Module 1: National legislation - NORWAY

National and EU laws and guidance that regulate the scientific use of animals in Norway.

Relevant laws, regulations and guidelines

- Animal welfare act («Lov om dyrevelferd»)
- Regulation on the use of animals in research (Norw: "Forskrift om bruk av dyr i forsøk")

Norway has also entered into international agreements undertaken to adhere to the EU laboratory animals Directive (2010-63) and the Council of Europe Convention on laboratory animals (ETS 123).

The Animal welfare act applies for all issues that affect the welfare of vertebrates, cephalopodes, cyclostomata, decapodes and honey bees. § 13 cover animals used in research, education and medical testing.

The Regulation on the use of animals in research applies especially for use of animals in research, education and testing.

The following issues are covered by the Regulation on the use of animals in research.

- Scope of the regulation - § 1
- Area of application - §§ 2, 3
- Definitions - § 4
- Approvals
- Approvals of institutions for animal experiments- §§ 5, 12
- Approval and Application of animal experiments - §§ 6, 7
- Project summary - § 8
- Compliance with the principles of the 3Rs - § 9
- Purpose of the study - § 10
- Methods, test strategies and endpoints - §11
- Ban of certain experiments - § 13
- Anesthesia and analgesia - § 14
- Termination of experiments - § 15
- Euthanasia and killing - § 16
- Reuse of animals - § 17
- Rehoming of animals - § 18
- Endangered species - § 19

- Primates - § 20
- Animal bred for purpose - §22
- Stray animals of domestic species - § 23
- Demands to competence - § 24
- Named persons with special responsibility for oversight - § 25
- Animal welfare body - § 26
- Named veterinarian or fish health specialist - § 27
- Responsibility of primary investigator - § 28
- Housing and care - § 28
- The physical plant and equipment - § 30
- Recordkeeping - § 31
- Records for dogs, cats and primates - § 32
- Marking of dogs, cats and primates - § 33
- Breeding plan for primates - §34
- Documentation - § 35
- Annual report - § 36
- Administrative issues - §§ 37-41

For institutions that are accredited by AAALAC international the following guidelines will also apply

- The guide to the care and use of laboratory animals
- European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe;(ETS 123)
- Guide for the Care and Use of Agricultural Animals in Research and Teaching (if such species are relevant)

Related regulation

Other laws and regulations for animals. There are several other regulation that apply for different activities that might influence animal welfare and are therefore relevant for animals in research, some examples are:

- Regulations on commercial transport of animals («Forskrift om næringsmessig transport av dyr»)
- Regulation on killing of animals
- Regulation on import and export of animals
- Veterinarians and other animal health personnel act («Lov om veterinærer og annet dyrehelsepersonell»)

Other laws and regulations for animal experiments and work with animals. There are also other laws and regulation related to animal experiments like

- Regulation of drugs («Forskrift om legemidler»)
- Gene modified animals (GMO)

        - Gene Technology act («Lov om framstilling og bruk av genmodifiserte organismer m.m. genteknologiloven»).
        - Regulation on enclosed use of GM animals («Forskrift om innesluttet bruk av genmodifiserte dyr»)
        - Regulation on enclosed use of GM microorganisms
        - («Forskrift om innesluttet bruk av genmodifiserte mikroorganismer»)
        - Regulation on marking, transport, import and export of GMO («Forskrift om merking, transport, import og eksport av genmodifiserte organismer»)
    - Health and safety regulations
        - Work environment act («Arbeidsmiljøloven»)
        - Regulation on work practice («Forskrift om utførelse av arbeid»)
        - Regulation for work places («Arbeidsplassforskriften»)
        - Regulation on preventive measures and limits («Forskrift om tiltaks- og grenseverdier»)
        - Radiation protection act («Lov om strålevern og bruk av stråling»)
        - Regulation on radiation protection ("Strålevernforskriften")
        - Regulation on use of humane cells and tissues ("Forskrift om håndtering av humane celler og vev»)
    - Regulations for wildlife research
        - Catching of wildlife for scientific purposes
        - The Svalbard Environmental Protection Act
        - Regulation for motor traffic in Svalbard
        - Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES)
    - Administrative laws and regulation
        - Administration act (Forvaltningsloven)
        - Public transparency in administrasjon act (offentlighetsloven)

Authorization needed before acting as user, breeder or supplier of laboratory animals - authorization required for projects and individuals.

Institutions (User, breeder or supplier) Institutions (User, breeder or supplier of laboratory animals must be approved by Mattilsynet (The Norwegian Food Safety Authority). Both the physical plant as wells as organization of personnel and activities must be approved.

Institutions must define an

- Animal welfare body
- Name persons with special responsibility for oversight
- Develop system and policy documents

Annual report of animal use previous year must be submitted within March 1 to Mattilsynet.

Applicant and participants: Must as a minimum fulfill training program in accordance with Appendix E of the regulation that covers:

1. Regulation of the use of animals in research
2. Ethics related to relationship between humans and animals, intrinsic value of life and arguments for and against use of animals in research
3. Basic relevant biology, anatomy, physiology, reproductions and genetics for the species in question.
4. Animal welfare, care and enrichment
5. Species specific handling
6. Animal health and hygiene
7. Recognition of species specific signs of fear, pain or other harm
8. Anesthesia, analgesia and Euthanasia
9. Humane end-points
10. 3R
11. Design of experiments

Persons must maintain and document competence through continuous practice and education.

Persons designing experiments (Function B) must have received adequate training in the scientific discipline relevant to the work to be performed, and have specific knowledge of the relevant animal species' biology, including their physiological and behavioral needs.

Persons who carry out procedures (function A), care of animals (Function C) or kills animals (Function D) shall be supervised when they perform tasks until they have demonstrated that they master the necessary skills.

Mattilsynet considers that FELASA C course recommendations for the teaching of theory meets requirements for theoretical training for function A = those who perform experiments and functional B = those designing procedures and projects.

Those who have already FELASA C courses must:

- Familiarize themselves with the new Norwegian regulations of July 1 2015
- Must relate to the requirement for continuing education

Those who have a FELASA C course from another country must take a course module in national Norwegian regulations.

Persons with special oversight responsibility are to ensure that everyone working with animals meets the requirements of education and training, and also constantly updating and training.

It is each researcher's responsibility to make sure your CV is up to date in relation to the requirements for continuous updating and training in laboratory animal science.

Individual projects: Permission to use animals in research must be obtained from Mattilsynet after application in FOTS («Forsøksdyrforvaltningens tilsyns- og søknadssystem»)

https://asp.gitek.no/fdu/pmws.dll/Login?RestoreSession=r4byycEd0uY28GRD

Some general requirements to projects:

- Applicant and participants competence (of all personnel involved)
- Public project summary
- Information on severity (expected pain and discomfort)
- Demonstrate compliance to 3R
- Harm-benefit assessment
- Animals to be used (number, sex, species)

In addition applicant has to provide information on

- Funding body
- Planned start and end of experiments
- Public access of information
- Background and purpose
- Rationale for using the chosen animal model.
    - If relevant: deviant phenotype that may impact animal welfare
- Sedation, analgesia and anesthesia
- Calculating number of animals (experimental groups and group sizes)
- Methods description
    - Preparation of animals
    - Procedures
    - Monitoring and sampling
    - Supervision of animals
    - Method for euthanasia
    - Criteria for humane endpoints and actions to be taken

Approval can be valid for maximum 4 years. For wildlife experiments max 2 years.

Sources of information and support available.

- Lovdata – all Norwegian laws and regulation are available from the government here
  - www.lovdata.no
  - https://lovdata.no/dokument/SF/forskrift/2015-06-18-761
  - https://lovdata.no/dokument/NL/lov/2009-06-19-97
- Mattilsynet (the Norwegian Food Safety Authority)
  - http://www.mattilsynet.no/dyr_og_dyrehold/dyrevelferd/forsoksdyr
- norecopa – the Norwegian national consensus platform for alternatives to use of animals
  - www.norecopa.no
  - Q&A from Mattilsynet http://norecopa.no/eu-direktivet-2010/63/eu
- Institutional Animal Welfare Body – give advice on several issues
- Designated veterinarian in the institution - give advice on several issues

Personnel mentioned in Article 24, 25 and 26, their statutory duties and other responsibilities under the Norwegian legislation.

Specific requirements for personnel (Article 24 in EU directive 2010/63)

According to §§ 24 and 25 in the regulation on animal experimentation personnel working with animals at breeders, suppliers and users shall have the minimum competence described in Appendix E before they start to plan/design experiments, care for of euthanize animals.

The minimum demands in Appendix E are:

1. The regulation of animal experimentation
2. Ethics related to the relationship between humans and animals, the intrinsic value of life and arguments for and against use of animals for scientific purposes.
3. Basic and relevant species specific biology related to anatomy, physiology, breeding, genetics and changes in genetics
4. Animal behavior, housing, care and environmental enrichment.
5. Species specific handling methods
6. Animal health procedures and hygiene
7. Species specific signs of fear, pain or other negative impact for the most common research animals.
8. Anesthesia, analgesia and euthanasia
9. Use of humane endpoints
10. Demands to replacement, reduction and refinement

11. Design of experiments (if relevant)

Persons responsible for planning experiments (function B) shall be adequately educated in the scientific field they work within and have specific competence in the relevant species biology, physiology and behavioral needs of the species in question.

Persons performing procedure (Function A), animal caretakers (function C) or killing animals (Function D) shall be supervised until they demonstrate that they master the necessary skill.

The institution must describe written procedures that safeguard these requirements.

Named persons with special responsibility for oversight shall:

- Control animal welfare and caretaking
- Make sure that all staff have access to relevant information about the species in question
- Safeguard that persons working with animals fulfill demands to competence.

Designated veterinarian (Article 25 in EU directive 2010/63)

According to § 27 in the regulation on animal experimentation all institutions shall have a named veterinarian or fish-health specialist[1] with special competence in laboratory animal medicine.

The veterinarian or fish-health specialist shall:

- Give advice on animal welfare and treatment
- Evaluate if animal is fit to live a good life after and experiment is terminated
- Evaluate if an animal can be used in another experiment after the first is terminated
- Evaluate if an animal is fit for rehoming after termination of an experiments:
    - If an animal is rehomed a veterinary journal with veterinary medicine and social issues for the animal shall follow the animal
- Give advice to the animal welfare body (preferably the veterinarian they should be a permanent member of the animal welfare body)
- Any deviation from housing conditions defined in the regulation in appendix F, part B Species specific demands of animal experimentation must be based on a veterinary-medical evaluation

Animal-welfare body (Article 26 in EU directive 2010/63)

According to § 26 in the regulation of animal experimentation the institution shal have an animal welfare body (“Dyrevelferdsenhet”)

[1] Fish-health specialists are persons who have completed an Integrated Master Programme in Aquamedicine and are authorized as by Mattilsynet. Fish-health specialists are only competent for this function as long as the institution only keeps aquatic animals but not sea ling mammals

The animal welfare body shall

- Give advice in acquiring, housing care and use of animals
- Give advice on compliance with the 3R (replacement, reduction and refinement)
- Provide information on technical and scientific progress on replacement, reduction and refinement
- Develop and review internal operation routines to monitor, report on an follow up animal welfare issues
- Monitor how experiment impact animal welfare
- Identify and give advice on factors that contribute to further replacement, reduction and refinement
- Give advice for rehoming of animals

A recordkeeping of all advices and decisions made by the Animal welfare body shall be stored for minimum of 3 years and be available on the request from Mattilsynet.

The Animal welfare body shall as a minimum consist of the person with special responsibility for oversight. If the institutions use animals for research the animal welfare body shall have at least one member with relevant scientific knowledge.

The roles and responsibilities of the local animal welfare bodies and the national committee for the protection of animals used for scientific purposes.

The role and responsibility of the local animal welfare bodies is described above.

Mattilsynet (the Norwegian Food Safety Authority) is the national authority responsible for

- Approving and inspecting users, suppliers and breeders (Physical plant and organization)
- Approve applications for animal experiments
- Give permission to other people than veterinarian and fish health specialist to administer total or local anesthesia on the condition that they have received training and this must be clear from the project description and project approval.
- Withdraw or suspend approval if the trial is not conducted in accordance with the regulation or approval
- Authority to approve and exempt from the ban against cardiac puncture in anesthetized animals when not a part of a terminal procedure.
- Authority to approve other euthanasia methods than described in the regulation appendix C Authority to approve reuse of animals
- Authority to approve the use of animals that are not bred for experimental purposes
- Authority to approve the use of strayed domestic animals
- Authority to approve reuse of animals
- Review record from the animal welfare body

- Review animal journals
- Approve exemption for housing conditions
- Approve single housing of animals

Responsible for compliance at an establishment and how this responsibility may be exercised (e.g. through the local AWB).
The person responsible for compliance of the regulation should be a person with adequate influence on recourses.

Procedure regulated under National legislation (minimum threshold of pain, suffering, distress or lasting harm).

The regulation of animal experimentation apply for

Experiments i.e. any use of animals for scientific or educational purpose and for medical purposes that can cause pain, fear, lasting harm or other negative impact larger or equal to injection of a needle using good veterinary practice. This also applies for any interventions that causing animals to be born or hatched as well as establishing or maintaining gene modified animal colonies with similar negative impact for the animals. An experiment might also be a work program with a defined scientific aim and consisting of one or more procedures. For animals that are not bred or hold for the use of organs or tissues can be used for scientific purposes, euthanasia of these animals is not considered as experiments.

Field Experiments i.e. an experiment taking place outside an approved use facility.

Facility: i.e. Plant, building, group of building or other rooms, including those that are not enclosed and mobile installation with its interior and equipment.

Breeder: i.e. physical or judicial person that breed species listed in Appendix D with the purpose of using them, or their organs or tissue for scientific purposes.

Supplier: i.e. physical or judicial person, exempt from breeders that supply animals for use in experiments or organ/tissues for scientific purposes

User: i.e. physical or judicial person who use animal in experiments

Endangered species: i.e. species that are categorized as critically endangered or vulnerable in the Norwegian red list.

Primary responsibility for animals undergoing procedures.

Responsibility for animals in experiments. The primary investigator/project leader (project license holder) is responsible for the animals in their experiments.
He/she is has to safeguard that

a. Cause of any unnecessary pain, fear, lasting harm of other negative impact is eliminated as soon as possible
b. That experiments are performed in exact accordance with the approval and decision made by Mattilsynet
c. Any deviations and compensatory actions are recorded.

Species, including respective stages of development that are included in the scope of the Directive / National law.

The Regulation apply for

- Live vertebrates
- Decapods
- Cephalopods
- Honey bees

The regulation also apply for early life stages if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development including mammal fetuses in the last trimester and larvae of vertebrates that nurture themselves (after start feeding)

The following species must be bred for scientific purposes.

1. Mice (Mus musculus)
2. Rat (Rattus norvegicus
3. Guinea pig (Cavia porcellus)
4. Syrian/golden hamster (Mesocricetus auratus)
5. Chinese hamster (Cricetulus griseus)
6. Mongolian gerbil (Meriones unguiculatus)
7. Rabbit (Oryctolagus cuniculus)
8. Dog (Canis familiaris)
9. Cat (Felis catus)
10. Avv species ogf non-human primates
11. Frogs (Xenopus (laevis, tropicalis), Rana (temporaria, pipiens))
12. Zebrafish (Danio rerio)

Circumstances in which animals under the scope of the regulatin should be humanely killed or removed from the study to receive veterinary treatment.

Animal must be killed
If unforeseen pain cannot be relieved by painkillers

Humane endpoints
Death as endpoint shall be avoided and replaced by earlier humane endpoints. If death is unavoidable, the experiment shall be designed so that

a. Death is caused for as few animals as possible
b. Duration and intensity of any ham is minimized
c. A pain-free death is safeguarded as long as possible

Any experiment with death as endpoint is classified as severe.

Rehoming of animals after experiments must be made after veterinary evaluation of the animals

Describe the legislative controls over the killing of animals bred or used for scientific procedures.

Killing and all handling related to the act of killing animal shall not cause unnecessary pain, fear or other harm and have to be performed taking animal welfare concerns.

Killing method are described in appendix C to the regulation
Other methods can only be used after approval from Mattilsynet

- On unconscious animals
- When purpose of experiments require a similar killing methods as usued for farm animals

Death must be confirmed by either

- Confirmation of circulator arrest
- Destruction of brain
- Dislocation of neck
- Out bleeding
- Confirmation of rigor mortis