Act of 12 January 1977, concerning rules relating to scientific procedures on animals

This is a non-official English translation of the Dutch Act on Animals used for scientific purposes. Where appropriate specific reference is made to elements of the EU Directive 2010/63/EU.
Suggestions for changes and corrections are welcome. Please send them to j.b.prins@lumc.nl and/ or m.fentener@erasmusmc.nl.

§ 1. General

Article 1

1. For the purposes of the provisions under this act[1] the following is understood:

a. *Procedure:* any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of 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. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, and also includes the killing of animals solely for the use of their organs or tissues or body fluids for a purpose mentioned in article 1c;
b. *project:* a programme of work having a defined scientific objective and involving one or more procedures;
c. *establishment*: any installation, building, group of buildings or other premises and may include a place that is not entirely enclosed or covered, and mobile facilities;
d. *breeder:* any natural or legal person breeding animals as referred to in the Directive in order to use these in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not;
e. *supplier:* any natural or legal person, other than a breeder, supplying animals to be used in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not;
f. *user:* any natural or legal person using animals in procedures, whether for profit or not;
g. *debilitating condition:* a restriction of the normal physical or psychological ability of a person to function[2];
h. *self-sustaining breeding colony:* a colony in which animals are bred only within the colony or are acquired from other colonies but are not taken from the wild and where the animals are kept in such a way that they are accustomed to humans;
i. *Directive:* the directive to be designated by Our Minister.

2. For the purposes of the provisions under this act shall also mean:

Our Minister: Our Minister of Economic Affairs;

Inspector: on the basis of a designation under Article 20: the locally competent inspector of the national public health inspectorate.

3. An amendment to the Directive will apply for the application of the provisions under or pursuant to the Law on animal experimentation with effect from the date on which the amended Directive will have to be implemented.

Article 1a

Upon exercise of powers by or under this Act the recognition of the intrinsic value of the animal is used as a general principle.

[1] Largely according to EUDir Article 3
[2] EUDir Article 8.1.a.i

Article 1b[3]

1. This act shall apply where animals:

a. Are used for scientific or educational purposes; or
b. Are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.

2. This act shall apply until the animals referred to in the first subparagraph have been killed, rehomed or returned to a suitable habitat or husbandry system.

3. This act shall apply to all animals present at a breeder, supplier, and user, except insofar as it can be demonstrated that the animals are present for purposes other than those listed in the first paragraph..

4. The elimination of pain, suffering, distress or lasting harm by the adequate level of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Act.

5. This act shall apply to the following animals:

a. live non-human vertebrate animals, including:
   - **independently feeding larval forms; and**
   - **foetal forms of mammals as from the last third of their normal development;**
b. live cephalopods, and other invertebrate species designated by general administrative order, which can reasonably be expected to suffer when used in a procedure.

6. This Act shall apply to animals used in procedures which are at an earlier stage of development than that referred to in point (a) of paragraph 5, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.

7. This act shall not apply to the following:

a. non-experimental agricultural practices;
b. non-experimental clinical veterinary practices;
c. veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;
d. practices undertaken for the purposes of recognised animal husbandry;
e. practices undertaken for the primary purpose of identification of an animal;
f. 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.

Article 1c[4]

Notwithstanding article 2, second and third paragraphs, procedures may be carried out for the following purposes only:

a. basic research;
b. translational or applied research with any of the following aims:
   - the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;
   - the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or
   - the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;
c. any of the aims in point b regarding the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;
d. protection of the natural environment in the interests of the health or welfare of human beings or animals;

[3] Largely according to EUDir Article 1
[4] Largely according to EUDir Article 5

e. research aimed at preservation of the species;
f. higher education, or training for the acquisition, maintenance or improvement of vocational skills;
g. forensic inquiries

Article 1d[5]

1. A procedure shall be performed only when the objective cannot be obtained with a scientifically satisfactory method or testing strategy not entailing the use of live animals.

2. The number of animals used in projects shall be reduced to a minimum without compromising the objectives of the project.

3. Breeding, accommodation and care, and methods used in procedures, shall be refined to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. When a choice of methods as meant in the first paragraph is possible, the choice shall be made in accordance with article 10, second paragraph.

Artikel 1e[6]

1. When in a new procedure an animal on which no procedure has previously been carried could also be used, an animal already used in one or more procedures may only be reused provided that the following conditions are met:

a. the actual severity of the previous procedures was 'mild' or 'moderate';
b. it is demonstrated that the animal's general state of health and well-being has been fully restored;
c. the further procedure is classified as 'mild', 'moderate' or 'non-recovery'; and
d. it is in accordance with veterinary advice, taking into account the lifetime experience of the animal.

2. In exceptional circumstances, by way of derogation from point a of paragraph a, a project license may be issued for a project in which animals are reused, if:

a. a veterinarian has examined the animal prior to the procedure; and
b. the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

§ 2. Establishment license

Article 2

1. It is prohibited to perform procedures without an establishment license from Our Minister.

2. The establishment license regarding the use of animals in procedures as referred to in article 1c, points b to and including f, shall be valid only for procedures aimed at the interest of human or animal health or nutrition, whether or not directly.

3. If Our Minister considers that a significant other interest so warrants, he may provide for the establishment license that it also applies to the execution of procedures as intended by article 1c, points b to and including f, aimed at the other interest as mentioned in the establishment license, whether or not directly.

4. Pursuant to article 28, first paragraph, last sentence of the Act on Services[7], paragraph 4.1.3.3. of the General Administrative Law Act[8] shall not apply to an application for an establishment license referred to in the first paragraph.[9]

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[5] Largely according to EUDir Article 4
[6] Largely according to EUDir Article 16
[7] Dienstenwet
[8] Algemene wet bestuursrecht
[9] Implementing EUDir Article 2.2

Article 3

1. Our Minister may lay down rules specifying what information shall be provided with the application for an establishment license and after the establishment license has been issued.

2. A fee as determined by Ministerial Regulation is due together with an application. The fee referred to in the preceding sentence shall be such that it covers the cost of processing the application.

Article 4

1. A decision on an application for an establishment license shall be issued within eight weeks. Our Minister can extend this term once with a maximum of eight weeks.

2. Our Minister shall decide in accordance with other Ministers concerned.

3. The licensing of an establishment shall be announced in the Government Gazette[10]. The main points of the establishment license with regard the purpose of the procedures and the restrictions and conditions as laid down by the establishment license shall be listed. Application of the preceding sentence can be omitted in case there are objections, provided that grounds for this are indicated in the notice.

Article 5

An establishment license can only be refused if:

a. there is well-founded apprehension that the licensee would not observe the rules applicable to him under this Act;
b. a previously granted establishment license to this applicant has been revoked on other grounds than those mentioned in article 7, second paragraph, under b, and two years have not yet passed since the decision on withdrawal became final.

Article 6

1. An establishment license may be granted subject to restrictions and for a limited period.

2. Conditions may be attached to an establishment license. The conditions may be amended, supplemented or withdrawn.

3. In the establishment license is specified[11]:
a. the person within the establishment responsible for ensuring compliance with the law;
b. the persons referred to in article 13f, third paragraph; and
c. the person referred to in article 14.

Article 7

1. An establishment license shall be revoked if:

a. the information provided with the application proves to be so incorrect or incomplete that a different decision would have been taken if the correct conditions had been known during the evaluation of the application.
b. there has been a significant change to the structure or the function of an establishment of a user that could negatively affect the animal welfare.

2. An establishment license may otherwise be revoked if:

a. the licensee has not complied with the requirements set by this Act and applicable to him;
b. no operations have been carried out using the establishment license for a continuous period of one year.

3. In cases where the establishment license may be revoked, may, instead, a restriction be added to the establishment license.

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[10] Staatscourant

[11] EUDir Article 20

4. Article 4, second paragraph shall apply mutatis mutandis.

5. A decision taken pursuant to the first or second paragraph shall be published in the Government Gazette.

Article 8

1. An establishment license under this Act shall be granted to a natural person or a legal entity; it is bound to the natural or legal person to whom it was issued.

2. If the licensee is a natural person, the establishment license shall remain effective to the benefit of the assignees for a period of six months after the licensee has passed away. Where an application for a new establishment license has been submitted within this period, the former establishment license remains in effect until a final decision has been made on the application. Article 7 shall apply for the duration of this establishment license.

§ 3. Procedures and projects

Article 9

It is prohibited to conduct a procedure if the person designing the project and the procedure does not meet the requirements on expertise and competence pursuant general administrative order [12].

Article 10

1. It is prohibited to conduct a procedure with an objective:

a. that, according to generally knowable, expert opinion, can also be achieved through other means than a procedure, or a procedure with fewer animals or less harm than is the case with the procedure in question;
b. that can be achieved using another method or test strategy not entailing the use of live animals, which is recognised under the legislation of the European Union[13];
c. where the benefit does not outweigh the harm to the animal.

2. In case there are different options to conduct a procedure, the procedure is selected that best meets the following criteria and is expected to provide satisfactory results:

a. the minimum number of animals shall be used;
b. the animals being used are those animals that are the least sensitive to pain, suffering, distress or lasting harm;
c. the procedure concerned shall cause the least pain, suffering, distress or lasting harm to the animals.

3. It is prohibited to conduct a procedure by means of LD50/LC50 test-methods.

4. The prohibition referred to in the third paragraph may be waived by Our Minister for a period of five years maximum if it is demonstrated that there is no alternative to the methods mentioned in that paragraph.

Article 10a

1. It is forbidden to carry out a project without a project license from the Central Authority for Scientific Procedures on Animals.[14]

2. Upon submission of a project license application a project proposal is added that has been aligned with the animal welfare body.

3. The Central Authority for Scientific Procedures on Animals shall reach a on a project proposal after consultation of an ethical review committee pursuant article 18a and pursuant articles 2, second and third paragraph, 9, 10, 10a2, 10a4, 10b, 10d to and including 10h, 11, 13 and 13f.

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[12] Decree / Het Dierproevenbesluit 2014

[13] Largely according to EUDir Article 4.1

[14] Centrale Commissie Dierproeven (CCD)

4. The costs associated with the advice of a recognised ethical review committee referred to in the third paragraph, shall be covered by the applicant of a project license.

5. Documents and information to be submitted together with an application for a project license shall be determined by Ministerial Regulation. Rules for the application fee that has to be paid upon submission of the application shall be determined by Ministerial Regulation. The application fee referred to in the previous sentence shall be determined such that it covers the cost of processing the application.

6. The receipt of the application for a project authorization shall be acknowledged by the Central Authority for Scientific Procedures on Animals as quickly as possible. Thereby is stated the period within which a decision about the application shall be taken.

7. The project evaluation[15] shall be performed with a degree of detail appropriate for the type of project and that is necessary to assess whether the project meets the criteria as set by article 10a2.

8. The Central Authority for Scientific Procedures on Animals shall give its judgement and makes this known to the applicant within forty working days of receipt of the application. If justified by the complexity or the multi-disciplinary nature of the project, this period may be extended once with a maximum of fifteen working days. The extension and its duration shall be duly motivated and be brought to the notice of the applicant before the expiry of the defined period.[16]

9. Pursuant to article 28, first paragraph, last sentence of the Act on Services[17], paragraph 4.1.3.3. of the General Administrative Law Act[18] shall not apply to an application for a project license referred to in the first paragraph.

10. The project license is limited to the procedures that are part of the project proposal based on which the project evaluation was performed and without prejudice to article 10a5 to the categories of severity in which these procedures have been classified.

Article 10a1

1. The project license referred to in Article 10a, first paragraph, shall specify the following:

    a. the user who undertakes the project;
    b. the persons responsible for the overall implementation of the project and its compliance with the project license;
    c. the establishments in which the project will be undertaken, where applicable; and
    d. any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.

2. Conditions may be attached to the project license referred to in 10a, first paragraph.

3. Projects involving non-human primates and projects involving procedures classified as severe or a procedure referred to in article 10b, second paragraph, shall undergo a retrospective assessment.

4. The project authorization referred to in Article 10a, first paragraph, shall be granted for a period not exceeding five years.

5. A project license may cover multiple generic projects to be carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.

6. The Central Authority for Scientific Procedures on Animals shall accept data resulting from a procedure conducted in another Member State, which has been adopted on the basis of legislation of the European Union, unless further animal testing is necessary in connection with

[15] EUDir Art. 38
[16] EUDir Art. 41
[17] Dienstenwet
[18] Algemene wet bestuursrecht

that information to protect the public health, safety or the environment.

7. The non-technical summary of the project for which the Central Authority for Scientific Procedures on Animals has granted a project license and any supplements thereto shall be published by or pursuant to a general administrative order[19]. Rules on the submission of the non-technical summary and any supplement thereto by the applicant or licensee shall be set by Ministerial Regulation.

8. If the proposed project requires the release of the animal in question, a project license will be granted only if the Central Authority for Scientific Procedures on Animals has been assured that everything possible will be done to ensure the welfare of the animal and release will only take place if the state of health of the animal allows such and no there is no risk to public health and the environment.

Article 10a2[20]

1. The Central Authority for Scientific Procedures on Animals shall issue a project license for a project only where:

a. the project is justified from a scientific or educational point of view or required by law;
b. the aims of the project justify the use of animals;
c. the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible; and
d. the project is designed in accordance with article 9.

2. The project evaluation shall consist in particular of the following:

a. an evaluation of the objectives of the project and the predicted scientific benefits or educational value;
b. an assessment of the compliance of the project with article 10;
c. an assessment of the classification of the severity of procedures;
d. a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;
e. an assessment of the reasons why being deviated from the under or by or pursuant to the provisions of the articles 1e, first paragraph, 10e, second to and including fourth paragraph, 10f, first and fourth paragraph, 10g, first paragraph, 10h, first paragraph, 11, first paragraph, 13, third paragraph, 13c, second paragraph, or of the reasons referred to in Article 13f, second paragraph, section f;
f. a determination as to whether and when the project should be assessed retrospectively.

3. Where pursuant to Article 10a1, first and third paragraphs, it was decided that the project shall be assessed retrospectively, the Central Authority for Scientific Procedures on Animals assesses the following aspects, after consultation of the ethical review committee which has given prior advice on the project proposal, on the basis of the documentation submitted by the user as indicated by the Central Authority for Scientific Procedures on Animals:[21]

a. whether the objectives of the project were achieved;
b. the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and
c. any elements that may contribute to the further implementation of article 10.

Article 10a3

Before a user starts with the execution of a procedure that is part of a project for which a project license has been granted, the execution thereof shall be aligned with the animal welfare body.

Article 10a4[22]

1. By or pursuant to a general administrative order a simplified administrative procedure for projects

[19] Decree / Dierproevenbesluit 2014
[20] Largely according to EUDir Article 38
[21] Largely according to EUDir Article 39, first paragraph
[22] Largely according to EUDir Article 42

containing procedures classified as non-recovery, mild or moderate and not using non-human primates may be adopted if:

a. these projects are necessary to satisfy regulatory requirements;
b. in these projects animals are being used for production or diagnostic purposes with established methods; or
c. in these projects animals are being killed solely for the purpose of obtaining organs and tissues.

2. When a simplified administrative procedure applies, a project shall be evaluated according to article 10a, third and seventh paragraph, and the term mentioned in article 10a, eighth paragraph, first sentence shall not be exceeded.

3. Where a project, which has been assessed under a simplified procedure, is changed in a way that may have a negative impact on animal welfare, the project can only go ahead if the Central Authority for Scientific Procedures on Animals has given a favourable judgement on the change.

4. Articles 10a, first and sixth paragraphs, 10a1, fourth and fifth paragraphs and 10a5, fourth paragraph, shall apply to a project to which the simplified procedure applies.

Article 10a5[23]

1. Where a project for which the Central Authority for Scientific Procedures on Animals has granted a project license, is changed in a way that may have a negative impact on animal welfare, the change shall be submitted for review to the Central Authority for Scientific Procedures on Animals.

2. A changed project referred to in the first paragraph may only take place if the Central Authority for Scientific Procedures on Animals has given a favourable judgement on the changed project.

3. The amendments referred to in the first paragraph shall be assessed in accordance with article 10a2. Article 10a, third, seventh and eighth paragraphs, shall apply mutatis mutandis.

4. The Central Authority for Scientific Procedures on Animals may withdraw the project license where the project is not carried out in accordance with the project license.

Article 10b[24]

1. A procedure shall be classified as non-recovery, mild, moderate or severe by the user according to the criteria specified in the Directive.

2. It is prohibited to perform a procedure if it involves severe pain, suffering, distress or lasting harm that is likely to be long-lasting and cannot be ameliorated.

3. If due to exceptional circumstances and scientifically justifiable reasons it is necessary to perform procedures that involve severe pain, suffering or distress that are likely to be long-lasting and cannot be ameliorated[25], Our Minister may grant an exemption of the second paragraph for a maximum of five years. This period may be extended once for a period of five years.

Article 10c

1. It is forbidden to execute a procedure otherwise than in accordance with the project license, unless the change has no or positive impact on the animals welfare according to judgement of the animal welfare body.

2. A change referred to in the first paragraph shall be reported to the Central Authority for Scientific Procedures on Animals.

Article 10d

It is forbidden to execute a procedure for development of new or testing of existing cosmetics

[23] Largely according to EUDir Article 44
[24] Largely according to EUDir Article 15
[25] Largely according to EUDir Article 55.3

covered by rules under the Commodities Act[26].

Articles 10e[27]

1. It is forbidden to execute a procedure using the following species:

- chimpanzee (pan troglodytes)
- bonobo (pan paniscus)
- orang-utan (pongo pygmaeus)
- gorilla (gorilla gorilla).

2. Other non-human primates than those listed in the first and referred to in the third paragraph shall not be used in procedures, unless it is demonstrated that the objective of the procedure cannot be achieved by the use of animals belonging to a species other than a non-human primate species by means of a scientific justification and the procedure has a purpose as referred to in:

a. article 1c, section b, first indent, or section c and has the aim and is undertaken in view of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or
b. article 1c, section a or e.

3. Notwithstanding the first paragraph, non-human primates belonging to species designated under a general administrative order shall not be used in a procedure, unless it is shown that the objective of the procedure cannot be achieved through the use of animals belonging to a species other than a non-human primate species by means of a scientific justification, and the objective cannot be achieved by the use of animals belonging to another non-human primate species than designated in a general administrative order and the purpose of the procedure is one as referred to in:

a. article 1c, section b, first indent, or section c, and has the purpose and is undertaken in view of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening diseases clinical conditions in human beings; or
b. article 1c, section e.

4. Animals, other than non-human primates, and belonging to endangered species or endangered species designated under a general administrative order shall not be used in a procedure, unless it is demonstrated that the purpose of the procedure cannot be achieved through the use of animals belonging to species than the endangered species designated under a general administrative ruling by means of a scientific justification and the purpose of the procedure is one as referred to in article 1c, section b, first indent, section c, or section e.

5. Notwithstanding the provisions in the first paragraph, non-human primates shall only be used in procedures where they are offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies from the date set by the Directive.

6. Breeders of non-human primates shall apply a strategy with the aim to increase the proportion of animals that are offspring of non-human primates bred in captivity.

7. Notwithstanding the first paragraph, Our Minister may grant an exemption for five years for the use of non-human primates for the aims referred to in article 1c, section b, first indent, or section c if there is scientific justification that the use of non-human primates is essential for humans, and is not undertaken in view of the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions and as far as the aim cannot be achieved through the use of an another species than a non-human primate. This period may be extended once for a period of five years.

Article 10f[28]

1. Animals taken from the wild shall not be used in procedures.

2. Notwithstanding the first paragraph, a project license may be granted for a project which contains a procedure referred to in the first paragraph, if it is shown that the aim of the procedure cannot

[26] Warenwet
[27] Largely according to EUDir Article 8, 7, 10
[28] Largely according to EUDir Article 9

be achieved through the use of an animal that has been purpose bred for use in a procedure by means of a scientific justification.

3. The capture of animals in the wild shall be carried out only by competent persons using methods which do not cause the animals avoidable pain, suffering, distress or lasting harm.

4. Any animal found, at or after capture, to be injured or in poor health shall be examined by a veterinarian or another competent person. With regard to these animals measures are taken in order to allow the animals to suffer as little as possible.

5. Notwithstanding the fourth paragraph, the measures referred to in paragraph 4 may be waived if there is scientific justification.

Article 10g[29]

1. Procedures shall be carried out in a user's establishment.

2. Notwithstanding the first paragraph a project license may be granted for a project in which procedures are carried out outside of a user's establishment if is demonstrated by scientific justification that the objective of the procedure cannot be achieved if the procedure is carried out in a user's establishment.

3. Procedures may be carried out only within the framework of a project.

Article 10h[30]

1. Stray and feral animals of domestic species shall not be used in procedures.

2. Notwithstanding the first paragraph a project license may be granted for a project in which the animals referred to in the first paragraph are being used. if:

a. there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health; and
b. there is scientific justification to the effect that the purpose of the procedure can be achieved only by the use of a stray or a feral animal.

Article 11[31]

1. Animals belonging to the species listed in the Directive may only be used in procedures where those animals have been bred for use in procedures.

2. Notwithstanding the first paragraph a project license may be granted for a project in which procedures are carried out with animals have not been bred for use in procedures if is demonstrated by scientific justification that the aim of the procedure cannot be achieved if the procedure is carried with an animal that has been bred for use in procedures.

Article 11a

1. It is forbidden to breed or deliver animals in view of their use in procedures without an establishment license of Our Minister.

2. A license referred to in the first paragraph may be refused only if the requirements regarding organisation and personnel as designated under a general administrative order are not met.

The articles 3 to and including 7 shall apply mutatis mutandis.

3. Pursuant to article 28, first paragraph, last sentence of the Services Act, paragraph 4.1.3.3. of the General Administrative Law Act shall not apply to an application for a license referred to in the first paragraph.

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[29] Largely according to EUDir Article 12
[30] Largely according to EUDir Article 11
[31] Largely according to EUDir Article 10

Article 12 [Revoked 18-12-2014]

Article 13[32]

1. A procedure is carried out under general or local anaesthesia unless it is inappropriate, and that analgesia or another appropriate method is used to ensure that pain suffering, distress or the lasting harm of the animal are kept to a minimum. A procedure that involves serious injuries that may cause severe pain shall not be carried out without anaesthesia.

2. When deciding on the appropriateness of using anaesthesia, the following shall be taken into account:

a. whether anaesthesia is judged to be more traumatic to the animal than the procedure itself; and
b. whether anaesthesia is incompatible with the purpose of the procedure.

3. An animal shall not be given any drug to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia. Notwithstanding the previous sentence, if an animal is given a drug to stop or restrict their showing pain, the use of this drug shall be scientifically justified. The justification shall be accompanied by the details of the anaesthetic and analgesic regimen.

4. Animals, which may suffer pain once anaesthesia has worn off, shall be treated with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods provided that it is compatible with the purpose of the procedure.

5. As soon as the purpose of the procedure has been achieved appropriate action shall be taken to minimise the suffering of the animal.

Article 13a[33]

1. A procedure shall be deemed to end when no further observations are to be made for that procedure or, as regards new genetically modified animal lines, when the progeny are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle.

2. At the end of a procedure, a decision to keep an animal alive shall be taken by a veterinarian or by another competent person. An animal shall be killed when it is likely to remain in moderate or severe pain, suffering, distress or lasting harm.

3. Where an animal is to be kept alive, it shall receive care and accommodation appropriate to its state of health.

Article 13b[34]

1. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points.

2. Where death as the end-point is unavoidable, the procedure shall be designed so as to:

a. result in the deaths of as few animals as possible; and
b. reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

Artikel 13c[35]

1. Animals are killed by a competent person with minimum pain, suffering and distress in the establishment of a breeder, supplier or user. However, in the case of a field study, an animal may be killed by a competent person outside of an establishment of a breeder, supplier or user.

2. In relation to the animals covered by the Directive, the appropriate method of killing as set by

[32] Largely according to EUDir Article 14
[33] Largely according to EUDir Article 17
[34] Largely according to EUDir Article 13, third paragraph
[35] Largely according to EUDir Article 6

the Directive shall be used.

3. Notwithstanding the second paragraph a project license may be granted for a project in which a method of killing is used, which is not set by the Directive, if is demonstrated by scientific justification that the aim of the procedure cannot be achieved with the methods as set by the Directive. Furthermore, Our Minister may grant an exemption or derogation from the second paragraph, if the alternative method of killing is considered at least as humane as the appropriate methods as set by the Directive, on the basis of scientific justification.

Where an animal has to be killed in emergency situations for animal welfare, public health, public security, animal health or environmental reasons this may be done outside of the establishment of a breeder, supplier or user by a person other than a competent person. In that case the second and third paragraph shall not apply.

Article 13d[36]

Animals used or intended to be used in procedures may be allowed to be released for adoption or returned to a suitable habitat or husbandry system appropriate to the species, if:

a. the state of health of the animal allows it;
b. there is no risk to public health, animal health or the environment; and
c. appropriate measures have been taken to safeguard the well-being of the animal.

§ 4. Requirements for breeder, supplier and user

Article 13e[37]

The breeders, suppliers and users from which animals are intended to be rehomed shall have a rehoming scheme in place that ensures socialisation of the animals that are rehomed.
In the case of wild animals, where appropriate, a programme of rehabilitation shall be in place before they are returned to their habitat.

Article 13f[38]

1. Without prejudice to their obligation to comply with the relevant regulations related to their establishment license or exemption, the breeder, supplier and user are obliged to ensure they have sufficient staff and the animals are properly cared for, handled and housed, taking into account rules pursuant to general administrative order.

2. Rules referred to in the first paragraph may relate to:

a. the expertise and competence of those who take care of the animals and kill them;
b. the expertise and competence of those who carry out procedures;
c. the dimension and the construction of the accommodation in which the animals are housed;
d. cleaning and heating of the accommodations;
e. the nutrition of the animals;
f. the option to deviate from the rules referred to in the first paragraph for scientific or animal welfare reasons.

3. The breeder, supplier and the user shall have one or several persons on site who shall:

a. be responsible for overseeing the welfare and care of the animals in the establishment;
b. ensure that the staff dealing with animals have access to information specific to the species housed in the establishment;
c. be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

4. The user shall have persons specified in article 10a1, first paragraph, who ensure that:

[36] Largely according to EUDir Article 19
[37] Largely according to EUDir Article 29
[38] Largely according to EUDir Article 24

a. any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped; and
b. a project is carried out in accordance with the project proposal on the basis of which a project license has been granted and where that is not the case to ensure that appropriate measures to rectify it are taken and recorded.

5. By or pursuant to general administrative order rules may be laid with respect to persons referred to in the third and fourth paragraph.

Article 14[39]

1. Each breeder, supplier and user shall have a designated veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.

2. By or pursuant to general administrative order rules may be laid with respect to the veterinarian or suitably qualified expert referred to in the first paragraph.

Article 14a[40]

1. The breeder, supplier and the user shall set up an animal-welfare body.

2. Notwithstanding the first paragraph, by or pursuant to general administrative order categories of breeders, suppliers and users can be designated which are not required to set up an animal-welfare body. If they do not set up an animal-welfare body, they shall ensure that the functions of the animal-welfare body are carried out in a manner specified in a general administrative order.

3. Any advice of the animal-welfare body and decisions taken will be kept for at least three years.

Article 14b[41]

1. The animal-welfare body shall include at least the person or persons referred to in article 13f, third paragraph, section a. By or pursuant to general administrative order categories of experts may be appointed who also sit on the animal-welfare body.

2. In the case of a user establishment, a scientist will sit on the animal welfare body in addition to the persons referred to in the first paragraph.

3. The person referred to in article 14 shall bring input into the animal-welfare body.

4. The proposal for determining a general administrative order pursuant the first paragraph shall not be made earlier than four weeks after the draft has been presented to both Chambers of the States General[42].

Article 14c[43]

1. The animal-welfare body shall carry out the following tasks:

a. advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
b. advise the staff on the application of the requirement referred to in article 1d of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
c. establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
d. follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement;

[39] Largely according to EUDir Article 25
[40] Largely according to EUDir Article 26
[41] Largely according to EUDir Article 26
[42] Parliament
[43] Largely according to EUDir Article 27

e. advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.

2. By or pursuant to general administrative order additional tasks may be assigned to the animal-welfare body and further rules may be set with regard to the tasks assigned to the animal-welfare body.

Article 15[44]

The breeder, supplier and the user are obliged to record and to submit data to Our Minister with regard to the breeding, the procurement, the supply, the setting free or rehoming, the keeping and killing of animals and with regard to projects in which animals are used in accordance with rules to be set pursuant to general administrative order[45]. By or pursuant to general administrative order additional subjects may be designated on which records shall be kept.

Article 15a[46]

1. The breeder, the supplier and the user shall keep information on each dog, cat and non-human primate by and pursuant to general administrative order[47].

2. Each dog, cat and non-human primate shall have an individual history file, which follows the animal as long as it is kept for the purposes of this Act and fulfils the requirements as set by general administrative order.

3. By or pursuant to general administrative order rules may be set with regard the provision of identification marks with the animals referred to in the first paragraph in connection with the maintenance of a record of these animals.

§ 5. Suspensive effect of appeal

Article 16 [Revoked 18-12-2014]

Article 17

The operation of the decision to amend or revoke an establishment license or exemption shall be suspended until the appeal period has expired or where appeal has been set, has been decided on the appeal.

§ 6. Central Authority for Scientific Procedures on Animals and animal ethics committee

Article 18[48]

1. There shall be a Central Authority for Scientific Procedures on Animals. The committee's task is to exercise the powers referred to in articles 10a, first paragraph, 18a, first paragraph and 18f, first paragraph.

2. The committee consists of a maximum of fifteen members, including the chairperson. In the project evaluation referred to in article 10a2 the committee takes into account in particular the presence of expertise and consists of people who are experts in the field of:

a. scientific areas and areas of scientific use for which the animals will be used including replacement, reduction and refinement in the respective areas;
b. experimental design, including statistics where appropriate;
c. veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;
d. animal husbandry and care, in relation to the species that are intended to be used;
e. ethics;
f. experimental animals and their protection;
g. areas set by or pursuant to general administrative order.

[44] Largely according to EUDir Article 30
[45] Ministerial Regulation
[46] Largely according to EUDir Article 31 and 32
[47] Ministerial Regulation
[48] Paragraph 2 is largely according to EUDir Article 38, third paragraph

3. In the project evaluation the committee may take into account the advice of independent and impartial experts who are not members of the committee.

4. The chair and other members of the committee are appointed for a period of five years. After the expiration of the time for which they are appointed, they may be reappointed for the maximum period of five years.

5. The committee shall appoint from among its members one or more deputies for the chairperson.

6. A deputy may be appointed for each member.

7. Our Minister shall make staff available for the purpose of carrying out the tasks referred to in the first paragraph.

8. The committee shall regulate its procedure by rules. The regulations contain a provision that the evaluation of a project takes place in an independent and impartial manner.

9. The Framework Act on independent administrative bodies[49] applies to the committee in as far it concerns decisions taken by the committee for the implementation of this Act.

10. Before a decision is taken pursuant to article 2, third paragraph, the committee shall be heard.

Article 18a

1. The Central Authority for Scientific Procedures on Animals may accredit animal ethics committees tasked to advise on the evaluation of project proposals referred to in article 10a, third paragraph, in accordance with or pursuant to this Act.

2. An animal ethics committee can only be accredited when is evident from its rules:

a. that it consists of at least seven members, including the chairperson who is not in an employment relationship with the establishment license holder pursuant to article 2, on whose project license application's evaluation an advise is issued;
b. that the committee when advising on the evaluation of a project licence application in particular takes into account the presence of expertise and consists of people who are experts regarding:
   - scientific areas and areas of scientific use for which the animals will be used including replacement, reduction and refinement in the respective areas;
   - experimental design, including statistics where appropriate;
   - veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;
   - animal husbandry and care, in relation to the species that are intended to be used;
   - ethics;
   - experimental animals and their protection;
   - areas set by or pursuant to general administrative order.
c. that at least two of the experts referred to in *b* are not involved in the use of animals in procedures;
d. that in addition to the chairperson, at least half of the number of members is not in an employment relationship with the establishment license holder pursuant to article 2, on whose project license application's evaluation an advise is issued;
e. that, if they are involved in the carrying out of a project, the other members shall not participate in the drafting of the advice on that project license application;
f. that, in the drafting of the advise, the person referred to in article 13f, third paragraph, section a will be involved as an advisor;
g. that the advising on the evaluation of a project licence application takes place in an impartial, independent and impartial manner.

And whose rules also comply with requirements set by general administrative order.

3. The committee may take into account the advice of independent and impartial experts, who are not members of the committee, in the evaluation of a project licence application.

Article 18b

[49] Kaderwet zelfstandige bestuursorganen

1. The Central Authority for Scientific Procedures on Animals shall bring an accreditation referred to in article 18a, first paragraph, to the attention of Our Minister forthwith.

2. Accreditation referred to in article 18a, first paragraph shall be announced in the Government Gazette through the care of Our Minister. Articles 4, first and third paragraph, and 6, first paragraph apply mutatis mutandis, provided it being understood that the Central Authority for Scientific Procedures on Animals is meant where Our Minister has been written.

Article 18c

1. Anyone shall provide data and information to the Central Authority for Scientific Procedures on Animals if requested and shall give access to data and documents that are within reason necessary to the implementation of the tasks referred to in article 18, first paragraph.

2. The Central Authority for Scientific Procedures on Animals may set a deadline by which the data, information and documents referred to in the first paragraph shall be provided.

Article 18d

An accredited animal ethics committee pursuant to article 18a shall notify in writing of a amendment of her rules to the Central Authority for Scientific Procedures on Animals.

Article 18e [Revoked 18-12-2014]

Article 18f

1. The Central Authority for Scientific Procedures on Animals withdraws an animal ethics committee's accreditation if the animal ethics committee:

    a. no longer meets the requirements referred to in article 18a, second paragraph, in view of the conditions of accreditation;
    b. when advising on the evaluation of a project license application does not or insufficiently take into account article 10a, third paragraph, or the policies on the evaluation of project license applications by the Central Authority for Scientific Procedures on Animals.

2. The Central Authority for Scientific Procedures on Animals may withdraw the accreditation if the animal ethics committee within the course of one year has been consulted for advice on less than a certain number of applications as set by general administrative order.

3. The animal ethics committee shall be notified in writing of the withdrawal. Article 18b applies mutatis mutandis.

Article 18g

The members of the animal experiments committees are bound to secrecy all that theirs is known in their capacity, insofar they are not authorized or required in their capacity to communicate it.

§ 7. National Committee for the protection of animals

Article 19[50]

1. There shall be a National Committee for the protection of animals used for scientific purposes.

2. The National Committee performs the following tasks:

    a. advising Our Minister, Central Authority for Scientific Procedures on Animals and the animal-welfare bodies on the acquisition, breeding, accommodation, care and use of animals in procedures;
    b. ensuring sharing of best practice;

[50] Paragraph 2 is largely according to EUDir Article 49

c. exchanging information with National Committees of other Member States on the operation of animal-welfare bodies, the evaluation of project licence applications and ensuring the dissemination of best practices within the European Union;
d. other duties assigned by Our Minister.

3. The National Committee is composed of a maximum of ten members. Article 12 of the Framework Act on Advisory Bodies shall apply mutatis mutandis.

4. A deputy may be appointed for each member.

5. The members of the Committee shall be appointed by Our Minister for a period of five years and members may be suspended and dismissed by Our Minister. After the expiry of the term for which the members have been appointed, they may be reappointed for a term not exceeding five years.

6. The Committee shall appoint two deputies for the chairperson from among its members.

7. The Committee shall regulate its processes by rules.

8. Our Minister shall make staff available to the committee for the purpose of carrying out the tasks referred to in the second paragraph.

9. Article 2 of the Act on compensation advisory bodies and committees shall apply mutatis mutandis.

§ 8. Final provisions

Article 20

1. Civil servants designated by decision of Our Minister are tasked with oversight of compliance with the provisions under or pursuant tot his Act.
2. A decision as referred to in the first paragraph is announced by publication in the Government Gazette.

Article 21 [Revoked 01-01-1998]

Article 22

1. The inspector is authorised to enter a private residence without the consent of the occupant and take with him the necessary equipment.

2. Where provisions for the entry of a location apply in the interest of a procedure, the officials referred to in article 20 shall as much as possible observe these provisions upon entry of that location.

Article 23

1. The breeder, supplier and user will keep all relevant documents, including the project license granted, for at least three years after the expiration of this license and keep these at the disposal of Our Minister.

2. Notwithstanding the first paragraph, documentation of projects that have to be subjected to retrospective assessment, is kept at least until this assessment has been completed.

Article 24

Our Minister is authorised to impose an order subject to administrative penalties to enforce the obligation laid down in Article 5:20, first paragraph, of the General Administrative Law.

Article 25

1. Violation of article 1c, 1d, 1e, 2, 9, 10, 10a, first and second paragraph, 10a4, third paragraph, 10a5, first paragraph, 10b, second paragraph, 10c, 10d, 10e, 10f, 10g, 10h, 11, 11a, first paragraph, 13, 13a, second and third paragraph, 13b, 13c, 13d, 13e, 13f, 14, 14a, 14b, 14c,

15, 15a and 23, or of a regulation pursuant to article 6, second paragraph, 10a1, second paragraph, 11a, second paragraph, of 16, second paragraph, attending an establishment license, project license, recognition or exemption, is prosecutable.

2. Acting in violence of articles 1c, 1d, 1e, 2, 10, 10a, first and second paragraph, 10a4, third paragraph, 10a5, first paragraph, 10b, second paragraph, 10c, first paragraph, 10d, 10e, 10f, 10h, 11, 11a, first paragraph, 13, 13a, second and third paragraph, 13b, 13c en 13d, 13f, first, third paragraph, section a, and fourth paragraph, is a crime. The other offenses according to the first paragraph are violations.

3. The offences defined as crimes according to the second paragraph, are punished with imprisonment not exceeding six months or a fine of the fifth category; the offences that are violations according to the second paragraph, are punished with imprisonment not exceeding three months or a fine of the fourth category.

Article 26

The investigation of the offenses referred to in article 25 can be done by the officials referred to in article 141 of the Code of Criminal Procedure[51], and the officials referred to in article 20.

Article 27

For those, for whom at the time article 2, first paragraph comes into force, the carrying out of procedures belongs to its scope of activities, the prohibition stated in that paragraph shall not apply during three months after that date, and, if within that period an application for a license referred to in that paragraph has been submitted, moreover not until the order making a decision on the application, has become final. Article 4, first paragraph, continues inapplicable with regard to such a licence application.

Article 28

After the entry into force of the Act of (date) amending the Act on animal experimentation (Stb. Year and number) the Decree[52] is also based on article 13f of this Act.

Article 29

This Act may be cited as the Law on animal experimentation.

Article 30

1. Article 18 of this Law shall enter into force on the day following the date of issue of the Government Gazette in which it is published.

2. Her various other provisions enter into force on times to be determined by Us.

We order and command that this be published in the Government Gazette and that all ministries, authorities, bodies and officials whom it may concern shall enforce the diligent implementation.

Gegeven ten Paleize Soestdijk, 12 januari 1977, JULIANA.

De Staatssecretaris van Volksgezondheid en Milieuhygiëne, HENDRIKS.

Uitgegeven de tweeëntwintigste februari 1977.

De Minister van Justitie, VAN AGT.

[51] Wetboek van Strafvordering

[52] Dierproevenbesluit