Protection of animals used for scientific or educational purposes.

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ACT

of 15 January 2015

protection of animals used for scientific or educational purposes.[1]

Chapter 1

General provisions

Article 1. [Subject matter and scope of application of the Act]

1. The Act sets out the principles and conditions for the protection of animals used for scientific or educational purposes.

1) the principles for:
   a) carrying out procedures and experiments,
   b) carrying out operations by breeders, suppliers and users,
   c) carrying out inspections of breeders, suppliers and users,

2) conditions in which animals used for scientific or educational purposes are kept and the manner of handling these animals;

3) tasks and competencies of ethical commissions for animal experiments.

2. The Act shall not apply to:

1) veterinary services in the meaning of the Act of 18 December 2003 on veterinary establishments (Dz.U., 2004, No. 11, item 95, as amended), as well as to agricultural practices, including animal husbandry and breeding of animals carried out in accordance with animal protection regulations, for purposes other than carrying out procedures;

2) clinical veterinary trials carried out in accordance with Art. 37ah-37ak of the Act of 6 September 2001 – Pharmaceutical Law (Dz.U., 2008, No. 45, item 271, as amended);

3) activities undertaken for the purpose of identification of animals;

4) capture of wild animals for the purpose of taking biometric measurements and determining their taxonomic classification;

5) activities which, in accordance with good veterinary practice, do not cause pain, suffering, distress or lasting harm equivalent to or more severe than that caused by the introduction of a needle.

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Article 2. [Legal definitions]

1. Definitions used in the Act shall mean:

1) animals – live vertebrate animals, including: independently feeding larval forms; and fetal forms of mammals as from the last third of their normal fetal development or at a stage of development earlier than that, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, it is likely to experience pain, suffering, distress or lasting harm, after it has reached the last third of their normal fetal development, as well as live cephalopods

2) laboratory animals:

a) animals belonging to the following species: mouse (Mus musculus), rat (Rattus norvegicus), guinea pig (Cavia porcellus), Syrian hamster (Mesocricetus auratus), Chinese hamster (Critetulus griseus), Mongolian gerbil (Meriones unguiculatus), rabbit (Oryctolagus cuniculus), dog (Canis familiaris), cat (Felis catus), common frog (Rana temporaria), leopard frog (Rana pipiens), African clawed frog (Xenopus laevis), tropical clawed frog (Xenopus tropicalis), zebra fish (Danio rerio),

b) non-human primates that are the offspring of non-human primates which have been bred in captivity,

c) non-human primates that are not the offspring of non-human primates which have been bred in captivity, specified in the regulations issued on the basis of paragraph 3

– which are bred solely for the purposes specified in Art. 3 or whose tissues or organs are intended to be used for such purposes;

3) wild animals – animals living in the wild in the meaning of Art. 4 item 21 of the Act of 21 August 1997 on the protection of animals (Dz.U., 2013, item 856 and Dz.U., 2014, item 1794);

4) farm livestock – livestock in the meaning of Art. 2 item 1 of the Act of 29 June 2007 on the organization of farm livestock rearing and breeding (Dz.U., No 133, item 921, as amended)

5) natural habitat - natural habitat in the meaning of Art. 5 item 17 of the Act of 16 April 2004 on nature conservation (Dz.U., 2013, item 627, as amended);

6) procedure - means any form of using animals for the purposes specified in Art. 3, 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, as well as any actions 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 conditions in which the animal experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle; this definition excludes killing of an animal solely for the use of its organs or tissues for the purposes specified in Art. 3.

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7) experiment - means a research programme involving a procedure or procedures, carried out for a specific scientific or educational purposes;

8) establishment - means any building, temporary construction structure or other premises where animals used or intended to be used in a procedure or whose tissues and organs are to be used for the purposes specified in Art. 3 are kept;

9) breeder - means any natural or legal person, or an organisational entity without the status of a legal person, breeding animals with a view to their use in procedures or in order to use their tissue or organs for the purposes specified in Art. 3;

10) supplier – means any natural or legal person, or an organizational entity without the status of a legal person, other than a breeder, which is supplying animals with a view to their use in procedures or in order to use their tissues or organs for the purposes specified in Art. 3;

11) user - means any natural or legal person, or an organisational entity without the status of a legal person, using animals in procedures

2. Every time when this Act refers to a Member State of the European Union, this shall also mean a Member State of the European Free Trade Association (EFTA) – parties to the Agreement on the European Economic Area.

3. The minister competent for science-related matters shall determine, by way of a regulation, a list of non-human primates which are not the offspring of non-human primates bred in captivity, which are bred solely for the purposes specified in Art. 3 or whose tissues or organs are intended to be used for such purposes, with a view to ensuring protection of these animals.

Article 3. [Scientific or educational purposes]

Procedures shall be performed only for the purposes of:

1) carrying out research:
   a) basic research in the meaning of Art. 2(3)(a) of the Act of 30 April 2010 on the principles for financing science (Dz.U., 2014, item 1620),
   b) applied research in the meaning of Art. 2(3)(b) of the Act of 30 April 2010 on the principles for financing science, including translational research which applies findings from research on animals into clinical practice, provided that their aim is to:
   – prevent diseases, diagnose or treat diseases or dysfunctions in human beings, animals or plants,
   – assess, detect, regulate or modify physiological conditions in human beings, animals or plants;
   c) research aimed at preservation of the species,
   d) forensic medicine research;

2) ensuring animal welfare or seeking an improvement in the conditions in which farm livestock are being bred and kept;

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3) developing and manufacturing medicinal products, foodstuffs in the meaning of the Act of 25 August 2006 on the safety of food and nutrition (Dz.U., 2010, No. 136, item 914, as amended), animal feed and other substances or products, or testing their quality, effectiveness and safety for the purposes mentioned under 1(b) and 2 above.

4) protecting the natural environment in the interests of the health or welfare of human beings or animals;

5) providing education at the level of higher education or training for the acquisition or improvement of professional competency;

Article 4. [Application of the provisions of the Act on the protection of animals]
In the scope not regulated by the provisions of the Act on the protection of animals used for scientific or educational purposes, the Act of 21 August 1997 on the protection of animals shall apply.

Chapter 2

Principles applicable to carrying out procedures

Article 5. [Permissibility of procedure performance]
1. Performance of procedures is permissible only in the situations when:

1) no other research method ensuring that the aims specified in Art. 3 are achieved without the use of animals can be used (principle of replacement);

2) the number of animals used in the procedure has been reduced to the level necessary for achieving the aims specified in Art. 3 (principle of reduction);

3) animals used in the procedure are kept in the conditions appropriate for their species and the research methods used in the procedures have been so chosen as to reduce to the minimum or eliminate pain, suffering, distress or the possibility of lasting harm inflicted on the animals (principle of refinement).

2. It is prohibited to perform a procedure if the procedure results in severe pain, suffering or distress, which is likely to be long-lasting and cannot be alleviated.

3. It is prohibited to perform a procedure for the purpose of obtaining data which have already been generated outside the Republic of Poland in other Member States of the European Union as a result of the performance of procedures recognised by the legislation of the European Union, and specifically with regard to animal feeds, biocidal products, medicinal products, chemical substances, plant protection products, medical products or foodstuffs, unless confirmation of that data is necessary in order to use it in research whose purpose is the protection of public health, safety or the environment.

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4. If it is possible to choose between procedures, the procedures shall be selected with consideration to the requirements that the procedure shall:

1) be designed so as to:

a) use the minimum number of animals,

b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

2) result in minimum levels of pain, suffering or distress, or to the lowest extent cause the risk of lasting harm;

3) be the procedure most likely to provide the planned results.

Article 6. [Principles of performing procedures]

1. Procedures shall be planned and performed in such a way that death of the animals as the end-point will be avoided, with the provision, however, that if the health of animals used in the procedure indicates the impending death – these animals are killed (early and humane end of the procedure).

2. If avoiding death as an end-point is not possible, the procedure shall be planned and performed so as to reduce the number of deaths among the animals to the lowest extent possible and reduce to the minimum the duration and intensity of suffering experienced by these animals.

3. Killing of animals, referred to in paragraph 1, shall be done in the manner determined in Article 16(1) and (2).

Article 7. [Permissible procedures]

Following the approval by a local ethical commission for animal experiments, it is permissible to use in the procedures:

1) animals belonging to species referred to Article 2(1)(2) – in cases where the aims of the procedure, specified in Art. 3, cannot be achieved with the use of laboratory animals;

2) primates listed in Annex A to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (O.J. EC L 61 of 03.03.1997, p. 1, as subsequently amended; O.J. EU Polish special edition, Chapter 15, vol. 3, p. 136, as subsequently amended), hereinafter: "Regulation (EC) No. 338/97", which do not fall within the scope of Article 7(1) of that Regulation – only in the procedures carried out with the purpose of research referred to in Art. 3:

a) Article 3(1)(b) tiret one or Article 3(3), undertaken for the purpose of prevention, diagnosis or treatment of debilitating physical or mental conditions or potentially life-threatening diseases in humans,

b) item 1(c)

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– where the purpose of the procedure cannot be achieved by the use of animal species not listed in that Annex and by the use of species other than non-human primates;

3) primates other than those listed under (2) above – only in the procedures carried out with the purpose of research referred to in:

a) item 1(a) or (c),

b) Article 3(1)(b) tiret one or Article 3(3), undertaken for the purpose of prevention, diagnosis or treatment of debilitating physical or mental conditions or potentially life-threatening diseases in humans,

– where the purpose of the procedure cannot be achieved by the use of species other than non-human primates;

4) specimens of endangered species, except for non-human primates listed in Annex A to Regulation (EC) No 338/97, which do not fall within the scope of Article 7(1) of that Regulation – exclusively in the case of procedures undertaken with the view to carry out research referred to in Article 3(1)(b) tiret one, Article 3(1)(c) and Article 3(3) – where it is not possible to achieve the purpose of the procedure using an animal species not mentioned in that Annex.

Article 8. [Prohibited procedures]

1. Prohibited procedures are those undertaken on:

1) great apes;

2) wild animals;

3) stray and abandoned animals in the meaning of Art. 4(16) of the Act of 21 August 1997 on the protection of animals, excluding farm livestock.

2. The local ethical commission may, in exceptional cases, based on scientific justification presented by the user, give consent that the procedure may involve the use of the following:

1) animals belonging to species referred to in paragraph 1(2) – in cases where the aims of the procedure, specified in Art. 3, cannot be achieved with the use of laboratory animals;

2) animals referred to in paragraph 1(3) – if the objective of the procedure is to investigate the health and wellbeing of those animals or prevent a serious threat caused by those animals to the health of human beings, animals or the environment, and where that purpose may be achieved only with the use of those animals.

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Article 9. [Place of performing procedures]

1. Procedures shall only be performed:

1) within the scope of an experiment;

2) at the establishment run by the user who was entered in the register maintained by the minister competent for science-related matters.

2. Procedures may be performed at a location other than that specified in paragraph 1(2), if their purpose cannot be achieved when they are undertaken at the user's establishment.

3. A procedure shall be carried out in the environment specific for a wild animal if the procedure can achieve its objective(s) when carried out in such environment and if that would reduce the stress caused to the animal by the performance of the procedure.

Article 10. [Procedure severity classification]

1. According to procedure severity, determined in relation to the intensity of pain, suffering, distress or lasting harm to which an animal may be exposed during the performance of a procedure, all procedures should be classified into the following categories:

1) terminal, non-recovery;

2) mild;

3) moderate;

4) severe.

2. Procedures are classified into the categories mentioned in paragraph (1) in accordance with Annex VIII to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (O.J. EU L 276 of 20.10.2010, p. 33).

Article 11. [Course of the procedure]

1. A procedure:

1) shall begin with the preparation of an animal for observation;

2) shall end when the observation of the animal is discontinued, and – in the case of a genetically modified animal line – when it is not envisaged that the offspring of these animals will suffer lasting harm or will experience pain, suffering or distress.

2. At the end of a procedure a veterinarian shall take a decision on:

1) keeping the animal used in the procedure alive or

2) killing the animal used in the procedure – where there are justified grounds to believe that, when the experiment ends, the animal will suffer lasting harm or that it will continue to experience severe or moderate pain, suffering and distress.

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3. Should the procedure involve the use of animals other than laboratory and farm animals, the decision referred to in paragraph 2 may be taken by a person suitably qualified with regard to the anatomy, physiology and behavior of those animal species.

Article 12. [Re-use of an animal in the procedure]

1. Reuse of an animal in a procedure in order to avoid use of another animal not yet used in a procedure is allowed, provided that consent to do so is obtained from a veterinarian who, after examining the animal and taking into consideration its life experiences concluded that the animal has fully recovered to general health and wellbeing.

2. An animal that has been used:

1) in a procedure classified as 'mild' or 'moderate' – may be re-used in a procedure classified as 'terminal, non-recovery', 'mild' or 'moderate';

2) once in a procedure classified as 'severe' – may be, in exceptional cases and after consent has been obtained from the local ethical commission for animal experiments, re-used in a procedure classified as 'terminal, non-recovery', 'mild' or 'moderate', on the basis of the justification to re-use that animal, presented by the user.

Article 13. [Procedures that cause pain or severe harm]

1. Procedures that result in severe harm and severe pain in the animals used are carried out under general or local anaesthesia, and after medicinal products or veterinary medicinal products with pain-relieving properties have been administered.

2. Procedures other than those described in paragraph 1 are carried out under general or local anaesthesia and after using:

1) medicinal products or veterinary medicinal products with pain-relieving properties, or

2) other methods, in particular sedatives, to ensure that the pain, suffering and distress of the animals used are reduced to a minimum.

3. In the case referred to in paragraph 2, a procedure may be used without general or local anaesthesia only where the use of anaesthesia:

1) would cause the animal to experience pain, suffering or distress stronger than the procedure alone, or

2) is not compatible with the purpose of the procedure

– following the approval by a local ethical commission for animal experiments, given on the basis of the justification presented by the user in support of the application for waiving the requirement to use anaesthesia.

4. In cases where an animal may suffer pain once general or local anaesthesia has worn off or after a procedure carried out in a way described in paragraph 3 was finished, the animal shall be treated with medicinal products or veterinary medicinal products with pain-

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relieving properties or with other methods, especially sedatives, ensuring that the pain is reduced to a minimum.

Article 14. [Drugs that restrict showing pain]

1. Giving to an animal which is being used in a procedure any medicinal products or veterinary medicinal products that prevent or restrict the animal from showing pain is only allowed when:

1) at the same time an appropriate level of general anaesthesia, local anaesthesia, medicinal products or veterinary medicinal products with pain-relieving properties are administered;

2) approval by the local ethical commission for animal experiments has been obtained – on the basis of the scientific justification presented by the user, accompanied by the details of the regimen used for the general or local anaesthesia, or medicinal products or veterinary medicinal product with pain-relieving properties.

2. It is prohibited to use any measures that prevent the animals used in procedures from uttering voice.

Article 15. [Setting free and rehoming of animals]

1. An animal that is left alive after the end of a procedure shall receive:

1) care and, where necessary, also veterinary care;

2) accommodation standards appropriate to its species and health condition.

2. An animal that is left alive after the end of a procedure may be returned by the user to the natural habitat appropriate to its species or rehomed with a new carer only when:

1) the state of health of the animal allows it;

2) there is no danger to public health, animal health or the environment; and

3) accommodation standards provided to the animal are appropriate to its health condition and species.

Article 16. [Killing an animal]

1. Should a decision be taken to kill an animal used in the procedure, the animal shall be killed by a suitably qualified person, as determined in Art. 21(3)(2), exclusively with the use of methods specified in Annex IV to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

2. The animal shall be killed in a manner that reduces pain, suffering and distress to a minimum.

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3. The provisions of paragraphs 1 and 2 shall be applied when killing an animal whose tissues or organs are to be used for the purposes specified in Art. 3.

4. The provision of paragraph 1 shall not apply in the event of an emergency where the animal needs to be killed because of its wellbeing, a threat to the health of human beings or animals, or a threat to the natural environment.

Chapter 3

Requirements with regard to operations carried out within the scope of using animals for scientific or educational purposes

Article 17. [Requirements applicable to establishments]

1. An entity that carries out operations within the scope of using animals for scientific or educational purposes shall keep any such animals at an establishment where:

1) it is ensured that appropriate accommodation standards adapted to the species in question are provided, including the ability to meet the physiological and etological needs of the animals kept;

2) appropriate equipment and devices, adapted to the needs and features of the animal species kept, have been provided.

2. The entity referred to in paragraph 1 shall ensure that the animals kept at the establishment are provided with:

1) care that guarantees welfare of the animals and maintenance of proper health condition, including:
   a) daily inspection of environmental conditions,
   b) immediate removal of irregularities detected with regard to environmental conditions, wellbeing and health condition;

2) transport adapted to the species concerned, in accordance with the requirements specified in the regulations on the protection of animals and animal health and on combating infectious diseases in animals.

Article 18. [Requirements applicable to establishments operated by users]

An entity that carries out operations as a user within the scope of using animals for scientific or educational purposes may carry out its operations at an establishment which, apart from meeting the conditions determined in Art. 17, shall meet the following requirements:

1) it is adapted to suit the type and number of procedures carried out;

2) it is designed and equipped in a way as to:
   a) ensure reliable results of procedures,

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b) reduce to a minimum the pain, suffering, distress or possibility of a lasting harm caused to the animals during the performance of procedures.

Article 19. [Delegation of legislative powers – minimum requirements concerning establishments]

The minister competent for agriculture-related matters shall determine, by way of a regulation, the minimum requirements:

1) that should be met by the establishment,

2) concerning the scope of care provided to animals kept at the establishment

– taking into consideration the physiological and etological needs of the animal species kept at the establishment and the requirement to ensure wellbeing, proper health condition and appropriate care of the animals kept there.

Article 20. [Competence of personnel]

The entity referred to in Article 17(1) shall designate as a person taking care of animals kept at the establishment an individual who:

1) holds at least post-primary vocational or secondary education certificate;

2) has been trained with regard to taking care of animals used or intended for use in procedures;

3) has completed 3 months of practical training with regard to taking care of animals used or intended for use in procedures, under the supervision of a veterinarian or a person designated by the breeder, supplier or user.

Article 21. [Specific requirements for personnel]

1. The entity referred to in Art. 18 shall designate a person responsible for the planning and execution of procedures and experiments who has expertise on the animal species used in the procedures and:

1) holds a PhD in the area of biological, pharmaceutical, medical, veterinary or agricultural sciences, has completed a course of training with regard to carrying out experiments on animals, and has at least 3 years of work experience allowing the acquisition of practical skills in this regard, or

2) holds a PhD in the area of science other than those mentioned in (1) above or a higher education diploma confirming studies completed in the area of biological, pharmaceutical, medical, veterinary or agricultural sciences, completed postgraduate studies or a course of training with regard to carrying out experiments on animals, and has at least 4 years of work experience allowing the acquisition of practical skills in this regard.

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2. The entity referred to in Art. 18 shall designate for the performance of procedures a person who:

1) holds a higher education diploma confirming studies completed in the area of biological, pharmaceutical, medical, veterinary or agricultural sciences, has completed a course of training with regard to carrying out experiments on animals and participated in the performance of procedures for at least one year under the supervision of a person designated by the user and acquired practical skills in this regard, or

2) holds a higher education diploma confirming studies completed in a discipline other than those listed in (1), completed postgraduate studies or a course of training with regard to carrying out experiments on animals, and participated in the performance of procedures for at least 2 years under the supervision of a person designated by the user and acquired practical skills in this regard, or

3) holds a secondary education diploma and vocational training compatible with the scope of procedures performed, and participated in the performance of procedures for at least 2 years under the supervision of a person designated by the user and acquired practical skills in this regard.

3. The entity referred to in Art. 18 shall designate:

1) for participation in carrying out procedures, a person who:
   a) is a student, or
   b) performs technical tasks related to dealing with and handling of animals

   – and who has been trained on how to care for and handle animals used or intended for use in procedures;

2) for killing the animals used in a procedure, a person who:
   a) holds at least post-primary vocational or secondary education certificate;
   b) has been trained on the methods used to kill animals used in procedures,
   c) has completed 3 months of practical training with regard to performing tasks related to killing the animals used in procedures under the supervision of a veterinarian or a person who kills animals at the user's establishment.

Article 22. [Delegation of legislative powers – scope of training with regard to protection of animals]

The minister competent for science-related matters shall determine, by way of a regulation, the scope of curricula for training, practical work experience and internships, referred to in Art. 20(2) and (3), Art. 21, and Art. 24(2)(2) and (2)(3), as well as sample specimens of the documents confirming the completion thereof, with the view to ensure that training participants will acquire knowledge and practical skills requisite for correct performance of the tasks mentioned in Art. 20 and Art. 21 and the duties specified in Art. 24(1).

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Article 23. [Contract for veterinary services to be provided at the establishment]
The entity, referred to in Art. 17(1), shall enter into a contract with a veterinary physician, under which veterinary services, in the meaning of the Act of 18 December 2003 on veterinary establishments, shall be provided at the establishment.

Article 24. [Designating a person to perform supervisory duties and organize training]
1. The entity referred to in Article 17(1) shall designate at the establishment a person responsible for:

1) supervision over:
a) staff taking care of animals kept at the establishment,
b) the wellbeing of animals kept at the establishment;

2) ensuring that persons referred to in Art. 20 and Art. 21 have access to information on animal species kept at the establishment;

3) organizing training for persons referred to in Art. 20 and Art. 21.

2. The person designated for performing the duties specified in paragraph 1 shall:

1) hold at least a secondary education certificate and an occupational title of a technician or a diploma confirming his/her occupational qualifications in occupations related to keeping and breeding animals;

2) have completed training within the scope requisite for performing supervisory duties over persons taking care of animals;

3) have at least 2 years of work experience in a job position related to taking care of animals.

Article 25. [Duties within the scope of animal welfare]
1. The entity referred to in Article 17(1) shall ensure that the following duties concerning animal welfare are performed at the establishment:

1) providing advice:
a) in matters related to ensuring welfare of animals,
b) concerning the obligation to apply the principles of replacement, reduction and refinement (3Rs),
c) in the matter of:
– finding a new carer for animals that won't be used in procedures,
– carrying out rehabilitation of wild animals before they are released back into their natural habitat,
d) in matters related to training organized;

2) developing and reviewing the internal rules concerning handling and taking care of animals kept at the establishment;

3) monitoring the cases where animals are killed for the purpose of obtaining organs or tissues;

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4) monitoring the wellbeing of animals kept at the establishment;

5) reporting to the entity referred to in Article 17(1) cases where the wellbeing of animals kept at the establishment is compromised and determining actions to be taken in order to restore the wellbeing;

6) controlling the course of experiments and their results, taking into consideration the impact of these experiments on the animals used in them, and evaluating the compliance of these experiments with the principles of replacement, reduction and refinement.

2. The duties specified in paragraph 1 may be performed by a person or persons who meet the requirements concerning education and occupational experience specified in Art. 24(2) and, in the case of an establishment carrying out operations indicated in Art. 18, also a member of academic staff who meets the requirements concerning education and professional experience specified in Art. 21(1).

3. In order to perform the duties specified in paragraph 1 the entity referred to in Article 17(1) shall establish an Animal Welfare Advisory Team, whose members should include the person or persons mentioned in paragraph 2.

4. The entity referred to in Article 17(1) shall ensure performance of the duties specified in paragraph 1 by:

1) designating at the establishment a person or persons to perform these duties;

2) entering into a contract for performance of these duties.

5. The contract for performance of the duties specified in paragraph 1 may be executed with the same person or persons by not more than five breeders, suppliers or users who keep animals in holding rooms where the total combined floor space of those rooms does not exceed 100 m^2.

6. When performing the duties specified in paragraph 1, the persons referred to in paragraph 2 shall cooperate with the veterinary physician referred to in Art. 23.

7. The veterinary physician referred to in Art. 23 shall communicate information concerning the welfare of animals kept at the establishment to the persons referred to in paragraph 2.

8. The persons referred to in paragraph 2 shall prepare documentation which will indicate, specifically, actions that have been taken in order to remove irregularities detected when carrying out duties specified in paragraph 1, and deliver the documentation to the entity referred to in Article 17(1).

9. The entity referred to in Article 17(1) shall:

1) keep the documentation referred to in paragraph 8 for 3 years from the date when the last entry was made;

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2) provide the National Ethical Commission for animal experiments with information concerning performance of duties specified in paragraph 1.

Chapter 4

Operations of breeders, suppliers and users

Article 26. [Register of breeders, suppliers and users]

Carrying out operations consisting of breeding or supplying animals or performing procedures shall require an entry in the register of breeders, suppliers and users (hereinafter: "the register").

Article 27. [Entry in the register]

1. An entity that intends to carry out operations mentioned in Art. 26 shall lodge with the local veterinary authority (*powiatowy lekarz weterynarii*) an application requesting confirmation of compliance with the requirements necessary for carrying out these operations.

2. By way of an administrative decision the local veterinary authority shall:

1) confirm compliance with the requirements necessary for carrying out the operations mentioned in Art. 26, provided that the requirements, specified in Art. 17, Art. 18, Art. 20, Art. 21, Art. 23, Art. 24 and Art. 25(1) and (2), and in the regulations issued pursuant to Art. 19, are met;

2) refuse to issue the decision referred to in point (1) if the requirements necessary for carrying out the operations mentioned in Art. 26, specified in Art. 17, Art. 18, Art. 20, Art. 21, Art. 23, Art. 24 and Art. 25(1) or (2), or in the regulations issued pursuant to Art. 19, are not met;

3. The application referred to in paragraph 1 shall indicate:

1) the name and surname, address and place of residence or the business name, address and registered office of the applicant, with the provision that in the case where the applicant is an individual carrying on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

2) the type of operations planned to be conducted;

3) the name and surname of the veterinarian referred to in Art. 23;

4) the name and surname of the person referred to in Art. 24(1) and Art. 25(2);

5) the list of animal species which will be bred, supplied or used in procedures or whose tissues or organs will be intended to be used for the purposes specified in Art. 3.

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4. An entity that intends to conduct operations which involve performance of procedures shall enclose information on having complied with the requirements specified in Art. 18 with the application referred to in paragraph 1.

5. An entity that intends to conduct operations which involve breeding of non-human primates shall specify in the application referred to in paragraph 1 its strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

6. The final decision referred to in paragraph 2(1) and the application referred to in paragraph 1 shall be immediately delivered by the local veterinary authority to the minister competent for science-related matters.

Article 28. [Making entry in the register, deleting entry from the register]

1. The minister competent for science-related matters shall:

1) enter the breeder, supplier or user into the register, within 14 days from the date of receipt from the local veterinary authority of the final decision referred to in Art. 27(2)(1);

2) strike out from the register a breeder, supplier or user at the request of:

a) the local veterinary authority – in the case of:

– flagrant violation of the requirements specified for carrying out the operations to which the entry applies,

– failure of the breeder, supplier or user to remove irregularities in the operations to which the entry applies by the deadline referred to in Art. 58,

b) the breeder, supplier or user – in the case of discontinuance of the operations to which the entry applies.

2. Flagrant violation of the requirements specified for carrying out the operations to which the entry applies shall mean the situation when, during an inspection, the local veterinary authority finds that:

1) a requirement specified in Art. 23 or in Art. 25(2) has not been met, or

2) the requirements specified in Art. 17, Art. 18, Art. 20, Art. 21, Art. 24, or in the regulations issued pursuant to Art. 19, have not been complied with on three occasions, or

3) an experiment was carried out without authorization for doing so.

Article 29. [Data in the register]

1. The minister competent for science-related matters shall maintain the register in an electronic format.

2. The register shall list:

1) name and surname or business name of the breeder, supplier or user;

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2) address and place of business where the breeder, supplier or user carry out their operations;

3) data referred to in Art .27(3)(2-5);

3. The breeder, supplier or user entered in the register shall notify in writing the minister competent for science-related matters on any change in the data referred to in Art. 27(3)(3) and (4) within 7 days from the date of any such change.

4. To a change concerning place of business, type of business operations, animal species bred, supplied or used in procedures, the provisions of Art. 27 shall apply, as appropriate.

5. Data contained in the register, excluding the data referred to in Art. 27(3)(3) and (4), shall be published in the Public Information Bulletin on the website of the minister competent for science-related matters.

Article 30. [Keeping animal records]

1. Within the scope of their operations, each breeder, supplier or user shall keep animal records which should contain:

1) information on the number and species of animals kept, bred, acquired, supplied, used in procedures, returned to their natural habitat or rehomed with a new carer;

2) information on the origin of the animals, including whether they were bred for use in procedures;

3) date of acquisition, supply, return of the animal to its natural habitat or rehoming the animal with a new carer;

4) the name and surname, address and place of residence or the business name, address and registered office of the entity from which the animals were acquired, with the provision that in the case where that entity is an individual carrying on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

5) the name and surname, address and place of residence or the business name, address and registered office of the entity to which the animals were supplied, with the provision that in the case where that entity is an individual carrying on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

6) information on the number and species of animals which died or were killed in the establishment, providing specific information on those killed exclusively for the purpose of obtaining organs or tissues and, in the case of animals which died, also on the cause of their death, unless not known;

7) the name and surname, address and place of residence or the business name, address and registered office of the entity to which the animal referred to in Art. 15(2) was rehomed, with the provision that in the case where that entity is an individual carrying

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on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

8) information on the number and type of experiments carried out – in the case of users;

9) information concerning every dog, cat and non-human primate – immediately after their birth or on the date of acquisition, including:

a) the date and place of birth of the dog, cat and non-human primate, if known,

b) data contained in a permanent individual identification marker by which dogs, cats and non-human primates are marked,

c) information on the breeding facility from which the dog, cat and non-human primate came from,

d) information on having bred the animal for use in procedures,

e) information that the animal is an offspring of animals bred in captivity – in the case of a non-human primate,

f) reproductive and veterinary information and information on the behaviour of the dog, cat or non-human primate towards humans and animals,

g) information on the number and type of experiments in which the dog, cat or non-human primate was used.

2. Within the scope of their operations, each breeder, supplier or user shall keep the data contained in records for the animals for the period of:

1) 5 years from the date when the last entry was made – in the case of data referred to in paragraph 1(1-8);

2) 3 years from the death of the animal or from its return to the natural habitat specific to its species or rehoming it with a new carer – in the case of data referred to in paragraph 1(9).

3. Information referred to in paragraph 1(9)(f) shall be delivered to the animal's new carer.

4. Based on the data contained in the records, each user shall each year, by 31 March, deliver to the minister competent for science-related matters the information on:

1) animals used in procedures and, specifically, the aims and categories of the procedures and the regulations which indicate the obligation to carry out the procedures;

2) animals killed exclusively for the purpose of obtaining their organs or tissues.

5. Each breeder and supplier shall each year, by 31 March, deliver to the minister competent for science-related matters information concerning the animals intended for use in procedures.

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Article 31. [Marking of animals]

1. Each breeder, supplier or user shall provide permanent individual identification marking to every dog, cat or non-human primate, in the least painful manner possible, not later than at the time of weaning.

2. Where a dog, cat and non-human primate is transferred from one breeder, supplier or user to another before it is weaned, and it is not practicable to mark it before the transfer, the breeder, supplier or user receiving the animal shall:

1) list the data that allow identification of the animal and its mother in the records referred to in Art. 30(1);

2) immediately mark the animal with a permanent individual identification mark.

3. The minister competent for agriculture-related matters shall determine, by way of a regulation, the method to be used for marking dogs, cats and non-human primates and the data that to be included in the permanent individual identification mark, taking into account the characteristics of the animals to be marked and the need to ensure their identification on the basis of the data contained in that mark.

Chapter 5

Ethical commissions for animal experiments

Article 32. [Authorities competent for authorizing experiments]

1. Authorities competent for the matters of granting and modifying authorizations for carrying out experiments shall be the National Ethical Commission for Animal Experiments (*Krajowa Komisja Etyczna do Spraw Doświadczeń na Zwierzętach*; hereinafter: "the Commission") and local ethical commissions for animal experiments (hereinafter: "local commissions").

2. Local commissions, in the number not exceeding 11, shall be formed taking into account the location of establishments where experiments are carried out and the number of experiments carried out in each of these establishments.

Article 33 [National Ethical Commission for Animal Experiments – duties and operations]

1. The duties of the Commission include:

1) formulating and presenting:

a) to breeders, suppliers and users – opinions and requests in matters concerning protection of animals used for scientific or educational purposes.

b) to users – opinions on cooperation with regard to reciprocity in making available organs and tissues obtained from animals,

c) to breeders – guidelines for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity;

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2) developing good practices and sharing them with users, in particular within the scope of planning and execution of procedures, using the principles of replacement, reduction and refinement, and on alternative methods used;

3) presenting to the minister competent for science-related matters and the minister competent for agriculture-related matters requests and conclusions resulting from the annual report summarizing the results of inspections of breeders, suppliers and users;

4) appointing and recalling members of local commissions:

5) cooperation with the European Commission in:

a) developing and approving research methods which ensure that the scope of information obtained without any use or with the use of a lower number of animals, or with the use of animals in a way causing them less pain, is the same of wider than that which would be obtained when carrying out procedures that use animals (alternative methods),

b) designating laboratories performing tests with the view to approve alternative methods for the purposes of the Union Reference Laboratory which acts as the European Centre for the Validation of Alternative Methods;

6) disseminating information about alternative methods and promoting these methods;

7) presenting to the person or persons referred to in Art. 25(2) opinions in matters related to the acquisition, breeding, accommodation, care and use of animals in procedures and the dissemination and sharing of good practices within that scope;

8) exchanging information with relevant authorities of other Member States of the European Union within the scope of the duties to be carried out by the Commission and within the scope of the performance at the establishments of breeders, suppliers and users of the duties specified in Article 25(1), as well as disseminating and sharing good practices within that scope.

2. Each year, by 30 June, the Commission shall deliver to the minister competent for science-related matters the information on authorizations granted for performance of experiments and, specifically, on the number and purposes of experiments carried out.

3. The Commission is an authority of higher rank relative to local commissions, in the meaning of the Code of Administrative Procedure, in matters concerning giving authorizations referred to in Article 36(1)(1).

4. Resolutions of the Commission may be challenged in administrative courts.

5. The Commission acts on the basis of its Rules and Regulations approved each time by the minister competent for science-related matters.

6. Good practices, referred to in paragraph 1(2), the information on alternative methods and an annual inspection report referred to in Art. 62, shall be published in the Public Information Bulletin on the website of the minister competent for science-related matters.

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Article 34. [Composition of the National Commission]

1. The Commission shall comprise 15 members, appointed and recalled by the minister competent for science-related matters, of whom:

1) 9 members, each of whom should hold at least a PhD and have expertise or experience in the use of animals for scientific or educational purposes, shall represent biological, pharmaceutical, medical, agricultural or veterinary sciences;

2) 3 members shall represent the humanities or social sciences, in particular in the fields of philosophy, ethics or law;

3) 3 members shall represent NGOs and non-profit organizations which pursue the statutory objective of protecting animals.

2. A person who:

1) has been convicted by a final and binding sentence for a criminal offence committed intentionally or an intentional fiscal offence; or

2) has been punished by means of a final and binding decision of a disciplinary committee or a court ruling in matters of professional liability

may not be a member of the Commission.

3. The Commission's term of office lasts 4 years.

4. Any Commission member may not stay in the Commission for more than two consecutive terms of office.

5. Meetings of the Commission shall be attended by a representative of the minister competent for science-related matters.

6. The minister competent for science-related matters shall appoint the Commission Chairperson from among Commission members.

Article 35. [Recall and expiry of the term of office of a member of the National Commission]

1. The minister competent for science-related matters shall recall a Commission member, should any of the circumstances referred to in Art 34(2) occur.

2. A Commission member shall immediately notify the minister competent for science-related matters of an occurrence of any of the circumstances referred to in Art 34(2).

3. The minister competent for science-related matters may recall a member of the Commission, if that person has been absent at 4 consecutive Commission meetings.

4. The term of office of a Committee member shall expire in the case of:

1) death;

2) being recalled;

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3) resigning from the Commission.

5. Should there be a need to replace a missing member with another person, the minister competent for science-related matters shall appoint a new Commission member for a period up to the end of the current term of office, subject to the principles referred to in Art 34(1). The incomplete term of office shall not be included in the calculation of the period specified in Art. 34(4).

Article 36. [Duties of local commissions]

1. The duties of local commissions shall include:

1) giving authorization for:

a) carrying out an experiment, including approval for:

– re-use of an animal in a procedure – in the case referred to in Art. 12(2)(2),

– performance of a procedure without general or local anaesthesia – in the case referred to in Art. 13(3),

– administration to the animal in a procedure of medicinal products or veterinary medicinal products that prevent or restrict the animal from showing pain – in the case referred to in Art. 14(1)(2),

– use in a procedure the animals referred to in Art. 7 and Art. 8(1)(2) and (3),

– change of an experiment – in the case referred to in Art. 51(1),

2) revoking the authorization for an experiment;

3) evaluating the experiment according to the criteria specified in Art. 53(2), hereinafter: "retrospective assessment", and keeping the results of such retrospective assessment;

4) delivering, at the request of the local veterinary authority carrying out inspection of a user with regard to experiments, the information requisite for the correct conduct of such inspection;

5) publishing in the Public Information Bulletin, on the website of the minister competent for science-related matters, non-technical summaries of experiments.

2. Each year, by 31 March, the local commission shall deliver:

1) to the Commission the information on authorizations granted for performance of experiments and, specifically, on the number and purposes of experiments carried out.

2) to the minister competent for science-related matters and to the Commission the information concerning retrospective assessments carried out and published non-technical summaries of experiments.

3. The local commission shall act on the basis of its Rules and Regulations approved each time by the Commission.

4. Publishing of non-technical summaries of experiments shall be subject to the Act of 4 February 1994 on copyright and related rights (Dz.U., 2006, No. 90, item 631, as amended); and the Act of 30 June 2000 – Industrial Property Law (Dz.U. , 2013, item 1410).

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Article 37. [Composition of a local commission]

1. A local commission comprises 12 members who are appointed and recalled by the Commission, of whom:

1) 6 members, each of whom should hold at least a PhD and have expertise or experience in the use of animals for scientific or educational purposes, shall represent biological, pharmaceutical, medical, agricultural or veterinary sciences;

2) 3 members shall represent the humanities or social sciences, in particular in the fields of philosophy, ethics or law, including one representative of an organization with statutory objectives including protection of patient rights;

3) 3 members shall represent NGOs and non-profit organizations which pursue the statutory objective of protecting animals.

2. The provisions of Art. 34(2-4) and Art. 35 shall apply, as appropriate, to the members of a local commission.

Article 38. [Independence of commission members]

1. In performing their duties members of the Commission and members of local commissions shall act independently of local public administration and breeders, suppliers and users.

2. Except for the cases specified in the Code of Administrative Procedure, a member of the Commission or a local commission shall be exempt from participation in the proceedings in matters concerning authorizations referred to in Art. 36(1)(1), if that member is the person who:

1) has planned and is responsible for an experiment subject to the proceedings in matters concerning such authorization;

2) is carrying out an experiment subject to the proceedings in matters concerning such authorization or is participating in such an experiment;

3. The provisions of Art. 24(3) of the Code of Administrative Procedure shall accordingly apply to a member of the Commission or a local commission, referred to in paragraph 2.

4. Members of the Commission and local commissions shall not reveal any information they obtained in relation to their performance of duties specified in Art. 33(1) and Art. 36(1)(1) and (3). This obligation shall remain in force after the termination of membership in the Commission or a local commission.

Article 39. [Financing the operations of the National Commission and local commissions]

1. The operations of the Commission and local commissions shall be financed from the portion of the state budget assigned to the minister competent for science-related matters.

2. For their participation in meetings of their respective commissions, members of the Commission and local commissions are entitled to compensation and reimbursement of the

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cost of travel, according to the principles determined in the regulations issued on the basis of Art. 775(2) of the Labour Code,

Article 40. [Application of the provisions of the Code of Administrative Procedure]
Within the scope not regulated by this Act, the proceedings taken by the Commission and local commissions in matters concerning authorizations referred to in Art 36(1)(1) shall be governed by the provisions of the Code of Administrative Procedure.

Article 41. [Delegation of legislative powers – functioning of commissions, suggesting candidates for commission members]
The minister competent for science-related matters shall determine, by way of a regulation:

1) the method of functioning of the Commission and local commissions, including the manner of confirming the submission of an application for authorization of an experiment, taking into consideration the scope of duties of the Commission and local commissions and ensuring the conditions for efficient performance of duties assigned to these commissions;

2) territorial jurisdiction of local commissions, taking into consideration efficient performance of the duties assigned to these commissions, including the processing of applications requesting authorization of an experiment within the deadline determined in Art. 48(2), and taking into account the locations of establishments where experiments are carried out and the number of experiments carried out in each of these establishments.

3) the method of appointing candidates to the Commission and local commissions, taking into account the requirements concerning the expertise and experience of the persons nominated as candidates to these commissions;

4) a sample form for registering a candidate for the Commission or a local commission, with the view to ensure a uniform set of information provided;

5) the compensation awarded to members of the Commission and local commissions and the terms of disbursement thereof, taking into account roles performed by members of the Commission and local commissions and the scope of their duties.

Chapter 6

Principles governing performance of experiments

Article 42. [Authorization for an experiment]
Experiments shall be carried out after an authorization by a local commission has been issued at the request of the user.

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Article 43. [Application for an authorization]

1. The user shall lodge an application requesting authorization of an experiment with the local commission holding territorial jurisdiction over the location of the establishment where the experiment is to be carried out.

2. In the case of an experiment carried out at multiple establishments or outside the site of an establishment, the user shall lodge the application with the local commission holding territorial jurisdiction over the location of the establishment where the person who has designed and is responsible for experiment is employed.

3. The sample form for an application, developed by the Commission, shall be published in the Public Information Bulletin, on the website of the minister competent for science-related matters.

Article 44. [Content of an application]

1. Application requesting authorization of an experiment shall contain:

1) the name and surname, address and place of residence or the business name, address and registered office of the user, with the provision that in the case where the user is an individual carrying on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

2) indication of the establishment where the experiment will be carried out and, if the experiment will be carried out outside the establishment, the location of the experiment, along with the justification of an experiment carried out outside the establishment;

3) the description of the experiment, including information on the scientific or educational purpose that is planned as the objective of the experiment;

4) justification for the use of animals in the experiment, providing details of their place of origin, numbers, species, age or developmental age;

5) description of the accommodation conditions in which the animals used in the experiment are to be kept;

6) description of the planned procedures included in the experiment, justification for these procedures and the proposed category of severity;

7) the name and surname of the person who designed and is responsible for the experiment, and the competencies of that person;

8) names and surnames of the persons carrying out the experiment and those participating in the experiment, and their competencies;

9) description of how the principles of replacement, reduction and refinement have been applied in the experiment;

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10) indication of the types of measures planned to be used in the animals used in the experiment:

a) types of anaesthesia,

b) medicinal products or veterinary medicinal products with pain-relieving properties or other methods, in particular sedatives, to ensure that pain, suffering or distress are reduced to a minimum;

11) justification for not applying general or local anaesthesia – in a case referred to in Art. 13(3);

12) justification for administering to the animal when using in the procedure medicinal products or veterinary medicinal products that prevent or restrict the animal from showing pain – in a case referred to in Art. 14(1);

13) indication whether an early and humane end of the procedure will apply – in the case referred to in Art. 6(1);

14) indication of the planned methods for killing animals;

15) justification for re-use of an animal in a procedure – in the case referred to in Art. 12(2)(2);

16) justification for re-applying an experimental procedure – in a case referred to in Art. 5(3);

17) justification for the use of animals referred to in Art. 7 and Art. 8(1)(2) and (3);

18) the planned date of commencement and end of the experiment.

2. If:

1) the planned experiment envisages the use of wild animals:

a) the application shall contain the name and surname of the person who will acquire the animals and the manner in which they are acquired,

b) if the animal belongs to protected species – the application should be accompanied with a statement concerning the granting of authorization referred to in Art. 56 of the Act of 16 April 2004 on nature conservation;

2) the planned experiment shall be carried out in a way in which the animal is used in the manner determined in Art. 12, the application should be accompanied with the authorization for re-use of the animal, issued by a veterinarian.

Article 45. [Non-technical experiment summary]

1. An application for authorization of an experiment shall be accompanied by a non-technical experiment summary providing:

1) information on:

a) scientific and educational objectives of the experiment, including expected damage that it may cause in animals used in it, and the benefits it will bring to the development of science and didactics, within the scope specified in Art. 3,

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b) the number and species of animals which are to be used in the experiment;

2) description how the principles of replacement, reduction and refinement will be applied in the experiment;

2. The sample form of a non-technical experiment summary, designed by the Commission, shall be published in the Public Information Bulletin, on the website of the minister competent for science-related matters.

Article 46. [Simplified application]

1. If the procedures in the experiment meet all of the following conditions:

1) the procedures are classified as 'terminal, non-recovery', 'mild' or 'moderate';

2) non-human primates are not to be used in the procedures;

3) the obligation to run the procedures results from the regulations, especially those concerning animal feeds, biocidal products, medicinal products, chemical substances, plant protection products, medical products and foodstuffs, or if animals are used in the procedures for production or diagnostic purposes using established methods

– the user may lodge a simplified application for authorization of the experiment.

2. The application referred to in paragraph 1 shall indicate:

1) the name and surname, address and place of residence or the business name, address and registered office of the user, with the provision that in the case where the applicant is an individual carrying on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

2) the establishment where the experiment will be carried out and, if the experiment will be carried out outside the establishment, the site of the experiment, along with the justification of an experiment carried out outside the establishment;

3) the description of the experiment, including information on the scientific or educational purpose that is planned as the objective of the experiment;

4) the name and surname of the person who designed and is responsible for the experiment, and the competencies of that person;

5) the regulations which result in the obligation to run the procedures or the production or diagnostic purposes justifying the experiment;

6) information on the origin, number and species of animals planned to be used in the experiment;

7) description of the planned procedures included in the experiment and the proposed category of severity;

8) the planned date of commencement and end of the experiment.

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9) information referred to in Art .44(1)(10-12) and (15-17).

Article 47. [Experiment evaluation]

1. Prior to giving authorization for an experiment, the local commission shall evaluate whether:

1) the scientific or educational purpose justifies the experiment or whether the obligation to run the experiment results from the regulations, especially those concerning animal feeds, biocidal products, medicinal products, chemical substances, plant protection products, medical products and foodstuffs;

2) the experiment will be carried out in accordance with the principles of replacement, reduction and refinement and, specifically, whether the planned results of the experiment justify the use of animals;

3) the procedures included in the experiment were correctly classified into the categories listed in Art. 10(1);

4) information referred to in Art .44(1)(2), (11), (12) and (15-17) provide the basis for granting authorization for the experiment to be carried out at the location and in the manner indicated in the application;

5) the relation of the harm caused by the experiment to its benefits for humans, animals or the environment, taking into account whether the suffering, pain and distress caused to animals are justified by the expected result of the experiment and taking into account ethical considerations;

6) the experiment should undergo retrospective assessment and if so by what date.

2. When carrying out the evaluation of the experiment the local commission shall take into account relevant areas of expertise, in particular the following:

1) areas of science in which the experiment is planned;

2) experiment planning, including statistical analysis – where justified;

3) medical and veterinary practice with regard to the animals used in the experiment;

4) breeding and care of animals used in the experiment..

3. The local commission shall keep the results of the evaluation of the experiment for 3 years from the date of the end of the experiment indicated in the application.

Article 48. [Giving authorization for an experiment]

1. After the evaluation of the experiment in accordance with Art. 47(1) and (2), the local commission shall adopt a resolution:

1) to give authorization for the experiment;

2) to refuse authorization for the experiment.

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2. The local commission shall deliver to the applicant the resolution on giving or refusing authorization for the experiment within 40 working days from the date of receipt of an application which meets the requirements specified in Art. 44(1) or Art. 46(2).

3. Where justified by the complexity or the multi-disciplinary nature of the experiment, the local commission may extend the period referred to in paragraph 2 once, , notifying the applicant of the extension before the expiry of that period an indicating the reasons for the extension. The extension may be for up to 15 working days.

4. The provision of paragraph 3 does not apply to an application referred to in Art. 46(1).

5. The local commission shall adopt the resolution on giving authorization for an experiment by the majority of 2/3 of votes in the presence of at least half of the statutory number of members.

6. If the resolution on giving authorization for an experiment fails to reach the required majority of votes, the local commission shall refuse authorization for the experiment.

Article 49. [Content of authorization]

1. The resolution on giving authorization for an experiment shall indicate:

1) the name and surname, address and place of residence or the business name, address and registered office of the user that will carry out the experiment, with the provision that in the case where the user is an individual carrying on business as a natural person and the individual's address and place of residence are different from the address and place of business, the address and place of business should be provided;

2) the name and surname of the person who designed and is responsible for the experiment;

3) the conditions for carrying out the experiment – in accordance with the description of the experiment provided in the application for its authorization;

4) the establishment where the experiment will be carried out and, if the experiment will be carried out outside the establishment, the location of the experiment;

5) the date by which the experiment will undergo retrospective assessment –- if the experiment will be subject to such assessment.

2. If wild animals are to be used in the experiment the resolution on giving authorization for the experiment shall contain the name and surname of the person who will acquire the animals and the manner in which they will be acquired,

3. The authorization for an experiment shall be given for a specified period, not longer than 5 years.

Article 50. [Authorization for more than one experiment]

If the obligation to carry out the experiment results from the regulations, especially those concerning animal feeds, biocidal products, medicinal products, chemical substances, plant

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protection products, medical products and foodstuffs, or if animals are used in the experiment for production or diagnostic purposes, the resolution on giving authorization for an experiment may cover more than one such experiment carried out by the same user.

Article 51. [Changes in the experiment]

1. Introducing in the experiment a change which may have a negative impact on the welfare of animals used, shall require authorization by the local commission, granted at the request of the user planning to make such change, lodged with the local commission which granted the authorization for the experiment.

2. The application referred to in paragraph 1 shall provide justification for the change referred to in paragraph 1.

3. The local commission shall re-evaluate the experiment in accordance with Art. 47(1) and (2), taking into account the impact of the change referred to in paragraph 1 on the welfare of animals. The results of the re-evaluation of an experiment shall be kept in accordance with the provisions of Art. 47(3).

4. If the local commission refuses authorization for the change specified in paragraph 1, the experiment may be carried out in accordance with the authorization granted initially.

Article 52. [Documentation concerning the experiment]

1. The user shall maintain and keep the documentation concerning the experiment, including the application requesting authorization for the experiment, the application referred to in Art. 51(1) and the resolution on giving authorization for an experiment for 3 years from the date of the end of the experiment, and in the case where the documentation concerns an experiment subject to retrospective assessment – by the end of that assessment, however for not less than for 3 years from the date when the experiment ended.

2. After the end of an experiment which is subject to retrospective assessment, the user shall immediately deliver to the local commission the documentation referred to in paragraph 1.

Article. 53. [Retrospective assessment]

1. The local commission shall carry out retrospective assessment based on the documentation submitted by the user, in the case of experiments:

   1) in which non-human primates are used;

   2) which include a procedure classified as ‘severe’.

2. Retrospective assessment means checking whether:

   1) the scientific or educational objectives of the experiment have been achieved;

   2) the procedures included in the experiment were correctly classified into the categories listed in Art. 10(1);

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3) the conclusions resulting from the experiment may contribute to further implementation of the principles of replacement, reduction and refinement.

3. The local commission may carry out retrospective assessment also in cases other than those specified in paragraph 1, when this results from the evaluation of the application requesting authorization for the experiment, including the planned procedures included in the experiment, their proposed severity category, the scientific or educational objective that is planned to be achieved as the result of the experiment, and the number, species, age and developmental stages of animals which are planned to be used in the experiment.

4. Immediately after carrying out retrospective assessment the local commission shall:

1) communicate to the user the results of the assessment;

2) return to the user the documentation referred to in paragraph 1.

5. The local commission shall keep the results of retrospective assessment of the experiment for 3 years from the date of the end of the assessment.

Chapter 7

Inspections

Article 54. [Inspecting breeders, suppliers and users]

1. The local veterinary authority with jurisdiction over the location of the establishment shall carry out inspections of breeders, suppliers and users within the scope of their operations for which entry in the register is required.

2. If the experiment is performed outside the establishment, the inspection of the user shall be carried out by the local veterinary authority with jurisdiction over the site of the experiment.

3. The purpose of carrying out inspection referred to in paragraphs 1 and 2 is to check whether the operations of a breeder, supplier and user are in compliance with the principles specified in Chapter 2 and the requirements specified in Chapters 3, 4 and 6.

4. The frequency of inspections shall be determined on the basis of risk analysis, with the provisions that:

1) breeders, suppliers and users of non-human primates shall be inspected at least once a year;

2) each year:

a) at least one-third of inspections are carried out without notice,

b) at least one-third of users are subject to inspection.

5. The risk analysis referred to in paragraph 4 shall be carried out taking into consideration:

1) the number and species of animals kept at the establishments;

2) the record to-date concerning compliance of breeders, suppliers and users with the provisions of the Act, including information on non-compliance;

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3) the number and type of experiments carried out – in the case of users;

Article 55. [Expert participation in inspections]

1. The local veterinary authority may carry out an inspection of a user, concerning experiments, with the participation of an expert who is a member of academic staff whose education, experience and skills are compatible with the scope of experiments carried out by the user, which will ensure an effective and correct inspection. Participation of an expert in an inspection shall be subject to the provisions of Art. 19(3)(4) and (5) and Art. 19(4) and (5) of the Act of 29 January 2004 on Veterinary Inspection (Dz.U., 2010, No. 112, item 744, as amended).

2. For their participation in inspections, experts are entitled to compensation and reimbursement of the cost of travel, according to the principles determined in the regulations issued on the basis of Art. 775(2) of the Labour Code. Costs related to participation of experts in inspections shall be financed from the portion of the state budget assigned to the minister competent for science-related matters.

3. The minister competent for science-related matters shall determine, by way of a regulation, the manner in which experts participating in inspections are appointed and the amount of their compensation, taking into account their competencies and actual workload.

4. The minister competent for science-related matters shall maintain a list of experts and publish that list in the Public Information Bulletin on the minister's website. The list shall contain the expert's name and surname and information on his/her education, expertise and skills.

Article 56. [Cooperation with local commission with regard to inspections]

1. Within the scope of the duties referred to in Art. 54, the local veterinary authority shall cooperate with the local commission and may apply to the local commission for information necessary for the inspection to be carried out correctly, in particular before carrying out inspection referred to in Art. 55(1).

2. The local commission may request the local veterinary authority to carry out an inspection referred to in Art. 54(1)

Article 57. [Suspending an experiment]

1. The local veterinary authority shall order, by way of an administrative decision, that an experiment be suspended in cases where it was determined during an inspection that a procedure in which animals are used is not a part of the experiment for which authorization was granted.

2. If the user performs procedures that are part of an experiment in a way incompatible with the conditions specified in the authorization for the experiment or if the user has not obtained the authorization referred to in Art. 51(1), the local veterinary authority shall:

1) specify the date by which the detected irregularities have to be removed;

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2) order, by way of an administrative decision, that the procedure or the experiment be suspended until the irregularities detected are removed, if they may expose the animals to unnecessary pain, suffering or distress.

3. Decisions referred to in paragraph 1 and in paragraph 2(2) shall be implemented immediately.

Article 58. [Removal of irregularities]

If a breeder, supplier or user carries out operations in a way incompatible with the requirements specified in Art. 17, Art. 18, Art. 21, Art. 24 or in the regulations issued pursuant to Art. 19, the local veterinary authority shall specify the deadline by which the detected irregularities have to be removed

Article 59. [Call for removal of irregularities and deletion from the register]

1. In cases where a breeder, supplier or user fails to remove the detected irregularities, referred to in Art. 58, the local veterinary authority shall issue an administrative decision confirming non-compliance with the requirements for carrying out operations referred to in Art. 26.

2. The local veterinary authority shall immediately deliver the final decision referred to in paragraph 1 to the minister competent for science-related matters along with the application for deleting the breeder, supplier or user from the register.

Article 60. [Application for revoking authorization for an experiment]

In cases where a breeder, supplier or user fails to remove the detected irregularities referred to in Art. 57(2)(1), the local veterinary authority shall lodge with the local commission an application for revoking the authorization referred to in Art. 48(1)(1).

Article. 61. [Information duties of the local veterinary authority]

The local veterinary authority shall deliver to the minister competent for science-related matters and the Commission information on detected violations which provide the basis for imposing a financial penalty referred to in Art. 69 paragraphs 1, 2 and 4, along with the inspection report.

Article 62. [Report on inspections carried out]

Based on information provided by local veterinary authorities, the national veterinary authority shall each year and not later than by 30 June submit to the minister competent for science-related matters and the Commission a report on the inspections that have been carried out.

Article 63. [Application of the regulations on Veterinary Inspection]

In matters not regulated in this Act the applicable provisions shall be those of the Act of 29 January 2004 on Veterinary Inspection.

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Chapter 8

Cooperation with the European Commission and Member States

Article 64. [National contact point]

The minister competent for science-related matters shall act as the national contact point and cooperate with the European Commission and authorities of Member States other than the Republic of Poland within the scope of protection of animals used for scientific or educational purposes.

Article. 65. [Information duties of the minister competent for science-related matters]

1. Based on the information provided by the Commission, local commissions, breeders, suppliers, users and the national veterinary authority, the minister competent for science-related matters shall provide to the European Commission:

1) annually – information concerning:
   a) the number, species and origin of animals used in procedures,
   b) objectives and types of experiments in which animals were used,
   c) cases where animals were re-used in procedures,
   d) procedure categories and the number of changes concerning their classification, along with information on the reason for these changes;

2) every 5 years – information on the implementation of EU regulations concerning protection of animals used for scientific or educational purposes.

2. The minister competent for science-related matters, after consulting with the Commission, shall each year and not later than by 31 August publish in the Public Information Bulletin on the minister's website the information referred to in paragraph 1(1).

3. The minister competent for science-related matters shall determine, by way of a regulation, the detailed scope of information referred to in paragraph 1, the manner in which the information is to be provided and sample forms on which the information will be provided, with the view to ensure that the information delivered to the European Commission is correct and complete, and taking into consideration the regulations concerning the manner of providing information about animals used in experiments, issued on the basis of Art. 54(4)of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

Chapter 9

Penal provisions

Article 66. [Breach of statutory duties]

1. Anyone who in relation to their operations within the scope of using animals for scientific or educational purposes:

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1) exposes animals to unnecessary pain, suffering, distress or lasting harm,

2) uses animals in procedures included in an experience without obtaining authorization for their use

shall be subject to a fine, partial restriction of freedom or prison sentence for a term of up to 2 years.

2. Anyone who causes death of an animal in cases specified in paragraph 1

shall be subject to a prison sentence for a term of up to 3 years.

Article 67. [Preventing or obstructing inspections]

1. Anyone who obstructs an inspection carried out on the basis of the provisions of this Act or prevents such inspection from being carried out

shall be subject to a fine, partial restriction of freedom or prison sentence for a term of up to one year.

2. The same penalty shall be imposed on anyone who uses the information obtained in relation to an inspection for purposes other than protection of animals used for scientific or educational purposes.

Article 68. [NGOs and non-profit organizations]

In the proceedings concerning offences specified in Art. 66(1)(1), the rights of the injured party may be exercised by an NGO or a non-profit organizations which pursue the statutory objective of protecting animals.

Chapter 10

Administrative penalties

Article 69. [Financial penalties]

1. A financial penalty shall be imposed on a breeder, supplier or user who:

1) carries out operations without an entry in the register referred to in Art. (26):

2) does not ensure to animals kept at the establishment the conditions specified in Art. 17, Art. 18 or in the regulations issued pursuant to Art. 19;

3) does not designate persons referred to in Art. 20 and Art. 21, or designates persons who do not meet the requirements specified in Art. 20 and Art. 21, or does not designate the person referred to in Art. 24(1) or designates a person who does not meet the requirements specified in Art. 24(2);

4) acting in breach of the duty specified in Art. 23 does not enter into a contract with a veterinary physician for veterinary services to be provided at the establishment;

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5) acting in breach of the duty specified in Art. 25(2) does not designate person or persons or does not enter into a contract with a person or persons for the purpose of performing the duties specified in Art. 25(1), or designates for the performance of those duties with a person or persons who do not meet the requirements specified in Art. 21(1) or Art. 24(2);

6) does not prepare or submit the documentation referred to in Art. 25(8);

7) does not keep the documentation referred to in Art. 25(8) or does not keep that documentation for a period indicated in Art. 25(9)(1);

8) does not keep animal records referred to in Art. 30(1), maintains those records in a way incompatible with the requirements of that provision or does not keep the records in compliance with Art. 30(2);

9) fails to mark a dog, cat or non-human primate or marks the animal in a way incompatible with the requirements specified in Art. 31 paragraphs 1 and 2.

2. A financial penalty shall be imposed on a user who kills an animal in a way incompatible with the requirements specified in Art. 16(1) or (2).

3. A financial penalty shall not be imposed on a user who kills an animal in a way that does not meet the requirements specified in Art. 16(1) or (2) in cases where circumstances specified in Art.16(4) have occurred.

4. A financial penalty shall be imposed on a user who:

1) carries out an experiment without authorization for doing so or in a manner incompatible with the conditions specified in the resolution on giving authorization for the experiment.

2) does not maintain or keep the documentation on carrying out an experiment, referred to in Art. 52(1) or does not submit that documentation to the local commission in the case indicated in Art. 52(2);

Article 70. [Amount of financial penalty]

1. The financial penalty for violations specified in Art. 69 shall be in the range of PLN 1,000 to PLN 50,000.

2. When determining the amount of penalty, the following factors shall be taken into consideration:

1) type and circumstance of the violation;

2) impact of the violation on causing pain, suffering, distress or lasting harm to the animals;

3) duration of the violation;

4) record to-date concerning the operations of the breeder, supplier or user;

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Article 71. [Imposing and enforcing financial penalties]

1. Financial penalties shall be imposed by way of an administrative decision by the minister competent for science-related matters.

2. Financial penalties represent income of the state budget and shall be paid to the bank account of the minister competent for science-related matters within 14 days from the date when the decision about imposing the penalty became final.

3. The financial penalties and any interest thereon shall be subject to enforcement under the provisions on enforcement proceedings in administration.

4. Within the scope not regulated in this Act, the provisions of Section III of the Act of 29 August 1997 – Tax Ordinance shall apply to financial penalties, as appropriate (Dz.U. 2012, item 749, as subsequently amended).

Article 72. [Time limitation]

A financial penalty may not be imposed when 5 years elapsed from the date of committing an offence specified in Art. 69 paragraphs 1, 2 and 4.

Chapter 11

Changes to existing regulations

Article 73.

The following changes shall be made in the Act of 21 August 1997 on the protection of animals (Dz.U., 2013, item 856 and Dz.U., 2014, item 1794);

1)in Article 2:

a) paragraph 1 shall read:

"1. The Act shall regulate handling of vertebrate animals, including vertebrate animals used for scientific or educational purposes, within the scope not regulated in the act of 15 January 2015 on the protection of animals used for scientific and educational purposes (Dz.U., item 266).”,

b) paragraph 2 shall be repealed;

2) item 19 in Article 4 shall read:

"19) "laboratory animals" – shall mean laboratory animals in the meaning of Art. 2(1)(2) of the Act of 15 January 2015. on the protection of animals used for scientific and educational purposes;";

3) in Article 6 paragraph 2(1) shall read:

“1) intentional injury or mutilation caused to an animal, which does not represent a legally permitted surgery or procedure in the meaning of Art. 2(1)(6) of the Act of

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15 January 2015 on the protection of animals used for scientific and educational purposes, including marking of warm-blooded animals by hot branding or freeze branding, and any surgical procedures performed with a view to alter the animal's appearance and carried out for the purpose other than saving its health or life, and specifically tail docking or ear clipping of dogs;";

4) in Article 34 paragraph 4(1)(a) shall read:

"a) killing animals in cases indicated in the Act of 15 January 2015 on the protection of animals used for scientific or educational purposes,";

5) in Article 38 paragraph 4 shall read:

"4. An NGO or non-profit organization referred to in paragraph 2 shall hand over the animal, free of charge, to:

1) an animal shelter, if it is a domestic animal, or

2) the farm indicated by the head of a rural community (mayor of a town or city) if the animal represents farm livestock, or

3) a zoo or an animal shelter, if it is a laboratory animal or an animal used for entertainment, shows, films, sports or kept in zoos.".

Article 74.

The following changes shall be made to the Act of 29 January 2004 on Veterinary Inspection (Dz.U., 2010, No. 112, item 774, as amended):

1) in Article 3 paragraph 2:

a) in item 4 the following text of point (e) shall be added:

"e) inspection of the operations of a breeder, supplier and user, carried out pursuant to the Act of 15 January 2015 on the protection of animals used for scientific and educational purposes (Dz.U., item 266), including the following scope:

– keeping animals used or intended for use for scientific or educational purposes,

– keeping animal records,

– carrying out experiments;",

b) point (j) in item 5 shall be repealed;

2) in Article 19:

a) after paragraph 1a the following text of paragraph 1aa shall be added:

"1aa. Within the scope of an inspection carried out by employees of the Inspection pursuant to the Act of 15 January 2015 on the protection of animals used for scientific and educational purposes, with the participation of an

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expert referred to in Art. 55(1) of that Act, expert shall commence inspection duties after presenting the document authorizing the expert to carry out these duties, issued by a competent Inspection authority.”,

3) in paragraph 3 item 1 shall read:

“1) carrying out inspections of farms, centres (organizations), facilities, establishments in the meaning of Art. 2(1)(8) of the Act of 15 January 2015 on the protection of animals used for scientific and educational purposes, installations, equipment or transport vehicles;”;

a) after paragraph 5 the following text of paragraph 5a shall be added:

“5a. The provisions of paragraph 3 items 4 and 5 and paragraphs 4 and 5 shall apply to an expert referred to in Art. 55(1) of the Act of 15 January 2015 on the protection of animals used for scientific and educational purposes, who carries out inspection duties within the scope of an inspection performed pursuant to that Act.”.

Article 75.

In the Act of 11 January 2004 on animal health protection and fighting against infectious animal diseases (Dz.U., 2014, item 1539) in Art. 1 item 1:

1) point (l) shall read:

“1) keeping or breeding animals for the purposes of animal shows, protection and saving animal species,”;

2) point (m) shall be repealed.

Article 76.

In the Act of 2 July 2004 on the freedom of business activities (Dz.U., 2013, item 672, as subsequently amended.) the following changes shall be made:

1) in Article 75 paragraph 1 item 27 shall be repealed:

2) in Article 84a item 2 shall read:

“2) veterinary supervision, pursuant to the Act of 21 August 1977 on the protection of animals (Dz.U., 2013, item 856 and Dz.U., 2014, item 1794), the Act of 6 September 2001 – Pharmaceutical Law (Dz.U., 2008, No 45, item 271, as subsequently amended), the Act of 27 August 2003 on veterinary border control (Dz.U., 2014, items 1424 and 1662), the Act of 10 December 2003 on veterinary inspection in trade (Dz.U., 2004, No 16, item 145, as subsequently amended), the Act of 29 January 2004 on Veterinary Inspection (Dz.U., 2010, No. 112, item 744, as amended), the Act of 11 January 2004 on animal health protection and fighting

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against infectious animal diseases (Dz.U., 2014, item 1539), the Act of 16 December 2005 on products of animal origin (Dz.U., 2014, item 1577), the Act of 22 July 2006 on animal feeds (Dz.U., 2014, item 398), and the Act of 15 January 2015 on the protection of animals used for scientific and educational purposes (Dz.U., item 266);".

Chapter 12

Final and transitional provisions

Article 77. [Entities listed in previously existing registers]

1. As of the date of entry into force of this Act, the following entities mentioned in the registers referred to in Art. 22 of the Act repealed in Art. 83:

1) breeding entities in the meaning of Art. 2 item 9 of the Act repealed in Art. 83 shall become breeders in the meaning of this Act;

2) experimental entities in the meaning of Art. 2 item 10 of the Act repealed in Art. 83 shall become users in the meaning of this Act;

3) suppliers in the meaning of Art. 2 item 11 of the Act repealed in Art. 83 shall become suppliers in the meaning of this Act;

2. The minister competent for science-related matters shall, by right of his/her office enter breeding entities, experimental entities and suppliers mentioned in paragraph 1, in the register referred to in Art. 26.

Article 78. [Experiments carried out before the entry of the Act into force]

1. Experiments for which authorization was granted before the date of entry of this Act into force, shall be carried out in accordance with the regulations current at that time, provided, however, that they are carried out not later than by 1 January 2018.

2. Documentation concerning animals, referred to in Art. 11(3) of the Act repealed in Art. 83, shall be kept by breeders, suppliers or users for 3 years from the date of marking the animals.

3. Records for experimental animals, referred to in Art. 19(1) of the Act repealed in Art. 83, shall be kept by the user for 3 years from the date when the last entry was made.

4. Records for experiments, maintained pursuant to Art. 21 of the Act repealed in Art. 83, shall be kept by the user for 3 years from the date when carrying out the experiment finished.

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Article 79. [Proceedings not completed by the date of entry of the Act into force]

1. The regulations applicable to the proceedings in the matter of granting authorization for an experiment, which were initiated before the date of entry of this Act into force but not concluded before that date, shall be those which applied before that date.

2. Experiments for which authorization was granted in the proceedings referred to in paragraph 1 shall be carried out in accordance with the regulations current at that time, provided, however, that the experiments are carried out not later than by 1 January 2018.

Article 80. [To-date composition of the National Ethical Commission and local ethical commissions]

1. The National Ethical Commission and local ethical commissions, appointed pursuant to the provisions of the Act repealed in Art. 83, shall perform the duties of the Commission and local commissions until members of these commissions are appointed pursuant to the provisions of this Act.

2. The minister competent for science-related matters shall appoint Committee members within 6 months from the date of entry of this Act into force.

3. The Commission shall appoint members of local commissions within 6 months from the date when the minister competent for science-related matters appointed members of the Commission.

4. Terms of office commenced before the date of entry of this Act into force shall not be included in the calculation of the period specified in Art. 34(4).

5. Local ethical commissions, appointed pursuant to the provisions of the Act repealed in Art. 83, shall hand over the documentation:

1) concerning authorization for carrying out experiments;

2) related to supervision over carrying out experiments

– to local commissions indicated by the Commission appointed pursuant to this Act, within one month from the date when those local commissions were appointed.

Article. 81. [Information duties of the minister competent for science-related matters]

1. The minister competent for science-related matters shall for the first time provide the European Commission with the data referred to in Art. 65(1):

1) item 1 - by 10 November 2015;

2) item 2 - by 10 November 2018;

2. Users shall for the first time provide the minister competent for science-related matters with the information referred to in Art. 30(4) by 30 September 2015.

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Article 82. [Keeping secondary legislation in force]

1. Secondary legislation issued pursuant to Art. 11(7), Art. 16(5) and Art. 31(5) of the Act repealed in Art. 83 shall remain in force until the date when new secondary legislation, issued pursuant to Art. 22, Art. 31(3) and Art. 41, comes into force, not longer, however, than for 6 months from the date of entry of this Act into force.

2. Secondary legislation issued pursuant to Art. 10(5)(1) of the Act repealed in Art. 83 shall remain in force until the date when new secondary legislation, issued pursuant to Art. 19, comes into force, not longer, however than by 31 December 2016.

Article 83. [Derogation provision]

The Act of 21 January 2005 on experiments on animals shall be repealed (Dz.U., No 33, item 289, as subsequently amended)

Article 84. [Entry into force]

This Act shall come into force after 3 months from the date when it is published.

[1] This Act shall implement Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (O.J. EU L 276 of 20.10.2010, p. 33).

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