Laws and regulations associated with animal experiments

Adrian Smith

The main purpose of this chapter is to give a short introduction to Norwegian and international laws and regulations that apply to the use of laboratory animals. These take into consideration the principles of the three R’s.

The Animal Welfare Act

According to the Norwegian Protection Act of 20th December 1974, no-one can conduct biological experiments on animals without special authorization. Such authorization shall be given by a board appointed by the Norwegian Food Safety Authority for a four year period. The board is called the Norwegian Animal Research Authority (NARA; Forsøksdyrvalget, FDU), and has 8 members in this period:
- 1 lawyer (leader)
- 2 veterinarians
- 2 researchers
- 1 doctor
- 1 representative for animal welfare organisations
- 1 animal technician

Each member has a personal deputy. The Secretariat’s address is:
Forsøksdyrvalget, Felles postuttak, Postboks 383, 2381 Brummundal
Telephone: 23 21 68 00
Fax: 23 21 68 01
Email: fdu@matilsynet.no

N.B. The Animal Protection Act was replaced by a new Animal Welfare Act on 1 January 2010. The regulatory model in use today is however still based on chapter VI of the Animal Protection Act. A new version of the Regulation on Animal Experimentation will be produced in 2010-2011. This may lead to changes in the regulatory model. Chapter VI of the Animal Protection Act is cited at the end of this chapter.

The Regulation on Animal Experimentation

The Regulation on Animal Experimentation as stipulated by the Ministry of Agriculture on 15th January 1996 describes the work of the NARA and states how biological experiments shall be conducted. The NARA is responsible for the approval of:
- Laboratory animal units
- Animal species that may be used there
- Competent persons responsible for the laboratory animal units
- Field studies
- Research protocols with the competent persons are not able to process them selves

In addition, the NARA receives copies of all applications that have been approved by the competent persons, engages in advisory activities and produces an annual report on laboratory animal activities in Norway.

Animal Protection Act

Norwegian Animal Research Authority (NARA) (Forsøksdyrvalget, FDU)

 Approved Unit with approved competent person

 Field research research

Figure 1. Permission for animal experimentation is either given by the competent person at an approved animal unit, or by the Norwegian Animal Research Authority.

The competent person at each laboratory submits an annual report to the NARA.
The NARA has the right and duty to conduct unannounced inspections. In addition, the police, members of the Norwegian Food Safety Authority and the state animal protection committees (dyrevernemnden) have the right to inspect laboratory animal units.

The European Convention

In March 1986, the Council of Europe put out for signing and ratification a European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes. Norway was the first country to ratify this Convention in July 1986, which was subsequently also ratified by Sweden (1988), Spain (1989), Finland (1990), Belgium, Cyprus, Germany, Greece and Switzerland.

The Convention came into full effect for Norway on 1st January 1991. The Norwegian Regulation on Animal Experimentation of 15th January, 1996 ensures full compliance with the Convention. This regulation includes a requirement for education of all those involved with laboratory animals, new requirements for the suppliers of laboratory animals and demands for veterinary supervision at laboratory animal facilities. The use of laboratory animals at Norway is reported annually to the Council of Europe in Strasbourg.

Excerpts from the old Animal Protection Act:

Chapter VI Use of animals in teaching and research.

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.
Kapittel I. - Generelle bestemmelser

§ 1. Intention
The intention of this Act is to promote good animal welfare and respect for animals.

§ 2. Scope
The Act applies to conditions which affect welfare of or respect for mammals, birds, reptiles, amphibians, fish, decapods, octopi and honey bees. The Act applies equally to the development stages of the animals referred to in cases where the senses apparatus is equivalent to the development level in living animals.

The Act applies, subject to the limitations allowed for by agreement with foreign nations or organisations, to Norwegian land territory, territorial waters, the Norwegian economic zone, aboard Norwegian ships and aircrafts, on installations located on the Norwegian continental shelf, and to Svalbard, Jan Mayen and the dependencies. The King may in regulations lay down specific requirements for Svalbard, Jan Mayen and the Norwegian dependencies, taking into regard local conditions.

§ 3. General requirement regarding the treatment of animals
Animals have an intrinsic value which is irrespective of the usable value they may have for man. Animals shall be treated well and be protected from danger of unnecessary stress and strains.

§ 4. Duty to help
Anybody who discovers an animal which is obviously sick, injured, or helpless, shall as far as possible ensure the animal gets help. If it is impossible to provide adequate help, and the animal is domestic or a large wild mammal, the owner, or the police should be alerted immediately.

If it is obvious that the animal will not survive or recover, the person who discovered the animal may kill it at once. However, animals from holdings or large wild mammals shall not be killed if it is possible to alert the owner, a veterinarian or the police within reasonable time.

Necessary expenses for action under this Section shall be covered by the state, but the expenses related to helping domestic animals may be recovered from the animal keeper or the owner.

The requirements in the first and second article apply equally for persons who injure animals, but a person responsible for injury to an animal may not claim reimbursement of expenses for action taken.

The King may issue more specific regulations regarding covering of expenses.

§ 5. Duty to alert
Anyone who has reason to believe that an animal is exposed to mistreatment or serious neglect regarding the environment, supervision and care, shall as soon as possible alert the Food Safety Authority or the police. The duty to alert applies subject to the limitations of other legislation.

Anyone who becomes aware that a large number of wild or stray animals are exposed to sickness, injury or other abnormal suffering shall as soon as possible inform the Food Safety Authority or the police.

§ 6. Competence and responsibility
The animal keeper shall ensure that animals are looked after by appropriately competent personnel. Others shall have the competence necessary to carry out the activity they are involved in.

Parents and carers with parental responsibility may not allow children less than 16 years of age to have independent responsibility for animals.

The animal keeper must not transfer animals to people if there is reason to believe that they cannot or will not treat the animal in an appropriate way.

The King may issue specific regulations regarding requirements for education, training and competence, including approval and authorisation of personnel.

§ 7. Requirement for registration or approval
The King may issue specific regulations regarding establishment, placement, development and operation of activities covered by this Act. This includes regulations regarding approvals, withdrawal of approvals, reporting, registration and certification and withdrawal or expiry of certification.

§ 8. Industrial methods, equipment and technical solutions
The animal keeper shall ensure that industrial methods, equipment and technical solutions which are applied to animals are suitable for the purpose of ensuring the animals’ welfare. Anybody who markets or trades in new industrial methods, equipment and technical solutions which are used for animals shall ensure that they are tested and found to be suitable, taking into account animal
welfare.

The King may issue specific regulations regarding trade and use of certain industrial methods, equipment and technical solutions, including certification and documentation regarding suitability.

§ 9. Medical and surgical treatment
Medical and surgical treatment shall be carried out taking into account the animal’s welfare, and protect the animal’s ability to function and its quality of life.

Surgical incision or removal of body parts must not be carried out unless it is done for the justifiable reason of sustaining or improving the animal’s health. Marking of animals in holdings is nevertheless permitted. The removal of horns and castration is permitted when it is necessary for animal welfare reasons, or other specific reasons.

In the case of painful incision, necessary anaesthetic and pain relief shall be used.

The King may issue specific regulations regarding medical and surgical treatment, including setting specific conditions for or banning certain forms of such treatment and make exceptions from the second article.

§ 10. Identity marking of animals
When marking animals the methods used shall be appropriate and not subject the animal to behavioural limitations or other stress or strains.

The King may issue specific regulations regarding requirements for marking of animals, including require and forbid marking and marking methods, require that marked animals shall be registered in a register and determine who shall have access to the information in such a register. Specific regulations may also prescribe requirements for re-homing or killing unmarked animals without compensation to the owner.

§ 11. Transportation
Transportation shall take place in such a way as to ensure least possible strain for the animal. Animals shall only be transported when they are in such a condition that it is justifiable to complete the whole journey.

The method of transport shall be suitable with regard to the safety of the animals and the animals’ specific character. The animals shall have necessary supervision and care during transportation. The King may issue specific regulations regarding transportation of animals.

§ 12. Killing of animals
Killing of animals, and handling in connection with the killing, shall take place having regard to the animals’ welfare. Anyone using equipment for stunning or killing shall ensure that it is suitable for the purpose and maintained. Animals which are owned or in any way kept by people must be stunned before being killed. The stunning method shall ensure loss of consciousness which lasts from the killing starts until death occurs. The requirement for stunning before killing does not apply if the animal is killed using a method which provides immediate unconsciousness. After the killing of the animal it shall be ensured that the animal is dead.

Killing under emergency circumstances shall take place in compliance with the first and second article if possible.

Animals shall not be killed as an independent form of entertainment or competition.

The King may issue specific regulations regarding requirements for environment, equipment and handling in connection with killing of animals. The King may make exceptions to the provisions in the second article for animals other than terrestrial animals and marine mammals.

§ 13. The use of animals for testing, education and medical activities
In order to breed, keep, trade, kill or use animals for testing purposes, for educational purposes other than education in general care and treatment, or in connection with medical activities, both the institution and the person responsible for the relevant activity must be approved by the control authority.

Approvals referred to in the first article cannot be given if the intention can be achieved without the use of animals, or if the animals may be subjected to unnecessary stress or strains. The number of animals used shall be restricted to the number necessary, and the animals should be subjected to least possible strain.

In approvals made under this requirement exceptions can be made from Act 15 June 2001 number 75 relating to veterinarians and other animal health personnel § 18 first article nr. 3, in order that persons who are not veterinarians or fish health biologists can carry out complete or local anaesthetisation of the animal.

The King may issue specific regulations regarding the use of animals in testing, education and medical activities, including prohibition of certain types of testing and medical activities, approval and exceptions to the requirement for approval.

The King may issue specific regulations regarding exceptions from the provisions in Chapter I and II of this Act for the use of animals in testing.

§ 14. Specific prohibitions
It is forbidden to:

a) Subject animals to violence,
b) Abandon animals in a helpless condition,
c) Have sexual interaction with or carry out sexual activities with animals, and
d) Use live animals for feed or bait.
§ 15. Buildings, fences and other minor installations
Buildings, fences and other minor installations shall be designed or built and maintained in such a way that animals are not subjected to danger of unnecessary stress and strains. Barbed wire shall not be used in fences in order to limit traffic of animals.

The person responsible for the building, fence and fittings shall carry out inspections and take necessary action in order to discover, prevent and reduce the risk for unnecessary stresses and strain.

The King may issue specific regulations regarding buildings, fences etc., including banning and requiring removal of such installations. The King may also issue regulations regarding exceptions from the ban against the use of barbed wire in fences.

§ 16. Traceability
The King may, for the purpose of protection of animal welfare, issue specific regulations regarding traceability for animals or animal products.

The King may issue specific regulations regarding labelling of animal products, including regulations regarding obligatory and voluntary labelling schemes.

§ 17. Trading etc. in animal products
The King may in regulations limit, establish requirements for or ban, production, trading, import and export of products from animals which are covered by this Act. This applies subject to the limitations of agreement with a foreign nation or international organisation or public international law in general.

§ 18. Access to property and the obligation to assist
The control authority shall be given unhindered access to the place or premises where there is reason to believe that animals are held or other activity covered by this Act takes place. Where the control authority is not given unhindered access and there is reason to believe that animals are being subjected to unnecessary stress and strains, the control authority can, if necessary, gain access with the assistance of the police. The police shall have equivalent access when requested to assist by the control authority. Foreign inspectors may participate in inspections etc. when this is necessary in order to fulfil Norway’s international obligations.

Any person who is subject to control under this Act shall provide, free of charge, necessary premises, furniture and fixtures, assistance and equipment, to assist the control, and otherwise give appropriate help to facilitate the control.

§ 19. Obligation to provide information, documentation and control activities
The animal keeper and any person who has duties under this Act shall, on request from the control authority, provide information, notification, reports, documentation and access to documents which are of significance for the control authority’s compliance control under this Act, or requirements made under this Act. Others who may have relevant information shall, on request from the control authority, provide the necessary details.

The King may issue specific regulations regarding the content of the obligation to provide information and documentation, and the obligation to establish and carry out systematic control activities.

§ 20. Hunting, catching and fishing
Hunting, catching and fishing shall be carried out in such a way as to be conducive with appropriate animal welfare standards.

The King can issue as a supplement to the first article specific regulations regarding the hunting, catching and fishing of wild animals.

The King may issue specific regulations regarding hunting, catching and fishing of animals which are owned or in some other way held in captivity, including training for such activity, and banning such activities or making specific requirements for approving such activities.

§ 21. Capturing and handling of animals that live in the wild
The King may issue specific regulations regarding capturing and handling animals that live in the wild including conditions for and bans against such activities.

Chapter II. Animal keeping

§ 22. General conditions for keeping animals
Animals can only be kept if they can adapt to the method of keeping in a satisfactory way with regard to animal welfare.

The King may issue specific regulations in order to limit or ban the breeding, and keeping of certain animal species, breeds or strains.

§ 23. The animals’ living environment
The animal keeper shall ensure that animals are kept in an environment which is consistent with good welfare, and which meets the animals’ needs which are specific for both the species and the individual. The environment shall give the animals opportunity to carry out stimulating activities, movement, rest and other natural behaviour. The animals’ living environment shall stimulate good health and condition, and contribute to safety and well being. Animals shall have access to suitable and safe shelter outside the normal grazing periods.

The King may issue specific regulations
regarding requirements for animals' living environment, including regulations regarding suitable and safe shelter, action to prevent, discover and extinguish fire, and exceptions from the requirement for shelter.

§ 24. Attention, care and feeding
The animal keeper shall ensure that the animal receives good supervision and care, including securing that:

a) feed, pastures and water are of good quality, satisfy the animal’s need for nutrition and fluids, and stimulate good health and welfare. Animals shall not be fed or hydrated forcibly unless it is done for animal health reasons,

b) animals are protected from injury, disease, parasites and other dangers. Sick and injured animals shall be given appropriate treatment and be killed if necessary,

c) spreading of infectious diseases is limited, and that

d) animals, where appropriate, are suitably tame in order to be handled and cared for in an acceptable manner with regards to animal welfare.

The King may issue specific regulations regarding the extent of supervision and care required, and regarding protection and treatment of animals.

§ 25. Breeding
Breeding shall encourage characteristics which give robust animals which function well and have good health. Reproduction, including through methods of gene technology, shall not be carried out in such a way that it:

a) changes genes in such a way that they influence the animals’ physical or mental functions in a negative way, or continues such genes,

b) reduces the animals’ ability to practice natural behaviour, or

c) stimulates general ethical reactions.

Animals reproduced through gene technology as cited in the second article shall not be used for subsequent breeding. The King may issue specific regulations regarding breeding of animals in conflict with the principles in this Section.

§ 26. Training, showing, entertaining and competition
Any person who train animals and who use animals which are used for showing, entertainment and competitions, including those who organise such activities, shall ensure that the animals:

a) are capable of carrying out the activity without being exhausted or injured,

b) are not subjected to, or influenced by, substances or treatment which can render the activity unacceptable with regards to animal welfare,

c) are not intentionally subjected to fear, injury or unnecessary stress and strains, and

d) are not trained for or used in fights with other animals or people.

The King may issue specific regulations regarding training, showing and competitions etc., including setting requirements regarding specific approval, or banning various forms of such activity, banning the use of certain species and banning certain forms of substances and treatment.

The King may make exceptions from the first article.

§ 27. Trading of animals and professional care of animals belonging to others
Any person who sells or transfers animals to someone else shall provide the person who receives the animal with necessary information regarding conditions which are of relevance to the animal’s welfare.

The King may issue specific regulations regarding import, export, trading, re-homing, raffling, renting and borrowing of animals as well as professional care of animals belonging to others, including issue a ban against such activities.

The King may issue specific regulations regarding which information should follow the animal when the animal is transferred from one person to another.

§ 28. The release of animals into nature
An animal can only be released from captivity into nature to live wild if the animal has a good possibility to adapt to and survive in its new environment.

The King may in regulations establish requirements for or bans against the release of animals into nature.

Chapter III. Administrative orders and sanctions

§ 29. Charges and fees
The King may issue specific regulations regarding the collection of fees in order to cover the costs of supervision, control and specific services under this Act and regulations made under this Act.

The King may issue specific regulations regarding the obligation for businesses covered by the Act concerning food production and food safety of 19 December 2003 No 124(The Food Act) to pay a charge on foodstuffs. The charge shall cover the costs of supervision and control under this Act of keeping and use of animals for food production, when the costs are not covered by the fees referred to in the first article.

The King may issue specific regulations
regarding the obligation for producers or importers to pay a charge on feed for animals which are not used for food production. The charge shall cover the cost of supervision and control under this Act of the keeping and use of animals which are not used for food production, and when the costs are not covered by the fees referred to in the first article.

The King may issue specific regulations regarding the calculation of fees and charges, and the recovery and payment of these.

In the case of delayed payment of charges and fees, interest shall be paid in accordance with the Act 17 December 1976 No 100 concerning interest on delayed payments.

Charges and fees may be recovered by execution proceedings.

§ 30. Control and decisions
The Food Safety Authority carries out controls and may issue decisions necessary to ensure compliance with this Act or regulations under this Act.

The Food Safety Authority establishes animal protection boards in order to satisfy the lay man principle in animal welfare work. The boards are a part of the Food Safety Authority.

The King may delegate authority to public or private organisations other than the Food Safety Authority, and issue specific regulations concerning the appointment of an appeal body in such cases.

The King may issue specific regulations regarding the control practise, and the appointment of, the composition of and management of control authorities.

§ 31. Compensation
In the case of radical decisions to restrict grazing in order to protect farm animals from predators under § 30, the owner of the animal has a right to economic compensation. The King may issue specific regulations regarding the right to, conditions for and calculation of such compensation.

§ 32. The execution of orders, temporary custody of animals etc.
In the case of a control authority’s decision not being followed, or the responsible person is unknown, or it is necessary to carry out the action without delay, the control authority is permitted to implement necessary action itself. The control authority or the police may, subject to decision, take temporary custody of animals, or in other ways ensure that the animal receives the necessary supervision and care. Decisions issued by the police will be repealed if they are not confirmed by the control authority within 7 days. The responsibility for animals covered by a police decision is transferred to the control authority when the decision is confirmed.

Temporary custody of animals shall not last longer than necessary. If the control authority decides that the animal cannot be returned to the owner, the animal shall be euthanized. If the owner agrees, the animal may be re-homed or sold.

Action under the first and second article can be carried out at the expense of the animal keeper. Money outstanding may be recovered by execution proceedings.

When the control authority requests assistance, the police shall assist in the execution of control and decisions.

The King may issue specific regulations regarding the execution of orders and temporary custody of animals.

§ 33. Ban against activities covered by the Act
If necessary, the Food Safety authority may ban from activities under this Act, any person who fails to comply with substantial orders, or seriously or repeatedly violates decisions made under this Act. The ban may apply to all or some species, one or several activities, for a certain period or indefinitely.

In connection with criminal proceedings, the court may impose a ban equal to that referred to in the first article.

§ 34. Non-compliance fee
The control authority may impose a non-compliance fee on any person who intentionally or negligently fails to comply with regulations in or under this Act.

The size of the charge shall be determined subject to the seriousness of the breach, profits made by the responsible person in connection with the breach and costs on the part of the control authority in connection with control actions and administration of the case.

Non-compliance fees owed, may be recovered by execution proceedings.

The King may issue specific regulations regarding non-compliance fees, including the determination and calculation of the fees.

§ 35 Enforcement damages
The control authority may impose, on any person who fails to comply with a decision within the stated deadline, enforcement damages, either as a one off imposition or as running damages imposed daily.

The size of the damages shall be determined subject to the importance of the implementation of the decision, and which costs are likely to incur.

The enforcement damages may be determined in connection with the issuing of the decision when it is considered necessary that the deadline is met.

Enforcement damages owed may be recovered by execution proceedings. The control authority may abandon incurred execution proceedings.

The King may issue specific regulations regarding the determination and calculation of
enforcement damages.

§ 36. The establishment of data registers
The control authorities may establish new or connect to existing data registers when it is necessary in order to fulfil the intention of the Act or comply with international agreements to which Norway is a party. Such registers may not without permission from the person concerned, contain personal data which are sensitive, as defined in Act 14 April 2000 No 31 concerning the handling of personal information § 2 nr. 8.

The King may issue specific regulations regarding the obligation to provide information to such registers.

§ 37. Punishment
Intentional or grossly negligent violation of the requirements in or under this Act or decision issued under this Act is punishable with fines or imprisonment for a maximum of 1 year, or both, provided the offence is not subject to more severe penal provisions. Aiding and abetting are punished in the same way.

Serious violations are punishable with imprisonment for a maximum of 3 years. When determining the seriousness of the violation, the scale and effect of the violation and the level of guilt shall be taken into account. The regulations in the first and second article do not apply in the case of breach of §§ 4, 5 and 6.

Chapter IV. Concluding Regulations.

§ 38. Entry into force and status
The King may issue specific regulations necessary to ensure compliance with Norway’s obligations under the EEA Treaty, hereunder decide that such regulations in the case of conflict shall take precedence over this Act.

§ 39. Amendments in other Acts
a) In Act 15. June 2001 No. 75 concerning veterinarians and other animal health personnel, § 14 Emergency assistance shall read as follows: Animal health personnel are obliged as soon as possible, after a request, to administer such help as they are able to give – either personally or by deputy – when it is judged from available information that immediate help is necessary. The obligation ceases in the event of lawful absence or when help is administered in time by other animal health personnel.

The help that the animal health personnel administers under the previous article entitles the individual to claim an appropriate fee from the state in the case where he or she, after having made a claim, does not receive payment from the client or the person responsible for payment. In the event of the client or the animal health personnel having an obligation to help under the Animal Welfare Act § 4 and the animal is wild or the owner or responsible person is not known, the animal health personnel can claim an appropriate remuneration from the state for necessary help.

The ministry may issue regulations regarding when immediate help is necessary for example by defining what necessary help is, appropriate remuneration and other conditions regarding remuneration under this section.

In § 31, the first sentence in the first article shall read as follows: The Council shall be an advisor for the veterinary authorities in cases concerning disciplinary matters, sound business practice and veterinary medicine.

b) Act 2. July 1999 no. 64 concerning health personnel, the following amendments apply:
§ 23 no 4 shall read:
4. that information can be passed on when weighty private or official interests render the transfer of information rightful,
§ 23 nr. 5 shall read:
5. that information can be given when health personnel, during the practising of their profession, have reason to believe that animals are being subjected to such abuse or serious neglect with regards to environment, supervision and care that it is considered rightful to give information to the Food Safety Authority or the police or The existing § 23 nr. 5 is given the new no § 23 nr. 6.

c) In the Act 19. December 2003 No 124 regarding food production and food safety (The Food Act) the following changes apply:
§ 20 is repealed
§ 40. Entry into force and transitional provisions
This Act comes into force as from the date set by the King. As of this date the following Acts are repealed: Act 20 December 1974 No 73 regarding animal protection and Act 19 April 2002 No 11 concerning the amendment of Act 20 December 1974 No 73 regarding animal protection.

Regulations or administrative decisions issued pursuant to Act 20 December 1974 No 73 regarding animal protection will continue to apply until they are repealed.