Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Notice of the Ministry of the Environment

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Part I. General Principles

1. Basic idea

While providing animals for a scientific use is essential for the advancement of life sciences, development of medical technology, etc., and other purposes, when using them for a scientific purpose, in light of the fact that animals are living beings, consideration shall be given to the appropriate use of such animals by such means as using alternative methods to that of the use of animals as much as possible and reducing the number of animals provided for such use as much as possible, within the extent that the purpose of the scientific use can be attained, and endeavors shall be made to properly care for and keep the animals and provide them for a scientific use with a sense of gratitude and responsibility, taking into account their physiology, ecology, habits, etc., in order to ensure that a method that minimizes the pain and distress to the animal as much as possible shall be used, within the limit necessary for such use. In addition, through the proper care and keeping of Laboratory Animals, endeavors shall be made to prevent infringement on the life, body or property of humans and to preserve the surrounding living environment.

2. Selection of animals

The Manager shall endeavor to ensure that the kinds, etc. of Laboratory Animals to be cared for or kept are selected in an organized manner considering such conditions as the location and the status of development of the Facility and the caretaking ability of the Caretaker.

3. Dissemination of these Standards

In order to ensure that the care and keeping of Laboratory Animals and their scientific use are carried out by an appropriate method from the viewpoint of the welfare and management of animals while maintaining objectivity and transparency as needed, the Manager shall endeavor to properly disseminate these Standards within the Facility by taking such measures as establishment of a committee that provides instructions on compliance with these Standards or the securing of an equivalent function, and formulation of guidelines conforming to these Standards. In addition, the Manager shall endeavor to develop a system for carrying out such dissemination effectively and efficiently by mutually coordinating with related organizations and other organs or by other methods.

4. Others

The Manager shall periodically inspect the status of compliance with these Standards and with the guidelines conforming to these Standards, and publish the results by an appropriate method. Meanwhile, the Manager shall endeavor to have an external organ, etc. verify said inspection results insofar as possible.

Part II. Definitions

In these Standards, the meanings of the terms set forth in the following items shall be as prescribed respectively in those items:

- (1) Experiment, etc.—An act of providing animals for use in education, testing and research or the manufacture of biological preparations, or for any other scientific use
- (2) Facility—A facility for caring for, keeping, or performing an Experiment, etc. on Laboratory Animals
- (3) Laboratory Animal—An animal categorized as a mammal, bird or reptile cared for or kept in a Facility to be provided for use in an Experiment, etc. (including an animal being transported to be introduced into the Facility)
- (4) Manager—A person who manages the Laboratory Animals and the Facility (including a person who is responsible for the care and keeping of Laboratory Animals, such as the head of a research institute)
- (5) Laboratory Animal Manager—A person who supports the Manager and takes charge of management of the Laboratory Animals
- (6) Experiment Performer—A person who performs an Experiment, etc.
- (7) Caretaker—A person who cares for or keeps Laboratory Animals under a Laboratory Manager or an Experiment Performer
- (8) Manager, etc.—A Manager, Laboratory Animal Manager, Experiment Performer, or Caretaker

Part III. Common Standards

- 1. Maintaining the health and safety of animals
- (1) Method of the care and keeping

The Laboratory Animal Manager, Experiment Performer, and Caretaker shall endeavor to maintain the health and safety of the Laboratory Animal, considering the following matters:

- A. They shall secure an environment for carrying out appropriate feeding and watering, the necessary health management, and the care and keeping of the Laboratory Animal that give consideration to such aspects as the kind and habit of the animal, according to the physiology, ecology, habits, etc. of the Laboratory Animal and within the extent that does not impede the attainment of the purpose of the care and keeping of the animal.
- B. They shall carry out necessary health management to prevent the Laboratory Animal from receiving an injury (excluding one pertaining to the purpose of the

Experiment, etc.; hereinafter the same shall apply in this (b)) or from developing a disease other than the disease pertaining to the purpose of the Experiment, etc. (excluding one pertaining to the purpose of the Experiment, etc.; hereinafter the same shall apply in this (b)). Meanwhile, if the Laboratory Animal receives an injury or develops a disease, provide appropriate treatment within the extent that does not impede the attainment of the purpose of the Experiment, etc.

- C. The Laboratory Animal Manager shall, when introducing a Laboratory Animal into the Facility, ensure that that the health of the Experiment Performer, Caretaker, and other Laboratory Animals will not be impaired, by conducting appropriate quarantine, isolated rearing, etc. as needed, and shall take measures for helping the acclimatization or adaptation of the Laboratory Animal to the care environment as needed.
- D. When caring for or keeping different kinds of or multiple Laboratory Animals within the same Facility, they shall accommodate the animals in a manner that gives consideration to their combination, within the extent that does not impede the attainment of the purpose of the Experiment, etc.
- (2) Structure of the Facility, etc.

The Manager shall endeavor to appropriately develop the Facility he/she manages according to the physiology, ecology, habits, etc. of the Laboratory Animal, considering the following matters:

- A. He/she shall develop a floor area and space where individual Laboratory Animals are able to easily conduct daily actions, such as stand up, lie down, flap wings, swim, etc. in a natural form, within the extent that does not impede the attainment of the purpose of the Experiment, etc.
- B. In order to avoid causing excess stress on the Laboratory Animals, he/she shall ensure that the Facility has a structure, etc., capable of maintaining an appropriate temperature, humidity, ventilation, lighting, etc., within the extent that does not impede the attainment of the purpose of the Experiment, etc.
- C. He/she shall ensure that the floor, interior walls, ceiling, and auxiliary equipment have a structure that is easy to keep hygienic and to manage, such as being easy to clean, and have a structure that is unlikely to cause injury, etc. to the Laboratory Animals due to a protrusion, hole, hollow, slope, etc.
- (3) Education and training, etc.

The Manager shall assign a person who has knowledge and experience concerning Laboratory Animals as the Laboratory Animal Manager. In addition, he/she shall endeavor to ensure that necessary education and training are provided respectively for the Laboratory Animal Manager, Experiment Performer, and Caretaker.

2. Preservation of the living environment

The Manager, etc. shall endeavor to preserve the Facility and the living environment surrounding the Facility by preventing environmental contamination and bad smells caused by microorganisms, etc. and vermination through

appropriate disposal of waste matter, etc. of Laboratory Animals and constant cleaning of the Facility, and by preventing noise through development, etc. of the Facility or equipment.

- 3. Prevention of harm, etc.
- (1) Structure of the Facility and the method of the care and keeping

When caring for or keeping a Laboratory Animal, the Manager, etc. shall endeavor to prevent the Laboratory Animal from causing harm to humans or causing problems in relation to preservation of the environment by taking the following measures:

- A. The Manager shall develop a Facility with such structure and strength that prevent the Laboratory Animal from escaping.
- B. The Manager shall carry out necessary health management to prevent the Laboratory Animal Manager, Experiment Performer, and Caretaker from developing a disease originating from the Laboratory Animal.
- C. The Manager and Laboratory Animal Manager shall secure the structure of the Facility and the method of the care and keeping that enable the Experiment Performer and Caretaker to work without hazard.
- D. The Laboratory Animal Manager shall ensure that the number and the conditions of the Laboratory Animals cared or kept are confirmed through routine management and maintenance/inspection of the Facility and periodic patrol of the Facility.
- E. The Laboratory Animal Manager, Experiment Performer, and Caretaker shall endeavor to mutually provide necessary information for preventing the Laboratory Animal from causing harm, by conducting the following:
- (i) The Laboratory Animal Manager shall provide the Experiment Performer with information on the method of handling the Laboratory Animal, and provide the Caretaker with necessary instructions on the care and keeping of the Laboratory Animal.
- (ii) The Experiment Performer shall provide the Laboratory Animal Manager with information on the Laboratory Animal used for Experiment, etc., and provide the Caretaker with necessary instructions on the care and keeping of the Laboratory Animal.
- (iii) The Caretaker shall make a report on the status of the Laboratory Animal to the Laboratory Animal Manager and Experiment Performer.
- F. The Manager, etc. shall take necessary measures to prevent a person who is unrelated to the care and keeping of the Laboratory Animal or to the Experiment, etc. from having contact with the Laboratory Animal.
- (2) Care and keeping of venomous animals

When caring for or keeping a venomous animal, such as a venomous snake, endeavors shall be made to prevent the Laboratory Animal from causing harm to humans by keeping first-aid medicine such as antitoxic serum and developing a

system whereby a medical doctor may promptly provide first-aid treatment when an accident occurs.

(3) Response upon escape

The Manager, etc. shall take necessary measures to prevent the Laboratory Animal from escaping from the facility where it is kept, etc. In addition, the Manager shall specify in advance measures such as capturing, etc. in the case where the Laboratory Animal escapes, and endeavor to prevent it from causing harm to humans or causing problems in relation to preservation of the environment upon escape, and when a Laboratory Animal which has the risk of causing harm to humans escapes to the outside of the Facility, he/she shall promptly contact related organs.

(4) Response upon emergency

The Manager shall prepare in advance a plan on measures to be taken upon an emergency, such as an earthquake or a fire, which conforms to the regional disaster prevention plan, in cooperation with related administrative organs, and when an emergency situation occurs, the Manager, etc. shall promptly endeavor to protect the Laboratory Animal and to prevent the Laboratory Animal from causing harm to humans or causing problems in relation to preservation of the environment by escaping.

4. Acquisition of knowledge on zoonotic infections, etc.

The Laboratory Animal Manager, Experiment Performer, and Caretaker shall endeavor to acquire sufficient knowledge of and collect information on zoonotic infections. In addition, the Manager, Laboratory Animal Manager, and Experiment Performer shall endeavor to develop a system to contact public health organizations, etc. so as to be able to take necessary measures promptly at the time of occurrence of zoonotic infections.

5. Ensuring proper management of the record of the Laboratory Animal

In order to ensure the proper care and keeping of the Laboratory Animal, the Manager, etc. shall endeavor to properly manage the record of the Laboratory Animal, such as developing a ledger on the acquisition source, rearing history, medical history, etc. of the Laboratory Animal. In addition, with regard to a Laboratory Animal having the risk of causing harm to humans, etc., they shall endeavor to take an identification measure, such as attaching a name tag, leg bank, microchip, etc., within the extent technically possible.

6. Handling upon transport

When transporting a Laboratory Animal, endeavors shall be made to secure the health and safety of the Laboratory Animal and prevent the Laboratory Animal from causing harm to humans, etc., considering the following matters:

A. The fatigue of and the pain and distress of the Laboratory Animal shall be minimized by using a method that enables transport in as short a time as possible, etc.

- B. Appropriate feeding and watering shall be carried out for the transported Laboratory Animal as needed, and an appropriate temperature shall be maintained in the vehicle, etc. used for the transport through ventilation, etc.
- C. The Laboratory Animals shall be transported by appropriately dividing them into groups in consideration of their physiology, ecology, habits, etc., and the vehicle, container, etc. to be used for transport shall be selected from those that have the necessary size, structure, etc. for securing the health and safety of the Laboratory Animals and for preventing the Laboratory Animals from escaping.
- D. Necessary measures shall be taken to prevent the environment from being contaminated by microorganisms possessed by the Laboratory Animal and the waste matter of the Laboratory Animal, etc.
- 7. Handling upon abolition of the Facility

When abolishing the Facility, in light of the fact that the Laboratory Animal is a living being, the Manager shall endeavor to transfer the Laboratory Animal he/she cares for or keeps to another Facility, in order to achieve its effective use. When it is unavoidable to destruction the Laboratory Animal, he/she shall endeavor to do so based on the Guidelines relating to the Methods of Destruction of Animals (Notice of the Prime Minister's Office No. 40 of July 1995; hereinafter referred to as the "Guidelines").

Part IV. Individual Standards

- 1. Facility for performing Experiment, etc.
- (1) Considerations upon performing Experiment, etc.

The Experiment Performer shall endeavor to appropriately use the Laboratory Animal within the extent necessary for attaining the purpose of the Experiment, etc. In addition, he/she shall minimize the pain and distress to the animal as much as possible by administering an anesthetic, analgesic, etc. or giving consideration to the timing of ending the experiment, such as shortening the period for providing the Laboratory Animal for use in an Experiment, etc. as much as possible, and taking appropriate steps, such as maintaining warmth, within the extent that does not impede the attainment of the purpose of the Experiment, etc.

(2) Subsequent measures

When destroying a Laboratory Animal for which an Experiment, etc. has ended or has been interrupted or a Laboratory Animal which has received unrecoverable damage from a disease, etc., the Laboratory Animal Manager, Experiment Performer, or Caretaker shall promptly perform the destruction based on the Guidelines, such as using a chemical or physical method of administering more than the lethal dose of anesthetic or dislocating the cervical spine. In addition, they shall appropriately dispose of the carcass of the Laboratory Animal in order to prevent it from harming the health of humans or the living environment.

2. Facility for producing Laboratory Animals

Young or old animals shall not be provided for breeding. In addition, in order to avoid imposing an excessive burden on animals by providing them for breeding without reason, breeding shall be conducted an appropriate number of times. However, this shall not apply when there are special circumstances, such as when animals are provided for breeding for the purpose of maintaining the pedigree. Also, when transferring a Laboratory Animal, accountability to the transferee shall be fulfilled by providing information on its physiology, ecology, habits, etc., the method of proper care and keeping, infectious diseases, etc.

Part V. Application Mutatis Mutandis and Exclusion from Application

The Manager, etc. shall endeavor to comply with the purport of these Standards also when providing an animal other than one categorized as a mammal, bird or reptile for use in an Experiment, etc. In addition, these Standards shall not apply to a Manager, etc. who cares for or keeps a Laboratory Animal for the purpose of conducting education or testing and research concerning the care and keeping of livestock or breeding and improving livestock and a Manager, etc. who cares for or keeps a Laboratory Animal for the purpose of observing the ecology. Meanwhile, the care and keeping of animals for the purpose of observing the ecology shall be carried out in accordance with the Standards relating to the Care and Keeping of Animals at Home (Notice of the Ministry of the Environment No. 37 of May 2002).