



# How Different Countries Control Animal Experiments Outside Recognized Establishments

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## Summary

*An increasing number of countries now have laws, regulations, or official guidance specific to animal experimentation that include work outside of research facilities and impose constraints beyond those set by general or animal welfare legislation. These regulations etc. judge what is permissible against Three Rs criteria, and some also expect a harm-benefit analysis. Live vertebrates are covered in nearly all countries that have regulations, and some add decapods and/or cephalopods, and a few include animals killed for scientific purposes. Japan excludes fish, and in the USA only mammals (excepting Rattus and Mus species) are included in work not publicly funded.*

*The regulatory systems vary from the requirement only of a permit to a central three-level licensing system (with research establishment, scientific project, and researcher authorizations), plus local ethical review of proposed work and inspection by a national body. Most systems require a prior ethical appraisal by an establishment committee that would include work undertaken outside the research facility. For off-site work good scrutiny of proposals and records would help offset the lack of routine monitoring by animal care staff, veterinarians, and institutional management, as well as the difficulty of inspection.*

*However, controls on off-site work are absent in many countries, and, where present, they are likely to be weaker than for studies within establishments. So much depends on the researchers themselves, and employing establishments and funders can help by facilitating training and encouraging attitudes that take due consideration of the impact on the animals studied.*

*Keywords: animal experimentation, laws, regulations, guidance, work in the wild*

## 1 Introduction

The nature of certain scientific research on animals requires that the animals are studied outside of an establishment animal house or laboratory. For example, research on wild animals in their natural environment, investigation of the impact of river or coastal management on fish populations, and studies on domesticated animals under farm or home conditions that cannot be adequately replicated in a scientific establishment. This is a subset of scientific use to which a country's laws and regulations on animal experimentation will apply, but with particular considerations (among which, for work on wildlife, will be compliance with conservation and environmental legislation). The objective of this review was to consider the variety of approaches to regulation taken by a selection of countries on different continents, looking first at the control systems for animal experiments in general and then at how these might operate for work outside recognized research or testing facilities. In many countries the control system is not detailed completely in the various Acts but rather in the regulations and guidelines or codes of practice.

There are countries, chiefly in South America, Africa, and Asia where there is no national animal welfare legislation and no national control over animal experiments, whether within or outside research establishments. Others have general animal welfare legislation under which researchers undertaking stud-

ies on farms or in the wild might be prosecuted for causing excessive suffering, so there is a measure of constraint. However, many have some specific animal experimentation provisions in legislation, regulations, or national guidance. The list includes, in Africa, Kenya, South Africa, Tanzania, Uganda; in Asia, India, Japan, Singapore, South Korea, Taiwan, Thailand; in Australia/Oceania, Australia, Fiji, New Zealand, Solomon Islands; in Europe, all 27 EU Member States, plus Iceland, Norway, Switzerland, Turkey; in North America, Canada, the USA; and in South America, Brazil, Peru. Guidance may not be mandatory, but it sets a level of expectation, and where there are requirements these range from just the need for a permit to a central three-level licensing system (with authorizations for the research establishment, the scientific project, and the person carrying out the procedures), plus local ethical review of proposed work and inspection by a national body. To illustrate different approaches countries with differing systems were chosen, including one from each continent.

## 2 Selection of countries studied

The sample was restricted to those countries in which the legislation was in English or an official translation was available, and/or where there were articles in English explaining the operation



of the legislation. The UK was chosen because of its 135-year history of operation of legislation in this area; Norway as a non-EU European country, and one with a significant amount of field research, for which an account of the operation (and translation of the regulations) was provided by Smith (1998). The USA is a major player in animal research and testing, and Canada has produced internationally respected guidelines. Alberta is one Canadian province in which accord with the national guidelines is specifically incorporated into provincial regulations (Canada: Province of Alberta, 2008). Australia provided an example of a mandatory central code of practice, with Queensland an arbitrary selection for relevant state law. Japan was taken as a Far Eastern country because there are official English translations of the key documents, and it is the main country involved in scientific whaling – a particular and contentious case of work outside recognized establishments. Tanzania is one of the few African countries to have legislation in this area, and Brazil is a South American country with recent national legislation on animal experimentation, for which there is guidance in English (Marques et al., 2009).

### 3 Ethical basis

The general ethic for scientific use is well summarized in the preamble to the Council of Europe Convention ETS 123 (1986) which provides for the "... protection of live animals used for experimental and other scientific purposes." It recognizes "that man has a moral obligation to respect all animals and to have due consideration for their capacity for suffering and memory," but nevertheless accepts "that man in his quest for knowledge, health, and safety has a need to use animals where there is reasonable expectation that the result will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing, and as beasts of burden."

Where there is regulation of scientific use there is general international consensus that this should apply to painful or distressing procedures, and that the Three Rs principles should be applied, taking these as Replacement – using non-sentient material that replaces use of animals in experiments or tests, Reduction – using the minimum number of animals for the scientific objectives, and Refinement – avoiding, alleviating, or minimizing potential pain, distress and other adverse effects. EU Directive 2010/63 in Article 1 gives an international standard at which regulation would apply as "pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice," and it explicitly invokes the Three Rs by name in Article 4 (EU, 2010). The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 2004 (Australian NHMRC, 2004), the Canadian Council on Animal Care Guidelines on: animal use protocol review 1997 (CCAC, 1997), and the USA's Institute of Laboratory Animal Resources: Guide for the Care and Use of Laboratory Animals 2011 (ILAR, 2011) all include sections on the Three Rs.

In legislation the approach usually is apparent from the text. For example, Japan's Act on Welfare and Management of Animals 1973 (Japan, 2009) was amended in 2006 to include Three Rs wording "... consideration shall be given to ... alternative meth-

ods to that of the use of animals ... and reducing the number of animals ... a method that minimizes the pain and distress to the animal as much as possible shall be used" (Article 41 (1) (2)). In the UK's Animals (Scientific Procedures) Act 1986, section 5 (5) specifies that a license for a program of work shall only be granted if "... the purpose ... cannot be achieved satisfactorily by any other reasonably practicable" non-animal method and ... the "procedures to be used are those which use the minimum number of animals, ... cause the least pain, suffering, distress, or lasting harm, and are most likely to produce satisfactory results" (UK, 1998). There is Three Rs wording in Norway's Animal Welfare Act 2010 (Norway, 2010) and Tanzania's Animal Welfare Act 2008, and Brazil's Law N° 11794 (Brazil, 2008) calls for minimum numbers and minimal suffering (Article 14 s4). The USA Animal Welfare Act 1966 as amended (USC, 2009) has much on refinement, but includes minimizing numbers and consideration of alternatives, and the relevant US Federal Regulations (US CFR, 2009) expect that proposals will be examined for whether they meet requirements to refine procedures and consider replacement alternatives.

The other general ethical consideration is that studies should be subject to harm-benefit (or "cost-benefit") analysis. As put in the UK's Animal (Scientific Procedures) Act 1986 section 5 (4), this should "weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the programme" of scientific work (UK, 1998). This approach can be found in the Tanzanian Act, in Norway's Guidelines regarding the Animal Welfare Act (Norway, 2009), in EU Directive 2010/63 (EU, 2010), which the 27 EU states are in the process of transposing into national laws, and in the Australian Code (Australian NHMRC, 2004). It is implicit for some types of experiments in Article 15 of Brazil's Law N° 11794 (Brazil, 2008). Whereas in the USA and Japan, such an analysis is not a legal requirement or expected practice, there may be scope for institutions to set their own requirements. At the University of Minnesota, for example, in scientific projects involving animals "the benefits of animal use must outweigh the ethical cost" (University of Minnesota, 2011).

A harm-benefit analysis is distinct from the scientific evaluation expected for all scientific work. It allows for the possibility of studies with high scientific merit that would involve unacceptable animal suffering or the use of species (like higher primates and perhaps some cetaceans) of such high sensitivity that what is proposed is considered unacceptable. It also provokes consideration of whether studies that have scientific validity may have so little potential impact as not to be worth the amount of animal suffering involved, however mild.

These ethical considerations provide the basis for approving studies or issuing permits, and for judging compliance of work carried out.

### 4 Animals covered

With some exceptions in the USA and Japan, the law or practice in all the countries sampled covers live vertebrates; sometimes, as in UK law and the recent EU Directive, including later stages of fetal development. In the US, the Health Research Extension



Act 1985 and Public Health Service policy (US, 2002, 2004), which give requirements for publicly funded research, include all live vertebrates, but the Animal Welfare Act (USC, 2009) is restricted to warm-blooded animals, excluding rats (genus *Rattus*), mice (genus *Mus*), and birds. In Japan the authoritative Science Council Guidelines exclude fish (Science Council of Japan, 2006). Some states extend regulation to certain invertebrates in addition to vertebrates. In Tanzania “animal” includes “any invertebrate” (Tanzania: Animal Welfare Act, 2008). Norway’s Regulations on Animal Experimentation include decapods, and the 2010 Act adds squid and octopus (Norway, 2010a). The 2010 EU Directive covers cephalopods. The Australian Code refers to cephalopods (Australian NHMRC, 2004), but state law may include others and Queensland’s covers malacostracan crustaceans, citing as examples a number of decapod species (Australia: Queensland, 2009).

## 5 Controls and monitoring arrangements

Although there is much variation in detail, there are essentially two regulatory approaches: one in which there is central registration of research establishments, but approval of proposed studies, and control and monitoring of the work and personnel are delegated to the institution, and the other in which central involvement extends to the establishment, and/or the experimental work, and/or the people carrying it out. The USA provides an example of the former. Research facilities are registered, and detailed regulations set by the Department of Agriculture. Since the 1985 amendments to the Animal Welfare Act, an institutional committee has been required, whose functions include reviewing proposed studies and inspecting the work (USC, 2009). The UK is an example of the latter, with licensing at national level for the establishment, the scientific program, and the persons performing procedures on the animals. In both these countries there is external monitoring through a national inspectorate, but the UK inspectors are also involved in the approval process and ongoing harm-benefit analysis, so there is ethical appraisal at the national level. In addition, the UK, through a condition on the establishment’s certificate, mandates a local ethical review process.

Different countries have various mixes of central and local assessment and monitoring. Brazil’s Law No 11794 (Brazil, 2008) specifies an institutional Ethics Committee on the Use of Animals that registers researchers and reports to a National Council for the Control of Animal Experimentation, which may itself assess more contentious proposals. Japan’s Science Council Guidelines (2006) place responsibility for assessment and monitoring with the director of the institution, advised by an Institutional Animal Experiment Committee. Norway’s law and regulations require approval of research institutions and of proposed field studies (and certain others) by a Norwegian Animal Research Authority, but a local “competent person” approved by the Authority can evaluate many of the studies at the institution (Norway, 2010a,b). Monitoring is similarly split between the national authority and the local person. Tanzania’s law requires a permit for the person experimenting issued centrally, a matter on which the national Animal Welfare Committee could advise (Tanzania: Animal Welfare Act, 2008).

Australia’s national Code stipulates that an Animal Ethics Committee (AEC) must assess proposals and monitor the work (Australian NHMRC, 2004), and in Canada the 1993 CCAC Guide (CCAC, 1993) specifies institutional Animal Care Committees with those functions. In both countries, however, the legislation is devolved and varies between state and territories in Australia and between provinces in Canada. Queensland’s Animal Care and Protection Act 2001 (Australia: Queensland, 2009) requires conformity with the Australian Code, and its registration of researchers includes specifying which AECs will oversee the work. Alberta’s regulation 203/2005 under the Animal Protection Act 2000 requires a person owning or with “custody, care or control” of a research animal to keep to the various CCAC Guides and guidelines (Canada: Province of Alberta, 2008).

There are strengths and weaknesses of both central and delegated approaches. Placing proposal assessment and monitoring at the institutional level emphasizes local responsibility, allows for some variation in ethical approach, and promotes day-to-day monitoring, while central assessment and/or monitoring is likely to be less susceptible to local influences and more able to promote national standards. Central control at different levels also means sanctions can be applied at several levels and be tailored to be dissuasive and proportionate.

The strength of the controls is likely to depend on the extent to which they are mandatory, and in the countries surveyed there is a range from local voluntary arrangements in Japan to full legal sanctions against the persons involved, as in the UK and Queensland. Commonly it is the institution that is accountable and expected to apply its own disciplinary measures. Another important factor in the robustness of a system of controls is the independence and expertise of those involved in applying them. For an institution, or a national system with a small expert base, one risk in the appraisal of studies outside the establishment is that the only scientists with relevant expertise may well be the proposers themselves.

The importance of monitoring was highlighted by the FELASA Working Group Report on Ethical Evaluation (FELASA, 2005), which stated “For effectiveness and credibility, it is vital that all ethical review processes have means of ensuring that their decisions actually are implemented, and their recommendations given due weight, in practice. The power to stop animal studies, when, for example authorisations are exceeded or unexpected adverse events occur that prejudice their justification, should be built into the process.” Good monitoring and inspection are essential for this. The prospective evaluation decisions presume adequate monitoring and inspection; without it, prospective evaluation and approval may educate but not be respected in practice. As indicated above, the level of monitoring is highly variable, ranging from reliance on reports of concern from members of the public through firm and knowledgeable institutional monitoring to a full-scale national inspection program with site visits sufficiently frequent to detect problems.

## 6 Particular considerations for work outside recognized establishments

General ethical considerations are the same, irrespective of the place where the scientific work is carried out. However, for wild-



life work a harm-benefit analysis may need to include effects on animals other than those studied, e.g., from habitat disturbance or altered behavior of animals released after sampling. In many of the countries considered, the system expects the research facility to bear a measure of responsibility for the scientific work on its premises, but there also is recognition that studies may have to take place outside the establishment, and that the institution's responsibility extends to work outside undertaken by those for which it has management responsibility.

However, the ability to exert control and monitor activities is different off-site. A research or testing facility may be considered to have five roles related to the animals, with differing responsibilities. There is the person doing the procedures who should minimize adverse effects of the procedures on the animals; the person planning and supervising the study and responsible for the good conduct of the science; an institutional manager in charge of the facility, who provides housing and care and is responsible for its standards and smooth operation; a veterinary surgeon providing professional advice and expertise; and a person looking after the day-to-day care of the animals. The expertise needed and the relationship to the animals is different in each case. Ideally there would be a different person in each role.

Work outside recognized establishments falls into two main categories: studies undertaken at places such as farms that are not research facilities, and work in the wild. The former usually would have someone in charge of the facility, staff caring for the animals, and a veterinarian who can attend on site. These persons, however, would not be under the management control of the research institution, and the local staff's standards, culture, and training may be quite different. For work in the wild, three of these roles (manager, care provider, and veterinarian) would normally be absent, placing more responsibility on the researchers themselves, so keeping of good records and inspection of these and the conduct of the work on site is particularly important.

Studies in the wild also present particular difficulties. It may be harder to reduce numbers by efficient design and to refine procedures. For example, there is likely to be bias in what is captured or observed, and the ability to reduce or apportion variation is limited. Capture is likely to cause stress and other adverse effects – as may the presence of an observer. The after-effects of a procedure may be difficult to judge or offset. An animal released after procedures may be at a social, mating, or foraging disadvantage, and the risk and extent of this may be unknown. Killing the animal as a way of limiting suffering may not be an option.

In addition, there are practical difficulties in monitoring by inspection. Seeing the work in progress depends on knowing where and when it is taking place. Inspection involves locating the site and timing a visit to coincide with regulated activity. For wildlife investigations, and for some farm studies, this may change from day to day. If an inspector joins the research team, as is necessary for many visits to remote or controlled locations or for much marine work, he/she may have difficulty remaining objective, particularly if this entails many days of living with the team.

With these difficulties, closer scrutiny might be expected, and inspection of off-site work might be given a priority not based

simply on the severity of the study. However, work outside recognized research facilities may not even come within the regulations, if only the studies carried out in an establishment are considered regulated, or if the animal concerned is not covered, or the procedures are not considered to come above the threshold of pain or distress at which regulation applies.

Most of the legislation or regulations sampled had some recognition that certain work could take place outside establishments and would be covered by the general controls. In the UK the recognition is by exemption, on scientific grounds, from the requirement to undertake scientific work on animals at a recognized facility, and EU Directive 2010/63 (Article 12) takes the same approach (EU, 2010). Norway's regulations (Norway, 2010b) and Australia's Code (Australian NHMRC, 2004) both have a specific section on field experiments, and there are CCAC guidelines on the care and use of wildlife (CCAC, 2003). In the USA, publicly funded work would cover wildlife studies on all vertebrates, and the Institute of Laboratory Animal Resources Guide (ILAR, 2011) recognizes that there are particular considerations for work on agricultural animals and in the wild. However, under the US Animal Welfare Act, although field studies are mentioned, the definition of "animal" excludes birds, amphibians, reptiles and fish, so studies on these that were not publicly funded would be outside regulation (USC, 2009). For the animals that are covered, the regulations exclude non-invasive field studies, so any consideration of the impact on the animals through habitat disturbance would be outside the ethical review. For field studies that are within the regulations, institutions can be exempted from the requirement to inspect. In Japan much depends on the director of the institution, but any studies on fish would be excluded.

## 7 Conclusions

The general picture is that, for scientific studies outside recognized establishments, controls under legislation or regulation are absent in many countries, vary in robustness in those countries that do have them, and are likely to be weaker than for studies carried out at a research facility. However, these controls are not the only ones. Conformity with national guidance, even if not mandatory, may be necessary to secure funding. Furthermore, editorial policy on what is considered publishable may exert an influence, and there may be expectations from peer groups and local culture.

In the several countries where prior ethical appraisal is required, at the national, regional or institution level, there is scope to promote good standards of animal welfare and science. Much depends on the approvers establishing that they have a legitimate interest in work carried out outside the establishment, asking probing questions, expecting good records, scrutinizing these, and making sure they inform the next decision on approval. Also, inspection or monitoring of work in progress would help provide reassurance on the conduct of the studies. However, even with the best controls, application of the Three Rs depends heavily on the researchers, and improving this involves addressing their knowledge, skills, and attitudes. Establishments and funding agencies can play an

important role in this by facilitating training and encouraging attitudes that take due consideration of the impact on the animals studied.

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