Japanese concept and government policy on animal welfare and animal experiments

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Abstract
The Law for the Humane Treatment and Management of Animals has been amended on June 1, 2006. With this amendment, the 3R principle has been entirely stipulated in the article of the law, and detailed government guidelines have been formulated.

Under this Japanese regulation system based on the law, the person who maltreat and abandon laboratory animals without any scientific needs can be punished. And each institution should establish in-house regulations based on governmental policies, and whether the person in observe the law and related guidelines or not is monitored by not legislative measures of government, but by the self-control system managed by each institution itself.

The principal reason of the adoption of this self-control system in Japan is that most of animal experimentation is "the public act" that brings the welfare of human beings in future, and bioscience itself should not be regulated only from the aspect of humane treatment of animals. Proper treatment of animals is mere additional consideration in weighing the public benefits against the public disadvantages involved.

Keywords: 3Rs, humane treatment, amendment of the law, self-control, peer-review

History of the amendment of the law
The Law for the Humane Treatment and Management of Animals has been amended on June 2005, and enforced on June 2006. With this amendment, the 3R principle has been entirely stipulated in the article of the law, and consequently detailed guidelines have been formulated by government so that improper act might not be done.

In considering how to amend the law, there was various kinds of opinion. Some animal protection group insisted that killing laboratory animal is pretty rude and cruel action, and animal experimentaiton must be prohibited by government strictly. On the other hand, there were another animal protection group, they thought animal experimentation is usefull for humane beings, and main point is the introduction of well-being of laboratry animals by adequate control.

Through these debates, to put in order roughly, we could recognize two issues as described the below (Fig. 1).

1)Whether it is reasonable to regulate animal experimentation by legislative measures or not. This issue is that which is better for national interest, "legislative strict restrictions on all procedures" or "self-contorol system by scientists themselves based on administrative guidelines".

2)How should we think and manage "care of laboratory animals" and "use of laboratory animals". Care and use are not only close conception, but also two different things.

As a result, members of Japanese Diet recognized ranking order between science and animal welfare, and concluded that appropriate animal experimentation can be accomplished by self-control, not by stringent legislative restriction.

Today's Japanese legal system -legal standing of the 3R principle
With the amendment of the Law for the Humane Treatment and Management of Animals, the 3R principle has been entirely stipulated in the article of the law, and detailed guidelines have been formulated by the several ministries concerned and the science council of Japan (Fig. 2).

According to these guidelines, control and monitoring of animal experiment procedures is performed by scientists themselves. This is why it seemed that bioscience itself should not be regulated from the animal welfare law. But based on the law, Maltreat action is punished strictly. This punishment act as a deterrent as to maltreat action. And each research institution has been establishing in-house regulations based on governmental policies, and whether the person is in keeping with the law and related guidelines or not is monitored by not
Fig. 1. Critical debate -two issues

Fig. 2. Framework of Japanese Legal System

Constitution of Japanese animal protection laws

The Law for the Humane Treatment and Management of Animals protects all kinds of animals from cruelty regardless of its usage. This law covers all domestic animals that are kept in anywhere -household, laboratory, zoo, ranch and so on (Fig. 3).

But this law functions differently depending on the category of animals. As for companion animals, this law functions as comprehensive restriction systems. In case of setting up a pet shop, we must obtain local government's permission beforehand and observe the permission standards on facilities and management. This is why, if the maltreat action might happen, physical public nuisance may be caused seriously in public. On the other hand, as for laboratory animals and farm animals, this law mainly offers the basic philosophy and administrative guidance about how to care and management of animals. In case of setting up a animal laboratory, we need not obtain government's permission based on this law. Because it is not necessary to control all act and all procedures of animal treatment in terms of pursuit of animal welfare. But the person who maltreat and abandon laboratory animals or farm animals without any scientific needs or socially adequate needs can be punished. Its maximum penalty is imprisonment for one year or a fine of one million yen.

With this amendment of the law, fundamental national policy on animal treatment has been established by the ministry of the environment based on the amended law. In this policy the Ministry of the Environment determined the significance of "animal welfare" (Table 1). That is to say, "we should not deny that we have to use and kill animals for our living, instead we must pay enough respect to the life of animals and must do humane treatment. That is what we call "animal welfare". We should distinguish private opinion and public opinion. In other words, in order to do adequate animal welfare, we must discriminate emotion and rule. Consensus-building considering original culture and social climate is legislative measures of government, but by the self-control system, so what we call "peer-review system".

In Japanese administration system, how to care laboratory animals in terms of animal welfare is mainly determined by the Law for the Humane Treatment and Management of Animals, and which is administrated by the Ministry of the Environment. On the contrary that, how to use laboratory animals in terms of science and industry is ruled by the various law related to science, prevention of infectious diseases and agriculture, and which is administrated by mainly 3 ministry, Ministry of Education, Sports, Science and Technology and the Ministry of Health, Labor and Welfare, Ministry of Agriculture, Forestry, Fisheries.

Our future problem is that scientist should improve what needs to be improved. For example according to the survey of the ministry of the environment, only half of research institutions answered "all staff knows the law". This fact does not directly mean that maltreat action has been being done in the laboratry as usual. As a matter of fact, contents of guidelines is nothing special, only common practice is written in the guidelines. So without guidelines, good scientist can do animal welfare well. But in order to give evidence to prove scientist's proper treatment, validation system of self-control such as a cross check or inspection by an outside organization must be built.
important." This policy making system is expected to reinforce and support promoting better relations with animals in future.

**Differentiation of 3R conception**

As mentioned before, with the amendment of the law, the article written for the use of animals for scientific purposes have been altered. Before this amendment, only Refinement was stipulated in the article of the law, but after this amendment of the law, the rest of 3R principle, Replacement and Reduction have been added, and the 3R principle has been given legal standing (Table 2).

Of all 3R, especially "Refinement" has the detailed guideline based on the law, which is called "the standards relating to the care and management of laboratory animals and relief of pain". Why only "Refinement" has detailed guideline based on the law? That is why "Replacement and Reduction" are considered as the technical items which is closely related to the animal experimentation as science. Certainly these two principle are one of the philosophy about animal welfare, but we will try to give body to these two principles, at once we come to realize that we cannot perform these two principles without the scientifical knowledge of animal experimentation. 3R is the principle for animal welfare, moreover 3R is the principle for scientifical methods of animal experimentation. But investing into details, each principle of 3R is different respectively. Unlike "Refinement", "Replacement and Reduction" are principle that represent technical methods of animal experimentation, so Japanese Diet concluded that these two principles ought not to be dealt with the animal welfare law specifically. Such role-sharing arrangement between animal welfare and science, as it were, "diferenciation of 3R conception" has been done through the amendment of the law. I think, as a result, Japanese animal experimentation control system has become one of the most reasonable regulation in the world.

**Table 1. Fundamental National Policy on Animal treatment 2006 (an extract)**

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<th>(&quot;Animal welfare&quot; means; )</th>
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**Table 2. Description of 3R (in the article of amended Law)**

| Article 41 Where an animal is used for for the purposes of education, testing, research, manufacturing of biologic products or other scientific purposes, consideration shall be given to proper use of animals such as use of alternative methods not using animals and using as few animals as possible with in the limits to fulfill the purposes. |
| 2. When an animal is used for scientific purposes, methods that do not cause pain or distress to the animals should be used within the limits to fulfill the purposes. |
| 3. When an animal is beyond recovery after use for scientific purposes, the person who used the animal for such scientific purposes must immediately dispose of the animal by a method that causes the animal as little pain and distress as possible. |
| 4. The minister of the environment may, after consultation with the heads of the administrative agencies concerned, prescribe applicable standards with regards to the methods in paragraph 2 and the measures in the preceding paragraph. |

**References**
