

Related laws and regulations related to experimental animals and animal experiments

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Introduction

The analysis using experimental animals is indispensable in medical science research targeting various diseases.

However, animal experiments must proceed properly according to certain rules and in accordance with experimental plans that give due consideration to animal welfare.

In this course, the minimum understanding required for an animal experimenter is the "Act on Welfare and Management of Animals," which stipulates animal welfare, and the "Act on Animal Welfare and Management," which stipulates the promotion of appropriate animal experiments. We will explain related laws and regulations and guidelines, focusing on the Basic Guidelines for the Implementation of Animal Experiments.

Content of the course

Overview : Promoting animal welfare as stipulated by law and appropriate animal testing under institutional management

1. Act on Welfare and Management of Animals (Ministry of the Environment)
2. Standards for the Care and Storage of Laboratory Animals and Alleviation of Pain (Ministry of the Environment)
3. Basic Guidelines for Implementation of Animal Experiments, etc. at Implementing Agencies Under the Jurisdiction of the Ministry of Health, Labor and Welfare (Ministry of Health, Labor and Welfare)
4. Guidelines for Proper Conduct of Animal Experiments (Science Council of Japan)
5. Other major relevant laws and regulations

Summary : Flow from the formulation of the experiment plan to the execution of the experiment and the submission of the experiment report^{#3}

Overview: Promoting animal welfare as stipulated by law and appropriate animal testing under institutional management

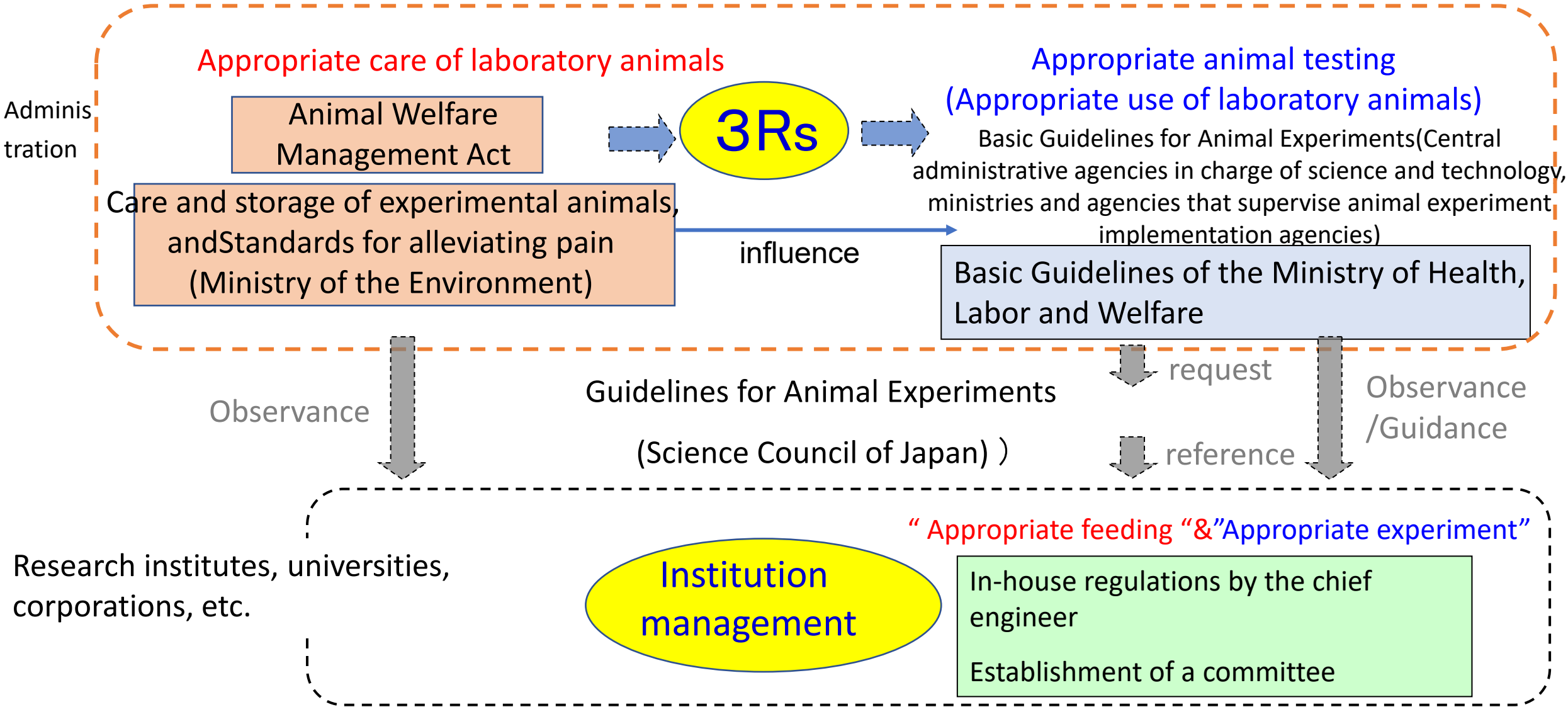
Experimental Animals and Animal Experiments

【 Secretariat description】

Experimental animals: Animals bred purposefully for testing, research, education, or other scientific uses.

Animal experiments: Experiments in which experimental treatments are applied to animals and the reactions of animals are observed for the purpose of obtaining new scientific knowledge.

Outline: Promoting **animal** welfare as stipulated by law and appropriate animal **experiments** under institutional management



1 .Act on Welfare and Management of Animals

Experimental animals are managed under the "Act on Welfare and Management of Animals" in the same way as pets.

Poor environment = abuse

June 1, 2020:

Enforcement of the Revised Animal Welfare Law

Why did the rules for keeping pets become stricter?

Main amendments to the Animal Welfare Act;

Preventing animal cruelty:

- Strengthen penalties for animal killing crimes to imprisonment with work for not more than five years or a fine of not more than 5 million yen.
- Added imprisonment to penalties for abandoning pets.
- Obligation to report abuse to veterinarians.
- Possibility of on-site inspections by local governments for owners who breed poorly.

Merchant regulations:

From 2021: Sales of puppies and kittens under 56 days old are prohibited. The size of the cage and the number of births of mother dogs and mother cats are numerically regulated.

From 2022: Microchipping commercial and breeding dogs and cats.

Dangerous Animal Regulations:

Dangerous animals such as black bears and lions are not allowed as pets.

Asahi Shimbun April 14, 2021

**劣悪な環境下で
犬5匹飼育容疑**
ワニや蛇も 逮捕

劣悪な環境で犬を飼育したとして、警視庁は東京都大田区南蒲田2丁目の職業不詳、桑添亜紀容疑者(46)を動物愛護法違反(虐待)容疑で逮捕し、14日発表した。「虐待に当たるとは思っていないかった」と話しているという。

蒲田署によると、逮捕容疑は12日午前、動物の排泄物が堆積した自宅の室内で犬5匹を飼育したというもので、犬は餌を与えられていたが、栄養失調の状態だった。現場にはネズミの死骸も落ちていたという。

桑添容疑者宅は戸建てで、犬7匹と猫2匹のほか、ワニや蛇、大トカゲ、イグアナ、フクロウなど24種類の動物計58匹を飼育。室内には動物の排泄物がたまり、近所から悪臭の苦情が相次いでいたという。

桑添容疑者は署に対し、3年前に動物愛護団体から犬2匹を引き取って飼育を始めたと説明。その後、繁殖するなどして7匹まで増えたという。昨年はペットショップではかの動物も買い集めるようになり、「コロナ禍で趣味の旅行に行けなくなり、ペットの数が増えていった」と話しているという。(大山稜)



Arrested of suspicion of keeping 5 dogs, crocodiles and snakes in a poor environment:

The Metropolitan Police Department announced on the June 14th, that Aki Kuwazoe (46 years old), whose occupation is unknown, was arrested on suspicion of **violating the Animal Welfare Act (abuse)** in okyo, for raising a dog in a poor environment. . "I didn't think she was abusing them," she said. According to the Kamata police station, she was arrested on the morning of the 12th for breeding five dogs in her house where animal excrement was piled up. The dog had been fed but malnourished.

Mouse carcass was also found at the scene. Kuwazoe's home is independent house, had 58 animals of 24 different kinds, including 7 dogs, 2 cats, crocodiles, snakes, giant lizards, iguanas, and owls. Animal excrement accumulated in the rooms. Neighbors complained of a foul odor. Kuwazoe told police that she adopted two dogs from an animal welfare group three years ago and started raising them. After that, they increased to seven due to breeding. Since last year, she started collecting other animals at a pet shop, and she said, "The number of pets has increased because I can't go on hobby trip due to the COVID crisis."

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Imprisonment was added. The aim is to prevent the increasing animal cruelty.

Dr. Ho: Has the law changed that stipulated rules for keeping pets?

A: It is the revised Animal Welfare Law that came into force on June 19th. If an owner abandons a pet, Imprisonment was added to the penalties that were previously limited to a fine. Penalties for killing or injuring a pet have also been raised from "imprisonment up to 2 years or a fine of up to 2 million yen" to "imprisonment up to 5 years or a fine of up to 5 million yen".

Mr. Ho: Why did it become strict?

A: According to the Metropolitan Police Department's summary, animal cruelty incidents to dogs and cats tend to increase. Animal protection groups and other groups have also pointed out that the penalties are too light compared to the penalties for damaging property. The whole society should take care of animals.

Mr. Ho: It seems difficult to find pet abuse.

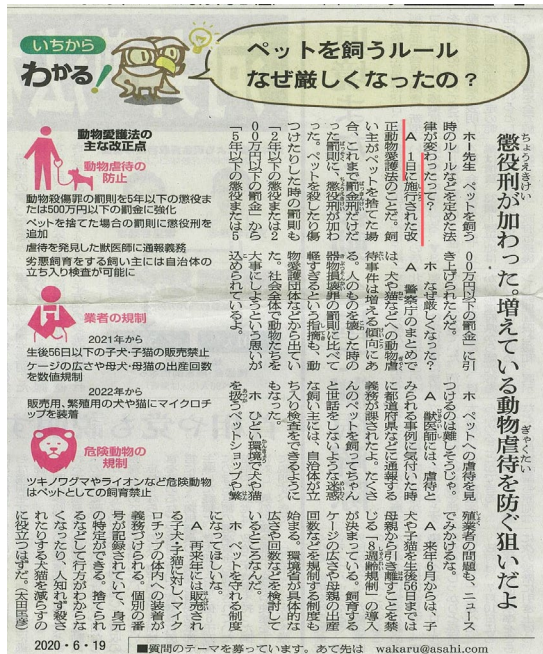
A: Veterinarians are obligated to report to the prefectures when they notice a case of abuse. Local governments are now able to conduct on-site inspections for annoying pet owners who have too many pets and don't take good care of them.

Dr. Ho: We also see in the news about problems with pet shops and breeders who treat dogs and cats in terrible conditions.

A: From next June, it's decided to introduce an "8-week-old regulation" that prohibits separating puppies and kittens from their mothers until they are 56 days old. A system will also be introduced to regulate the size of cages to be raised and the number of births. The Ministry of the Environment is considering the specific size and number of times for mothers.

Mr. Ho: I want a system that protects pets.

A: In the year after next, puppies and kittens to be sold will be obligated to have microchips attached to their bodies. Numbers will be recorded to allow identification. It will help reduce dogs and cats that are abandoned and lost or killed in secret.



Act on Welfare and Management of Animals

Revised June 2, 2006, final revision June 19, 2019

(Ministry of the Environment)

1) A legal system that does not regulate animal experiments, but specializes in **the welfare of (experimental) animals** (recognizing them as living things and handling them appropriately) and the **appropriate management of animals** (prevention of harm and nuisance, etc.)

(It was made clear that the need **for animal testing in scientific research** should not be judged from the perspective of animal welfare and management.)

2) Classification by breeding style of animals

Lifelong breeding: Pet animals, exhibition animals, etc.

⇒ Philosophy law/Regulation law

Non-lifetime breeding: Experimental animals, livestock, etc.

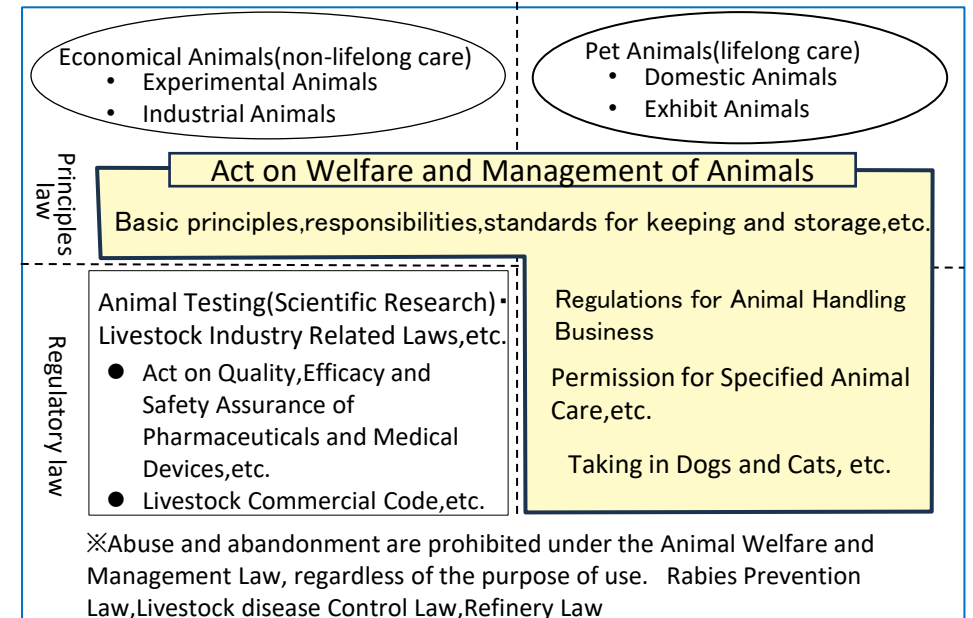
⇒ Philosophy law

3) Core Principles Clause (Article 2):

also refers to adequate feeding and watering

(Newly established in the 2013 revision)

4) Article 41: Methods and follow-up measures, etc. when animals are used for scientific purposes (Clarification of **the 3Rs principle**)



Act on Welfare and Management of Animals

Article 41. Methods, follow-up measures, etc. when animals are used for scientific purposes

Principle of 3Rs

Principles for the appropriateness of laboratory animal care and animal testing

“The purpose of scientific use can be achieved”

① Use of alternative methods (Replacement)

Are there alternatives that do not use animals? *Is it possible to replace in vitro & in silico experiments?*

② Reduce usage (Reduction)

Design an experimental design that yields reliable data with a small number of animals.

③ Relief of pain (Refinement)

The pain should be reduced as much as possible without hindering the purpose of the experiment. (e.g. setting humane endpoints*)

※ Criteria for discontinuing experimental procedures or euthanizing animals that should be predetermined at the planning stage of the experiment

2. Standards for the Care and Storage of Laboratory Animals and Alleviation

of Pain (Ministry of the Environment)

Other breeding and storage standards set by the Ministry of the Environment

- Standards for raising and keeping domestic animals
- Standards for breeding and storage of exhibited animals
- Standards for raising and keeping industrial animals, etc.

Well-being of **Laboratory Animals**

1) Animal Welfare Management Act

➡ Observance of 3Rs, etc. ⇒ Conceptual part

2) **Appropriate use of scientific animals**

3) Care and storage of experimental animals, alleviation of pain during experiments, follow-up measures (Method of euthanasia) etc. ⇒ **Substantial action part**

Commentary on standards for breeding and storage of experimental animals and alleviation of suffering

Edited : Ministry of the Environment, Nature Conservation Bureau,
General Affairs Division, Animal Welfare Management Office

Written by : Research Group on Standards
for Breeding and Storage of Laboratory Animals



Ministry of
the Environment

• October 2017

• Created based on the on-site work performed by practitioners who manage laboratory animals and conduct animal experiments.

Standards for the care and storage of laboratory animals and the alleviation of suffering

The Guideline for Raising and Keeping of Laboratory Animals

April 28, 2006 notification, September 2013 notification

(Ministry of the Environment)

1) General principles

Basic concept : Providing animals for scientific use is essential for the progress of life sciences and medical technology. Consider **the appropriate use of animals** by observing the **3Rs**. We will strive to prevent infringement on human life, body, or property and **to preserve the surrounding living environment** through proper care and storage of experimental animals.

2) Definition

- Administrator : Person who manages experimental animals and facilities (research director, etc.)
- Laboratory animal manager : Person who assists the manager and is in charge of managing laboratory animals
- Experimenter : Person who conducts experiments, etc.
- Breeder : A laboratory animal manager or a person engaged in the care and storage of laboratory animals under the supervision of an experimenter

3) Common standards

- Item 4 : Acquisition of knowledge related to common infectious diseases between humans and animals
- Item 6 : Handling during transportation

4) Individual criteria : Also mentions **humane endpoints and euthanasia methods**

3. Basic Guidelines for Implementation of [Animal Experiments](#), etc. at Implementing Agencies Under the Jurisdiction of the Ministry of Health, Labor and Welfare (Ministry of Health, Labor and Welfare)

1) General rules

2) Responsibilities of the head of the implementing agency (1) Formulation of internal regulations (2) Establishment of animal experiment committee (3) Approval of animal experiment plan (4) Understanding of implementation results of animal experiment plan (5) Implementation of education and training, etc. (6) Self-assessment, evaluation and verification (7) Disclosure of information on animal experiments, etc.

3) Responsibilities of animal experiment director Obtain approval for the animal experiment plan, implement it appropriately, and report the implementation results.

4) Animal Care and Use Committee Review animal experiment plans and advise on implementation results.

5) Considerations in implementing animal experiments, etc. 3Rs, safety control

6) Care and storage of experimental animals

7) Others When outsourcing animal experiments, etc. to another institution, the outsourced parties shall also conduct animal experiments, etc. appropriately based on these guidelines.

(Excerpts from revisions made in 2015)

Thorough compliance with laws and guidelines and enhancement of transparency

Responsibilities of the head of the implementing agency

⑥ Self-check, evaluation and verification : Regularly inspect and evaluate [the compliance with this guideline and internal regulations for animal experiments](#) at the implementing institution. Efforts shall be made to have a person [other than the research institution verify the results](#) of the inspection and evaluation.

External verification

4. Guidelines for Proper Conduct of Animal Experiments (Science Council of Japan, June 2006)

- Explanation of specific requirements and background from a scientific point of view -

<https://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-20-k16-2.pdf>

<<History of development of laws, regulations, guidelines, etc. concerning laboratory animals and animal experiments in Japan>>

Raising and keeping laboratory animals	Use of laboratory animals (animal experiments)
1973: Act on Protection and Management of Animals 1980: Animal Care and Storage Standards (PrimeMinister's Office) 1999: Act on Welfare and Management of Animals Revision of the (Animal Welfare and Management Act) 2000: The Animal Welfare Management Act was enacted due to the reorganization of ministries and agencies. Jurisdiction transferred from the Prime Minister's Office to the Ministry of the Environment 2005: Revision of the Animal Welfare Management Law(Supplementary resolution: Strengthening the effectiveness of the 3Rs, etc.) 2006: Care and storage of experimental animals Standards for pain reduction (Ministry of the Environment notification)	1980: Formulation of Animal Testing Guidelines (Recommended by the Science Council of Japan) 1987: Animal testing at universities, etc. (Ministry of Education notice) 2004: Promoting public understanding of animal testing In order to do so (recommendation) (Science Council of Japan, Section 7) 2006: To the implementing agency under the jurisdiction of the Ministry of Health, Labor and Welfare Basic guidelines for conducting animal experiments (Ministry of Health, Labour and Welfare) 2006: Guidelines for Proper Conduct of Animal Experiments (Section 2, Science Council of Japan)

Regulatory system for animal experiments in each country

Regulation Regime of Animal Experiments

		by regulator				Institutional Approval of Experimental Plan	Final Approver (Person Responsible) for Animal Testing
		Main laws	Facility Certifi.	Facility Inspec.	Implem. license		
Japan		+	—	—	—	+	Head of institution
		Animal Welfare Management Act	Specific animal permit	Exter. Verificati.	Training		
USA		+	—	+	—	+	Head of institution
		Animal welfare law	Regis.(excluding mice, rats, and birds)	Dep. Agriculture	Training		
Canada		+	—	—	—	+	Head of institution
		State Animal Testing Law*	CCAC-accredited	Exter. Verificati.	CCAC-accredited		
UK		+	+	+	+	—	Home Secretary
		Animal (Scie. Procedure) Act	Home Minister	Ministry of the Inte.	Home Minister		
Germany		+	+	+	+	—	Municipality
		Animal Welfare Management Act	Municipality	Municipality	Municipality		
France		+	+	+	+	+	Head of institution
		Law 2013-118	Minister of Agriculture	Municipality	Minister of Agriculture	The final decision is made by the Ministry of Education and Research.	

Breeding is regulated by laws and regulations
Experiments are respected by institutions

Experiments are regulated by law
Breeding is included in experiments

* Ontario, CCAC: Canadian Council on Animal Care

5. Other major relevant laws and regulations

1) Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act)

- Breeding
 - Escape prevention equipment, etc. (installation of mouse returners)
 - Indication of "Recombinant animals, etc. being reared"
- Transportation
 - Information provision form for genetically modified animals when transferring, etc.
 - Put in a container that is designed to prevent escape
 - Display "handle with care"
- Others
 - Individual identification

2) Act on the Prevention of Damage to Ecosystems, Etc. by Specified Alien Species

- Bullfrog ○ Rhesus monkey ○ Cynomolgus monkey

3) Other

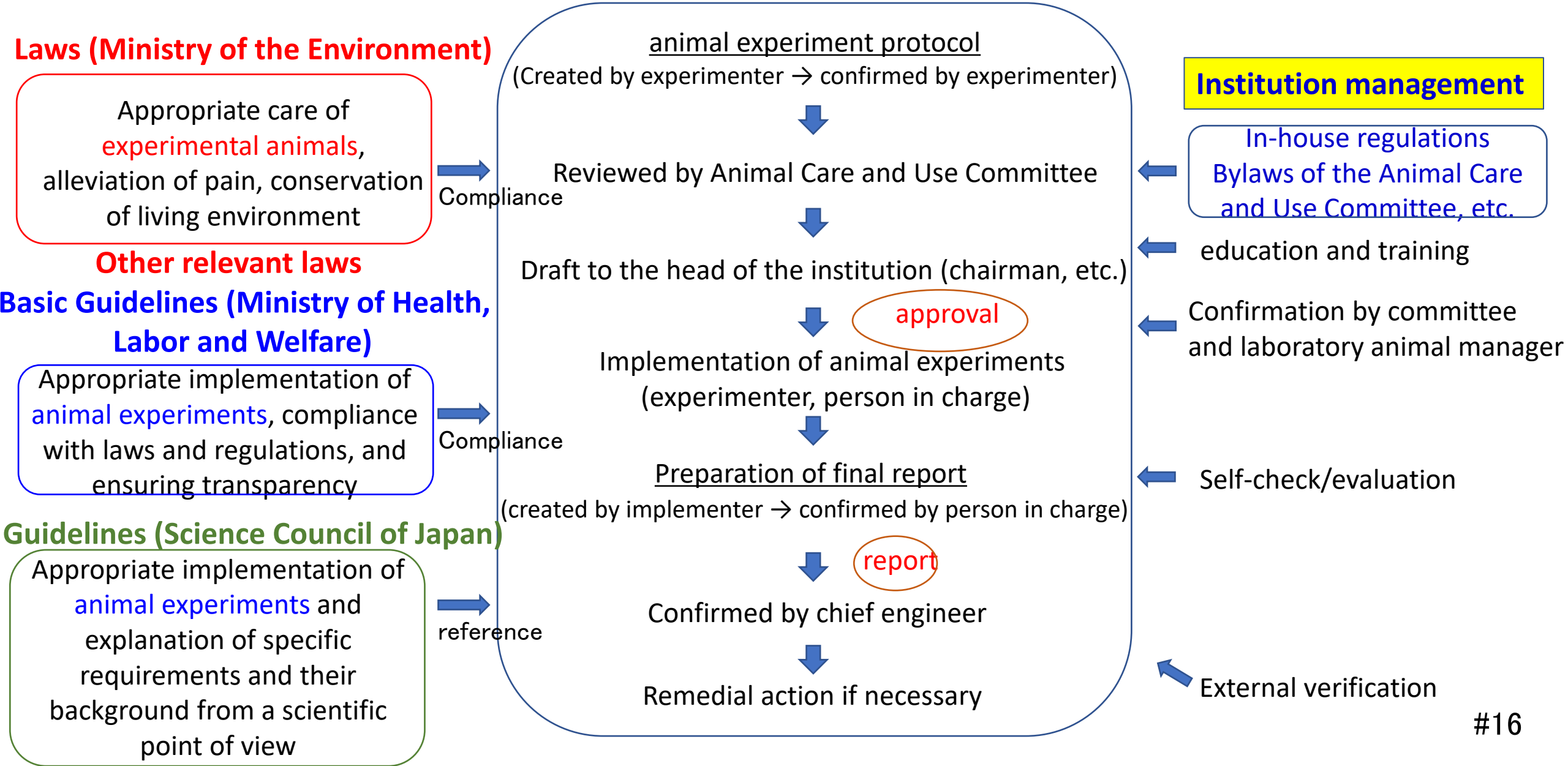
Chemicals for use on animals

- Narcotics and Psychotropics Control Law, etc.

Occupational health and safety of implementers, etc.

- Act on Prevention of Radiation Hazards due to Radioactive Isotopes, etc.

Summary: Flow from the formulation of the experiment plan to the execution of the experiment and the submission of the experiment report



Related laws and regulations related to experimental animals and animal experiments

1) Act on Welfare and Management of **Animals** (Animal Love Act)

Standards for the care and storage of **laboratory animals** and the alleviation of suffering (standards for breeding and storage)

- (Experiment) Legal system specializing **in animal welfare** and appropriate management (prevention of harm and nuisance, etc.)
- Clarification of the **3Rs** principle

2) Other relevant laws and regulations

- Handling of genetically modified organisms (Cartagena Law), handling of invasive alien species, Narcotics and Psychotropics Control Law

3) Basic guidelines concerning the implementation of animal experiments, etc.

at implementing agencies under the jurisdiction of the Ministry of Health, Labor and Welfare

- Responsibilities of the director of the implementing institution, responsibilities of the person in charge of animal experiment, animal experiment committee, etc.

4) Guidelines for proper conduct of **animal experiments**

- Explanation of specific requirements and their background from a scientific point of view

5) It is extremely important for each researcher (experimenter) to understand and practice laws, basic guidelines, guidelines, etc. in order to conduct appropriate animal experiments under institutional management!