Please note: This is NOT an authorised translation of the Norwegian Regulation on Animal Experimentation *(Forskrift om forsøk med dyr)*. The text of this Regulation may well undergo changes in the future. Please look upon this translation accordingly.

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Regulation on Animal Experimentation

Pronounced by the Ministry of Agriculture, January 15, 1996, in accordance with the Animal Protection Act of December 12, 1974, nr 73, §§22 and 30, after royal proclamation of 19.11.76, amended November 17, 1998.

Chapter 1. General Provisions

§1 Aims

The aim of the Regulation is to ensure that animals governed by the Regulation receive correct treatment and are not subjected to unnecessary pain and suffering.

§2 Area of application

The Regulation regulates experimentation with animals, and in addition the breeding, rearing and keeping of animals that are to be utilized in experiments. The Regulation applies even though tranquillizing, sedative or analgesic preparations are used in an experiment, including experiments conducted on totally anaesthetized animals that are euthanized whilst still under anaesthesia.

Exceptions are

- treatment and surgery conducted as part of a clinical veterinary procedure, which uses a recognized method.

- simple marking of animals, withdrawal of blood samples and collection of natural secretions or excretions, should there not be reason to assume that the experiment will affect the animal's normal way of life, or cause other than slight pain or discomfort of a highly temporary nature.

- experiments having to do with breeding/rearing, feeding and environment (domestic animals and aquatic organisms) should there not be reason to assume that the experiment will produce a non-physiological state in the laboratory animal.

In any case of doubt, the Norwegian Animal Research Authority will decide whether an experiment is encompassed by the Regulation.

§3 Definitions

The following definitions apply in this Regulation:

laboratory animal

living mammals, including embryonic forms and foetal stages, birds, fish, reptiles, amphibians, with their free-living immature stages, and decapods. Fertilized eggs are exempted from the Regulation.

experiment

the use of animals for the acquisition of knowledge of a biological, psychological, ethological, physical or chemical nature, also when this is a necessary part of the education an institution provides. The use of animals in the production of reagents such as antigens and antibodies, etc., routine diagnostics, testing activity, and establishment of transgenic stocks, is considered to be an experiment.

the Norwegian Animal Research Authority (Utvalg for forsøk med dyr, forsøksdyrutvalget)

a publicly appointed committee with the authority to consider, approve and inspect experiments with animals that fall within the bounds of the Regulation.

laboratory animal unit

a locality approved by the Norwegian Animal Research Authority for use in animal experimentation.

field experiment

an experiment not conducted in an approved laboratory animal unit.

breeding/rearing activities

an activity in which animals are bred or reared with the intent to use them in experimentation.

supply activity

activity, apart from breeding/rearing, that provides animals for use in experiments.

reuse

repeated use of animals for new and independent experimentation, in which another animal could have been utilized instead.

Chapter II. Approval, permits, responsibility

§4 Approval of an laboratory animal unit

A laboratory animal unit is to be approved by the Norwegian Animal Research Authority before the unit comes into operation. An approval notice issued by the Authority is to be displayed at a prominent location in the unit.

Plans for new laboratory animal units or significant refurbishment of existing laboratory animal units are to be submitted to the Authority. Approval shall only be given should the standard, equipment, staffing and routines be such as not to adversely affect the animals' health or well-being.

The Authority may impose any conditions considered necessary before giving its approval.

§5 Approval and registration of breeding, rearing and supply activities

Breeding and supply activity, and the person responsible for this activity, must be approved by and registered with the Norwegian Animal Research Authority. The Authority may impose any conditions considered necessary before giving its approval.

§6 Approval of a competent person within the unit or company

Every laboratory animal unit must appoint a competent person (*ansvarshavende*). This person must be approved by the Norwegian Animal Research Authority after application by the unit or company. Approval may be given for up to four years at a time.

The competent person is required to possess a university or college education with a scientific background that the Authority finds appropriate, and with experience in animal experimentation. The Authority may also approve a person without university or college education should the person be able to document other competence that the Authority finds appropriate. The competent person must have his or her workplace at the unit or company where he or she is the competent person.

The competent person shall keep his or her professional abilities and skills up to date through attendance at approved coursework in laboratory animal skills. Relevant professional literature must be available at the unit.

Re-approval of the position of competent person may be made dependent on such professional development.

§7 Requirement for permission

All persons wishing to conduct experimentation involving animals, which is covered by the Regulation, must obtain permission from the Norwegian Animal Research Authority or from a person delegated by the Authority.

The Norwegian Animal Research Authority may set general and/or specific conditions for permission.

Animal experiments, with the exception of field experiments, may only be carried out in facilities approved by the Authority. Should special situations exist, the Norwegian Animal Research Authority may allow conduction of the experiment in the absence of the specified facilities.

§8 General requirements for permission to experiment

Experiments with animals may only be carried out for the acquisition of knowledge, taking legitimate scientific or social considerations.

For experiments that may be assumed to cause pain, and where the goal of the experiment is such that the use of anaesthesia or analgesic preparations is not possible, special demands on the scientific or practical value of the experiment must be made.

Permission for the use of animals in experimentation must only be given if other scientifically acceptable methods that do not require the use of animals are not possible in practice.

An applicant for an experiment that will use animals is required to document the alternative methods that exist and to describe these in the application.

§9 Permission for an institution or company to conduct an experiment

Upon receipt of an application, permission to conduct an experiment may be given to an institution or company possessing an approved laboratory animal unit under the leadership of an approved competent person.

Permission must specify the species of animals that are to be utilized.

Permission may be given for up to four years at a time and may be withdrawn with immediate effect should the conditions for approval be altered or no longer exist.

§10 Permission for field experimentation

Upon receipt of an application, permission to conduct a field experiment, or other experiments not conducted in an approved laboratory animal facility, may be given to an institution, company or an individual. The Norwegian Animal Research Authority may require that a person other than the person receiving the permission is to take part in or supervise the experiment.

The applicant must document the goals, type of experiment, size of the experiment including the species and numbers of individuals of each species, the duration of the planned experiment, and where the field experiment will take place. in addition, the applicant must at any given time provide any information the Authority may require.

Permission may be given for up to two years at a time and may be withdrawn with immediate effect should the conditions for approval be altered or no longer exist.

§11 The functions of the competent person

The competent person is committed to ensure that all activities involving laboratory animals in an institution or company comply with relevant laws and regulations, and with the prerequisites that may have been placed by the Norwegian Animal Research Authority. The Authority may delegate authority to approve experiments that fall within the framework of the institution's or company's approval document to the competent person. Experimentation must not begin before the experimental design is approved by the Norwegian Animal Research Authority or the competent person.

Should the competent person be in doubt as to whether the experiment falls within the framework of the approval document provided, or for other reasons finds it difficult to make a decision concerning a case, the application together with a statement by the competent person is to be forwarded to the Norwegian Animal Research Authority for a decision.

On the basis of the recommendation of the competent person, the Norwegian Animal Research Authority may approve the use of laboratory animals by the institution or company in connection with routine diagnosis, production of biological products and in its testing activities. The Norwegian Animal Research Authority may impose the necessary prerequisites for its approval.

The competent person's own experiments must always be approved in advance by the Norwegian Animal Research Authority.

Plans for experiments that are assumed to cause prolonged or significant pain, are to be considered exclusively by the Norwegian Animal Research Authority.

No permission for such experimentation on animals may be given for more than two years at a time.

Chapter III. Care of animals, and planning and carrying out an experiment.

§12 Care and supervision of animals

All animals used in, or intended to be used in experimentation, including breeding stock, are to be provided with the housing and environmental conditions, freedom of movement, and feed and water necessary for their health and prosperity. The housing and environmental conditions provided must satisfy the guidelines in Appendix A of the Council of Europe's Laboratory Animal Convention of March 18, 1986.

The animals must be inspected daily, and they are to be attended to and checked carefully and as often as necessary. This means that a shift system must be established for surveillance of the animals outside of normal working hours.

Persons who care for and supervise laboratory animals must have received a form of training approved by the Ministry of Agriculture.

Each laboratory animal unit that does not have its own veterinary surgeon as competent person, must enter into a contract with a named veterinary surgeon who shall provide advice on the animals' housing, environment and treatment. This veterinary surgeon must fulfil the standard of competence required by the Ministry of Agriculture.

§13 Planning and conducting an experiment.

Persons who conduct, or plan to conduct, experiments must have received a form of training approved by the Ministry of Agriculture.

Experiments are to be thoroughly planned, carried out and quality-controlled in order to ensure that the minimum number of animals is used. The animals must not be subjected to unnecessary suffering. If the methods to be used are previously untried or there is uncertainty as to how many animals need to be used, a pilot study is to be carried out. In cases of doubt, the Norwegian Animal Research Authority will decide whether the animals in the experiment could be subjected to unnecessary suffering.

Wild species that are not readily tamed must not be kept in captivity longer than necessary.

For animals in laboratory animal units and, where possible, during field experiments, a card record is to be kept of every cage with animals used in an experiment. The card used for this purpose must provide the researchers' names, arrival date of the animal or animals, the date of commencement of the experiment, and a running record of all surgical procedures used. In addition, it shall be stated whether the animals have been used in previous experiments, with the provision of the date of commencement of the first experiment.

§14 Painful experimentation

Should an experiment be assumed to be painful, anaesthesia must be used, except if the aims of the experiment prevent this and the Norwegian Animal Research Authority has approved the absence of anaesthesia in the particular experiment. The experiment must not be commenced before the anaesthesia has taken effect and must be concluded before its effect has worn off.

When it must be assumed that an animal feels pain, analgesic drugs shall be given, except if the aims of the experiment prevent this and the Norwegian Animal Research Authority has given specific approval for the avoidance of the use of analgesic agents. Should unforeseen pain not be treatable, the animal must be euthanized immediately.

Should there not be reason to assume that the intensity of pain experienced in an experiment exceeds the pain intensity of anaesthesia, anaesthesia may be omitted.

Blood sampling from the heart, and injections into the heart, may only be conducted under total anaesthesia. The animal must be kept totally anaesthetized until it is euthanized, unless the Norwegian Animal Research Authority has provided specific permission for the animal to be revived from the anaesthesia.

§15 Reuse of experimental animals

Animals that have been used in experiments that may be assumed to have produced pain must not be used in new experiments that might produce anything more than insignificant pain or discomfort.

The competent person decides whether animals used in experiments are to be euthanized, of if they can be used in new experiments. For wild animals used in experiments, liberation must be considered.

§16 Euthanasia of laboratory animals

Euthanasia of laboratory animals must be carried out in such a way that the animal not be subjected to unnecessary suffering.

Exsanguination of animals must be carried out under total anaesthesia. Euthanasia of animals and methods of euthanasia must be considered a part of the approved experimental design.

Chapter IV. Record keeping, marking of and the origins of laboratory animals

§17 Record keeping

All laboratory animal units are required to maintain a log book. The book shall contain information on the receipt of animals, the supplier, species, number and usage, all with reference to a project number. In particular, information on the animals' status at arrival is to be entered in a separate column. In addition, a log is to be kept that consecutively records all animals that are brought into the unit, what the animals are to be used for and whether they are moved out of the unit again.

Every breeding/rearing unit is to keep a journal of all breeding animals with information on health and births, the date of receipt and delivery of animals, the numbers of animals that are received or delivered and the names and address of the supplier or recipient. All supply units are to maintain a journal with information on the species and numbers of animals that are supplied, the supplier's name and the name and address of the recipient. In particular, information relevant to the health and well-being of the animals is to be noted as a separate entry. The journal is to be kept for at least three years from the date of the last entry.

§18 Marking of dogs and cats

Dogs and cats are to be marked individually. Marking shall be permanent and is to be done as soon as the animal is weaned or the first time it is brought onto the premises of the supplier or the laboratory animal unit. Marking must cause the animal the least possible discomfort.

A journal containing the identity of each individual dog and cat housed is to be kept. If unmarked dogs or cats are transferred from one approved unit to another, they must be accompanied by identity papers.

§19 Requirements concerning the separate origins of laboratory animals

The following species must, should they be used for experimentation in an approved laboratory animal unit, be acquired directly or indirectly from an approved breeding/rearing unit or supply unit:

Common name	***Latin name***
Mouse	*Mus musculus*
Rat	*Rattus norvegicus*
Guinea Pig	*Cavia porcellus*
Syrian Hamster	*Mesocricetus auratus*
Mongolian Gerbil	*Meriones unguiculatus*
Rabbit	*Oryctolagus cuniculus*
Dog	*Canis familiaris*
Cat	*Felis catus*

The Ministry of Agriculture may add species to or remove species from this list.

Stray or feral domestic animals are not to be used for experimentation.

Chapter V. Administrative Regulations

§20 Inspection

The Norwegian Animal Research Authority, or personnel appointed by it, may at any time inspect localities mentioned in §§4 and 5, all animals that are held there, and attend experiments.

§21 Complaints

Decisions of the Norwegian Animal Research Authority may be appealed to the Norwegian Food Safety Authority, Central Unit.

§22 Dispensation

The competent person may grant dispensation from the requirements for the completion of coursework and training in laboratory animal skills (§§6, 12 and 13) for persons who, through their work with laboratory animals before the introduction of the Regulation, have acquired the level of competence and experience that the Ministry of Agriculture finds satisfactory.

§23 Instructions for the Norwegian Animal Research Authority

The Norwegian Food Safety Authority, Central Unit, shall prepare a set of instructions governing the work of the Norwegian Animal Research Authority.

§24 Interim and annual reports

Any institution, company or person who has received permission to conduct experiments on living animals shall send a report on a special form to the Norwegian Animal Research Authority within March 1 of each year, documenting the experiments that have been conducted in the course of the previous calendar year.

The Norwegian Animal Research Authority shall, within June 1 each year, send a report of its activities for the previous calendar year to the Norwegian Food Safety Authority, Central Unit. The statistical information specified in Appendix B of the European Council's Laboratory Animal Convention of March 18, 1986 must at the very least be supplied as an appendix to the report.

§25 Penalty Clauses

Violation of this Regulation or any of the instructions given in accordance with it, is punishable in accordance with the Animal Protection Act, §31, of December 20, 1974, nr 73.

§26 Commencement and interim regulations

This Regulation takes effect on February 1, 1996. The Regulations on biological experimentation with animals, pronounced by the Ministry of Agriculture on December 22, 1977, in accordance with the Animal Protection Act of December 20, 74, nr 73, §§21 and 22, after Royal proclamation of November 19, 1976, is repealed from the same day.

The instructions in §§6, 12 and 13 on coursework/training requirements in laboratory animal science take effect on July 1, 1998, with the exception of persons who, in relation to §12, third point, care for or supervise experimental animals, for whom the Regulation takes effect on July 1, 1999. The instructions in §5 concerning approval/registration of breeding/rearing and supply units take effect on July 1, 1997.

More information about the Ministry's rules on compulsory training may be found on the webpages of the Laboratory Animal Unit, Norwegian School of Veterinary Science.

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