



## POSITION STATEMENT ON GLOBAL STANDARDS FOR THE CARE AND USE OF ANIMALS IN LABORATORIES

### PREPARED BY THE INTERNATIONAL COALITION FOR ANIMAL WELFARE

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The International Coalition for Animal Welfare (ICFAW), on behalf of the more than 12 million supporters of our member organizations,<sup>1</sup> welcomes the decision by the OIE Animal Welfare Working Group to set up a group on animals in laboratories with the intention to:

- provide guiding principles to develop standards for animals in laboratories;
- make recommendations for future strategies on animals in laboratories;
- advise on how to assist and support OIE member countries; and
- advise on strengthening links between key stakeholders.

Standards for the care and use of animals in laboratories differ greatly from country to country, as do systems for oversight of these activities. Member states of the European Union, as well as Australia, Japan, New Zealand, the United States, and several other countries, have promulgated national legislation to regulate, by varying degrees, the care and use of animals used in research, testing, education and training, and production of biological materials. However, many OIE members do not have any specific legislation or enforceable national standards relating to the use of animals in laboratories. ICFAW will comment on the four areas as laid out above.

#### Guiding Principles to Develop Standards for Animals in Laboratories

ICFAW recommends that these principles should include the following areas:

#### Scope in Relation to Species Covered

Many countries recognise the need to protect all 'living vertebrates' within the scope of their legislation concerning animal experiments. Some, however, have gone further by including certain classes of invertebrates (e.g., Canadian standards recognise the sentience of cephalopods, and the European

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<sup>1</sup> The member organisations of the International Coalition for Animal Welfare, representing more than 12 million individual supporters internationally, include: Compassion in World Farming, Eurogroup for Animals, the Humane Society of the United States and Humane Society International, the International Fund for Animal Welfare, the Japanese Farm Animal Welfare Initiative, the National Council of SPCAs, the Royal Society for the Prevention of Cruelty to Animals, and the World Society for the Protection of Animals.

Commission is currently proposing to extend protections not only to cephalopods, but also decapods and cyclostomes) and foetal animals while others (e.g., United States and Japan) provide protection for only selected mammalian and avian species.

**ICFAW Recommendation:** The OIE guidelines should cover 1) all vertebrates (free living and in the final trimester of development) and 2) invertebrate species who are believed to be sentient.

#### **Scope in Relation to Procedures Covered**

Some countries' legislation provides comprehensive coverage of all animal use for scientific purposes (i.e., basic and applied research, testing, education and training, and production of biological materials). In many cases, however, there are gaps in coverage).

**ICFAW Recommendation:** The OIE guidelines should cover 1) all aspects of the animals' lives, including breeding/capture, transportation, housing, husbandry and euthanasia; 2) their use in all procedures related to research, testing, training and education; and also 3) animals used or killed for the primary purpose of harvesting biological material.

#### **Minimum Standards for Animal Housing**

ICFAW believes that, for as long as animal use continues, it is essential to provide high quality housing and husbandry that meets animals' physical, psychological and social needs, and allows them to express a wide range of natural behaviours. Inappropriate husbandry can cause serious animal suffering in the form of boredom, anxiety, fear or frustration—in some circumstances this can cause more distress than the scientific procedures themselves and such suffering can have a negative impact on the quality of research and testing. A number of laws regulate the space requirements for animals in laboratories. These present the *minimum* requirements, not the *optimum* requirements. The 'quality' of the environment is also critically important; animals need a complex environment with the provision of environmental enrichment. Guidance should be provided on both space allowances and enrichment standards.

**ICFAW Recommendation:** All animals should be provided with accommodation and care appropriate to the physical, psychological and social needs of the species, allowing for freedom of movement, the expression of a wide range of natural behaviours, and adequate food and water.

#### **A Procedure to Agree a Cost/Benefit Analysis of the Use of the Animal**

It is essential that each and every project involving animal use undergoes a critical ethical review. This involves identifying and weighing the potential costs or harms to the animals against the potential benefits of the experiment, and so encourages a more critical assessment of the necessity and justification for animal use. The ethical review also requires detailed consideration of all opportunities for implementing the 3Rs as a means of limiting the negative impact on the animals—by reducing the numbers of animals used, refining procedures to minimize or eliminate suffering, and wherever possible avoiding or replacing animal use. Since poor animal welfare affects the quality of scientific results, the process of ethical review benefits science as well as animal welfare. Retrospective review of research projects is also essential, since this informs future cost/benefit assessments and contributes to ongoing application of the 3Rs.

**ICFAW Recommendation:** Ethical review must be a mandatory part of the process of licensing and control of animal use. This should include representation from members independent of the establishment, and those whose primary concern is animal welfare. The ethical review must include a cost/benefit analysis, taking into account all potential harms to animals throughout their lifetime experience. Physical and psychological harms should be considered during all stages of animal use, including those associated with breeding/capture, transport, housing, husbandry, handling, procedures and their effects, and euthanasia. Appropriate experimental design and implementation of all 3Rs (replacement, reduction and refinement) are also key factors that must be addressed. Local and national processes should authorise projects only where the research

benefits are likely to outweigh the harms to animals. Individuals vary in their perception of the relative values of harms and benefits, and so ethical review should incorporate a variety of perspectives to ensure a fair assessment.

### **Strictly Limiting the Re-use of Animals**

ICFAW accepts that under certain limited circumstances, animals who have previously been used in a minor procedure may be re-used in a second and unrelated experiment in the interests of achieving an overall reduction in animal use. However, the goal of reduction should not come at the expense of the welfare of an animal previously used.

**ICFAW Recommendation:** The OIE guidelines should stipulate that an animal already used in a procedure may only be re-used in a second and unrelated experiment if 1) the first procedure was classified as 'mild'; 2) it is demonstrated that the animal's general state of health and well-being has been fully restored; and 3) the further procedure is classified as 'mild' or 'non-recovery'.

### **Promotion and Mandatory Use of 3Rs (Replacement, Reduction and Refinement) Methods**

Whereas EU legislation prohibits experiments on animals where alternative methods are reasonably and practicably available, no other country has implemented such a requirement on a large scale. Consequently, available replacement, reduction and refinement measures are being greatly underutilised (e.g., in regulatory testing). There is also inadequate funding and co-ordination of research aimed at the further development and application of the 3Rs in all areas of animal use for scientific purposes other than toxicity testing.

**ICFAW Recommendation:** The OIE guidelines should require full use of available 3Rs methods, with an emphasis on replacement, and encourage member countries to develop overarching national strategies for the replacement of all animal use for scientific purposes. In the interim, the 3Rs principles should be incorporated into all national and sectoral legislation impacting the use of animals for scientific purposes, and regulatory testing requirements should be revised regularly to incorporate valid alternative methods.

### **A System of Supervision and Control**

It is essential that a responsible authority is agreed for the authorisation and control of the use of animals. This should cover authorisation of establishments, projects and persons, and correct conduct of the ethical review, as well as giving powers of sanction to revoke such authorisation in cases of non-compliance. In the past decade, progress has been made in a number of countries to widen the consultation process to include a panel of relevant experts from the academic, business, user and animal welfare communities. These ethical review panels allow for further transparency and inclusion regarding authorisation of animal experiments.

**ICFAW Recommendation:** The OIE guidelines should call for a clearly defined and effective system of licensing, control and inspection covering animal breeding and supplying establishments, as well as those conducting the experiments. Ethical review panels should be established in all OIE countries at both a national and local level.

### **Meaningful Data Collection and Data Sharing**

Greater transparency and accountability in relation to animal use is essential to ensure accurate monitoring and identification of key issues of concern and general trends. This requires the production of informative statistics of animal use on an annual basis, and a database of comprehensive summaries of all authorised projects. Both must include meaningful information regarding the nature, level and duration of animal suffering, and the purpose of the experiments. As well as openness regarding the use of animals, transparency in terms of the way animal experiments are regulated is also essential. The public should be able to judge whether it has confidence in the nature of the regulatory process, including the way that

decisions are made regarding the justification for animal use, who makes such decisions, and the criteria used. Transparency with regard to decisions to fund research is also very important. Governments, industry, research funders and scientists using animals are all accountable in these respects.

**ICFAW Recommendation:** There should be a system of transparent data collection and disclosure at a national level. These data should be comprehensive and meaningful to enable inter-country comparisons to be made. Levels of suffering (taking duration into account) must be reported in the statistics as a contribution to transparency and openness. All countries and companies should make a commitment to share data to reduce the duplication of procedures on animals.

### **The Training of Personnel Who Handle the Animals and Supervise the Experiments**

An assurance that any personnel working with animals are properly trained in the principles of animal care and ethical issues (particularly the application of the 3Rs principles) is essential not only to protect the welfare of the animal but also to enhance the reputation of the institution. There should be adequate veterinary care to ensure the welfare of the animal before, during and after any procedure. This care should cover preventative programmes, disease surveillance and monitoring for abnormal behaviours, as well as advice on humane endpoints and euthanasia.

**ICFAW Recommendation:** The OIE guidelines should stipulate that all persons involved with animal use must have appropriate education and training, and be competent in the necessary skills relevant to their responsibilities. This includes personnel responsible for the design and/or conduct of procedures, animal accommodation and care, and the health and welfare of all breeding, stock and experimental animals. Education and training covers knowledge, skills and attitude. The guidelines should specifically cover measures for veterinary care including what responsibilities and advice these would entail.

### **Sources of Animals**

Whilst there is a range in the existing legislation of animals who cannot be used in experiments, ICFAW recognises that some animals are bred for use. Certain legislation, such as in the European Union, already prohibit the use of stray dogs and cats.

**ICFAW Recommendation:** There should be a system of authorisation and control of breeding and supplying establishments. All species commonly used in laboratory research such as rodents, rabbits, dogs, cats and non-human primates should be obtained from a breeder of these animals. Acquisition of domestic animals, such as cats and dogs, from random sources should be prohibited.

### **Exclusion of Certain Species**

The numbers of great apes being used in laboratories has declined over the past few decades, an acknowledgement of their sentience and underlining the capacity to exclude certain species from use.

**ICFAW Recommendation:** Great apes should not be used and replacement of all primates should be an urgent priority.

### **Fate of Animals**

It is important that the care of animals used in laboratories extends to their end fate such as humane euthanasia or re-homing. Standards should include methods, training and authorisation of personnel and other alternatives to euthanasia. The role of the veterinarian in this aspect will be crucial.

**ICFAW Recommendation:** All animals slated to be killed in an authorised establishment should be euthanised by a person trained and competent in the appropriate methods of euthanasia which should be clearly defined. The veterinary care should include recommendations on end points and euthanasia to ensure all endpoints are humane and that animals are killed with the minimum level

of pain and distress. Consideration should be given to re-homing animals. Re-homing schemes need to be carefully set up and in the best interests of the animals concerned.

### **Levels of Suffering in the Procedure**

There should be a system for objectively categorising the level of animal suffering which covers both the nature and duration of pain, distress and suffering, and takes into account the lifetime experience of the animal. Levels of suffering must be defined in the Guideline and used to inform the ethical review and authorisation process. The level of suffering that *actually* occurs must be assessed and used to inform future ethical reviews and to help drive implementation of the 3Rs. Levels of suffering must be reported in the statistics as a contribution to transparency and openness.

**ICFAW Recommendation:** Levels of suffering should be defined, and those levels at and above which animals experience substantial or severe pain, distress or suffering should not be permitted.

### **Recommendations for Future Strategies on Animals in Laboratories**

The OIE should acknowledge that 1) any agreement on the first OIE standards on the use of animals in laboratories should be only the first step; 2) there needs to be a holistic approach to ensuring implementation and enforcement of the standards; and 3) the standards are being implemented in the member countries of greatest need. Such an approach can only occur with all stakeholders involved. The OIE, with 172 member countries, is uniquely placed to achieve this.

**ICFAW Recommendation:** ICFAW believes that future strategies on animals in laboratories agreed by the OIE should be undertaken after there is a strategic assessment on the numbers of animals, trends in these numbers and the severity bands of procedures undertaken. These assessments should be done on a regional basis. It is expected that OIE countries will face challenges on implementing and enforcing any global standards (see below). A regular review is essential to monitor progress and focus assistance on those countries and regions where it is most required. Once this has been completed, reassessing the guidelines can be undertaken.

### **Advisement on How to Assist and Support OIE Member Countries**

**ICFAW Recommendation:** Support is expected to be necessary in many of OIE member countries. The OIE should undertake an analysis of its members and map current use and trends in animals against current legislative and policy tools. Based on this information, it should agree regional assistance for the most important countries (i.e., those countries where large numbers of animals are used and implementation and enforcement of the guidelines are poor). This assistance could include running training courses: 1) for drawing up legislative requirements, 2) for enforcement and inspection personnel, and 3) for those involved in ethical review processes and the use and supply of animals. ICFAW is prepared to assist in this and already undertakes courses in countries such as Poland, Republic of Korea, and Taiwan for members of ethical review panels and for inspectors.

### **Advisement on Strengthening Links Between Key Stakeholders**

**ICFAW Recommendation:** ICFAW believes collaboration amongst all stakeholders is important and that a key stakeholder group should be set up on a regional and national level both to oversee implementation of the guidelines and to discuss recommendations to the OIE Regional Boards for forwarding to the OIE General Assembly as part of the review of the implementation and effectiveness of these Guidelines. The group could operate on similar representation to the ethical review panels (i.e., balanced representation of animal welfare groups, business, the user community, academia and lay persons).