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Transportation of Laboratory Animals

Recommendation No. 011/2023 of the National Committee for the Protection of Animals Used for Scientific Purposes for the Federal Republic of Germany, 14 April 2023.

The German Federal Institute for Risk Assessment (BfR) assumes the tasks of the National Committee for the welfare of animals used for scientific purposes in accordance with section 15a of the Animal Welfare Act (TierSchG) in conjunction with Section 45 of the [Ordinance on the protection of animals used for experiments or other scientific purposes](#) (TierSchVersV) in accordance with Article 49 of Directive 2010/63/EU (hereinafter: National Committee).

The tasks of the National Committee include advising the competent authorities for the approval of animal experiments and the animal welfare committees of the research institutions on various topics related to animal experiments. These include the acquisition, breeding, housing and care of laboratory animals and the use of vertebrates and cephalopods in animal experiments. In addition, the National Committee ensures that a dialogue is maintained in this regard at both national and EU level.

The following recommendation of the National Committee deals with the question of which legal requirements apply to the transportation of laboratory animals and whether the European Animal Transportation Regulation, Regulation (EC) No. 1/2005 and the National Animal Welfare Transportation Ordinance (TierSchTrV) apply to the laboratory animal sector. In particular, it addresses the question of what needs to be considered in the case of sick and injured laboratory animals, as well as newborn and pregnant animals. In addition, it considers which special features apply to the transportation of farm animals, that are used in experiments, and which requirements apply to transporters of experimental animals.

Animal transportation takes place regularly as part of the breeding and trading of laboratory animals. Even during ongoing animal experiments, laboratory animals may still need to be transferred from one facility or company to another facility or company in order to conduct further tests on these animals in a different location. The animals may have already undergone treatments or interventions prior to transportation that impair their state of health.

The National Committee was asked what legal framework conditions apply to the transportation of laboratory animals in general, as well as for sick or injured, newborn or pregnant laboratory animals and farm animals in particular, and what technical requirements must be met when transporting laboratory animals.

I. General Requirements for the Transportation of Laboratory Animals

There are no special laws governing the transportation of laboratory animals. Relevant legal provisions, which also apply to laboratory animals, are therefore the European Animal Transport Regulation, Regulation (EC) No. 1/2005¹ and, at national level, the Ordinance on the Welfare of Animals during Transportation and the Implementation of Regulation (EC) No. 1/2005 of the Council (in short: Animal Protection Transportation Ordinance - TierSchTrV),²

¹ <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32005R0001&from=de>

² Sections 2a, paragraph 2 and 12, paragraph 2 TierSchG form the enabling provision for the TierSchTrV.

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which refers to the European Animal Transportation Regulation and supplements it with national regulations. Unlike a policy such as Directive 2010/63/EU, the European Animal Transportation Regulation is already directly applicable law, which binds all national authorities and the courts.³ In addition, when transporting laboratory animals, the relevant provisions of the Animal Welfare Act (TierSchG) and the associated Ordinance on the Protection of Animals used for Experiments or other Scientific Purposes (TierSchVersV) must be observed. Other legal bases such as the Animal Diseases Act (TierSG), the Infection Protection Act (IfSG), the Genetic Engineering Safety Ordinance (GenTSV) and the Ordinance on Safety and Health Protection for Activities with Biological Agents (Biological Substances Ordinance - BioStoffV) may also be applied depending on the circumstances of the transportation, since they regulate further measures or legal provisions in each case.

The transportation regulations are detailed and govern a wide range of requirements that must be observed when transporting animals. This recommendation focuses on the transportation of sick, injured, newborn or pregnant laboratory animals and farm animals intended for use in experiments (cf. sections III-VI).

Crucial to the scope of application of the European Animal Transport Regulation is that it is initially a matter of transporting living vertebrates (Article 1, paragraph 2 of Regulation (EC) No. 1/2005, then by definition only referred to as “animals”) and this is carried out as part of an economic activity (cf. Article 1, paragraph 5 of Regulation (EC) No. 1/2005). The term “economic activity” does not primarily refer to the actual transportation service, but it is sufficient if transportation occurs within some economic context on the part of the operator or their client.⁴ According to the case law of the European Court of Justice (ECJ), the term according to Article 1, paragraph 5 of Regulation (EC) No. 1/2005 covers any activity designed to offer goods or services on a market.⁵ An additional intention to make a profit is not required.⁶ The existence of a permit according to Section 11, paragraph 1 of the TierSchG may imply that transportation of the animals in itself constitutes an economic activity.⁷ However, this must

³ Cf. Article 288, Paragraph 1 TFEU; Metzger, in: Lorz/Metzger, TierSchG, 7th ed. 2019, Preliminary Remark (Vorbemerkung) to Regulation (EC) 1/2005, see recital 1.

⁴ Hirt/Maisack/Moritz/Felde/Hirt, 4th ed. 2023, Regulation (EC) No. 1/2005, Article 1, paragraph 4; Metzger, in: Lorz/Metzger, 7th ed. 2019, Article 1 of Regulation (EC) 1/2005, see recital 9.

⁵ ECJ, Judgement of 10 January 2006 – C-222/04, Reports of Cases 2006, no. I-00289, paragraph 108, with reference to ECJ, judgement of 18 June 1998 - C-35/96, Reports of Cases 1998, no. I-3851 = EuZW 1999, 93, paragraph. 36 - Commission/Italian, and ECJ, judgement of 12 December 2000 - C-180/98 to C-184/98, Pavlov et al., Reports of Casesno. 2000, no. I-6541, paragraph 75.

⁶ Cf. ECJ, judgement of 3 December 2015, – C-301/14, according to which a non-profit animal welfare organisation can also fall under the application of the European Animal Transportation Regulation (EC) No. 1/2005 when transporting stray dogs to another EU member state; also Germany's Federal Administrative Court (BVerwG), judgement of 7-July 2016 – C 23.15, the Higher Administrative Court (OVG) of NRW, decision of 14 March 2013 – 20 B 34/13 with reference to the Higher Administrative Court (OVG) of Schleswig-Holstein, judgement of 6 December 2012 – 4 LB 11/11; in addition, Recital No. 12 of Regulation (EC) 1/2005 states that “transport for commercial purposes is not (limited to) cases in which there is a direct exchange of money, goods or services. In particular, it also includes cases in which a direct or indirect profit arises or is sought.”

⁷ Transportation of commercially bred laboratory animals would therefore fall under the concept of economic activity (cf. For example Paragraph 11, sSection 1, No. 8 lit. a TierSchG, which clearly includes animals that are bred or kept commercially). Hirt/Maisack/Moritz/Felde also see permission according to article 11 TierSchG as an indication of economic activity, Hirt/Maisack/Moritz/Felde/Hirt, 4th ed. 2023, Regulation (EC) No. 1/2005, Article 1, see recital 4. It becomes more difficult to assess, e.g. in laboratory animal facilities such as universities, which regularly have a permit according to

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be verified individually for the respective circumstances of transportation. According to the wording chosen in Regulation (EC) No. 1/2005 Article 1, paragraph 5, in cases of doubt the transporter must prove that he is not subject to the EU Animal Transport Regulation.⁸ The National Committee therefore recommends involving the competent authority in individual decisions on the transportation of laboratory animals and, if necessary, specifying how such proof should be provided.

Article 3 of Regulation (EC) No. 1/2005 defines the general conditions applicable to the transportation of animals. It contains a large number of undefined legal terms, each of which should be assessed on the basis of current scientific knowledge.⁹ In concrete terms, this means that a precautionary approach should be taken, i.e. “all necessary arrangements have been made in advance to minimise the length of the journey and meet animals’ needs during the journey” (lit. a)). Appropriately trained or suitably qualified personnel (lit. e, as well as recital no. 14, Article 17 and Annex IV of Regulation (EC) No. 1/2005) must be deployed for this purpose. In addition, the animals must be “fit for transport” (lit. b). The fitness for transport of the animals must always be assessed on a case-by-case basis. Specific legal requirements can be found in Annex I of Regulation (EC) No. 1/2005.

II. Requirements for the Transporters

In principle, laboratory animals can be transported by a professional transport company or by the facility itself, provided that the facility has the appropriate staff and equipment, as well as transport containers and means of transportation appropriate for the animal species in question (see specifically Regulation (EC) No. 1/2005, Annex I, Chapter II, Means of Transport and Chapter III, Transportation Practice).

Articles 10 and 11 of Regulation (EC) No. 1/2005 specifically stipulate that transport companies require a license issued by the relevant competent authority if the animals are to be transported over a distance of 65 km (e.g. Article 6, Paragraph 7 of Regulation (EC) No. 1/2005).¹⁰ This also applies to the transport of animals by the scientific facility itself. In addition, the accompanying personnel must be appropriately trained (e.g. proof of qualification, Article 17, paragraph 2 of Regulation (EC) No. 1/2005) and the transporter must possess appropriate equipment, even for transportation that does not exceed a distance of 65 km, and transport vehicles to avoid pain, suffering or harm to the transported animals. Correspondingly, the management of a facility or company pursuant to Paragraph 1, Section 1, Sentence 3 of TierSchVersV that transports animals itself must ensure that the laboratory animals are transported in such a way that no avoidable pain, suffering or harm is caused to them.

Paragraph 11, Section 1, No. 1 TierSchG, but which does not necessarily imply an economic (e.g. commercial) activity. Here it would have to be assessed whether a corresponding service is provided indirectly. The KMK Guidelines on the distinction between economic and non-economic activity at universities (KMK-IIIc-4120/6.1.2) for the application of EU state aid law provides information on which services of a university can be regarded as economic activity.

⁸ Hirt/Maisack/Moritz/Felde/Hirt, 4th ed. 2023, Regulation (EC) No. 1/2005 Article 1, see recital 4.

⁹ Metzger, in: Lorz/Metzger, TierSchG, 7th ed. 2019, (EC) Transportation Regulation Article 3, see recital 5.

¹⁰ Detailed information on transportation and especially on the certificate of competence for persons who transport animals can be found in the “Handbuch für Tiertransporte der AG Tierschutz der LAV” (“Manual for transporting animals” see fn. 11), p. 20 ff. (C2).

III. Transportation of Sick or Injured Laboratory Animals

Regulation (EC) No. 1/2005 allows the exception that sick or injured animals can be considered fit for transportation provided that transportation takes place in connection with an animal experiment in accordance with Directive 2010/63/EU (Annex I, Chapter I, Fitness for Transport, no. 3, lit. b of Regulation (EC) No. 1/2005).¹¹ In this case, the injuries or illnesses of a laboratory animal must be “part of the research programme”) in accordance with the wording of Annex I, Chapter I, Fitness for Transport, No. 3, lit. b Regulation (EC) No. 1/2005. In the case of experiment-related illnesses or injuries, e.g. via surgical intervention, these would have to have been caused by a corresponding treatment or an intervention according to Paragraph 7, Section 2 TierSchG, i.e. they would have to correspond to the official project approval and thus be legal.¹² It must therefore be necessary for the desired scientific knowledge that the animals are transported according to their state of health.

The exemption makes it clear that for laboratory animals the actual principle from Annex I Chapter I no. 3, lit. a Regulation (EC) No. 1/2005, whereby “slightly injured or ill” animals can be transported, does not apply in principle. In general, all laboratory animals covered by an project authorisation can be classified as fit for transport in the sense of Regulation (EC) No. 1/2005, provided transportation forms part of the animal experiment permit. The appraisal of whether the animals are transportable despite the injuries or illnesses caused by the experiment is therefore the responsibility of the licensing authority after reviewing the license application and can only be carried out if a corresponding license has been granted in accordance with Paragraph 8, Section 1 TierSchG.

IV Transport of Laboratory Animals Under Safety Conditions

In the case of experiments that are subject to a safety level according to the Biological Substances Ordinance or the Technical Rules for Biological Agents (TRBA), e.g. in the case of experiments with infectious agents, the laws and regulations mentioned must be observed.¹³ In general, the containers for transporting these organisms or animals must be closed, dimensionally stable, unbreakable and escape-proof, liquid-tight and marked accordingly (permanent labelling).¹⁴ There may be different legal requirements, depending on whether the transportation is internal or external.¹⁵ In the case of the transportation of genetically modified

¹¹ The reference to the repealed Directive 86/609/EEC is to be read as a reference to Directive 2010/63/EU, see Article 62, Paragraph 2 of Directive 2010/63/EU; cf. also the so called Handbuch für Tiertransporte (as of 2021) of the animal welfare working group of the consumer protection working group of the federal states (Länder, LAV), p. 38, <https://www.fli.de/de/service/handbuecher-der-ag-tierschutz-der-lav/> (manual and appendices).

¹² Cf. Hirt/Maisack/Moritz/Felde/Hirt, 4th ed. 2023, Regulation (EC) No. 1/2005, Annex I, Chapter I. Transportability, see recital 6b.

¹³ See under I. and under <https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html>.

¹⁴ Cf. the Technical Rules for Biological Agents in “Experimental Animal Husbandry” (TRBA 120), July 2012 edition, 1st revision of 3/31/2017, GMBI. No. 10-11, for internal transport, available at: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/pdf/TRBA-120.pdf?__blob=publicationFile&v=6.

¹⁵ Detailed information on safety measures when handling biological substances can be obtained from the Federal Institute for Occupational Safety and Health.

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animals, the relevant legal provisions must also be observed, whereby various recommendations can be consulted.¹⁶

V. Transportation of Agricultural Laboratory Animals

If the facility observes the requirements for the transportation of animals mentioned under point II (e.g. transportability of the animals, transport qualification, etc.), no further special features apply to agricultural laboratory animals, so that both the facility itself (in compliance with the statutory provisions) and an approved professional, commercial transport company is allowed to transport these animals.

Given their dual nature as farm animals and laboratory animals, it must be noted that once farm animals have been specifically selected for the experiment, they are no longer purely farm animals and both the regulations for animal transportation and the special regulations for laboratory animals apply. This should also apply if these animals are collected for use in a pending experiment.

VI. Transportation of Pregnant or Newborn Laboratory Animals

As previously stated, Annex I of Regulation (EC) No. 1/2005 regulates the transportability of animals. According to Annex I, Chapter I, no. 1, animals may only be transported if they are fit for transportation and if it is guaranteed that they will be spared unnecessary injuries and suffering. Annex I, Chapter I, no. 2 stipulates that injured animals and animals with physiological weaknesses or pathological conditions are fundamentally not fit for transport. This applies in particular to pregnant animals in an advanced stage of gestation (90% or more) or animals that gave birth less than seven days ago (Regulation (EC) No. 1/2005 Annex I, Chapter I, no. 2, lit. c). According to this, mice with an average gestation period of 21 days, for example, may no longer be transported from the 19th day of pregnancy. Newborn mammals may also not be transported if the umbilical wound has not yet completely healed (Regulation (EC) No. 1/2005 Annex I, Chapter I, No. 2, lit. d). This circumstance would have to be checked for each newborn laboratory animal on a case-by-case basis.

As previously described under point III, Annex I, Chapter I, No. 3, lit. b of Regulation (EC) No. 1/2005 defines an exception for the transport of sick or injured laboratory animals.¹⁷ From the point of view of the National Committee, however, newborn or pregnant animals are not sick or injured animals, but these animals should be subsumed under the term “animals with physiological weaknesses”. Since Annex I, Chapter I, no. 3 only refers to sick or injured animals and does not include the animals with physiological weaknesses listed in Annex I, Chapter I, no. 2, the National Committee is of the opinion that the exemption regulation does not apply to newborn and pregnant laboratory animals. Pregnant or newborn animals, which are referred to in Regulation (EC) No. 1/2005 Annex I, Chapter I, no. 2, lit. c, may therefore not be

¹⁶ For the transportation of genetically modified mice and rats, please see also the recommendations of Gesellschaft für Versuchstierkunde (GV-SOLAS), as of December 2012, available at: https://www.gv-solas.de/wp-content/uploads/2018/11/gen_2022_04_11_Transport-GV-Maus-und-Ratte_12-2021.pdf. The Federation of European Laboratory Animals Science Association (FELASA) appears to be working on a recommendation for the transportation of laboratory animals, see: <https://felasa.eu/working-groups/present/id/4>.

¹⁷ Sick or injured animals can be considered fit for transportation if the illness or injury is related to an experimental programme according to Directive 86/609/EEC (replaced by Directive 2010/63/EU).

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transported even if said transportation is in connection with an animal experiment in accordance with Section 7, paragraph 2 of TierSchG.

2. Closing Remarks

Statements and recommendations of the National Committee pursuant to Article 49 of Directive 2010/63/EU are intended to help standardise the interpretation and application of animal welfare law in Germany. The legally binding interpretation of animal welfare law is the sole responsibility of the German courts or the European Court of Justice.

Recommendations of the National Committee for the Animal Welfare Act on the Bf3R website

https://www.bf3r.de/de/empfehlungen_des_nationalen_ausschusses_tierschg_-_276697.html (in German)

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Food and Agriculture (BMEL). The BfR advises the Federal Government and the German federal states ("Laender") on questions of food, chemicals, and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

About the Bf3R

The German Centre for the Protection of Laboratory Animals (Bf3R) was founded in 2015 and is an integral part of the German Federal Institute for Risk Assessment (BfR). It co-ordinates nationwide activities with the goals of restricting animal experiments to only those which are considered essential, and guaranteeing the best possible protection for laboratory animals. Moreover, it intends to stimulate research activities and encourage scientific dialogue.

This text version is a translation of the original German text which is the only legally binding version. Please note that the text is only a recommendation.