

GWT -Gesellschaft für wissenschaftlichen Tierschutz mbH- commissioned an aiic conference interpreter\*) to produce an English translation of the "Regulation for the Protection of Animals Used for Experimental or Other Scientific Purposes (Animal Welfare Regulation Governing Experimental Animals - TierSchVersV) of 1st August, 2013 (Federal Law Gazette [BGBl. I p. 3126)".

GWT, together with Charles River Research Models and Services Germany GmbH and TransMIT GmbH, project area laboratory animal science – hereinafter called Providers – assumed responsibility for the funding.

**Liability disclaimer of the conference interpreter, GWT mbH and the other Providers mentioned:**

**The conference interpreter made the translation to the best of his knowledge and ability and was not influenced by any third parties. He does not assume any guarantee beyond this assurance.**

**The Providers cannot warrant that the content of the translation made is correct, complete and up-to-date. In the event of any discrepancies, the German version shall have exclusive validity.**

**The translation of the German Animal Welfare Act is intended to provide guidance to the requirements of that Act for the benefit of non-German speakers. All statements should be seen in the context of the German-language Animal Welfare Act.**

**The translation merely serves as an indication and can thus in no way replace skilled individual advice from an attorney-at-law on the basis of the German version of the Animal Welfare Act.**

<sup>1)</sup> The contact data of the aiic conference interpreter can be obtained from GWT.

Munich, 26.01.2015

# Regulation for the Protection of Animals Used for Experimental or Other Scientific Purposes (Animal Welfare Regulation Governing Experimental Animals - TierSchVersV)

German acronym TierSchVersV

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Quotation in full:

“Animal Welfare Regulation Governing Experimental Animals of 1st August, 2013 (Federal Law Gazette [BGBl. I pp. 3125, 3126), amended by Article 6 of the Regulation of 12th December, 2013 (BGBl. I p. 4145)”

**Note:** Amendment by article 6 Reg of 12.12.2013 I 4145 (no. 72) established in text form, document not yet finally processed

## Footnote

(+++ Text established, document not yet processed +++)

(+++ Official reference by the legislator to EC law:

Implementation of

EU Dir. 63/2010 (CELEX no: 320010L0063) +++)

The Reg. was adopted as Article 1 of the Reg. of 1.8.2013 I 3125 by the Federal Ministry of Food, Agriculture and Consumer Protection after hearing the Animal Welfare Commission, in agreement with the Federal Ministries of Education and Research, the Environment, Nature Conservation and Reactor Safety, Transport, Building and Urban Development, Economics and Technology and Defence, with the consent of the Bundesrat (Federal Council). Pursuant to Article 4 of this Reg., it entered into force on 13.8.2013.

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## **Chapter 1 Keeping vertebrates and cephalopods for use in animal experiments or for other scientific purposes**

### **Sub-chapter 1 Requirements concerning keeping and concerning facilities and establishments**

#### **Section 1 Requirements concerning the keeping of vertebrates and cephalopods**

(1) The director of a facility or the person responsible for an establishment in which vertebrates or cephalopods are kept which are intended for use in animal experiments or whose tissue or organs are intended to be used for scientific purposes shall ensure that

1. the animals are kept, also while they are being used in animal experiments, in a manner that complies with the requirements resulting from Annex III to Directive 2010/63/EU of the European Parliament and of the Council of 22nd September, 2010, on the protection of animals used for scientific purposes (OJ L 276 of 20.10.2010, p. 33) in the version applicable at any particular time,
2. at least once a day the animals' state of health is checked by means of a direct inspection, and the conditions under which they are kept and the proper functioning of the resources

used for keeping them are checked by means of suitable measures,

3. the animals are transported in such a way that they are not caused any avoidable pain, suffering or distress, and
4. remedial action is taken without delay as soon as it is established that the requirements specified in numbers 1 to 3 are not being met or the animals are being caused avoidable pain, suffering or distress.

Where Article 33(2) in combination with Annex III to Directive 2010/63/EU stipulates that requirements must be applied as of a time specified there, sentence 1 number 1 shall be applied as of the time specified there. Sentences 1 and 2 shall also apply to facilities and establishments in which the animals mentioned there are bred or kept for the purpose of being supplied to third parties.

(2) The competent authority may authorise exceptions to the requirements under subsection 1 sentence 1 number 1 if

1. it is shown, with scientific reasoning, that this is indispensable in view of the purpose of the animal experiment, or
2. this is necessary for reasons of animal welfare or animal health.

(3) This shall not prejudice Appendix A of the European Convention of 18th March, 1986, for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes.

## **Section 2 Requirements concerning the killing of vertebrates and cephalopods**

(1) Vertebrates and cephalopods defined in Section 1 subsection 1 may only be killed

1. on the premises of a facility or establishment for the purposes of Section 1 subsection 1,
2. by a person who meets the requirements of Appendix 1 Chapter 2, and
3. under anaesthesia, when stunned, or otherwise only when the greatest possible care has been taken to prevent pain and suffering.

Premises for the purposes of sentence 1 number 1 shall also mean mobile or only partially enclosed or roofed locations. Sentence 1 number 1 shall not apply if an animal is killed in the course of an animal experiment which is conducted outside a facility or establishment under Section 15 subsection 1 sentence 3. Sentence 1 number 2 shall not apply if an animal is killed in the course of an animal experiment which serves basic, further or advanced training purposes, provided the killing takes place in the presence and under the supervision of a person who meets the requirements needed under sentence 1 number 2.

(2) Furthermore, vertebrates defined in Section 1 subsection 1 may only be killed subject to the provisos of Appendix 2, the method to be used being the one which

1. means the least stress for the animal and
2. is compatible with the purpose of the experiment.

Sentence 1 shall not apply to the killing of animals

1. which are unconscious and insensitive, provided they do not recover consciousness and sensibility before death and provided that the lack of consciousness and sensibility is monitored until the death of the animal is established with certainty, or
2. which are used in agricultural research, if the purpose of the experimental project makes it necessary for the animals to be kept under comparable conditions to the keeping of farm or working animals for gainful purposes and they are killed in a manner that satisfies the requirements of Annex I to Regulation (EC) No. 1099/2009 of the Council of 24th September, 2009, on the protection of animals at the time of killing (OJ L 303 of 18.11.2009, p. 1) in the version applicable at any particular time.

(3) The competent authority can authorise the use of a method of killing that does not comply with the requirements of subsection 2 sentence 1 if

1. according to scientific knowledge, that method does not involve greater pain and suffering than a method that does comply with the requirements or

2. in a case where an animal is killed in the context of being used in an animal experiment, it is explained with scientific reasoning that the use of that method is indispensable and ethically acceptable in view of the purpose of the animal experiment.

### **Section 3 Requirements concerning expertise**

(1) The director of a facility or the person responsible for an establishment for the purposes of Section 1 subsection 1 shall ensure that

1. the persons entrusted with caring for the animals possess the knowledge and skills laid down in Annex 1 Chapter 1 and
2. the persons entrusted with killing the animals possess the knowledge and skills laid down in Annex 1 Chapter 2.

Sentence 1 shall not apply to persons who carry out the activities mentioned there for the purpose of basic, further or advanced training in the presence and under the supervision of a person with the knowledge and skills required under sentence 1 numbers 1 or 2.

(2) The person under the obligation laid down in subsection 1 sentence 1 shall also ensure that persons under subsection 1 sentence 1 undergo regular further training with regard to the knowledge and skills described there, and persons who are entrusted with carrying out animal experiments on vertebrates or cephalopods in the facility or establishment undergo regular further training with regard to the knowledge and skills required under Section 16 subsection 1 sentence 1.

### **Section 4 Organisational obligations**

For facilities and establishments for the purposes of Section 10 subsection 1 sentences 1 and 2 of the Animal Welfare Act, the owner or body responsible for the facility or the person responsible for the establishment shall appoint one or more persons on the spot, who

1. shall be responsible for monitoring the care and welfare of the animals located in the facility or in the establishment,
2. shall guarantee that persons who deal with the animals have access to information on the species accommodated in the facility or establishment, and
3. shall ensure that
  - a) the persons entrusted with tasks in the field of caring for or killing the animals satisfy the requirements of Section 3 subsection 1 and
  - b) the persons who carry out animal experiments satisfy the requirements of Section 7 subsection 1 sentence 3 of the German Animal Welfare Act and of Section 16

and receive constant further training in this respect.

### **Section 5 Animal welfare officer**

(1) For facilities and establishments for the purposes of Section 10 subsection 1 of the Animal Welfare Act, the owner or body responsible for the facility or the person responsible for the establishment shall, before commencing the activity, appoint one or more animal welfare officers and notify the competent authority of the appointment. The notification shall also include a statement of the position and powers of the animal welfare officer in accordance with the requirements of subsection 6 sentence 3.

(2) The animal welfare officer may not also be the person responsible for breeding or keeping the animals for the purposes of Section 11 subsection 1 sentence 1 number 1. The competent authority may permit exceptions if this is objectively appropriate because of the material and staffing resources of the facility or establishment and this does not conflict with any animal welfare issues. If an animal welfare officer of a facility or establishment in which animal experiments are conducted conducts an experimental project himself, a different animal welfare officer must monitor that experimental project.

(3) Only persons with a degree in veterinary medicine may be appointed animal welfare officers. They must possess the knowledge and skills required for the discharge of their duties described in subsection 4 and have the reliability needed for the task. The animal welfare officer shall be obliged to keep the knowledge and skills required for his task up to date by means of regular further training courses. The competent authority may authorise exceptions to sentence 1 if

evidence has been provided of the knowledge and skills required under sentence 2.

(4) The animal welfare officer shall be obliged

1. to ensure compliance with regulations, conditions and requirements in the interests of animal welfare and
2. to advise the facility or establishment and the persons involved in keeping the animals, especially with regard to the well-being of the animals at the time of purchase, the accommodation and care, and also with regard to their medical treatment.

The animal welfare officer of a facility or establishment in which animal experiments are conducted shall also be obliged

1. to comment on every application for authorisation of an experimental project and to present those comments to the competent authority on request,
2. within the facility or establishment to encourage the development and introduction of methods and means of satisfying the requirements of Section 7 subsection 1 sentence 2 and of Section 7a subsection 2 numbers 2, 4 and 5 of the Animal Welfare Act and
3. to advise the persons involved in conducting animal experiments especially with regard to the use of the methods and means mentioned in number 2 and to keep them informed of technical and scientific developments.

(5) The facility or the establishment shall

1. support the animal welfare officer in the performance of his duties in such a way that he can perceive his tasks to the full, and
2. inform the animal welfare officer of all experimental projects in the cases of subsection 4 sentence 2.

They shall ensure that the animal welfare officer undergoes regular further training.

(6) The animal welfare officer shall not be bound by any instructions in the discharge of his duties. He may not suffer any disadvantages because of the discharge of his duties. His position and powers shall be laid down in the Statutes, internal instructions or in a similar form. In this context, it shall be ensured that the animal welfare officer can present his suggestions or misgivings directly to the decision-making body in the facility or establishment. If more than one animal welfare officer is appointed, their fields of responsibility shall be defined.

## **Section 6 Animal welfare committee**

(1) For facilities and establishments for the purposes of Section 10 subsection 1 sentences 1 and 2 of the Animal Welfare Act, the owner of or body responsible for the facility or the person responsible for the establishment shall, before commencing the activity, appoint an animal welfare committee. At least the following shall be members of the animal welfare committee:

1. every animal welfare officer under Section 5,
2. one or more persons entrusted with the care of the animals and
3. a scientific member or one or more persons who conduct animal experiments, if the facility or establishment has such persons.

The animal welfare committee shall be chaired by an animal welfare officer.

(2) The tasks of the animal welfare committee shall be

1. to support the animal welfare officers in the performance of their duties under Section 5 subsection 4 sentence 1 number 2 and sentence 2 numbers 2 and 3,
2. to participate in laying down internal working procedures relating to the implementation and assessment of the supervision of the animals' welfare and any consequential measures adopted in this respect, and monitor adherence to the working procedures,
3. to follow the development of animal experiments and their results, taking the effects on the animals used into consideration and
4. to offer advice with regard to the development and implementation of programmes under Section 10 subsection 2.

In addition, the animal welfare committee can advise the staff of the facility or establishment involved in keeping, using or breeding the animals, especially with regard to their well-being.

(3) The owner of or body responsible for the facility or the person responsible for the establishment shall ensure that records are kept of recommendations made by the animal welfare committee in the course of performing the tasks mentioned in subsection 2 sentence 1 and on all decisions made in view of those recommendations, and that the records are stored for at least three years. The records shall be submitted to the competent authority on request.

## **Section 7 Keeping records**

(1) Anyone who is obliged to keep records under Section 11a subsection 1 sentence 1 number 1 of the Animal Welfare Act, shall keep a record book in the establishment or business premises in accordance with sentences 2 and 3. Every change in the population shall be entered indelibly in the record book under sentence 1 with the following details:

1. number and species of the animals bred, acquired, handed to third parties, used in animal experiments and accommodated or moved in accordance with Section 10,
2. origin of the animals, including a statement as to whether they were bred for use in animal experiments,
3. time when the animals were purchased, supplied or accommodated or moved in accordance with Section 10,
4. name and address of the person from whom the animals were purchased,
5. name and address of the recipient of the animals,
6. number and species of the animals killed in a facility or establishment or which died for other reasons and, in the latter case, the cause of death, if known,
7. anything unusual with regard to the state of health of the animals.

Dogs, cats and primates shall be listed individually with the following additional details:

1. identity of the animal,
2. place and date of birth, if known,
3. in the case of primates: whether it is an offspring of primates bred in captivity. Sections 239 and 261 of the German Commercial Code shall apply *mutatis mutandis*.

(2) The records described in subsection 1 shall be stored for at least five years, calculated from the beginning of the year following the creation of the record, and presented to the competent authority on request.

## **Section 8 Special records in the case of dogs, cats and primates**

(1) Notwithstanding Section 7, the party under an obligation to keep records under Section 11a subsection 1 sentence 1 number 1 of the Animal Welfare Act shall keep separate records in each case for dogs, cats and primates in accordance with sentence 2 and subsection 2 number 1. With respect to the animal concerned, the records shall comprise all the important reproductive, veterinary and behavioural information regarding the animal and details of the experimental projects in which it has been used.

(2) The party under an obligation to keep the records under subsection 1 shall

1. begin keeping the records without delay after the birth of the animal,
2. in the event of the animal's being handed over to a third party in cases other than those mentioned in Section 10, hand over to the third party the complete records concerned without delay,
3. in the case of the animal's being accommodated under Section 10, provide the new keeper with the veterinary and behavioural information under subsection 1 sentence 2 relating to the animal contained in the records which is important for the accommodation and veterinary care and
4. store the records, except where they have been passed on under number 2, for three years after the accommodation or movement of the animal under Section 10 or otherwise after the



death of the animal and present them to the competent authority on request.

### **Section 9 Tagging dogs, cats and primates**

(1) Anyone who breeds dogs, cats or primates which are intended for use in animal experiments or whose tissue or organs are intended to be used for scientific purposes shall permanently tag the animal concerned no later than the time of weaning, using the method which is suitable for the purpose of the experiment and causes the animal concerned the least pain, suffering and distress, such that the tag allows its identity to be determined.

(2) Anyone who acquires dogs, cats or primates which have not been tagged for delivery or use for the purposes mentioned in subsection 1 sentence 1 shall perform the tagging under subsection 1 without delay and, upon request, shall furnish the competent authority with the evidence that they are animals bred for such purposes.

(3) Anyone required to tag animals under subsection 1 or subsection 2 shall keep a register of the tagged animals specifying the species, date and tag and present it to the competent authority on request.

### **Section 10 Other accommodation or release of vertebrates and cephalopods**

(1) Vertebrates or cephalopods which have been used in animal experiments or are intended to be used in animal experiments, but whose use is no longer contemplated, may be permanently accommodated outside a facility or establishment for the purposes of Section 1 subsection 1, in a housing system suitable for the species concerned or, in the case of animals taken from Nature, moved to a suitable habitat, if

1. the animals' state of health permits it,
2. the animals do not pose any risk to the health of human beings or other animals or to the environment, and
3. appropriate steps have been taken to ensure the well-being of the animals.

(2) Anyone who accommodates animals under subsection 1 must have a programme for such accommodation, in the course of which it is ensured that the animals to be accommodated are acclimatised. Wherever necessary for reasons of animal welfare, animals taken from Nature may only be moved in the context of a programme of release into a suitable habitat.

## **Sub-chapter 2**

### **Permit under Section 11 subsection 1 sentence 1 number 1 of the Animal Welfare Act**

#### **Section 11 Conditions for a permit**

(1) The permit under Section 11 subsection 1 sentence 1 number 1 of the Animal Welfare Act may only be granted if

1. the person responsible for the activity has the technical knowledge and skills required for the activity because of his training or his professional or other contact with animals so far,
2. the person responsible for the activity has the necessary reliability,
3. in the facilities and establishments used for the activity
  - a) suitable premises and equipment are present and
  - b) sufficient expert staff are available,so that it is possible to keep the animals in a manner that satisfies the requirements of Section 2 of the Animal Welfare Act and Section 1 subsection 1,
4. it is ensured that the persons under Section 3 subsection 1 sentence 1 numbers 1 and 2 can at all times furnish the evidence that they possess the knowledge and skills mentioned there, and
5. it can be expected that Sections 4 to 9 will be complied with.

In the case of sentence 1 number 1, the necessary technical knowledge and skills shall be demon-

strated upon request in a technical interview with the competent authority.

(2) The permit can, if necessary for the protection of the animals, be granted subject to time limitations, conditions and requirements.

### **Section 12 Applying for the permit**

The application for the grant of the permit under Section 11 subsection 1 sentence 1 number 1 of the Animal Welfare Act shall state

1. the name and address of the applicant,
2. the facilities and establishments used for the activity, including the rooms and equipment and staff available there,
3. the species of the animals concerned and, based on the species, the capacities for keeping them,
4. the name of the person responsible for the activity,
5. the presence of persons according to Section 3 subsection 1 sentence 1 numbers 1 and 2 and Section 4 and
6. the name of the animal welfare officer according to Section 5.

The application shall have evidence of the knowledge and skills according to Section 11 subsection 1 sentence 1 number 1 enclosed with it.

### **Section 13 Permit document, notification of changes**

(1) The persons under Section 12 sentence 1 numbers 4 and 6 shall be specified in the permit document.

(2) If any of the persons mentioned in subsection 1 changes, the holder of the permit shall notify the competent authority of the change without delay. The permit shall be revoked within one month after receipt of the notification of the change if, because of the changes notified, the conditions for the grant of the permit are no longer met. Sentence 1 shall apply *mutatis mutandis* to any change in the facts under Section 12 sentence 1 number 2, unless it is ruled out that that change will be detrimental to the well-being of the animals.

## **Chapter 2 Implementation, authorisation and notification of animal experiments**

### **Section 14 Application to animals at an early stage of development**

Sections 7 to 9 of the Animal Welfare Act and Sections 15 to 43 shall also apply to the implementation of animal experiments, including the authorisation and notification of experimental projects

1. in which
  - a) larvae of vertebrates, if they are capable of feeding independently, or
  - b) foetuses of mammals as of the last trimester of their normal development before birth are used or are intended to be used or
2. in which vertebrates other than those mentioned in number 1 are used or are intended to be used in a stage of development before birth or hatching, if the animals are intended to live beyond that stage of development and are likely to feel pain or suffering or suffer distress after birth or hatching.

## **Sub-chapter 1 Implementation of animal experiments**

## **Section 15 Requirements concerning premises and facilities**

(1) Animal experiments on vertebrates and cephalopods may only be carried out on the premises of a facility or establishment for the purposes of Section 1 subsection 1. Section 2 subsection 1 sentence 2 shall apply *mutatis mutandis*. In derogation from sentence 1, an animal experiment may be carried out outside a facility or establishment if it is shown, with scientific reasoning, that this is necessary in view of the purpose of the experiment.

(2) Notwithstanding Section 1 subsection 1 number 1, the premises, equipment and items in the facility or establishment under subsection 1 sentence 1 which are intended for the conduct of animal experiments on vertebrates and cephalopods must

1. be suitable for this purpose and satisfy the requirements of Annex III Part A number 1.3 of Directive 2010/63/EU and
2. guarantee by their design, construction and method of functioning that the animal experiments are conducted in a targeted manner so that reliable results are obtained using the smallest possible number of animals and causing the least possible pain, suffering and distress.

## **Section 16 Requirements concerning expertise**

(1) Animal experiments on vertebrates and cephalopods may only be carried out by persons who possess the knowledge and skills required by Annex 1 Chapter 3. Furthermore, animal experiments may only be carried out

1. by persons with a degree in veterinary medicine, medicine or dental medicine,
2. by persons with a degree in science, provided they demonstrably possess the necessary knowledge and skills, or
3. by persons who have demonstrably acquired the necessary knowledge and skills in the course of completing vocational training.

Notwithstanding sentence 1, animal experiments involving operational procedures on vertebrates may only be carried out

1. by persons with a degree in veterinary medicine, medicine or dental medicine or
2. by persons with a degree in science or further training following a course of studies in science at a place of higher education, provided they demonstrably possess the necessary knowledge and skills.

Sentences 2 and 3 shall not apply to animal experiments under Section 7 subsection 2 sentence 2 number 1 of the Animal Welfare Act which are performed in accordance with procedures that have already been tested. The competent authority shall authorise exceptions to sentences 2 and 3 if evidence of the knowledge and skills has been furnished in some other way.

(2) In derogation from Section 7 subsection 1 sentence 3 of the Animal Welfare Act and subsection 1 sentences 1 to 3, animal experiments serving the purpose of basic, further or advanced training may also be carried out by persons who do not satisfy the requirements mentioned there, provided this is done in the presence and under the supervision of a person who does meet the requirements.

(3) Animal experiments may only be carried out if persons who planned the experimental project and the proposed animal experiments possess the knowledge and skills required for that purpose, including the knowledge and skills under Appendix 1 Chapter 3 and furnish evidence thereof to the competent authority on request.

## **Section 17 Analgesia and anaesthesia**

(1) When experiments are carried out on vertebrates and cephalopods, it shall be ensured by applying analgesic agents or procedures that pain and suffering in the animal used are alleviated to the lowest possible level.

(2) Experiments on vertebrates or cephalopods may only be carried out under a general or local anaesthetic. Sentence 1 shall not apply if

1. the pain involved in the conduct of the experiment is less for the animal concerned than the pain and suffering involved in anaesthesia or

2. the purpose of the experiment precludes anaesthesia and the experiment does not lead to serious injury to the animal concerned.

In the case of vertebrates, the anaesthesia may only be administered by a person who satisfies the requirements of Section 7 subsection 1 sentence 3 of the Animal Welfare Act and of Section 16 subsection 1 sentence 2, or, if the application of the anaesthesia serves the purpose of basic, further or advanced training, and is performed in the presence and under the supervision of such a person.

(3) If in the case of an anaesthetised vertebrate or cephalopod it is to be expected that pain will occur when the anaesthesia wears off, the animal must be treated in time with analgesic agents or procedures. This shall not apply, in so far as it is ethically acceptable, if it is shown, with scientific reasoning, that the treatment with analgesic agents or procedures is irreconcilable with the purpose of the animal experiment. In the case of a vertebrate or cephalopod which is not anaesthetised, no agents may be used which prevent or impair the ability to show pain.

### **Section 18 Re-use of vertebrates and cephalopods**

(1) A vertebrate or cephalopod which has already been used in an experimental project may only be used in a further experimental project, for which an animal that has not previously been used could also be used, if

1. the animal has not been used in an animal experiment which is to be classified as “severe” pursuant to Article 15(1) in combination with Annex VIII to Directive 2010/63/EU,
2. its general state of health and well-being have been completely restored,
3. in the course of the further experimental project, the animal is not used in an animal experiment which is to be classified as “severe” pursuant to Article 15(1) in combination with Annex VIII of Directive 2010/63/EU, and
4. the re-use is in harmony with the recommendation of a veterinary surgeon, which takes account of the nature and extent of the pain, suffering and distress which the animal concerned has experienced throughout its entire life so far.

(2) In derogation from subsection 1 number 1, the competent authority may authorise the use of a vertebrate or cephalopod in a further experimental project if the animal

1. has not been used more than once in an animal experiment which is to be classified as “severe” pursuant to Article 15(1) in combination with Annex VIII to Directive 2010/63/EU,
2. in the course of the further experimental project, is not used in an animal experiment which is to be classified as “severe” or “moderate” pursuant to Article 15(1) in combination with Annex VIII to Directive 2010/63/EU, and
3. has been examined by a veterinary surgeon beforehand.

### **Section 19 Use of bred vertebrates and cephalopods**

(1) Vertebrates and cephalopods may be used in animal experiments only if they have been bred for such a purpose. The competent authority may, if this is compatible with the protection of the animals, authorise exceptions hereto if it is shown, with scientific reasoning, that the use of animals other than those bred in accordance with sentence 1 is necessary.

(2) Subsection 1 sentence 1 shall not apply to the use of horses, cattle, pigs, sheep, goats, chicken, pigeons, turkeys, ducks, geese or fish, with the exception of zebrafish.

### **Section 20 Use of wild animals**

(1) Animals taken from the wild shall not be used in animal experiments. The competent authority may authorise exceptions hereto if the purpose of the experiment cannot be achieved by the use of other animals.

(2) Vertebrates or cephalopods to be taken from the wild may only be captured by persons who possess the knowledge and skills needed for that purpose. Pain, suffering or distress may only be caused to the animals to the extent which is unavoidable for the capture.

(3) If, at or after capture under subsection 2, it is found that the animal is injured or in a poor state of health, it shall be examined by a veterinary surgeon or another competent person, and steps shall be taken to ameliorate the animal’s pain, suffering and distress to the lowest possible level

compatible with the purpose of the animal experiment.

### **Section 21 Use of stray or feral pets**

Stray or feral animals of species which are usually kept in human care may not be used in animal experiments. The competent authority may authorise exceptions hereto if

1. the animal experiment is being conducted in order to satisfy a fundamental need for studies into the health and well-being of those animals or into serious threats to the environment or the health of human beings or animals and
2. it is shown with scientific justification that the purpose of the animal experiment can only be achieved by the use of an animal according to sentence 1.

### **Section 22 Use of protected species**

Vertebrates listed in Annex A to Regulation (EC) No. 338/97 of the Council of 9th December, 1996, on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61 of 3.3.1997, p. 1), in the version applicable at any particular time, which are not primates, and cephalopods may not be used in animal experiments. Sentence 1 shall not apply if

1. the animal experiment serves
  - a) the purpose of preventing, identifying or treating diseases, suffering, physical injuries or physical complaints in human beings or animals or the development and production of, and testing the quality, efficacy or safety of substances or products with regard to the purposes mentioned in Section 7a subsection 1 sentence 1 number 2 of the Animal Welfare Act or
  - b) research in connection with the preservation of species,  
and
2. it is shown with scientific justification that the purpose of the animal experiment mentioned in number 1 cannot be achieved by the use of species other than those mentioned Annex A to Regulation (EC) No. 338/97.

Sentence 1 shall not apply to animals born and bred in captivity or artificially propagated according to Article 7(1) of Regulation (EC) No. 338/97. Sentence 2 shall not apply to animal experiments which serve basic research.

### **Section 23 Use of primates**

(1) Primates shall not be used in animal experiments.

(2) Subsection 1 shall not apply, subject to subsections 4 and 5, if

1. the animal experiment serves
  - a) basic research,
  - b) the purpose of preventing, identifying or treating diseases, suffering, physical injuries or physical complaints in human beings which can be life-threatening or lead to a reduction in physical or mental capacity, or the development and production of, and testing the quality, efficacy or safety of substances or products with regard to the impairments to human health mentioned, or
  - c) research in connection with the preservation of species,  
and
2. it is shown with scientific justification that the purpose mentioned in number 1 of the animal experiment cannot be achieved by the use of species other than primates.

(3) In derogation from subsection 2 number 1, the competent authority can also authorise the use of primates in an animal experiment if the animal experiment serves research with the purpose of preventing, identifying or treating diseases, suffering, physical injuries or physical complaints in human beings other than those mentioned in subsection 2 number 1 b), if it is shown with scientific justification that the use of primates is indispensable in order to achieve the above-mentioned purpose of the animal experiment.

(4) In the case of primates which are listed in Annex A to Regulation (EC) No. 338/97 and do not fall

under Article 7(1) of Regulation (EC) No. 338/97, subsection 1 shall not apply if

1. the animal experiment
  - a) serves the purpose of preventing, identifying or treating diseases, suffering, physical injuries or physical complaints in human beings which can be life-threatening or lead to a reduction in physical or mental capacity, or the development and production of, and testing the quality, efficacy or safety of substances or products with regard to the impairments to human health mentioned, or
  - b) research in connection with the preservation of speciesand
2. it is shown with scientific justification that the purpose of the animal experiment mentioned in number 1 cannot be achieved by the use of species other than those mentioned in subsection 1 and in Annex A to Regulation (EC) No. 338/97 and primates which do not fall under Article 7(1) of Regulation (EC) No. 338/97.

Sentence 1 shall not apply to animal experiments which serve basic research.

(5) In derogation from subsection 1, the competent authority can authorise the use of great apes in an animal experiment if

1. the animal experiment serves
  - a) the purpose of preventing, identifying or treating diseases, suffering, physical injuries or physical complaints in human beings which are life-threatening or lead to a reduction in physical or mental capacity, and which have appeared unexpectedly, or the development and production of, and testing the quality, efficacy or safety of substances or products with regard to the impairments to human health mentioned, or
  - b) research in connection with the preservation of species,and
2. it is shown, with scientific reasoning, that
  - a) there are grounds for assuming that the conduct of the animal experiment is indispensable in order to achieve the purpose of the animal experiment mentioned in number 1 and
  - b) that the purpose cannot be achieved by the use of species other than great apes.

Sentence 1 shall not apply to animal experiments which serve basic research.

### **Section 24 Origin of primates to be used**

(1) Primates listed in Annex II column 1 of Directive 2010/63/EU may, from the dates set out in Annex II column 2 of Directive 2010/63/EU, only be used in animal experiments if they are the offspring of primates which have been bred in captivity or if they are sourced from self-sustaining colonies for the purposes of Article 10(1) subparagraph 3 of Directive 2010/63/EU.

(2) In derogation from subsection 1, the competent authority may authorise the use of primates listed in Annex II column 1 of Directive 2010/63/EU of different stock or origin if it is shown with scientific justification that the use of those primates is necessary.

### **Section 25 Conduct of particularly stressful animal experiments**

(1) Animal experiments on vertebrates or cephalopods which are likely to lead to lasting or repeated considerable pain or suffering for the animals used may only be conducted if the intended results justify the assumption that they will be of outstanding importance for essential human or animal needs, including the solution of scientific problems.

(2) Animal experiments under subsection 1 may not be conducted if the considerable pain or suffering might last for a long time and cannot be ameliorated. In derogation from sentence 1 the competent authority can authorise the conduct of an animal experiment under sentence 1 if the conditions of subsection 1 are met and it is shown, with scientific reasoning, that the conduct of the animal experiment is indispensable because of the importance of the findings sought.

## **Section 26 Authorisation in special cases**

(1) Authorisation under Section 23 subsections 3 or 5 or Section 25 subsection 2 sentence 2 shall be granted by the competent authority with the proviso that the authorisation will be revoked in the event of a decision by the European Commission under Article 55(4) subparagraph 2 b) of Directive 2010/63/EU.

(2) If the competent authority grants an authorisation under subsection 1, it shall notify the Federal Ministry of Food, Agriculture and Consumer Protection (Federal Ministry) thereof without delay. The notification under sentence 1 shall include detailed reasons for the decision by the competent authority regarding the presence of the respective conditions for such authorisation. After receipt of the notification under sentence 1, the Federal Ministry shall inform the European Commission in accordance with Article 55(4) subparagraph 1 of Directive 2010/63/EU based on the notification of the competent authority under sentence 2.

## **Section 27 Achievement of objective**

(1) As soon as the objective of an animal experiment has been achieved, steps shall be taken to reduce the pain, suffering and distress for the animals used to the lowest possible level.

(2) Animal experiments shall be planned and conducted in such a way that the objective of the experiment can be achieved without the need for the animals used to die as a direct consequence of the effects of the experiment. It shall in particular be ensured in this context that the imminent death of an animal as a consequence of the effects of the experiment shall be recognised at as early a stage as possible and the animal is in this case killed without delay and avoiding pain and suffering to the greatest extent possible. Sentences 1 and 2 shall not apply if the deaths of the animals used as a direct consequence of the effects of the experiment are indispensable in order to achieve the objective of the animal experiment; in this case, the experiment shall be conducted in such a way that

1. as few of the animals used as possible die and
2. the duration and intensity of the pain and suffering endured by the animals is reduced to the lowest possible level and death is ensured with pain and suffering avoided to the greatest extent possible.

## **Section 28 Procedures after completion, follow-up treatment**

(1) After the completion of an animal experiment, a veterinary surgeon or other competent person shall decide whether a vertebrate or cephalopod used which is no longer intended for further use in the experimental project concerned should be left alive or, if there is good reason, killed. If primates, single-toed ungulates, even-toed ungulates, dogs, hamsters, cats, rabbits or guinea pigs have been used, they shall be presented to a veterinary surgeon without delay for examination.

(2) If after the completion of an animal experiment a vertebrate or cephalopod used can, according to the judgment of the veterinary surgeon or the competent person, only remain alive while enduring more than slight pain, suffering or distress, the animal shall be killed painlessly without delay.

(3) Animals other than those mentioned in subsection 2 shall be killed painlessly if there is good reason and it is necessary in the judgment of a competent person.

(4) If an animal is to remain alive after the completion of an animal experiment, it must be tended to and accommodated in accordance with its state of health and be observed by a veterinary surgeon or other competent person, and if necessary be provided with medical care.

## **Section 29 Keeping records of animal experiments**

(1) In the records to be kept under Section 9 subsection 5 sentence 1 of the Animal Welfare Act, for each experimental project in which vertebrates, cephalopods or decapods are used, the purpose and the number and species of the animals used, the nature and conduct of the animal experiments and the names of the persons who have conducted the animal experiments shall be stated. If vertebrates are used, their origin, including the name and address of the previous owner shall be stated. In the case of dogs, cats and primates, the sex, any tagging performed on the animal under Section 9 and, in the case of dogs and cats, the breed shall be stated.

(2) The records under subsection 1 shall be signed by the persons who have conducted the animal experiments and by the director of the experimental project or his deputy. If the records are

created electronically, they shall be printed out without delay after the completion of each part-experiment of the experimental project and signed by the director of the experimental project or his deputy. Sections 239 and 261 of the German Commercial Code shall apply *mutatis mutandis*. Records on an experimental project shall be preserved for five years, beginning with the completion of the animal experiment, and presented to the competent authority on request.

### **Section 30 Duties of the director**

(1) The director of the experimental project or, if he is prevented, his deputy shall ensure that the provisions of Sections 15 to 25 and 27 to 29 are complied with.

(2) The director of the experimental project or, if he is prevented, his deputy shall ensure that as soon as the implementation of the experimental project causes avoidable pain, suffering or distress to an animal, this is eliminated without delay. In addition, he shall ensure that the experimental project is conducted

1. in accordance with the authorisation under Section 8 subsection 1 sentence 1 of the Animal Welfare Act or, in the case of an experimental project under Section 8a subsection 1 of the Animal Welfare Act, in accordance with the details provided in the notification under Section 36 subsection 1 and
2. in compliance with all the instructions, conditions and requirements laid down by the competent authority with regard to the experimental project.

In this context, he shall ensure that in the case of any deviation in this respect, suitable remedial measures are adopted and that records are kept of the deviations and the remedial measures adopted.

## **Sub-chapter 2**

### **Authorisation and notification of experimental projects**

#### **Section 31 Applying for the authorisation**

(1) The application for the authorisation of an experimental project under Section 8 subsection 1 sentence 1 of the Animal Welfare Act shall be submitted in writing to the competent authority. The application

1. shall state
  - a) name and address of the applicant,
  - b) a description of the experimental project, including the objective pursued by it,
  - c) the species, origin, life stage and number of the animals intended for the experimental project, including their calculation
  - d) the nature and conduct of the proposed animal experiments, including the planned use of agents and methods or the purpose of anaesthesia or analgesia and the circumstances under which, if present, an animal will no longer be used in the animal experiments,
  - e) the place, time of commencement and expected duration of the experimental project,
  - f) the name, address and expertise of the director of the experimental project and his deputy, of the persons by whom the experimental project or the proposed animal experiments have been planned, of the persons conducting it and of the persons who may be responsible for the follow-up treatment and,
  - g) if killing the animals is contemplated, the procedure to be used for this purpose,
2. shall show, with scientific reasoning,
  - a) that the conditions of Section 8 subsection 1 sentence 2 number 1 a) and b) of the Animal Welfare Act are met,
  - b) the severity classification of the experiment,
3. shall furnish evidence that the conditions of Section 8 subsection 1 sentence 2 numbers 2 to



5 of the Animal Welfare Act are met, and

4. shall show that the conditions of Section 8 subsection 1 sentence 2 numbers 6 to 8 of the Animal Welfare Act are met.

(2) The application shall have a summary of the experimental project with the details under Section 41 subsection 1 sentence 2 enclosed with it.

### **Section 32 Authorisation procedure, time limits for processing**

(1) The competent authority shall notify the applicant of its decision on the application within 40 working days of receipt of an application complying with the requirements of Section 31. If the scope and difficulty of the examination of compliance with the requirements under Section 8 subsection 1 sentence 2 of the Animal Welfare Act justify it, the competent authority may once extend the period mentioned in sentence 1 by up to 15 working days in accordance with subsection 2 sentence 3.

(2) After receipt of an application under Section 31 subsection 1 sentence 1, the competent authority shall issue the applicant with confirmation of receipt without delay. It shall be stated in the confirmation of receipt that the applicant will be notified of the decision on the application within the period mentioned in subsection 1 sentence 1. The applicant shall be notified of any extension under subsection 1 sentence 2 no later than the expiry of the period mentioned in subsection 1 sentence 1, stating the reasons.

(3) After receipt, the competent authority shall without delay examine an application received under Section 31 subsection 1 sentence 1 for completeness. If it does not comply with the requirements of Section 31, the competent authority shall inform the applicant thereof without delay, identifying the missing details and documents. The applicant's attention shall be drawn to the fact that the commencement of the period mentioned in subsection 1 sentence 1 presupposes the receipt of an application complying with the requirements of Section 31.

(4) The competent authority shall inform the committee under Section 15 subsection 1 sentence 2 of the Animal Welfare Act without delay of applications it has received for the authorisation of experimental projects and shall give it an opportunity to comment within a reasonable time. The competent authority may also submit to the committee notifications of changes to authorised experimental projects for comments, if required by the scope and difficulty of the examination.

(5) Subsection 4 shall apply, *mutatis mutandis*, to the competent department of the German armed forces, with the proviso that the committee under Section 15 subsection 3 sentence 2 of the Animal Welfare Act must be heard. The security interests of the armed forces shall be taken into account. If animal experiments are to be conducted on behalf of the armed forces, the committee shall likewise be informed thereof and given an opportunity to comment before the commission is placed; this shall not prejudice Section 15 subsection 1 of the Animal Welfare Act. The Land authority with competence for the authorisation of the experimental project shall be informed thereof. The competent department of the armed forces shall send it the comment on request.

### **Section 33 Authorisation document, time limitation**

(1) The authorisation document shall include

1. the details of the director of the experimental project and his deputy,
2. a statement of the facilities or establishments in which or, in the cases of Section 15 subsection 1 sentence 3, the location at which the experimental project is to be conducted,
3. a decision on whether and at what time the experimental project is to be evaluated retrospectively under Section 35, and
4. where applicable, any restrictions applied to the authorisation.

(2) The authorisation shall be subject to a time limitation of no more than five years. If the authorisation is granted with a time limitation of less than five years, it shall be extended no more than twice by up to one year in each case following an informal, reasoned application, provided that the maximum duration of the authorised experimental project does not exceed five years as a result and provided that since the first grant or first extension of the authorisation, no changes have been made to the authorised experimental project or only those changes have occurred which

1. have been notified under Section 34 subsection 1 sentence 1 number 4 or subsection 2 sentence 1 and have not been objected to by the competent authority or
2. have been authorised under Section 34 subsection 3.

### **Section 34 Notification of changes to authorised experimental projects**

(1) Changes to authorised experimental projects shall not require re-authorisation, provided that

1. the purpose of the experimental project remains the same,
2. the degree of pain, suffering and distress caused to the animals used is not increased by the changes,
3. the number of animals used is not increased significantly and
4. the competent authority has been notified of these changes in advance.

The changes shall not be made before two weeks have passed since receipt of the notification under sentence 1 number 4 unless the competent authority has stated by then that there are no objections to the changes.

(2) If the director of the experimental project or his deputy changes, the holder of the authorisation shall notify the competent authority of the change without delay. The authorisation shall be revoked by the competent authority within one month of receipt of the notification of the change if the director of the experimental project or his deputy do not satisfy the requirements of Section 8 subsection 1 sentence 2 number 2 of the Animal Welfare Act.

(3) Changes other than the ones mentioned in subsection 1 sentence 1 and subsection 2 sentence 1 shall require authorisation by the competent authority. Section 8 subsection 1 sentence 2 of the Animal Welfare Act and Sections 31 to 33 shall apply to the authorisation of the changes *mutatis mutandis*.

### **Section 35 Retrospective evaluation of experimental projects**

(1) When the competent authority authorises an experimental project, it may at the same time stipulate that the experimental project shall be evaluated by the competent authority after completion and at what time that evaluation is to be performed. An evaluation under sentence 1 shall be provided for if the experimental project involves the conducting of

1. animal experiments in which primates are used,
2. animal experiments which are to be classified as “severe” pursuant to Article 15(1) in combination with Annex VIII to Directive 2010/63/EU, or
3. animal experiments under Section 25 subsection 2.

(2) In the course of the evaluation under subsection 1 sentence 1, the competent authority shall examine the following on the basis of documents which are to be submitted by the applicant under Section 31 subsection 1 sentence 1 on request if they are necessary for carrying out the evaluation:

1. whether the result notified matches the purpose of the experimental project stated in the application under Section 31 subsection 1 sentence 2 number 1 b),
2. the distress caused to the animals used,
3. the number and species of the animals used,
4. the severity of animal experiments conducted pursuant to Article 15(1) in combination with Annex VIII to Directive 2010/63/EU, and
5. whether any conclusions should be drawn from this with regard to the requirements under Section 7 subsection 1 sentence 2 and Section 7a subsection 2 numbers 2, 4 and 5 of the Animal Welfare Act.

### **Section 36 Notification of experimental projects under Section 8a subsection 1 of the German Animal Welfare Act**

(1) The notification of an experimental project under Section 8a subsection 1 of the Animal Welfare Act shall state:

1. the details under Section 31 subsection 1 sentence 2 number 1,
2. the legal basis for the notification in the case of an experimental project under Section 8a subsection 1 number 1 of the Animal Welfare Act and
3. description and evidence under Section 31 subsection 1 sentence 2 numbers 2 to 4.

The notification shall be made in writing.

(2) The implementation of the experimental project shall not commence before twenty working days have passed since receipt by the competent authority of a notification complying with the requirements of subsection 1 unless the competent authority has stated by then that there are no objections to the implementation.

(3) After receipt of a notification under Section 8a subsection 1 of the Animal Welfare Act, the competent authority shall issue the notifying party without delay with a confirmation of receipt stating the date of receipt of the notification. In the confirmation of receipt, attention shall be drawn to the period under subsection 2.

(4) An experimental project notified under Section 8a subsection 1 of the Animal Welfare Act shall not be conducted after five years have passed since the expiry of the period mentioned in subsection 2 or after receipt of the statement under subsection 2.

### **Section 37 Collective notification, notification of changes to notified experimental projects**

(1) If it is proposed to conduct more than one experimental project of the same kind under Section 8a subsection 1 of the Animal Welfare Act, the notification of the first experimental project shall suffice if the probable number of experimental projects is also stated in the notification. By 15th February of each year, the notifying party shall inform the competent authority of the number of experimental projects conducted in the previous calendar year, stating the species and total

number of animals used.

(2) If the underlying facts stated in the notification under Section 36 subsection 1 sentence 1 numbers 1 and 2 change during the experimental project, the competent authority shall be notified of those changes without delay. Section 34 subsection 1 sentence 2 shall apply *mutatis mutandis*.

(3) Section 36 subsection 4 shall apply *mutatis mutandis*.

### **Section 38 Examination of notified experimental projects or changes thereto**

In the event of the receipt of a notification under Section 36 subsection 1, the competent authority shall within the period mentioned in Section 36 subsection 2 examine whether the conditions specified in Section 8 subsection 1 sentence 2 numbers 1 to 8 of the Animal Welfare Act apply with regard to the notified experimental project or whether the implementation of the experimental project must be prohibited under Section 16a subsection 2 of the Animal Welfare Act. In the event of the notification of changes under Section 34 subsection 1 sentence 1 number 4 or Section 37 subsection 2 sentence 1, sentence 1 shall apply *mutatis mutandis*, with the proviso that the examination shall be performed within two weeks.

### **Section 39 Notification of experimental projects on decapods**

(1) The notification of an experimental project under Section 8a subsection 3 of the Animal Welfare Act shall state:

1. the purpose of the experimental project,
2. the species of the animals intended for the experimental project,
3. the nature and implementation of the proposed animal experiments, including anaesthesia,
4. the place, time of commencement and expected duration of the experimental project and
5. the name, address and expertise of the director of the experimental project, his deputy and the persons conducting it, and also of the persons who may be responsible for the follow-up treatment and.

Section 36 subsection 1 sentence 2, subsections 3 and 4 and Section 37 subsections 1 and 2 sentence 1 shall apply *mutatis mutandis*.

(2) The implementation of the experimental project shall not commence before two weeks have passed since receipt by the competent authority of a notification complying with the requirements of subsection 1 unless the competent authority has stated by then that there are no objections to the implementation. The period mentioned in sentence 1 may be extended by the competent authority, if necessary, to up to four weeks; the applicant shall be notified of the extension no later than the expiry of the period mentioned in sentence 1, stating the reasons.

(3) In the event of the receipt of a notification under subsection 1 sentence 1, the competent authority shall examine whether compliance with the regulations of Section 7 subsection 1 sentences 2 and 3 and Section 7a subsections 1 and 2 numbers 1, 2, 4 and 5 of the Animal Welfare Act, of Section 20 subsection 1 and Sections 27 and 28 subsections 3 and 4 is ensured with regard to the notified experimental project or whether the implementation of the experimental project must be prohibited under Section 16a subsection 2 of the Animal Welfare Act.

### **Section 40 Preservation obligation**

The holder of an authorisation or, in the case of experimental projects under Section 8a subsection 1 or 3 of the Animal Welfare Act, the notifying party shall preserve

1. a copy of the application under Section 31 and the authorisation document under Section 33 or, in the case of experimental projects under Section 8a subsections 1 or 3 of the Animal Welfare Act, a copy of the notification under Section 36 subsection 1 or Section 39 subsection 1 sentence 1 and
2. all other documents which have been sent to him by the competent authority in connection with the authorisation or notification and the implementation of the experimental project,

for at least three years beyond the end of the period of validity of the authorisation or, in the case of experimental projects under Section 8a subsections 1 or 3 of the Animal Welfare Act, beyond the expiry of the period mentioned in Section 36 subsection 4, also in combination with Section 39 subsection 1 sentence 2. In the case of experimental projects which are to be subjected to an evaluation

under Section 35, the documents mentioned in sentence 1 shall be preserved until the completion of the evaluation, if the evaluation is only completed after the expiry of the period mentioned in sentence 1.

### **Section 41 Publication of summaries**

(1) Within three months after granting an authorisation under Section 8 subsection 1 sentence 1 of the Animal Welfare Act, the competent authority shall send the Federal Institute for Risk Assessment (Federal Institute) a summary of the experimental project authorised for the purpose of publication by the Federal Institute. The summary shall state the following on the basis of the details in the authorisation application:

1. the purposes of the experimental project,
2. the expected benefit of the experimental project,
3. the distress expected to be caused to the animals proposed to be used,
4. the number and species of the animals proposed to be used and
5. compliance with the requirements of Section 7 subsection 1 sentence 2 and Section 7a subsection 2 numbers 2, 4 and 5 of the Animal Welfare Act.

The summary may not contain any personal data or data relating to the facility. Nothing in this shall prejudice the regulations for the protection of intellectual property rights and the protection of trade and business secrets.

(2) The summary shall be published on the internet by the Federal Institute within twelve months after being sent by the competent authority. The relevant website shall be announced by the Federal Institute in the Federal Gazette (Bundesanzeiger).

### **Section 42 Animal experiment committees**

(1) The majority of the members of the committees to be appointed under Section 15 subsection 1 sentence 2 and subsection 3 sentence 2 of the Animal Welfare Act must have necessary the specialist knowledge in veterinary medicine, medicine or a scientific discipline in order to be able to assess animal experiments.

(2) Members shall also be appointed to the committees under Section 15 subsection 1 sentence 2 of the Animal Welfare Act who have been selected on the basis of suggestions by the animal welfare organisations and who are suitable for assessing animal welfare issues because of their experience; the number of these members must be at least one third of the committee members.

(3) Members should also be appointed to the committees under Section 15 subsection 3 sentence 2 of the Animal Welfare Act who have been selected on the basis of suggestions by the animal welfare organisations and who are suitable for assessing animal welfare issues because of their experience.

### **Section 43 Informing the Federal Ministry**

The authorities with competence under the laws of a Land shall inform the Federal Ministry about cases of fundamental importance in the authorisation of experimental projects, especially about the cases in which the authorisation of experimental projects has been refused on the grounds that the conditions of Section 7a subsection 2 number 3 of the Animal Welfare Act were not met, or in which the committee under Section 15 subsection 1 of the Animal Welfare Act or the animal welfare officer expressed reservations with regard to the presence of these conditions. Personal data must not be sent.

## **Chapter 3 Administrative offences**

### **Section 44 Administrative offences**

(1) An administrative offence for the purposes of Section 18 subsection 1 number 3 a) of the Animal Welfare Act shall be deemed to be committed by any person who through intent or negligence

1. conducts an animal experiment contrary to Section 15 subsection 1 sentence 1 or Section 17 subsection 2 sentence 1,
2. uses an agent contrary to Section 17 subsection 3 sentence 3,
3. contrary to Section 30 subsection 1, does not ensure compliance with the regulations of Section 15 subsection 1 sentence 1 or
4. contrary to Section 30 subsection 1, does not ensure compliance with the regulations of Section 17 subsection 2 sentence 1 or subsection 3 sentence 3.

(2) An administrative offence for the purposes of Section 18 subsection 1 number 3 b) of the Animal Welfare Act shall be deemed to be committed by any person who through intent or negligence

1. contrary to Section 2 subsection 1 sentence 1 number 1, kills a vertebrate or cephalopod,
2. contrary to Section 5 subsection 1 sentence 1 number 1, does not appoint an animal welfare officer, or does not do so in good time,
3. contrary to Section 7 subsection 1 sentence 1, does not keep a record book, or does not do so correctly, or not completely or not in the prescribed manner,
4. contrary to Section 7 subsection 2, does not preserve a record mentioned there, or does not do so for at least five years, or does not submit it, or does not do so in good time,
5. contrary to Section 8 subsection 1 sentence 1, does not keep a record, or does not do so correctly or not completely,
6. contrary to Section 8 subsection 2 number 2, does not hand over a record, or does not do so correctly or not completely or not in good time,
7. contrary to Section 8 subsection 2 number 4, does not preserve a record for at least three years, or does not submit it, or does not do so in good time,
8. contrary to Section 9, does not tag an animal mentioned there, or does not do so correctly, or not in the prescribed manner or not in good time,
9. contrary to Section 9 subsection 2, does not furnish the evidence mentioned there,
10. contrary to Section 30 subsection 1, does not ensure compliance with the provisions of Section 29 subsection 1,
- 10a. contrary to Section 30 subsection 1, does not ensure compliance with the provisions of Section 29 subsection 2,
11. conducts an experimental project contrary to Section 36 subsection 2 or subsection 4,
12. contrary to Section 37 subsection 1 sentence 2, also in combination with Section 39 subsection 1 sentence 2, does not provide information, or does not do so correctly, or not completely or not in good time,
13. makes a change contrary to Section 37 subsection 2 sentence 2,
14. commences an experimental project contrary to Section 39 subsection 2 sentence 1 or
15. contrary to Section 40, does not preserve a document mentioned there, or does not do so for the prescribed period.

## **Chapter 4**

### **Transitional and final provisions**

#### **Section 45 Tasks under Article 49 of Directive 2010/63/EU**

The Federal Institute shall advise the competent authorities and the animal welfare committees under Section 6 on matters relating to the acquisition, breeding, accommodation or care of vertebrates and cephalopods under Section 1 subsection 1 or the use of vertebrates and cephalopods in animal experiments and shall ensure that there is an exchange regarding tried and tested practices in this respect. In addition, it shall exchange information with committees set up in

other Member States of the European Union under Article 49 subsection 1 of Directive 2010/63/EU concerning

1. the work of the animal welfare committees under Section 6 and
  2. the assessment of experimental projects,
- including tried and tested practices in this respect.

## **Section 46 Advice on alternatives to animal experiments**

The Federal Institute shall advise the competent authorities on matters relating to alternatives to animal experiments.

## **Section 47 Non-prejudiciality clause**

Nothing in this shall prejudice the regulations of nature conservation law, hunting law and fisheries law.

## **Section 48 Transitional provisions**

(1) Sections 1 and 3 to 6 shall apply as of 1st January, 2014, to facilities and establishments in which, on 12th August, 2013, vertebrates or cephalopods are kept

1. which are intended to be used in animal experiments, or
2. whose tissue or organs are intended to be used for scientific purposes

Sentence 1 shall also apply to facilities and establishments in which the animals mentioned there are bred or kept for the purpose of being supplied to third parties. For facilities and establishments under sentence 1 in which animal experiments are conducted on vertebrates, Section 8b of the Animal Welfare Act shall continue to apply until 31st December, 2013, in the version applicable up to 13th July, 2013.

(2) Anyone empowered on 12th July, 2013, under Section 8b subsection 2 of the Animal Welfare Act in the version applicable on 12th July, 2013, to act as an animal welfare officer shall retain that power as long as he continues to exercise the activity.

(3) Anyone empowered under Section 9 subsection 1 of the Animal Welfare Act in the version applicable on 12th July, 2013, to conduct animal experiments in the course of his activity performed on 12th July, 2013, shall retain that power as long as he continues to exercise the activity.

(4) Sections 14 to 41 and Section 44 shall not apply to animal experiments

1. whose authorisation was applied for according to the regulations of the Animal Welfare Act in the version applicable until 13th July, 2013, before this Regulation came into force, complying with the requirements of its Section 8 subsection 2, or
2. whose implementation was notified according to the regulations of the Animal Welfare Act in the version applicable until 13th July, 2013, before this Regulation came into force, and was not objected to by the competent authority.

## **Annex 1 knowledge and skills required for the care or killing of animals or the planning or implementation of animal experiments**

(Source: Federal Gazette - BGBl. I 2013, 3140 - 3141)

### Chapter 1 Care of animals

1. Valid legal regulations on the keeping and care of animals which are intended to be used in animal experiments or whose tissue or organs are intended to be used for scientific purposes.
2. Principles of biology and appropriate species-specific biology with regard to anatomy and physiological characteristics.
3. Animal behaviour and requirements for and methods of keeping, including enrichment of the housing facilities (general and species-specific).
4. Animal health management and hygiene.
5. Recognition of species-specific pain and suffering in the species most frequently used for animal experiments.
6. Requirement pursuant to Section 7 subsection 1 sentence 2 number 2 of the Animal Welfare Act.
7. Handling animals in a manner appropriate to their behaviour.



## Chapter 2 Killing of animals

1. Valid legal regulations on the killing of animals for scientific purposes or of animals which are intended to be used in animal experiments.
2. Ethics with regard to the relationship between humans and animals, intrinsic value of life.
3. Principles of biology and appropriate species-specific biology with regard to anatomy and physiological characteristics.
4. Basic knowledge of animal behaviour.
5. Basic knowledge of physics and chemistry in so far as they are needed for the method of killing concerned.
6. Suitability and capacity of the respective method of killing.
7. Anaesthesia, pain relieving methods and killing, including the procedures which involve the least stress for the animals.
8. Species-specific methods of handling, where appropriate.
9. Conducting the killing in a proper manner and, where appropriate, prior stunning of the animals causing the least possible pain or suffering.
10. Maintenance of the equipment or facilities needed for the killing and, where appropriate, prior stunning.
11. Recognition of species-specific pain and suffering in the species most frequently used for animal experiments.

## Chapter 3 Planning and implementation of animal experiments

1. Valid legal regulations on the implementation of animal experiments.
2. Ethics with regard to the relationship between humans and animals, intrinsic value of life and arguments for and against the use of animals for scientific purposes.
3. Principles of biology and appropriate species-specific biology with regard to anatomy and physiological characteristics, breeding, genetics and genetic modification.
4. Animal behaviour and requirements for and methods of keeping, including enrichment of the housing facilities (general and species-specific).
5. Animal health management and hygiene.
6. Species-specific methods of handling and experiments.
7. Recognition of species-specific pain and suffering in the species most frequently used for animal experiments.
8. Use of end-points as pain-free as possible.
9. Requirements of the principle of the indispensability of animal experiments pursuant to Section 7 subsection 1 sentence 2 and Section 7a subsection 2 numbers 2, 4 and 5 of the Animal Welfare Act.
10. Planning of procedures and projects, where appropriate.
11. Relevant experimental techniques and operative procedures.
12. Research and evaluation of scientific literature, including any on alternatives to animal experiments.
13. Anaesthesia and pain relieving methods.
14. Wherever the killing the animals is also contemplated in the course of implementation, the

knowledge and skills under Chapter 2.

15. Biometric statistics.

**Annex 2 (to Section 2 subsection 2)  
Methods of killing**

(Source: BGBl. I 2013, 3142 - 3143)

1. For the killing of animals in one of the categories of animals mentioned in line 1 of the table, only those procedures may be used which are listed in column 1 lines 2 to 9 and which are indicated by a cross (+) in the column relating to the category of animal concerned, observing the provisos contained in the notes. In this context, the least stressful method shall always be chosen, provided this is reconcilable with the purpose of the experiment.

	Fish	Amphibians	Reptiles	Birds	Rodents	Rabbits	Dogs, cats, ferrets and foxes	Large mammals	Primates
Anaesthetic overdose	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>	+ <sup>1</sup>
Captive bolt			+ <sup>2</sup>			+		+	
Exposure to carbon dioxide				+	+ <sup>3</sup>				
Cervical dislocation				+ <sup>4</sup>	+ <sup>5</sup>	+ <sup>6</sup>			
Concussion / percussive blow to the head	+	+	+	+ <sup>7</sup>	+ <sup>8</sup>	+ <sup>9</sup>	+ <sup>10</sup>		
Decapitation				+ <sup>11</sup>	+ <sup>12</sup>				
Electrical stunning	+ <sup>13</sup>	+ <sup>13</sup>		+ <sup>13</sup>		+ <sup>13</sup>	+ <sup>13</sup>	+ <sup>13</sup>	
Inhalation of inert gases (argon, nitrogen)				+	+			+ <sup>14</sup>	
Shooting with pistol or rifle with appropriate weapons and ammunition			+ <sup>15</sup>				+ <sup>16</sup>	+ <sup>15</sup>	

2. The killing of the animals using the procedures mentioned under number 1 shall be completed by one of the following methods:
  - a) confirmation of permanent cessation of the circulation,
  - b) destruction of the brain,
  - c) severing the spinal cord in the neck,
  - d) exsanguination or
  - e) confirmation of the onset of *rigor mortis*,