

Department of Environment and Organic Agriculture

File number: 16OZ14383/2020-18134
Ref. No. 46643/2020-MZE-18134

Handles: JUDr. Traplová
Phone: 221 812 346
E-mail jana.traplova@mze.cz
ID DS: yphaax8

Address: Těšnov 65/17, Nové Město, 110 00 Praha 1

Prague, 16.09.2020

DECREE

Ministry of Agriculture, Department of Environmental and Organic Agriculture, department of Protection of Animals (hereinafter only “Ministry of Agriculture”), which is the competent authority deciding bestowal, change, suspension or withdrawal of certificate of person who operates a user facility according to § 20, article 1, letter j) 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 administrative proceedings Ing. J. Nováková, according to the provisions of article 44 par. 1 of Act No. 500/2004 Coll., Rules of Procedure, as amended, on the basis of the provisions of article 20 par. 1 letter g) of the Animal Protection Act in the matter of the application for the granting of authorization to use experimental animals decided as follows:

A u t h o r i z a t i o n t o u s e e x p e r i m e n t a l a n i m a l s i s g r a n t 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 (hereinafter referred to as the applicant)

in facility of MediTox s.r.o., Pod Zámkem 279, 281 25 Konárovice:

- Building No. 2 – experimental barrier and conventional rooms for small laboratory animals,
- Building No. 3 – experimental rooms for dogs,
- Building No. 5 – experimental rooms for rabbits and small animals,
- Building No. 6 – experimental rooms for NHP and cats, surgical operation,
- Building No. 7 – laboratory of toxicology (necropsy room),
- Building No. 11 – experimental rooms for big animals
- Building No. 18 – experimental rooms for pigs,

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

for the type of activity:

- basic research (section 18 paragraph 1 letter a) of the Animal Protection Act,
- translational or applied research in order to
 1. to prevent diseases, ill health or other anomalies or their consequences in humans, animals or plants, to diagnose or treat them,
 2. to assess, detect, regulate or modify the physiological conditions of humans, animals or plants, or
 3. to improve the living and production conditions of animals kept for farming purposes,
 (section 18 paragraph 1 letter b), point 1, 2 and 3 of the Animal Protection Act
- for any of the objectives referred to in letter b) in the development, production or testing of the quality, efficacy and safety of medicinal products, food, feed and other substances and products, hence the goal
 1. to prevent diseases, ill health or other anomalies or their consequences in humans, animals or plants, to diagnose or treat them,
 2. to assess, detect, regulate or modify the physiological conditions of humans, animals or plants, or
 3. to improve the living and production conditions of animals kept for farming purposes,
- protection of the natural environment in the interests of the health or welfare of humans or animals (section 18, paragraph 1 letter d) of Animal Protection Act
- species conservation research (section 18 paragraph 1 letter e) of Animal Protection Act,
- higher education or training to acquire, retain or improve professional knowledge (section 18 paragraph 1 letter f) of Animal Protection Act.

with the use of animals:	With maximum body weight	With maximum daily number
laboratory mouse	≤ 20 g or ≥ 30 g	5.160 3.672
laboratory rat	≤ 200 g or ≥ 600 g	4.896 1.032
domestic guinea pig	≤ 200 g or ≥ 700 g	585 90
golden hamster	≤ 60 g or ≥ 100 g	2.808 1.404
domestic rabbit	3 – 5 kg and ≥ 5 kg Total:	84 96 180
domestic dog	≤ 20 kg	160
domestic cat	adult	96
domestic ferret	≥ 600 g or adult male	180 90
sub-human primates – rhesus macaque (<i>Macaca mulatta</i>)	≤ 3 years of age or ≥ 3 years of age	60 40
sub-human primates – cynomolgus monkey (<i>Macaca fascicularis</i>)	≤ 3 years of age or ≥ 3 years of age	60 40
domestic pig	≤ 50 kg or	297

	≥ 150 kg	60
--	----------	----

Animals of different weight categories will be used in the facility at the same time. In the case of housing animals in more weight categories, the total number of animals will be reduced in accordance with Decree No. 419/2012 Coll., On the protection of experimental animals, but there will always be animals of one species in the room.

The maximum daily number of animals shall not exceed the number of animals in the weight category up to 20 g in mice, up to 200 g in rats, up to 60 g in hamsters, up to 200 g in guinea pigs, over 600 g in ferrets, up to 50 kg in pigs and less than 3 years in non-human primates.

The person authorized for the care of experimental animals in the above facility is Ing. Jana Nováková, [REDACTED], number of the certificate of professional competence according to section 15d paragraph 3 of the Act on the Protection of Animals CZ 01543.

The designated veterinarian in the above facility is MVDr. Lukáš Pánek, [REDACTED], number of the certificate of professional competence according to section 15d paragraph 3 of the Act on the Protection of Animals CZ 02382.

The statutory body responsible for compliance with the Animal Protection Act is Jan Záborský – Chief Executive Officer, [REDACTED]

JUSTIFICATION

Application for the granting of an authorization to use experimental animals pursuant to Section 15b (1) of the Animal Protection Act and pursuant to Section 2, paragraph 1 of Decree No. 419/2012 Coll. on the Protection of Experimental Animals (hereinafter referred to as the "Decree"), was delivered to the Ministry of Agriculture on 22.5.2020. Administrative proceedings were initiated on that day.

The Ministry of Agriculture has in writing authorized MVDr. Jiří Dousek, Ph.D. and MVDr. Stanislav Špelda to assess the above-mentioned facility in accordance with Section 15c, Paragraph 5 of the Animal Protection Act. The assessors assessed the facility by on-site inspection, including the established documentation, they prepared a written report on the findings, which was submitted to the Ministry of Agriculture on 5.8.2020 in accordance with Section 15c (6) (a) (2) of the Animal Protection Act. The assessors recommended to grant the Authorization for use of experimental animals for a period of 5 years. The assessors did not find defects and shortcomings in the submitted documentation or in the technical equipment of the facility.

On the basis of the submitted application, the processed report and on the basis of the evaluation of the file material, the Ministry of Agriculture decided to grant authorization to use experimental animals for 5 years, due to meeting the specified conditions of breeding and use of experimental animals. and decree.

This decree replaces the decree of Ministry of Agriculture, ref. number 16OZ13404/2015-17214, 38706/2015-MZE-17214 from July 15, 2015. of July 15, 2008, Ref. No. 21688/2008-10001, about bestowal of accreditation upon the company MediTox s.r.o. seated Pod Zámkem 279, 281 25 Konárovice, Id. No. 25926713. The decision of the Ministry of Agriculture of 15

46643/2020-MZE-18134

Excerpt of the document

July 2015 came into force on 31 July 2015 and was valid until 31 July 2020. This decision did not expire at the end of the period specified therein, as the applicant submitted an application for another decision, which is to follow on from the previous decision, at least 60 days before the expiry date of the issued decision (section 20 paragraph 4 of the Animal Protection Act). The decision of 15 July 2015 is extinguished by the legal force of this decision.

In accordance with Section 23, Paragraph 1 of the Act on the Protection of Animals, the Ministry of Health is the state body responsible for approving the application for ethical approval submitted by the above-mentioned facility.

WARNING OF PARTICIPANTS

Pursuant to Section 152, Paragraph 1 of Act No. 500/2014 Coll., The Administrative Procedure Code, as amended, an appeal may be lodged with the Minister of Agriculture within 15 days from the date of notification of the decision by filing with the Ministry of Agriculture - Department of Environment and Ecological Agriculture.

(electronic signature)

Ing. Petr Jelínek

Director of Department

Imprint of the official stamp