# 

中国质检出版社中国标准出版社

# 实验动物机构 认可标准法规 实用手册

国际篇

中国质检出版社中国标准出版社

#### 图书在版编目(CIP)数据

实验动物机构认可标准法规实用手册.国际篇/史光华,吕京主编.一北京:中国标准出版社,2014.10

ISBN 978-7-5066-7615-1

I.①认··· Ⅱ.①史···②吕··· Ⅲ.①实验动物—国际标准—汇编 Ⅳ.①Q95-33 中国版本图书馆 CIP 数据核字 (2014) 第 180796 号



中国质检出版社 中国标准出版社出版发行

北京市朝阳区和平里西街甲2号 (100029) 北京市西城区三里河北街16号 (100045)

网址: www.spc.net.cn 总编室: (010) 64275323 发行中心: (010) 51780235 读者服务部: (010) 68523946 中国标准出版社秦皇岛印刷厂印刷 各地新华书店经销

开本 880×1230 1/16 印张 22.5 字数 587 千字 2014 年 10 月第一版 2014 年 10 月第一次印刷

定价 120.00 元

如有印装差错 由本社发行中心调换 版权专有 侵权必究 举报电话: (010) 68510107

## 编辑委员会

主编 史光华 吕京编 要光华 高 诚 要光华 高 诚 程树军 朱德生 陶雨风 蔡露敏 陶凌云 颜 如

### 前言

实验动物的质量直接关系到动物试验结果的准确性、可靠性,直接关系到相关科学研究的水平。随着科技的进步和人类认识的不断深入,实验动物的质量被赋予新的内涵, 抛开实验动物的福利与伦理不顾, 按照传统做法机械地谈论实验动物的质量, 已远远不能满足新时代对实验动物工作的需要。只有建立在保障实验动物福利和伦理水平基础上的动物质量, 才真正具有科学上的意义。

关注动物福利和伦理已是大势所趋。美国的农业部(USDA)和国立卫生研究院 (NIH)、欧盟的《REACH 法规》都对实验动物的福利提出了要求,我国科技部也出台 了《关于善待实验动物的指导性意见》。

在"十二五"国家科技支撑计划项目资助下,中国合格评定国家认可中心 (CNAS) 承担了《实验动物质量保证条件和认可评价关键技术的研究与示范》的研究 项目,致力于研究建立以动物福利伦理为核心、可与国家通行做法相接轨、并适合中国 国情的实验动物机构认可评价制度。GB/T 27416《实验动物机构 质量和能力的通用 要求》是该项目重要研究成果之一。它既是认可机构开展实验动物机构认可的技术评价 依据,也是实验动物机构获得认可需遵守的基本准则。

对于实验动物机构而言,要获得认可,了解并遵守国家相关政策和法律法规的规定,满足相关技术标准的要求是非常必要的。我们鼓励实验动物机构参考我国尚未引入的国外发达国家和组织的一些良好的作法。鉴于此,我们编辑了这本《实验动物机构认可标准法规实用手册》,以方便实验动物机构使用。

本手册的国内篇收入了我国关于实验动物机构的法律法规和相关政策,以及相关的现行有效的国家标准。通过甄别比较,在国际篇中,我们以节选和简介的形式选择介绍了部分国外发达国家和组织有关实验动物的法律法规和技术标准,便于实验动物机构借鉴和使用。

本手册可作为一本工具书,为那些旨在加强实验动物质量、福利和伦理管理水平,获得认可的机构提供支持和帮助。此外,本手册也可供与实验动物学、医生、生物学、兽医学等有关的研究机构的人员学习和使用。希望广大的科研工作者和管理人员就其中感兴趣的和有异议的问题,开展更为深入的研究,以期共同推动我国实验动物管理水平的进步。

本手册在编辑过程中难免存在疏漏和错误,请读者及时反馈和批评指正,以利于我们不断改进。

编者

2014 年 6 月

makasaran kecili melanda da

新京福思机业保存 (ASIA) 特惠克拉斯卡·

各出选择并持限施工基準下支持以前持续的公司分解工程的工程的证据

takan luthi kutan in manana tata kutakan espiritutekila materila tata.

表面的有"原生素的,我也是我看到,是因为了现代。我是我们还是我的地方是这个种。我们

가장가 가면 보면 되었다. 아들은 이 경기를 받는데 되었다. 그는 아마를 하게 한 때문에 가는 사람이 되었다.

Contract to the fire and the fire the f

the first Armana to Armana that is a second of the control of the

활약하다 2개 (1991년 전략 사람 본 1911년 ) 그 가는 바라 다른 지나 가는 제가 본 그 그 마른 크로드라마트

# 

第1	章 世界动物卫生组织 (OIE) ····································	1
1.1	陆地动物福利标准 ·····	
	动物的水上运输 Transport of Animals by Sea ······	3
	动物的陆路运输 Transport of Animals by Land ······	21
	动物的空运 Transport of Animals by Air ·····	40
	动物的屠宰 Slaughter of Animals ·····	50
	用于疾病控制目的的动物宰杀 Killing of Animals for Disease Control Purposes ···········	
	流浪犬的控制 Stray Dog Population Control ······	106
	研究和教育用动物的使用 Use of Animals in Research and Education	123
	动物福利和肉牛生产体系 Animal Welfare and Beef Cattle Productions Systems ···········	139
	动物福利和肉鸡生产体系 Animal Welfare and Broiler Chicken Production Systems ·····-	152
1.2	水生动物福利标准	162
	养殖鱼类运输福利 Welfare of Farmed Fish During Transport	163
	人类消费用养殖鱼的击昏与宰杀福利要求 Welfare Aspects of Stunning and Killing	
	of Farmed Fish for Human Consumption	169
	用于疾病控制目的的养殖鱼宰杀 Killing of Farmed Fish for Disease Control Purposes ········	174
第2	2章 欧盟	179
	《用于实验及其他科学目的的脊椎动物保护欧洲公约》(ETS123)介绍	181
	动物居住与护理指南	184
	《欧盟保护实验动物新指令》介绍 ·····	192
第3	3 章 典型发达国家	197
3. 1	美国	198

#### 实验动物机构认可标准法规实用手册 国际篇

	动物福利法	199
	犬、猫饲养, 护理, 治疗, 转运细则	221
	豚鼠和仓鼠的人道处理、护理、治疗和运输规范	233
	非人灵长类动物的人道主义护理、治疗和运输标准	241
	对狗、猫、兔、大鼠、豚鼠、人以外的灵长类和海洋中的哺乳动物以外的恒温动物的	
	人性化饲养,管理,处理和运输的实施细则	253
	美国政府关于在检测、研究和培训中脊椎动物的使用和管理原则	
	公共卫生署人道主义饲养和使用实验动物的政策	260
	实验动物饲养管理和使用指南(节选)	271
3. 2	日本・・・・・・	
	动物爱护及管理法(节选)	
	实验动物饲养及保管标准 ·····	281
	关于大学等使用实验动物的注意事项	284
	动物处分方法规则	285
	实验动物安乐死规则	286
3. 3	加拿大····	287
	实验用动物管理与使用指南 (节选)	288
	加拿大动物管理理事会的有关动物管理和使用的相关指导性文件	
	抗体制备(节选)	292
	选择科研、教学及试验用实验动物的合适终结点(节选)	297
	研究、教学和测试中农用动物的管理和使用指南(节选)	304
	科研、教学和检测过程中鱼类的管理和应用指导原则(节选)	309
	科学研究用动物的采购(节选)	330
	转基因动物 (1997) (节选)	337
	野生动物的管理和使用准则(节选)	339
	青年基金会关于科学交流会中动物实验的条例	351
	青年科学会关于在科研课题中使用活脊椎动物的条例	352

## 第1章 世界动物卫生组织(OIE)

- 1.1 陆地动物福利标准
- 1.2 水生动物福利标准

# 1.1 陆地动物福利标准

#### 动物的水上运输

#### CHAPTER 7, 2

#### Transport of Animals by Sea

Preamble: These recommendations apply to the following live domesticated animals: cattle, buffaloes, deer, camelids, sheep, goats, pigs and equines. They may also be applicable to other domesticated animals.

#### Article 7, 2, 1

The amount of time animals spend on a journey should be kept to the minimum.

#### Article 7.2.2

#### 1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to be hostile to others in a group situation should not be mixed.

The desire of some animals to control their personal space should be taken into account in designing loading and unloading facilities, transport vessels and containers.

Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i. e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. Animal handlers should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape and compromise the welfare of the animals.

Animal handlers should use the point of balance at the animal's shoulder to move animals,

adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

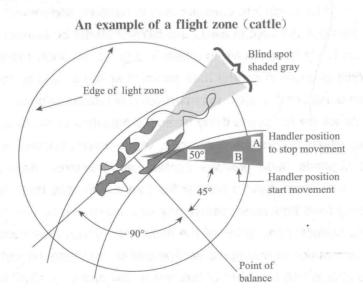
Domestic animals have a wide – angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

#### 2. Distractions and their removal

Design of new loading and unloading facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors-move a lamp or change lighting;
- -b) dark entrances-illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- animals seeing moving people or equipment up ahead-install solid sides on chutes and races or install shields;
- d) dead ends-avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences-remove them;
- f) uneven floors or a sudden drop in floor levels-avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment-install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- clanging and banging of metal objects-install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals-redirect or reposition equipment.



# Handler movement pattern to move cattle forward Return path leaving flight zone. Path to move animals forward Point of Balance

Article 7, 2, 3

#### Responsibilities

Once the decision to transport the animals by sea has been made, the welfare of the animals during their journey is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article. These recommendations may also be applied to the transport of animals by water within a country.

The management of animals at post - discharge facilities is outside the scope of this chapter.

#### 1. General considerations

- a) Exporters, importers, owners of animals, business or buying/selling agents, shipping companies, masters of vessels and managers of facilities are jointly responsible for the general health of the animals and their fitness for the journey, and for their overall welfare during the journey, regardless of whether duties are subcontracted to other parties during transport.
- b) Exporters, shipping companies, business or buying/selling agents, and masters of vessels are jointly responsible for planning the journey to ensure the care of the animals, including:
  - choosing appropriate vessels and ensuring that animal handlers are available to care for the animals;
  - ii) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
  - iii) correct loading of the ship, provision of appropriate food, water, ventilation and protection from adverse weather, regular inspections during the journey and for appropriate responses to problems arising;
  - iv) disposal of carcasses according to international law.
- c) To carry out the above mentioned responsibilities, the parties involved should be competent regarding transport regulations, equipment usage, and the humane handling and care of animals.

#### 2. Specific considerations

a) The responsibilities of the exporters include:

- the organisation, carrying out and completion of the journey, regardless of whether duties are subcontracted to other parties during transport;
- ii) ensuring that equipment and medication are provided as appropriate for the species and the journey;
- iii) securing the presence of the appropriate number of animal handlers competent for the species being transported;
- iv) ensuring compliance of the animals with any required veterinary certification, and their fitness to travel;
- v) in case of animals for export, ensuring compliance with any requirements of the importing and exporting countries.
- b) The responsibilities of the owners of the animals include the selection of animals that are fit to travel based on veterinary recommendations.
- c) The responsibilities of the business or buying/selling agent include:
  - i) selection of animals that are fit to travel based on veterinary recommendations;
  - ii) availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals at the start and at the end of the journey, and for emergencies.
- d) The responsibilities of masters of vessels include the provision of suitable premises for animals on the vessel.
- e) The responsibilities of managers of facilities during loading include:
  - i) providing suitable premises for loading the animals;
  - ii) providing an appropriate number of animal handlers to load the animals with minimum stress and the avoidance of injury;
  - iii) minimising the opportunities for disease transmission while the animals are in the facilities;
  - iv) providing appropriate facilities for emergencies;
  - v) providing facilities, veterinarians or animal handlers capable of killing animals humanely when required.
- f) The responsibilities of managers of facilities during unloading include:
  - providing suitable facilities for unloading the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit;
  - ii) providing animal handlers to unload the animals with minimum stress and injury;
  - iii) minimising the opportunities for disease transmission while the animals are in the facilities:
  - iv) providing appropriate facilities for emergencies;
  - v) providing facilities, and veterinarians or animal handlers capable of killing animals humanely when required.
- g) The responsibilities of the animal handlers include humane handling and care of the animals, especially during loading and unloading.
- h) The responsibilities of the Competent Authority of the exporting country include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;

- ii) approving facilities, containers, vehicles and vessels for the holding and transport of animals;
- iii) setting competence standards for animal handlers and managers of facilities;
- iv) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;
- v) monitor and evaluate health and welfare of the animals at the point of loading.
- i) The responsibilities of the Competent Authority of the importing country include:
  - i) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;
  - ii) approve facilities, containers, vehicles and vessels for the holding and transport of animals;
  - iii) setting competence standards for animal handlers and managers of facilities;
  - iv) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;
  - v) ensuring that the exporting country is aware of the required standards for the vessel transporting the animals;
  - vi) monitor and evaluate health and welfare of the animals at the point of unloading;
  - vii) give animal consignments priority to allow import procedures to be completed without unnecessary delay.
- j) The responsibilities of veterinarians or in the absence of a veterinarian, the animal handlers travelling on the vessel with the animals include:
  - humane handling and treatment of animals during the journey, including in emergencies, such as humane killing of the animals;
  - ii) possess ability to report and act independently;
  - iii) meet daily with the master of the vessel to obtain up to date information on animal health and welfare status.
- k) The receiving Competent Authority should report back to the sending Competent Authority on significant animal welfare problems which occurred during the journey.

#### Article 7. 2. 4

#### Competence

- All people responsible for animals during journeys should be competent to carry out the relevant responsibilities listed in Article 7. 2. 3 Competence in areas other than animal welfare would need to be addressed separately. Competence may be gained through formal training and/or practical experience.
- 2) The assessment of competence of animal handlers should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a journey, including appropriate space allowance, feed, water and ventilation requirements;
  - b) responsibilities for the welfare of animals during the journey, including loading and unloading;

- c) sources of advice and assistance;
- d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
- e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a veterinarian;
- f) relevant authorities and applicable transport regulations, and associated documentation requirements;
- g) general disease prevention procedures, including cleaning and disinfection;
- h) appropriate methods of animal handling during transport and associated activities such as assembling, loading and unloading;
- i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including euthanasia;
- species specific aspects and age specific aspects of animal handling and care,
   including feeding, watering and inspection; and
- k) maintaining a journey log and other records.
- 3) Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a journey, including appropriate space allowances, and feed, water and ventilation requirements;
  - b) relevant authorities and applicable transport regulations, and associated documentation requirements;
  - c) appropriate methods of animal handling during transport and associated activities such as cleaning and disinfection, assembling, loading and unloading;
  - d) species specific aspects of animal handling and care, including appropriate equipment and medication;
  - e) sources of advice and assistance;
  - f) appropriate record keeping; and
  - g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

#### **Article 7.2.5**

#### Planning the journey

#### 1. General considerations

- a) Adequate planning is a key factor affecting the welfare of animals during a journey.
- b) Before the journey starts, plans should be made in relation to:
  - i) preparation of animals for the journey;
  - ii) type of transport vessel required;
  - iii) route, taking into account distance, expected weather and sea conditions;
  - iv) nature and duration of journey;

- v) daily care and management of the animals, including the appropriate number of animal handlers, to help ensure the health and welfare of all the animals;
- vi) avoiding the mixing of animals from different sources in a single pen group;
- vii) provision of appropriate equipment and medication for the numbers and species carried; and
- viii) emergency response procedures.

#### 2. Preparation of animals for the journey

- a) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.
- b) There should be planning for water and feed availability during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.
- extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
- d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.
- e) Behaviour modifying (such as tranquillisers) or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian. Treated animals should be placed in a dedicated area.

#### 3. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, journey planning should take into account the following:

- When possible and agreed by the Veterinary Authority of the importing country, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.
- b) Medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.
- c) Mixing of animals from different sources in a single consignment should be minimized.

#### 4. Vessel and container design and maintenance

a) Vessels used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non – slippery