

DECREE
of 15 January 2009
amending Decree No 207/2004 Coll., on the protection, breeding
and use of experimental animals

The Ministry of Agriculture provides according to Section 29 para 1 for the implementation of section 17 para 4, section 17a para 3, section 17b para 3, section 17c para 4, section 17d para 1, section 17e para 10, section 17f para 6, section 18b para 5 and section 18f para 8 of Act No 246/1992 Coll., on the protection of animals against cruelty, as amended by Act No 77/2004 Coll. and Act No 312/2008 Coll.:

Article I

Decree No 207/2004 Coll., on the protection, breeding and use of experimental animals is amended as follows:

1. In section 1 a new paragraph 1 is inserted which including the footnote No 1 shall read as follows:

“(1) This Decree incorporates the relevant Community legislation¹⁾ and stipulates the requirements and conditions for the protection of experimental animals against cruelty, conditions of breeding, use and transport of experimental animals.

¹⁾ Council Directive 86/609/EEC of 24 November 1986 on rapprochement of legal and administrative regulations of member states related to protection of animals used for experimental or other scientific reasons.

Directive of the European Parliament and of the Council 2003/65/EC of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.

Commission Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes.

The existing paragraphs 1 and 2 are renumbered to paragraphs 2 and 3.

2. In section 2 para 1 in the introductory parts of the provision the words “persons operating” are inserted after the word “animals”.
3. In section 4 para 1 in the introductory parts of the provision the words “persons operating” are inserted after the words “(hereinafter referred to as “care of animals”)”.
4. Section 5 para 1 shall read as follows:

“(1) Adequate ventilation should be provided in animal enclosures for usual laboratory animal species to satisfy the requirements of the animals housed. The purpose of the

ventilation system is to provide sufficient fresh air of an appropriate quality and to keep down the levels and spread of odours, noxious gases, dust and infectious agents of any kind. It also provides for the removal of excess heat and humidity. The air in the room shall be renewed at frequent intervals, with the ventilation rate of fifteen air changes per hour being the minimum, where stocking density is low the number of air changes may be reduced, however not to less than eight air changes per hour. The ventilation system should be so designed as to avoid noise louder than 60 dB and air flow higher than 0.3 m per second at the height of 160 cm above the floor.”

5. In section 5 the following sentence is added to the end of the paragraph: “In barrier systems there shall be a permanent excess pressure of at least 40 Pa, while when working under the negative pressure its value shall be at least 20 Pa.”
6. In section 7 para 1 at the end of the text of letter a) the following words are added “during transport the care of animals shall be provided according to the physiological needs of individual animal species in keeping with the values given in Annex 2 Table 1 and in Annex 12 to this Decree“.
7. In section 11 para 1 the point 1 shall read as follows:
“1. Identification of persons operating a user establishment,“.
8. In section 11 para 1 a new point 5 is inserted after point 4 which shall read as follows:
“5. Name, surname, title and the number of the certificate of qualification of the person managing the activities of the board of experts pursuant to section 17 para 1.“

The existing points 5 to 24 are renumbered to 6 to 25.

9. In section 11 para 1 point 8 shall read as follows:
“8. The purpose of an experiment pursuant to section 15 para 1 of the Act,“.
10. In section 11 para 1 point 12 the words “breeding and” are inserted after the word “data“.
11. In section 11 para 2 the words “A user establishment” are replaced by the words “A person operating a user establishment“.
12. In section 11 para 3 the words “User establishment“ are replaced by “A person operating a user establishment“ and words “between the user establishment and“ are replaced by the word “with”.

13. In section 12 the letter “g” is replaced by letter “h”.
14. In the heading of section 13 the word “user” is replaced by the words “person operating a user”.
15. In section 13 para 1 the word “user” is replaced by the words “person operating a user”.
16. In section 13 para 2 letter a) the following words are added at the end of the text of point 6 “, including the address, precise location, name or other designation of individual premises where experiments on animals are conducted”.
17. In section 13 para 2 letter b) in point 3 the number “5” is replaced by the number “6”.
18. In section 13 para 3 the words ”A user establishment“ are replaced by the words ”A person operating a user establishment who“.
19. In section 13 para 4 the words “and the results of examinations of feed and drinking water“ are added at the end of the text of letter c).
20. In section 13 para 4 letter e) the words ”Central Commission for Animal Welfare (hereinafter referred to as the “Central Commission“)” are replaced by the words “Ministry of Agriculture (hereinafter referred to as the “Ministry“)”.
21. In section 13 para 4 a new letter f) is inserted which shall read as follows:
„f) documentation of used animals in relation to the relevant experimental projects conducted since the last accreditation, however no longer than during the last 5 years,“.

The existing letters f) to h) are renumbered to letters g) to i).

22. In section 13 para 4 letter g) the words ”Central Commission“ are replaced by the word ”Ministry”.
23. In section 13 para 4 letter i) the words ”Central Commission in accordance with Section 17f para 5 letter b) point 2 of the Act“ are replaced by the word “Ministry“.

24. In section 13 para 5 the words “Central Commision“ are replaced by the words “Ministry and shall elaborate a written opinion of the evaluators of the user establishment, the specimen of which is given in Annex 10 to this Decree“.
25. In the heading of section 14 the words “breeding and supplying“ are replaced by the words “a person operating a breeding and supplying“.
26. In section 14 para 1 the words “breeding and supplying“ are replaced by the words “a person operating a breeding and supplying“.
27. In section 14 para 2 letter a) the words “including the address, precise location, name or other designation of individual premises in which the animals are kept“ are added at the end the text of point 6.
28. In section 14 para 2 letter b) the point 1 is repealed.
The existing points 2 and 3 are renumbered to points 1 and 2.
29. In section 14 para 2 letter b) point 1 the number “5“ is replaced by the number “6“.
30. In section 14 para 3 the words “and results of examination of feed and drinking water” are added at the end of the text of letter c).
31. In section 14 para 3 letter f) the words “Central Commission” are replaced by the word “Ministry“.
32. In section 14 the words “and elaborate a written opinion of evaluators of a breeding and supplying establishment, the specimen of which is given in Annex 11 to this Decree“ are added at the end of the text of para 4.
33. In section 16 para 1 letter c) the number “10“ is replaced by number “11“.
34. In section 16 para 2 the word “A user“ is replaced by the words “A board of experts of the user“.

35. In section 17 the words “section 21 para 3 letter e)” are replaced by the words “section 20 para 1 letter j)” and the words “section 12 and 13” are replaced by the words “section 13 and 14”.
36. In section 18 para 1 letter b) the number “7” is replaced by number “6”.
37. In section 18 the para 4 is repealed.

The existing para 5 to 8 are renumbered to para 4 to 7.
38. In section 18 para 4 in the first sentence the number “7” is replaced by number “6”.
39. In section 18 para 4 in the second sentence the word “5” is replaced by number “6”.
40. In section 18 para 7 the number “7” is replaced by number “6”.
41. In section 19 para 1 the number “7” is replaced by number “6”.
42. In Annex 2 the words “during an experiment” are added at the end of the heading of Table 6.
43. In Annex 2 new tables No 7 and 8 are inserted which, including the headings, shall read as follows:

TABLE 7
Guidelines for keeping cats in enclosures

	Floor area in (m ²) (shelves exclusive)	Shelves (m ²)	Height (m)
Minimum for adult animal	1,5	0,5	2
For each additional animal add	0,75	0,25	-

TABLE 8
Guidelines for keeping ferrets (*Mustela putorius furo*)

	Minimum enclosure size (cm ²)	Minimum floor area per animal (cm ²)	Minimum height (cm)
Animals up to 600 g	4500	1500	50
Animals over 600 g	4500	3000	50
Adult males	6000	6000	50
Jill and litter	5400	5400	50

The existing Tables 7 to 13 are renumbered to Tables 9 to 15.

44. In Annex 2 the Table 11 shall read as follows:

TABLE 11
Guidelines for keeping macaques and vervets ¹⁾

	Minimum enclosure size (m ²)	Minimum enclosure volume (m ³)	Minimum volume per animal (m ³)	Minimum enclosure height (m)
Animals less than 3 years of age	2,0	3,6	1,0	1,8
Animals from 3 years of age	2,0	3,6	1,8	1,8
Animals held for breeding purposes ²⁾			3,5	2,0

¹⁾ Animals may be held individually only under exceptional circumstances.

²⁾ In breeding colonies additional enclosure space/volume is not required for the young up to 2 years of age housed together with their mother.

45. In Annex 2 a new Table 16 is inserted which shall read as follows:

TABLE 16
Guidelines for keeping *Xenopus laevis* (Clawed frog) ¹⁾

Body length (cm) (measured from snout to vent)	Minimum water surface area (cm ²)	Minimum water surface area for each additional animal in group-holding (cm ²)	Minimum water depth (cm)	Optimal temperature	Relative humidity
< 6	160	40	6	18 - 22°C	100 %
6 - 9	300	75	8		
9 - 12	600	150	10		
> 12	920	230	12,5		

¹⁾ These recommendations apply to holding (i.e. husbandry) tanks but not to those tanks used for natural mating and super-ovulation which require smaller individual tanks. Space requirements are determined for adults in the indicated size categories. Juveniles and tadpoles should either be excluded, or dimensions should be altered accordingly.

46. Annex No 6 shall read as follows:

Annex No 6 to Decree No 207/2004 Coll.

A specimen form of an experimental project

This table shall be completed by the experiment leader (section 18a para 2 letter b) of Act No 246/1992 Coll.):

EXPERIMENTAL PROJECT No	
in accordance with section 11 of Decree No 207/2004 Coll., on the protection, breeding and use of experimental animals	
1.	Identification of persons operating a user establishment:
	Applicant – name of legal person or name and surname of natural person operating the establishment
	Identification Number, where assigned
	Registration number, where assigned
	Address of the seat or place of business of the applicant (<i>including the postal code and the district</i>)
	Authorised representative of the applicant – name, surname, title
2.	Number of the decision on granting accreditation and its validity
3.	Experiment leader – name, surname, title and number of the certificate of qualification pursuant to section 17 para 1 of Act No 246/1992 Coll.
	Deputy experiment leader (if appointed) - name, surname, title and number of the certificate of qualification pursuant to section 17 para 1 of Act No 246/1992 Coll.
4.	Person responsible for the care of animals in the user establishment - name, surname, title and number of the certificate of qualification pursuant to section 17 para 1 of Act No 246/1992 Coll.
5.	Person managing the activities of the board of experts of the user establishment - name, surname, title and number of the certificate of qualification pursuant to section 17 para 1 of Act No 246/1992 Coll.
6.	Name of the task, study, or grant identification
7.	Description of the study objectives, specifying the envisaged benefit, including the characteristics of applied substances, or classification of substances into indication groups, except for the output control of batches of substances
8.	Pursuant to section 15 para 1 of Act No 246/1992 Coll. the experiment shall be conducted for the purpose of (<i>mark an X in the relevant box</i>):
	a) avoidance or prevention of diseases, disorder and other abnormality or their effects in man, animals or plants, including the manufacture, quality, effectiveness and safety testing of drugs, substances or products
	b) diagnosis or treatment of diseases, disorders or other abnormality or their effects in man, animals or plants
	c) assessment, detection, regulation or modification of physiological conditions in man, animals or plants
	d) protection of the environment in the interests of the health or welfare of man or animal
	e) education, unless the aim can be achieved otherwise
	f) maintenance or reproduction of live material for scientific purposes
	g) scientific research
	h) judicial proceedings
9.	Methodological procedures for work with animals

.....
Date, signature of the authorised representative of the applicant

This table is to be completed by the board of experts of the user establishment (section 18b para 1 of Act No 246/1992 Coll.):

OPINION OF THE BOARD OF EXPERTS OF THE USER ESTABLISHMENT ON THE EXPERIMENTAL PROJECT NO

Members of the board of experts		
Name	Signature	Date

This table is to be completed by the competent state authority (section 18b para 2, section 23 para 1 letter a) of Act No 246/1992 Coll.):

The experimental project includes the permission to use animals Ref. No.	
Date of issue of the permission	
Stamp and signature of the competent state authority	

This table is to be completed by the experiment leader (section 18a para 2 letter c) of Act No 246/1992 Coll.):

Date of notification of the competent veterinary administration authority on the approval of the experimental project	
Date and signature of the experiment leader	

This table is to be completed by the board of experts of the user establishment (section 18 para 7 of Act No 246/1992 Coll.):

Date of approval to commence the experiment	
Date and signature of a member of the board of experts of the user establishment	

47. Annex No 7 shall read as follows:

Annex No 7 to Decree No 207/2004 Coll.

Specimen application for granting accreditation to a person operating a user establishment

APPLICATION FOR GRANTING ACCREDITATION TO A PERSON OPERATING A USER ESTABLISHMENT pursuant to Section 13 of Decree No 207/2004 Coll., on the protection, breeding and use of experimental animals			
1. IDENTIFICATION OF THE ESTABLISHMENT			
<i>Applicant – name of legal person or name and surname of natural person operating the establishment</i>			
Identification number, where assigned		Registration number, where assigned	
Address of the seat or place of business of the applicant (<i>including the postal code and district</i>)			
Addresses of all establishments intended for the conduct of experiments on animals (<i>including postal codes and districts</i>); specification of premises, including their precise location, name, or other designation of individual premises where experiments on animals are conducted			
Competent state authority with respect to the focus of activities of the applicant			
Authorised representative of the applicant – title, name, surname			
Person authorised to act as a proxy of the applicant in administrative procedure – title, name, surname, mailing address		Telephone	
Person responsible for the care of animals – title, name, surname		Certificate number pursuant to section 17 para 1 of Act No 246/1992 Coll.	
2. Applicant applies for granting			
<i>Mark an X in the relevant empty box</i>			
first accreditation		renewal of accreditation	
3. TYPE OF ACTIVITY OF THE ESTABLISHMENT – PURPOSE OF EXPERIMENT (section 15 para 1 of Act No 246/1992 Coll.)			
<i>Mark an X in the box stating the activities performed by the establishment</i>			
a) avoidance or prevention of diseases, disorder and other abnormality or their effects in man, animals or plants, including the manufacture, quality, effectiveness and safety testing of drugs, substances or products			
b) diagnosis or treatment of diseases, disorders or other abnormality or their effects in man, animals or plants			
c) assessment, detection, regulation or modification of physiological conditions in man, animals or plants			
d) protection of the environment in the interests of the health or welfare of man or animal			
e) education, unless the aim can be achieved otherwise			
f) maintenance or reproduction of live material for scientific purposes			
g) scientific research			
h) judicial proceedings			
4. SPECIES OF BRED OR USED ANIMALS			
<i>State the species of animals and their maximum number with respect to the daily capacity of the establishment /*/</i>			
Animal species	Number	Animal species /*/	Number /*/
Laboratory mice (<i>Mus musculus</i>)			

Laboratory rats (<i>Rattus norvegicus</i>)			
Guinea pigs (<i>Cavia porcellus</i>)			
Hamsters			
Rabbits (<i>Oryctolagus cuniculus</i>)			
Domestic dogs (<i>Canis familiaris</i>)			
Domestic cats (<i>Felis catus</i>)			
Quails (<i>Coturnix coturnix</i>)			
Primates			
5. ACCREDITATIONS GRANTED SO FAR PURSUANT TO ACT No 246/1992 Coll.			
<i>State the reference numbers of decisions, data of their delivery to the applicant and validity of the decisions</i>			
6. APPLICANT DECLARES THAT			
<ul style="list-style-type: none"> - he/she agrees with the conduct of accreditation procedure, including the evaluation of establishment by evaluators appointed in accordance with Act No 246/1992 Coll., - he/she shall present to the evaluators the data as referred to in section 13 para 2, 3, 4 of Decree No 207/2004 Coll., - data stated in this application and other data for accreditation procedure have been and will be completed truthfully, - agrees with the disclosure of the name of establishment and the name of municipality of its seat. 			
Date of dispatch of the application		Stamp and signature of the applicant	

Notes:

/*/ The maximum daily number of animals is a theoretically determined daily number of animals which equals the full capacity of the premises for animals equipped for the given species, or the capacity for which the premises were built.

Entities conducting experiments on other animal species than those listed in the first column shall enlist the specific animal species concerned.

RECORDS OF THE MINISTRY OF AGRICULTURE		
Reference number	Date of delivery	Received by (signature)

48. Annex No 8 shall read as follows:

Annex No 8 to Decree No 207/2004 Coll.

Specimen of application for granting a certificate to a person operating a breeding or supplying establishment

APPLICATION FOR GRANTING A CERTIFICATE TO A PERSON OPERATING A BREEDING OR SUPPLYING ESTABLISHMENT pursuant to section 14 of Decree No 207/2004 Coll., on the protection, breeding and use of experimental animals			
1. IDENTIFICATION OF THE ESTABLISHMENT			
<i>Applicant – name of legal person or name and surname of natural person operating the establishment</i>			
Identification number, where assigned		Registration number, where assigned	
Address of the seat or place of business of the applicant (<i>including the postal code and district</i>)			
Addresses of all establishments intended for breeding or supplying animals (<i>including postal codes and districts</i>); specification of premises, including their precise location, name, or other designation of individual premises where animals are kept			
Competent state authority with respect to focus of activities of the applicant			
Authorised representative of the applicant – title, name, surname			
Person authorised to act as a proxy of the applicant in administrative procedure – title, name, surname, mailing address			Telephone
2. APPLICANT APPLIES FOR GRANTING			
<i>Mark an X in the relevant empty box</i>			
<input type="checkbox"/> first certificate		<input type="checkbox"/> renewal of the certificate	
3. TYPE OF ACTIVITY OF THE ESTABLISHMENT (section 3 letter x, y) of Act No 246/1992 Coll.)			
<i>Mark an X in the box stating the activities performed by the establishment</i>			
<input type="checkbox"/> breeding animals		<input type="checkbox"/> supplying animals	
4. SPECIES OF BRED OR SUPPLIED ANIMALS AND THEIR MAXIMUM NUMBERS			
<i>State the species of animals and their maximum number with respect to the daily capacity of the establishment /*/</i>			
Animal species	Number	Animal species /*/	Number /*/
Laboratory mice (<i>Mus musculus</i>)			
Laboratory rats (<i>Rattus norvegicus</i>)			
Guinea pigs (<i>Cavia porcellus</i>)			
Hamsters			
Rabbits (<i>Oryctolagus cuniculus</i>)			
Domestic dogs (<i>Canis familiaris</i>)			
Domestic cats (<i>Felis catus</i>)			
Quails (<i>Coturnix coturnix</i>)			
Primates			
5. CERTIFICATES GRANTED SO FAR PURSUANT TO ACT No 246/1992 Coll.			
<i>State the reference numbers of decisions, data of their delivery to the applicant and validity of the decisions</i>			

6.	APPLICANT DECLARES THAT	
	<ul style="list-style-type: none"> - he/she agrees with the conduct of procedure for granting a certificate, including the evaluation of establishment by evaluators appointed in accordance with Act No 246/1992 Coll., - he/she shall present to the evaluators the data as referred to in section 14 para 2, 3, of Decree No 207/2004 Coll., - data stated in this application and other data for procedure for granting a certificate have been and will be completed truthfully, - agrees with the disclosure of the name of establishment and the name of municipality of its seat. 	
	Date of dispatch of the application	Stamp and signature of the applicant

Notes:

/*/ The maximum daily number of animals is a theoretically determined daily number of animals which equals the full capacity of the premises for animals equipped for the given species, or the capacity for which the premises were built.

Entities conducting experiments on other animal species than those listed in the first column shall enlist the specific animal species concerned.

RECORDS OF THE MINISTRY OF AGRICULTURE		
Reference number	Date of delivery	Received by (signature)

49. Annex No 9 shall read as follows:

Annex No 9 to Decree No 207/2004 Coll.

Formal requisites of the certificate of professional competence to manage, conduct and control experiments on animals pursuant to section 17 para 1 of Act No 246/1992 Coll., on the protection of animals against cruelty, as amended

CZECH REPUBLIC

The Ministry of Agriculture

issues

Certificate of professional competence to manage, conduct and control experiments on animals pursuant to section 17 para 1 of Act No 246/1992 Coll., on the protection of animals against cruelty, as amended

Registration number of the certificate.....

Title, name, surname.....

Data and place of birth.....

Name and address of the training centre.....

Date of successfully passed examination.....

Signature of the chairman of the Board of examiners

Signature of the representative of the Ministry of Agriculture and stamp of the Ministry of Agriculture

50. Annex No 10 shall read as follows:

Annex No 10 to Decree No 207/2004 Coll.

Specimen opinion of evaluators of the user establishment

OPINION OF EVALUATORS OF THE USER ESTABLISHMENT	
pursuant to Act No 246/1992 Coll., on the protection of animals against cruelty, as amended, and Decree No 207/2004 Coll., on the protection, breeding and use of experimental animals	
1.	IDENTIFICATION OF EVALUATORS
	Title, name, surname
	Certificate number pursuant to section 17 para 1 of Act No 246/1992 Coll.
2.	IDENTIFICATION DATA OF THE EVALUATED ESTABLISHMENT
	Ref. No assigned by the Ministry of Agriculture (<i>stated in the application for granting accreditation</i>)
	Name of legal person or name and surname of natural person operating the establishment
	Identification number, where assigned
	Registration number, where assigned
	Address of the seat or place of business of the applicant (<i>including the postal code and district, if it is in the territory of the CR</i>)
	Addresses of all establishments intended for the conduct of experiments on animals (<i>including postal codes and districts</i>); specification of premises, including their precise location, name, or other designation of individual premises where experiments on animals are conducted
	Competent state authority with respect to focus of activities of the applicant
	Authorised representative of the applicant – title, name, surname
	Person authorised to act as a proxy of the applicant in administrative procedure – title, name, surname
Person responsible for the care of animals – title, name, surname	
Certificate number pursuant to section 17 para 1 of Act No 246/1992 Coll.	
3.	TYPE OF ACTIVITY OF THE ESTABLISHMENT – PURPOSE OF EXPERIMENT (section 15 para 1 of Act No 246/1992 Coll.)
	<i>Mark an X in the box stating the activities performed by the establishment</i>
	a) avoidance or prevention of diseases, disorder and other abnormality or their effects in man, animals or plants, including the manufacture, quality, effectiveness and safety testing of drugs, substances or products
	b) diagnosis or treatment of diseases, disorders or other abnormality or their effects in man, animals or plants
	c) assessment, detection, regulation or modification of physiological conditions in man, animals or plants
	d) protection of the environment in the interests of the health or welfare of man or animal
	e) education, unless the aim can be achieved otherwise
	f) maintenance or reproduction of live material for scientific purposes
g) scientific research	

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	h) judicial proceedings
4.	DATA SUBMITTED BY THE APPLICANT pursuant to section 13 of Decree No 207/2004 Coll.
	<i>Mark an X in the empty box with data submitted by the establishment</i>
	GENERAL DATA
	the original or certified copy of the document of legal personality
	power of attorney of the person authorised to act as a proxy in the administrative procedure
	a certificate of occupancy or original or a certified copy of a binding expert opinion of the competent veterinary administration authority as a part of the planning, building procedure and certificate of occupancy procedure, if required by special legislation, and a written opinion on activities of the user establishment
	rules of operation
	technological procedures
	documents describing the nature of premises of the user establishment
	organisation chart
	SPECIAL DATA
	a document designating the person responsible for the care of animals and the certificate of his/her professional competence pursuant to section 17 para 1 of Act No 246/1992 Coll.
	a document on setting up and composition of the board of experts and the certificates of their professional competence pursuant to section 17 para 1 or section 26 of Act No 246/1992 Coll.
	a list of work positions which in accordance with Decree No 207/2004 Coll. can be held only by persons holding a certificate of professional competence pursuant to section 17 and section 18 para 6 letter c) of Act No 246/1992 Coll., supplemented by a list of employees indicating whether they were granted the certificate or not
	documents on breeding and use of animals
	records of the number of animals for the last three years unless the activity is newly launched by the user establishment
	opinion of the Ministry of Environment in case of a person operating a user establishment who applies for accreditation for experiments on wild animals
	DATA PRESCRIBED FOR THE RENEWAL OF ACCREDITATION
	records of the number of used, bred, purchased or supplied animals, with the evidence of their origin
	records of the number of dead animals
records of inspections of the state of health of the animals, including the results of laboratory tests and the results of feed and drinking water tests	
records of supervisory authorities	
all experimental projects, including documents, which were not approved by the board of experts of the user establishment, competent state authority or the Ministry of Agriculture	
documents on the used animals with regard to the respective experimental projects conducted since the last accreditation, however for no more than last 5 years	
supporting documents provided to the competent state authority for the purposes of registration of animals pursuant to the binding guidelines of the Ministry of Agriculture	
changes in accreditation data	
other data based on the requirements of the Ministry of Agriculture	
5.	EVALUATION OF SUBMITTED DOCUMENTS
	Defects and deficiencies identified in submitted documents
6.	ANIMAL SPECIES AND THEIR MAXIMUM DAILY NUMBERS
	Reasons for changes in case of lower number of animal species or lower number of animals than stated in the application for accreditation
7.	EVALUATION OF SPACE CAPACITY OF THE ESTABLISHMENT AND TECHNICAL EQUIPMENT OF PREMISES FOR BREEDING EXPERIMENTAL ANIMALS
	Defects and deficiencies identified in the technical equipment of the establishment
8.	RECOMMENDED MEASURES
	to be adopted immediately prior to the issuance of decision on granting accreditation
	of a long-term nature, to be adopted by the set deadline

9.	OPINION OF EVALUATORS FOR GRANTING ACCREDITATION <i>(delete where not applicable)</i>	
	RECOMMENDED for the period of:	NOT RECOMMENDED
	Reasoning of the recommendation for the period shorter than 3 years <i>(in case of the first accreditation)</i> , or 5 years <i>(in case of the renewal of accreditation)</i>	Reasons why the recommendation was not given
10.	PROPOSAL TO SUSPEND THE ADMINISTRATIVE procedure for the purpose of elimination of identified deficiencies	
	Deficiencies due to which the suspension of administrative procedure is proposed	
11.	DECLARATION OF THE APPLICANT	
	The applicant declares that he/she does not conduct experiments on animals in any other premises than those inspected in the course of evaluation, and that he/she has acquainted himself/herself with the content of the opinion.	
12.	ADDRESSES OF THE COMPETENT ANIMAL PROTECTION AUTHORITY AND COMPETENT VETERINARY ADMINISTRATION AUTHORITY to which the decision on granting accreditation will be sent pursuant to section 17d para 5 of Act No 246/1992 Coll.	

Date	
Signatures of evaluators	
Signature of the person authorised to act as a proxy of the applicant in the administrative procedure	
Date of delivery of the opinion to the MoA	

51. Annex No 11 shall read as follows:

Annex No 11 to Decree No 207/2004 Coll.

Specimen opinion of evaluators of the breeding and supplying establishment

OPINION OF EVALUATORS OF THE BREEDING AND SUPPLYING ESTABLISHMENT	
pursuant to Act No 246/1992 Coll., on the protection of animals against cruelty, as amended, and Decree No 207/2004 Coll., on the protection, breeding and use of experimental animals	
1.	IDENTIFICATION OF EVALUATORS
	Title, name, surname
	Certificate number pursuant to section 17 para 1 of Act No 246/1992 Coll.
2.	IDENTIFICATION DATA OF THE EVALUATED ESTABLISHMENT
	Ref. No assigned by the Ministry of Agriculture (<i>stated in the application for granting a certificate</i>)
	Name of legal person or name and surname of natural person operating the establishment
	Identification number, where assigned
	Registration number, where assigned
	Address of the seat or place of business of the applicant (<i>including the postal code and district, if it is in the territory of the CR</i>)
	Addresses of all establishments intended for breeding or supplying animals (<i>including postal codes and districts</i>); specification of premises, including their precise location, name, or other designation of individual premises where animals are bred
	Competent state authority with respect to focus of activities of the applicant
	Authorised representative of the applicant – title, name, surname
	Person authorised to act as a proxy of the applicant in administrative procedure – title, name, surname
3.	TYPE OF ACTIVITY OF THE ESTABLISHMENT
	<i>Mark an X in the box stating the activities performed by the establishment</i>
	breeding animals supplying animals
4.	DATA SUBMITTED BY THE APPLICANT pursuant to section 14 of Decree No 207/2004 Coll.
	<i>Mark an X in the empty box with data submitted by the establishment</i>
	GENERAL DATA
	the original or a certified copy of the document of legal personality
	power of attorney of the person authorised to act as a proxy in the administrative procedure
	a certificate of occupancy or original or a certified copy of a binding expert opinion of the competent veterinary administration authority as a part of the planning, building procedure and certificate of occupancy procedure, if required by special legislation, and a written opinion on activities of the breeding or supplying establishment
	rules of operation
	technological procedures
	documents describing the nature of premises of the breeding or supplying establishment
	organisation chart
SPECIAL DATA	

	a list of work positions which in accordance with Decree No 207/2004 Coll. can be held only by persons holding a certificate of professional competence pursuant to section 17 and section 18 para 6 letter c) of Act No 246/1992 Coll., supplemented by a list of employees indicating whether they were granted the certificate or not	
	documents on breeding of animals	
	DATA PRESCRIBED FOR THE RENEWAL OF THE CERTIFICATE	
	records of the number of bred, purchased or supplied animals, with the evidence of their origin	
	records of the number of dead animals	
	records of inspections of the state of health of the animals, including the results of laboratory tests and the results of feed and drinking water tests	
	records of supervisory authorities	
	changes in data relevant for granting a certificate	
	other data based on the requirements of the Ministry of Agriculture	
5.	EVALUATION OF SUBMITTED DOCUMENTS	
	Defects and deficiencies identified in submitted documents	
6.	ANIMAL SPECIES AND THEIR MAXIMUM DAILY NUMBERS	
	Reasons for changes in case of lower number of animal species or lower number of animals than stated in the application for granting a certificate	
7.	EVALUATION OF SPACE CAPACITY OF THE ESTABLISHMENT AND TECHNICAL EQUIPMENT OF PREMISES FOR BREEDING EXPERIMENTAL ANIMALS	
	Defects and deficiencies identified in the technical equipment of the establishment	
8.	RECOMMENDED MEASURES	
	to be adopted immediately prior to the issuance of decision on granting a certificate	
	of a long-term nature, to be adopted by the set deadline	
9.	OPINION OF EVALUATORS FOR GRANTING A CERTIFICATE <i>(delete where not applicable)</i>	
	RECOMMENDED for the period of:	NOT RECOMMENDED
	Reasoning of the recommendation for the period shorter than 3 years <i>(in case of the first certificate)</i> , or 5 years <i>(in case of renewal of the certificate)</i>	Reasons why the recommendation was not given
10.	PROPOSAL TO SUSPEND THE ADMINISTRATIVE procedure for the purpose of elimination of identified deficiencies	
	Deficiencies due to which the suspension of administrative procedure is proposed	
11.	DECLARATION OF THE APPLICANT	
	The applicant declares that he/she does not breed animals in any other premises than those inspected in the course of evaluation, and that he/she has acquainted himself/herself with the content of the opinion.	
12.	ADDRESSES OF THE COMPETENT ANIMAL PROTECTION AUTHORITY AND COMPETENT VETERINARY ADMINISTRATION AUTHORITY to which the decision on granting a certificate will be sent pursuant to section 17e para 6 of Act No 246/1992 Coll.	

Date	
Signatures of evaluators	
Signature of the person authorised to act as a proxy of the applicant in the administrative procedure	

Date of delivery of the opinion to the MoA	
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52. Annex No 12 shall read as follows:

Annex No 12 to Decree No 207/2004 Coll.

Guidelines for the transport of laboratory animals

TABLE 1

Number of animals in a transport container – mice

Weight of animals (in g)	Number of animals in a container			
	Standard container		Container with a filter	
	Summer	Winter	Summer	Winter
less than 14	35	43	30	40
15 – 20	30	38	25	37
21 – 25	25	35	22	33
26 – 30	20	33	20	30
31 – 50	20	25	18	25
50 – 100	10	10	10	10

TABLE 2

Number of animals in a transport container – rats

Weight of animals (in g)	Number of animals in a container			
	Standard container		Container with a filter	
	Summer	Winter	Summer	Winter
less than 50	20	25	14	18
51 – 100	15	20	11	14
101 – 150	13	18	9	12
151 – 200	9	14	8	10
201 – 250	7	12	6	8
251 – 300	6	10	5	7
301 – 350	5	8	4	6
351 – 500	4	5	3	5
501 – 800	2	2	2	2

TABLE 3

Number of animals in a transport container – guinea pigs

Weight of animals (in g)	Number of animals in a container			
	Standard container		Container with a filter	
	Summer	Winter	Summer	Winter
less than 300	6	7	5	6
300 – 500	4	5	3	4
501 – 1 000	2	2	2	2

TABLE 4

Number of animals in a transport container – rabbits

Weight of animals (in kg)	Number of animals in a container	
	Container with a filter	
	Summer	Winter
less than 2.5	2	2
over 2.5	1	1

TABLE 5

Number of animals in a transport container – hamsters, gerbils

Weight of animals (in g)	Number of animals in a container			
	Standard container		Container with a filter	
	Summer	Winter	Summer	Winter
any	up to 10	up to 10	up to 10	up to 10

TABLE 6

Size of transport containers

Mice, rats, guinea pigs, hamsters, gerbils	68 x 50 x 17 cm
Rabbits	71 x 46 x 38 cm

Notes to tables 1 to 6:

Transport container: a packaging (box) made of a special rigid cardboard or plastic.

Standard container: a transport container for animals in conventional husbandry systems.

Container with a filter: a transport container for animals in barrier systems (cannot be open during the transport!).

Article II

Effect

This Decree shall take effect on the day of its promulgation.

Minister:

Mgr. Gandalovič manu propria