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# **Current Laboratory Animal Laws Regulations, Policies & Administration in China**

中国实验动物法规和管理体系

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# 中国实验动物科学的发展

## Laboratory Animal Science in China

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- 1918年 齐长庆首次开始繁殖小鼠用于实验。在此之后，中国从印度、日本、欧洲和美国引入了很多动物品系

The first known appearance of laboratory animals in China was in 1918, when Dr. Changqing Qi bred mice for experiments

- 1949 年 很多近交系小鼠在国内繁殖成功：C-1、TA-1、615、TA-2等

Chinese scientists cultivated many inbred mouse strains such as C-1, TA-1, 615 and TA-2 in 1949

- 1982年 第一届国际实验动物会议举行

The first national LAS conference took place in 1982

- 1983年 国家卫生部颁布了第一个实验动物管理条例

The Ministry of Public Health (MPH) issued the first LA regulations in 1983

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- 1988年 国家科技部建立了最初的中国实验动物管理部门。随后，各省市和自治区也开始成立相应的管理部门，颁布相应的法律法规。

In 1988, the Ministry of Science and Technology (MOST) established its primary administrative responsibility for LAS in China with the Regulation on the Administration of Laboratory Animals used in research, education and testing. Most provinces, municipalities, and autonomous regions began to issue similar regulations to strengthen oversight.

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# 中国实验动物管理机构

## Framework of the Chinese Lab Animal Administration System



**MOST**, Ministry of Science and Technology; **PDST**: provincial department of science and technology; **CALAS**: Chinese Association for Laboratory Animal Sciences

虚线部分表示**CALAS**是独立于**MOST**的机构，它没有管理地方协会和学会的权力，但是它通过监督、教育、培训等对这些协会学会进行监督。The dotted arrows indicate that CALAS is independent from MOST; it has no power to administer the provincial associations and institutions but plays a role in the self-regulation of lab animal science (e.g., through supervision, continuing education and training, etc.

# 实验动物相关政策法规

## Relevant Regulations & Policies for Laboratory Animal in China

类别 Type		文件名称 Name	发布机构 Administration
行政法规 Administrative statute	国务院批准 Approved by State Council	实验动物管理条例 guideline on Administration of Lab Animals	科技部 MOST
法律 Law	地方法律 Provincial law	地方实验动物管理办法（北京、湖北、云南） Provincial Regulation on Administration of Lab Animals (Beijing, Hubei, Yunnan)	地方人民代表大会 Provincial People's Congress
国家规章 National regulation	多部门联合发布 Joint ministries	实验动物质量管理办法 Regulation on the Management of Lab Animal Quality Control	科技部等七部委 Seven ministries
	单个部门发布 Single ministry	实验动物管理法规 Regulation on the Management of Lab Animals	科技部、卫生部、食品药品监督管理局、农业部 MOST, MOH, SFDA, MOA
国家文件 National document	国家部门 Ministry	国务院各部门发布的文件 Document issued by Ministries of State Council	国家各有关部门 Ministries
地方规章 Provincial regulation	地方部门 Province	地方法规、指导性政策 Provincial regulations, guidelines	地方政府 Provincial governments
地方文件 Provincial document	地方部门 Province	地方政府发布的文件 Document issued by provincial governments	地方政府 Provincial governments
技术标准 Standard	国家标准 National	实验动物相关的国家标准 National standards regarding lab animals	国家质检总局 AQSIQ
	国家部门标准 Ministerial	实验动物相关的国家部门标准 Ministerial standards regarding lab animals	农业部、卫生部 MOH; MOA
	地方标准 Provincial	实验动物相关的地方标准 Provincial standards regarding lab animals	地方质监局 Provincial AQSIQ
	产品标准 Product	实验动物产品标准 Standards for lab animal products	公司 Companies

# 实验动物标准体系及质量管理

## Lab Animal Standards and Quality Control

- **1994年**，国家技术监督局颁布了一系列国家标准，与实验动物相关的有**47**项  
In 1994 the China State Bureau of Technical Supervision issued a series of national standards, 47 of which apply to lab animals
- **2001年**，国家对这些国家标准进行了修订，并将与实验动物相关的标准扩增到了**83**项  
The 2001 revision of these standards increased the number to 83
- **2005年**，中国实验动物标准化管理国家技术委员会成立，并颁布了**97**项实验动物质量控制的国家标准。标准内容涉及微生物、遗传、饲料、环境和设施、**SPF**鸡等领域  
In 2005 National Technical Committee on Laboratory Animal Science of the Standardization Administration of China was established and set 93 standards for lab animal quality control covering five areas: microbiology, genetics, feedstuff and SPF chickens
- 除此之外，医学和农业部也建立了相应的实验动物质量相关的标准。在某些发达省市（北京、上海、广东和江苏）以及一些大型生物医药公司则执行自行设定的更高的标准  
In addition, other entities, such as the ministries of medicine and agriculture, have set lab animal quality standards. And some of the more developed provinces and cities (e.g., Beijing, Shanghai, Guangdong, and Jiangsu) impose their own standards, as do some larger companies or enterprises for their products

# 实验动物质量控制体系

## Lab Animal Quality Control Network

- “九五”计划期间，实验动物发展计划应运而生，该计划的建立促进了实验动物质量控制体系的形成，而后者进一步促进了由科技部和地方科技厅监督的实验动物质量监测中心的形成  
The Laboratory Animal Development Program for the Ninth Five-Year Plan established a national lab animal quality control network, which determines requirements for lab animal quality monitoring centers overseen by MOST and the PDSTs
- 为监管地方实验动物质量监测中心，科技部颁布了相应的纲领和具体标准  
MOST subsequently issued the Guideline and Detailed Criteria for the Review of Provincial Laboratory Animal Monitoring Centers
- 实验动物质量监测中心的目的在于探索研究实验技术、培训技术员、视察机构、对地方实验动物管理体系进行年审以及对具有争议的监测结果进行仲裁  
The task of these centers is to explore research on testing techniques, train technicians, carry out site inspections and annual review of provincial lab animal monitoring centers, and arbitrate disputed monitoring results
- 实验动物质量控制体系包含涉及微生物、寄生虫、遗传、病理、饲料、环境和设施的六个国家中心以及**26**个地方省市中心  
The quality monitoring network comprises six national centers covering microbiology, parasitology, genetics, pathology, feedstuff, environment, and facilities, as well as 26 provincial centers in 23 provinces

# 许可证制度

## Licensing System

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- 建立针对实验动物生产及使用方面的许可证制度是实验动物发展计划的进一步要求  
The establishment of national unified licensing system for lab animal breeders and users was a further aim of the Laboratory Animal Development Program
- 所有机构在繁殖或使用实验动物及其相关产品时必需先经过审核获得繁殖/使用许可证  
All institutes must be accredited and obtain a breeder or user license before handling lab animals or producing lab animals and related products
- 实验动物使用许可证管理办法（试行）对于许可证申请、审核、批准、设施检查和监督作了详细规定  
The subsequent (temporary) Regulation on the Management of Laboratory Animal Licenses (MOST 2001) details requirements and procedures for license application, review, and supervision
- 许可证由科技部进行登记，地方科技厅对许可证拥有单位进行每年一次的访问检查  
Licenses are registered by MOST and administered by the PDSTs, which review license holders annually through site visits and reports



# 许可证申请流程

## License Application Procedure



# 实验动物种子中心和繁殖中心

## Lab Animal Seed Centers and Breeding Centers

- 关于实验动物种子中心的运行及具体操作程序，科技部出台了**3**条规章制度
  - 国家种子中心管理办法（科技部1998）：规定了种子中心的任务、组织机构、经费、管理、检测和监管等方面内容
  - 国家啮齿类实验动物种子中心引种、供种实施细则（科技部1998）：涵盖了实验动物引种供种时的申请、项目要求、提供以及补偿等方面
  - 关于当前许可证发放过程中有关实验动物种子问题的处理意见（科技部1999）：适用于种子中心的啮齿类、转基因小鼠、兔、小型猪、比格犬、SPF鸡、猴、水生动物和其他一些动物的管理
- **MOST has issued three regulations for the operating procedures of lab animal seed centers**
  - Regulation on the Management of National Laboratory Animal Seed Centers (MOST 1998b), which applies to the tasks, organization, fees and management, inspection, and supervision of the centers
  - Detailed Rule on National Rodent Seed Centers to Introduce and Supply Laboratory Animals (MOST 1998c), covers applications, protocols, supply, and reimbursements related to the introduction and supply of lab animals
  - Guideline on Problems Related to Laboratory Animal Seed in Issuing Licenses (MOST 1999), is applicable to ten seed centers (or resource bases): for rodents, genetically modified mice, rabbits, miniature pigs, beagles, SPF chickens 2, monkeys, and aquatic and special animals

# 实验动物的等级（按微生物学控制标准）

## Lab Animal Classification

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1. 普通动物 **Conventional**
2. 清洁动物 **Clean**
3. 无特定病原体动物 **SPF**
4. 无菌动物 **Germ-free**

其中大小鼠必需为**2、3、4**级；豚鼠、仓鼠、兔可以为以上任何等级；犬和猴只有**1、3**两种等级。每种等级动物体内微生物必需符合国家标准

Mice and rats for breeding and use must conform to grades 2, 3 and 4; guinea pigs, hamsters and rabbits can be maintained in any of the grades; dogs and monkeys are subject to the conventional and SPF grades. Each grade of animals must fulfill the requirements of the national standards

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# 饲料 Diet

- 法规规定：实验动物饲料配方必需经过鉴定，无污染，未变质发霉；蔬菜或水果必需充足且新鲜

According to the regulations, Lab animals must be fed with certified formula diets. It is forbidden to feed animals any mildewed, bad, or polluted feedstuff. Vegetables or fruit for animal food must be adequate and fresh

- 饲料供应商必需获得畜产品供应商资格证

Many companies that produce diet for large lab animal institutions are required to obtain a lab animal product supplier license

- 实验动物营养方面的国家标准规定了不同品系不同用途动物饲料成份和质量方面的要求（如：繁殖料、维持料、指定配方料等）

National standards for lab animal nutrition also cover the composition and quality of feed for different strains and uses (e.g., growth and reproduction, maintenance, and special dietary needs)

# 饮用水 Drinking Water

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- 普通级动物饮用水必需达到与人类饮用水相同等级的卫生标准  
Conventional animals must have drinking water of the same hygiene standards as that for human use
  - 更高级的动物饮水必需经灭菌消毒  
Higher-grade animals should be supplied with sterilized drinking water
  - 在屏障环境中饲养的**SPF**级动物饮水必需经过滤纯化  
SPF animals bred in barrier facilities get filtered and purified water from drinking water machines
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# 垫料 Bedding

- 法规规定：垫料应干净、干燥、无毒、无昆虫、无传染源和污染物，并应根据不同等级动物要求作相应处理

The statute stipulates that “bedding materials shall be treated according to the requirements of different grades of lab animals and must be clean, dry, nontoxic, and free of insects, infectious agents, and pollutants.”

- 实验动物环境国标指出：不同种类的垫料都应经过高压或辐射灭菌

The national standards for lab environments state that “all types of bedding materials shall be sterilized with high pressure or radiation.”

# 转基因动物

## Transgenic Animals

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- 转基因技术的发展带动了转基因动物的研发，目前大于**10,000**小鼠基因被敲除。在中国，约有十几所机构实验室在开展转基因或基因敲除小鼠的研究  
Genetically modified organisms are increasing in number with the development of gene modification techniques. To date, more than 10,000 mouse genes have been “knocked out.” In China, more than ten institutions have labs to develop transgenic or knockout mice
- 为此，国家出台了基因工程安全管理办法（科技部 **1993**）以防止人类、环境以及生态系统的遗传污染，该条例明确了生物安全等级和评估、申请、安全控制方法以及违反处罚  
The aim of the Regulation on the Administration of Genetic Engineering Safety (MOST 1993) is to prevent genetic contamination of humans, the environment, and the ecosystem. The regulation defines biosafety levels and evaluation, application, safety control methods, and penalties
- 农业转基因生物安全管理条例（农业部 **2001**）要求各国家部门联合建立一个上报转基因生物安全问题的机制。此后，农业部于**2002**年**1**月集中发布了《农业转基因生物安全评价管理办法》、《农业转基因生物进口安全管理办法》、《农业转基因生物标识管理办法》。《农业转基因生物加工审批办法》等多项规章  
The Statute on the Administration of Transgenic Organism Biosafety in the Agriculture System (MOA 2001) calls for the establishment of a cross-ministry collaborative network to address problems related to the biosafety of transgenic organisms. MOA has also issued related regulations covering safety evaluation, export and import supervision, labeling systems and product review

# 动物福利 Animal Welfare

- 关于善待实验动物的指导性意见（科技部 **2006**）是国家发布的第一部关于动物福利的指导性纲领

The Guideline on the Humane Treatment of Laboratory Animals (MOST 2006a) is the country's first broad animal welfare regulation

- 该指导性纲领规定了每个研究机构必需建立机构实验动物饲养管理和使用委员会（**IACUC**）以监督和评价实验动物饲养管理和使用计划的各个方面

The guidelines require each institution to establish an IACUC to oversee and evaluate all aspects of its animal care and use programs



# 动物福利 Animal Welfare

- 纲领规定必需采用有效的方法以：Effective measures should be taken to
  - 保护实验动物免于受伤害、饥饿、干渴、不适、恐惧、疾病和疼痛  
protect lab animals from injury, hunger or thirst, discomfort, fear, disease, and pain
  - 确保提供其干净舒适的饲养条件和兽医保健，充足的饮水和饲料，允许其展示自然行为  
ensure that they receive good husbandry and veterinary care in a clean, comfortable environment, have access to feedstuff and water of sufficient quantity and quality to maintain health, and perform natural behaviors
  - 确保设施环境满足其行为和生理需求（如：大动物必需有足够的空间以满足其活动以及容纳特定玩具）  
The facility and environment must provide for the animals' behavioral and physiological needs
- 纲领突出了对于降低动物疼痛抑郁方面的要求，即：**3R**在动物试验中的重要性  
Pain and distress are a particular focus of the guidelines, which call for adherence to the 3Rs during every stage of the animal experiment
- 实验结束后应按照终点判定原则对动物实施安乐死——首次在中国法规中出现终点判定标准  
After an experiment, animals should be euthanized according to humane endpoint principles, the first appearance of such criteria in China's policies

# 动物福利相关政策

## Animal Welfare-related Policies in China

发布时间 Time	发布机构 Dept	文件名称 Name	主要内容 Main Content
1988	科技部 MOST	实验动物管理条例 Guideline on Administration of Lab Animals	动物福利方面：饲料、饮水、垫料的要求和雇佣合格的员工 Animal welfare is implied in requirements relating to feedstuff, drinking water, bedding, and qualified persons
1997	科技部 MOST	九五计划期间的实验动物发展项目 Laboratory Animal Development Program for the Ninth Five-Year Plan	第一次使用“动物福利”和“3R”这两个说法 First use of the words “animal welfare” and “3Rs” in ministry documents
2005	北京实验动物管理委员会办公室 BAOLA	北京市实验动物福利伦理审查指南 Guidelines of Beijing Municipality on the Review of Welfare and Ethics of Laboratory Animals	类似于机构内部IACUC，伦理审核指南 Similar to guidelines for IACUCs; provincial ethical review process required in each academic institution
2006	科技部 MOST	关于善待实验动物的指导性意见 Guidelines on the Humane Treatment of Laboratory Animals	第一部关于动物福利的指导性纲领 The first regulation on animal welfare, addressing possible animal welfare problems in husbandry, feeding, use, and transport

# 实验动物的进出口以及运输

## Import, Export, and Transportation of Lab Animals

- 从国外引进的作为繁殖种群的实验动物必需提供该品系动物的背景资料并交由国家实验动物种子中心登记，由科技部统一管理  
**Lab animals brought from overseas as animal breeder for breeding must have complete background data and be registered in the national lab animal seed centers administered by MOST**
- 为预防传染性和寄生虫性疾病、虫害、植物性疾病以及其他危害性生物在国内外的传播，国务院于**1991**年出台了中华人民共和国进出口动植物检疫条例实施细则。另外，科技部正在起草拟定一项专门针对实验动物进出口的法规  
**The quarantine of imported and exported lab animals is covered by the Law of the People's Republic of China on the Quarantine of Animals and Plants in Imports and Exports (Chinese People's Congress 1991). This law aims to prevent the spread (within or outside China) of infectious or parasitic diseases of animals, insect pests, diseases dangerous to plants, and other harmful organisms. In addition to these policies, MOST is drafting a regulation that applies specifically to the import and export of lab animals**
- 在运输中，动物笼具应确保安全、干净，通风应符合要求，提供充足的食物和饮水，运输中应降低应激，尤其在恶劣天气时，必要时提供适当的兽医保健  
**During transport animals must be placed in safe, clean, standardized cages with adequate ventilation. Food and water must be provided. To reduce stress, effective measures should be taken to make the animals comfortable, especially in adverse weather conditions, and, if confinement is to be prolonged, veterinary care must be provided**
- 不同种类、品系和等级的动物不能混淆  
**Animals of different species, strains, or grades must not be transported in the same cage**

# 法律法规的执行及未来发展—法规

## Implementation and Future Development - Regulations

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- 科技部正在考虑起草关于实验动物、转基因动物、患病动物（传染性）运输方面的法规。新的法规将具体明确与实验动物和动物产品质量相关的各个方面。动物管理委员会办公室将加强对这些法律法规的管理。中国实验动物学会也会协助法规的起草、强化管理以及后续的教育与培训
  - MOST is considering further regulations on the transport of lab animals, genetically modified animals, and infectious disease animal models. New detailed regulations will address every aspect of the quality of lab animals and related products, and AOLAs in each PDST will strengthen the administration of these regulations. CALAS, with its large number of members and specialists, also has a role in the drafting and enforcement of regulations, industry self-discipline, and continuing education and training
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## 法律法规的执行及未来发展—国家标准

## Implementation and Future Development – National Standards

- 国家标准是为实验动物生产和使用单位确保实验动物质量而制订的强制性标准  
China's national standards serve to ensure lab animal quality by setting mandatory criteria for lab animal breeder and user licenses
- 随着大动物在科研中运用越来越多，国家正在起草适用于大动物的相关标准，如：狗、小型猪、猴、牛和羊  
Additional national standards will be drawn up for larger laboratory animals (e.g., dogs, miniature pigs, monkeys, cows, and sheep) as their use increases
- 除此之外，动物饲养繁殖和使用过程中如何科学地人道地对待动物的国家标准以及更多关于实验动物及其产品的更具体的国家标准也将陆续出台  
In addition, National standards for humane treatment and handling techniques will also be established in the future. More detailed national standards for lab animals and related products are in development to promote consistency

# 法律法规的执行及未来发展—管理

## Implementation and Future Development – Governance

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- 地方科技厅通过动物管理委员会办公室监管实验动物的质量和管理。后者通过监督、许可证、年审、现场检查等途径执行国家法规

China's PDSTs oversee the quality and care of lab animals through their AOLAs, which implement Chinese policies through supervision, licensing, review of annual reports, site visits

- 不同地区经济发展不同，法规执行效果也不同。北京、湖北和云南三省市已经加强了实验动物法律的执行，但是其他省市动管办隶属于省实验动物机构或协会，执行法规的权力较小。广东、江苏和黑龙江正准备将其地方法规制订成法律以便于加强对实验动物的监管

Different levels of economic development in each province are associated with varying degrees of effectiveness. Three provinces (Beijing, Hubei, and Yunnan) have strengthened their lab animal administration statutes; AOLAs in other provinces are affiliated with provincial lab animal institutions or associations with less power to implement administration policies. Guangdong, Jiangsu, and Heilongjiang are preparing to legislate their provincial statutes as law in the near future, thus improving oversight of LAS in these provinces

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# 法律法规的执行及未来发展—工作人员资格

## Implementation and Future Development – Qualified Staff

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- 雇佣经过培训，具有资格的员工对于执行实验动物相关法规是一个关键因素。越来越多大学和学院开设实验动物专业，越来越多的高校毕业生加入实验动物行业，同时也提高了实验动物工作人员的素质  
Qualified personnel are key to the implementation of lab animal regulations, and the education levels of lab animal staff in China are increasing with improvements in college curriculum. More universities and colleges offer LAS programs, and more graduate students are entering the LAS industry for better jobs
  - 所有实验动物工作人员都必需接受相关培训，参加资格考试获得上岗证，以确保其掌握实验动物的基本知识，了解实验动物相关法律法规  
In addition, all LAS staff are required to take a training course and pass an exam before they receive a license to handle animals, to ensure that they have mastered the basic knowledge to comply with regulations and standards
  - 目前，在中国约有**100,000**多人从事实验动物行业的，其中**85%**为动物实验者，**15%**在实验动物饲养中心。这些人员中**84%**为生物医药或医学专业，**7%**为兽医专业，**3%**为生物专业，**1%**为实验动物专业以及另外**5%**为人畜共患病、环境等专业  
More than 100,000 staff work with lab animals in China—85% in experiments and 15% in lab animal centers. Their educational backgrounds are in biomedicine or medical science (84%), veterinary science (7%), biology (3%), lab animal science (1%), and other specialized areas (e.g., zoology, environment, computer science; 5%)
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## 法律法规的执行及未来发展—设施和设备

## Implementation and Future Development – Facility & Equipment

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- 在北京、上海、广东和江苏这些发达城市，屏障设施普及率已达**70%**之多，虽然在大部分省市仍然使用普通设施，但是，独立通风笼盒和通风柜的使用越来越普遍

The proportion of barrier environments is now 70% in highly developed provinces such as Beijing, Shanghai, Guangdong, and Jiangsu. Although in most provinces conventional environments are still the norm, isolation environments are increasing with the use of individually ventilated cages and exhaust-ventilated cage rack systems

- 另外，一些跨国企业逐步在中国建立自己的实验动物设施，引入先进的设备，带动了中国实验动物设施和设备的发展

Moreover, new companies, including some foreign enterprises, are producing lab animal facilities and bringing with them higher-quality equipment. Thus the quality of facilities and equipment is greatly improving thanks to increasing investment both domestic and foreign

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# 法律法规的执行及未来发展—动物福利相关法律

## Implementation and Future Development – Animal Welfare Law

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- 与美国的公共卫生署政策相比，中国目前还没有与动物福利相关的政策，但是很多国家部门和国家食品药品监督管理局相继把实验动物质量列入其今后的发展计划中。科技部也意识到建立动物福利法规迫在眉睫  
China does not yet have a policy to ensure animal welfare (comparable, for example, to the US Public Health Service [PHS] Policy), but many ministries and provinces as well as the State Food and Drug Administration have begun incorporating lab animal quality in their funding or new product development
  
  - 因此我们可以预见，不久中国就会出台关于动物福利的法规以**1**) 在实验项目审核和批准过程中将动物福利列为重点考虑，**2**) 作为政府立项投入资金的参考  
In the wake of MOST (2006a), we anticipate that there will soon be a policy or regulation like the USPHS policy that will (1) take into account animal welfare in the review and approval of research protocols and (2) guide Chinese government funding only for projects that meet its requirements for animal welfare
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# 结束语 Conclusions

政府建立了一系列法规标准以确保实验动物和动物实验的质量，而这些法规政策的执行同时也促进了实验动物在中国的发展

The government has established a series of regulations and standards to ensure the quality of lab animals and related activities, and these policies and their implementation have stimulated the development of LAS in China

中国正尽最大努力使实验动物设施和实验室达到国际标准，成为世界级的研究中心

China has been making efforts to achieve international standards for its lab animal facilities and research laboratories and aims to be a world-class research center in the near future

目前，中国已有三十几家机构获得AAALAC认可，越来越多的国外研究机构和医药公司将资金投入中国实验动物市场

More than 30 Chinese institutions are accredited by AAALAC more and more research institutions and pharmaceutical companies around the world are looking to China for investment opportunities in animal-related businesses