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Date 190304 translation version 1.0

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The Swedish Board of Agriculture
Book of Statutes
The Swedish Board of Agriculture
551 82 Jönköping
Telephone: 036-15 50 00
www.jordbruksverket.se

The Swedish Board of Agriculture's Regulations And General Advice on Laboratory Animals;

Decided on December 21, 2017.

The Swedish Board of Agriculture prescribes[1] the following with support of §§ 26, 29, 32, 40–41, 41 b, 41c, 47, 50-52, 54 a, 55, and 75 of the Animal Welfare Ordinance (1988:539).

In addition, the Swedish Board of Agriculture decides on the following general advice.

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[1] Directive 2010/63/EU of the European Parliament and Council of September 22, 2010, on the protection of animals used for scientific purposes (EUT L 276, 20.10.2010, p. 33, Celex 32010L0063).

CH.1. BASIC PROVISIONS

§ 1 This statute contains provisions on the conditions for the protection of laboratory animals, as well as the conditions for the protection of other animals kept in facilities for laboratory animals.

§ 2 Basic provisions on laboratory animals are included in the Animal Welfare Act (1988:534) and the Animal Welfare Ordinance (1988:539).

Further provisions on animal welfare are provided in

1. Regulation (EC) no. 1223/2009 of the European Parliament and of the Council of November 30, 2009, on cosmetic products[2],
2. Swedish Board of Agriculture regulations (SJVFS 2008:67) on official animal welfare control,
3. Swedish Board of Agriculture regulations and general advice (SJVFS 2010:2) on transport of living animals and Council regulation (EC) no. 1/2005 of December 22, 2004, on protection of animals during transport and related operations and on amending of Directives 64/432/EEC and 93/119/EC and regulation (EC) no 1255/97[3],
4. Swedish Board of Agriculture regulations (SJVFS 2008:19) on fees in certain matters according to § 67 of the Animal Welfare Ordinance (1988:539), as well as
5. Swedish Animal Welfare Agency regulations (DFS 2006:6) on animals in education.

§ 3 Provisions on contained use of genetically modified animals are included in

1. Ch. 2 and 1. Environmental Code (1998:808),
2. regulation (2000:271) on contained use of genetically modified organisms, as well as
3. Swedish Board of Agriculture regulations (SJVFS 1995:33) on use of genetically modified animals.

§ 4 Provisions for import of laboratory animals are included in the Swedish Board of Agriculture regulations (SJVFS 1996:24) on entry of certain live animals as well as sperm,

[2] EUT L 342, 22.12.2009, p. 59 (Celex 32009R1223).
[3] EUT L 3, 5.1.2005, p. 1 (Celex 32005R0001).

eggs, and embryos from certain animals.

§ 5 Provisions on commercial activities with threatened animals are included in

1. Council regulation (EC) no. 338/97 of December 9, 1996, on the protection of species of wildlife and plants through control of their trade[4],
2. Commission regulation (EC) no. 865/2006 of May 4, 2006, on detailed rules for application of the Council regulation (EC) no. 338/97 on the protection of species of wildlife and plants through control of their trade[5],
3. Species Protection Ordinance (2007:845), as well as
4. Swedish Environmental Protection Agency regulations (NFS 2009:10) on protection of species.

§ 6 Provisions on keeping of wildlife are included in

1. The Hunting Act (1987:259),
2. The Hunting Ordinance (1987:905), as well as
3. Swedish Environmental Protection Agency regulations and general advice (NFS 2002:20) on wildlife enclosures and enclosures for garden centres, etc., to prevent damage caused by hares.

§ 7 Provisions on animal bi-products are included in

1. Regulation (EG) no. 1069/2009 of the European Parliament and of the Council of October 21, 2009, on health rules for animal bi-products and derived products not intended for human consumption and on repealing regulation (EC) no. 1774/20026, as well as
2. Commission Regulation (EU) no. 142/2011 of February 25, 2011, implementing regulation (EU) no. 1069/2009 of the European Parliament and of the Council on health rules for animal bi-products and derived products not intended for human consumption and on implementing Council Directive 97/78/EC regarding samples and items exempt from veterinary checks at the border[7].

Definitions

§ 8 In these regulations, the following terms mean:

3R-principle	The principle to replace animal experiments with methods free of animals, to reduce the number of animals used in animal experiments and refine the use of animals in animal experiments to reduce their suffering or increase their wellbeing.
Adjuvant	Agent that reinforces the effect of other treatment or corresponding.

[4] EGT L 61, 3.3.1997, p. 1 (Celex 31997R0338).
[5] EUT L 166, 19.6.2006, p. 1 (Celex 32006R0865).
[6] EUT L 300, 14.11.2009,ps. 1 (Celex 32009R1069).

Animal breeders, suppliers and users	Physical or legal persons (entity) who, under contract or law, are responsible for or handle laboratory animals, regardless of if this is permanent or temporary.
Animal experiments	In these regulations, the term has the same meaning as in § 1c of the Animal Welfare Act (1988:534).
Animal health professionals	In these regulations, the term has the same meaning as in Ch. 1, § 4 of the Animal Health Care Act (2009:302) on activities within animal health care.
Animal welfare body	Body that, according to § 20 first paragraph 4 Animal Welfare Act (1988:534), shall be present at activities that are referred to in § 19a of mentioned law to perform the duties as specified in Ch. 5 of these regulations.
Cat	Animal belonging to the species Felis catus.
Cattle	Animal belonging to the species Bos taurus.
Chicken	Animal belonging to the species Gallus gallus domesticus.
Chinese hamster	Animal belonging to the species Cricetulus griseus.
Dog	Animal belonging to the species Canis lupus familiaris.
Dove	Animal belonging to the species Columba livia domesticus.
Duck	Animal belonging to the species Anas platyrhynchos domesticus.
Endangered species	The species listed in Annex A to Council Regulation (EC) no. 338/97 of December 9, 1996, on protection of species of wildlife and plants through control of their trade and that are not covered by the scope of article 7.1 in that regulation.
Endpoint	The planned time for ending an animal experiment when no further observations are to be made for the experiment in question or, when it comes to new genetically modified animal strains, when one no longer can observe or expect the offspring to experience suffering to the same or greater extent than that caused by introduction of a needle.

Equines	The domesticated forms of animals belonging to Equus sp. (i.e., horse, donkey, mule, and hinny).
Establishment license	In these regulations, the term has the same meaning as the establishment licenses specified in § 19a of the Animal Welfare Act (1988:534).
Ethical approval of animal experiments	Approval of an animal experiment from an ethical perspective by a Regional Ethics Committee according to § 21 of the Animal Welfare Act (1988:534).
Ethologist	The ethologist referred to in Ch. 3, § 2 in these regulations and who has such education as specified according to Ch. 6, § 11 in these regulations.
Expert	Such a person with special competence referred to in § 20 first paragraph 2 of the Animal Welfare Act (1988:534) and who is employed at or linked to activities referred to in § 19a of mentioned law to perform the duties as specified in these regulations.
Facility for laboratory animals	An establishment, building, group of buildings, or other premises for laboratory animals, including laboratory facilities and other premises, where animal experiments are conducted. The definition also covers spaces that are not fully enclosed or have ceilings, as well as mobile facilities.
Ferret	Animal belonging to the species Mustela putorius furo.
Formal competence	Registration/licensing or approval as animal health professionals, including further education within their own profession.
Genetically modified animals	Animals with altered genome where the genetic material has been altered using gene technical, chemical, or other similar methods, including breeding with such animals.
Gerbil	Animal belonging to the species Meriones unguiculatus.
Goat	Animal belonging to the species Capra aegagrus hircus.
Golden hamster	Animal belonging to the species Mesocricetus auratus.
Goose	Animal belonging to the species Anser anser domesticus.

Guinea pig	Animal belonging to the species Cavia porcellus.
Humane endpoint	The pre-set limit for an animal's suffering when the animal, for reasons of animal welfare, shall be withdrawn from an animal experiment, regardless of whether the end of the experiment has been reached.
Immunization	Supply of an immunogenic substance, i.e., a substance capable of inducing an immune response and which is given to activate the immune system.
Keeping	Keeping of laboratory animals where the laboratory animals are neither raised nor used in animal testing or provided.
Laboratory animal veterinarian	Such a veterinarian as referred to in § 20 first paragraph 2 Animal Welfare Act (1988:534) and who is employed at or linked to activities referred to in § 19a of mentioned law to perform the duties as specified in these regulations.
Laboratory animals	In these regulations, the term has the same meaning as in § 1b of the Animal Welfare Act (1988:534).
License holder	In these regulations, the term has the same meaning as in § 19a second paragraph 1 Animal Welfare Act (1988:534).
Mouse	Animal belonging to the species Mus musculus.
Named Animal Care and Welfare Officer (NACWO)	Such a head as referred to in § 20 first paragraph 1 Animal Welfare Act (1988:534) and who is employed at or linked to activities referred to in § 19a of mentioned law to perform the duties as specified in these regulations.
Named Information Officer (NIO)	Such a head as referred to in § 20 first paragraph 1 Animal Welfare Act (1988:534) and who is employed at or linked to activities referred to in § 19a of mentioned law to perform the duties as specified in these regulations.
Named Training and Competence Officer (NTCO)	Such a head as referred to in § 20 first paragraph 1 Animal Welfare Act (1988:534) and who is employed at or linked to activities referred to in § 19a of mentioned law to perform the duties as specified in these regulations.
Non-human primates	Animal belonging to the order Primates except humans.

Non-technical summary	In these regulations, the term has the same meaning as in § 41a of the Animal Welfare Ordinance (1988:539).
Pig	Animal belonging to the species Sus scrofa domesticus.
Poultry	Domesticated birds of the groups turkeys (Meleagridae), ducks (Anatinae), geese (Anser), quail (Coturnix), and Guinea fowl (Numididae), as well as chicken (Gallus gallus).
Principal Investigator	The researcher to be identified as applicant for ethical approval for animal testing and who is employed or linked to activities referred to in § 19a of the Animal Welfare Act (1988:534) to perform the duties as specified in these regulations.
Privately owned animals	Animals that temporarily are used in animal experiments but that primarily are kept for other purposes than laboratory animal activities and that predominantly are privately owned.
Procedure	All use, invasive or non-invasive, that may cause the animal pain, suffering, distress, or lasting harm to the same or greater extent than that caused by introduction of a needle which has been performed according to good veterinary medicine practice.
Purpose-breeding	Breeding of animals for scientific purposes.
Quail	Animal belonging to the species Coturnix coturnix.
Rabbit	Animal belonging to the species Oryctolagus cuniculus.
Rat	Animal belonging to the species Rattus norvegicus.
Real competence	That which one has practical knowledge and ability to perform independently in a safe way.
Sedate	To administer pharmaceuticals with tranquilizing effect.
Sheep	Animal belonging to the species Ovis aries.
Suffering	Physical or mental suffering caused by, e.g., pain, discomfort, distress, fear, permanent injury, or prevention of expressing natural behaviour.
Supply	Sale or other delivery of laboratory animals from anyone other than those who have bred the animals.

Treatment ban	In these regulations, the term has the meaning that personnel who do not belong to the animal health professionals may not perform such tasks as specified in Ch. 4, § 1 of the Animal Health Care Act (2009:302) on activities within animal health care.
Turkey	Animal belonging to the species Meleagris gallopavo.
Zebra finch	Animal belonging to the species Taeniopygia guttata.
Zebra fish	Animal belonging to the species Danio rerio.

CH.2. ESTABLISHMENT LICENSE, APPROVAL OF FACILITIES FOR LABORATORY ANIMALS, AND ETHICAL APPROVAL OF ANIMAL EXPERIMENTS

§ 1 Provisions for establishment licenses are also found in §§ 19a–20 of the Animal Welfare Act (1988:534).

§ 2 Provisions for preliminary approval of facilities for laboratory animals are also found in § 55 of the Animal Welfare Ordinance (1988:539).

§ 3 Provisions for ethical approval of animal experiments are also contained in § 21 of the Animal Welfare Act (1988:534), §§ 41–41a and 41c of the Animal Welfare Ordinance (1988:539), as well as in Ch. 7 in these regulations.

§ 4 Provisions on fees for establishment licenses and ethical approval of animal testing are found in the Swedish Board of Agriculture's provisions (SJVFS 2008:19) on fees in certain matters according to § 67 of the Animal Welfare Ordinance (1988:539).

§ 5 In addition to that which is specified in §§ 40 and 41 of the Animal Welfare Ordinance (1988:539), an establishment license according to § 19a of the Animal Welfare Act (1988:534) and ethical approval of animal experiments according to § 21 first paragraph of the Animal Welfare Act (1988:534) are required from a Regional Ethics Committee for experiments with

1. mammalian fetuses and bird fetuses from and including the last third of their normal development, and
2. independently feeding larval forms.

Licenses according to the first paragraph are also required for all earlier developmental stages of vertebrate animals and cephalopods if there is risk of causing them suffering in a later stage.

Establishment License

§ 6 An establishment license is valid for a maximum of five years.

§ 7 An application for an establishment license according to § 19a of the Animal Welfare Act shall be sent to the Swedish Board of Agriculture and shall include the following information:

1. Applicant's name and personal code number (Swedish Personnummer) and contact information. If the applicant is a legal person (legal entity), please state the legal person's organisational number and the deputy's contact information.
2. Type of activity or activities to which the application relates.
3. Description of the activity or activities to which the application relates.
4. The animal species intended to be used and kept within the establishment.
5. Approved facilities for the laboratory animals intended to be used and kept.
6. Name and contact information of the Named Animal Care and Welfare Officer (NACWO). In addition, information regarding the education and competence of the NACWO must be provided.
7. Name and contact information of the Named Information Officer (NIO).
8. Name and contact information of the Named Training and Competence Officer (NTCO).
9. Name and contact information of the Named Veterinary Surgeon (NVS), or where applicable, expert. In addition, information must be provided on the veterinarian's, or where applicable, the expert's education and competence.
10. Applicant's signature, or where applicable, the deputy's signature.

§ 8 The Swedish Board of Agriculture assesses if it is more appropriate with an expert rather than a laboratory animal veterinarian in each individual case

§ 9 In the event of a change of license holder, named officer, laboratory animal veterinarian, or where applicable, expert, a notification of the change shall be sent to the Swedish Board of Agriculture and the County Administrative Board in the county or those counties in which the activity is conducted, within four weeks. The notification must be in writing and shall include the signature of the license holder, or where applicable, the new license holder's signature. For laboratory animal activities conducted within the Swedish Armed Forces, a notification shall be sent within four weeks to the Swedish Board of Agriculture and to the Swedish Armed Forces Inspector for Health and Environment. The notification must be in writing and shall include the signature of the license holder, or where applicable, the new license holder's signature.

A new application for an establishment license shall be sent to the Swedish Board of Agriculture if the Board of Agriculture, after being notified according to the first paragraph, deems that the license needs to be renewed.

Approval of Facilities for Laboratory Animals

§ 10 Animal experiments shall be conducted at an approved facility for laboratory animals. If there are scientific reasons for this, a Regional Ethics Committee may decide that an animal experiment may be performed outside of a laboratory animal facility.

Preliminary Approval

§ 11 An application for preliminary approval of a laboratory animal facility according to § 55 of the Animal Welfare Ordinance (1988:539) shall be sent to the Swedish Board of Agriculture and shall include the following information:

1. Applicant's name and personal code number (Swedish Personnummer) and contact information. If the applicant is a legal person (legal entity), please state the legal person's organisational number and the deputy's contact information.
2. Type of activity or activities.
3. Species intended to be kept in the facility.
4. Description of the facility including drawings.
5. Description of the facility's automated systems.
6. Description of how the laboratory animals at the facility will be cared for and fed.

§ 12 A preliminary approval is valid for three years, and the construction or change shall have been started within this time. The Swedish Board of Agriculture may decide on a shorter time.

When the construction or change is completed, a notification of inspection shall be made to the Swedish Board of Agriculture.

Inspection and Approval

§ 13 After inspection according to § 55 of the Animal Welfare Ordinance (1988:539), the Swedish Board of Agriculture shall decide on the approval of the laboratory animal facility. Application for approval shall be made to the Swedish Board of Agriculture.

Ethical Approval of Animal Experiments

§ 14 An application for ethical approval of animal experiments shall be submitted by the Principal investigator via the e-service 'Application for Ethical Approval of Animal Experiments' which is available on the Swedish Board of Agriculture's website[7] and shall be sent to the Regional Ethics Committee as set out in the decision according to Ch.7, § 3 in these regulations.

Provisions for amending an existing ethical approval of animal experiments is available in Ch. 5, § 6, and Ch. 7, §§ 28-31.

§ 15 The electronic application for ethical approval shall contain relevant, and where applicable, motivated information about:

1. Applicant's name, contact information, and professional title.
2. Establishment license for the activity in which the animal experiment is to be conducted.
3. The location, facility or, where applicable, the county in which the experiment is to be carried out.
4. The purpose of the experiment, its benefit, and proposed severity classification.
5. Competence and staff required to enable the experiment to be conducted in a correct way.
6. The need to use animals in the experiment. The number of laboratory animals and their origin as well as their developmental stage shall also be specified here.
7. Use of methods for 3R in connection with using laboratory animals in the planned animal experiment.
8. In what way unjustified duplication of animal experiments shall be avoided.
9. Strategy for obtaining qualified results and statistics with the lowest number of laboratory animals, with the lowest possible level of suffering for the laboratory

[7] www.jordbruksverket.se

animals and, where appropriate, environmental impact.
10. Planned use of pain relief, anesthesia, and other methods to reduce the suffering of laboratory animals throughout their whole lifetime.
11. An account of how the laboratory animals are to be kept and cared for during and, if relevant, after the animal experiment.
12. An account of any reuse of laboratory animals and its overall effect on the laboratory animals.
13. Use of mild humane end-points and end-points as well as planned killing methods for the animal experiment.

§ 16 The application for ethical approval of animal testing shall be accompanied by a non-technical summary. The non-technical summary shall

1. inform about the purpose and benefit of the animal experiment,
2. inform about the suffering of the laboratory animals,
3. include information on the number and type of laboratory animals to be used, as well as
4. show how the requirements for the 3R-principle are fulfilled according to § 19 of the Animal Welfare Act (1988:534).

The Regional Ethics Committee shall send the non-technical summaries for approved animal experiments, including any appendices, to the Swedish Board of Agriculture for publication.

The non-technical summary shall be anonymous, therefore it must not include the name or address of the applicant or its staff.

Exceptions from the Requirement for Establishment License or Ethical Approval of Animal Experimentation

Privately owned animals

§ 17 When privately owned animals are used according to § 18 and §§ 22–25, the following conditions, in addition to the conditions specified in the mentioned paragraphs, shall be fulfilled:

1. the owner of the animals shall have been informed of what the animal experiment entails,
2. the owner of the animals shall have given consent to use of the animals,
3. the owner of the animals has received information that they can recall their consent at any time without having to motivate this decision, as well as
4. compensation for more than actual costs may not be paid to the owner of the animals.

General Advice For § 17.2
Consent can be given in writing on a separate document or by oral consent which is noted in the animal's record.

Privately owned animals kept in their normal environment

§ 18 Animal experiments where privately-owned animals are kept in their normal environment may be conducted without establishment license or ethical approval of animal testing. Animals

in such exceptions are also exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

The exceptions in the first paragraph apply provided that the animals, due to the animal experiment, are not

1. killed,
2. subjected to surgical procedure, injection, blood loss, or other forms of penetration of the skin or mucous membranes,
3. restrained in any way above and beyond what is permitted when housing the species when not involved in animal testing, or
4. subjected to other actions that may cause the animal to suffer.

The provisions in this paragraph apply to all privately-owned animals in captivity, including domestic animals moving freely in nature but are not feral domestic animals, as well as animals in enclosures, but not animals in a facility for public display.

Free-living wildlife or feral domestic animals

§ 19 Observation studies of free-living wildlife or feral domestic animals may be performed without ethical approval of animal experiments provided that the animals are not

1. captured,
2. killed,
3. driven, or
4. subjected to other actions that may cause the animal to suffer.

Animals covered by the first paragraph are exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

§ 20 Ringing (banding) of wild birds may be performed without establishment license or ethical approval of animal experimantation provided that

1. ringing (banding) does not include other procedures with the bird, than capturing, measuring, weighing, banding with foot rings, and thereafter setting them free (releasing), as well as
2. ringing (banding) takes place with ringing (banding) license issued by Bird Ringing Centre, Swedish Museum of Natural History.

Animals covered by the first paragraph are exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

Zoo animals

§ 21 Observation studies on great apes (*Pongidae*) and gibbons (*Hylobatidae*) in a facility approved for public display according to § 37 of the Animal Welfare Ordinance (1988:539) may be performed without establishment license or ethical approval provided that the animal, due to the experiment, is not:

1. killed,
2. subjected to surgical procedure, injection, blood loss, or other forms of penetration of the skin or mucous membranes,
3. restrained in any way above and beyond what is permitted when housing the species when not involved in animal testing,
4. subjected to other actions that may cause the animal to suffer, as well as
5. that the animal’s environment is not changed in a way that goes beyond what is

permitted when housing the species when not involved in animal experiments.

Animals covered by the first paragraph are exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

§ 22 Animal experiments on animals in a facility approved for public display according to § 37 of the Animal Welfare Ordinance (1988:539) may be performed without establishment license or ethical approval if the experiment entails:

1. observation studies,
2. research with the purpose of improving animal welfare, or
3. research with the purpose of protecting the species.

Exceptions from establishment license or approval from an Ethics Committee according to the first paragraph apply provided that the animal is not

1. killed,
2. subjected to surgical procedure, injection, blood loss, or other forms of penetration of the skin or mucous membranes,
3. restrained in any way above and beyond what is permitted when housing the species when not involved in animal experimants, or
4. subjected to other actions that may cause the animal to suffer.

For animal experiments according to the first paragraph, the animals' environment may not be changed in a way that has negative impact from the perspective of animal protection or animal health.

Animal experiments according to the first paragraph may not involve release of laboratory animals.

Animals covered by the first paragraph are exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

Animals in education

§ 23 In the education of personnel performing animal health services, no establishment license or ethical approval of animal experiments is required if:

1. only privately-owned animals are used,
2. the animals only are subjected to such surgical procedures, or other actions that may cause suffering, that are part of the treatment to which the animals would have been exposed anyway,
3. the practical procedures are performed at the veterinarian's responsibility,
4. the education either
   a) takes place within the formal competence for animal health personnel,
   b) takes place in connection with delegation according to Ch. 3 of the Swedish Board of Agriculture's regulations and general advice (2013:41) on obligations for keepers and staff in animal health care, or
   c) constitutes the practical part of a basic course in management of pharmaceuticals or basic education in anesthesia and pain relief according to Ch. 4, §§ 10e or 10f of the Swedish Board of Agriculture's regulations and general advice (2013:41) on obligations for keepers and staff in animal health care.

Animals covered by the first paragraph are exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

§ 24 In the education of personnel who professionally vaccinate animals, without belonging

to animal healthcare personnel or of keepers who use conditional management of pharmaceuticals, no establishment license or ethical approval of animal experiments is required if

1. only privately-owned animals are used,
2. the animals only are subjected to such injections that are part of the treatment to which the animals would have been exposed anyway,
3. the practical procedures are performed at the veterinarian's responsibility, as well as
4. the education either
   a) constitutes the practical part of a basic course in vaccination and management of pharmaceuticals according to Ch. 4, §§ 19 or 20 of the Swedish Board of Agriculture's regulations and general advice (2013:41) on obligations for keepers and staff in animal health care, or
   b) constitutes the practical part of a basic course in conditional management of pharmaceuticals according to Ch. 5, § 8 of the Swedish Board of Agriculture's regulations and general advice (2013:41) on obligations for keepers and staff in animal health care.

§ 25 Teaching of students at high school level, university level, vocational school level, or corresponding, may be conducted without ethical approval of animal experiments provided that

1. only privately-owned animals are used,
2. the animals only are subjected to such surgical procedures, or other actions that may cause suffering, that are part of the treatment to which the animals would have been exposed anyway,
3. The education concerns future work with animals and aims at acquiring, maintaining or developing students' professional skills,
4. The use is shown in the course syllabus of the course and is necessary in view of the purpose of the education, as well as
5. animal healthcare professionals are present during teaching and the handling/treatment of the animals takes place under the responsibility of the animal health personnel.

Animals covered by the first paragraph are exempt from the requirement of purpose-breeding according to § 19 of the Animal Welfare Act (1988:534).

Exceptions from the Requirements of Education, Record-Keeping, and Reporting of Statistics

§ 26 Activities according to §§ 17-25 are exempt from the requirements on

1. education according to Ch. 6 in these regulations,
2. record-keeping according to Ch. 8 in these regulations,
3. reporting of statistics according to Ch. 13 in these regulations, as well as
4. animal experiments shall be conducted on an approved facility for laboratory animals according to § 10.

CH.3 LICENSE HOLDER'S RESPONSIBILITY

§ 1 Provisions concerning the license holder's responsibility to ensure that the activity is

conducted according to the Animal Welfare Act (1988:534), the regulations which have been notified under law, as well as the EU-regulations supplemented by the act are contained in § 19b of the Animal Welfare Act (1988:534).

§ 2 The license holder shall be able to demonstrate that there is sufficient personnel and resources for the laboratory animal operation so that the tasks according to these regulations can be performed.

In a laboratory animal facility housing primate, there shall be sufficient access to an ethologist.

§ 3 The license holder shall give officers named in the establishment license, the laboratory animal veterinarian, the expert, ethologist, and the principal investigator sanction and authorisation to perform their duties and tasks.

§ 4 The license holder shall ensure that consultation in planning of animal experiments is conducted according to the requirements in Ch. 4, § 4.

§ 5 The license holder shall ensure that within the establishment, there is an animal welfare body according to 20 § 4 of the Animal Welfare Act (1988:534). The license holder may give the animal welfare body additional tasks beyond those required by these regulations.

§ 6 The license holder is responsible for education of the personnel according to Ch. 6 in these regulations and shall be able to report to the County Administrative Board the education efforts performed and the status of education and competence of each person.

License holders within the Swedish Armed Forces shall report on the requirements in the first paragraph to the Armed Forces Inspector for health and environment.

License holders in the first or second paragraph are also responsible for education and competence of personnel active before January 1, 2013, fulfill the requirements in Ch. 6 in these regulations.

§ 7 The license holder is responsible for record-keeping according to Ch. 9 in these regulations and to submit statistics to the Swedish Board of Agriculture according to Ch. 13 in these regulations.

§ 8 The license holder is responsible for the availability of work instructions for the facility, which are specified in Ch. 15, §§ 6 and 7.

§ 9 The license holder is responsible for establishing enrichment plans according to Ch. 16, § 20 for species kept at the facility, and implementing and updating the plans as needed.

The license holder is responsible for establishing relevant plans for the operation according to Ch. 16, §§ 5 and 6, and implementing and updating these as needed.

CH. 4 EXPERIMENTAL PLANNING, ETC.

Purpose of the Experiment

§ 1 Animal experiments may only be performed for any of the following purposes:

1. Basic research.

2. Research on which effects diseases, ill health, or other deviating conditions have on humans, animals, or plants, and how they are avoided, prevented, diagnosed, or treated.
3. Research entailing evaluation, detection, control, or modification of physiological conditions in humans, animals, or plants.
4. Research with the purpose of improving animal welfare.
5. Development, manufacture or testing of quality, effect, and safety of pharmaceuticals, food, feed, and other substances or products. This applies only for the purposes referred to in item 2–4.
6. Research for species protection.
7. Protection of the natural environment to preserve human health or welfare.
8. Protection of the natural environment to preserve animal health or welfare.
9. Forensic examinations.
10. Use in university education or in education aimed at acquiring, maintaining, or developing professional skills, provided that the use is specified in the course syllabi and is necessary with regards to the purpose of the education.

General Advice For § 1.10

Before the animal experiment, students should have the opportunity to discuss animal welfare and ethics in the use of laboratory animals, including animals in education. They should also receive information about the current ethical approval.

Students should prepare for the activity by, for example, using animals that have been killed for other reasons, models/dummies, film clips, or study visits.

§ 2 Animal experiments that are unlikely to cause suffering to the same or greater extent than caused by insertion of a needle conducted according to good veterinary practice may also be performed for purposes other than those specified in § 1.

Experimental Planning

§ 3 In addition to specifications in § 19 of the Animal Welfare Act (1988:534), animal experiments shall be designed so that

1. they lead to the least suffering and the lowest degree of permanent damage to the laboratory animals,
2. Animal species with the least ability to experience suffering are used, as well as
3. they follow good scientific practice.

§ 4 When planning animal experiments, the principal investigator should specifically consider, motivate, and describe

1. the animal experiment’s end-point,
2. the animal experiment’s humane end-point,
3. how to assess the pain, discomfort, or other suffering of the laboratory animals, as well as
4. the need for supervision according to Ch. 11, § 4–5.

The principal investigator, the NACWO, the laboratory animal veterinarian, or the expert or ethologist where applicable, as well as the personnel conducting animal experiments or care for laboratory animals in connection to animal experiments shall consult in planning of the animal experiment. The NACWO shall ensure that the requirements in the first paragraph are fulfilled.

General Advice For § 4, Second Paragraph
Additional staff with experience or knowledge of the 3R-principles for animal experiments should be included in these consultations.

§ 5 The humane end-point for animal experiments shall be as early and as mild as possible. The humane end-point must have clear assessment criteria.

§ 6 Use of death as end-point in an animal experiment shall be avoided as much as possible and shall be replaced by early and mild end-points. When it is unavoidable to use death as end-point, the animal experiment shall be designed so that

1. as few laboratory animals as possible die natural deaths,
2. the duration and the intensity of the suffering of the laboratory animal is minimised, as well as
3. the death of the laboratory animal is as pain-free as possible.

§ 7 An animal experiment may not be conducted if there is a method or test strategy to obtain the same result, and this method or test strategy does not involve the use of live laboratory animals and is approved by EU legislation.

§ 8 Results developed in another member state using animal experiments that are recognized by EU legislation shall be accepted unless additional animal experiments are required with regards to these results to protect public health, public safety, or the environment.

CH 5. ANIMAL WELFARE BODY (AWB)

Purpose and Composition of the AWB

§ 1 Provisions on the overall tasks of the Animal Welfare Body are contained in § 20.4 of the Animal Welfare Act (1988:534).

§ 2 The Animal Welfare Body shall consist of at least

1. the NACWO
2. veterinarian or expert,
3. an ethologist, where applicable,
4. a scientist, as well as
5. a representative for personnel caring for the animals.

When raising, providing, or keeping animals, there is no need for a scientist to be included.

To make decisions according to § 6, all competencies according to the first paragraph shall be included in the vote. Decisions are made using simple majority of the competencies specified in the first paragraph. The license holder shall give the Animal Welfare Body instructions for how decisions are to be made when a simple majority cannot be attained.

Tasks of the AWB

§ 3 The Animal Welfare Body shall give the personnel who handle laboratory animals advise with regards to animal welfare in connection with acquisition, keeping, care, and use of laboratory animals.

The Animal Welfare Body shall produce and review internal routine descriptions for

monitoring, reporting, and following up welfare of the laboratory animals as well as for the overall animal welfare work in the operation.

General Advice For § 3, Second Paragraph

The Animal Welfare Body should review the plans referred to in Ch. 16, 5-7 and § 20.

§ 4 The Animal Welfare Body shall actively work for prioritizeng good animal care being within the operation.

The Animal Welfare Body shall advise personnel on how to apply the 3R-principle as well as inform about the technical and scientific development in that area.

The Animal Welfare Body shall follow the development and result of the animal experiments that are conducted within the operation with regards to the animal welfare effects for the laboratory animals that are used. In connection with this, the Animal Welfare Body shall identify and advise about the factors that further contribute to the 3R-principles.

§ 5 The Animal Welfare Body shall give advice when rehoming laboratory animals, including suitable methods for socializing the laboratory animals.

§ 6 The Animal Welfare Body may, after application from the principal investigator, decide on amendments of a current ethical approval of animal testing providing that the amendment

1. does not risk to affect the welfare of the laboratory animals in a negative way,
2. does not affect the possibility to attain the purpose or goal of the experiment,
3. does not negatively affect
   a) the experiment's severity classification,
   b) end-point or humane end-point,
   c) experiment times,
   d) laboratory animals' supervision during the animal experiment, as well as
   e) housing, care, or marking that requires approval of an Ethics Committee.

If the Animal Welfare Body deems that the amendment of the ethical approval does not fulfill the conditions in the first paragraph, the Animal Welfare Body shall decline the case.

§ 7 The Animal Welfare Body's decision according to § 6 shall contain at least the following information:

1. Contact information to the Animal Welfare Body.
2. The reference number of the decision on ethical approval of animal experimentation to which the amendment application refers.
3. Date of the Animal Welfare Body's decision and who participated in the decision.
4. What the Animal Welfare Body has decided.
5. Justification of the decision.

In case the Animal Welfare Body decides on an amendment of an ethical approval of animal testing, a copy of the decision shall be sent to the relevant Regional Ethics Committee and the relevant County Administrative Board.

For the Animal Welfare Body within the Swedish Armed Forces, a copy of the decision shall be sent to the relevant Regional Ethics Committee and the Armed Forces Inspector for health and environment.

§ 8 The Animal Welfare Body shall keep a record about the advice given by the Animal

Welfare Body and about decisions made in connection with advising. The NIO shall ensure that decisions according to Ch. 5, § 6 are saved for at least three years from the day that the approval from the Regional Ethics Committee expires, and that the records are saved for at least three years.

Upon request, the NIO, according to the first paragraph, shall ensure that decisions and records are made available to the Swedish Board of Agriculture, the regional Ethics Committee, the Central Ethics Committee, and the County Administrative Board. In matters regarding the Swedish Armed Forces' laboratory animal operations, decisions and records shall be made available to the Armed Forces Inspector for health and environment instead of the County Administrative Board.

CH. 6. EDUCATION AND COMPETENCE

General

§ 1 The NTCO according the establishment license, shall ensure that the requirements for education and competence in this chapter are followed.

§ 2 Persons who use, breed, provide, or keep laboratory animals shall have education according to this chapter before they may:

1. conduct animal experiments,
2. design animal experiments,
3. care for laboratory animals, or
4. kill laboratory animals.

§ 3 Education according to § 2 refers to:

1. education that is specifically targeted to the requirements specified in this chapter, or
2. relevant competence and practical skills for the requirements specified in 2 and §§ 5–13, and which have been acquired through other education and can be substantiated by certificates or curriculum where content of the education is shown, or
3. relevant expertise and real competence which have been acquired through work with the types of animals and tasks to which the requirement relates and that can be substantiated by certificates or equivalent assessment of the competence.

§ 4 Animal care takers at a facility that is not approved as a laboratory animal facility according to Ch. 2 in these regulations do not have to undergo training/education according to this chapter, even if the laboratory animals at the facility are temporarily included in animal experiments.

§ 5 Personnel, after they have undergone training/education according to this chapter, shall work under supervision when they perform tasks according to § 2 and until they have shown that they have obtained real competence for the task.

Personnel shall be continuously trained/educated.

§ 6 Those who design animal experiments shall have relevant scientific education and have knowledge of the species to be used.

General Advice For § 6

Those who design animal experiments within biomedical research should have one of the following undergraduate programs

1. *medical education,*
2. *biology education with zoological or biomedical focus,*
3. *veterinary education, or*
4. *other college or university education with equivalent education in zoology, anatomy, and physiology as the education programs specified in items 1-3.*

§ 7 The NACWO in the establishment license shall have education at least equivalent to the requirements for those who design animal experiments according to Table 1 in § 13.

The NIO in the establishment license, shall have education at least equivalent to the basic requirements for those who care for laboratory animals according to Table 1 in § 13.

The NTCO in the establishment license, shall have education at least equivalent to for those who care for laboratory animals according to Table 1 in § 13.

§ 8 A laboratory animal veterinarian shall have a license to work as veterinarian in Sweden and have education at least equivalent to the requirements for those who design animal experiments according to Table 1 in § 13.

§ 9 In operations with biomedical focus, pharmaceutical development, or the equivalent, the laboratory animal veterinarian who is named in the establishment license shall, have special expertise within laboratory animal medicine, in addition to the education specified in § 8.

If the laboratory animal veterinarian does not have the expertise within laboratory animal medicine required according to the first paragraph, then the license holder shall, together with the laboratory animal veterinarian, develop an education plan for how the laboratory animal veterinarian is to acquire that expertise.

§ 10 An expert shall have education at least equivalent to the requirements for those who design animal experiments according to Table 1 in § 13, as well as the experience and competence required for the activity.

§ 11 An ethologist, according to Ch. 3, § 2 in these regulations, shall have a degree within zoology or animal science with ethology focus. The ethologist shall also have experience of primate ethological work as well as education at least equivalent to the requirements for those who design animal experiments according to Table 1 in § 13.

§ 12 Those who capture laboratory animals living in the wild according to § 22a of the Animal Welfare Act (1988:534) shall have education that includes the following elements:

1. Handling of the laboratory animals.
2. Different methods of capturing, including immobilisation and handling of any by-catch.
3. Minimizing stress and suffering for the laboratory animal.
4. Methods of release.
5. Applicable legislation within species protection and hunting.

Those who capture laboratory animals according to the first paragraph shall also have education relevant for the species and at least equivalent to the requirements for those who conduct animal experiments according to Table 1 in § 13.

Content of Education

§ 13 Those who design animal experiments, conduct animal experiments, care for laboratory animals, or kill laboratory animals according to § 1 shall have education within the areas specified in Table 1. Education in practical elements only needs to involve use of laboratory animals if the person undergoing training/education may need to perform such elements themselves in their professional role. Part of the education in practical elements may take place through supervised work according to § 5.

The content of the different elements according to Table 1 may be adapted to the species with which the person being trained will work, and if the person being trained will conduct animal experiments, design animal experiments, care for laboratory animals, or kill laboratory animals.

General Advice For § 13

In applicable parts, education according to § 13 should take place according to the European Commission's document" Caring for Animals – aiming for better science-Directive 2010/63/EU on the protection of animals used for scientific purposes – Education framework. Working document on drafting of a common education framework to meet the requirements of the directive, Brussels, February 19–20, 2014"[8].

Table 1

	Conducts experiments	Designs experiments	Cares for laboratory animals	Kills laboratory animals
Basic Requirements for Education				
National legislation on the acquisition of laboratory animals, animal husbandry, care and use of laboratory animals	X	X	X	X
Basic and appropriate species-specific biology regarding anatomy, physiological properties, breeding, genetics, and genetic alterations	X	X	X	X
Ethics in connection with the relationship between humans and animals, the inherent value of life, arguments for and against using animals for scientific purposes, animal welfare and the 3R-principle	X	X	X	X
Animal behavior, husbandry, and enrichment	X	X	X	X
Methods for the 3R-principle	X	X	X	X

[8] This document is available in Swedish at www.jordbruksverket.se

Disease prevention, animal health science and hygiene	X	X	X	X
Recognition of species-specific distress, pain and suffering	X	X	X	X
Humane killing methods (theory)	X	X	X	X
Task-Specific Requirements for Education				
End-point and humane end-point	X	X	X	X
Anesthesia and pain relief	X	X		X
Species-specific animal experiment methodology with regards to handling laboratory animals and animal experiments	X	X		
Humane killing methods (skill)				X
Designing animal experiments and projects		X		

CH.7. ETHICAL REVIEW OF ANIMAL RESEARCH

Basic Provisions

§ 1 Provisions on ethical review are also contained in § 21 of the Animal Welfare Act (1988:534), as well as §§ 41, 41a, 41c, 41d, 45, and 46 of the Animal Welfare Ordinance (1988:539), and in Ch. 2, § 15-16 of these regulations.

§ 2 In Ch. 2, §§ 17-25, there are regulations about which animal experiments are exempt from the requirement of ethical approval.

The Regional Animal Ethics Committees

§ 3 In a special decision[9], The Swedish Board of Agriculture has announced how many regional animal ethics committees there shall be, what is the required quorum for the committee, localisation of the committees, and distribution of applications between the committees.

§ 4 A Regional Animal Ethics Committee shall meet as often as necessary to fulfill the requirements in this chapter.

Handling of cases

§ 5 A Regional Animal Ethics Committee shall decide in the case at the latest 40 work days

[9] 2015-05-12. Decision about the number of Regional Animal Ethics Committees, localization, case allocation, as well as number of members, Ref no. 5.2.18-4703/15 www.jordbruksverket.se.

after a complete and correct application has been received by the committee.

The committee may extend the time in the first paragraph by another 15 work days if the case is of such complicated nature that this is necessary. The committee shall communicate this as well as motivate the reasons for the extension to the applicant within the first 40 work days.

General Advice For § 5, First Paragraph

An application shall be considered complete when the committee has received enough information to perform the ethical review.

§ 6 A Regional Animal Ethics Committee shall as soon as possible notify the applicant

1. that it has received the application for ethical approval, as well as
2. when the decision will be made at the latest, providing that the application is complete.

§ 7 A Regional Animal Ethics Committee shall check that the application for ethical approval includes the requested information and that there is a relevant establishment license.

If the application is incomplete or incorrect, the committee shall as soon as possible communicate to the applicant that there is a need for supplementary information. At the same time, the committee shall communicate if this means that the decision will be made later.

§ 8 A Regional Animal Ethics Committee shall check that the non-technical summaries, submitted by the applicant according to Ch. 2, § 16, contains the requested information and, if needed, request supplementary information from the applicant.

The Committee shall supplement the non-technical summaries with

1. the severity classification as established by the Committee,
2. any additions or amendments that have been decided, as well as
3. any decision on retrospective assessment, including which parts and from what aspect.

Second paragraph 2 only applies if amendments entail that the non-technical summaries would become inaccurate.

§ 9 A Regional Animal Ethics Committee may call applicants to preparation meeting and committee meeting to obtain information on the matter. Applicants may attend the meeting by remote means.

§ 10 A Regional Animal Ethics Committee shall notify relevant County Administrative Boards about the time and location of the committee's meetings. For matters regarding the Swedish Armed Forces, the Armed Forces Inspector for health and environment shall be notified about the time and location of the committee's meetings. License holders, Named Officers, laboratory animal veterinarians, and experts who the application concerns, as well as representatives for County Administrative Boards may be present at the committee's meetings and have the right to be heard.

General Advice For § 10

License holders, named officers, laboratory animal veterinarians, experts, and representatives for County Administrative Boards or the Swedish Armed Forces who

have notified that they intend to attend the committee's meeting should receive complete decision-making information materials.

§ 11 A Regional Animal Ethics Committee shall keep minutes of their committee meetings. The minutes shall specify which matters were discussed and what decisions were made.

§ 12 A copy of the minutes according to § 11 shall be sent to

1. members of the relevant regional animal Ethics Committee,
2. The Swedish Board of Agriculture,
3. relevant County Administrative Board or, where applicable, the Armed Forces Inspector for health and environment, as well as
4. relevant license holder.

Ethical Review of Animal Research

§ 13 The Animal Welfare Act (1988:534), § 21, states that an animal experiment shall be reviewed by a Regional Animal Ethics Committee (ethical review of animal experiment). During the review, the committee shall perform a harm, benefit analysis of the experiment from an ethical perspective, where the laboratory animal's suffering shall be weighed against the expected benefit that the animal experiment may result in for humans, animals, or the environment.

The same paragraph also specifies that the Regional Ethics Committee shall review if the conditions in § 19.1–3 of the Animal Welfare Act (1988:534) are fulfilled. The committee shall establish the experiment's severity classification according to § 21 of the Animal Welfare Act (1988:534).

General Advice For § 13

In cases where there is high uncertainty of the consequences of an animal experiment, the committee should only approve that the animal experiment is performed with a smaller number of laboratory animals or otherwise to a limited extent (pilot study).

§ 14 The ethical review of animal experiment shall ensure that the experiment's purposes justify the use of laboratory animals, and that

1. the animal experiment is justified by scientific reasons,
2. the animal experiment is conducted for educational reasons, or
3. the animal experiment is prescribed by law.

§ 15 When reviewing the experiment, a Regional Animal Ethics Committee shall consider expertise, particularly within

1. relevant scientific areas for the experiment, including matters on 3R,
2. design of the animal experiment, including the statistical design,
3. veterinary medicine within laboratory animal science or other veterinary field of expertise, as well as
4. husbandry and care of the species intended to be used.

§ 16 A Regional Ethics Committee shall ensure that the experiment is designed so that it can be performed in the most considerate and environmentally friendly way possible.

§ 17 In case of an application for exceptions from the following regulations, the Regional Ethics Committee shall review if there are scientific reasons to grant such exceptions:

1. Ch. 10, § 2, that non purpose-bred laboratory animals of species that shall be purpose-bred may be used in animal experiments.
2. Ch. 10, § 4, that stray and feral domestic animals may be used in animal experiments
3. Ch. 10, § 5, that animals caught in nature may be used in animal experiments.
4. Ch. 10, § 6, to take measures to minimise suffering when capturing wild animals.
5. Ch. 10, § 8, that great apes (Pongidae) and gibbons (Hylobatidae) may be used in animal experiments.
6. Ch. 10, § 9, that threatened species and primates may be used in animal experiments.
7. Ch. 11, § 8, that a laboratory animal that may experience pain when the anesthesia has worn off, does not have to be treated with pain-relieving methods or killed.
8. Ch. 12, § 10, to use killing methods other than those specified in these regulations.
9. Ch. 14, § 6, that the experiment may use the ascites method.
10. Ch. 14, § 9, that the genotyping may be performed through tissue tests in a way other than avoiding damage to cartilage and skeletal parts as much as possible.
11. Ch. 14, § 10, that certain animal experiments may be conducted.
12. Ch. 16, § 10, that laboratory animals may be kept and cared for in other ways than that specified in these regulations.

In addition to that which is specified in the first paragraph, a Regional Ethics Committee may decide on exemptions according to Ch. 15, § 28.

Severity Classification of Animal Experiments

§ 18 When classifying severity according to § 21 of the Animal Welfare Act (1988:534), all interventions on or treatments of laboratory animals within a defined animal experiment must be considered.

The classification should be based on the most serious effects that it can be expected that an individual laboratory animal will experience after all appropriate refinement techniques have been used.

§ 19 When classifying, a Regional Ethics Committee shall consider the type of experiment and, on a case by case basis, assess the following factors:

1. Types of procedures and handling of the laboratory animal.
2. Type, intensity, duration, frequency, and any cumulative effect of the suffering caused to the laboratory animal in the experiment.
3. The number of and nature of procedures to which the laboratory animal will be subjected.
4. Prevention of the possibility to express natural behavior, including limitations in the standard of housing, and care of the laboratory animal.

General Advice For § 19

Examples of how animal experiments shall be classified, if consideration is only given to the type of animal experiment, are contained in Annex VIII, § III, in the Directive of the European Parliament and of the Council *2010/63/EU of September 22, 2010, on protection of animals used for scientific purposes*[10] *and in the European Commission's*

[10] EUT L 276, 20.10.2010, s. 33 (Celex 32010L0063).

document "Caring for Animals – aiming for better science- Directive 2010/63/EU on protection of animals used for scientific purposes- Project Evaluation and Retrospective Assessment. Working document on project evaluation and retrospective assessment, Brussels, 18-19 September 18-19, 2013"[11]*, as well as in the European Commission's document" Caring for Animals – aiming for better science- Directive 2010/63/EU on protection of animals used for scientific purposes – Framework for assessment of severity. Working document assessment of severity, Brussels, July 11-12, 2012"*[12].

§ 20 In order to arrive at a classification for the experiment, the following factors shall be considered:

1. The animal's species and genotype.
2. The animal's maturity, age and gender.
3. The animal's training experience with respect to the experiment.
4. If the animal is to be reused, the actual severity of the previous animal experiments.
5. The methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions.
6. Humane end-point and end-point.

§ 21 Animal experiments performed completely under general anesthesia, from which the laboratory animal shall not regain consciousness, shall be classified in the category terminal.

Animal experiments in which the laboratory animal is killed for the sole purpose of using organs or tissues, without prior use, shall be classified in the category terminal, with the addition"organ". However, a genetically modified laboratory animal with intended and demonstrated harmful phenotype shall be classified according to the severity which its genetic change is expected to cause.

§ 22 The following animal experiments shall be classified in the category mild

1. animal experiments that are expected to cause a short period of mild suffering for the laboratory animal, as well as
2. animal experiments that do not entail any significant impairment of the laboratory animal's well-being or general condition.

§ 23 The following animal experiments shall be classified in the category moderate

1. experiments that are expected to cause the animal a short period of moderate suffering,
2. experiments that are expected to cause the animal a long or several short periods of mild suffering, as well as
3. experiments that entail a moderate impairment of the animal's well-being or general condition.

§ 24 The following animal experiments shall be classified in the category severe

1. animal experiments that are expected to cause the laboratory animal a short period of severe suffering,
2. animal experiments that are expected to cause the laboratory animal a long or several

[11] The document is available at www.jordbruksverket.se

[12] The document is available at www.jordbruksverket.se

short periods of moderate suffering, as well as
3. animal experiments that entail a severe impairment of the animal's well-being or general condition.

§ 25 A Regional Ethics Committee may approve several animal experiments in a group providing that the experiments are of the type generic animal experiments conducted by the same applicant if the animal experiments are intended to fulfill legal requirements or involve the use of laboratory animals for production or diagnostics using established methods. 'Generic animal experiments' refers to a series of standardized experiments.

The Animal Ethics Committee's Decision

§ 26 Decisions from the Regional Ethics Committee shall include:
1. Name of the principal investigator.
2. Information about the operating license within which the animal experiment is conducted.
3. Information about the facility or location where the animal experiment is going to be conducted.
4. Period of validity of the ethical approval.
5. Motivation of the decision.
6. Severity classification of the animal experiment.
7. Any special conditions, including if there is to be retrospective assessment of the animal experiment and, if so, when the evaluation shall take place.
8. Any dissenting opinion according to § 19 of the Administrative Procedure Act (1986:223).
9. Established fee according to the Swedish Board of Agriculture's regulations and general advice (SJVFS 2008:19) on fees in certain matters according to § 67 of the Animal Welfare Ordinance (1988:539).
10. How the decision may be appealed, where applicable, to the Central Ethics Committee.

§ 27 A Regional Ethics Committee shall send a copy of the decision according to § 26 as well as a copy of the accompanying application to:
1. Relevant County Administrative Board or, where applicable, the Armed Forces Inspector for health and welfare.
2. The license holder.
3. The NACWO.

Application for Amendment of an Existing Animal Ethical Approval

§ 28 When applying for an amendment of an existing ethical approval according to § 21 of the Animal Welfare Act (1988:534), which risks adversely affecting the welfare of the laboratory animal, the Regional Ethics Committee shall review the application considering the contents of the existing approval.

> ***General Advice For § 28***
> *If an application for amendment of an existing ethical approval entails that the matter becomes difficult to grasp, the Regional Ethics Committee should request the submission of a new application for ethical approval.*

§ 29 If the amendment of an existing ethical approval according to § 28 affects the contents in the non-technical summary that the applicant has submitted according to Ch. 2, § 16, the applicant shall supplement the summary and attach it to the application for amendment.

§ 30 In connection with the amendment of the existing ethical approval according to § 28, the Regional Ethics Committee shall, as needed, also amend the classification of the experiment's severity according to § 21 of the Animal Welfare Act (1988:534).

§ 31 In connection with the amendment of the existing ethical approval according to § 28, the Regional Ethics Committee shall also decide, as needed, on retrospective assessment of the experiment according to Ch. 7, §§ 32–35.

Retrospective Assessment

§ 32 In § 21 fourth paragraph of the Animal Welfare Act (1988:534) it is specified that, when reviewing the case, it shall also be decided if retrospective assessment shall be done of the animal experiment. Provisions that it is the Central Ethics Committee that is to perform the evaluation are contained in § 21b.2 of the same legislation. Additional provisions on retrospective assessment are contained in §§ 49d and e of the Animal Welfare Ordinance (1988:539).

§ 33 The following animal experiments shall be subject to retrospective assessment:

1. All animal experiments where primates are used.
2. All animal experiments classified as ”severe”.
3. Other animal experiments that the Regional Ethics Committee has decided shall be evaluated.

General Advice For § 33.3

Animal experiments according to § 33.3 may be those where there is a need to obtain additional knowledge of how the used methods have affected the laboratory animals. Also, the selection of species may also be a reason for retrospective assessment of the animal experiment. Retrospective assessment of animal experiments, where exemptions from Ch. 14, § 10, have been granted, should be performed if this can contribute to development of knowledge.

§ 34 When evaluating animal experiments according to § 33.3, the Regional Ethics Committee shall specify and motivate the questions to which the evaluation should be limited and, when suitable, what documentation is to be collected according to § 35.

§ 35 The principal investigator shall ensure that the required documentation to enable retrospective assessment is collected and is made available to the Central Ethics Committee.

General Advice For § 35

The laboratory animal veterinarian or expert as well as, where applicable, ethologist should participate in the supervision of the laboratory animals in the animal experiments subject to retrospective assessment, so that their expertise can be used in the documentation on which the evaluation is to be based.

CH. 8 RECORDS, ETC.

General

§ 1 The NIO shall ensure that the following documentation, in applicable parts, is readily available to those who work with the laboratory animals at the laboratory animal facility:

1. Decision on establishment license according to § 19a of the Animal Welfare Act (1988:534).
2. Decision on preliminary approval of the laboratory animal facility according to § 55 of the Animal Welfare Ordinance (1988:539) and approval of the laboratory animal facility according to Ch. 2, § 13 of these regulations.
3. Such records as specified in §§ 4–6, 8, and 9.
4. Documentation on ethical approval of animal experiment according to § 10.
5. Plans according to Ch. 11, §§ 18-20, Ch. 15, § 6, and Ch. 16, §§ 5-7 and 20.

The head of information shall ensure that the documentation according to 1–5 is saved according to §§ 10–11 in this chapter as well as Ch. 5, § 8.

§ 2 The NACWO shall ensure that records are kept according to §§ 4–9 in this chapter and that the following documentation, when applicable, is readily available to those who work with the laboratory animals at the laboratory animal facility:

1. Such records as specified in § 7.
2. Complete decision on ethical approval of animal experiment including application.

§ 3 The NACWO specified in § 2 shall ensure that there is information about the principal investigators name as well as the reference number for the decision on ethical approval of animal experiment attached on each cage, box, room, or corresponding space where there are laboratory animals.

Record-Keeping

§ 4 Records shall be kept individually for all laboratory animals used in animal experiments. However, a record may be kept for a group of laboratory animals providing that

1. the laboratory animals are covered by the same ethical approval of animal experiment and are subjected to the same procedures,
2. the laboratory animals are kept in the same cage, box, room, or corresponding, as well as
3. it applies to other animals than primates, dogs, cats, or rabbits.

Record Content

§ 5 When new laboratory animals arrive at a laboratory animal facility, the following information shall be recorded:

1. Arrival date.
2. From whom the animals are acquired, and birthplace for primates, dog, and cat, if that information is available.
3. The origin of the laboratory animals including if they are purpose bred and when it

comes to primates, if they are offspring of primates bred and raised in captivity.
4. Identity according to marking, if available.
5. If a primate, dog, or cat has arrived at the laboratory animal facility before it has been weaned and it has not been possible to mark the animal with its identity, then the identity of the animal's mother shall be noted in the record.
6. Species and, where applicable, breed, or strain.
7. Gender, when this is suitable.
8. Birth date or weaning date, if these are known.
9. When keeping a record for a group, the number of animals.

§ 6 For all laboratory animals kept at a laboratory animal facility, the following information shall be recorded continuously:

1. Relevant information about husbandry, care, and supervision.
2. Information about diseases and injuries as well as any actions which have been taken due to the mentioned.
3. Date of death or killing which is not part of an animal experiment. The cause for killing shall be recorded as well as cause of death if known.

§ 7 For laboratory animals used in animal experiments, performed procedures including time for these shall be recorded in chronological order. The following information shall be included in the record:

1. Reference number of the ethical approval of animal experiment.
2. The principal investigators instructions and other documentation as specified in Ch. 11, § 1.
3. If the laboratory animal has been used before, according to Ch. 11, §§ 15 and 16, and if so in which animal experiments.

§ 8 When laboratory animals are sold, set free or rehomed, the following information shall be recorded:

1. Date when the laboratory animals were sold, set free, or rehomed.
2. When applicable, the recipient's name and address.

Individual Documentation of Primates, Dogs, and Cats

§ 9 Every purpose-bred primate, dog, and cat, if the animal is kept as a laboratory animal, shall be accompanied by individual documentation with the animal's life history. When the animal is born, or as soon as possible thereafter, the documentation shall be started and contain all relevant information about reproduction, veterinary and social conditions for the individual animal, as well as in which animal experiments the animal has been used.

Saving of Records

§ 10 Application for ethical approval of animal experiment, including decision, shall be saved for at least three years from the date that the approval expires. If the application was rejected, then the documentation shall be saved for at least three years and forty working days after the complete and correct application arrived at the Regional Animal Ethics Committee.

For animal experiments where a retrospective assessment is to be performed according to Ch. 7, §§ 32–35 in these regulations, then documentation according to the first paragraph shall be saved until the retrospective assessment has been completed.

§ 11 Records according to this chapter and the documentation according to § 9 shall be saved for at least five years from the date of the last information entries.

CH. 9 IDENTIFICATION MARKING OF LABORATORY ANIMALS

General

§ 1 The NTCO, according to the establishment license, shall ensure that the requirements for education and competence in this chapter are followed.

The NACWO shall ensure that marking of all experimental animals is performed according to this chapter.

Identification marking of Primates, Dogs, Cats and Rabbits

§ 2 A primate, dog, cat, or rabbit at an animal experiment facility shall have an individual permanent identity marking. At the latest, the animal shall be marked in connection with weaning. The marking shall be provided in the least painful way for the animal.

§ 3 An unmarked primate, dog, cat, or rabbit that has been acquired solely for use in breeding shall be provided with an identity marking as soon as possible.

§ 4 Upon request from the County Administrative Board, anyone having unmarked primates, dogs, or cats shall specify the reasons as to why the animals have not been marked.

Upon request from the Armed Forces Inspector for health and environment, any laboratory animal procedures within the Swedish Armed Forces having unmarked primates, dogs, or cats shall specify the reasons as to why the animals have not been marked.

Marking Methods

§ 5 Laboratory animals may be marked with the methods specified in this chapter by a person who

1. has an education at least equivalent to those caring for laboratory animals and where marking for the animal species and the relevant method has been included both as a theoretical and practical element, or
2. fulfills the requirements for the procedure according to Ch. 5, § 3 of the Swedish Board of Agriculture’s regulations and general advice (SJVFS 2013:41) on the obligations of animal keepers and personnel in animal health care and the requirements for the species in question according to Ch. 5.4, §§ 3-7 and 9 of the same regulations.

§ 6 The following invasive marking methods are permitted on laboratory animals of all species providing that the method is suitable for the species and size:

1. Tattoo.
2. Freeze marking.
3. Application of ear tags.
4. Implantation of microchip.

§ 7 In addition to that specified in § 6, mouse, rat, gold hamster, Chinese dwarf hamster, vole, gerbil, and Guinea pig may be marked using ear holes or ear notching.

§ 8 In connection with animal experiments, fish may be marked by other invasive marking methods than those specified in § 6 if it takes place under anesthesia and the marking has been approved by a Regional Animal Ethics Committee.

§ 9 Further regulations on marking of horse, cattle, sheep and goat, pigs, and dogs are contained in

1. Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC about the methods for the identification of equidae[13,]
2. Swedish Board of Agriculture regulations (SJVFS 2007:12) on marking and registration of cattle,
3. Swedish Board of Agriculture regulations and general advice (SJVFS 2007:14) on marking and registration of sheep and goats,
4. Swedish Board of Agriculture regulations and general advice (SJVFS 2007:13) on marking and registration of pigs, as well as
5. Swedish Board of Agriculture regulations (SJVFS 2008:41) on marking and registration of dogs.

CH. 10 PROVISIONS CONCERNING CERTAIN ANIMALS USED IN ANIMAL EXPERIMENTS

Purpose-breeding

§ 1 Provisions for purpose-breeding are also contained in § 19.4 of the Animal Welfare Act (1988:534).

§ 2 The following species and groups of species shall be purpose-bred:

1. All species of genetically modified vertebrate animals.
2. Frog of the species Xenopus laevis, X. tropicalis, Rana temporaria and R. pipiens.
3. Zebra fish.
4. Quail.
5. Mouse.
6. Rat.
7. Guinea pig.
8. Gold hamster.
9. Chinese dwarf hamster.
10. Gerbil.
11. Rabbit.
12. Ferret.
13. Dog.
14. Cat.
15. Primates.

Species not specified in the first paragraph are exempt from the requirement on purpose-

[13] EUT L 59, 3.3 2015, p 1-53.

breeding according to § 19.4 of the Animal Welfare Act (1988:534).

A Regional Animal Ethics Committee may grant an exemption from the requirement of purpose-breeding according to the first paragraph if there are scientific reasons.

§ 3 Animals of species specified in § 2, first paragraph, may be used in animal experiments even if they are not purpose-bred providing that the following conditions are fulfilled:

1. The purpose of the animal experiment cannot be achieved using purpose-bred laboratory animals of the same or other species.
2. Those who run the operation do not own the laboratory animal.
3. The owner of the animal is informed of what the experiment entails and gives written consent to use of the animal.
4. The owner of the animal is not compensated for more than actual costs.
5. The laboratory animal is not kept at a laboratory animal facility during the experiment.
6. The laboratory animal may not be subjected to surgical procedures only depending on the animal experiment, except for simpler procedures.
7. A Regional Animal Ethics Committee has granted an exemption from the requirement of purpose-breeding according to § 2, third paragraph.

Only the first paragraph 1 and 7 apply to the use of stray and feral domestic animals as well as animals living free in the wild of species that shall be purpose-bred according to § 2, first paragraph.

General Advice For § 3.6

Simpler procedures may be blood samples, urine samples, and skin biopsies.

Stray and Feral Domestic Animals

§ 4 Stray and feral domestic animals may not be used in animal experiments.

A Regional Animal Ethics Committee may grant an exemption from the prohibition in the first paragraph if there are scientific reasons and then only providing that

1. there is an essential need for studies of such animals' health and welfare, or
2. such animals can pose a serious threat to the environment or other animals' or human health.

The prohibition according to the first paragraph does not apply to animal experiments that are exempt from the requirement of an operating license and ethical approval of animal experiments according to Ch. 2, § 19 in these regulations.

Capturing and Releasing Wild Animals

§ 5 Captured wildlife living free in the wild may not be used in animal experiments.

A Regional Animal Ethics Committee may grant an exemption from the prohibition in the first paragraph if there are scientific reasons.

When using such animals as specified in the first paragraph, special consideration shall be given to acclimatization, quarantine, husbandry, and care of the animals.

§ 6 Provisions on capturing of wildlife living free in the wild can be found in § 22a of the Animal Welfare Act (1988:534), the Species Protection Regulation (2007:845), the Hunting

Act (1987:259), the Hunting Ordinance (1987:905), the Fisheries Act (1993:787), and the Fisheries Ordinance (1994:1716).

If a laboratory animal is found to be sick or injured during or after capture, it shall be examined by a veterinarian or other competent person and measures shall be taken to minimise the animal's suffering. At the capture sites there shall be suitable and sufficient transport containers and means of transport if a laboratory animal needs to be moved for examination or treatment.

A Regional Animal Ethics Committee may grant an exemption from the requirement of taking action to minimise the suffering of the animal in connection with capture if there are scientific reasons.

§ 7 Regulations on releasing wildlife are contained in Ch. 11, §§ 17 and 20.

Primates and other Endangered Animals

§ 8 Great apes (*Pongidae*) and gibbons (*Hylobatidae*) may not be used in animal experiments.

The prohibition in the first paragraph does not apply for animal experiments that are conducted at facilities approved for public display of animals according to § 37 of the Animal Welfare Ordinance (1988:539) and

1. the animals are not subjected to anything that may result in suffering for the animal, or
2. the experiments are observation studies that may be performed without an operating license or ethical approval of animal experiment according to Ch. 2, § 21 of these regulations, or
3. a Regional Animal Ethics Committee has granted permission to do so.

§ 9 Endangered species and all primates except great apes (*Pongidae*) and gibbons (*Hylobatidae*) may only be used in animal experiments providing that

1. there are scientific reasons which mean that the purpose of the animal experiment cannot be achieved with the use of other species than endangered species or primates,
2. the animals are only used in animal experiments for the purposes specified in Table 1 below, as well as
3. a Regional Animal Ethics Committee has granted permission to do so.

Table 1 Permitted Purposes of Animal Experiments

	Primates	**Endangered primates**	**Other Endangered Species**
1. Basic research	**X**		
2. Research on which effects diseases or other ill health have on humans, animals, or plants, as well as how these are to be prevented, diagnosed, or treated	**X***	**X***	**X**
3. Development, manufacture, or testing of quality, efficacy and safety of pharmaceuticals, foods, feed, and other substances or products. This only applies for the purposes specified in 2.	**X***	**X***	**X**
4. Research aiming at the survival of the species.	**X**	**X**	**X**

* Only applies for animal experiments performed to avoid, prevent, diagnose, or treat disabling or potentially life-threatening clinical conditions in humans. The term ”disabling clinical condition” refers to a reduction of an individual’s normal physical or psychological functional ability.

§ 10 The breeder of primates shall have a strategy for increasing the proportion of laboratory animals that are offspring of primates bred in captivity.

§ 11 Common marmoset (*Callithrix jacchus*) may only be used in animal experiments if they are offspring of animals that have been bred in captivity or if they are from self-sustaining colonies. The term” self-sustaining colony” refers to a separate population in captivity where the animals are born and raised only within the colony, or are taken from other self-sustaining colonies, but are not captured in the wild, and where the animals are kept so that they are used to humans.

CH. 11 ACTIONS IN CONNECTION WITH ANIMAL EXPERIMENTS

General

§ 1 The principal investigator shall ensure that personnel who will perform an animal experiment, or care for laboratory animals in connection with the animal experiment, can take part of the application for ethical approval and the decision on ethical approval of the animal experiment.

The principal investigator shall ensure that personnel according to the first paragraph receive written instructions on

1. end-point and humane end-point for the animal experiment,
2. how the laboratory animals’ suffering is assessed and continously documented, as well as
3. how supervision of the laboratory animals before, during, and after procedures within the animal experiment, shall take place.

§ 2 The principal investigator shall ensure that all unnecessary suffering within the framework

for an animal experiment is prevented and, if present, is stopped. The principal investigator shall also ensure that measures are taken according to §§ 9–11.

The NACWO shall ensure that the principal investigator prevents and stops suffering according to the first paragraph.

If there are uncertainties in the assessment of if the laboratory animal is subjected to unnecessary suffering according to the first paragraph, then the laboratory animal veterinarian or expert shall be consulted. If the laboratory animal veterinarian or expert have another opinion than the principal investigator or named officer, this shall be noted in the record.

§ 3 The principal investigator shall ensure that the animal experiment is performed according to the ethical approval.

The NACWO shall document any non-compliance and which measures have been taken to rectify non-compliance with the ethical approval.

Surveillance During Animal Experiments

§ 4 Surveillance of the laboratory animals during animal experiments shall take place to such an extent that it can be guaranteed that the laboratory animals are not exposed to greater suffering than necessary. If needed, there shall also be surveillance during night time. Written plans shall be established for how the person monitoring the animals shall act in case of both expected and unexpected effects.

> ***General Advice For § 4***
> *If information about the expected course of events is missing, surveillance shall take place at such frequent intervals that the laboratory animals do not risk being subjected to more suffering than necessary.*

§ 5 A laboratory animal veterinarian or expert shall participate in surveillance of the laboratory animals at

1. all animal experiments classified as severe,
2. animal experiments where the Regional Animal Ethics Committee has decided that it is suitable, as well as
3. in other animal experiments where the veterinarian or expert has assessed it to be suitable. The principal ivestigator shall inform the designated laboratory animal veterinarian or expert about when an animal experiment according to the first paragraph will begin.

Anesthesia

§ 6 Provisions on anesthesia of laboratory animals are also contained in § 53 of the Animal Welfare Ordinance (1988:539).

§ 7 Laboratory animals may not be given drugs preventing them from or limiting their ability to express pain unless they receive adequate anesthesia or pain relief at the same time. In these cases, a scientific motivation shall be given, accompanied by information on the anaesthesia or analgesia.

§ 8 A laboratory animal that is expected to experience pain when the anesthesia has worn off

shall be treated with preventive and postoperative analgesics or other suitable pain-relieving methods. If this is not possible, the laboratory animal shall be euthanized immediately.

A Regional Animal Ethics Committee may grant an exemption from the first paragraph providing that

1. it is necessary considering the purpose of the animal experiment,
2. the laboratory animals are not exposed to severe suffering, as well as
3. suffering of the laboratory animals is limited using sedatives to the extent that it is possible.

Measures at Termination of Animal Experiments

§ 9 An animal experiment shall be ended as soon as the end-point according to the ethical approval for the animal experiment has been reached.

§ 10 A laboratory animal shall be taken out of the animal experiment before the end-point is reached if

1. the humane end-point, according to the ethical approval, is reached, or
2. it is subjected to unexpected suffering that cannot be revoked.

§ 11 A laboratory animal shall be killed after it has been taken out of animal experiments or when the end-point has been reached.

Despite the first paragraph, a laboratory animal may be kept alive if it is unlikely that the animal will continue to experience moderate or severe pain, suffering, distress, or permanent harm and

1. a laboratory animal veterinarian or expert has determined that the laboratory animal shall continue to live, or
2. it is not specified by the ethical approval for animal experiment that the laboratory animal shall be killed.

§ 12 If a laboratory animal is not killed after it has been taken out of an animal experiment and there is risk that it will suffer, then suitable measures shall be taken immediately to minimise suffering.

§ 13 A laboratory animal no longer used in animal experiments shall be cared for and housed according to these regulations if it is housed at a laboratory animal facility. Care and accommodation shall be adapted to the laboratory animal’s state of health.

If the requirements in the first paragraph cannot be fulfilled, then the laboratory animal shall be killed as soon as possible.

Use

§ 14 Laboratory animals may not be used for more than one procedure.

Continued Use

§ 15 Despite of what is specified in § 14, a laboratory animal may be used for additional procedures if this is necessary to attain a specific scientific purpose.

General Advice For § 15

For assessment if several procedures are covered within one and the same animal experiment, the European Commission document "Caring for Animals – aiming for better science- Directive 2010/63/EU on the protection of animals used for scientific purposes –Framework for assessment of severity classification. Working document on assessment of severity classification, Brussels, July 11-12, 2012"[14] *may be used.*

Reuse

§ 16 Despite of what is specified in §§ 14 and 15, a laboratory animal that has been used in one or several procedures may be used in a new procedure, when a different animal on which no procedure has previously been performed could also be used, providing that

1. a Regional Animal Ethics Committee has not decided otherwise,
2. a designated laboratory animal veterinarian or expert has assessed that it is suitable from an animal welfare perspective for the individual laboratory animal, considering what the laboratory animal has been subjected to previously,
3. the actual severity that the individual laboratory animal has experienced previously was "mild" or "moderate",
4. the laboratory animal's state of health and well-being has been fully restored, as well as
5. the new severity to which the individual laboratory animal will be subjected is assessed to be "terminal", "mild", or "moderate".

Rehoming or Release After Animal Experiment

§ 17 A laboratory animal may be rehomed, returned to a suitable habitat or to a husbandry system that is appropriate for the species provided that

1. the laboratory animal's state of health allows it,
2. the greatest measures have been taken to ensure the laboratory animal's well-being, as well as
3. there is no danger to public health, animal health or the environment.

§ 18 When rehoming, a plan for socialisation of the laboratory animals shall be established.

§ 19 If a primate, dog, or cat is rehomed, the individual documentation according to Ch. 8, § 9 shall accompany the laboratory animal.

§ 20 When needed, there shall be a rehabilitation program in place before wild laboratory animals are returned to their habitat.

CH.12 KILLING OF LABORATORY ANIMALS

General About Killing

§ 1 Laboratory animals may only be killed in a facility for laboratory animals unless the

[14] The document is available at www.jordbruksverket.se

Swedish Board of Agriculture has approved, in the establishment license, that animal experiments may be performed outside a laboratory animal facility.

§ 2 In case of an emergency where a laboratory animal must be killed immediately for reasons of animal welfare, animal health or public health, public safety, or the environment, other methods than those specified in these regulations may be used. In such cases, the requirements in §§ 1 and 6 do not apply

§ 3 Provisions for prescribing drugs for killing animals are contained in the Swedish Board of Agriculture's regulations (SJVFS 2013:42) on drugs and drug use.

§ 4 Provisions on the possession of weapons and the right to use firearms in the killing of animals are contained in the Weapons Act (1996:67) as well as in the Weapons Ordinance (1996:70).

§ 5 Additional provisions on killing wild animals are contained in Swedish Environmental Protection Agency's regulations and general advice (NSF 2002:18) on hunting and state wildlife.

Education and Competence for Killing

§ 6 The person who is to kill, anesthetize, stun, or sedate a laboratory animal before killing, should be well acquainted with the method of killing, anesthesia, stunning, or sedation to be used and have education according to Ch. 6.

Methods of Killing

General Provisions

§ 7 After killing, death of the laboratory animal shall be confirmed before further action is taken with the body. Such a verification shall be done on all laboratory animals.

The confirmation shall take place by confirming permanent cessation of circulation or, when there is no risk that the laboratory animals may be subjected to suffering, confirmation of the onset of rigor mortis. In cases where this is not possible, death shall be ensured by destruction of the brain, exsanguination or cervical dislocation.

If it is suspected that a laboratory animal is not dead, renewed killing measures should be taken immediately.

8 § Laboratory animals of the species fish, amphibians, reptiles, birds, rodents, rabbit, dog, cat, ferret, cattle, sheep, goats, equines, pigs, primates, and other large mammals shall be killed using one of the methods specified in Table 1 and as otherwise specified in this chapter.

Table 1 Methods of Killing[*]

	Anesthetic overdose[1]	Injection of chemical agents in uncon-	Carbon dioxide	Cervical dislocation	Forceful blow to the head	Decapitation	Inert gases (Ar, N_2)	Shooting with live ammunition	Exsanguination of unconscious animals	Pithing of unconscious animals

		scious animals								
Fish	X	X			X	X¤			X	X
Amphi-bians	X	X			X$^{\Delta}$	X¤				X
Reptiles	X	X			X$^{\Delta}$	X¤		X¤		X
Birds	X	X	X♦	X$^{\Delta}$	X$^{\Delta}$	X$^{\Delta}$	X		X	
Rodents	X	X	X$^{\Delta}$	X$^{\Delta}$	X$^{\Delta}$	(X)$^{\Delta}$	X		X	
Rabbits	X	X		X$^{\Delta}$	X$^{\Delta}$				X	
Dogs, cats, ferrets	X	X			X$^{\Delta}$			(X)¤	X	
Cattle, sheep, goats	X	X						X¤	X	
Equines	X	X						X¤	X	
Pigs	X	X					X	X¤	X	
Primates	X	X								
Other large mammals	X	X						X¤	X	

[1] Here, anesthetic overdose also refers to other chemical agents with anesthetic effect, however, not ether and chloroform.

[*] = The Swedish Board of Agriculture may decide on exemptions from Table 1 for the use of methods considered to be at least as humane. A Regional Animal Ethics Committee may approve another method of killing during procedures according to § 10.

$^{\Delta}$ = restricted due to age or weight

¤ = only on unconscious animals

♦ = only chickens, turkeys, quail, and day-old poultry chicks

□ = only under field conditions

(X) = may only be used if it is not possible to use other methods.

§ 9 Despite what is specified in § 8, laboratory animals shall be killed according to Council Regulation (EC) no. 1099/2009 of 24 September 2009 on the protection of animals at the time of killing[15] and the Swedish Board of Agriculture's regulations and general advice (SJVFS 2012:27) on slaughter and other killing of animals, in the following cases:

1. Laboratory animals that are to be used for human consumption.
2. Species not specified in § 8.
3. Laboratory animals where the purpose of the animal experiment requires that they are kept and killed according to the regulations that apply for the corresponding species that are not subject to animal experiments.

The first paragraph, § 2, is only valid provided there are detailed provisions for killing of the relevant species in the regulations. Otherwise they shall be killed according to §§ 7-8.

[15] EUT L303, 18.11.2009, p. 1, (Celex 32009R1099).

§ 10 A Regional Animal Ethics Committee may approve that another method of killing is used in an animal experiment if there are scientific reasons which entail that the purpose of the experiment can not be achieved if a killing method specified in these regulations is used.

§ 11 If a killing method according to these regulations only may be used on unconscious laboratory animals according to § 8, Table 1, the animals shall be anesthetized or stunned according to one of the following alternatives:

1. According to Table 2 in § 29.
2. According to Council Regulation (EC) no. 1099/2009[17].
3. According to the Swedish Board of Agriculture's regulations and general advice (SJVFS 2012:27) on slaughter and other killing of animals.
4. According to other acceptable methods from the perspective of animal welfare.

Anesthetic agents and other killing agents

§ 12 All species may be killed using anesthetic overdose which shall be administered to the laboratory animal in a suitable way. Other chemical agents that are specifically intended for the purpose, and that lead to the laboratory animal falling asleep and then dying, may be used.

In connection with killing according to the first paragraph, if needed, the laboratory animals shall be sedated before the anesthetic is administered.

§ 13 All species may be killed by injection of chemical agents without anesthetic effect. The agents shall be specifically intended for the purpose and for the species in question. The laboratory animal shall be unconscious when the agent is administered.

Carbon dioxide

§ 14 Rodents older than 10 days may be killed using carbon dioxide.

When killing according to the first paragraph, the space where the laboratory animal is exposed to the gas shall be designed so that the laboratory animals are not injured. It shall be possible to visually inspect the laboratory animals during the killing procedure.

When killing according to the first paragraph, the space where the laboratory animal is kept shall be filled gradually with carbon dioxide, and the laboratory animal shall be subjected to a carbon dioxide content of at least 80 percent by volume. Killing shall take place so that all laboratory animals in the space quickly become unconscious and die shortly thereafter. The laboratory animals shall be kept in the space until they have died.

§ 15 When killing chickens and turkeys using exposure to carbon dioxide in a stable or in a tunnel, the procedure shall take place according to the Swedish Board of Agriculture's regulations and general advice (SJVFS 2012:27) on slaughter and other killing of animals.

§ 16 When killing quail and day-old poultry chicks, the laboratory animals shall be brought into a space with the highest possible concentration of carbon dioxide. The gas shall be supplied in pure form. The laboratory animals shall be kept in the space until they have died.

Cervical dislocation

§ 17 Rodents, rabbits, and birds weighing less than 1 kg may be killed by cervical dislocation (dislocation of the neck). Rodents and rabbits weighing more than 150 g and birds weighing more than 250 g shall be unconscious when they are killed.

Blow to the head

§ 18 A blow to the back of the head shall be struck with such force and precision that it results in immediate unconsciousness and death. A blow to the back of the head may be used to kill a smaller amount of

1. newborn puppies, kittens, and ferret puppies,
2. birds weighing less than 5 kg, as well as
3. rabbits, rodents, reptiles, and amphibians weighing less than 1 kg.

Decapitation

§ 19 Birds weighing less than 250 g may be killed by decapitation.

§ 20 Rodents may be killed by decapitation only if other methods are not possible to use and they weigh less than 1 kg. If the laboratory animal weighs more than 250 g it shall be unconscious when it is killed.

§ 21 When killing fish, reptiles, and amphibians the brain shall be destroyed immediately after decapitation.

Inert gases (Ar, N_2)

§ 22 Birds, rodents, and pigs may be killed using inert gases such as argon and nitrogen.

General Advice For § 22

The space where the laboratory animals are exposed to the gas should be designed so that the laboratory animals are not injured. It should be possible to visually inspect the laboratory animals during the killing procedure. Killing with gas shall take place in such a way that all laboratory animals quickly become unconscious and thereafter die. The laboratory animals shall be kept in the space until they have died.

Killing with firearms

§ 23 Cattle, sheep, goats, horses, pigs, and other large mammals and reptiles may only be killed with firearms at a distance unless it is possible to capture the laboratory animals without subjecting them to greater suffering than what the killing can entail. When killing with firearms at a distance; cattle, equines, sheep, goats, dogs, cats, and ferrets shall be shot in the chest. Reptiles shall be shot in the head.

General Advice For § 23

Killing with a shot to the chest should be supplemented with exsanguination. However, this does not apply when killing dogs and cats.

§ 24 Dogs and cats may be killed with a shot to the head if they have been caught in a trap, are injured, or for other reasons have significantly restricted freedom of movement. At such a killing the laboratory animal shall be shot so that the brain is hit and damaged in such a way that the laboratory animal immediately becomes unconscious and does not regain consciousness before the laboratory animal dies.

§ 25 Killing with firearms shall be done by experienced shooters using handguns or rifles intended for hunting or killing purposes. The firearm's charge and ammunition must be adapted to the species and the size of the laboratory animal.

Exsanguination

§ 26 Exsanguination shall be performed by opening both carotid arteries, the common blood vessel from which these veins originate, or from another central blood vessel.

§ 27 Exsanguination of cattle, sheep, goats, reindeers, deer, other ruminants, pigs, equines, poultry, ratites, and rabbits shall take place according to the Swedish Board of Agriculture's regulations and general advice (SJVFS 2012:27) on slaughter and other killing of animals.

Pithing

§ 28 Pithing shall be performed in such a way that a narrow, sharp instrument is inserted and rotated in the laboratory animal's brain through the opening between the skull and the cervical spine. The instrument shall first be inserted forward against the brain stem and then backwards against the spinal cord.

Stunning Methods Before Killing

§ 29 Fish, amphibians, reptiles, birds, rodents, rabbits, dogs, cats, ferrets, cattle, sheep, goats, equines, pigs, primates, and other large mammals may be stunned using methods specified in Table 2 and in such a way as specified in this chapter.

Table 2 Stunning Methods Before Killing

	Anesthetic agents	*Captive bolt*	*Forceful blow to the head*	*Electrical stunning*
Fish	X		X	X
Amphibians	X			X
Reptiles	X	X*		
Birds	X		Xº	X
Rodents	X			
Rabbits	X	X	XΔ	X
Dogs, cats, ferrets	X			X
Cattle	X	X		

Sheep and goats	X	X		X
Equines	X	X		
Pigs	X	X		X
Primates	X			
Other large mammals	X	X		X

$^{\Delta}$ = restricted due to age or weight

^{o} = only poultry

* = only large reptiles

Anesthetic agents

§ 30 All species may be anesthetized (stunned) with anesthetic agents intended for the purpose and given to the laboratory animal in an appropriate way.
In connection anesthetizing (stunning) according to the first paragraph, the laboratory animal shall be sedated before administering the anesthetic agent.

Ether or chloroform may not be used when anesthetizing (stunning) laboratory animals according to the first paragraph.

Captive bolt

§ 31 When a captive bolt is used to stun laboratory animals, the laboratory animal shall be shot so that the brain is hit, and the animal immediately becomes unconscious.

§ 32 A captive bolt shall be placed and used in the manner specified in the Swedish Board of Agriculture's regulations and general advice (SJVFS 2012:27) on slaughter and other killing of laboratory animals in cases where there are instructions for this.

§ 33 After stunning with a captive bolt, the laboratory animal shall be killed immediately.

Blow to the head

§ 34 Blow to the head may be used to stun single rabbits and poultry weighing less than 5 kilos as well as single fish. On rabbits and poultry, the blow shall strike the back of the head. The blow shall be struck in such a way that the laboratory animal becomes unconscious immediately. After the blow the laboratory animal shall immediately be exsanguinized or killed in another suitable way.

When using mechanical systems, more than single fish may be stunned by a blow to the head.

Electrical stunning

§ 35 Fish, amphibians, birds, rabbits, dogs, cats, ferret, sheep, goats, and pigs may be stunned using electrical current.

When stunning according to the first paragraph, special equipment for the purpose shall be used. The equipment shall ensure that a prescribed current is reached, clearly indicate that the

current circuit is closed, and have a gauge that shows the voltage and current in the closed circuit. In case of individual stunning the equipment shall have a device that measures the resistance and that prevents use of the equipment unless a minimum current can be reached. The electrodes shall be well maintained and clean.

Electrical stunning according to the first and second paragraph shall immediately (within 20 seconds) be followed by exsanguination or another suitable method of killing. Stunning with electricity shall be performed as specified in the Swedish Board of Agriculture's regulations and general advice (SJVFS 2012:27) on slaughter and other killing of animals.

CH. 13 REPORTING OF STATISTICS

§ 1 The license holder is responsible for reporting and submitting statistics according to § 3 to the Swedish Board of Agriculture using the form provided on the Swedish Board of Agriculture's website.

§ 2 For animal experiments performed within the same calendar year, the information shall have been received by the Swedish Board of Agriculture at the latest by March 1 of the following calendar year. If animal experiments performed during two calendar years are terminated on time, the information may be reported to the Swedish Board of Agriculture by March 1 of the year during which the experiment is terminated. For animal experiments performed for more than two calendar years, the information must be reported to the Swedish Board of Agriculture by March 1 of the year after the laboratory animals were killed, died, or taken out of animal experiments.

§ 3 Any establishment using laboratory animals shall report annually the following statistics in the form:

1. User information.
2. Region or sector.
3. NACWO.
4. Organisation or equivalent.
5. Laboratory animal statistics including species, number of laboratory animals, reuse of laboratory animals, birthplace/origin, source and generation of non-human primates, genetic status as well as production of a new genetically modified strain.
6. Experiment information containing EU statistics.
7. Experiment information with national statistics.
8. Purpose of the animal experiment.
9. Test according to legislation.
10. Statutory requirements with the origin of the legislation.
11. The experiment's actual severity.

General Advice For § 3

To fill in the form for statistics, use the Commission's Implementing Decision of 14 November 2012 on establishing a common format for the submission of information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes[16] *or the Swedish Board of*

[16] EUT L 320, 17.11.2012, p. 33. (Celex 32012D0707).

Agriculture's guidelines[17].

CH. 14 SPECIAL PROVISIONS FOR CERTAIN ANIMAL EXPERIMENTS

Immunization, Production of Anti-bodies, and Joint Diseases, as well as Autoimmune Disease Models

§ 1 Immunisation with oil-based or gel-based adjuvant must not take place by injection into the bloodstream or abdominal cavity of the laboratory animal.

The prohibition according to the first paragraph does not apply for induction of autoimmune diseases in mice and rats by immunisation with oil-based or gel-based adjuvant in the animal's abdominal cavity.

§ 2 Immunisation may not take place by injection into a rabbit's paw or sole.

§ 3 The following routes of injection in the laboratory animal should not be used to induce arthritis:

1. Injection into foot pad of mouse and rat.
2. Injection into muscles of mouse.

§ 4 If adjuvant is required for immunization, the injection volume should be as small as possible and adapted to species and injection site.

Highly irritating adjuvants may only be used if necessary.

§ 5 When drawing blood for production of polyclonal antibodies, only so much blood may be drawn that there is no more than a mild and short-term negative effect on the laboratory animal. Blood may not be drawn more frequently than that which enables complete recovery of the blood volume, hemoglobin count, and the number of blood cells before blood is drawn again. When planning for drawing blood, consideration should be given to the animal's sensitivity to blood loss.

The final collection of blood or serum from a single laboratory animal in connection with killing (exsanguination, end-loss) may be done without limitation of blood volume but only on unconscious animals.

General Advice For § 5

1. For production of polyclonal antibodies and for other animal experiments, not more than 10% of the total blood volume should be drawn. If maximal blood volume is drawn, it should take place with an interval of at least 14 days.

2. When drawing blood, volume substitution should be considered taking the animal's sensitivity to blood loss into account.

§ 6 It is prohibited to produce monoclonal antibodies from hybridoma in the abdominal cavity of a laboratory animal, so-called Ascites method. Hybridoma refers to a cell culture which is produced by fusion of a specific antibody-forming lymphocyte and a tumor cell and that is

[17] www.jordbruksverket.se

capable of continuous proliferation while constituting monoclonal antibodies.

A Regional Animal Ethics Committee may grant an exemption from the provisions in the first paragraph if the Ascites method is the only way to eliminate an infection in an in vitro culture, or repeated animal experiments to multiply the antibody with in vitro technology has failed.

Production of Genetically Modified Animals

§ 7 In the application for ethical approval of animal experiments for production of experimental animals with altered genome using genetic engineering, chemical or other similar methods, the principal investigator shall especially justify and describe

1. method of production, including treatment of parent animals,
2. how genotype of the laboratory animals is to be checked,
3. how phenotype of the laboratory animals shall be characterized with respect to possible deviations and disabilities,
4. what suffering the methods used for genotyping and characterisation can cause for the laboratory animals, as well as
5. humane endpoint with regards to unexpected phenotypic deviations.

In addition, in the application the principal investigator shall according to the first paragraph as far as possible especially justify and describe

1. which genes are affected by the change,
2. which phenotypic deviations the gene changes can be expected to cause and when these are expected to occur, including expected effects on litter size and survival, as well as
3. what suffering the gene changes may cause for the laboratory animals.

§ 8 When genotyping genetically modified laboratory animals, primarily non- invasive methods or leftover tissue from marking according to Ch. 9, §§ 6 and 7 shall be used. Such methods do not need approval from a Regional Animal Ethics Committee.

§ 9 If genotyping must to be performed by tissue sampling, the sample may only be as large as is required for satisfactory genotyping. As well, sampling shall be performed so that damage to cartilage and skeletal parts are avoided as much as possible. Such methods shall be approved by a Regional Animal Ethics Committee, and in the application, it shall be specified why methods according to § 8 cannot be used.

Tests to Determine Acute Toxicity

§ 10 Animal experiments may not be performed for producing a lethal dose or concentration of a substance or a mixture of substances.

A Regional Animal Ethics Committee may grant an exemption from the first paragraph providing that

1. there is a documentation requirement, that is, EU legislation requires this to protect animal welfare or human health or the environment, as well as
2. the test is carried out according to the test methods specified in a Commission Regulation or other international test methods deemed appropriate by the Commission or European Chemicals Agency, or other test methods if they fulfill the provisions specified in Annex XI of the European Parliament’s and Council’s regulation (EC) no. 1907/2006 of 18 December 2006 on Registration, Evaluation,

Authorization, and Restriction of Chemicals (Reach), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Commission regulation (EEC) no. 793/93 and Commission regulation (EC) no. 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC[18].

General Advice For § 10

The content of the documentation requirement should be specified by regulations or by general advice from the relevant European authority.

§ 11 In the application for exceptions according to § 10, the principal investigator shall describe

1. documentation requirements according to § 10,
2. why other methods cannot be used,
3. where it is stated that the authority requiring the test does not approve that the information is produced in another way, as well as
4. if the substance or substances have been tested previously.

General Advice For § 11 §

1. The documentation requirements in question shall be described in such a way that it is clearly specified which pages, paragraphs, or similar are relevant.

2. Reporting according to item 3 should be made by a statement from the authority or other documentation showing that another method than the one applied for, is not sufficient to fulfill the documentation requirements.

§ 12 For acute toxicity test, the humane endpoints may not be set later than at the earliest sign of a life-threatening condition or significant pain, distress, or other equivalent condition.

CH. 15 GENERAL ABOUT FACILITIES FOR LABORATORY ANIMALS

General Design

§ 1 Facilities for laboratory animals shall be designed and able to be used to give the laboratory animals a suitable environment considering their physiological and behavioral needs.

§ 2 Installations and equipment shall be safe, functioning and provided with protection, so that they cannot be damaged by the laboratory animals or cause injuries to laboratory animals.

§ 3 Installations and equipment shall be adapted to the animal experiments that are performed. Also, they shall be designed in such a way and have a function such that

1. the animal experiments can be performed as efficiently as possible with reliable results,
2. a minimal number of laboratory animals can be used, as well as
3. the laboratory animals are subjected to minimal suffering.

§ 4 Facilities for laboratory animals shall be designed so that surveillance of the laboratory

[18] EUT L 396, 30.12.2006, p. 3 (Celex 32006R1907).

animals can be carried out according to Ch. 16, § 13.

§ 5 Facilities for laboratory animals shall be designed and maintained so that unauthorized persons cannot gain access and unwanted animals are prevented from entering, and that experimental animals kept in the facilities cannot escape.

§ 6 The NIO shall make sure that there are current work instructions for

1. how any defects in buildings and equipment shall be prevented and corrected, as well as
2. other tasks and work duties relevant for animal welfare.

General Advice For 6
Instructions according to 2 may be instructions about actions in case of fire, power failure, or malfunction of mechanical systems, etc.

§ 7 The NACWO shall make sure that the staff works according to the instructions in § 6, and that there are clear instructions regarding actions in case of emergencies posted in highly visible places.

Holding Rooms for Laboratory Animals

§ 8 Holding rooms for laboratory animals shall be cleaned regularly. Interior, equipment, and installations shall de designed in a suitable way considering cleaning and decontamination of infectants.

§ 9 Holding rooms shall be made of materials and have a surface layer that are not harmful to the health of the laboratory animals, that are resistant to required cleaning and decontamination methods, and that are resistant to the wear and tear caused by the laboratory animals. Cleaning and decontamination methods do not apply to consumables.

§ 10 The floors of the holding rooms for laboratory animal shall be adapted to the nature and age of the laboratory animals and be designed to facilitate the removal of urine and faeces.

Isolation and rooms for sick animals

§ 11 There shall be rooms where new laboratory animals arriving at the facility can be isolated until their health status has been determined and any health risks for laboratory animals at the facility can be assessed and minimised.

§ 12 It shall be possible to keep sick or injured laboratory animals separate and in such a way that recovery of the laboratory animal is facilitated.

General Advice For 12
Sick and injured laboratory animals shall be kept in a climate to which they are accustomed. For laboratory animals kept in outdoor climates, there should be a space that can be heated.

Rooms Where Animal Experiments Are Performed

§ 13 If it is unsuitable to carry out animal experiments or observations in the animals' rooms, then rooms for these procedures should be provided

If needed, there shall be laboratory equipment for carrying out simple diagnostic tests, post-mortem examinations, as well as collection of samples.

§ 14 If surgical procedures are required under aseptic conditions, there should be rooms adapted to this. In such cases there shall also be rooms adapted for post-operative care.

Service Areas

§ 15 Store rooms shall be designed, used and maintained to safeguard good quality of feed and bedding material. These areas shall be protected against vermin and insects, as far as possible. Other materials that may be contaminated or present a hazard to the laboratory animals shall be stored separately.

§ 16 The cleaning and washing areas shall be designed so that it is possible to decontaminate and clean used equipment to the extent that is needed. The cleaning process shall be designed to separate the flow of clean and dirty equipment.

§ 17 All feed and water containers, troughs, and other tools used when feeding the animals shall be cleaned regularly and sterilized when needed.

Environment and Climate Control

Ventilation and temperature

§ 18 When keeping animals indoors, the holding rooms shall have necessary installations for heating and ventilation, ensuring a suitable indoor environment for the laboratory animals. Air pollution in holding rooms shall be kept at lowest possible levels to not be harmful to the health and well-being of the laboratory animals in other regards.

Air circulation and windows shall be arranged and located so that laboratory animals are not subjected to draughts, or to temperatures or humidity which may have a negative impact on the well-being of the laboratory animals.

§ 19 The temperature and relative humidity in the holding rooms shall be adapted to the housed species, breeds, and strains, as well as to the age of the laboratory animals.
The temperature shall be measured and registered daily.

> ***General Advice For § 19***
> *If the relative humidity is important for the species in question, it should be measured daily.*

§ 20 Laboratory animals may not be housed only in outdoor areas during weather conditions that may cause them suffering or discomfort.

Lighting

§ 21 There shall be enough lighting for care and surveillance of the laboratory animals.

§ 22 The laboratory animals shall have regular periods of light/dark and a light intensity adapted to the species.

If the natural light does not provide a suitable period of light/dark, controlled lighting shall be provided to satisfy the animals' biological needs**.**

> ***General Advice For § 22***
> *Lighting in areas for birds with their resting place on perches should be turned on and off with an automatic, time-controlled dimming function or equivalent. Birds should have access to dim nightlight.*

§ 23 Light fixtures shall be positioned, and the light intensity shall be controlled so that the laboratory animals are not subjected to discomfort or injured. When keeping albino animals, the light shall be adjusted considering their sensitivity to light.

Noise, alarms, and back-up systems

§ 24 Noise levels and frequencies, including ultrasound and infrasound, shall not adversely affect welfare of the laboratory animals.

§ 25 A laboratory animal facility with heating systems and mechanical ventilation systems shall be provided with alarm systems that are activated outside the range for high and low temperatures, as well as at any malfunction of the alarm system.

The alarm system shall be designed so that the alarm is perceived in a satisfactory manner and, as far as possible, so that alarm sounds, or alarm light signals disturb the laboratory animals as little as possible. The sound of alarm systems shall be outside the sensitive hearing range of the laboratory animals so that it does not conflict with the audibility of the alarm for humans.

The equipment in the first and second paragraph shall be checked regularly.

§ 26 Where needed, holding rooms shall be provided with noise insulation and noise-absorbing materials.

§ 27 A laboratory animal facility relying on electric power for operation of the facility shall have a back-up system. The back-up system shall safeguard the necessary functions for maintaining safety of the laboratory animals in case of a power failure.

The first paragraph does not apply if safety of the laboratory animals can be maintained in another way.

Exceptions

§ 28 A Regional Animal Ethics Committee may grant exceptions from the provisions in §§

1–5 and 8–27.

The exceptions in the first paragraph apply providing that:

1. The principal investigator has requested and justified this in the ethical application.
2. It is necessary considering the purpose of the animal experiment.
3. There are scientific reasons, animal welfare reasons, animal protection reasons, or national or international documentation requirements.

The first paragraph only applies for the time of the animal experiment. The time period for when the exception is to be used shall be specified in the application.

CH. 16 COMMON PROVISIONS FOR CARE AND ACCOMODATION

General

§ 1 Basic provisions on how animals are to be handled, kept, and cared for are contained in the Animal Welfare Act (1988:534) and in the Animal Welfare Ordinance (1988:539).

§ 2 The provisions in Ch. 16–26 only apply to laboratory animals that are held in facilities for laboratory animals.

§ 3 The NACWO shall ensure that there are written work instructions for care of the laboratory animals and that staff handling the animals follow those instructions.

The NACWO shall according to the first paragraph ensure that surveillance takes place according to § 13, paragraph 1.

§ 4 The NIO shall ensure that the following information is readily available to staff handling the species and strains housed in the laboratory animal facility:

1. Enrichment plan according to § 20.
2. Information about protection of the laboratory animals in case of unexpected external events of importance to animal welfare.
3. Information about the 3R-principle.
4. Information about the species and strains housed at the laboratory animal facility.

General Advice For § 4

Unexpected external events can be, for example, fire, power failure, or flood.

§ 5 The laboratory animal veterinarian or, where applicable, the expert, shall produce a written plan for the operation's preventive animal welfare and health.

The plan shall be updated as needed and shall contain

1. procedures for regular health monitoring and health inventories,
2. programs for microbiological surveillance,
3. plans for handling outbreak of disease,
4. definitions of health parameters,
5. procedures for the introduction of new laboratory animals to the facility, as well as
6. routines for hygiene.

6 § The laboratory animal veterinarian or the expert shall produce a written plan that is kept up-to-date and adapted to the operation. The plan shall include procedures for

1. stunning,
2. anesthesia,
3. sedation,
4. pain relief,
5. surgical procedures including pre- and postoperative care, as well as
6. killing.

In the absence of activities requiring actions according to the first paragraph, a plan according to these items does not have to be produced.

§ 7 The laboratory animal veterinarian or, where applicable, the expert, shall in consultation with an ethologist, if one is involved in the operation, give the guidance and advice needed for the physical and psychological well-being of the laboratory animals. As a basis for this guidance and advice, they shall produce a written plan for assessing the physical and psychological well-being of the laboratory animals, including habituation and training programs adapted to the laboratory animals and the animal experiments. This plan shall be kept up to date.

Exceptions

§ 8 Laboratory animals may be held in a facility that is not approved as a facility for laboratory animals if

1. the operating license allows this,
2. the laboratory animals are not subjected to surgical procedures only due to the animal experiment, except for simpler procedures, as well as
3. the laboratory animals are kept in a herd or under similar circumstances where the main purpose of animal husbandry is not the use of laboratory animals.

General Advice For § 8, paragraph 2
Simpler procedures can be blood tests, urine samples, and skin biopsies.

§ 9 In connection with advance approval and approval, the Swedish Board of Agriculture may grant permission to hold laboratory animals in a smaller area than that specified in these regulations if the laboratory animals are used or shall be used in animal experiments with

1. agents belonging to risk class 2 at the lowest, according to the Swedish Work Environment Authority regulations (AFS 2005:1) on microbiological work environment risks – infection, toxicity, hypersensitivity, or
2. genetically modified microorganisms in L- or R-activity according to the Swedish Work Environment Authority regulations (AFS 2011:2) on contained use of genetically modified microorganisms.

The first paragraph does not apply to primates.

§ 10 A Regional Animal Ethics Committee may grant exceptions from the provisions in:

1. Ch. 16, §§ 13–15 1st paragraph, §§ 16–26,
2. Ch. 17, §§ 3–7,
3. Ch. 18, §§ 2–7,
4. Ch. 19, §§ 2–3 1st paragraph and §§ 4–10,
5. Ch. 20, 2–5 1st paragraph, and § 5 3rd paragraph, § –8
6. Ch. 21, §§ 2–6,

7. Ch. 22, §§ 2–9 and 11,
8. Ch. 23, §§ 2–5,
9. Ch. 24, §§ 2– 5,
10. Ch. 25, §§ 2– 5, and
11. Ch. 26, §§ 2–6 and §§ 8–13.

The exceptions in the first paragraph apply providing that:

1. The principal investigator has requested and justified this in the ethical application.
2. It is necessary considering the purpose of the animal experiment.
3. There are scientific reasons, animal welfare reasons, animal protection reasons, or national or international documentation requirements.

The first paragraph only applies for the time of the animal experiment. Starting point and end-point of the animal experiment shall be specified in the application for ethical approval of animal experiment.

§ 11 Laboratory animals may be held and cared for in a manner other than those specified in these regulations if a veterinarian has prescribed this for reasons of veterinary medicine.

§ 12 The provisions in Ch. 15–26 may be departed from if the purpose of the research requires the Laboratory animals to be held according to provisions that apply to farm animals or aquaculture animals not involved in animal experiments.

Surveillance

§ 13 Surveillance of laboratory animals must take place at least once a day in a way that is safe for the experimental animals, and so that the laboratory animals are disturbed as little as possible. Newborn, sick, or injured laboratory animals and laboratory animals that behave abnormally should be inspected more often. This also applies to laboratory animals late in gestation.

Surveillance according to the first paragraph shall ensure detection of sick or injured laboratory animals, as well as laboratory animals that for other reasons are subjected to or risk being subjected to suffering. Appropriate measures to alleviate the suffering of laboratory animals shall be taken as soon as possible.

Those who inspects laboratory animals shall have education that at least fulfills the requirements for those who care for laboratory animals according to Ch. 6 in these regulations.

General Advice for § 13

To facilitate inspection, if needed it should be possible to move the enrichment or temporarily lift it out of the animal enclosure.

§ 14 The environmental conditions of the enclosures in which the laboratory animals are kept shall be checked daily. Any deficiencies that are detected shall be remedied as soon as possible.

Group Housing

§ 15 Unless otherwise specified in Ch. 17–26, laboratory animals that are not naturally solitary shall be kept in stable social pairs or groups of compatible individuals.

Despite the provisions of the first paragraph, laboratory animals may be kept individually if any of the following conditions are met:

1. The laboratory animal has been kept in a group and, due to an unforeseen event, becomes single temporarily and cannot be put together with another compatible laboratory animal.
2. If it applies to breeding that is not already included in an ethical approval and where the male is removed from the female. The male animal can then be removed from the female for a limited period and kept alone if it cannot be kept with a compatible female.
3. It is necessary for shorter time periods for introduction of laboratory animals.
4. When compatibility between laboratory animals could not be achieved so that they need to be separated for recovery or until a new compatible laboratory animal can be found.
5. When a laboratory animal is given special care.
6. To prevent the spread of infection.

General Advice For § 15

1. Couples and groups of laboratory animals should be made up of young laboratory animals. Laboratory animals kept in groups should be able to seek protection and get out of sight of each other.

2. When it has not been possible to achieve compatibility, and this has resulted in abnormal levels of aggressiveness, apparent weight loss, or other physiological or behavioral stress reactions, then laboratory animals should be separated and, if possible, placed together with other laboratory animals.

3. If it is not possible to find a compatible individual, the laboratory animal should be given extra access to other enrichment.

4. The time for which the laboratory animal is kept individually should be limited to a minimum

5. Visual, auditory, olfactory and/or tactile contact shall be maintained between the laboratory animals, even when they are kept individually.

§ 16 Introduction or reintroduction of laboratory animals in established groups shall be carefully monitored and take place in such a way that problems of incompatibility and disrupted social relationships are avoided.

Enclosures and Enrichment

§ 17 Laboratory animals shall always have access to suitable bedding materials as well as enough attractive resting and sleeping areas so that all laboratory animals can rest and sleep at the same time.

During the reproductive period, the laboratory animals shall have access to appropriate nesting materials and shelter.

§ 18 Laboratory animals shall be housed in a space of enough complexity so that they can express a wide range of natural behaviours. Laboratory animals shall also be given some degree of control to choose their environment to reduce stress-induced behavior.

19 § Laboratory animals shall have access to enrichment. The enrichment shall be adapted to the laboratory animals' species and individual needs of the animals in question. This also applies to species that are not included in the special regulations in Ch. 17–26p.

> ***General Advice For §§ 18 and 19***
> *1. The natural behaviors that should primarily be facilitated are the animals' needs for movement, rest, comfort, employment, foraging, hiding, and social interaction. Enrichment of the environment can be achieved by providing possibility to, e.g., physical exercise, investigative behaviors, as well as fine motor and cognitive activities that are appropriate for the species. Recreation possibilities and interior design that increase the animal's ability to use the entire volume of the enclosure should also be prioritized.*
> *2. Feeding routines and feed devices should be designed to stimulate foraging behaviours.*
> *3. Loose environment enrichment objects shall be such that the laboratory animals can investigate, carry, as well as manipulate them. Enrichment shall be available in such an amount that competition is minimised.*

Enrichment Plan

§ 20 At a laboratory animal facility the laboratory animal veterinarian or the expert shall, in consultation with an ethologist, if one is involved in the operation, produce a written plan for enrichment of the laboratory animals' environment. The plan shall be implemented, reviewed regularly, and updated if necessary. The plan shall ensure that the animals' environment does not fall short of the requirements according to §§ 18 and 19.

Incompatible Species

§ 21 Laboratory animals of incompatible species that require different environmental conditions may not be housed in the same room if they can be disturbed by each other, or if their different environmental condition requirements cannot be satisfied.

Predators and Prey

§ 22 Predators and prey may not be housed within sight, smell, or sound of each other.

Breeding

§ 23 Newborn or young laboratory animals should be kept with the mother or equivalent substitute as long as they need nursing or care by the mother.

Feed and Water

§ 24 The space where the laboratory animals are fed shall be large enough, for all laboratory animals to eat at the same time and designed to minimise competition between the laboratory animals.

§ 25 In § 3 of the Animal Welfare Act (1988:534) it is specified that animals shall be given sufficient feed and water of good quality which is adapted to the species. The feed shall be palatable for the animals, have such nature and be presented in such a way that it meets the animals' behavioral needs. The animals shall always have access to drinking water.

The feed shall be of good hygienic quality and, when selecting raw materials, production, preparation, and presentation of the feed, the risk of chemical, physical, and microbiological contamination shall be minimised. Systems for automatic feeding shall be carefully monitored.

The feed shall be packaged, transported, and stored to avoid contamination, deterioration or destruction.

§ 26 When automatic watering systems are used, they shall be checked, serviced, and flushed regularly. If cages with solid bottom are used, care shall be taken to minimise the risk of flooding.

CH. 17 SPECIAL PROVISIONS FOR MOUSE, RAT, GERBIL, HAMSTER, AND GUINEA PIG

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for mouse, rat, gerbil, gold hamster, Chinese dwarf hamster, and guinea pig.

> ***General Advice For § 4 of the Animal Welfare Act***
> *Mice, rats, gerbil, and hamsters should not be weaned before three weeks of age. Guinea pigs should not be weaned before four weeks of age.*

Exceptions for Group Housing

§ 2 Hamsters may be housed individually.

Enclosure and Enrichment

§ 3 The laboratory animals shall be kept in cages with solid bottom.

§ 4 Nesting materials shall always be available.

Feed

§ 5 The laboratory animals should have enough access to feed considering their fast metabolism. Guinea pigs should have daily access to hay or other roughage.

Environment and Climate Control

Ventilation and temperature

§ 6 The relative humidity in the enclosures shall be above 40 percent.

Space Requirements

§ 7 The laboratory animals shall have at least the spaces specified in Table 1–9. In these tables, 'Minimum height' refers to the distance between the enclosure floor and the top of the enclosure. This height shall be found in more than 50 percent of the enclosure prior to the addition of enrichment devices.

When planning animal experiments, consideration shall be given to growth of the animals to ensure that adequate space is provided for the duration of the experiment.

Table 1 Mouse

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
up to 20	330	60	12
over 20 to 25	330	70	12
over 25 to 30	330	80	12
over 30	330	100	12

Table 2 Mouse, breeding

	Minimum floor area (cm^2)	**Extra floor area per offspring exceeding 10 (cm^2)**	**Minimum height (cm)**
female with litter	330	-	12
Breeding pair with litter	380	-	12
trio of strain with ≤5 offspring/female*	500	-	12
trio of strain with >5 offspring/female*	500	25	12

* until weaning at 3 weeks of age.

*Table 3 Mouse, breeding – weaned mice**

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
up to 20	950	40	12
over 20	1,500	30	12

* Weaned mice may be kept at these higher stocking densities for the short period after weaning until transfer,

provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 4 Rat

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
up to 200	800	200	18
over 200 to 300	800	250	18
over 300 to 400	800	350	18
over 400 to 600	800	450	18
over 600 to 800	1,500	600	18
over 800	1,800	900	18

Table 5 Rat, breeding

	Minimum floor area (cm^2)	**Extra floor area per offspring 8-10 (cm^2)**	**Extra floor area per offspring exceeding 10 (cm^2)**	**Minimum height (cm)**
female with litter	800	-	-	18
Breeding pair with litter	1,200	-	-	18
trio with ≤4 offspring/female	1,600	-	-	18
trio with >4 offspring/female*	1,600	45	30	18

* until weaning at 3 weeks of age.

*Table 6 Rat, breeding – weaned offspring**

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
up to 50	1,500	100	18
over 50 to 100	1,500	125	18
over 100 to 150	1,500	150	18
over 150 to 200	1,500	175	18
up to 100	2,500	100	18
over 100 to 150	2,500	125	18
over 150 to 200	2,500	150	18

* Weaned rats may be kept at these higher stocking densities for the short period after weaning until transfer, provided that the laboratory animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 7 Gerbil

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**

up to 40	1,200	150	18
over 40 to 150	1,200	250	18
over 150	1,200	350	18
Breeding pair or trio with litter	1,200	-	18

Table 8 Hamster

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
up to 60*	1,500	100	14
up to 60	800	150	14
over 60 to 100	800	200	14
over 100 to 140	800	250	14
over 140	800	320	14
Breeding pair /female with litter	800	-	14

* Applies to breeding. Weaned hamster may be kept at these higher stocking densities for the short period after weaning until transfer, provided that the laboratory animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 9 Guinea pig

Body weight (g)	**Minimum floor area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
up to 200	1,800	200	23
over 200 to 300	1,800	350	23
over 300 to 450	1,800	500	23
over 450 to 700	2,500	700	23
over 700	2,500	900	23
Breeding pair with litter	2,500	*	23

* For each additional female, add another 1000 cm^2.

CH. 18 SPECIAL PROVISIONS FOR RABBITS

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16 and contain specific provisions for rabbits.

General Advice For § l 4 of the Animal Welfare Act

1. Rabbits should not be weaned before the age of six weeks.

2. Sexually mature males should be castrated before being group-housed.

Enclosure

§ 2 Rabbits older than 10 weeks shall have access to a elevated area. It shall be possible for

the laboratory animals to lie down, sit, as well as easily move on and under the elevated area.

The elevated area according to the first paragraph shall at least be of the measurements specified in Table 4 in § 7 but may not be larger than at least 60 percent of the minimum floor area having full roof height according to Table 2–3 in § 7.

§ 3 If rabbits younger than 10 weeks are provided with a elevated area, it shall measure at least 55 cm × 25 cm. The height above the floor shall be such that the laboratory animals can lie down, sit, as well as easily move on and under the elevated area.

§ 4 If there are scientific or veterinary reasons for not providing an elevated area, the enclosure's surface, according to Table 2 and 3 in § 7, shall be 33 percent larger for a single rabbit and 60 percent larger for two rabbits.

Feed

§ 5 Rabbits should have daily access to roughage.

Breeding

§ 6 Does shall have access to a nest box with roof and nesting materials at the latest from a week before expected delivery date and for at least four weeks thereafter.

Space Requirements

§ 7 Rabbits shall at least have the spaces according to Table 1–4.

Table 1 Kits up to 10 weeks

Age	**Minimum Floor Area (cm^2)**	**Floor area per animal (cm^2)**	**Minimum height (cm)**
From weaning up to and incl. 6 weeks	4,000	800	40
From and incl. 7 weeks up to and incl. 10 weeks	4,000	1,200	40

Table 2 Rabbits from 10 weeks

Final Body Weight (kg)	**Minimum Floor Area for 1-2 animals (cm^2)**	**Minimum Additional Area/animal 3-6 individuals (cm^2)**	**Minimum Additional Area/animal over 6 individuals (cm^2)**	**Enclosure Minimum Height (cm)**
up to 3	3,500	3,000	2,500	45
over 3 to 5	4,200	3,000	2,500	45
over 5	5,400	3,000	2,500	60

Table 3 Doe with litter

Doe Weight	**Minimum**	**Addition for**	**Incl. Nest Box**	**Minimum**

(kg)	Floor Area (cm^2)	Nest Boxes (cm^2)		Height (cm)
over 3	3,500	1,000	4,500	45
over 3 to 5	4,200	1,200	5,400	45
over 5	5,400	1,400	6,800	60

Table 4 Size of elevated area

Final Body Weight (kg)	Area (cm x cm)	Height from Enclosure floor (cm)
under 3	55*25	25
From and incl. 3 up to and incl. 5	55*30	25
over 5	60*35	30

CH. 19 SPECIAL PROVISIONS FOR CATS

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for cats.

General Advice For § 4 of the Animal Welfare Act
Cats should not be separated from the mother before the age of 12 weeks.

Surveillance

§ 2 During the daily surveillance of cats, check especially for social stress.

Group-Housing

§ 3 Cats may not be single-housed for more than 24 hours.
Cats that are repeatedly aggressive towards other cats may be housed individually for a longer period than 24 hours if a compatible companion cannot be found.

Enclosure and Enrichment

§ 4 The space shall be provided with nest boxes or other resting places at different levels. There shall be enough room for all cats to lie down on the shelves at the same time. The size of the shelves shall be at least as is specified in Table 2 in § 10.

§ 5 There shall be enough litter boxes faeces and urine. The litter boxes shall be big enough and provided with enough absorbent material.

§ 6 Areas for feeding and litter boxes shall be at least 0.5 metre apart and must not be interchanged.

§ 7 The enclosure shall be provided with scratch devices and climbing structures so that the

entire volume of the space can be utilized.

Breeding

§ 8 Females with kittens younger than four weeks of age or in the last two weeks of pregnancy may be housed individually.

§ 9 A queen with kittens shall have access to a next box with bedding material.

Space Requirements

§ 10 Cats shall have access to at least the spaces specified in Table 1-2.

Table 1 Cats

	Minimum floor area* **(m^2)**	**Per animal (m^2)**	**Height (m)**
Adult cat (older than 16 weeks)	5	1	2
Female with litter younger than 12 weeks	5	2.5	2
Growing animal, 12 – 16 weeks	5	0.7	2

* Excluding shelves

Table 2 Space shelf

Minimum area for first animal (m^2)	**Add for each additional animal (m^2)**
0.5	0.25

General Advice For § 10
For a female with a litter, the space should be increased gradually so that the enclosure for litters at the age of 16 weeks meets the space requirements for adult cats.

CH. 20 SPECIAL PROVISIONS FOR DOGS

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for dogs.

General Advice For § 4 of the Animal Welfare Act
Puppies should not be separated from the bitch before 8 weeks of age.

Enclosure

§ 2 There shall be visibility barriers between the enclosures. However, the wall facing the corridor and a part of the wall between enclosures may be made of transparent material.

§ 3 The space shall have elevated resting areas with enough room for all dogs to lie down at the same time.

Breeding

§ 4 The whelping pen shall be designed so that the bitch can move away from the puppies to another compartment or to an elevated area.

Outdoor Space

§ 5 Dogs shall have access to outdoor space (runs).

The first paragraph does not apply if the Swedish Board of Agriculture has approved that outdoor space is missing in connection with the preliminary approval or approval of the laboratory animal facility.

Dogs not having free access to outdoor space shall be walked outdoors.

General Advice For § 5

Dogs shall be walked at least twice a day for a total walking time of at least two hours.

§ 6 In the outdoor area there shall be adequate protection against rain, snow, wind, and sun. As well, the ground shall be drained.

§ 7 Outdoor spaces shall have elevated resting areas.

Space Requirements

§ 8 Dogs shall have access to space of at least the size specified in Table 1. The height shall be at least 2 metres.

Part of the enclosure in the first paragraph may be made up of an outdoor area. However, dogs must have access to an internal area corresponding to at least 50% of the minimum space to be made available to the dogs according to Table 1.

A nursing bitch or bitch with litter shall be provided with the same space as a single bitch of equivalent weight. The puppies may then be housed in the same space until they are 12 weeks of age. Thereafter the puppies shall be regarded as separate individuals according to Table 1.

Table 1 Dog

	< 5 kg	**5-10 kg**	**10-20 kg**	**20-30 kg**	**30-40 kg**	**> 40 kg**
Space for one dog (m^2)	6	10	14	16	18	20
Add for each additional dog(m^2)	2	3	4	5	6	7

If several dogs of different sizes are housed in the same enclosure, the size of the space shall be calculated as follows. Size is based on the space required for a dog of the largest size (upper row in the table). To this, add the spaces required for each additional dog in each size class (lower row in the table).

Exceptions from Space Requirements During Experiments

§ 9 If the Regional Animal Ethics Committee approves an exception according to Ch. 16 § 10, a dog may be single-housed temporarily on 2 m^2 if it weighs less than 20 kg and on 4 m^2 if it weighs more than 20 kg. Dogs may not be single-housed for more than four hours at a time.

CH.21 SPECIAL PROVISIONS FOR FERRETS

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for ferrets.

General Advice For § 4 of the Animal Welfare Act
Ferret puppies should not be separated from the jill before eight weeks of age.

Enclosure

§ 2 Ferrets shall have access to nest boxes or nest burrow with suitable and enough nesting material.

§ 3 Ferrets may not be housed on grid floors.

Breeding

§ 4 During the weaning period, a jill with puppies shall have access to an area inaccessible to the puppies.

Environment and Climate Control

Ventilation and temperature

§ 5 Ferrets housed outdoors shall have next boxes or nest burrows that protect against the cold.

Space Requirements

§ 6 Ferrets shall have access to at least the spaces specified in Table 1.

Table 1 Ferret

	Minimum area (m^2)	**Area per animal (m^2)**	**Shortest side (m)**	**Height (m)**
Weaned ferrets	2	1	1	1
Female with litter	2	-	1	1

CH. 22 SPECIAL PROVISIONS FOR PRIMATES

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for primates.

Surveillance

§ 2 Primates shall be monitored at least twice daily. There shall also be permanent monitoring systems, enabling monitoring of all primates. The systems shall be designed so that the person monitoring animal experiments cannot be seen or heard by the laboratory animals being monitored.

Group-Housing

§ 3 Primates shall be housed in pairs or groups.

Enclosure and Enrichment

§ 4 Spaces for primates shall contain visual barriers and different escape routes to minimise aggression between laboratory animals and to provide a sense of security. The interior shall make is possible for the laboratory animals to express natural behavior needs, stimulate movement, and permit escape upwards.

> ***General Advice For § 4***
> *Suitable interior are shelves, ropes, pipes, and other structures that increase the usability and complexity of the space. Shelves should be placed at different levels within the enclosure.*

§ 5 Enrichment shall be adapted to the primates' species-specific and individual needs.

> ***General Advice For § 5***
> *Suitable enrichment is feeding routines and feeding devices that are designed to stimulate foraging behaviour. Suitable supplementary enrichment are objects that stimulate investigative behaviors, as well as fine motor and cognitive activities. These objects should be replaced and changed to give variation. The laboratory animals should be trained to have contact with and cooperate with humans.*

Breeding

§ 6 Depending on species, young primates may not be separated from the mother until they are 6–12 months of age.

§ 7 Long-tailed macaques, rhesus monkeys, and vervet monkeys may not be separated from the mother before 12 months of age. Other species of macaques and vervets may not be separated from the mother before eight months of age.

§ 8 Marmosets, tamarins, and baboons may not be separated from the mother before eight months of age. Squirrel monkeys may not be separated from the mother before six months of age.

Outdoor Space

§ 9 Primates shall have access to both indoor and outdoor areas. The outdoor areas must be designed to provide adequate protection against rain, snow, wind, and sun.

In case of unsuitable weather, a laboratory animal veterinarian or, an expert where applicable, may after individual assessment decide that the laboratory animals should not be allowed outdoors for reasons of animal welfare or for veterinary reasons.

Exceptions for Outdoor Space

§ 10 Primates may be housed without access to outdoor areas if they are used in animal experiments with

1. agents belonging to minimum risk class 2 according to the Swedish Work Environment Authority's regulations (AFS 2005:1) on microbiological work environment risks – infection, toxin effect, hypersensitivity, or
2. genetically modified microorganisms in L- or R-activities according to the Swedish Work Environment Authority's regulations (AFS 2011:2) on contained use of genetically modified microorganisms.

Space Requirements

§ 11 Primates shall have at least the areas specified in Table 1–3.

Table 1 Macaques and vervets

Primate species	**Minimum area (m^2)**	**Minimum height (m)**	**Minimum volume per additional animal (m^3)**
Long-tailed macaques, rhesus monkey, and vervets*	2.0	2.0	2.0
Long-tailed macaques, rhesus monkey, and vervets in group for breeding*	4.0	2.0	3.5***
Other macaques and vervets <3 years of age**	2.0	1.8	1
Other macaques and vervets >3 years of age*	2.,0	1.8	1.8
Other macaques and vervets in group for breeding	3.5	2.0	3.5***

* Maximum two laboratory animals may be housed in an enclosure of minimum dimensions.

** Maximum three laboratory animals may be housed in an enclosure of minimum dimensions.

*** In breeding groups, no additional volume increase is required for laboratory animals up to two years of age held with their mother.

Table 2 Marmosets, tamarins, and squirrel monkeys

Primate species	**Minimum area (m^2)**	**Minimum height (m)**	**Minimum volume per additional animal (m^3)**
White marmosets*	1.0	2.0	0.5
White marmosets, family group for breeding*	2.0	2.0	0.5**
Other marmosets*	0.5	1.5***	0.2**
Tamarins*	1.5	1.5***	0.2**
Squirrel monkeys*	2.0	1.8	0.5**

* Maximum two laboratory animals may be housed in an enclosure of minimum dimensions.

** In breeding groups, no additional volume increase is required for laboratory animals up to 5 months of age held with their family.

*** The enclosure's top part must be at least 1.8 m above the floor.

Table 3 Baboons

	Minimum area (m^2)	Minimum height (m)	Minimum volume per additional animal (m^3)
Animals less than 4 years of age*	4	1.8	3
Animals from 4 years of age*	7	1.8	6
Animals held for breeding purposes		2	12**

* Maximum two laboratory animals may be housed in an enclosure of minimum dimensions.

** In breeding groups, no additional volume increase is required for laboratory animals up two years of age held with their mother.

CH. 23 SPECIAL PROVISIONS FOR CATTLE, SHEEP, GOATS, PIGS, AND EQUINES

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for the domesticated forms of cattle, sheep, goats, pigs, and equines.

General Advice For § 4 of the Animal Welfare Act

1. Sheep and goats shall normally be held outdoors grazing or otherwise given the opportunity to be outdoors in summertime.

2. Cattle, sheep, and goats shall also be given the opportunity to be outdoors at other times than summertime.

3. Bulls and calves younger than six months shall be given the opportunity to be outdoors.

4. Pigs shall be given the opportunity to be outdoors and, at such times, the animal shall be provided with facilities to regulate its body temperature.

5. Equines shall have access to grazing in summertime.

Exceptions from Group Housing

§ 2 Equines may be held solitary in an enclosure, provided they have visual, hearing, odor, and sensory contact with other horses.

Outdoor Space

§ 3 Equines shall normally have the opportunity to daily move freely using their natural gaits.

Space Requirements

§ 4 Cattle, sheep, pigs, goats, and pigs shall have at least the space specified in Table 1–4.

Table 1 Cattle

Body weight (kg)	Minimum enclosure size (m^2)	Floor area per animal (m^2)	Space at feed trough for ad-libitum feeding of polled cattle (m/animal)	Space at feed trough for restricted feeding of polled cattle (m/animal)
up to 100	2.5	2.3	0.1	0.3

over 100 to 200	4.25	3.4	0.15	0.5
over 200 to 400	6	4.8	0.18	0.6
over 400 to 600	9	7.5	0.21	0.7
over 600 to 800	11	8.75	0.24	0.8
over 800	16	10	0.3	1

Table 2 Sheep and goats

Body weight (kg)	**Minimum enclosure size (m^2)**	**Minimum floor area/animal (m^2)**	**Minimum partition height (m)**
less than 20	1	0.7	1
over 20 to 35	1.5	1	1.2
over 35 to 60	2	1.5	1.2
over 60	3	1.8	1.5

Table 3 Space at trough for sheep and goats

Body weight (kg)	**Space at feed trough for ad libitum feeding (m/animal)**	**Space at feed trough for restricted feeding (m/animal)**
less than 35	0.17	0.35
over 35 to 60	0.17	0.45
over 60 as well as pregnant ewes	0.17	0.5

Table 4 Pigs

Live weight (kg)	**Minimum enclosure size*** **(m^2)**	**Minimum floor area per/animal (m^2)**	**Minimum lying space per animal** (m^2/animal)**	**Minimum space at feed trough (m/animal)**
less than 5	2	0.2	0.13	0.17
over 5 to 10	2	0.25	0.16	0.18
over 10 to 20	2	0.35	0.22	0.20
over 20 to 30	2	0.5	0.28	0.22
over 30 to 50	2	0.7	0.40	0.26
over 50 to 70	3	0.8	0.52	0.29
over 70 to 100	3	1	0.70	0.35
over 100 to 150	4	1.35	1.0	0.44
over 150 to 200	5	2.5	1.3	0.45
Adult (con-ventional) boars	7.5	7.5	6.0	0.50

* Pigs may be confined in smaller enclosures for short periods of time, for example by partitioning the main enclosure using dividers, when justified by veterinary or experimental reasons, for example where individual

food consumption is required.
** At thermoneutral conditions.

§ 5 Equines shall have access to at least the space specified in Table 5. The shortest side of the enclosure shall be minimum 1.5 times the wither height of the animal. The height of indoor enclosures shall permit the laboratory animals to rear to their full height.

Table 5 Equines

Wither height (m)	**Minimum floor area/animal (m^2/animal)**			**Minimum enclosure height (m)**
	For each animal held singly	**For each animal held in groups of four or more animals**	**Foaling box/mare with foal**	
1.00 to 1.40	9	6	16	3
1.40 to 1.60	12	9	20	3
over 1.60	16	(2 × wither height)^2	20	3

CH. 24 SPECIAL PROVISIONS FOR BIRDS

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for zebra finches, pigeons, domestic fowl, turkeys, ducks, geese, and quails.

Enclosure and Enrichment

§ 2 Zebra finches and pigeons shall be able to fly short distances. Therefore, the enclosures shall be long and narrow, unless they are large enough for this requirement to be fulfilled.

§ 3 Domestic fowl and pigeons shall have access to perches to such extent that all have space to rest at the same time. Domestic fowl shall also have access to bedding that satisfies their behavior needs of pecking, scratching, and sandbathing.

§ 4 Ducks and geese shall have access to a pond.

Space Requirements

§ 5 Birds shall have access to at least the space specified in Table 1–8.

Table 1 Zebra finches

Group size	**Minimum enclosure size (m^2)**	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**
up to 6	1	100	2
between 7 and 12	1.5	200	2
between 13 and 20	2	200	3
for each additional	0.05	-	1 per 6 birds

bird above 20			

Table 2 Pigeons

Group size	**Minimum enclosure size (m^2)**	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**	**Minimum length of perch per bird (cm)**	**Minimum area per bird (m^2)**
up to 6	2	200	5	30	0.33
between 7 and 12	3	200	5	30	0.25
for each additional bird above 12	0.15	-	5	30	0.18

Table 3 Domestic fowl

Body weight (g)	**Minimum enclosure size (m^2)**	**Minimum area per bird (m^2)**	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**
up to 200	1	0.025	30	3
over 200 to 300	1	0.03	30	3
over 300 to 600	1	0.05	40	7
over 600 to 1,200	2	0.09	50	15
over 1 200 to 1,800	2	0.11	75	15
over 1 800 to 2,400	2	0.13	75	15
over 2,400	2	0.21	75	15

Table 4 Turkeys

All enclosure sides shall be at least 1.5 m long.

Body weight (g)	**Minimum enclosure size (m^2)**	**Minimum area per bird (m^2)**	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**
up to 0.3	2	0.13	50	3
Over 0.3 to 0.6	2	0.17	50	7
over 0,6 to 1	2	0.3	100	15
over 1 to 4	2	0.35	100	15
over 4 to 8	2	0.4	100	15
over 8 to 12	2	0.5	150	20

over 12 to 16	2	0.55	150	20
over 16 to 20	2	0.6	150	20
over 20	3	1	150	20

Table 5 Ducks

Body weight (g)	**Minimum enclosure size (m^2)**	**Area per bird (m^2)***	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**
up to 300	2	0.1	50	10
over 300 to 1,200**	2	0.2	200	10
over 1,200 to 3,500	2	0.25	200	15
over 3,500	2	0.5	200	15

* This shall include a pond of minimum area 0.5 m^2 per 2 m^2 enclosure with a minimum depth of 30 cm. The pond may constitute up to 50 % of the minimum enclosure size.

** Pre-fledged birds may be held in enclosures with a minimum height of 75 cm.

Table 6 Geese

Body weight (g)	**Minimum enclosure size (m^2)**	**Area per bird (m^2)***	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**
up to 500	2	1	200	10
over 500 to 2,000	2	1	200	15
over 2,000	2	1	200	15

* This shall include a pond of minimum area 0.5 m^2 per 2 m^2 enclosure with a minimum depth of 30 cm. The pond may constitute up to 50 % of the minimum enclosure size.

Table 7 Ducks and geese, minimum pond size

	Area (m^2)	**Depth (cm)**
Ducks	0.5*	30
Geese	0.5*	between 10 and 30

* Pond sizes are per calculated per 2 m^2 enclosure. The pond may constitute up to 50 % of the minimum enclosure size.

Table 8 Quails

Body weight (g)	**Minimum enclosure size (m^2)**	**Area per bird housed in pairs (m^2)**	**Area per additional bird housed in groups (m^2)**	**Minimum height (cm)**	**Minimum length of feed trough per bird (cm)**
up to 150	1	0.5	0.1	20	4
over 150	1	0.6	0.15	30	4

Exceptions from Space Requirements During Experiments

§ 6 If the Regional Animal Ethics Committee approves an exception according to Ch. 16, § 10, the following minimum dimensions apply:

1. For breeding studies, pairs of zebra finches may be held in enclosures with suitable enrichment where the floor area is at least 0.5 m2 and a minimum height of 40 cm.
2. Domestic fowl may be held in enclosures with suitable enrichment and with a floor area of at least 0.75 m2, provided that the density in Table 3, § 5, is followed.
3. Turkeys may be held in enclosures with suitable enrichment and with a floor area of at least 0.75 m2 and a minimum height of 50 cm for birds weighing less than 0.6 kg, 75 cm for birds weighing less than 4 kg, and 100 cm for birds weighing over 4 kg. This applies provided that the density in Table 4, § 5, is followed.
4. Ducks and geese may be held in enclosures with suitable enrichment and with a floor area of at least 0.75 m2, provided that the density in Table 5–6, § 5, is followed.

CH. 25 SPECIAL PROVISIONS FOR AMPHIBIANS AND REPTILES

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for amphibians, terrestrial snakes, and aquatic turtles. The provisions in this chapter do not apply to semi-aquatic or arboreal and terrestrial salamanders.

Enclosure and Enrichment

§ 2 Aquatic amphibians and aquatic turtles shall be kept in water. Semi-aquatic and terrestrial amphibians shall have access to both land and water parts.

§ 3 Amphibians shall have access to hiding places designed so that all laboratory animals can hide at the same time.

General Advice For §§ 2 and 3

Laboratory animals covered by this chapter should have access to hiding places or camouflaging interior adapted to the needs of the species. Aquatic amphibians should have hiding places on the bottom of the enclosure. Aquatic turtles should have access to hiding places on both land and water parts. Amphibians not completely aquatic and terrestrial snakes should have access to bottom substrate. The substrate's moisture content should be adapted to the needs of the species. Arboreal amphibians should have an interior enabling them to both move and rest above ground.

Environment and Climate Control

§ 4 Temperature, light, and water supply aquaria and tanks should be adapted to the needs and tolerance limits of the individual amphibians and reptiles.

General Advice For § 4

Temperature and light intensity as well as light frequency should be adapted to the needs and tolerance limits of the individual amphibians and reptiles. The laboratory animals should have the possibility to be in areas with different thermal zones and different light intensity.

Space Requirements

§ 5 The laboratory animals shall have access to at least the spaces specified in Table 1–5. If required, smaller individual tanks may be used for natural mating and super ovulation.

The surfaces in Table 1 apply to adult animals. For holding of juveniles and tadpoles the measurements shall be adjusted in proportion to the size of the animals.

Table 1 Aquatic amphibians

Animal length*, salamanders (cm)	**Animal length**, frogs and toads (cm)**	**Minimum area (m^2)**	**Minimum area per animal in group housing (m^2)**	**Minimum water depth (cm)**
up to 10	up to 5	0.09	0.015	15
11-15	5.5-7.5	0.15	0.025	15
16-20	8-10	0.25	0.04	20
21-40	10.5-20	0.5	0.085	20
41-60	20.5-30	1.0	0.17	30
more than 60	more than 30	1.5	0.5	50

* Salamanders length measured from tip of snout to tip of tail.

** Length of frogs and toads measured from tip of snout to lower back.

Table 2 Semi-aquatic amphibians

Animal length* (frogs and toads) (cm)	**Minimum area** (m^2)**	**Minimum area per animal in group housing (m^2)**	**Minimum height*** (cm)**	**Minimum water depth (cm)**
up to 5	0.15	0.02	20	10
5.5-7.5	0.35	0.05	30	10
more than 7.5	0.4	0.07	30	15

* Length of frogs and toads measured from tip of snout to lower back.

** One-third land division and two-thirds water division enabling laboratory animals to be fully submerged.

*** Measured from the surface of the land division up to the inner part of the top of the terrarium. Furthermore, the height of the enclosures shall be adapted to the interior design.

Table 3 Arboreal and terrestrial amphibians

Animal length* (frogs and toads) (cm)	**Minimum area** (m^2)**	**Minimum area per animal in group housing (m^2)**	**Minimum height*** (cm)**	**Minimum water depth (cm)**
up to 2.5	0.09	0.01	30	10
3-5	0.15	0.02	30	10
5.5-7.5	0.35	0.05	40	10
8-10	0.4	0.07	40	15
more than 10	0.5	0.12	40	15

* Length of frogs and toads measured from tip of snout to lower back.

** One-third land division and two-thirds water division enabling laboratory animals to be fully submerged.

*** Measured from the surface of the land division up to the inner part of the top of the terrarium. Furthermore, the height of the enclosures shall be adapted to the interior design.

Table 4 Terrestrial snakes

Body length (cm)*	**Minimum floor area (cm^2)**	**Minimum area for each additional animal in group housing (cm^2)**	**Minimum enclosure height (cm)****
up to 30	300	150	10
over 30 to 40	400	200	12
over 40 to 50	600	300	15
over 50 to 75	1,200	600	20
over 75	2,500	1,200	28

* Measured from snout to tip of tail.

** Measured from the surface of the land division up to the inner part of the top of the terrarium. Furthermore, the height of the enclosures shall be adapted to the interior design.

Table 5 Aquatic turtles

Body length (cm)*	**Minimum water surface area (cm^2)**	**Minimum addition of water surface area for each additional animal in group housing (cm^2)**	**Minimum water depth (cm)**
op to 5	600	100	10
over 5 to 10	1,600	300	15
over 10 to 15	3,500	600	20
over 15 to 20	6,000	1,200	30
over 20 to 30	10,000	2,000	35
over 30	20,000	5,000	40

* Measured in a straight line from the front edge of the shell to its back edge.

CH. 26 SPECIAL PROVISIONS FOR FISH

§ 1 The provisions in this chapter apply in addition to the provisions in Ch. 16, and contain specific provisions for fish.

General

§ 2 The water volume, surface (area), depth, and flow shall be adapted to the size, quantity, age, health, and well-being of the fish, as well as environmental conditions, way of living, and feeding method. Fish shall be able to swim in a way that is normal for the species.

General Advice for § 2

1. The water volume should not be less than 40 litres unless the fish is specially adapted to small volumes of water.

2. When keeping larger fish, e.g., cod, the aquarium shall have a length at least four times the length of the fish.

§ 3 Fish shall be handled as little as possible.

Group Housing

§ 4 Group size and composition shall be adapted to the social structure and needs of the different species. Stocking density shall be based on the total needs of the fish with regards to environmental conditions, health, and well-being.

> ***General Advice For § 4***
> *Fish should have at least 1 litre of water per fish that is less than 5 cm long, and at least 4 litres of water per fish that is 5-10 cm long. Fish that are robust with a heavy build in relation to their length should have a greater water volume per fish.*

Enclosure Enrichment

§ 5 An aquarium or corresponding space shall have an interior design and a bottom substrate that corresponds to that found in the natural environment of each fish species.

§ 6 At least one side of an aquarium or corresponding space shall be opaque unless the interior design gives equivalent protection for the fish.

Breeding

§ 7 If especially strict hygiene is required for spawning or keeping of fry, the requirements for enrichment in Ch. 16, §§ 17–19 do not apply.

§ 8 When transitioning from living to manufactured feed, special attention shall be paid to fry. Transition shall take place in a way that is suitable for the species.

Environment and Climate Control

Water supply and water quality

§ 9 Water supply to aquaria or corresponding spaces shall be adapted to the needs and tolerance limits of the individual fish. Fish shall be given time to adapt to any change in water quality.

§ 10 Water quality parameters such as, e.g., oxygen concentration, carbon dioxide concentration, pH, and salinity shall be maintained at suitable levels for the species.

Equipment for aeration of the water shall be installed where required. pH shall be kept as stable as possible. Concentrations of nitrogen compounds shall be kept low. The water shall be filtered or treated where necessary to remove substances that are hazardous to the fish.

§ 11 The water quality parameters shall be adapted to each fish species and stage of development so that fish can sustain normal activity and normal physiological processes.

Temperature

§ 12 The water temperature shall be adapted to the needs of the fish species and shall be kept as stable as possible. Changes in temperature shall take place gradually.

Noise and vibrations

§ 13 Whenever possible, equipment causing noise or vibrations, such as generators or filtration systems, shall be separate from aquaria or corresponding spaces.

CH. 27 OTHER PROVISIONS

Exceptions

§ 1 If there are special reasons the Swedish Board of Agriculture can decide on exceptions from the provisions in:

1. Ch. 2, §14,
2. Ch. 5, § 2,
3. Ch. 9, § 6,
4. Ch. 12, §§ 8 and 27,
5. Ch. 15, §§ 1-5 and 8-27
6. Ch. 16, §§ 13-15 1st paragraph., §§ 16-19 and 20-26,
7. Ch. 17, §§ 3-7,
8. Ch. 18, §§ 2-7,
9. Ch. 19, §§. 2-10,
10. Ch. 20, §§ 2-8,
11. Ch. 21, §§ 2-6,
12. Ch. 22, §§ 2-11,
13. Ch. 23, §§ 2-5,
14. Ch. 24, §§ 2-5,
15. Ch. 25, §§ 2-5, and
16. Ch. 26, §§ 2-13.

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1. This constitution enters into force July 15, 2018
2. The constitution repeals the Swedish Board of Agriculture's regulations and general advice (2012:26) on laboratory animals.

LEIF DENNEBERG

Jessica Johansson
(Laboratory Animals and Pets Unit)