

NATIONAL CHARTER ON THE ETHICS OF ANIMAL EXPERIMENTATION *

PREAMBLE

Given that animals are sentient beings, subject to suffering, with cognitive and emotional capacities and physiological and behavioural needs specific to each species,

Given that alternatives to the use of animals for research, teaching and regulatory testing are not always available,

Given that in all experimental activities, humankind should go beyond the unique application of regulations for the protection of animals used for scientific purposes,

Given that, to address this expectation, animal experimentation ethics committees have been created by public and private institutions and those committees should operate under shared principles,

Given that these committees formulate their opinions based on the principles of a charter as described in Articles R. 214-117, R. 214-119 and R. 214-134 of the French Rural and Maritime Fishing Code,

The Comité National de Réflexion Ethique sur l'Expérimentation Animale (French national committee for consideration of ethics in animal experimentation) proposes the following Charter to serve as a reference for those involved in animal experimentation, institutions and ethics committees.

Article 1: Respect for the animal

Ethics in animal experimentation is based on the duty of humankind to respect animals as living and sentient beings, subject to experiencing pain, suffering and distress.

Article 2: Individual responsibility

Any use of animals in experiments engages the moral responsibility of each person involved.

Article 3: Responsibility of institutions

Institutions are morally responsible for experiments carried out on animals in their premises or on their behalf.

Article 4: Competencies

Responsibility implies, at all levels of intervention, regularly updated ethics training and regulatory, scientific and technical proficiency appropriate to the species used.

Competencies should be solicited as often as necessary from specialists in the physiology, ethology or medicine of the animals concerned.

Article 5: General principles

Careful consideration of the scientific, ethical and societal justification for using animals is required before any experimental approach.

Methods and techniques aimed at eliminating or reducing to an absolute minimum the harm done to animals must be sought systematically. The development and promotion of these methods and techniques should be widely encouraged.

** Charter proposed by the Comité National de Réflexion Ethique sur l'Expérimentation Animale (French national committee for consideration of ethics in animal experimentation) in 2008 and updated in 2014. The term 'animal experimentation' is used in accordance with current French legislation (Article R 214-87 et seq. of the French Rural and Maritime Fishing Code)*

The concern to optimise the living conditions, housing and care of the animals used should be permanent and expressed throughout their lives.

The opinions of an ethics committee must be requested before conducting any experiment involving animals.

Article 6: Ethical approach for animal experimentation

Before undertaking any experiment involving animals, careful consideration of the following items must be taken:

- the absence of adequate alternative methods to pursue an identical objective,
- the usefulness of the planned experiment with respect to studies performed by others,
- the relevance of the chosen methods and the probability that they will yield tangible results,
- the suitability of the animal models in pursuit of the specified scientific objectives pursued,
- the extent of animal suffering relative to the expected results,
- the biological and cognitive characteristics of the concerned species,
- the choice of species, where non-domestic species are involved, so that they do not threaten biodiversity,
- the use of the smallest possible number of animals,
- the choice of the living, housing, care and use conditions of animals, such that their physiological and behavioural needs are respected as much as possible.

Article 7: The role of animal experimentation ethics committees

Ethics committees must serve as a forum for open dialogue and reflection.

They shall give opinions on projects using animals for scientific purposes, abiding to the principles set out in the present Charter.

These opinions shall be justified and may be accompanied by recommendations.

Ethics committees shall participate to the promotion of the ethical principles laid out in this Charter.

Article 8: Composition of animal experimentation ethics committees

Ethics committees bring together multidisciplinary expertise to enable the formulation of fully informed opinions.

They include representatives from civil society and veterinary medicine.

Article 9: Professional conduct of animal experimentation ethics committees

Ethics committees shall exercise independence and impartiality and shall guarantee the confidentiality of documents submitted to them.

They shall take into account the opinions or recommendations of the *Comité National de Réflexion Ethique sur l'Expérimentation Animale*.

APPENDIX

to the National Charter on the Ethics of Animal Experimentation

This annexe presents modalities for the implementation of the National Charter on the Ethics of Animal Experimentation (the Charter) developed by the *Comité National de Réflexion Ethique sur l'Expérimentation Animale* (French national committee for consideration of ethics in animal experimentation; "CNREEA" hereafter). It is intended for ethics committees, all personnel involved in animal experimentation and their associated institutions.

I. ROLE

Animal experimentation ethics committees are competent authorities. As such, their mission is to carry out the mandatory ethical evaluation of projects submitted to them in accordance with the principles laid out in the Charter. Furthermore, the Charter establishes a role for ethics committees in promoting all ethical principles and practices in animal experimentation.

Any establishment using animals for experimental purposes ("user establishment") must be affiliated with a unique ethics committee. Several user establishments may associate with each other to create a joint committee.

II. STRUCTURE AND OPERATIONS

In conformity with Article R.214-118 of the French Rural and Maritime Fishing Code, the minimal composition of an ethics committee includes:

- one person whose function is to design experimental procedures and projects,
- one person whose function is to carry out experimental procedures on animals,
- one person who ensures competencies in the care and killing of animals,
- one veterinarian,
- one person not specialised in matters relating to the use of animals for scientific purposes.

Additionally, an ethics committee requires:

- a **multidisciplinary representation** that allows the expression of a plurality of sensibilities,
- a **competency** that is in line with the field(s) of activity of the user establishment(s) referring to the committee. If necessary, the committee may call upon external expertise,
- the obligation for all its members to respect the **strict confidentiality** of the debates and experimental projects discussed,
- the necessary **independence** and **impartiality** to justify and elaborate its opinions freely. To this end, members of the ethics committee volunteer for the function and do not receive any compensation specifically attached to the mission.

Finally, the composition and organisation of an ethics committee must ensure its essential **reliability**.

III. IMPLEMENTATION

The institutions with which the user establishments are associated will provide the ethics committees the means necessary to fulfil their roles.

Ethics committees ensure that they can provide their responses in a **timely manner** compatible with the requirements of both the applicable regulations and the research activity.

Projects are submitted to all ethics committee members for opinion.

a) Ethical evaluation of projects submitted for authorisation

The ethical evaluation of projects aims at ensuring that projects are justified, that their objectives absolutely require the use of animals and that experimental procedures are carried out under state-of-the-art conditions for the animals. This evaluation is necessary and must take place prior to the delivery of the project authorisation by the minister in charge of research who has referred the matter to the relevant committee.

The minimal components of a project are an objective (which may be scientific, educational or regulatory), an animal model, and an experimental procedure. Experimental procedures are classified according to their degree of severity (mild, moderate, severe, non-recovery).

During the ethical evaluation of a project, the committee analyses the objective presented in order to determine the ethical acceptability of the chosen model and the associated experimental procedures and methodology. However, ethics committees cannot act as a substitute for the science or education committees of an institution.

The **ethical evaluation** is based on various aspects of the experiment:

- the preparation of the animal,
- the choice, development and use of the animal model,
- the detailed experimental protocol, which must address animal sentience and species-specific features, and describe clearly the impact of experimental procedures on the physiological and psychological state of the animals,
- the degrees of severity and humane endpoints, which must be specifically identified in the protocol, and the measures planned for the prevention and management or even the removal of suffering, notably pain, to the greatest extent possible. These latter measures must be diligently documented and based on recognised benchmarks,
- the use of statistical tools and/or appropriate analytical techniques to optimise the experimental methods used and to generate the maximum number of interpretable results.

The **opinions** of ethics committees are valid for a maximum of five years.

Those involved in animal experimentation and user establishments are responsible for monitoring the implementation of experimental procedures.

b) Participation in the promotion of ethics principles

Ethics committees must participate in the promotion of the ethical principles set forth in the Charter, particularly when animals other than those in the scope of mandatory project authorisation are used.

Ethics committees must endeavour to disseminate as widely as possible the knowledge and experience acquired in the field of animal experimentation and alternative methods, even when results are not published.

IV. RELATIONSHIP WITH THE CNREEA

Ethics committees for animal experimentation must be accredited. To this end, the ethics committee chairperson sends the ministry for research** an application for approval which includes the elements laid out in Article 1 of the French Order of 1 February 2013 concerning the ethical evaluation and authorisation of projects involving the use of animals for scientific purposes. In particular, the ethics committee chairperson will provide a signed declaration indicating the commitment of all committee members to uphold the principles of the Charter.

The elements included in the application are strictly confidential and stored at the ministry for research; under no circumstances will they be published.

Any changes concerning the composition of an ethics committee, or the list of user establishments affiliated with it, must be communicated to the ministry for research.

Ethics committees will provide an annual activity report to the CNREEA.

Ethics committees will share with the CNREEA any progress they observe that is likely to improve the welfare of animals and to reduce or even eliminate the suffering imposed on laboratory animals.

Ethics committees commit to take into account the recommendations and opinions issued by the CNREEA.