**ILAR J**

Volume 57, Number 3, 2016

***Global Laws, Regulations, and Standards for Animals in Research***

**Vasbinder and Locke. Global Laws, Regulations, and Standards for Animals in Research, pp. 261-265**

This article illuminates the laws and regulations governing laboratory animal use, which vary greatly across the globe. It is accepted worldwide that members of scientific community who use, care for, and produce animals in laboratories must at minimum assume responsibility for their well-being.

The extent of legal oversight, the nature of governmental enforcement authorities, available resources to regulatory institutions, religious beliefs and cultural traditions are often combined when establishing legal programs.

The 3Rs principle are a common factor in animal welfare programs worldwide and even in nations that have not yet established laboratory animal welfare laws, the 3Rs are understood and applies.

SUMMARY

OVERVIEW OF REGULATORY FRAMEWORK ACROSS THE GLOBE

United States has two national laws that impact lab animal research: The Animal welfare act (AWA) and the health research extension act (1985). The AWA promulgate regulations, inspect facilities, and enforce noncompliance. The Health research extension which is an amendment to the Public Health Services Act, applies to any institution receiving monies from the Public Health Service. The key to both laws is the IACUC, the AV and IO in assuring animal welfare.

CANADA: The Canadian system is decentralized, and regulation is based on custom and practice. Critical to the research animal oversight is the Canadian council on animal care which plays a central role in self-governance and oversight of animal research programs.

EUROPEAN UNION: Member states must comply with EU directive (2010/63/EU). The intent of the directive is to achieve greater consistency in their transposition with an aim to harmonize standards of regulation, training, and animal housing and care across all member countries.

LATIN AMERICA: Laws and regulations are dependent on economic factors. Political stability and cultural diversity are reflected in their laboratory animal laws and regimes. Most developed infrastructure exists in Brazil, Mexico and Uruguay while other Latin American countries have little or no legal framework.

CHINA: The responsibility primarily lies with the ministry of science and technology which administers the statute on the administration of laboratory animals (order #2). This statue covers all aspect of animal experimentation and lab animal care.

JAPAN: Implemented by law for humane treatment and management of animals (Law #105 1973) is a decentralized model. Institutions exercise self-regulation and oversight which is not restricted by legislation (shoji 2007). There are no formal inspections by government or reports required.

PACIFIC RIM COUNTRIES including Singapore, Thailand, Indonesia, Malaysia: have varying levels of infrastructure and regulatory frameworks that are influenced by economic development, culture and religion. The strong research environment in Singapore led to the development and implementation of “Guidelines on the Care and Use of Animals for Scientific Purposes”, published on October 20, 2004 by the National Advisory Committee for Laboratory Animal Research (NACLAR 2004). The guidelines describe the responsibility of institutions, scientists, and animal care staff when performing animal research, based on concepts of the 3Rs

INDIA: Indian parliament passed the Prevention of Cruelty to Animals Act of 1960. Under this act a committee was created to ensure the care and welfare of research animal subjects and develop appropriate guidelines. This act also established an animal welfare board to help unnecessary animal pain and suffering and ethical consideration for scientific experimentation is based on 5 founding principles.

AUSTRALIA: regulatory frameworks differ in each state but are based on the Australian Code of Practices for the Care and Use of Animal for Scientific Purposes, which was enacted in 1969 and last amended in 2004. Central to the code are the principles of the 3Rs.

THE GOAL: International Harmonization is very challenging because of these national and regional differences in laboratory animal law. AAALAC international which is a private, nonprofit organization that promotes humane treatment of animals in science through voluntary accreditation and assessment has identified a common set of performance standards that it applies to animal care and use programs globally : The Guide for the care and use of laboratory animals, The guide for the care and use of agricultural animals in research and training and the European convention for the protection of vertebrate animals used for experiments; and other scientific purposes is the three primary written standards used by AAALAC. Using these widely accepted guidelines enabled AAALAC to be consistent their assessment.

Other organizations that seeks to achieve global harmonization and improve international standards are: (CIOMS) Council for international organization of medical sciences, ILAR, The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the International Cooperation on Harmonization of Technical requirements for Registration of Veterinary Products

CONCLUSION: The opportunity to use animals in laboratory research is not an entitlement; it is a privilege accorded by society to certain members of the scientific community. An examination of existing legal systems, such as those outlined above, provides strong evidence that global laboratory animal laws, regulations, and policies will continue to be important societal concerns. Establishing a common language for these conversations is an important starting point, and it is hoped that articles such as this one, and the other articles in this issue, can be a catalyst for constructive dialogue. Implementation of the 3Rs in many legal frameworks as described in this issue demonstrates a global desire to drive quality science and animal welfare through judicious use of animals for research and affirms the global principle that utilizing animals in laboratory science will remain a controlled opportunity that society will continue to carefully manage through its laws.

QUESTION

1.   What are the 3 primary written standards used by AAALAC International?

ANSWER

1.  The Guide for the Care and Use of Laboratory Animals, The Guide for the care and use of agricultural animals in research and teaching and the European convention for the protection of vertebrate animals used for experimental and other scientific purposes.

**Locke. Ten Fundamental Legal Terms and Concepts That Are Useful in Understanding Laboratory Animal Law Across Nations, pp. 266-270**

Domain 5: Regulatory Responsibilities; K1. Laws, regulations, policies and standards

SUMMARY: As research become more globalized, there is a need to understand the laws and regulations of other countries This article helps address this need by defining 10 fundamental legal terms and concepts and explaining how these terms apply to laboratory animals.

1.  Constitution:

a.  A constitution defines the basic working principals of governance for a sovereign nation or entity.

b. A constitution usually provides the authority to control animal research and could place limits on theses controls.

2.  Common Law and Civil Law: There are 2 predominant systems of law found in the West

a.  Common Law is characterized by the application of a set of unchangeable principals to the fact of a case and applies case law precedent to decision making.  In other words, it is based on precedent and cases are decided consistently.  Common law is practiced in the British Isles (except Scotland) and countries that were colonized by the British Empire, including US and Canada.

b.   Civil Law is characterized by a rigid set of rules that are applied by judges without reference to precedent. Civil law is practiced in most of continental European countries, Scotland, the State of Louisiana, and Quebec.

3.   Directive: Under the EU, the term is defined as “a legislative act that sets out goals that all member states must achieve.”

4. EU:

a.  The EU is a political and economic union of 28 European countries created and amended by treaties.

5.  Law:

a.   The first definition is a rule of conduct or procedure established by custom, agreement, or authority.

b.  The second definition is the set of such costumes, practices or rules.

6.   “Private” or International Standards, Accreditation, and Licensing:

a.   There are a number of quasi-legislative bodies that set standards and establish norms for entities that use animals in research, like AAALAC

7.   Regulation: The term has different meaning in the US and EU legal systems

a.  In the US, regulations refers to rules promoted by the state and federal agencies to implement a law

b.  In the EU regulations refers to a binding legislative act that must be applied and adopted across all member states

8.  Transposition:

a.  Transposition is the process of adopting a regulation into national law

b.  Because the overreaching goal of the EU is to create a single market, it is essential that any agreed-upon actions be incorporated or transposed into national law.

9.  Treaty(ies) & Protocols:

a.   A treaty is defined as an agreement between 2 or more independent sovereign nations

b.  A protocol amends or supplements an already existing legal treaty

10. Welfarists & Abolitionists: There are 2 major philosophies toward laboratory animal law

a.  Welfarists philosophy is animals are considered property under law and aimed at improving the welfare aspects of animal during research

b.  Abolitionists believe animals are sentient beings, and no sentient being should be forced to engage in any activity, including a scientific experiment, against its will

QUESTIONS

1.  What country has a constitution that bans all animal experiments?

2.   Which nations constitutions contain protective provisions for animals

a. Japan

b.  United Kingdom

c.  Germany

d.  Switzerland

e.  Both c & d

f.   All the above

3.   True or False, civil law is practiced in Germany

ANSWERS

1.  The republic of San Marino

2.  e, both c & d

3.  True

**Griffin and Locke. Comparison of the Canadian and US Laws, Regulations, Policies, and Systems of Oversight for Animals in Research, pp. 271-284**

SUMMARY: Both countries oversight of research animal welfare is based on the “3R’s” Canada’s oversight tends to have a greater emphasis on guidance and policy whereas the U.S. relies more on legislation. The differences in lab animal oversight between the two countries is reflective of the difference in constitutions and governance. Canada is one of the most decentralized federations in the world, while the U.S.  is more hierarchical and centralized.

The US has two major laws for animals in research: The Animal Welfare Act (AWA) and the Health Research Extension Act (HREA). The AWA is a traditional command and control law that is administered by the USDA via facility inspections and violation enforcement. The HREA which amended the US public health service (PHS) act is applied to any research that is supported by the PHS and funded by the NIH.

In Canada, no direct federal legislation exists for animal-based research, but regulation is shaped by the criminal (cruelty) law, the federal health of animals act and spending / funding restrictions. Non-legislative oversight is used extensively by both countries via policies, guidelines and licensing requirements

In the US, the first large-scale animal activism occurred in the 1960’s after an article was published in Life Magazine about the use of dogs in biomedical research.  This led to the passage of the US Animal Welfare Act in 1966. Additional provisions for research facilities were added to the AWA in 1985 with the Improved Standards for Laboratory Animals Act amendment.  These provisions included the requirement for IACUC’s and inspections of lab animal facilities. The AWA is administered by the USDA.  A parallel law, the Health Extension Research Act (HREA) also passed in 1966 and was directed at facilities funded by the NIH and PHS. The HREA is administered by US Department of Health and Human Services.

 In Canada, the “Guiding Principles for the care of experimental animals was published in 1961 by the Committee on Animal Care of the Canadian Federation of Biological Societies. In 1968, the Canadian Council on Animal Care (CCAC) was formed with the support of the government departments involved in animal-based science and the universities. The mandate of the CCAC is to advance animal ethics and care for animals used in research and teaching in Canada. The CCAC certifies individual institutions every 3 years based on institutional compliance with the CCAC policy statements and guidelines and other CCAC-recognized standards. The CCAC provides certified institutions with a certificate of Good Animal Practice (GAP). The Canadian federal government supports the humane treatment of research animals via spending power.  All federal research grants awarded by National granting councils are contingent on the home institution holding a GAP certification by the CCAC. There is no legal or policy requirement for private sector companies to participate in the CCAC program. All provinces have some form of animal welfare legislation and many provinces also have some form of laboratory animal welfare legislation (AB, MB, ON, NS, QC, PEI).

The CCAC has developed a set of standards for research animal ethics and care and many guidelines. The US Guide for the Care and Use for laboratory animals was first developed in 1963 but has undergone many updates. The US PHS also has a Policy on Humane Care and Use of Laboratory Animals (OLAW). The HEA requires the approval of an Assurance by the PHS service prior to the commencement of any animal activities, and this Assurance must be renewed every 5 years, with an annual report to OLAW.

The AWA excludes “birds, rats of genus Rattus, and mice or the genus Mus bred for use in research.”  The HREA defines an animal as any live vertebrate animal. The CCAC covers all vertebrates and cephalopods. In both Canada and the US, considerable responsibility is placed on the local ACC (Canada) or IACUC (US). An ACC is required by the CCAC, AWA and HREA. The composition and responsibilities of the ACC/IACUC are defined by each group (CCAC, AWA, HREA).

CCAC requires an ethical evaluation of animal protocols requiring evidence of scientific, pedagogical or regulatory merit (peer review). The AWA and HREA do not require any ethical evaluation. Both the Canadian and US regulations require the provision of adequate training programs for staff and researchers. Both countries additionally require that adequate veterinary care is provided.

Under the AWA, laboratory animal suppliers must be licensed by the USDA and dealers are divided into two classes: Class A dealers produce animals specifically bred for research and class B dealers sell random source animals. The NIH discontinued funding for research on random sourced dogs and cats in 2014 and 2012 respectively.

In Canada CCAC expects institutions to purchase purpose-bred animals except when a particular size or breed of animal may be required, non-purpose bred animals may be acquired.

Animal re-use in both countries is similar to the Canadian guidelines stating that in general, animals are not permitted to be involved in a second study if they have been subjected to invasive procedures.  In the US, for humane reasons, the reuse of animals is not favored, especially if an animal has undergone invasive surgery or procedures.

CCAC guidelines for euthanasia describe conditionally acceptable and acceptable methods for euthanasia and the AWA and HREA require that euthanasia be humane and without pain unless justified by scientific reasons and approved by the IACUC.

Transportation of animals in Canada falls under the Health of Animals Act and is administered by the CFIA. The transport of lab animals in the US is subject to control by several US federal and state agencies and is explained in the NIH Guide.

Physical facility, animal husbandry and environment guidelines are described by the CCAC guidelines, AWA guidelines as well as the NIH Guide.

Facility assessment and inspection is carried out by the CCAC every 3 years and ACC site visits are required under the CCAC guidelines at least every 6 months.  The US facility inspections are carried out by the USDA and fall under the AWA.  The AWA provides a report of compliance or non-compliance. IACUC site visits are required under both the AWA and the HREA at least every 6 months and the facilities must make available the annual report to APHIS and OLAW.

QUESTIONS

1.  How many federal laws do the US and Canada have for animals in research respectively?

a.  1 US; 1 Canada

b.  2 US; 0 Canada

c.  1 US; 2 Canada

2. In what year was the AWA and HREA legislation passed in the US?

a.   1954

b.   1966

c.  1968

3.  True or False: In Canada, the CCAC requires the IACUC undertake an ethical evaluation of all animal protocols whereas there is no similar requirement under any of the US laws.

4.  True or False: Both the US and Canadian regulations require that suppliers of laboratory animals be licensed to do so.

ANSWERS

1.  b

2.  b

3. T

4. F

**Frasch. Gaps in US Animal Welfare Law for Laboratory Animals: Perspectives From an Animal Law Attorney, pp. 285-292**

Domain 5: Regulatory Responsibilities

SUMMARY: The views in this article are solely those of the author. This article presents what author views as gaps in the coverage of laboratory animals by the current laws and regulations. Four specific points are made to support this claim. First, that birds, rats, and mice are expressly excluded by the AWA. Secondly, that the minimum care standards put forth by the USDA are either insufficient (for example, the current dog exercise plan requirements) or completely absent (for example, no bird-specific standards for birds not bred for research). Third, that the reporting and disclosure requirements are too lax at the federal level and that plaintiffs are forced to the state level for remedy. Fourth, that enforcement of the AWA is difficult due to the classification of animals as property, resulting in difficulty in private citizens establishing standing to bring suit on behalf of the animals in question. To remedy these four gaps, the author proposes to: 1) Expand the definition of animal to include “any and all animals that are used in research”. 2) To improve and expand on minimum care requirements, to both revise current standards and provide standards for all animals used in laboratories. 3) To institute mandatory publicly accessible reporting for any facilities covered under USDA regulations and to implement a required certification training program for public members of the IACUC. 4) To add a citizen suit provision to the AWA to allow private individuals to bring suit against institutions for violations.

QUESTIONS

1. Which of the following species would be covered under the AWA?

a.  Horseshoe crabs

b.  Zebrafish

c.  Pigs on nutrient conversion studies

d.  Wild caught rats of the genus Rattus

e.  Eagles at wildlife recovery center

2. Which of the following is not required for an IACUC by the AWA?

a.   Attending Veterinarian

b.   Scientific Member

c.  Minimum of three members

d.   Non-affiliated member

3. According to the AWA, under what condition would it not be appropriate to exclude a dog from an exercise plan?

a. An exercise plan exclusion for all dogs on an approved IACUC protocol studying obesity.

b.  The attending vet intends to exempt a dog from the facility exercise plan during the recovery period from an unplanned leg fracture repair.

c.  The individual caging setup for a beagle colony allows the animals to go from indoor to outdoor at the individual dog’s discretion.

d.  All dogs in the colony are housed in groups in which all dogs have at least the minimum individual area required under the AWA.

ANSWERS

1. d

2. b

3. c

**Rivera et al. Laboratory Animal Legislation in Latin America, pp. 293-300**

SUMMARY:Regulations in laboratory animal care in Latin American countries have gained more importance in the last recent years. Only three countries in Latin America have detailed regulations and undergoing mechanisms in place for enforcement of regulations. These countries are Brazil, Uruguay and Mexico. Brazilian law covers all live nonhuman vertebrates, allows the use of animals only in institutions of higher education and technical schools of biomedical science, creates the National Council on the Control of Animal Experiments (CONCEA) and requires registration and licensing of institutions that breed, maintain or use experimental animals in a CONCEA database. As in Brazil, the Uruguayan regulations are specific to vertebrate animals; some specifics of the Uruguayan law include establishment of a National Commission for Animal Experimentation (CNEA), definitions and guidelines for breeding and use of animals, penalties for noncompliance and guidelines for regulatory implementation of the law itself. In contrast to the Brazilian and Uruguayan regulations, Mexican law is specific to certain rodents (mice, rats, gerbils, hamsters and guinea pigs) as well as rabbits, dogs, cats, pigs and nonhuman primates. Also, Mexican law was based on three internationally accepted documents: The United States National Research Council (NRC)*Guide for the Care and Use of Laboratory Animals*, the *Euthanasia Guidelines* of the American Veterinary Medical Association (AVMA), and the Canadian Council on Animal Care’s *Guide for the Care of Laboratory Animals* (CCAC).

For other nations impediments to the development of laboratory animal regulation include government priorities, instability of government regimes, economic challenges, and lack of infrastructure. However, a small number of other nations in the region have institutions that have voluntarily adopted the use of ethics committees and the application of international standards of animal care and use. The number of AALAC-accredited programs in the region is small but has increased in recent years. Also, societies for laboratory animal science and federations are leading education efforts in Latin America. These groups can play and important role in promoting the importance of consistent standards in research animal care and use.

QUESTIONS

1.   True or False. Brazilian, Uruguayan and Mexican laws are specific to certain rodents such as mice, rats, gerbils, hamsters and guinea pigs.

2.   True or False. A small number of countries in the region have organized societies and federations leading efforts in Latin America for the implementation and consistency of standards in research animal care and use.

3.  What are the impediments to the development of laboratory animal regulation in Latin America Countries?

a.   Government priorities

b.  Instability of government regimes

c.  Economic challenges

d.  Lack of infrastructure.

e.   All of the above

f.   None of the above

ANSWERS

1. False. Only Mexican law has specifics for rodents such as rats, mice, hamsters, gerbils and guinea pigs.

2. True

3. e

**Ogden et al. Laboratory Animal Laws, Regulations, Guidelines and Standards in China Mainland, Japan, and Korea, pp. 301-311**

Domain 5: Regulatory Responsibilities, K1. laws, regulations, policies and standards

SUMMARY: China, Japan, and South Korea (Korea) recognize modern society’s ethical concerns over the use of animals in research and each has developed their own regulatory framework to support the humane care and use of laboratory animals.

1. China

Laboratory animal affairs are regulated and administered in an integrated and multi-tiered governmental system. The Ministry of Science and Technology [MOST]) issued in 1988 the Regulations for the Administration of Affairs Concerning Experimental Animals, the supreme regulation that directly regulates every aspect of laboratory animal care and use, hereafter abbreviated as Admin Reg. According to the Admin Reg, the regulation and administrative oversight for laboratory animals reside in MOST and in provincial bureaus of science and technology (BOST).

Laboratory animals are defined as any animals bred and reared according to relevant standards and intended to be used in experiments or for other scientific purposes.

In China, there are two types of licenses, facility license (a breeder or user license, or both) and personal license. Licenses are administered by the BOSTs (usually through the administrative office of laboratory animals).

China Food and Drug Administration Good Laboratory Practice (GLP) regulations have requirements concerning animal facilities and animal care and use for animals employed in GLP studies. The Chinese Veterinary Medicine GLP regulations, which took effect on Dec 9, 2015, mandated the establishment of an institutional animal welfare review body and basic animal husbandry requirements in nonclinical research of veterinary medicines.

Some provinces have guidelines on ethics review or IACUC protocol review, such as the Guide of the Beijing Municipalities for the Review of Laboratory Animal Welfare and Ethics. Any activity involved with animal husbandry and animal experimentation shall start only after approval from the committee and is expected to receive routine supervision (i.e., post approval monitoring).

The final draft of Laboratory Animals - Codes of Welfare and Ethics, the potential first ever National Standard on Laboratory Animal Welfare in China, had been submitted to the National Technical Committee on LAS, Standardization Administration of China for review. It is expected that the standard will be approved for implementation in 2016.

The Ministry of Agriculture (MOA) has assigned the Chinese Veterinary Medical Association to draft welfare requirements of laboratory animals, a standard that is applicable to the animals used in agricultural research. The standard is under final review at MOA.

The State Technology Supervision Administration has issued about 100 standards for laboratory animal quality control.

The other governmental bodies, such as the MOA and Commission of Health and Family Planning, have their own laboratory animal quality standards. In addition, some of the more developed municipalities and provinces developed and implemented their own standards.

Laboratory animal seed resources in China are maintained and managed according to the Regulation on the Management of Laboratory Animal Quality. Through these laboratory seed centers (covering rodents, genetically modified mice, rabbits, miniature pigs, beagle dogs, SPF chickens, NHPs, and aquatic and special animals), MOST administers and regulates the importation, maintenance, and exportation of laboratory animals.

The GMO are covered on the Genetically Modified Animals Regulation on the Administration of Genetic Engineering Safety (MOST 1993) and Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering.

Laboratory animal institutions must have qualified managers, veterinarians, scientific staff, and technicians. They must have regular medical checks, receive training and obtain a personal license before caring and handling animals. The training curriculum is recommended by BOSTs, and they must pass an examination to be granted a personal license, which is valid for 5 years. The license can be renewed after receiving continuous training and passing a recertification exam.

In 2006, AAALAC International accredited its very first animal care and use program in China. As of early 2016, there were approximately 60 AAALAC-accredited units in China.

1. Japan

In Japan there is one main law to regulate the use of animals “Act on Humane Treatment and Management of Animals” (AHTMA) which mandates a self-regulation system for animal experimentation. There are also several ministry guidelines to provide administrative guidance. In addition, there are numerous voluntary guidelines provided by various organizations. The 3Rs concepts were incorporated into the AHTMA only in 2005. Despite multiple amendments, the registration of laboratory animal facilities, training of personnel, and regulatory inspections are still not required by Japanese law.

The “Standards Relating to the Care and Management of Laboratory Animals and Alleviation of Pain” (the standard) was issued from the Ministry of Environment in 2006.

The “Guidelines for Conduct of Animal Experiments” issued by the Science Council of Japan, describes very detailed issues on the care and use of laboratory animals for experimentation, and seems to be equivalent to the ILAR Guide.

While Japanese law does not require an attending veterinarian at each facility, veterinarians and others with LAS expertise are actively involved in promoting humane, ethical animal care and use in Japan through organizations and societies providing voluntary guidance, standards, and publications.

In 2005 the first Japanese facility was accredited by AAALAC International and as of early 2016 there were more than 20 AAALAC-accredited facilities in Japan.

1. South Korea

Animal experiments are regulated under two main laws in Korea, which are the Animal Protection Act (APA) established by the Ministry of Agriculture Food and Rural Affairs (MAFRA), and the Laboratory Animal Act (LAA) established by the Ministry of Food and Drug Safety (MFDS).

The principles behind the APA are characterized by two main points: first is to consider the welfare of laboratory animals and the second is to establish the IACUC to monitor animal welfare. The IACUC is appointed by the CEO. This IACUC is primarily concerned with protocol review and oversight but does not specifically oversee the management of the animal care and use program or facilities.

In 2015, the Guidelines for Reviewing Animal Study Protocols (vol. 1, rodents) were developed by the QIA and the Korean College of Laboratory Animal Medicine (KCLAM) for use by each local IACUC when reviewing rodent protocols. The Guidelines for Reviewing Animal Study Protocols is 38 pages long and includes classification of pain levels according to animal suffering, humane endpoints in rodents, methods for euthanasia of rodents, and other criteria for reviewing protocols.

Additional influences on animal research in Korea include laws on genetically modified organisms, GLP guidelines, cosmetic testing laws, certified training by the government, education and technician certification provided by KALAS, a government certification scheme to designate excellent animal research facilities, an assessment and accreditation program by the Korean Association for Laboratory Animals, and promotion of alternatives by both the Korean Society for Alternatives to Animal Experimentation and the Korean National information Center for the 3Rs. In addition, AAALAC International accredited the first facility in Korea in 1998 and as of early 2016, there were 18 AAALAC accredited facilities in Korea.

Comparison of laws, guidelines, and standards between China, Japan, and Korea

|  |  |  |  |
| --- | --- | --- | --- |
|   | China | Japan | Korea |
| License/registrationfor animal researchfacility | Required | Not required | Required |
| IACUC | Required | Recommended inguidelines, but notrequired by law | Required |
| IACUC membership | Vet and a personrepresenting an animalprotection organization | Vet and public membernot required by law | Vet and one personwith animal protectionexpertise |
| Role of IACUCin protocol review | Review and approve | Review andrecommend approvalby CEO | Review and approve |
| Attending veterinarian | Required | Recommended inguidelines, but notrequired by law | Required |
| Animals covered | Any animal, but focus onvertebrates | Vertebrates, excludingamphibians and fish | All vertebrates |
| Reporting togovernment | Annual | None, self-regulation | Annual |
| Government inspections | Annual | None, self-regulation | Guidance andsupervision byMFDS |
| Penalties fornoncompliance | Disciplinary action up to andincluding revoke of license | Fines and/or penalservitude | Fines and/or penalservitude |
| Alternatives/3Rs | Not currently included inregulations, but included inguidelines | Included | Included |
| College of LabAnimal MedicineSpecialty Board | None | JCLAM | KCLAM |

QUESTIONS

1. T/F. According to the Chinese definition of laboratory animals, only vertebrates are included as such
2. Which of the following provisions are included in the Admin Reg (China)?
	1. Authorized competent government body
	2. The classification of laboratory animals based upon their microbiological status
	3. The provision of suitable housing
	4. The use of certified animal breeds and strains
	5. a + c
	6. All of the above
3. T/F. The AdminReg (China) describes the ethical review and approval process
4. Which of the following are considered laboratory animals in Japan, as per the regulations?
	1. Mammals and birds
	2. Mammals, birds and reptiles
	3. Mammals, birds, reptiles and fish
	4. Mammals and fish
5. T/F. According to the “Guidelines for Conduct of Animal Experiments” of Japan, a veterinarian is a required member of the IACUC
6. In Korea, the Animal Experimentation Operating Committee main function is
	1. Organizing animal experiments
	2. IACUC
	3. Regulatory interface with the authorities
	4. CEO advisory body

ANSWERS

1. F (although the focus is mainly on vertebrates)
2. f
3. F (it is done at the province level, and only some have it incorporated into their regulatory framework)
4. b
5. F
6. b

**Retnam et al. Laws, Regulations, Guidelines and Standards for Animal Care and Use for Scientific Purposes in the Countries of Singapore, Thailand, Indonesia, Malaysia, and India, pp. 312-323**

Domain 5 (Regulatory Responsibilities), K1 (laws, regulations, policies, and standards, including international)

SUMMARY

Singapore: The birth of Singapore’s guidelines for the care and use of research animals took place in January 2003 when Mr. Philip Yeo Liat Kok was the Chairman of A\*STAR. Mr. Yeo appointed members to form the National Advisory Committee for Laboratory Animal Research (NACLAR), whose mission was to provide a set of national policies and guidelines for the acquisition, housing, and utilization of laboratory animals in biomedical research and address related scientiﬁc, ethical, and legal issues. The NACLAR Guidelines adopted best practices from countries such as Australia, Canada, New Zealand, and the United States, and organizations such as the Council for International Organizations of Medical Sciences. It stipulates that all proposed use of animals for scientiﬁc purposes must be evaluated by an Institutional Animal Care and Use Committee (IACUC) in compliance with the Guidelines. The Guideline is organized into three sections; the ﬁrst section, Guiding Principles for the Care and Use of Animals for Scientiﬁc Purposes, describes the overall guiding principles to promote the humane and responsible care and use of animals for scientiﬁc purposes in Singapore. The basis of the principles lies in the 3Rs—Replacement, Reduction, and Reﬁnement. The second section, Guidelines for Institutional Animal Care and Use Committee (IACUC), describes in detail the operational aspects pertaining to the IACUC. The third section, Training Guidelines, outlines the training scope and requirements for users of animals and animal facilities personnel.

QUESTIONS

1. As per NACLAR guidelines, the IACUC is required to conduct internal audits by reviewing the animal care and use program ----- and by conducting facility inspections at least ----

2. SPRING Singapore was appointed by the Ministry of Trade and Industry in 2007 to be the Singapore ’s Good Laboratory Practice (GLP) Monitoring Authority. True or False

3. As an appendix to the NACLAR guidelines, special considerations are provided for the care and use of -------------for scientiﬁc purposes and for the use of --------

ANSWERS

1. Semiannually; once a year

2. True

3. Nonhuman primates; transgenic animals

Thailand: The National Research Council of Thailand (NRCT) issued The Ethical Principles and Guidelines for the Use of Animals for Scientiﬁc Purposes (Ethical Principles) in 1999. The Ethical Principles and Guidelines for the Use of Animals for Scientiﬁc Purpose 1999 are comprised of ﬁve principles for which the scientists and institutions are responsible. The NRCT establishes in the Ethical Principles that the IACUC is responsible as the institutional oversight body. The Ethical Principles propose another set of “Rs”, 5 Rs—Reason, Responsibility, Reliability, Reproducibility, and Recorded. To motivate institutions to set up the required IACUC and improve compliance, the Standard of Institutional Animal Care and Use Committee (IACUC) was issued by the NRCT in 2012. NRCT also offers training programs for animal users, IACUC and animal caretakers. Animal Welfare and Protection of Cruelty to Animals Act was published in the Thai Royal Gazette in December 2014. The Animals for Scientiﬁc Purposes Act was published in the Government Gazette on March 13, 2015 and the act has 56 sections distributed in 6 chapters and transitional provisions.

QUESTIONS

1. True or False? As per the Animals for Scientific Purposes Act, an animal is defined as any living organism or nonhuman vertebrate in the animal kingdom, which also covers (a) any fetus of the living organism developed after an egg is fertilized by a sperm until reaching half the period of conception or incubation of an egg, depending on the kind of animal; and (b) any cell, not a gamete, which is able to develop and multiply itself into a fetus or any part of organ without changing original genetic code; 2. any other living organism, described in the Ministerial Regulation, namely insect, shrimp, crab, octopus.

2. The second part of the third chapter of the Animals for Scientific Purposes Act clearly states that any person who wishes to use or breed animals for scientiﬁc purposes must be -----. The procedures on animals such as (1) breed improvement, (2) breeding, (3) production, (4) stem cell study, (5) genetic modiﬁcation, and (6) cloning may be performed only after ------------ is informed

3. True or False? As per the Ethical Principles, the IACUC must be composed of at least seven members, and the chair must be an executive or their representative.

ANSWERS

1. True

2. Licensed; the Secretary-General of the NRCT

3. True

Indonesia: In Indonesia, animal welfare legislation was enacted in 1967 with the release of the Law of Republic of Indonesia No. 6 (Law of the Republic of Indonesia No. 6 1967), with several subsequent amendments made to the law. The Health Research Ethics Committee, in the Ministry of Health, developed the National Guidelines on Health Research Ethics, and a Teaching Guide Book for Ethics on Health Research. In addition, the Ministry of Research and Technology, the Ministry of Health, and the Ministry of Agriculture established the National Bioethics Committee in 2004.

QUESTIONS

1. True or False? Under the Animal Welfare section (Parts 2, Article 66) of the Animal Welfare Regulation, an “animal” is deﬁned as any vertebrate and some of invertebrates that can perceive pain.

2. There is no registration, licensing, inspection, oversight, or report requirement by the government for any institution or facility conducting animal research, teaching, or testing, with the exception, when ------ species are captured from the wild and transported, the requirements from Ministry of Forestry would be applied, as well as Conservation Law No. 5 (1990)

ANSWERS

1. True

2. Nonhuman primate

Malaysia: The Malaysian Animal Welfare Act 2015 (AWA 2015), along with the Animal (Amendment) Act 2013 (AA 2013), are the principal legislations that govern the care and use of laboratory animals in Malaysia. The use of non-domesticated species, which may include nonhuman primates and other wildlife species for research, is governed by the Wildlife Conservation Act 2010 (WCA 2010). In addition, the protection of aquatic mammals and ﬁsheries species is under the purview of the Malaysian Fisheries Act 1985 (FA 1985). The AWA 2015 is comprised of 9 parts and 64 sections. Of particular interest to the Malaysian research communities is Part II—Animal Welfare Board, sections 3 to 14 that deﬁned the functions and membership of the Animal Welfare Board (AWB); Part III—Licensing, sections 15 to 23 that deal with licensing matters for keeping and using animals; Part IV— Matters related to animal welfare, licensing requirements, animal transportation. The Malaysian Code for the Care and Use of Animals for Scientiﬁc Purposes (MyCode) was adapted and adopted with permission from the National Health and Medical Research Council-Australia, based on the Australian Code for the Care and Use of Animals for Scientiﬁc Purposes 7th Edition.

QUESTIONS

1. Animal Welfare Board (AWB) is an integral part of the AWA, 2015 and the membership of the board comprises of

a. Director General of the Department of Veterinary Services, who is also the chair,

b. Director Generals of the Department of Wildlife and National Parks Peninsular Malaysia, Department of Fisheries, and Department of Local Government,

c. The Dean of a Veterinary School appointed by the Minister from a public university in Malaysia,

d. One senior ofﬁcer each from the Ministries of Agriculture, Education, and Health

e. All of the above

2. Enforcement and compliance inspection activities as per AWA 2015 will be carried out by ---------

3. The major areas addressed by MyCode include

a. General principles for the care and use of animals in scientiﬁc research

b. Responsibilities of the institution and IACUC

c. Responsibilities of the researchers/investigators

d. Matters pertaining to the acquisition and care of animals in breeding and holding facilities

e. Role and responsibilities of the attending veterinarian

f. All of the above

ANSWERS

1. e

2. The enforcement division of the Department of Veterinary Services (DVS), Malaysia.

3. f

India: Indian Parliament passed the Prevention of Cruelty to Animals Act 1960 (Prevention of Cruelty to Animals Act 1960). Under this act, the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) was created to ensure the care and welfare of research animal subjects. The Breeding of and Experiments on Animals (Control and Supervision) Rules, regulate the experimentation on animals. As per Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, requires establishment of an Institutional Animal Ethics Committee (IAEC).

QUESTIONS

1. The ethical principles adopted by CPCSEA for use of animals in scientiﬁc experiments include

a. “Experiments on animals” may be carried out for the purposes of advancement by new discovery of physiological knowledge or of knowledge that is expected to be useful for saving or prolonging human life or alleviating suffering

b. Animals lowest on the phylogenetic scale that may give scientiﬁcally valid results should be used for any experimental procedure

c. Proper use of animals in experiments and avoidance or minimization of pain and suffering inﬂicted on experimental animals should be an issue of priority for research personnel

d. Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments

e. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline

f. All of the above

2. The IAEC shall include

a. A biological scientist and two scientists from different biological disciplines,

b. Veterinarian involved in the care of animal,

c. A scientist in charge of the animal facility of the establishment and a scientist from within or outside the institute,

d. Nonscientiﬁc, socially aware member,

e. Nominee of CPCSEA

f. All of the above

3. True or False? The chairperson of the committee and member secretary are to be nominated by the institution from amongst the eight members.

4. A -------- may be included while reviewing special projects using hazardous agents such as radioactive substance or infectious agents

5. The IAEC has the authority to require ----- of the institution or animals carrying on experiments on animals; the responsibility is placed on -------- and experiments involving operations are performed under the inﬂuence of ---------- to prevent the animals feeling pain.

6.  True or False? “Experiments” are deﬁned as any program or project involving use of animal(s) for the acquisition of knowledge of a biological, physiological, ethological, physical, or chemical nature and including the use of animal(s) in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity, and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering, or signiﬁcant gains in the well-being for people of the country or for combating any disease, whether of human beings, animals, or plants.

7. IAEC may approve animal experiments, up to the phylogenetic level of --------------

8. True or False? IAEC is not empowered to clear research project proposals that involve experimentation on animals higher on the phylogenetic scale than rodents; forward its recommendations for consideration by the CPCSEA.

9. An establishment shall acquire animals for experiments from -------- only; in case of non-availability of animals from registered breeders, the animals may be procured from ------------.

10. In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, --------- shall be responsible for the aftercare and rehabilitation of the animals after the experiment has ended

11. In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, investigators shall euthanize animals only

a. When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner

b. If during the course of experimental procedure, the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering

c. Where the nontermination of the life of the experimental animal will be life threatening to human beings or other animals.

d. All of the above

ANSWERS

1. f

2. f

3. True

4. Specialist

5. Registration; person in charge of the institution; some anesthetic of sufﬁcient power

6. True

7. Rodents (e.g., mice, rats, and rabbits)

8. True

9. Registered breeders; alternative legal sources

10. Investigators

11. d

**Timoshanko et al. Australian Regulation of Animal Use in Science and Education: A Critical Appraisal, pp. 324-332**

Domain 5: Regulatory Responsibilities

SUMMARY: This article summarizes Australia’s current regulatory framework and compares it to EU and US standards to point out 4 areas that could be improved to align the country with international best practices.

In Australia, animal use in science and education is regulated at both the national and state/territory levels, but legislative responsibility falls primarily to states and territories. Legislation differs amongst them, but the core features are: requirement of a license, requirement of an animal ethics committee (AEC), and rules regarding facility inspections and sanctions for breaching legislation. In order to promote regulatory uniformity, the Commonwealth introduced The Australian Code for the Care and Use of Animals for Scientific Purposes (“the Code”) in 1969, which applies to all living nonhuman vertebrates and cephalopods used in research and teaching. The Code has since been revised with the assistance of the National Health and Medical Research Council (NHMRC), state and territory governments, animal welfare groups, and in consultation with the public. The Code employs a principles-based approach to regulation and aims to promote ethical, humane, and responsible care and use of animals for scientific purposes. Victoria regulation was used as an example since it is one of the largest animal users in Australia. The Prevention of Cruelty to Animals Act 1986, which governs animal use in Victoria, accepts animal pain and distress when necessary for the purpose of scientific research. Other codes of practice and guidelines exist at the national level that focus on specific areas of animal use, but these are only enforceable if the research has been funded by the NHMRC. Promising developments in Australian animal research regulation in recent years are a change in AEC composition to provide a greater voice for the general public’s concerns and the promotion of rehoming of animals.

In the EU, the primary regulations of animal research are the Directive 2010/63/EU and the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes. The Directive regulates the use of animals with content largely drawn from the Convention, but is more stringent, and it is only binding to the extent that it is incorporated into domestic legislation. The Convention can be seen as a set of guidelines for states to implement in good faith. The regulatory framework in the US provides federal legislation via the Animal Welfare Act and the Health Research Extension Act. Weaknesses in the legislative framework are partially addressed through the Public Health Service policy, which requires the establishment of an IACUC and compliance with “The Guide.”

Australia’s significant use of animals raises serious doubts as to whether the 3Rs, but specifically replacement, are being given full effect in the Code. The authors propose 4 areas of regulatory reform:

1. Transparency: Australia needs to implement measures to promote transparency to reflect growing public concern about the use of animals and to be in harmony with the latest international regulatory developments. Only 57% of the public are aware that animals are used in experimental research in Australia, which is likely due to the lack of public information available. Requests for basic info such as statistics of animal use or names of license holders authorized to conduct animal research have, in some states, been refused. Freedom of Information requests in Victoria for the list of license holders have been denied due to concerns of endangering safety of researchers. Humane Research Australia has had its requests for information on the use of primates in research denied by state governments. This is vastly different in Europe, where details on number of procedures, type of animals used, and severity of procedures is published in the Annual Statistics of Scientific Procedures on Living Animals. In the EU, the Directive requires that nontechnical project summaries be published by Member States, so the public can access information regarding the use of animals for scientific purposes. These summaries must include the title, purpose, objectives and benefits, number and type of animals, predicted harms, how the 3Rs will apply, and in some cases, retrospective analysis post-study.

2. Competency: The Code states that people working with animals must be competent or supervised by a competent person, but the definition of “competent” is unclear. Also, there is no requirement in the legislation or Code to appoint a veterinarian to care for animals or perform surgical procedures. The requirement is only that veterinarian advice is available and accessible, that procedures conform to accepted veterinary standards, and that one of the AEC members be a person responsible for the routine care of animals at the institution. Concerns surround the competency of animal welfare person and lay person members of AECs as there is no requirement for the animal welfare appointee to possess relevant qualifications that may assist in understanding justification of animal use. Researchers do not have to disclose which alternatives have been considered so the lay person is forced to trust that all non-animal alternatives have been explored since they likely have little awareness of what alternatives actually exist.

3. National Authority: Authors propose the establishment of a national authority which could review and approve proposals for the use of animals in research and teaching. This would help ensure decisions are made with full knowledge of non-animal alternatives, whether the experiment is necessary, and it would oversee implementation of the Code. An analogous agency in Europe is The European Chemicals Agency (ECHA), which plays an important role in the Organization for Economic Cooperation and Development’s Quantitative Structure-Activity Relationship Toolbox initiative. The Toolbox provides publicly available information about 90,000 substances in order for data gaps in regulatory hazard assessments to be filled without animal testing. Other examples are the European Medicines Agency which aims to eliminate animals in medicine through shared information and international collaborations, and the European Partnership for Alternative Approaches to Animal Testing (EPAA) which facilitates collaboration in effectively implementing the 3Rs.

4. Greater Incentives: Australia should develop and promote incentives for the development and use of non-animal alternatives in scientific research. There is very little funding to develop alternatives to animal research. Looking at the UK, the National Centre for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs) has funded approximately £45 million of research into the 3Rs since 2004. Others that support similar efforts in Europe include the European Centre for the Validation of Alternative Methods, the Centre for Documentation and Evaluation of Alternatives to Animal Experiments, and the Federal Institute for Risk Assessment in Germany. In the US, the Interagency Coordinating Committee on the Validation of Alternative Methods was established to review available literature to assess the validity of tests. In addition, nonprofit groups such as the UK-based Universities Federation for Animal Welfare, US-based Johns Hopkins Centre for Alternatives to Animal Testing, and the UK’s Dr. Hadwen Trust all exist to provide incentives for non-animal research alternatives. The Commonwealth needs to evolve biomedical research in Australia by funding a dedicated center for animal alternatives. The first step may be the creation of an Independent Office of Animal Welfare, which could then be supported by a new Australian Centre for the Replacement, Refinement, and Reduction of Animals in Research.

QUESTIONS

1. Australia uses more animals per year than:

a. The US

b. The UK

c. China

d. Japan

2. According to this article, which one of the 3Rs is a primary concern that Australia is not addressing?

a. Replacement

b. Reduction

c. Refinement

d. Reproducibility

3. True/False: In the EU, the Directive is more stringent than the Convention.

ANSWERS

1. b

2. a

3. True

**Mohr et al. The Governance of Animal Care and Use for Scientific Purposes in Africa and the Middle East, pp. 333-346**

Domain 5 (Regulatory Responsibilities), K1 (laws, regulations, policies, and standards, including international)

SUMMARY

* + - This article provides an overview of the governance of the care and use of animals for scientific purposes in different regions of Africa and the Middle East, that is, North Africa and the Middle East, East Africa, Southern Africa, and West Africa.  It provides an overview of the governance of the care and use of animals for scientific purposes in different regions of Africa and the Middle East as a foundation for coordinated future advancement.
		- The intention is to present some of the most notable and readily identifiable examples of strengths and weaknesses that are observed in the region to serve as a baseline and guide for future programs aimed at building on successes and addressing identified challenges.
		- Animals are commonly used for scientific purposes in Africa and the Middle East. However, this field is often inadequately regulated, with many countries lacking national legislation, policies, or guidelines for the care and use of animals used for research, testing, or education.
		- Uncontrolled system where scientific quality and animal wellbeing cannot robustly be guaranteed, which may hinder acceptance (i.e., publication) of results by the scientific community and limit public confidence.
		- Though accepted international guidelines and best practice recommendations exist that could be adopted or adapted to meet local needs, the responsible conduct of research and animal welfare may not be prioritized in regions that are affected by instability, poverty, disease, or malnutrition.
		- To make such regional capacity strengthening efforts sustainable will require regional cooperation, the establishment of regional networks, harmonization of policies, pooled resources, and long-term investment in education, training, and infrastructure.

QUESTIONS

1.  The humane care and use of nonhuman animals for scientific purposes in Africa and the Middle East is generally at the level of most other developed countries? T/F

2. The ethical framework of The Three Rs?

a. Initially described in The Principles of Humane Experimental Technique

b. The Terrestrial Animal Health Code for the Use of Animals in Research and Education

c. The International Guiding Principles for Biomedical Research Involving Animals (Council for International Organizations of Medical Sciences [CIOMS], and the International Council for Laboratory Animal Science [ICLAS]

d.  a, b, c

3.  The Guide for the Care and Use of Laboratory Animals, produced by \_\_\_\_\_\_\_\_

4.  The Directive 2010/63/EU was written for \_\_\_\_\_\_\_\_

5.  The Three Rs represent the \_\_\_\_\_\_.

a.   Replacement of animals by nonanimal models when possible

b.  Reduction of the number of animal used to the minimum required to yield scientifically valid results

c.  Refinement of procedures and animal care standards to limit the potential for pain, suffering, distress, or lasting harm, thus improving animal wellbeing (Russell and Burch 1959)

d.   a, b, and c.

6.  The Guide for the Care and Use of Laboratory Animals, produced by \_\_\_\_\_\_\_\_\_\_\_\_\_\_

7.  In a number of these countries, regulations and guidelines addressing ethical issues in research primarily apply to research with human participants and do not include the care and use of animals or animal welfare. An exception \_\_\_\_\_\_\_\_\_\_.

8.   T or F:  Most North African and Middle Eastern countries of the common use of animals for research, testing, and education, but we notice the absence of specific laws governing animal care and use for scientific purposes.

9.  T or F: The absence of specific laws governing animal care and use for scientific purposes in most North African and Middle Eastern countries. An exception is Qatar, which in 2013 implemented the Qatar Supreme Council of Health Policies, Regulations and Guidelines for Research Involving Laboratory Animals “to assist institutions in the state of Qatar, in caring for and using animals for scientific purposes in ways judged to be scientifically, technically and humanely appropriate according to highest ethical principles”

10. T or F: Despite the absence of the of laws and formal guidelines governing the care and use of animals for scientific purposes researchers can publish their research in international peer-reviewed journals.

11. A motivation for positive change in the region may be imposed through trade negotiations and agreements with countries that have more refined standards and requirements for the care and use of animals for scientific purposes and advanced regard for animal welfare

12. The role to promote animal welfare education in the region has been largely fulfilled by \_\_\_\_\_\_\_\_\_

13. T or F: There is no uniform approach for dealing with inspection, oversight, and compliance in the East African countries.

14. T or F:  In Kenya, a license to perform animal experimentation may be granted only to a person who is registered under the Veterinary Surgeons Act or the Medical Practitioners and Dentists Act.

15. T or F: The majority of institutions in Kenya do not have established committees to review experimental protocols or to provide oversight regarding the use of animals in education and research.

16. T or F:  In East Africa there is a lack of specific regulation of the welfare of animals in research settings and an absence of effective enforcement mechanisms.

17. T or F: Southern Africa is defined here to include the 15-member states of the SADC (Southern African Development Community (SADC)).

18. Tor F: The OIE in 2011 (World Organization for Animal Health (OIE) report found that public awareness of animal welfare was generally low in most Southern African countries.

19. T or F: Few Southern African countries have dedicated legislation that governs animal use for scientific purposes, with this usually being covered in nonspecific terms in national animal protection acts.

20. The OIE report on the state of animal welfare in Southern Africa in 2011 identified that of the 15 regional countries, only \_\_\_\_\_\_\_\_ had a modern, comprehensive animal welfare Act.

21. \_\_\_\_\_\_ and \_\_\_\_\_\_\_\_were found to have fairly comprehensive animal protection acts, though these required updating and broadened scope.

22. T or F: Seven countries were considered to have outdated animal protection acts: Botswana, Lesotho, Malawi, Seychelles, Swaziland, Zambia, and Zimbabwe.

23. The Mauritius Animal Welfare Act of 2013 contains a dedicated section on

a. Animal experiments

b. A license from the minister is required to perform animal experiments

c. Makes provision for inspection of animal facilities.

d.  All above

24. \_\_\_\_\_\_\_\_has the most comprehensive governance framework for the care and use of animals for scientific purposes in the SADC region and likely in Africa, although the legislation is fragmented and requires review (Mohr 2013).

25. The SAVC (South African Veterinary Council) is the national Competent Authority that authorizes \_\_\_\_\_\_\_\_\_\_.

26. Minimum standards for research animal facilities (Department of Agriculture 2015) requires

a.  All breeding and experimental facilities to be registered with the SAVC.

b.  Minimum standards relate to infrastructure, procedures, personnel, husbandry, welfare, ethical review, biocontainment, and veterinary oversight of animal health and welfare.

c.   Facility registration requires a veterinary or para-veterinary professional, usually a designated veterinarian, to act as principal of the facility and take primary responsibility for ensuring minimum standards.

d.  All the above

27. The ethical review of animal care and use for scientific purposes (i.e., the equivalent of project “licenses”) in South Africa, as well as oversight of animal care and welfare, is performed by

28. The South African National Standard (SANS) for the Care and Use of Animals for Scientific Purposes (SANS 10386) (South African Bureau of Standards 2008) aims to?

a. Establish minimum national standards for animal care and use, based on international standards;

b.  To emphasize the responsibilities of researchers, teachers, and institutions that use animals;

c.  To ensure that the use of animals is always appropriately justified by the review of scientific and teaching protocols by animal ethics committees

d.  To ensure that animal welfare is appropriately considered

e. To ensure adherence to the Three Rs.

f.   All the above

29. T or F: Though not a legal prerequisite per se, many institutions have voluntarily adopted the SANS 10386 as minimum standard.

30. Since 2015, the minimum standards for research animal facilities have introduced, as regulatory requirement, that:

a.  Animal Ethics Committees (AECs) who evaluate animal care and

b.  Use in SAVC-registered research animal facilities must be compliant with SANS 10386:2008 (Department of Agriculture 2015).

c.  Both a and b

31. In the absence of formal standards and guidelines for the care and use of animals for scientific purposes in many Southern African countries, it is common to refer to international standards, including

a. The ILAR Guide

b. The OIE Terrestrial/Aquatic Animal Health Codes

c.  The CIOMS/ICLAS International Guiding Principles for Biomedical Research Involving Animals

d.  The European Union Directive 2010/63/EU

e.  All the above

32. Due to physical separation from countries with closely regulated standards for animal care and use, international best practice recommendations are often obtained from freely accessible online resources, including

a.  The UK National Centre for the Replacement, Refinement and Reduction of Animals in Research,

b. AAALAC International’s Reference Resources (AAALAC International 2016)

c.  The Federation of European Laboratory Animal Science Associations

d.  The South African Medical Research Council first published

e.  All the above a-d

33. The purpose of the SANS 10386

a.  Is to ensure the ethical and humane care and use of all animals involved in scientific activities, including in medicine, biology, agriculture, industry, veterinary, wildlife,

b.  Including use in research, teaching, field trials, product testing, diagnosis, the production of biological substances, and environmental studies.

c.  Covers all live nonhuman vertebrates and higher invertebrates (e.g., cephalopods and decapods),

d.  Including their eggs and fetuses, with the use of lower invertebrates also considered.

e.  a-d

34. The purpose of the SANS 10386 is to ensure the ethical and humane care and use of all animals involved in

a. Scientific activities, including in medicine, biology, agriculture, industry, veterinary, wildlife,

b.  Other animal sciences, including use in research, teaching, field trials, product testing, diagnosis, the production of biological substances, and environmental studies.

c.   a and b

35. The SANS requires that AEC membership includes at least four categories of members:

a.  Veterinarians,

b.  Persons with recent experience in the use of animals for scientific purposes, independent animal welfare organizations

c.  Independent persons who have not used animals for scientific purposes

d. All above

36. T or F: Animal Welfare and the Three Rs Public awareness of animal welfare is generally low in the Southern African region, with animal welfare networks ranging from well-developed in South Africa to limited or none in other SADC countries.

37. T or F: The South African NSPCA Animal Ethics Unit (National Council of Societies for the Prevention of Cruelty to Animals), established in 2001, promotes the Three Rs by serving on institutional AECs.

38. In South Africa, the SAVC audits research animal facilities that are registered with the SAVC to ensure compliance with ILAR Journal, 2016, Vol. 57, No. 3 | 339 regulatory minimum standards, pertaining inter alia to personnel competence

a. Scheduled substance control,

b. Veterinary oversight of animal health and welfare,

c.  Clinical infrastructure,

d. Husbandry and animal welfare standards,

e. Veterinary record-keeping, and ethical review

f.  All the above

39. The Department of Agriculture, Forestry and Fisheries audits research animal facilities with particular emphasis on?

a.  Biocontainment and

b.  Human health and

c.  Safety, in accordance with the Animal Diseases Act (Department Agriculture 1984) with certification of Biosafety

d.  a, b, c

40. Western Africa, \_\_\_\_\_\_\_has the highest number of tertiary institutions where animals are used in research, teaching, and testing.

41. T or F. The lack of legal governance frameworks is similar in most West African countries.

42. Nigeria, with 139 universities, there are no formal regulations regarding the use of animals for scientific purposes.

43. T or F: Some West African nations (e.g., Nigeria, Ghana, Senegal, Benin, and Gambia) do however have general animal welfare legislation, under which persons may be prosecuted for causing excessive suffering to animals.

44. Concern regarding animal welfare depends on several factors, including

a. Socio-economic conditions

b.  Culture

c. Religion

d.  Tradition

e.  a-d

45. T or F: There is no known legislation concerning the ethical review of animal use for scientific purposes in West African Countries.

46. T and F: In Ghana, the University of Ghana recently implemented an Institutional Animal Care and Use Committee (IACUC)

47. T or F: The Council for Scientific and Industrial Research (CSIR) in Ghana similarly enacted a standard operating procedure to ensure quality of review and a more efficient and consistent ethical review mechanism to prevent unnecessary pain and suffering before, during, and after procedures on animal subjects (Council for Scientific and Industrial research (CSIR)).

48. ACURET stand for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

49. Purpose of ACURET?

50. The main challenge relates to the mind-set within institutions for the principles of humane animal care and use?

a.  Many people do not view laboratory animals as being sentient, capable of pleasures and suffering.

b. Here religious backgrounds also play a role.

c. Another factor is poor resources for research and teaching.

d. Some scientists question why they should spend significant funds on animals when humans are starving or battling with poverty.

e. All the above

51. Now more are increasingly appreciating the need to pay attention to the welfare of research animals in order to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

52. T or F: Africa and the Middle East are largely unchartered in terms of animal care and use for scientific purposes. Information on the topic is difficult to find, since no database is readily accessible.

53. The summary of challenges to overcome in Africa and middle east?

a.  The significant geographic extent of the region, with its diversity of countries, socioeconomics, languages, cultures, and religions, makes broad capacity-development programs challenging.

b.  A major and real challenge is the sustainability of programs that are launched as well as the need to remain sensitive to moral theories and perceptions of animal use that may exist (Metz 2010).

c.  Resource limitations in large parts of the region imply that external funding will also be required. A need has been identified for a coordinated initiative to provide education and training in the laboratory animal sciences in the African continent (Mohr and Lewis 2015b).

d. a, b, and c

54. T or F: The mission of ICLAS is to promote and coordinate the development of laboratory animal science throughout the world, particularly in developing countries.

55. T or F: Of central importance to the African and Middle Eastern context, the goal of ICLAS is to achieve standardization.

ANSWERS

1. False: Impeded by the absence of standards, regulations, and enforcement; appropriate education and training of researchers, veterinarians, laboratory animal technologists, animal care staff, and animal ethics committees; and lack of wide societal acceptance of the ethical imperative of treating animals humanely.

2.  d. a, b, c

3.  a. The Institute for Laboratory Animal Research, also known as “The ILAR Guide”

4.  The Protection of Animals Used for Scientific Purposes (European Parliament and Council of the European Union 2010).

5. d

6.  The Institute for Laboratory Animal Research, also known as “The ILAR Guide”

7. Qatar

8. T

9. T

10. F

11. T

12. ICLAS

13. T

14. T

15. T

16. T

17. T

18. T

19. T

20. Tanzania

21. South Africa and Namibia

22. T

23. d

24. South Africa

25. Persons to perform scientific or clinical procedures on animals or to perform functions of registered veterinary or para-veterinary professionals, according to the specifications of the Veterinary and Para-Veterinary Professions Act and the Rules made thereunder.

26. d

27. Institutional Animal Ethics Committees and is regulated by legislation (Department of Agriculture 2015; Department of Health 2003, 2015) as well as by national standards (South African Bureau of Standards 2008).

28. F

29. T

30. c

31. e

32. e

33. e

34. c

35. d

36. T

37. T

38. F

39. d

40. Nigeria

41. T

42. T

43. T

44. e

45. T

46. T

47. T

48. Animal Care and Use in Research, Education and Testing

49. Was incorporated in Nigeria in 2014 as a multinational, interdisciplinary, nongovernmental organization with the aim to promote the humane care and use of animals for scientific purposes in developing countries, to adequately train researchers in the humane principles of the Three Rs, and to orient the approach of scientists to assume responsibility for

animal welfare.

50. e

51. Obtain valid and reproducible scientific data, it is anticipated that improved adherence to animal welfare principles will grow in West Africa.

52. T

53. d

54. T

55. F. Not to achieve standardization but rather that each country should be able to maintain a system of animal care and use oversight that reflects its own cultures, traditions, religions, laws, and regulations.

**Olsson et al. Protecting Animals and Enabling Research in the European Union: An Overview of Development and Implementation of Directive 2010/63/EU, pp. 347-357**

Domain 5: Regulatory Responsibilities; K1. Laws, regulations, policies and standards

SUMMARY

Background:In 1986, European Directive 86/609/EEC, regulating the use of animals in research, was one of the first examples of legislation to set standards for animal protection across the European Economic Community (now the EU). Under the EU, a directive is “a legislative act that sets out goals that all member states must achieve.” Another Europe-wide legal instrument regulating the use of animals in research was also published in 1986, The European Convention for the Protection of Vertebrae Animals used for Experimental and other Scientific Purposes (ETS123). While there are areas of overlap between the Convention ETS123 and Directive 86/609/EEC, there are some important differences. First, the Convention ETS123 was published by the Council of Europe and not the European Union. Second, Convention ETS123 is not a directive.  Conventions are only legally binding to the parties that ratify them, whereas the directive must be implemented by all member states. Convention ETS123 is one of the 3 primary standards used by AAALAC international for evaluating a laboratory animal care and use programs.

Starting in 2002, a process of revising European animal experimentation legislation was undertaken. The revisions were motivated by different standards between countries, by the exclusion of animals in education and by insufficient attention to the 3Rs and animal welfare. This resulted in Directive 2010/63/EU, which has regulated this activity in Europe since 2013.

Directive 2010/63/EU: Since this is a European Union Directive, transposition into national legislation is a necessary and important part of the implementation of the new legislation. Transposition is the process of adopting a regulation into national law. The goal of this paper was to provide an overview of the transposition process and an analysis of the potential to reach the different objectives of the directive. The analysis focuses on three separate issues:

1.   Minimum standards for laboratory animal housing and care: The standards for housing and caring for laboratory animals in the Directive are the sameas in Convention ETS123. Annex III of the directive sets a level playing field and harmonization across the different European member states.

2.   Restrictions on the use of certain animal species: The Directive restricts the use of endangered species, nonhuman primates, animals taken from the wild, and stray/feral animals of domestic species. The strongest restrictions are on great apes.

3.  Project review and authorization: The directive defines criteria that should be satisfied for authorization to take place by establishing requirements for authorization; information that should be provided in the application and aspects and expertise to be considered in evaluation.

While there is a high degree of harmonization in transposition of issues 1 and 2 between member states, there is considerable variation in transposition of issue 3.  There is no direct guidance in the directive and the system for project review and authorization is variable across member states.

QUESTIONS

1.  What is the former name of the European Union?

2.  True or False: Did the EEC (now the EU) publish the European Convention for the protection of Vertebrae Animal used for Experimental and other Scientific Purposes (ETS123)

3.   True or False: Is the “European Convention for the Protection of Vertebrae Animal for used for Experimental and other Scientific Purposes (ETS123)” one of the 3 primary standards used by AAALAC international for evaluating a laboratory animals care and use program.

4.   True or False: The standards for housing and caring for laboratory animals in Annex III of the Directive 2010/63/EU are differentthan in the Convention ETS123.

5. Directive 2010/63/EU restricts which of the following animals?

a.   Endangered animals

b.   Nonhuman primates

c.  Animals taken from the wild

d.  Stray /feral animals of domestic species.

e.   All the above

ANSWERS

1.   European Economic Community (EEC)

2.  False. The ETS123 was published in 1986 by the Council of Europe.

3. True

4.  False

5.  e. All the above

**Busquet et al. Can TTIP Improve Laboratory Animal Welfare in Safety Testing and 3Rs?, pp. 358-367**

Domain 5: Regulatory Responsibilities

K1 - Laws, regulations, policies, and standards, including international

SUMMARY: Current negotiation under the Transatlantic Trade Investment Partnership (TTIP) between the EU and US is missing opportunities to achieve coordinated progress with respect to lab animals and the 3Rs. There is imbalance between the two entities with respect to technology progress (USA is driving new methodologies) and regulatory frameworks (EU is more advanced in animal welfare laws). Both the EU directive and US laws incorporate the 3Rs, but differ in their approach. PHS policy supports self-regulation and USDA relies on IACUC for compliance. EU guidelines are more prescriptive.

European Union: The 28-member EU has multiple vertical legislative frameworks impacting lab animal-use, but is challenged with implementing and enforcing laws within each country. Animal welfare is included as a European value in the Treaty of the Functioning of the European Union (TFEU) but is not an official EU policy area. Multiple EU agencies (European Chemicals Agency; European Medicines Agency; European Food Safety Authority) foster novel technologies (*in silico, in vitro*). The last EU strategy for animal welfare implemented (2012-2015) mentions little about lab animals.

EU Directive 2010/63/EU focuses on protection of animals used for scientific purposes and seeks to harmonize current definitions, detail duties of the European Union Reference Laboratory for Alternatives to Animal Testing, and promote collaboration among members. This is the first EU legislation to call out the 3Rs and make them a legal requirement. The Cosmetics Directive provides regulatory framework for phasing out animal testing for cosmetics and implemented a testing and marketing ban. Registration, Evaluation, and Authorization of Chemicals (REACH), enacted in 2007, aims to improve protection of human and environmental health, requires vertebrate testing be undertaken as a “last resort”, and promotes alternative methods for assessing if substances are hazardous. The Test Methods Regulation, effected 2008, includes standardized and accepted methods for testing for hazardous chemicals. EU Directive 2001/83/EC established frameworks for human medicinal products and ensures the 3Rs are considered before animal testing. This directive was bolstered by Regulation 726/2004/EC, which focused on manufacturing, distribution, and marketing and includes additional regs for pediatrics, pharmacovigilance, etc. Regulations pertaining to Plant Protection Products and Biocidal Products encourage non-animal testing and sharing of animal data and alternative approaches, and have relaxed previous requirements like lethal-dose testing or # of spp. or route of exposure required. The 7th Environmental Action Plan, 2013, seeks to safeguard the health and well-being of EU citizens from environmental pressures and risks by developing chemical knowledge generated from non-animal testing where possible. Ultimately, the EU calls out the 3Rs both directly and indirectly, but correct application by member nations remains a challenge.

United States: Animal Welfare Act (AWA, 1966) is the primary US regulation governing lab animals, and is overseen by the United States Department of Agriculture (USDA). It has been amended 7 times with the 1985 changes having the most significant improvements for lab animal welfare as well as the establishment of Institutional Animal Care and Use Committees (IACUC). Specifically excludes research-bred birds, rats (genus: *Rattus*), and mice (genus: *Mus*). Provides engineering standards (housing, temp) but also allows for performance standards overseen by IACUC, Institutional Official (IO) or Attending Veterinarian (AV). The USDA issues policies to clarify regulations, including Policy 12, which refers to the 3Rs and requires investigators to consider alternatives to painful/distressful procedures, document literature searches for alternatives and demonstrate there are none.

The Public Health Service (PHS) encompasses multiple agencies including the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC). Any institution receiving PHS funding must file an Animal Welfare Assurance Statement (assures compliance with the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Test, Research, and Training) with the NIH’s Office of Laboratory Animal Welfare (OLAW). The Public Health Extension Act of 1985 covers all vertebrates and mandates PHS Policy, the guidelines for which are presented in the Guide for the Care and Use of Laboratory Animals (the Guide). The Guide is mostly performance-standard based but includes some practices as “must” or “should”. PHS Policy also mandates the IACUC to implement the 3Rs and the Guide.

US Food, Drug, and Cosmetic Act (FD&C) is supervised by the FDA, which does not restrict safety assessment data to non-animal testing methods; this may change with the Humane Cosmetics Act (2015), seeks to phase out animal testing and sale of cosmetics tested on animals. The Toxic Safety Control Act (TSCA, 1976) is analogous to REACH. The Chemical Safety for the 21st Century Act (2016) contains provisions to minimize/replace animal testing of chemical safety and requires the Environmental Protection Agency (EPA) to create a database of alternative testing. The Toxicology for the 21st Century program (Tox21) and the EPA’s ToxCast are examples of computer modeling and high-throughput methods of non-animal testing.

TTIP: Potential trade agreement between EU and US, negotiations started June 2013. Will include agreements in many sectors, including cosmetics, chemicals, pharmaceuticals, and probably pesticides and medical devices. Negotiations still ongoing, with EU periodically releasing status updates for transparency, while US releases no information. Regarding cosmetics, discord remains in realm of UV filters, as US remains committed to using animals for carcinogenic studies. Regarding chemicals, a “right to regulate from each side” compromise seems likely, and both the EU and US are investigating strategies to disseminate data regarding hazard/risk to avoid duplication of tests involving animals without compromising confidential business information.

Collaborations Outside the TTIP: Transatlantic cooperation regarding 3Rs already takes place outside the TTIP negotiations. The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) of the US and the EU’s Reference Laboratory for Alternatives to Animal Testing signed a memorandum of cooperation establishing the International Cooperation on Alternative Test Methods in 2009. The Innovative Medicine Initiative(IMI) is a public-private partnership between the European Community (EC) and European Federation of Pharmaceutical Industries and Associations, started in 2009, assists in developing pharmaceutical technologies or solving pharmaceutical dead-ends. The US Critical Path Institute (CPI) is a not-for-profit bringing scientists together to improve drug development and regulatory process for medical products. The IMI voluntarily shares info with the CPI.Tox21 (collaboration of EPA, NIH, FDA, National Toxicology Program, etc.) works to update safety assessment by embracing cutting-edge technologies and collaborating with many stakeholders, including EC Joint Research Centre.Horizon2020 and the EU-ToxRisk Consortium similarly allow US participation.

Conclusions: Opportunities to advance the 3Rs in the TTIP are scarce but do exist. The chemical sector should embrace data-sharing. Where US legislation lacks strong 3R emphasis, US regulatory agencies can emulate EU best practices. Ultimately, the low enthusiasm for incorporating the 3Rs in the TTIP may stem from the fact transatlantic cooperation already exists. Because academia and industry consume far more lab animals than safety testing, the use of alternatives in the global scientific community is urgently needed.

QUESTIONS

1. T/F: Registration, Evaluation, and Authorization of Chemicals (REACH) seeks to improve human and environmental health and considers vertebrate testing to be a primary objective.

2. T/F: Animal welfare is considered a European value in Article 13 of the Treaty of the Functioning of the European Union and is an official EU policy area.

3. Funding from which of the following agencies does not require filing of an Animal Welfare Assurance Statement with the Office of Laboratory Animal Welfare?

a. NIH

b. USDA

c. CDC

d. FDA

4. T/F: There is a strong drive to incorporate the 3Rs into the TTIP due to a long-standing unwillingness of non-governmental agencies in Europe and the US to collaborate outside this partnership.

ANSWERS

1. False. Vertebrate testing is considered a last resort.

2. False. It is considered a European value in the TFEU but is not an official EU policy area.

3. b, USDA

4. False. The drive to incorporate the 3Rs into the TTIP seems low, possibly due in part to close transatlantic collaboration that has been occur

**Guillen et al. Challenges** **and Opportunities in Implementation: The AAALAC International Perspective, pp. 368-377**

Domain 5:K1. laws, regulations, policies and standards

SUMMARY: The regulatory framework on the protection, care, and use of research animals is still heterogeneous. Differences across geopolitical areas exist not only at the legal level but, more important, also at the level of implementation of the existing regulations. Challenges and opportunities arising from these differences in North America, Europe, and the Pacific Rim are discussed in this article from the AAALAC International perspective.

Modern regulations and guidelines worldwide share the same core principles based on the 3Rs of Russell and Burch. International scientific organizations also refer to them in documents addressed to the scientific community: the World Health Organization in the chapter on the Use of Animals in Research and Education of the Terrestrial Code (OIE 2012), and the Council for International Organizations for Medical Sciences, along with the International Council for Laboratory Animal Science, through the International Guiding Principles for Biomedical Research Involving Animals (CIOMS-ICLAS 2012). despite the apparent homogeneity of the legal framework, there are still significant differences across geopolitical areas in the practical way the same principles are expected to be applied, the intensity of government control, and the final level of implementation of these principles and practices on the ground. The intensity of government control varies between countries that have different legal schemes and even between countries/regions that have very similar or even the same regulations. The main reason is the different level of resources, time, and personnel allocated to the responsible authorities at national and/or regional levels and the level of development of laboratory animal science in the area.

# The AAALAC International Approach

Since its inception, AAALAC International has accredited more than 950 animal care and use programs in 41 countries. In this diverse international landscape, a system has been implemented to promote consistency in the evaluation and accreditation of programs. There are several components to this system that AAALAC uses to implement this goal:

1. Adoption of Primary Standards: Since AAALAC was established in 1965, the successive editions of the Guide have served as the main reference document.

The Guide offers recommendations for all areas of an animal care and use program and serves as the basis for the self-assessment document (the Program Description) that institutions seeking accreditation have to complete. This is the first tool for harmonizing the accreditation process: all aspects of the animal care and use programs must be fully described following the Program Description template, regardless of their characteristics and location.

For the last edition of the guide the last edition of the Guide, AAALAC decided to incorporate other documents to serve as primary standards. They were the European Convention ETS 123 and the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide). Besides the primary standards, AAALAC also issues position statements to clarify the expectations for accreditation.

1. Applying the Performance-Based Approach: By not requiring a specific approach (harmonization is not the same as standardization), the evaluation focuses on the outcome of the process. Performance standards are not only useful for accreditation purposes, but they are also considered a tool to improve scientific discovery and animal welfare thanks to their flexibility and possibility for constant evolution

Performance standards should be science based and may also be shared and serve to harmonize animal care and use practices beyond the diverse regulatory environment.

1. Adapting the Council on Accreditation: Performance standards can be applied universally, but they have to be applied in concert with applicable regulations and in a variety of environments with respect to languages, sociocultural behaviors, and even religious beliefs. When AAALAC officially became AAALAC International in 1996, the Council on Accreditation (COA) was exclusively composed of members from North America. Later on, sections in Europe and the pacific rim were stablished.

1. Education and Outreach: In 2005 AAALAC established the position of senior director for education and outreach to help institutions achieve and sustain accreditation by providing topical education and outreach services based on the AAALAC International perspective.

The education and outreach program is designed to provide the information programs need to proactively manage animal care and use issues in ways that meet AAALAC International standards.

# Challenges and Opportunities in the United States

As in most regions of the world, government funding is the primary driver for noncommercial research in North America. In the United States, federal funding for research has historically seen rises and falls in funding based primarily on prevailing economic conditions. Of great concern is the trending of federal funding over the last decade. Since 2006, there has been a significant decline in the level of federal funds provided for research. Using a constant dollar calculation to account for inflation, it is projected that between fiscal year 2006 and fiscal year 2016, total federal investment in research and development will have fallen by 9.2%.

Another challenge that applies to all regulatory and/or oversight agencies in the United States is that of regulatory burden.

One of the primary concerns noted in the National Academies of Science report (2015) was the complexity of the multiple oversight systems associated with the care and use of animals and how the different missions and approaches of the National Institutes of Health, United States Department of Agriculture (USDA), and AAALAC affected institutions and research investigators.

One concern expressed was that some institutions treat AAALAC best practices as regulation. A subsequent recommendation in the report suggests that institutions should review whether they are accepting suggestions made by accrediting bodies and other nonfederal entities as if these suggested best practices had the force of agency regulations or policies.

Although challenges exist, there are also immense opportunities to enhance animal welfare and benefit science by reaching out to those programs that may not be familiar with the benefits obtained from the process of attaining and continuing accreditation. These types of organizations include smaller academic institutions using animals for biomedical research or teaching purposes and programs using agricultural animals for agricultural research and teaching. Also, the relatively recent focus by the USDA on expectations for continuous improvement, rather than just regulatory compliance with existing standards, provides a tremendous opportunity for organizations to leverage one of the primary benefits of accreditation.

# Challenges and Opportunities in Europe

The main feature of the European laboratory animal care and use environment, at least in the European Union, is that it is one of the most strictly regulated in the world.

First, some of the legal requirements go beyond the most significant primary standard used by AAALAC, the Guide. This is one of the main reasons why AAALAC adopted the ETS 123 as one of the primary standards, as it has served as the basis for the development of most of the European legislation.

Curiously, although the European regulations are very strict in some areas, considerations for other program areas are very limited. For example, the instructions for the veterinary care program or animal management.

In those countries where regulations are fully implemented and there is effective government control of animal research activities, institutions may consider that there is no need for an additional oversight system.

Other challenges exist in the diversity of languages, cultures, and socioeconomic development. The issue of languages and cultures is addressed by the diversity also represented in the COA and site visit teams. But the socioeconomic environment creates a deeper challenge concerning compliance with applicable regulations and accreditation standards. In a number of European countries, the competent authorities responsible for the implementation of the directive and the transposed national legislation lack the expertise and resources needed for full and effective implementation and control.

The financial crisis of the past years has had a significant impact on research capabilities of some countries and institutions.

During this period, more than a dozen accredited animal care and use programs in Europe have been closed down. This situation may also have kept an unknown number of programs from applying for the accreditation.

As opportunities, there is a trend to international harmonization in animal care and use practices, and AAALAC is playing an important role in this.

The consolidation and reduction of the size of companies due to the crisis was described as a challenge, but it is also an opportunity. Companies are now outsourcing not only preclinical studies but also more basic and discovery research, and when doing this they want research and testing to be conducted under the same quality and welfare standards.

While pharmaceutical companies are reducing in size and searching for external collaborations, academic institutions are also searching for external funding. Currently there are only a few academic programs accredited in Europe. The coordination of animal care and use programs in academia is more complex than in private companies: they are typically more decentralized, and the responsibilities and reporting lines are very often poorly defined. This makes. the application for accreditation more difficult for these institutions, but at the same time there is an increasing awareness of the benefits of the accreditation in terms of research collaborations.

Finally, another opportunity exists with agricultural programs.

The current situation in Europe shows a steady growth in the number of accredited programs.

# Challenges and Opportunities in the Pacific Rim

Language and the cultural diversity of the Pacific Rim countries has been a challenge, primarily due to difficulties in fully understanding the nuances of AAALAC’s processes, expectations, and standards.

Initially, language diversity was an impediment, but this has been successfully managed by using council members and ad hoc specialists who are fluent in languages in the Pacific Rim countries.

Consistency of the accreditation process throughout the region are also concerns. The site visit teams take into consideration the country’s regulatory requirements and apply the same harmonization approach and performance standards in the Pacific Rim as in the rest of the world. All institutions must comply with their own national guidelines, as they are fundamental requirements, especially when the engineering standards are more stringent than the Guide recommendations.

Several countries do not have an official laboratory animal veterinarian training program, and there are not enough veterinarians with board certifications. There is also a lack of pharmaceutical-grade drugs, especially anesthetics and analgesics, in some countries.

Interest in laboratory animal care and use standards and laboratory animal welfare has grown in this part of the world as a result of the accelerating pace of animal-based research being outsourced to Asia.

As per the opportunities, the Pacific Rim region is the fastest growing region of the AAALAC accreditation program.

AAALAC’s education and outreach program has supported annual conferences of most laboratory animal science associations and other symposia/workshops organized in the Pacific Rim region.

Most accredited programs (66% or 101 programs) belong to private organizations, and 14% (22 institutions) are academic institutions, which is lower than the overall percentage of global academic institutions (28%) and thus presents an opportunity for AAALAC.

QUESTIONS

1. According to EU regulations, the ethical evaluation of projects can be performed by:
	1. Institutional bodies
	2. External bodies
	3. Government bodies
	4. All of them
2. T/F. The Guide is a document generated by AAALAC.
3. How many primary standards, not including legislation, frame the animal care program expectations for AAALAC?
	1. 1
	2. 2
	3. 3
	4. 4
4. Currently the council of accreditation has:
5. Three sections in North America, 1 in EU and 1 in the Pacific Rim
6. 1 section in North America and 1 in the EU
7. The COA is based only in North America, but has members from other regions
8. None of the above
9. T/F. The majority of the accredited organizations of the pacific rim are located in P.R. China, Japan, India, and Korea
10. T/F. The European directive 2010/63 ensures a homogeneous approach to animal research in the EU member countries
11. T/F. One of the major opportunities worldwide for growth of the AAALAC accreditation is agricultural research

ANSWERS

1. d
2. F
3. c
4. a
5. F
6. F
7. T