

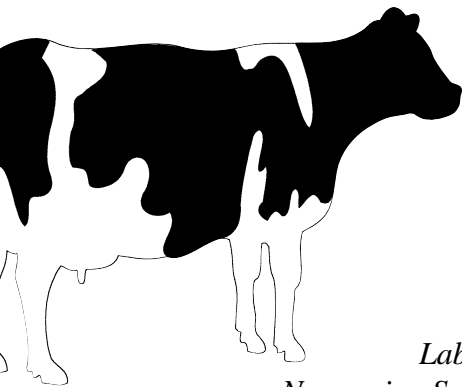
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# The regulation of animal experimentation in Norway:



## An introduction

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# **The regulation of animal experimentation in Norway: An introduction**

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Oslo, November 1998.

## **Introduction**

Norway has chosen a system for regulating its animal experimentation that is unique by international standards. It is important that all researchers understand how this system works. In addition, the use of experimental animals in Norway differs in a number of ways from traditional laboratory animal practice:

- fish are important experimental animals in Norway. In 1997, 91% of the live animals used in research were fish, largely Atlantic salmon.
- much of the research carried out in Norway consists of field projects. This work, by its very nature, is more difficult to monitor and requires extra vigilance by the researchers. Field research receives as much publicity in the mass media as does the use of traditional laboratory animals, despite the fact that many Norwegians have long traditions for hunting and fishing.
- Norway has a population of a mere 4.2 million, a coastline that stretches a distance equivalent to that between London and the Greek islands and a harsh winter climate. This imposes special responsibilities on those responsible for ensuring that animal experimentation is carried out to the highest ethical and legal standards. The animal welfare legislation applies also on Spitzbergen, with a few exceptions.

## **The Norwegian Animal Welfare Act**

Animal experimentation in Norway is regulated by the Ministry of Agriculture through the Norwegian Animal Welfare Act. The Act states that experiments may not be performed without special permission, to be granted by a board known as the National Animal Research Authority (NARA) (*Utvalg for forsøk med dyr* or *Forsøksdyrutvalget*) or persons to whom it delegates such authority. The relevant text from the Act is given in the Appendices.

Some research projects (particularly those using fish or wild species) may require prior approval from other Ministries in addition to that obtained from the NARA. This includes the use of transgenic animals (see below).

## **The European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes** **(Europakonvensjonen)**

The European Convention, drawn up by the Council of Europe in Strasbourg, was made available for signature in 1986. Norway was the first country to sign the Convention. The contents of the Convention began to apply in Norway on January 1st 1991. This necessitated changes in the Regulation issued within the power of the Animal Welfare Act. A new Regulation was issued on January 15th 1996. This came into effect on February 1st 1996, with the exception of certain paragraphs relating to compulsory training (see below). It is important that all researchers understand the scope of this Regulation and the way in which it is enforced. In addition, Norway has stricter practices in several areas when compared with other European countries. The full text of the Regulation is given in the Appendices.

## **The National Animal Research Authority (*Utvalg for forsøk med dyr* or *Forsøksdyrutvalget*)**

All animal experimentation in Norway has to be approved by a National Animal Research Authority (NARA), appointed by the Ministry of Agriculture, or by competent persons to whom the NARA has delegated authority. The NARA consists at present of 7 members, each with a personal deputy:

1 veterinarian (leader)

1 legal expert (deputy leader)

1 laboratory animal specialist

1 doctor

1 biologist

1 representative for Norway's animal welfare organizations

1 member to cover the use of transgenic animals

The Authority has a full-time secretary who is also a veterinarian, whereas the members themselves have other full-time positions in addition to this role.

The address of the secretary is: Utvalg for forsøk med dyr, Statens dyrehelsetilsyn, Postboks 8147 Dep., 0033 Oslo. Tel.: 22 24 19 78. Fax: 22 24 19 45. e-mail: [tore.wie@vetinst.no](mailto:tore.wie@vetinst.no)

The role of the NARA is to:

- approve and inspect Norway's laboratory animal units
- designate the animal species that may be housed there
- appoint a competent person (*Ansvarshavende*) at each unit to whom responsibility for approving research applications can be delegated
- handle applications for field research projects

The NARA holds regular meetings 8-9 times a year, usually in Oslo.

In addition, the Authority receives copies of all application forms that have been

approved locally by the competent persons. The Authority may in this way monitor local practices and call for reports on specific projects. The Authority may also be contacted for advice on interpretation of the current legislation, and it issues an annual report based upon statistics supplied by each of the country's laboratory animal units.

## **Norway's approved laboratory animal units**

Norway has approximately 80 approved laboratory animal units (*forsøksdyr-avdelinger*). Over half of these are situated in Oslo or the vicinity. The majority of the other units are either in the University towns of Trondheim, Bergen and Tromsø or consist of fish research stations around the coast. The housing conditions and management routines must meet the requirements stated in Appendix A of the European Convention. Each of these units has an approved competent person (*ansvarshavende*). Daily inspections of the animals in these units is mandatory. It is the competent person's task to ensure that sufficient resources are allocated to monitor the well-being of the animals in his/her care.

## **Approved competent persons (*ansvarshavende*)**

For practical reasons, the day-to-day approval of the majority of animal experiments in approved laboratory units is delegated to a competent person (*ansvarshavende*), appointed by the NARA at each facility for a period of 4 years at a time.

These persons have for all practical purposes the same authority as the NARA itself to scrutinize protocols and to pass judgement on their acceptability. They can approve applications from researchers, turn them down, or send them to the Authority for a decision. Projects may be approved for a maximum of 4 years at a time. Researchers are obliged to document that they have considered the use of alternatives to experimental animals.

The competent person may not, however, undertake the following tasks without special approval from the NARA:

- process his/her own research applications
- process applications for field research (i.e. projects outside the facilities for which he/she has responsibility), unless the NARA has given special approval
- process controversial protocols upon which he/she does not feel capable of passing judgement
- approve experimental protocols involving painful procedures where painkillers are deliberately withheld

These cases must be handled by the NARA.

Any project, at whatever level it has been approved, may be halted at any stage if one or more of the authorizing parties considers the experimental situation to be too great a burden on the animal in relation to the approved protocol or scientific gains.

The NARA may, at the suggestion of the local competent person, issue a more general approval to an institution that conducts routine work such as immunization or diagnostic services.

The competent person is required to send a annual report to the NARA, with statistics of the animals used and descriptions of the types of research performed, so that the NARA can send a national annual report to the Council of Europe in Strasbourg.

## **Availability and transport of experimental animals in Norway**

There are few approved suppliers of laboratory animals in Norway, since the laboratory animal environment is too small to justify large-scale animal breeding. Nevertheless, Norwegian regulations state that the following species must be obtained directly or indirectly from an approved breeding/rearing unit or supplier if they are to be used in research:

Mouse	<i>Mus musculus</i>
Rat	<i>Rattus norvegicus</i>
Guinea Pig	<i>Cavia porcellus</i>
Syrian Hamster	<i>Mesocricetus auratus</i>
Mongolian Gerbil	<i>Meriones unguiculatus</i>
Rabbit	<i>Oryctolagus cuniculus</i>
Dog	<i>Canis familiaris</i>
Cat	<i>Felis catus</i>

The Ministry of Agriculture may add or remove species from this list. Stray or feral domestic animals are not to be used for experimentation.

The majority of traditional laboratory animals used in Norway are therefore imported from abroad. This means that many laboratory animal facilities are to be considered as quarantine units, and the animals may not be removed from the unit. Practical issues arising from this situation should be discussed at as early a stage as possible with the local competent person or the NARA.

Good laboratory animal practice requires that the animal be acclimated to its environment in good time before the experiment. This is especially important for animals that have been imported from abroad. Researchers should be aware that laboratory animals may therefore not be available for several weeks. For this and other reasons, research protocols should be discussed well in advance with the local competent person or the NARA.

To facilitate the importation of laboratory animals or animal material, the National Institute of Public Health (*Statens Institutt for Folkehelse*) runs a centralized import facility (*Norsk Forsøksdyrsentral*). Many laboratory animal units use this service to supply the animals they need.

The researcher should be aware that local or national regulations designed to prevent

the spread of disease may also impose restrictions on the availability and transport of experimental animals. This applies particularly (but not exclusively) to farm animal species and fish. The local competent person, NARA or the veterinary field service can provide more information.

## **Inspection of laboratory animal facilities**

The NARA undertakes inspections of laboratory animal facilities and specific animal experiments. In addition, the Animal Welfare Act gives the right of inspection to the police, members of the State animal welfare committees (of which there is one in each veterinary district) and official veterinarians (district and county veterinarians). Otherwise, the local competent person may decide who is to be admitted to the unit, and upon which conditions.

## **Named veterinarians**

Approximately 75% of Norway's approved animal units are led by competent persons who do not possess a veterinary degree. These units are required to appoint a named veterinarian who can provide necessary veterinary medical help and who can assist the unit in management questions, including the introduction of prophylactic measures such as health monitoring.

Norway has one Veterinary School, situated in Oslo and with research departments in both the North and West of the country. There are approximately 2000 veterinarians in Norway, and the country is divided into 205 veterinary districts, each with a district veterinarian.

## **Field research**

Any experiment performed outside an approved laboratory animal unit is by definition field research. In the majority of cases, applications for field research are sent to the NARA for consideration. The Authority may wish to empower third party specialists with the right to follow the course of events. Norway's field veterinary service, and in particular the district veterinarians, are usually those given this task.

The Ministry does not encourage the habit of taking experimental animals out of an approved unit, for example to conduct measurements in another laboratory. In special cases this may, however, be necessary. It is imperative that the researcher raises such a wish at an early stage so that the competent person can, if necessary, contact the NARA for approval. An important exception to this rule is the used of wild animals in animal laboratories, where Norwegian legislation requires that animals that cannot be tamed be held in captivity as short as possible, and that release of the animals after the experiment is to be considered.

Field experiments may only be approved for a maximum of 2 years at a time, reflecting the authorities' concern for the welfare of these animals, used as they are under less controlled conditions.

## **Definition of an experimental animal**

The Regulation governing animal experiments defines an animal as:

*'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.'*

Animals that are humanely killed without prior treatment are not defined as experimental animals, and are therefore not included in the annual statistics. Acute experiments (where research is performed under terminal anaesthesia) are, however, defined as animal experiments.

## **Definition of an animal experiment**

The Regulation defines an animal experiment as:

*'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.'*

Furthermore, the Regulation states:

*'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.'*

## **Procedures considered to be unethical**

Norway has a small population and therefore a small laboratory animal environment. Members of this environment communicate with each other regularly, not least through training courses and email discussion groups. In this way, consensus has been established on a number of practices which, although lacking legal foundation, are considered to be unethical. These practices include blood sampling by retro-orbital puncture and the routine use of ether for anaesthesia.

A number of procedures are specifically mentioned in the Regulation governing animal experiments:

*'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 National Animal Research Authority has provided specific permission for the animal to be revived from the anaesthesia.'*

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

## **Compulsory training**

In keeping with the requirements of the European Convention, all persons involved in animal research, i.e. technicians, researchers, competent persons and named veterinarians, have to undergo approved training before they may plan or undertake animal experiments. These requirements came into force on July 1st 1998 for all categories except technicians, for whom the date is July 1st 1999. Such training must be approved by the Ministry of Agriculture. The Laboratory Animal Unit at the Norwegian School of Veterinary Science arranges courses for all personnel categories. This work is currently being intensified in the wake of the new legislation described above, and several other institutions are now arranging their own courses.

The Unit can give advice on the availability of such courses and whether previous training in laboratory animal science is likely to be approved by the Ministry. There are special rules for foreign researchers who do not speak Norwegian, and/or those who will be working on a limited project and who do not need full training.

It is the responsibility of the local competent person (or the NARA in the case of field research) to ensure that all personnel have the necessary training.

## **Regulation of the use of transgenic animals**

The creation of new transgenic lines and the use of transgenic animals are both defined as animal experimentation according to Norwegian law. Approval must be sought in advance not only from the NARA but also from the Ministry of Health and Social



Affairs. This is because the use of transgenic animals falls under the jurisdiction of the Gene Technology Act (*Genteknologiloven*). Under this Act approval needs to be obtained for the following:

- the laboratory animal facilities, to ensure that they are escape-proof and that they satisfy other certain minimum requirements.
- the research project itself
- infection studies involving genetically modified micro-organisms
- the use of naked DNA in experimental animals

Applications for approval of facilities and projects are handled by a committee with offices at the National Institute of Public Health (*Statens Institutt for Folkehelse*).

Their address is:

Avdeling for virologi,  
VIMV - GMO,  
Attn: Kathrine Stene-Johansen,  
Folkehelse,  
Postboks 4404 Torshov,  
0403 Oslo

Tel.: 22 04 22 88

Fax: 22 04 24 47

email: [kathrine.stene-johansen@embnet.uio.no](mailto:kathrine.stene-johansen@embnet.uio.no)

Applications should be sent well in advance of the project, to ensure that sufficient time is available for inspection and approval of the premises, including necessary structural modifications.

## **Some facts about animal research in Norway:**

- monkeys have not been used in Norway for the last 20 years
- the testing of cosmetics is not performed in Norway
- the number of living mammals used in research has been halved the last 10 years
- fish account for approximately 91% of all live animals used in Norwegian research

## **Other sources of information**

### Literature on laboratory animal science in Norway

The Laboratory Animal Unit has produced a comprehensive Compendium on laboratory animal science, with special reference to conditions in Norway. An English translation of this Compendium is available. A separate Compendium covers the use of fish as research animals (presently only available in Norwegian). Further information from:

Laboratory Animal Unit,  
Norwegian School of Veterinary Science,  
P.O. Box 8146 Dep.,  
0033 Oslo  
Tel.: 22 96 45 74 or 22 96 45 75  
Fax: 22 96 45 35  
email: [adrian.smith@veths.no](mailto:adrian.smith@veths.no)

Laboratory animal units on the Internet:

Several Norwegian laboratory animal units have their own web pages on the Internet. The Laboratory Animal Unit at the Norwegian School of Veterinary Science has its own server with comprehensive information about laboratory animal science in Norway:

<http://oslovet.veths.no>

The site includes electronic tours of the Unit in several languages, information about Norwegian legislation and training requirements, forthcoming courses and more general information about laboratory animal science.

Other laboratory animal units with their own Internet sites include:

NINA-NIKU (The Norwegian Foundation for Nature and Cultural Heritage Research):

<http://www.ninaniku.no/estart.htm>

NIVA (Norwegian Institute for Water Research), Marine Research Station, Solbergstrand, Drøbak:

[http://www.niva.no/engelsk/niva/e\\_mfs.htm](http://www.niva.no/engelsk/niva/e_mfs.htm)

Norwegian School of Veterinary Science, Department of Sheep and Goat Research:

<http://www.veths.no/isf/isf.htm>

Svanøy Foundation and Norwegian Red Deer Centre:

<http://www.svanoy.com/deerfarm.htm>

University of Tromsø, Medical Faculty:

<http://www.fm.uit.no/info/drift/dyr>

VESO Vikan Akvavet, Namsos:

<http://oslovet.veths.no/vikan/main.html>

Vivarium, Haukeland Hospital, Bergen:

<http://www.uib.no/vivariet/vivarium.default>

Other Internet sites of interest:

NetVet & The Electronic Zoo (the most comprehensive collection of Internet sites regarding animals):

<http://netvet.wustl.edu>

### Email discussion lists:

The Laboratory Animal Unit at the Norwegian School of Veterinary Science maintains email discussion lists for:

competent persons (*ansvarshavende*)

fish researchers

wildlife researchers

laboratory animal researchers

Please contact Adrian Smith ([adrian.smith@veths.no](mailto:adrian.smith@veths.no)) for more details.

## Appendices:

### Appendix 1.

Statistics for the use of experimental animals in Norway for 1997.

These statistics only report the use of live animals. Animals that are humanely killed without prior treatment, where research is performed on tissues *post mortem*, are not included in these or any other national statistics. Acute studies (i.e. where the experimental studies are performed upon an anaesthetized animal that is humanely killed before the anaesthesia wears off) are defined as animal experiments and these animals are therefor included in the statistics. Animals are only to be counted once, such that these figures do not include animals that entered an experiment in previous years and are still alive.

Fish constituted 91% of the experimental animals used in 1997. Dogs and cats amount to fractions of one percent of the total numbers:

Fish: 574,201

Mice: 29,326

Rats: 19,775

Pigs: 1,341

Hens and other birds: 1,385

Guinea-pigs: 91

Goats and sheep: 1,562

Rabbits: 305

Dogs: 85

Cats: 10

**Total: 630,169**

## **Appendix 2.**

Reporting animal experiments carried out in Norway.

The following is a suggestion for the wording of a statement that can be used when submitting the results of animal experiments performed at approved laboratory animal units in Norway to foreign scientific journals. The form should be signed by the competent person (*ansvarshavende*) in charge of the animal unit where the experiments were performed:

*To whom it may concern*

*Date:.....*

*The experiments/procedures described in this article/these articles submitted by*

*Dr/Mr/Mrs*

*have been approved by the local responsible competent person under the surveillance of the Norwegian Animal Research Authority (NARA) and registered by the Authority. The experiments/procedures have thus been conducted in accordance with the laws and regulations controlling experiments/procedures in live animals in Norway, i.e. the Animal Welfare Act of December 20th 1974, No 73, chapter VI, Sections 20-22 and the Regulation on Animal Experimentation of January 15th 1996.*

*In addition, Norway has signed and ratified The European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes of March 18th 1986. The Norwegian legislation conforms in all respects with the basic requirements of this Convention and guidelines prepared in pursuance of it.*

*(signature)*

*Approved competent person*

### **Appendix 3.**

Relevant text from The Norwegian Animal Welfare Act:

Section 20: Use of animals in teaching.

*It is forbidden to use live animals for teaching purposes unless necessary as a part of professional training. The Ministry may refuse to allow such use of animals if there is doubt as to its necessity.*

*Teaching must be carried out in such a way that the animal is not subjected to unnecessary suffering.*

Section 21: Use of animals in research, etc.

*No person may carry out biological research on animals without a special licence. A licence may be given if the aim is to find out what kind of disease animals or people suffer from, or if the purpose is to prevent or eradicate disease. A licence may also be granted if the purpose concerns research, preparation or testing of a medicine, drug, poison, etc. for use in people, animals or plants.*

*Such research must be carried out in such a manner that the animal is not exposed to the risk of suffering more than is strictly necessary for the purpose.*

*The person who has been granted a licence according to the provisions of the first paragraph, may, notwithstanding Section 9 of the Veterinary Surgeons Act, No. 3 of 10 December 1948, employ total or local anaesthesia on the animals concerned.*

Section 22: Licence to carry out research, etc.

*A licence in accordance with section 21 is granted by a committee which the Ministry appoints for terms of office of four years.*

*The King may issue regulations as to how this committee shall be established, terms of reference and working procedures, and on the possibility to carry out inspections.*

*The King may issue regulations that empower the committee, in limited areas, to delegate the authority to grant licences for biological research on animals to a person approved by the committee as being responsible for such research in an establishment or institution.*

*The Ministry is the body which shall deal with complaints concerning the decisions of the committee.*

## **Appendix 4.**

The Norwegian Regulation on Animal Experimentation (unofficial translation).

### **Regulation on Animal Experimentation**

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

### **Chapter I. 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 National Animal Research Authority (*Utvalg for forsøk med dyr, forsøksdyr-utvalget*): 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 National 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 National 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 National 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 National 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 upon 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 National Animal Research Authority or from a person delegated by the Authority.

The National 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 National 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 National 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 National 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.

Persons planning to undertake animal experiments shall send an application to the competent person on a designated application form, enclosing the research protocol. They shall provide all the information required at any time by the National Animal Research Authority, including the aims, type and extent of the experiment, species and animal numbers to be used and duration of the study. The competent person shall, within one week of approving a protocol, send the Authority a copy of the application bearing the project number, for all projects which, in the competent person's opinion, fall within the general approval given to the institution, as indicated on the institution's document of approval.

Experimentation must not begin before the experimental design is approved by the National 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 National Animal Research Authority for a decision.

On the basis of the recommendation of the competent person, the National 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 National 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 National Animal Research Authority.

Plans for experiments that are assumed to cause prolonged or significant pain, are to be handled exclusively by the National 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 National 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 National 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 National 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 National Animal Research Authority has given 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, or 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 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:

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

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 National 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 National Animal Research Authority may be appealed to the Norwegian Animal Health 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 National Animal Research Authority

The Norwegian Animal Health Authority, Central Unit, shall prepare a set of instructions governing the work of the National 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 National 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 National Animal Research Authority shall, within June 1 each year, send a report of its activities for the previous calendar year to the Norwegian Animal Health 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 Welfare 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 Welfare Act of December 20, 74, nr 73, §§21 and 22, after Royal proclamation of November 19, 1976, are 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.

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

<http://oslovet.veths.no>



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