

Ministry of Agriculture
Animal Commodities Dept.

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Ref. No. 38706/2015-MZE-17214

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Prague, 15.07.2015

D E C R E E

Ministry of Agriculture, Animal Commodities Dept. (hereinafter only “Ministry of Agriculture”), which is the competent authority deciding bestowal, change, suspension or withdrawal of the authorization for using of experimental animals according to § 20, article 1, letter g) of Law No. 246/1992 Collection of Laws of the Czech Republic, about protection of animals against mistreatment, as amended (hereinafter only “law about protection of animals”), in proceedings commenced on the basis of application submitted by the company MediTox s.r.o., represented in the administrative proceedings by Mgr. Vladimíra Mamiňáková acting under power of attorney dated 29.04.2015, according to provision of § 44 article 1 of Law. No. 500/2004 Collection of Laws of the Czech Republic, rules of administrative procedure, valid version, and on the basis of provision § 20, article 1, letter g) of law about protection of animals, in the case of application for bestowal of authorization for using of experimental animals, has decided as follows:

**A u t h o r i z a t i o n f o r u s i n g o f e x p e r i m e n t a l a n i m a l s
i s b e s t o w e d**

according to § 15b, § 20, article 1, letter g) of the law about protection of animals upon the company **MediTox s.r.o. seated Pod Zámkem 279, 281 25 Konárovice, Id.No. 25926713** (hereinafter only “applicant”),

for operating the user facility Pod Zámkem 279, 281 25 Konárovice,

- building No. 2 – experimental rooms for mice or rats or hamsters or guinea pigs or cats or ferrets or rabbits – experimental rooms No. 1 and 2 (southern part) and experimental rooms No. 3-6 (northern part),
- building No. 3 – experimental rooms for dogs – room No. 1, 2 and 3,
- building No. 5 – experimental rooms for rabbits – room No. 2,
- building No. 6 – experimental rooms for monkeys – room No. 6,
- building No. 11 – experimental rooms for pigs – rooms No. 1 and 2
- building No. 18 – elevated ground floor – experimental rooms for monkeys – rooms No. 1, 2 and 3,

for a time period of **5 years** beginning from legal force of this decision,

for the purposes according § 18, article 1, letters a), c), d), e), and f) of the law about protection of animals, thus with the aim of:

- basic research,
- for any of the objectives referred to in point b) in the development, manufacturing or testing of the quality, effectiveness and safety of drugs, food, feeds and other substances or products,
- protection of environment focused on health and good living conditions of humans or animals,
- scientific research aimed at preservation of the species,
- higher education or training in order to obtain, maintain or improve expert knowledge,

with the use of animals:	with the maximum daily numbers:	of that:	up to:
laboratory mouse	5000	1000	< 20 grams
		2000	20 – 25 grams
		1000	25 – 30 grams
		1000	> 30 grams
laboratory rat	5000	1000	< 200 grams
		1000	200 – 300 grams
		1000	300 – 400 grams
		1000	400 – 600 grams
		1000	> 600 grams
domestic guinea pig	2500	500	< 200 grams
		500	200 – 300 grams
		500	300 – 450 grams
		500	450 – 700 grams
		500	> 700 grams
golden hamster	5000	1000	< 60 grams
		2000	60 – 100 grams
		2000	> 100 grams
domestic ferret	220	80	< 600 grams
		70	> 600 grams
		70	adult males
domestic pig		40	< 70 kilograms
		32	50 – 100 kilograms
		22	100 – 150 kilograms
domestic rabbit	310		
domestic dog	108		
domestic cat	220		
sub-human primates – rhesus macaque (<i>Macaca mulatta</i>), Javanese macaque	146		

Building No. 2 allows reaching maximal daily numbers just in alternative animal housing setup. It is possible use cumulative housing of appropriate rodent species in case of lower daily numbers. Domestic pig can be housed in stated numbers in alternative setup.

The person responsible for care of experimental animals in the above-mentioned user facility is Ing. Jana Nováková, her certificate number, according to § 15, article 3 of the law about protection of animals, is CZ 01543.

Designated veterinarian according to § 15f, article 5 of the law about protection of animals is MVDr. Lukáš Pánek, his certificate according to § 15, article 3 of the l, is CZ 02382.

The person responsible for law about protection of animals compliance is Jan Záborský, MBA, LL.M.

J U S T I F I C A T I O N

The application for bestowal of authorization for using of experimental animals according to § 15b, article 1, the law about protection of animals, and according to § 2, article 1 of public notice No. 419/2012 Collection of Laws of the Czech Republic, about protection, breeding and use of experimental animals (hereinafter only “public notice”) was submitted to Ministry of Agriculture of the Czech Republic on May 04, 2015. This is the date of starting the administrative procedure.

After removing defects in the submission, the Ministry of Agriculture, in accordance with § 15c, article 5 of the law about protection of animals, authorized the adjudicators MVDr. Jiří Dousek, Ph.D. and MVDr. Stanislav Špelda to assess the above-mentioned user facility (the facility in which animals are used for experiments). The adjudicators assessed the user facility by physical check on the spot, inclusive of the prescribed documentation; they wrote the adjudicators’ assessment, and on June 29, 2015 they submitted it to the Ministry of Agriculture in accordance with § 15c, article 6, letter a) point 2 of the law about protection of animals; in their expert opinion they recommended bestowal of the accreditation for a time period of 5 years. The adjudicators found no fundamental defects in the submitted documentation and technical equipment of the facility.

On the basis of submitted application, the developed assessment, and on the basis of evaluation of documentation material, the Ministry of Agriculture decided about bestowal of accreditation upon person operating user facility to the applicant for the time period of 5 years, namely with regard to fulfilling the specified conditions of breeding and use of experimental animals, which are in accordance with the law about protection of animals and the public notice.

In accordance with the provision of § 15b, article 3 of the law about protection of animals, the accreditation was bestowed upon the applicant for a time period of 5 years, because this is the case of repeated bestowal of accreditation.

The applicant has paid the fee of administration according to item 74, letter c) of scale of fees – a supplement to the Law No. 634/2004 Collection of Laws of the Czech Republic, about the fees of administration, in the amount of CZK 10,000. This payment was carried out by bank transfer.

For the above-mentioned reasons it was decided what is given in the statement section of this decree.

This decree replaces the decree of Central Committee of Protection of Animals of July 02, 2010, Ref. No. 10984/2010-17210, about bestowal of accreditation upon the company BioTest s.r.o. seated Pod Zámkem 279, 281 25 Konárovice, Id. No. 25926713. This decree also replaces the decree of Central Committee of Protection of Animals of September 05, 2011, Ref. No.159771/2011-MZE-17214 about bestowal of accreditation upon the company BioTest s.r.o. seated Pod Zámkem 279, 281 25 Konárovice, Id. No. 25926713.

Competent state authority to approve experiment projects of foregoing applicant is according § 23, article 1 of the law about protection of animals Ministry of Health of the Czech Republic.

WARNING OF PARTICIPANTS

It is possible to submit a remonstrance according to § 152, article 1 of the Law No. 500/2004 Collection of Laws of the Czech Republic, rules of administrative procedure, valid version, within 15 days from announcement of the decision to the minister of agriculture, in the form of submission made at Ministry of Agriculture –Animal Commodities Dept.

Text of round stamp: Ministry of Agriculture of the Czech Republic

(signature)

Ing. Jiří Hojer

Director of Department of Animal Commodities

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