

**NB: Unofficial translation**

**Legally binding texts are those in Finnish and Swedish**

**Act on the Protection of Animals Used for Scientific or Educational Purposes  
(497/2013)**

Chapter 1 – **General provisions**

Section 1 – *Purpose of the Act*

- (1) The purpose of this Act is to ensure that animals are kept and used for scientific or educational purposes only for necessary and important reasons.
- (2) Further, the purpose of the Act is to ensure that only a minimum number of animals are used for scientific or educational purposes and that minimum pain, suffering, distress or lasting harm is caused to the animals.

Section 2 – *Scope of application*

- (1) This Act applies when:
  - 1) using or breeding live cephalopods or vertebrates for scientific or educational purposes; and
  - 2) breeding such animals for the supply of their organs or tissues for scientific or educational purposes.
- (2) When applying this Act, the same that applies to an animal also applies to its independently feeding larval forms and foetal forms of mammals as from the last third of their normal development. When applying this Act, the same that applies to an animal also applies to a specimen at an earlier stage of development than that mentioned above if, as a result of the procedures, it is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.
- (3) This Act applies even if the pain and suffering of an animal is eliminated and distress and lasting harm prevented by anaesthesia, analgesia or another method.

Section 3 – *Limitations to the scope*

- (1) This Act does not apply to
  - 1) non-experimental agricultural practices;
  - 2) non-experimental clinical veterinary practices;
  - 3) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
  - 4) practices undertaken for the purposes of recognised animal husbandry;
  - 5) practices undertaken for the primary purpose of identification of an animal;
  - 6) practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

Section 4 – *Relationship with other legislation*

- (1) Unless otherwise provided in this Act or under it or subject to an authorisation issued under this Act, the provisions of the Animal Welfare Act (247/1996) or issued under it apply to the keeping, care, treatment and handling of animals used for scientific or educational purposes.

- (2) Provisions on application of gene technology to animals are laid down in the Gene Technology Act (377/1995). Provisions on the transport of animals are laid down in Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 and in the Animal Transport Act (1429/2006). Provisions on the use of animals in testing cosmetic products are laid down in the Cosmetic Product Act (22/2005). Provisions on the capture, keeping in possession and killing of wild animals are laid down in the Nature Conservation Act (1096/1996) and Hunting Act (615/1993). Provisions on veterinary clinical trials are laid down in the Medicines Act (395/1987).

## Section 5 – Definitions

- (1) In this Act:
- 1) *a project* means a programme of work with a defined scientific or educational objective involving at least one procedure;
  - 2) *a procedure* means:
    - a) any use of an animal for experimental purposes or other scientific or educational purposes so that pain, suffering, distress or lasting harm equivalent to the feeling caused by the introduction of a needle in accordance with good veterinary practice may be caused to the animal; and
    - b) any course of action intended, or liable, to result in the birth or hatching of a genetically modified or other animal or the creation and maintenance of a genetically modified animal line in a way that pain, suffering, distress or lasting harm referred to in subparagraph a may be caused to animals; for an individual animal a procedure starts when the animal starts to be prepared for use in the procedure and ends when making observations from a live animal has been stopped;
  - 3) *a breeder* means any natural or legal person breeding animals referred to in section 16(1) for use in projects or for the use of their tissue or organs for scientific or educational purposes, or breeding other animals primarily for such purposes;
  - 4) *a supplier* means any natural or legal person, other than a breeder, selling, transmitting or otherwise supplying animals for use in projects or for the use of their tissue or organs for scientific or educational purposes; however, a natural or legal person occasionally selling or supplying an individual animal or otherwise a small number of animals for use in a project or for the use of their tissue or organs for scientific or educational purposes is not considered a supplier;
  - 5) *a user* means any natural or legal person carrying out projects;
  - 6) *an operator* means a breeder, supplier and user;
  - 7) *an establishment* means any installations, buildings, groups of buildings or other facilities in the possession of the operator relating to the activity referred to in this Act; and
  - 8) *the principle of replacement, reduction and refinement* means that, wherever possible, efforts are made to use other methods instead of animals; if animals need to be used, their number is reduced to the minimum without compromising the objective of the project, and efforts are made to reduce any pain, suffering, distress or lasting harm caused to the animals to the minimum.
- (2) The following shall not be considered a procedure referred to in paragraph 2 of subsection 1 above:
- 1) killing of an animal by a competent person using approved methods; or
  - 2) breeding of genetically modified animals or animals with a spontaneous mutation after the creation of the animal line if the modification or mutation does not cause pain, suffering, distress or lasting harm equivalent to, or higher than, the feeling caused by the introduction of a needle in such animals.

## Chapter 2 – Requirements for the operator

### Section 6 – General requirements

- (1) The operator shall take account of the specific needs and characteristics of each animal species in the care of animals.
- (2) The operator shall have adequate and appropriate facilities, installations and equipment for the activity practised. In addition, the design, construction and method of functioning of the facilities, installations and equipment of the user shall be such that the projects can be carried out as appropriately as possible while using the minimum number of animals and that the minimum degree of pain, suffering, distress or lasting harm is caused to the animals.
- (3) The operator shall have appropriately organised veterinary care for the medication and health care of animals and treatment of illness.
- (4) Further provisions on the care of animals, facilities needed for practising the activity and organisation of veterinary care are issued by Government Decree.

### Section 7 – Staff

- (1) The operator shall have the necessary number of competent staff considering the type and extent of the activity.
- (2) The operator shall designate a person who is familiar with the requirements for the activity laid down in this Act and under it (*person responsible for the activity*). The person responsible for the activity shall see that the statutory requirements are complied with when practising the activity. The operator shall see that the person responsible for the activity is allowed to manage the tasks in accordance with the relevant statutes and authorisation conditions.
- (3) The operator shall designate one or several responsible persons for each establishment tasked with:
  - 1) overseeing the welfare and care of the animals;
  - 2) ensuring that the staff dealing with animals have access to information specific to the animals kept in the establishment; and
  - 3) seeing that the staff are adequately educated and competent to perform their tasks.
- (4) The operator shall have a designated veterinarian for veterinary care and advisory duties relating to well-being and treatment of the animals. Where more appropriate considering the species of the animals kept or other similar reason, another suitably qualified expert may be charged with advisory duties relating to the well-being and treatment of animals. The designated veterinarian and expert shall have expertise in the use of animals for scientific or educational purposes. The designated veterinarian and expert of the user shall have completed the education concerning the use of animals for scientific purposes referred to in section 8(1).
- (5) Further provisions on the tasks of the staff are issued by Government Decree.

### Section 8 – Education and competence requirements for the staff

- (1) A project may be designed by a person who holds a higher education degree and who in addition to this has successfully completed the education in the use of animals for scientific or educational purposes in accordance with the teaching programme of a university or institution of higher education or approved by the Regional State Administrative Agency for Southern Finland.
- (2) The Regional State Administrative Agency for Southern Finland approves, upon application, a person who has successfully completed the necessary education in a country other than Finland as qualified to design projects in Finland. A condition for the approval is that the content of the education completed is equivalent to the education referred to in subsection 1.

- (3) A person who performs procedures on or cares for or kills animals shall have demonstrated that he or she has adequately knowledge and skills for the task before undertaking the task.
- (4) Further provisions on the content and completion of the education referred to in subsection 1 are issued by Government Decree. Further provisions on the education and competence requirements of the staff are issued by Government Decree.

#### Section 9 – *Animal welfare body*

- (1) The operator shall designate an animal welfare body including at least the person or persons responsible for the establishment referred to in section 7(3), designated veterinarian or other qualified expert referred to in section 7(4) and, when the operator is the user, at least one representative of science. However, a welfare body is not required if the activity is small in scale and the operator fulfils the tasks laid down for the welfare body by other means.
- (2) The tasks of the animal welfare body are to:
  - 1) advise the staff on matters related to the welfare of animals;
  - 2) develop and review the monitoring, reporting and follow-up in relation to the welfare of animals;
  - 3) follow the development and outcome of projects with regard to the welfare of animals; and
  - 4) decide on the rehoming or returning to a suitable husbandry system of an animal used or intended to be used in a project.
- (3) Records shall be kept of any advice given by the animal welfare body and decisions taken regarding that advice. The records shall be kept for at least three years from the last entry made to them.
- (4) Further provisions on the tasks of the animal welfare body are issued by Government Decree. Further provisions on the composition and records of the animal welfare body may be issued by Government Decree.

#### Section 10 – *Animal records and statistics*

- (1) The operator shall keep records on:
  - 1) the species and numbers of animals bred, acquired, supplied, used in procedures, rehomed or set free, names and addresses of the suppliers and recipients of animals and dates on which the animals have been acquired, supplied, released or rehomed;
  - 2) the origin of animals;
  - 3) medicines administered to the animals; and
  - 4) the species and numbers of animals which have died or been killed and the cause of death, when known.
- (2) The operator shall, where requested, compile statistics on information referred to in paragraphs 1 and 4 of subsection 1 and submit this to the Regional State Administrative Agency for Southern Finland.
- (3) An operator who is a user shall also keep records on projects to be implemented and compile statistics on animals used in them and on the actual severity of the procedures performed on them. The statistics shall be submitted to the Regional State Administrative Agency for Southern Finland within three months from the end of each calendar year.
- (4) The records and statistics shall be kept for at least five years from the last entry made to them.
- (5) Further provisions on the content, keeping and retention of records and statistics are issued by Government Decree. Provisions on animal species on which detailed records shall be kept are issued by Government Decree.

### Chapter 3 – **Project and procedure**

#### Section 11 – *Use of other methods instead of a project and procedure*

- (1) A project may be carried out only if it is in practice not possible to use another scientifically satisfactory method or testing strategy not entailing the use of a live animal to achieve the result set as the objective.
- (2) The number of animals used in a project may not be greater than necessary for achieving the objective. Another scientifically satisfactory method not entailing the use of a live animal or a method in which the total number of animals or the pain, suffering, distress or lasting harm caused to the animals can be reduced shall be used instead of a project or measure, also in part.

#### Section 12 - *Purpose of a project*

- (1) A project may be carried out for the following purposes only:
  - 1) basic research;
  - 2) translational or applied research with any of the following aims;
    - a) the avoidance, prevention, diagnosis or treatment of a disease, ill-health or other abnormality or their effects in human beings, animals or plants;
    - b) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or
    - c) the welfare of animals and improvement of the conditions of farm animals;
  - 3) for any of the aims in paragraph 2 in connection with the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs, feedstuffs and other substances or products;
  - 4) protection of the environment in the interest of the health or welfare of human beings or animals;
  - 5) research aimed at preservation of the species;
  - 6) forensic inquiries; and
  - 7) higher education or teaching for the acquisition, maintenance or improvement of vocational skills.

#### Section 13 – *General principles concerning a procedure*

- (1) A procedure may be performed in a project only. A procedure shall be performed, with due account to the achievement of its objective, involving an animal with the lowest capacity to experience pain, suffering, distress or lasting harm. A procedure shall be chosen and performed so as to cause minimum pain, suffering, distress or lasting harm to the animal, while the project is still likely to provide satisfactory results.
- (2) It is prohibited to perform procedures which involve severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated. Exemption from the prohibition is allowed only for exceptional and scientifically justifiable reasons referred to in Article 55(3) of Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes. A procedure may not be performed for studying the pain or suffering tolerance level of an animal.
- (3) Death as the end-point of a procedure shall be avoided and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to result in the death of as few animals as possible.
- (4) Further provisions on the choice of animals to be used in a procedure are issued by Government Decree. Further provisions on the choice of procedures and reducing the pain, suffering, distress or lasting harm caused to the animal may be issued by Government Decree.

#### Section 14 – *Use of analgesia*

- (1) The pain, suffering, distress or lasting harm caused to the animal in the procedure shall always be ameliorated in every possible way that is compatible with the purpose of the procedure, unless the pain, suffering, distress or lasting harm caused by the amelioration is greater than that caused by the actual procedure.
- (2) Procedures that involve serious injuries that may cause severe pain shall not be performed without anaesthesia.
- (3) No drug to stop or restrict their showing pain may be given to animals without an adequate level of anaesthesia or analgesia.
- (4) Further provisions on the use of anaesthesia and analgesia may be issued by Government Decree.

#### Section 15 – *Classification of severity of procedures*

- (1) The pain, suffering, distress and lasting harm caused to the animal in the procedure shall be assessed before undertaking the procedure. The severity of a procedure is determined according to the level of pain, suffering, distress or lasting harm that an individual animal is assumed to experience during the procedure. The severity of the procedure is assessed in the project authorisation application referred to in section 24 and specified in the project authorisation referred to in section 25.
- (2) The severity categories are:
  - 1) non-recovery;
  - 2) mild;
  - 3) moderate; and
  - 4) severe.
- (3) Further provisions on the assignment of procedures to severity categories are issued by Government Decree.

### Chapter 4 – **Animals**

#### Section 16 – *Requirement to breed for the purpose and origin of animals*

- (1) In all cases the aim should be to use animals in projects that are bred for use for scientific or educational purposes (*purpose-bred animal*). Unless otherwise provided in section 26(3), animals generally used in projects shall be purpose-bred. Further provisions on the animal that shall be purpose-bred are issued by Government Decree.
- (2) Unless otherwise provided in section 26(3), the following animals may not be used in a project:
  - 1) stray and feral animals of domestic species; and
  - 2) animals taken from the wild.
- (3) Where an animal is acquired from a party other than a breeder or supplier, this party shall be notified of the intended use of the animal.

#### Section 17 – *Taking an animal from the wild*

- (1) If taking an animal from the wild is allowed under section 26(3), an animal may only be captured by a person who has adequate knowledge of the capturing techniques and adequate skills for handling the animal. A method approved in the project authorisation which does not cause the animal avoidable pain, suffering, distress or lasting harm shall be used in the capture.
- (2) Further provisions on the capture of an animal and competence requirements of the person capturing the animal may be issued by Government Decree.

#### Section 18 – *Specification of animals*

- (1) The animal shall be marked or otherwise identified. Further provisions on the marking and identification of animals are issued by Government Decree.

#### Section 19 – *Reuse of an animal*

- (1) Unless otherwise provided in section 26(3), an animal on which one or more procedures have already been performed may be reused in a new procedure when a different animal on which no procedure has previously been performed could also be used only if:
  - 1) the actual severity of the previous procedures was mild or moderate;
  - 2) it can be demonstrated that the animal's general state of health and well-being has been fully restored;
  - 3) the further procedure is not classified as severe; and
  - 4) reuse is in accordance with advice of a veterinarian referred to in section 7(4), taking into account the lifetime experience of the animal.

#### Section 20 – *Killing of an animal*

- (1) An animal shall be killed with minimum pain, suffering and distress.
- (2) An animal shall be killed without delay if symptoms or changes occur in its behaviour, physiological conditions or appearance on the grounds of which it can be concluded to experience severe pain, suffering or distress unforeseen in the project authorisation which cannot be eliminated by medication or other action.
- (3) An animal shall be killed at the end of the procedure if it is likely to continue to suffer moderate or severe pain, suffering, distress or lasting harm.
- (4) A veterinarian or other competent person shall decide on the killing of an animal. A competent person means a person who has sufficient knowledge to assess the health and welfare of the animal and the pain, suffering and distress experienced by the animal.
- (5) An animal shall be killed in the establishment of the operator, unless the project concerned is carried out in field conditions.
- (6) If an animal is not killed at the end of the procedure action shall be taken to see to the welfare of the animal and it shall receive the necessary care. Further provisions on the killing of an animal are issued by Government Decree.

### Chapter 5 – **Authorisation requirement for operation**

#### Section 21 – *An operation authorisation and applying for the authorisation*

- (1) An operator shall have an authorisation to practice the activity from the Regional State Administrative Agency for Southern Finland or the Regional State Administrative Agency for Eastern Finland (*operation authorisation*).
- (2) The operation authorisation shall be applied for from the Regional State Administrative Agency for Southern Finland if the domicile of the applicant is within the area of operation of the Regional State Administrative Agency for Southern Finland, South-Western Finland or Western and Inland Finland, and from the Regional State Administrative Agency for Eastern Finland if the domicile of the applicant is within the area of operation of the Regional State Administrative Agency for Eastern Finland, Northern Finland or Lapland.
- (3) The authorisation application shall show the information that is the condition for granting the authorisation referred to in sections 6, 7 and 9. Further provisions on the content of the authorisation application are issued by Government Decree.

#### Section 22 – *Granting an operation authorisation*

- (1) An operation authorisation is granted if:

- 1) the applicant has appropriate facilities, installations and equipment available for the activity;
  - 2) the applicant has appropriate staff available for the activity;
  - 3) veterinary care required for the activity has been organized as specified in section 6(3); and
  - 4) other requirements for the practice of the activity laid down in this Act or under it are fulfilled.
- (2) An operation authorisation may also be granted for a limited period.
- (3) An establishment intended for the practice of the activity shall be inspected before granting the operation authorisation.

#### Section 23 – *Changes in the staff and activity*

- (1) The operator shall notify the Regional State Administrative Agency that granted the operation authorisation without delay of any changes in the persons referred to in section 7(2–4). The user shall notify the Regional State Administrative Agency for Southern Finland without delay of any changes in the persons referred to in section 25(2).
- (2) The operation authorisation shall be reapplied for if the activity or structures of the establishment are changed in a significant way that may have harmful impacts on the welfare of animals. The Regional State Administrative Agency that granted the authorisation shall be notified without delay of ceasing the activity.

### Chapter 6 – **Authorisation requirement for a project**

#### Section 24 – *A project authorisation and applying for the authorisation*

- (1) A project may be carried out only subject to an authorisation issued by the project authorisation board (*project authorisation*).
- (2) A project authorisation application to be drawn up on a project shall contain the following:
  - 1) project proposal that shows the justification concerning the project and use of an animal for the project laid down in sections 11–14;
  - 2) estimate of the severity category of procedures included in the project;
  - 3) non-technical project summary; and
  - 4) name of the person responsible for implementing the project.
- (3) Further provisions on the content of the project authorisation application are issued by Government Decree.

#### Section 25 – *Granting a project authorisation*

- (1) A project authorisation is granted if:
  - 1) the operator who is a user has an operation authorisation;
  - 2) the project is carried out for an approved purpose as specified in section 12;
  - 3) the project designer has qualifications referred to in section 8(1);
  - 4) the projects is justified from the scientific or educational point of view or required by law;
  - 5) the expected benefit from the project to human beings, animals or the environment is in an ethically justified proportion considering the harm to the animals;
  - 6) the project is designed so as to enable procedures to be performed in the most humane and environmentally sensitive manner possible; and
  - 7) the other requirements concerning the use of animals in a project laid down in this Act or under it are fulfilled.



- (2) The severity categories of the procedures included in a project referred to in section 15 are specified in the project authorisation. A person responsible for implementing the project is designated in the project authorisation.
- (3) A project authorisation may also be granted for multiple projects if they are implemented to satisfy regulatory requirements or if animals are used for production or diagnostic purposes with established methods. A project authorisation may be granted for no more than five years at a time.

#### *Section 26 – Conditions set in the authorisation and exemptions to be granted*

- (1) Conditions required for the protection of animals to ensure the welfare of animals during the project may be set out in the project authorisation.
- (2) It may be required in the project authorisation that retrospective assessment referred to in section 29 shall also be carried out for a project involving procedures classified as moderate if this is necessary due to:
  - 1) the scope of the project or number of procedures;
  - 2) the number or unusual species of animals to be used in the project; or
  - 3) other similar reason.
- (3) In a project authorisation exemption may be granted from:
  - 1) the requirement to breed for the purpose in section 16(1) if there is a scientifically justified need for the exemption;
  - 2) the prohibition in section 16(2)(1) if this is required by an essential need for studies concerning the health and welfare of animals or serious threats to the environment or to human or animal health and there is scientific justification that the purpose of the procedure can be achieved only by the use of a stray or feral animal of domestic species;
  - 3) the prohibition in section 16(2)(2) if there is scientific justification that the purpose of the project cannot be achieved by the use of a purpose-bred animal; and
  - 4) the requirement in section 19(1) in exceptional circumstances; an exemption may only be granted provided that the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering and a veterinarian inspects the animal before reuse.
- (4) Further provisions on the content of the authorisation decision may be issued by Government Decree.

#### *Section 27 – Amendment of a project authorisation*

- (1) An authorisation for implementing a project in a way that deviates from the authorisation granted to it shall be applied for from the project authorisation board. The application shall show the justification for amending the project.
- (2) The provision in subsection 1 notwithstanding, the Regional State Administrative Agency for Southern Finland may grant an authorisation for minor amendments concerning the project if:
  - 1) it is absolutely necessary for continuing the project and there is no time to submit the matter to the project authorisation board or its section without compromising the purpose of the project and amending the project cannot cause a change in the severity category of the project that would be more harmful to the animal ; or
  - 2) it is a question of continuing the period of validity of the project authorisation for a short time or a minor increase in the number of animals used.
- (3) The Regional State Administrative Agency for Southern Finland shall notify the project authorisation board of amendments concerning the authorisation.

#### *Section 28 – Setting free, rehoming and returning of an animal used in or intended for a project*

- (1) A project authorisation may allow the setting free of an animal taken from the wild used in a project if:
  - 1) the state of health of the animal allows it;
  - 2) setting free causes no danger to human or animal health or the environment; and
  - 3) it can be expected that the animal adapts to the wild without difficulty.
- (2) The animal welfare body may decide on the rehoming or returning to a suitable husbandry system of an animal used in or intended for a project if:
  - 1) the state of health of the animal allows it;
  - 2) rehoming or returning of the animal causes no danger to human or animal health or the environment; and
  - 3) it can be expected that the animal adapts to the new conditions.
- (3) Where necessary, the animal shall be gradually rehabilitated to the new husbandry system or habitat before it is rehomed, returned or set free.
- (4) Before deciding on a matter concerning setting free of an animal to the wild a statement on the authorisation application shall be requested, where necessary, from the Centre for Economic Development, Transport and the Environment in whose area of operation the animal is to be set free in the wild. Where necessary, the Centre for Economic Development, Transport and the Environment shall hear other authorities on the matter.
- (5) Further provisions on the conditions concerning the rehabilitation, rehoming, returning and setting free of an animal may be issued by Government Decree.

#### Section 29 – *Retrospective assessment*

- (1) Retrospective assessment shall be carried out for projects involving non-human primates as well as projects that include procedures classified as severe. In retrospective assessment the following shall be evaluated:
  - 1) whether the objectives of the project were achieved;
  - 2) the harm inflicted on animals, including the numbers and species of animals used and the actual severity of procedures; and
  - 3) any elements that may contribute to the further implementation of the principle of replacement, reduction and refinement.
- (2) The Regional State Administrative Agency for Southern Finland carries out the retrospective assessment. The holder of the project authorisation shall submit the information necessary for the retrospective assessment to the Agency within three months from the end of the project.
- (3) The Regional State Administrative Agency for Southern Finland shall submit the results of the retrospective assessment referred to in subsection 1 for information to the holder of the project authorisation and project authorisation board.
- (4) Further provisions on the information to be submitted for retrospective assessment and matters to be evaluated referred to in subsection 1 may be issued by Government Decree.

### Chapter 7 – **Project authorisation board**

#### Section 30 – *Appointment and composition of the project authorisation board*

- (1) The project authorisation board is appointed by the Government on the proposal of the Ministry of Agriculture and Forestry for five years at a time. The board has a chair and vice-chair and 16 other members with personal deputies. Equal representation of the different parts of the country in terms of practicing the operation referred to in this Act shall be taken into account in the composition of the board. The board operates in connection with the Regional State Administrative Agency for Southern Finland.
- (2) The chair and vice-chair of the board shall hold the Master's Degree in Law or equivalent higher education degree. The members and deputy members shall be known as skilled and

experienced persons competent in the use of animal for scientific purposes, of which four shall represent expertise in scientific research, four expertise in the care of animals used for scientific purposes and procedures performed on the animals, four veterinary expertise and four expertise in practical animal protection work or ethical questions.

- (3) The project authorisation board is divided into four sections. The project authorisation board appoints the members and deputy members to the sections in a way that the different kinds of expertise are equally represented. The board appoints a chair and vice-chair to the sections.
- (4) The project authorisation board has the right to hear outside experts.

#### Section 31 – *Preparation and processing of matters at the board*

- (1) Matters processed at the board or its section are prepared at the Regional State Administrative Agency for Southern Finland, from which the matters to be dealt with are also presented. The board or its section is convened by the chair of the board or section or, where this is prevented from doing this, by the vice-chair.
- (2) A decision on an authorisation application concerning a project shall be given within 40 working days from the submission of all information necessary for deciding on the matter to the Regional State Administrative Agency for Southern Finland. The Regional State Administrative Agency for Southern Finland shall send, without delay, the applicant for the project authorisation a notification of the application received and of the 40-day time period during which the decision is made. If justified due to the complicated or interdisciplinary nature of the project the time period for the decision can be extended by 15 working days. The Regional State Administrative Agency for Southern Finland shall notify the applicant of the extension of the time period and the justification for this before the end of the 40-day time period.
- (3) Minutes shall be drawn up of the meeting of the board and its section, signed by the chair and secretary of the meeting. Decisions of the board and its section are signed by the chair of the meeting and certified by the rapporteur.
- (4) Further provisions on the division of labour within the project authorisation board, processing of matters and other organization of the activity are issued in the rules of procedure, which are ratified by the Ministry of Agriculture and Forestry.
- (5) The provisions on the criminal liability for acts in office applies to the chair of the board and its sections and other members and deputy members while processing matters referred to in this Act. Provisions on the liability for damages are laid down in the Tort Liability Act (412/1974).

#### Section 32 – *Power of decision*

- (1) The authorisation to carry out a project is issued by the section of the project authorisation board or, if this is not unanimous, by the project authorisation board. If the section does not grant an authorisation to carry out a project the matter is transferred to the project authorisation board for decisions.
- (2) The project authorisation board has a quorum when the chair of the meeting and at least eight other members or deputy members are present. A section of the project authorisation board has a quorum when the chair of the meeting and three other members or deputy members are present.
- (3) If disagreement on deciding on the matter arises at the project authorisation board, the matter is decided by vote. The proposal supported by the majority and, in the event of a tie vote, the proposal supported by the chair is the decision of the board.
- (4) The chair of the board decides on matters relating to finances and other internal administration of the board. In the rules of procedure the power of decision on these matters may also be transferred to the vice-chair and rapporteur of the board.

### Section 33 – *Staff of the board*

- (1) The project authorisation board has full-time rapporteurs and clerical staff employed by the Regional State Administrative Agency for Southern Finland. The qualification requirement of the rapporteurs is a suitable higher education degree and good knowledge of the use of animals for scientific and educational purposes.

## Chapter 8 – **Authorities and their tasks**

### Section 34 – *General steering and control*

- (1) The general steering and control of the implementation of this Act is the responsibility of the Ministry of Agriculture and Forestry.

### Section 35 – *Control authorities*

- (1) The control of the compliance with the provisions issued in this Act and under it and the organization of the control is the responsibility of the Regional State Administrative Agency for Southern Finland within the area of operation of the Regional State Administrative Agency for Southern Finland, South-Western Finland and Western and Inland Finland, and of the Regional State Administrative Agency for Eastern Finland within the area of operation of the Regional State Administrative Agency for Eastern Finland, Northern Finland and Lapland.
- (2) The Regional State Administrative Agencies for Southern and Eastern Finland may also draw on the assistance of the other Regional State Administrative Agencies in the control.

### Section 36 – *Certain tasks of the Regional State Administrative Agency for Southern Finland*

- (1) In addition to the provisions on the tasks of the Regional State Administrative Agency for Southern Finland laid down elsewhere in this Act, the Agency:
  - 1) compiles and keeps for public viewing in an electronic form statistical information on the use of animals for scientific or educational purposes;
  - 2) publishes non-technical summaries of the project authorisations granted and sees that these are updated when retrospective assessment of the projects has been carried out ; and
  - 3) sees to the support services needed by the project authorisation board and advisory committee referred to in section 53.

## Chapter 9 – **Control**

### Section 37 – *General principles of organising the control*

- (1) The activity of the operators shall be controlled in an equitable manner and on a regular basis. The control shall be intensified if it is to be suspected that the activity or the establishment does not fulfil the requirements laid down in this Act or under it.

### Section 38 – *Control plan*

- (1) The Regional State Administrative Agencies for Southern and Eastern Finland shall draw up a control plan on the organisation of the control on an annual basis. The control plan shall show the inspections to be carried out, types of objects of control and their inspection frequency. In addition, the grounds for the risk assessment of the types of objects of control and grounds for the assessment of the implementation of the plan shall be presented in the plan.
- (2) Further provisions on the control plan and its content may be issued by Government Decree.

### Section 39 – *Right of access to information*

- (1) The Ministry of Agriculture and Forestry and the control authority have the right to obtain information and documents necessary for the control and inspection referred to in this Act from the operator, holder of the project authorisation as well as state authorities and the project authorisation board.
- (2) The right of access to information also applies to information necessary for the control which as information concerning the business or professional activity or economic position of a private person or corporation or information on the personal circumstances of a private person would otherwise be to be kept secret.

### Section 40 – *Right of inspection and attendance*

- (1) The control authority referred to in section 35 above has the right to carry out inspections required for the control of the compliance with the provisions laid down in this Act and under it as well as, for this purpose, gain access to facilities where an activity referred to in this Act is practised or where animals intended for the activity, animal feed or drink, or samples, substances, installations, equipment, implements or instruments to be used in the activity or documents or information concerning the activity are kept. However, an inspection may not be carried out in a facility used for a residential purpose on a permanent basis.
- (2) The Regional State Administrative Agencies for Southern and Eastern Finland have the right of attendance when a project is being implemented or a procedure performed. In addition, the Agencies have the right to attend a meeting of the project authorisation board.

### Section 41 – *Right to take samples*

- (1) Where necessary, the control authority has the right to take samples needed for the control without compensation from the animals used in practising the activity, animal feed and drink as well as substances used in the activity

### Section 42 – *European Union inspectors*

- (1) The provisions in sections 39–41 concerning the right of inspection and access to information and right to take samples of a Finnish authority also apply to European Union inspectors. If an inspection is carried out by a European Union inspector, the control authority shall collaborate with this.

### Section 43 – *Disclosure of secret information*

- (1) The secrecy obligation laid down in the Act on the Openness of Government Activities (621/1999) notwithstanding, information obtained when controlling the compliance with the provisions laid down in this Act or under it concerning the economic position, business or professional secret of a private person or corporation or personal circumstances of a private person may be disclosed to:
  - 1) authorities controlling the compliance with this Act for carrying out tasks under this Act;
  - 2) prosecuting, police or customs authorities for solving an offence referred to in Chapter 5, section 1 of the Coercive Measures Act (450/1987); and
  - 3) foreign bodies and inspectors referred to in the European Union legislation or international agreement binding on Finland when so required in the European Union legislation or agreement.

#### Section 44 – *Executive assistance*

- (1) The control authority is entitled to executive assistance from the police and customs authorities for carrying out tasks under this Act and provisions issued under it.

#### Section 45 – *Register of operators*

- (1) A register is kept of the operators for the control and planning of control.
- (2) The Regional State Administrative Agencies for Southern and Eastern Finland record the following information in the register:
  - 1) identification information referred to in section 4(2) of the Act on the Information Systems of Rural Business Administration (284/2008);
  - 2) animal species concerned in the activity;
  - 3) time of starting the activity and operation authorisations granted;
  - 4) whether the operator acts as a breeder, supplier or user referred to in section 5(1);
  - 5) name and contact information of the person responsible for the activity, persons responsible for the establishment referred to in section 7(3) and designated veterinarian referred to in section 7(4) and any other qualified expert; and
  - 6) ending the activity.
- (2) Information in the register kept on the operators is recorded to the information system referred to in the Act on the Information Systems of Rural Business Administration. The said Act applies to the register, unless otherwise provided in this Act.

#### Section 46 – *Project register*

- (1) The Regional State Administrative Agency for Southern Finland keeps a register of project authorisations for control and planning of control as well as statistics. The following information is recorded in the register:
  - 1) establishment of the user in which the project is carried out;
  - 2) number of the project authorisation and name of the holder of the authorisation as well as, for a project referred to in section 25(2), the name of the person responsible for the project;
  - 3) purpose of the project;
  - 4) animal species used in the project and number of animals of each species;
  - 5) envisaged time of starting and ending the project;
  - 6) severity categories of the procedures;
  - 7) whether retrospective assessment is to be carried out on the project; and
  - 8) information on the retrospective assessment.
- (2) Information is deleted from the register after three years from the end of the time period set in the project authorisation. However, if retrospective assessment is to be carried out on the project the information is not deleted until after three years from the completion of the retrospective assessment.
- (3) The Ministry of Agriculture and Forestry and Regional State Administrative Agencies for Southern Finland and Eastern Finland have the right to use the register to the extent required by their statutory tasks. Otherwise the provisions of the Personal Data Act (523/1999) and Act on the Openness of Government Activities apply to the collection and recording of personal data and use and disclosure of the information in the register.

### Chapter 10 – **Administrative enforcement measures and sanctions**

#### Section 47 – *Prohibitions, orders and urgent measures*

- (1) If it is found out in an inspection referred to in section 40 or otherwise that the provisions concerning the practising of the activity or the authorisation conditions set for the activity or for carrying out a project have not been complied with, the control authority shall prohibit the operator or holder of the project authorisation from continuing or repeating the action that is contrary to the provisions or authorisation conditions or order this to fulfil his or her obligations within a sufficient time limit considering the nature of the matter.
- (2) By derogation from subsection 1, as an urgent measure the control authority may:
  - 1) kill an animal used in the project or order it to be killed immediately if the behaviour, physiological conditions or appearance of the animal shows any symptoms or changes on the grounds of which it can be concluded to experience severe pain, suffering or distress unforeseen in the project authorisation and this cannot be eliminated by medication or other actions;
  - 2) kill an animal used in practising the activity other than that referred to in paragraph 1 or order it to be killed if this is absolutely required for animal protection reasons.
- (3) If a decision referred to in subsection 1 or 2 is made by the control authority referred to in section 35(2), the authority referred to in section 35(1) shall be notified of the decision without delay. Measures referred to in subsection 2 above shall be carried out at the operator's expense.

#### Section 48 – *Withdrawal of a project authorisation*

- (1) The Regional State Administrative Agency for Southern or Eastern Finland may withdraw a project authorisation if provisions or authorisation conditions concerning the project have been violated in an essential way and the defects have not been remedied within the reasonable time limit set by the control authority.
- (2) The Regional State Administrative Agency for Southern Finland withdraws a project authorisation if the European Commission so demands on the grounds specified in Article 55 of Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.
- (3) If the project authorisation is withdrawn the operator shall kill the animals used in the project or take other action approved by the competent Regional State Administrative Agency to rectify the situation so that no harm is caused to the welfare of animals.

#### Section 49 – *Withdrawal of an operation authorisation*

- (1) The Regional State Administrative Agency may withdraw an operation authorisation it has granted if the operator violates in an essential way the requirements concerning the activity laid down in this Act or the Animal Welfare Act or under these or the authorisation conditions or if the activity no longer fulfils the conditions for granting an authorisation and the operator does not remedy the defects within the reasonable time limit set by the control authority.
- (2) If the operation authorisation is withdrawn the animals kept in the establishment shall, at the operator's expense, be killed or moved to the establishment of another operator or other action approved by the Regional State Administrative Agency shall be taken to rectify the situation so that no harm is caused to the welfare of animals.

#### Section 50 – *Notice of a conditional fine and enforced compliance*

- (1) The Regional State Administrative Agencies for Southern and Eastern Finland may impose a notice of a conditional fine or enforced compliance to intensify a prohibition or order referred to in section 47.
- (2) Notice of a conditions fine cannot be imposed to a natural person to intensify an obligation to notify information if there is cause to suspect the person of a crime and the information in question is such that it concerns a matter that is the object of the suspected crime.

- (3) Provisions on the notice of a conditional fine and enforced compliance are laid down in the Act on Notice of a Conditional Fine (1113/1990).

#### Section 51 – *Penal provision*

- (1) One who intentionally or through negligence:
- 1) neglects the application of an operation authorisation referred to in section 21(1);
  - 2) carries out a project without an authorisation referred to in section 24(1) or contrary to the conditions set in the authorisation;
  - 3) acquires animals for use or uses animals in a project contrary to the conditions in section 16(1–3);
  - 4) violates the obligation concerning the specification of animals laid down in section 18;
  - 5) reuses an animal contrary to section 19;
  - 6) neglects the obligation concerning the killing of an animal laid down in section 20(1–3) or violates the obligation referred to in section 20(6) or kills an animal in a way other than by an allowable killing method;
  - 7) violates the obligation concerning the keeping of records or statistics laid down in section 10;
  - 8) violates the notification obligation laid down in section 23(1); or
  - 9) violates a prohibition or order issued under section 47
- shall be sentenced to a fine *for violating the Act on the Protection of Animals Used for Scientific or Educational Purposes*, unless a more severe penalty is laid down for the deed elsewhere in the law.
- (2) For a person who violates a prohibition or obligation imposed under this Act and intensified by a notice of a conditional fine the sentence may be waived for the same deed.

#### Section 52 – *Reference provisions concerning penalties*

- (1) Provisions on the penalty for an animal welfare infringement are laid down in section 54 of the Animal Welfare Act.
- (2) Provisions on the penalty for an animal welfare offence are laid down in Chapter 17, section 14, 14a and 15 of the Criminal Code (39/1889).

#### Chapter 11 – **Miscellaneous provisions**

##### Section 53 – *Council on the protection of animals used for scientific or educational purposes*

- (1) The council on the protection of animals used for scientific or educational purposes operates in connection with the Regional State Administrative Agency for Southern Finland. The aim of the council is to promote the implementation of the principle of replacement, reduction and refinement. The Government appoints the council for five years at a time.
- (2) Provisions on the tasks, composition and organisation of the activity of the council are laid down by Government Decree.

##### Section 54 – *Charges*

- (1) A charge is collected to the state for a performance by an authority and the project authorisation board. The provisions of the Act on Criteria for Charges Payable to the State (150/1992) shall be complied with in imposing the charges.

##### Section 55 – *Remunerations and compensations for costs*



- (1) The chair, vice-chair and members of the project authorisation board receive remuneration for the tasks they have carried out and compensation for travel costs in accordance with criteria ratified by the Ministry of Agriculture and Forestry.

#### Section 56 – *Appeal*

- (1) A decision of an authority and the project authorisation board made under this Act is appealed to the Administrative Court as laid down in the Administrative Judicial Procedure Act (586/1996). A decision of the Administrative Court may be appealed only if leave to appeal is granted by the Supreme Administrative Court. The provisions of the Act on Criteria for Charges Payable to the State apply to an appeal concerning a charge referred to in section 54 above.
- (2) In a decision made under this Act it may be ordered that the decision shall be complied with irrespective of appeal, unless otherwise provided by the appellate authority.
- (3) An appeal against a decision made under this Act concerning animal welfare shall be processed as urgent.

### Chapter 12 – **Entry into force and transitional provisions**

#### Section 57 – *Entry into force*

- (1) This Act enters into force on 1 August 2013.
- (2) This Act repeals the Act on the Use of Animals for Experimental Purposes (62/2006), hereinafter referred to as *the repealed act*. However, the Decree on the Use of Animals for Experimental Purposes (623/2006) issued under the repealed act remains in force.
- (3) Measures necessary for the implementation of the Act may be undertaken before the entry into force of the Act.

#### Section 58 – *Transitional provisions*

- (1) A person who has received or retained the qualifications for performing animal experiments under the repealed act shall be considered qualified to design projects and perform procedures.
- (2) An experimental animal establishment approved under the repealed act which is in operation upon the entry into force of this Act shall notify the competent authority referred to in section 21(1) of this Act within three months from the entry into force of this Act of:
  - 1) whether animals are kept for breeding, supplying or use for scientific or educational purposes;
  - 2) name and contact information of the person responsible for the activity;
  - 3) names and contact information of persons responsible for an establishment referred to above in section 7(3) of this Act; and
  - 4) composition of the animal welfare body referred to above in section 9(1) of this Act.
- (3) The provisions and authorisation conditions in force upon the entry into force of this Act apply to animal experiment authorisations granted under the repealed act if the animal experiment ends no later than 1 January 2018. For an animal experiment for which an authorisation has been granted before the entry into force of this Act and which ends after 1 January 2018 there shall be a project authorisation under this Act no later than 1 January 2018.
- (4) An animal experiment board in operation upon the entry into force of this Act continues its activity as a project authorisation board until a project authorisation board is appointed.