures.

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8. About the Authors

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Katsuhiko Omoe (DVM, Ph.D.) is an associate professor of the Department of Veterinary Medicine, Iwate University. He was responsible for researching human genetic disorders at a medical school and has researched the pathogenicity of various bacteria and viruses using laboratory animals. Currently, he is investigating the mechanisms of food poisoning by bacterial toxins and has developed a control approach, taught not only to students but also to health professionals. As an user of laboratory animals, he has provided a powerful lens through which to view the conduct of animal experimentation.