



Presidenza del Consiglio dei Ministri

ITALIAN NATIONAL BIOETHICS COMMITTEE

**ALTERNATIVE METHODOLOGIES, ETHICS
COMMITTEES AND CONSCIENTIOUS OBJECTION TO
ANIMAL TESTING**

18th of December 2009

INTRODUCTION

The opinion analyses methodologies alternative to animal testing in the context of the 3Rs model (replacement, reduction and refinement of experimentation methodologies applied on animals). The NBC, in line with the Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes and with other international documents on this topic, believes that it is advisable to limit animal testing to what is strictly necessary, reducing their number and controlling suffering and harm, and it expresses the hope for a development of the research and the application of alternative methodologies. The Committee clarifies that the document has not taken into consideration research on human embryonic stem cells as an “alternative” to animal testing, as it feels that the two experimentation methods are not equivalent either from a scientific or an ethical point of view.

The opinion focuses on ethics committees for animal testing, with particular reference to their establishment, composition and social relevance, hoping for a national and international coordination. In addition, the NBC analyses the 1993 Italian Law n° 413 “Regulations on Conscientious Objection to Animal Testing” which recognises that Italian citizens have the right to declare their conscientious objection, recommending that it is publicised, and that adequate formative avenues are set up (also contemplating the teaching of alternative methodologies at university). In the appendix we publish the results of an investigation (conceived and organised by Dr. Maria Paglia) carried out at the scientific faculties of Italian universities in order to monitor the state of application of the Law.

The document has been coordinated by Prof. Luisella Battaglia, with the contribution of Prof. Salvatore Amato, Prof. Adriano Bompiani, Prof. Cinzia Caporale, Prof. Lorenzo d’Avack, Prof. Riccardo Di Segni, Prof. Silvio Garattini, Prof. Laura Guidoni, Prof. Assunta Morresi, Prof. Demetrio Neri, Prof. Giancarlo Umani Ronchi. During the working group’s discussion Prof. Thomas Hartung, Prof. Rosagemma Ciliberti, Prof. Simone Pollo, Prof. Anna Laura Stammati, Prof. Flavia Zucco were consulted.

During the discussion at the plenary meeting, Prof. Luisella Battaglia, Prof. Adriano Bompiani, Prof. Stefano Canestrari, Prof. Roberto Colombo, Prof. Francesco D’Agostino, Prof. Antonio Da Re, Prof. Lorenzo d’Avack, Prof. Riccardo Di Segni, Prof. Carlo Flamigni, Prof. Romano Forleo, Prof. Silvio Garattini, Prof. Laura Guidoni, Prof. Luca Marini, Prof. Assunta Morresi, Prof. Demetrio Neri, Prof. Andrea Nicolussi, Prof. Laura Palazzani, Prof. Vittorio Possenti, Prof. Rodolfo Proietti voted in favour of the document. Prof. Cinzia Caporale voted against the document. Prof. Salvatore Amato and Prof. Marianna Gensabella, absent from the plenary meeting, communicated their agreement with the document.

The document is accompanied by a personal remark by Prof. Francesco D’Agostino.

The President

Prof. Francesco Paolo Casavola

PREMISE

1. THE 3Rs MODEL
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3. THE PROTECTION OF ANIMALS IN SCIENTIFIC RESEARCH AND THE ROLE OF ETHICS COMMITTEES FOR ANIMAL TESTING
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Premise

The document comes from the need to bring together, in a balanced and shared way, different values, all worthy of recognition, for example man's wellbeing, the promotion of scientific research, the reduction of suffering for animals subjected to testing, animal welfare in case of veterinary experimentation, and respect for the researchers' personal convictions. So far, animals have had, and will be probably continue to have, a fundamental role in scientific experimentation, but their declared usefulness in the development of knowledge does not diminish our duty to reduce their pain, suffering and harm to a minimum.

In scientific research, animals can be used:

- for general research, aimed mostly or solely to broadening knowledge;
- for research aimed at maximising human benefits (e.g. in order to trial drugs primarily aimed at curing human pathologies);
- for research aimed at maximising benefits for the animals on which the testing is carried out or for similar species (e.g. to test veterinary drugs).

It must be mentioned that currently they are used, for example:

- a. to understand physiological functions, biochemical mechanisms and the complex regulation of hormonal, circulatory and nervous systems, which can only be studied in a living organism;
- b. to create models of human pathology, using techniques of genetic engineering to develop diagnostic tests and therapeutic strategies for the treatment of man and animals;
- c. to study the toxic effects induced *in vivo* by drugs, prostheses, medical devices, food additives and polluting substances;
- d. very rarely for didactic purposes.

In case of commercialisation of pharmaceutical products and more in general of health products, mentioned in points (b) and (c), the Law makes it compulsory to first test them on animals.

Animal testing in Italy is regulated by a series of directives, starting with Legislative Decree 211/92 and the following modifications introduced by the 1993 Ministerial Decree (Legislative Decree n° 116, 27th of January 1992. Implementation of Directive n° 86/609/EEC regarding the protection of animals used for experimental or other scientific purposes). In addition, we must also consider the European Community Recommendation of the 18th of June 2007 relative to the *Guidelines for the accommodation and care of animals used for experimental or other scientific purposes* 2007/526/EC

(published in the Official Journal of the European Union L197, 30th of July 2007). The recommendation is applied to all types of experimentation for scientific purposes, also including research for veterinary use, defining experiment as: “the use of an animal for experimental or other scientific purposes which may cause pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition, but excluding the least painful methods accepted in modern practice of killing or marking an animal, commonly accepted as humane; an experiment starts when an animal is first prepared for use and ends when no further observations are to be made for that experiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesic or other methods, does not place the use of an animal outside the scope of this definition”.

The regulation explicitly contemplates that animal testing is carried out only if “another scientifically satisfactory method of obtaining the result sought, not entailing the use of animals, is (not) reasonably and practically available”. The Decree also tries to regulate animal testing, so that it is carried out by qualified personnel in order to minimise suffering, and that the animals are reared and stabled in adequate conditions. The testing is subjected to procedures that include the obligation to notify the ministry of all experimentations. In some cases, for example when the testing involves dogs, cats and non human primates (article 8), it is necessary to have the technical opinion of the Superior Institute for Health.

The experimentation can therefore be considered inadequate both by the Ministry and the Superior Institute for Health, and consequently not be authorised. The procedures must guarantee that the testing is in line with the principle of justification and that the tests are carried out with the least number of animals, with animals that have the lowest neurological development, with methods that involve the lowest level of pain, possibly using anaesthesia, and that, in any case, experimental protocols with the highest probabilities of giving sufficient results are chosen.

The National Bioethics Committee has already tackled more than once questions regarding animal bioethics¹ in which these issues have been mentioned, even if marginally. This document expressly concentrates its attention on two particular aspects: the study, the dissemination and the implementation of methods alternative (A.M.) to animal testing, and the question, strictly connected to this problem, of ethics committees and conscientious objection (C.O.)². This focus is justified both by the new and promising horizons offered by the development of advanced research methods, and by the significant change that the legal framework has undergone in these last years, gaining a strong ethical connotation with regards to recognising animal welfare. Life in all its facets has an immense bioethical value and animal life, in particular, deserves consideration and

¹ Documents and Opinions: *Caudectomy and conchectomy* (2006); *Bioethical Problems concerning the use of animals in activities linked to human health and well-being* (2005); *Ritual slaughtering and animal suffering* (2003); *Bioethics and veterinary science, animal wellbeing and human health* (2001); *Bioethical guidelines for ethics committees* (2001); *Opinion on the proposal for the moratorium on human Xenotransplantation clinical trials* (1999); *Animal testing and health of living beings* (1997); *Drugs' trials* (1992).

² Particular thanks go to Prof. Rosagemma Ciliberti, Prof. Thomas Hartung, Prof. Simone Pollo, Prof. Anna Laura Stamatati and Prof. Flavia Zucco, for their contribution to the Working Group.

respect. Inflicting futile, useless, cruel, disproportionate suffering to animals for experimental purposes is absolutely unacceptable, in particular if alternative experimentation methods can be found or promoted.

1. The 3Rs model

The hope of considerably reducing and, in some cases, eliminating the use of animals in testing, is summarised in the “3Rs system”: *Replacement, Reduction, Refinement*, formulated by William Russell and Rex Burch in the volume “The Principles of Human Experimental Technique” (1959). With this trinomial it is respectively intended:

- 1) the “replacement” of animals used in experimentation with alternative methods or, if this is not possible, the use of animals with a lower neurological development;
- 2) the “reduction” of the number of animals to the minimum quantity necessary to obtain scientifically reliable data;
- 3) the “refinement”, that is, the perfecting of procedures that would allow reducing to a minimum the animals’ suffering, distress and harm.

The book by Russell and Burch mostly addressed the scientific community that, in effect, from that moment started to dedicate more attention to the problem of how to employ more “humane” procedures in the treatment of test animals, a problem also developed by the same researchers in relation to the advancement of knowledge. The impulse to tackle the issue of Animal Testing (A.T.) in the wider sense, putting it in a specific bioethical perspective, starts however only in the 1970s, on the wave of publications destined to impose animal issues on the philosophical stage.³

In these years the use of the term “alternative” started to indicate an option in substitution to a given system and not simply another possibility. Therefore, it is not surprising that in 1978 David Smith put forward again the 3Rs model in the volume “Alternative to animal experiments”: a diction that has been considered ambiguous, as it would make us think of the immediate possibility of abolishing animal testing, which, in reality, is not what the 3Rs model proposes.

In 2002 the European Commission financed a bioethics project on “Quality of life” titled “Animal Alternatives: Scientific and Ethical Evaluation” (ANIMALSEE) with the precise task of updating the 3Rs system.

This interdisciplinary project – to which biologists, ethologists, philosophers, pharmacologists and toxicologists participated – has had the merit of allowing an effective dialogue between scholars of different disciplines. This discussion led to a clearer and more shared definition of A.M. and it has shown how the 3Rs model is strongly rooted in a bioethical prospect centred on protecting animal welfare without damaging the interest of the patients awaiting effective therapies.

A combined analysis of the ethical and scientific aspects of testing ensued, which allowed the scientific community to open up to a serene discussion about the issues raised by civil society. We must add that the alternative based on the 3Rs model represents a journey that links scientific

³ See in particular P. Singer’s work, *Animal Liberation*, Barnes & Noble, 1975 and T. Regan’s *Animal Rights*, University of California Press, 1983.

and economic interest and the more specific ethical interest of avoiding – or, at least, reducing as much as possible – animal sacrifice. This need must also be tempered by other important requests of civil society, which expects from scientific research remedies for illnesses and the reduction of environmental toxicity.

In order to evaluate the 3Rs model, we must stress that, with regards to the first R (“replacement”), at the moment there are no methods that allow the full verification of the efficacy and safety of a substance or a drug without using a living organism. However, in the last decade significant steps towards the development of alternative methods have been made, consisting primarily by *in vitro* techniques; that is, cellular and tissue cultures, micro-organisms, image technologies, mathematical and IT models. Still in the current state of knowledge, *in vivo* experimentation, although in many cases difficult to extrapolate to the human situation, continues to represent, today, the best available way to tackle, for example, the complex effects of drugs in the reduction of heart attacks or strokes, the action on appetite and satiety, analgesic action, the effects on the damages caused by cerebral trauma, hypertensive activity and so on. In addition we observe that it is not so much the extrapolation from a single animal species to man that counts, it is instead the possibility of a series of observations in many animal species that allows us to construct a catalogue of knowledge useful to understand if we must test on man and, if so, what are the possible toxic and therapeutic effects to take into consideration. In particular, techniques of genetic engineering allow us to create new models of human illnesses in test animals, with a better chance of extrapolation.

Also, some Committee members believe that alternative methodologies, in the current state of knowledge, must be intended not as a substitution, but as a complement to *in vivo* animal testing. In the hope that in the future alternative methodologies can be carried out and developed.

The second R (“reduction”) has the purpose of both reducing the number of animals used, and avoiding an excessive repetition of tests on animals. Further progress in the mutual recognition between European Union and non-European Countries, with regards to the procedures for the registration of drugs, could have a considerable effect in reducing the number of animals used for scientific or technological purposes. Important, in this sense, are the technological developments that let us carry out repeated sampling in a non-invasive way, allowing us, for example, to follow the same animals, without having to sacrifice them at different times, through CT scans, nuclear magnetic resonance, Doppler ultrasound scans, etc.

The third R (“refinement”) contemplates: planning research with sophisticated programming instruments, in order to reduce the suffering, distress and harm endured by the animals to a minimum; the institution of better testing procedures; the housing of the animals in environments suitable to each species, within a frame of more efficient Animal Care, which is also indispensable for the reliability of *in vivo* experimentation.

Many steps forward have been made thanks to the progress of knowledge in cellular and molecular mechanisms at the basis of physiological and pathological processes. Informatics has also opened horizons and unexpected possibilities for the elaboration of data, the construction of models, the theoretical verification of hypotheses. The technology associated to this new knowledge has evolved very rapidly, also pressed by the needs of the market.

Therefore, the scientific community today has extremely broad possibilities of study, which, seen in perspective, could allow to steadily decrease the use of animals and to improve testing conditions. Thanks to this progress it is also possible to think about a concrete implementation of the 3Rs model.

2. Alternative methodologies

In 1986 Europe decided to regulate this sector with the *European Convention for the Protection of Vertebrate Animals Used for Experimental or Other Scientific Purposes*⁴ (1986/123), to which followed the *Directive On the Approximation of Laws, Regulations and Administrative Provisions of the Member States Regarding the Protection of Animals Used for Experimental and Other Scientific Purposes* (1986/609).

On the basis of the Directive, at the European level an intense activity of research and validation (determination of the reliability and reproducibility of a method) developed, aimed both at identifying new *in vivo* methods which could be used for a regulatory activity, and at modifying some of the existing *in vivo* methods in order to reduce the number of animals used and minimise suffering and harm. The majority of the Countries of the European Community intervened, with appropriate regulations, to limit the use of animals, instituting specific commissions for the authorisation and control of the methods of research and experimentation. In particular, in Italy the Directive was transposed through Legislative Decree n° 116, 27th of January 1992, which expressly indicated the principle of preference of alternative methods (Article 17.1b). Circular n° 6 by the Ministry of Health, of the 14th of May 2001, recalled the experimenters' attention to the fact that "for any research activity the impossibility of using other scientifically valid alternatives to the use of animals must be demonstrated".

In the last twenty years, the scientific basis on which the Directive was established has changed considerably thanks to an evolution of the techniques in the field of animal testing, and European authorities – also taking into account the fact that the Directive's guidelines, keeping in mind the text of the abovementioned Convention, had a character that was more political than legal, and was indicative and open to free interpretations rather than tending to harmonise things -, proposed to revise them. The Proposal for a Directive stresses that animals have an intrinsic value that must be respected. The use of animals in the procedures also raises concerns in public opinion. Therefore, animals must always be treated as sentient creatures and their use in scientific procedures must be limited to those fields that promote scientific progress and are ultimately beneficial to the health of man and animals and the environment. For this reason, in the text there are a whole series of reinforcing measures for the protection of animals still used in scientific procedures that have as their focus: a) the increasingly more appropriate application of the 3Rs model; b) the development of alternative methodologies. A first result towards this has already been reached with

⁴ The Convention was adopted on the 31st of May 1985 and it was sent to be signed by the member States of the Council of Europe and those of the European Economic Community on the 18th of March 1986. It came into force on the 1st of January 1991, it was signed in 1987 by the European Community which, however, did not ratify the text before March 1998.

Directive n° 2003/15/CE that set up precise limitations for the sale of cosmetics tested on animals.

Another important contribution derived from the institution, in 1991, of the *European Centre for the Validation of Alternative Methods* (ECVAM), an institute of technical consultancy to the European Commission, whose task is to study, promote and “validate” the procedures that do not contemplate the use of animals. As “validation” of alternative methods, we intend the overall process through which the reliability and the pertinence of a certain test for a specific purpose are established.

An effect of the institution of the ECVAM has been the establishment, in each member state of the European Union, of “National Platforms for Alternative Methods” (IPAM in Italy), coordinated by the *European Consensus of Platforms on Alternatives* (ECOPA), which see the participation of industries, government bodies, research institutes and animal protection associations.

In this framework, a partnership between the European Commission and some companies in different industrial sectors (EPAA) has been established, in order to promote the development of new methods as modern and alternative approaches to animal testing, to guarantee the safety and the efficacy of chemical substances. The programme – 5 years long – is monitored through the annual conferences “Europe goes alternative”.

In April 2009, the ECVAM signed a cooperation agreement with the corresponding organisms in the United States (ICCVAM), in Japan (JACVAM) and in Canada (*Environmental Health Science and Research Bureau*), to improve the coordination at the international level in order to identify and disseminate alternative methods that can be reproduced and are based on unquestionable scientific foundations, dispelling any fear of risks for our health.

Moreover, the European Community has been, for some years, increasing research funding: the VII Framework Program (2007-2013) anticipates funds for projects aimed at finalizing alternatives to animal testing in medical research. We must however remember that if animals represent an often insufficient model of the human body, *in vitro* tests based on the use of cells cultivated outside of the complexities of a living organism, without the intervention of hormonal, humoral and nervous regulatory systems, would be even less representative. Even embryonic stem cells, animal and human, because of the peculiarity of their epigenetic and metabolic profile, are not representative of an experimental model alternative to that of an adult organism.

Therefore we face a considerable increase in the focus and sensitivity towards ethical and scientific problems relative to A.T. which, without overlooking the importance of the traditional models, forces us to research new, less invasive perspectives, more focused on finding the right balance between the needs of scientific knowledge and respect for animal life. As hoped for in the European Proposal for a Directive: “In addition to animal welfare benefits, alternative methods also have the potential to provide robust information through quality-controlled, state-of-the-art tests which could be faster and less cost-intensive than classical animal-based tests”.

The NBC highlights that in certain environments, even institutional, the expression “methods alternative to animal testing” includes also tests on human embryonic stem cells.

The NBC does not believe that this is the place to enter the debate about testing of human embryonic stem cells, and refers to previous⁵ and eventual future documents.

The NBC feels that it is unacceptable to consider “alternative”, in the sense of “scientifically and ethically equivalent”, methods involving tests on adult animal organisms and methods involving experiments on human embryonic cells.

Some NBC members⁶ in any case believe that any experimentation that involves the destruction of human embryos is illicit and morally unjustifiable, including those aimed at minimising animal testing at the cost of testing on human embryos.

3. The protection of animals in scientific research and the role of ethics committees for animal testing

The quality of scientific research and the reliability of the results have been strictly linked to a good laboratory practice and to animal welfare. It is a known principle that using animals that are already in a state of physical or psychological suffering in research can compromise the reliability and the reproducibility of the test results. The protection of lab animals, as contemplated by the law, is therefore intimately linked to the interests of the research and, in principle, there should not be any conflict between these interests and the need, increasingly felt, of a qualified *animal care*, that is, a lab animal science that includes the study of their biology, consideration for their rearing and environmental needs, the prevention and the treatment of eventual illnesses, the optimisation of the testing techniques and the improvement of anaesthesia, analgesia and euthanasia. From the beginning of the 1900s many steps forward have been made towards the optimisation of the quality and the animals’ state of health, and the standardisation of environmental and housing conditions to ensure animal welfare. This progress has certainly been supported not only by issuing suitable regulations, but – if the link between the interests of the research and an increasingly qualified *animal care* – also by the sense of responsibility of the researchers and the establishments in which they operate. Proof is that many research centres in Italy and in Europe have instituted internal control bodies, on the example of what has already happened, from the middle of the 1980s, in United States and Canada with the creation of *Institutional Animal Care and Use Committees* (IACUC). This is an evident sign that the presence of ethics committee (named in a variety of ways in the different establishments) is not felt as a sort of limitation, but as a valid help to pursue the objectives indicated by the laws in force on this issue. The dissemination of these bodies has

⁵ See the NBC documents: *The destiny of embryos resulting from medically assisted procreation (MAP) and not complying with the conditions for implantation* (2007); *Use for research purposes of cell lines h1 and h9 derived from human embryos* (2004); *Research using human embryos and stem cells* (2003); *NBC’s opinion on the therapeutic use of stem cells* (2000); *Identity and status of the human embryo* (1996)

⁶ Prof. Amato, Prof. Bompiani, D’Agostino, Prof. Da Re, Prof. Di Pietro, Prof. Fattorini, Prof. Forleo, Prof. Morresi, Prof. Nicolussi, Prof. Palazzani, Prof. Possenti, Prof. Proietti, Prof. Scaraffia, Prof. Umani Ronchi agreed. Prof. Gensabella expressed her agreement although she was absent from the plenary meeting.

occurred voluntarily, as neither the current European Directive nor Legislative Decree n° 116/92 include specific guidelines that require the presence and the implementation of these Committees in the establishments involved.⁷

An important step forward in the direction towards which a part of the world of animal testing is already moving, will happen if the abovementioned Proposal for a Directive, which revises the 1986 Directive, will become operative. This Proposal starts with observing the existence of an evident change in the cultural attitude of European society towards the importance attributed to animal welfare, also proven by the numerical success of public consultations launched on this issue in the past few years.⁸ Looking at this, we must accept that the measures currently in force with regards to the protection of animal welfare do not sufficiently respond to the expectations and are not able to guarantee an adequate transparency in this extremely controversial sector. As we said, it is true that many research centres have already, voluntarily, created ethics committees, and that the measures to control and inspect the observance of the law exist and work adequately: however there is no body giving an independent, public guarantee that goes beyond respecting the regulations: this is currently, in effect, entrusted to the researchers' self-discipline. We don't want here in any way to put into doubt their good faith but, looking at it carefully, the current situation is the same as that which, around the second half of the 1960s, led to the creation of ethics committees for humans trials: independent bodies as guarantee for public opinion and researchers, especially in a very controversial sector like the one under scrutiny.⁹ To respond to public opinion's expectations, the European Commission put forward the proposal of constituting, in every place rearing and using research animals, a "permanent and independent body of ethical assessment", with the fundamental task of promoting the ethical debate within the establishment, stimulating a climate favourable to care and providing the tools to practically and quickly apply the most recent technical and scientific developments inherent to the 3Rs principles. As we said, this has been largely anticipated by many public and private establishments (at least those where testing is carried out), however, clearly the presence of these bodies will have more strength if they are dictated by the law.

We also highlight that these bodies' task will not only be to encourage the acquisition of a growing awareness of the ethical issues involved in animal testing. The most relevant novelty of the Proposal for a revision of the Directive is in the fact that, for the first time (see article 35) the concession of an authorisation to research projects by the competent authorities is subordinated to the acquisition of a positive ethical-scientific evaluation. This ethical evaluation must verify that the project satisfies a large number of

⁷ In this sense we stress the importance of bill number 258, *Directives for the protection of animals used for scientific or technological purposes*, that anticipates the compulsory institution of ethics committees, internal to the establishments where the testing takes place, which should support the experimentation and follow its evolution (www.senato.it/leg/15/BGT/Schede/Ddliter/24691.htm).

⁸ The consultation on the European Union's action Program for animal protection and welfare, received about 45,000 answers and slightly less (42,500) were received by the consultation on Directive 86/609/CEE.

⁹ In the document *Guidelines for ethics committees in Italy* of the 13th of July 2001, the NBC already advanced the idea that ethics Committees for pharmacological and clinical trials on human beings should also be given jurisdiction, after being integrated with a zoologist and a clinical veterinary, over the passing of protocols relative to animal testing.

requirements, detailed in the following article 37¹⁰, it must accompany the release of the authorisation to the research project and, in some cases (those involving “no or mild” procedures), it can even substitute the non-technical report that must be included in the request of authorisation. The task of compiling this ethical evaluation belongs to the permanent ethical assessment body discussed in article 26, which also has the task of re-examining every year all projects lasting longer than 12 months, eventually proposing, on the basis of the results, the modification or the renewal of the authorisation. These are therefore very important tasks, to satisfy which, however, the composition of these bodies in the manner contemplated in article 25 does not seem adequate. In fact, it is anticipated that these bodies will be made up of a veterinary doctor, the persons responsible for the animals’ welfare and care *within the establishment* and, in the case of a research organisation, of a selected member of the research personnel. In light of previous experiences, both with animals and with humans, this make-up is unsatisfactory in order to offer public guarantee that the research is ethical. It would be appropriate to expect that at least some members of these bodies are external to the establishment and that amongst them there is a bioethicist expert in animal welfare.

The last novelty of this revision Proposal is the creation of a national Committee for animal ethics and welfare (article 47), which on the one hand would advise the competent authorities and the web of permanent committees of ethical evaluation in the single establishments, and, on the other hand, would cooperate with similar committees in other countries, in order to share *best practices* within the European Union. In this case as well, we must highlight that some European countries (but also non-European) already have this kind of set-up, which however is missing in our country: after all, we must remember that in Italy there is no central institution also in the field of pharmacological and clinical trials on human beings, although it was contemplated in article 6 of the Decree of the 18th of March 1998.

Every establishment that carries out animal testing should have an ethics committee for animal testing (ECAT) with the task of evaluating research projects from a scientific and ethical point of view. The ECAT should establish the real need to use animals, verifying that there are no alternative methods of obtaining the same results. In addition, it should guarantee that the project respects the principles inherent to the concepts of reduction and refinement. The ECAT’s task should be to monitor the housing conditions with particular attention to rearing and animal welfare. The ECAT should be made-up of researchers, clinical and non-religious personnel, with the presence of members that are external to the establishment concerned.

In Italy, ECATs should substitute the current body contemplating an authorisation to carry out research projects on animals to be given centrally (Ministry of Health and Superior Institute for Health). ECATs’ deliberations – similarly to what happens for human trials – should be notified to an observatory recording all projects of experimental research that include the use of animals. The observatory should have the function of supervising; elaborating the data received highlighting eventual anomalies between the protocols and their practical realisations.

¹⁰ Amongst the criteria to be met: scientific justification, according to the analytical directives anticipated in previous articles.

4. Conscientious objection to animal testing (Law n° 413, 12th of October 1993)

The growing sensitivity of modern society towards animals found a significant expression in Law n° 413, 12th of October 1993, which recognised the right to “citizens who, in obedience to their conscience, exercising their freedom of thought, conscience and religion recognised by the Universal Declaration of Human Rights, by the Convention for the Protection of Human Rights and Fundamental Freedoms and by the International Covenant on Civil and Political Rights, oppose violence on all living beings” to “declare their conscientious objection to every act connected to animal testing” (article 1).

The law 413/1993 contemplates this possibility for “doctors, researchers and healthcare personnel in the roles of qualified, technical, nursing professionals and for the university students concerned”, who, once they have declared their conscientious objection, “are not required to take part directly in the activities and interventions specifically and necessarily directed to animal testing” (article 2).

With regards to the way this right can be exercised, article 3 clarifies that “conscientious objection is stated at the time of applying for employment or participating in a public contest”, “university students declare their conscientious objection to the professor teaching the course within which there can be activities or interventions of animal testing, at the beginning of the course”, “the declaration of conscientious objection can be withdrawn at any time”. These regulations presume that these are profound existential choices that imply, in their exercise and evaluation, significant coherence and continuity.

Of particular interest is subsection 5 of article 3, according to which “All public and private establishments legally allowed to carry out animal testing are obliged to communicate to all workers and students their right to exercise conscientious objection to animal testing. The establishments are also obliged by the current law to set up a form for the declaration of conscientious objection to animal testing”.

Unfortunately we must acknowledge that this double obligation – expressly contemplated by the law -, has been largely overlooked and that a very limited number of faculties have belatedly carried out those duties only after formal requests aimed at ensuring the outmost dissemination of the law.

Article 4 ratifies the prohibition of discrimination stating in subsection 1 that “no-one can be made to suffer negative consequences for refusing to practice or to cooperate to the execution of animal testing”, and supporting (subsection 2) the objectors’ right – “whether they are public or private employees, to be allocated, within the existing organic apparatus, to activities other than those requiring animal testing, retaining the same qualification and the same salary”.

As we can see, these are imperative instructions that include, in the following subsection 3, even universities, whose “competent bodies must make the attendance to laboratory exercises involving animal testing, voluntary”, and require the activation, “within courses”, “before the beginning of the academic year following the date of the coming into force of the current law, teaching methods that do not include activities of interventions of animal testing in order to pass the exam”.

Once again we recommend the faculties' secretarial offices to ensure "the outmost dissemination of the right to conscientious objection to animal testing".

Conscientious objection has, in our legislation, an exceptional nature and it is contemplated in clear laws, within which the sacrifice of inviolable rights like human life is believed to justify conscientious objection. Examples of this are conscientious objection to military service (Law n° 772, 15th of December 1972), conscientious objection to the voluntary interruption of pregnancy (Law n° 194, 22nd of May 1978) and conscientious objection to the application of medically assisted procreation techniques (Law n° 40, 19th of February 2004).

Therefore, it has been highlighted that, with the 1993 Law, the motivated refusal to inflict harm and suffering to animals has in some way become a part of the ethical basis for the development of personal identity and the promotion of social conscience (Articles 2 and 3 of the Constitution).

We must also observe that if Law n° 413/93 undoubtedly recognises the individual's freedom of conscience as an inviolable human right and therefore protects a subjective good-value, it attributes significant relevance also to the objective good-value animal welfare/life. In this sense, conscientious objection to animal testing, with its connections to animalist laws – globally inspired to the general principle "do not cause suffering, do not harm animals in vain" -, represents a turning point in our legislation for its high bioethical value.

In this perspective we can also place the new formulation of Article 727 of the Penal Code¹¹.

Years after, it is necessary to observe how the law has not yet been fully implemented. Currently – with regards to the situation in Europe – there is only a teaching position at the University of Konstanz and three courses, respectively at the universities of Hannover, Erlangen and Utrecht. In Italy still little has been done, despite the law establishes – as we have seen – the institution of "teaching methods that do not include activities of interventions of animal testing in order to pass the exam".

To monitor the knowledge of the law and its application, the working Group also sent a questionnaire to all scientific faculties of Italian Universities (pharmacy, medicine and surgery, mathematical, physical and natural sciences, veterinary medicine, biotechnological sciences) with questions reported in the appendix, together with the results of the investigation.

Synthesis and recommendations

In line with the "Proposal for a Directive of the European Parliament and the Council on the protection of animals used for scientific purposes" and with the most important international Documents on this issue, the NBC recommends:

¹¹ Article 727 Penal Code "Anyone who abandons domesticated animals or animals that have become accustomed to captivity is punishable with up to a year in prison and from 1,000 and 10,000 euros. The same penalty applies to anyone keeping animals in conditions incompatible with their nature, and causing grave suffering."

1. a better international coordination for the development and the validation of alternative methods aimed at producing the same level of scientific evidence as procedures conducted on animals, but without using them, or using a smaller number or involving less painful procedures;
2. the institution of Ethics Committees for animal testing exercising the function of discussing, approving and monitoring the complex problems relative not only to carrying out “in vivo” research projects but also to rearing methods and to managing the welfare of the test animals; the NBC recommends the presence, in the composition of the local bioethics Committees for animal testing, of some members who are external to the establishment;
3. the formalisation – within the establishments carrying out animal testing – of a formative course for all scientific and auxiliary personnel in order to improve professionalism and ethical awareness, referring to the principles of the 3Rs;
4. the full implementation of Law n° 413, 12th of October 1993, Regulations on conscientious objection to animal testing, which recognises (Article 1) to Italian citizens the right to declare their conscientious objection to animal testing.

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<http://www.ministerosalute.it>

Appendix

The working Group sent a questionnaire to all scientific faculties in Italian Universities (pharmacy, medicine and surgery, mathematical, physical and natural sciences, veterinary medicine, biotechnological sciences) with the following questions:

- **In your faculty, have students been informed of the possibility of exercising the right to conscientious objection, as anticipated in Article 3 point 5 of Law n° 413/93?**

(All public and private establishments that legally carry out animal testing are obliged to inform all workers and students of their right to exercise conscientious objection with regards to animal testing. The establishments themselves are also obliged to set up a form for the declaration of conscientious objection to animal testing by the current Law.)

- **Have there been cases of students or workers making such a request?**
- **Have you implemented “teaching methods that do not include activities or interventions of animal testing in order to pass the exam”, as required by Article 4, point 3 of the Law n° 413/93?**

(“In Universities, the competent bodies must make the attendance to laboratory exercises involving animal testing, voluntary. Within courses must implemented, before the beginning of the academic year following the date of the coming into force of the current law, teaching methods that do not include activities of interventions of animal testing in order to pass the exam. The faculties’ secretarial offices must ensure the outmost dissemination of the right to conscientious objection to animal testing.”)

For this investigation 128 scientific Faculties have been identified and all answered.

The answers to the questions, which arrived both by post and e-mail (as also indicated in the letter),¹² have been given by the Faculties’ Headmasters or by their delegate, in 2 cases a resume’ of the Faculty’s Council was sent.

All were sent a letter of thanks by the NBC for the collaboration offered and the NBC’s commitment to make the results known by drawing up a document with this investigation.

Results report

- With regards to the **first question**, 87 answered that they had implemented communication to make the possibility of conscientious objection known, 13 did not answer, 28 stated that,

¹² All the answers were filed, included in the table following this document, included in a file shared by the NBC under “conscientious objection”, listed on a paper matching/personal file, both e-mails and original letters are preserved at the Group’s secretarial offices.

as they did not carry out any animal testing activity they had not organised any way to disseminate this regulation.

- With regards to the **second question**, 29 specifically answered that, as they did not carry out any animal testing, they did not have any objector, in 10 Faculties some exercised conscientious objection, in the remaining 89 faculties there had not been any case of objection.
- With regards to the **third question**, 86 Faculties – not having animal testing in their courses or their thesis – do not carry out any Alternative Methodologies, 26 Faculties instead implemented A.M., Pisa instituted the National Interuniversity Association of Ethics Committees for Animal Testing (NIAECAT), 16 Faculties carry out animal testing with traditional methods.

FACULTY	CITY	answer	question 1 conscientious objection	question 2 objectors	question 3 alternatives
Faculty of Pharmacy	66013 Chieti (Chieti Scalo)	YES	NO	NO	NA
Faculty of medicine and surgery	67010 Coppito – L’Aquila	YES	YES	NA	NA
Faculty of mathematical, physical and natural sciences	67010 Coppito – L’Aquila	YES	NA	NA	NA
Faculty of veterinary medicine	64100 Teramo	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	85100 Potenza	YES	NA	NA	NA
Faculty of Pharmacy	88021 Roccelletta di Borgia (CZ)	YES	YES	NO	NA
Faculty of medicine and surgery	88100 Catanzaro	YES	YES	NO	NA
Faculty of Pharmacy	87036 Arcavacata di Rende (CS)	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	87036 Arcavacata di Rende (CS)	YES	YES	NO	NO
Faculty of medicine and surgery	80138 Naples	YES	NO	NO	NO
Faculty of mathematical, physical and natural sciences	81100 Caserta	YES	NA	NA	NA
Faculty of mathematical, physical and natural sciences	82100 Benevento	YES	YES	NO	YES
Faculty of Pharmacy	80131 Naples	YES	YES	NO	NA/NO
Faculty of medicine and surgery	80131 Naples	YES	YES	NO	NA
Faculty of veterinary medicine	80137 Naples	YES	NO	NO	NO
Faculty of Biotechnological sciences	80125 Naples	YES	NA	NA	NA
Faculty of mathematical, physical and natural sciences	80134 Naples	YES	YES	NO	NO
Faculty of Pharmacy	84084 Fisciano (SA)	YES	NA	NA	NA
Faculty of mathematical, physical and natural sciences	84081 Baronissi (SA)	YES	NA	NA	NA
Faculty of industrial chemistry	40136 Bologna	YES	NO	NO	NO
Faculty of Pharmacy	40126 Bologna	YES	YES	NO	NO
Faculty of medicine and surgery	40125 Bologna	YES	YES	NO	NA
Faculty of veterinary medicine	40064 Ozzano dell’Emilia (BO)	YES	YES	10	YES
Faculty of mathematical, physical and natural sciences	40126 Bologna	YES	NA	NA	NA
Faculty of Pharmacy	44100 Ferrara	YES	YES	NO	YES
Faculty of medicine and surgery	44100 Ferrara	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	44100 Ferrara	YES	YES	NO	NA
Faculty of Pharmacy	41100 Modena	YES	YES	NO	NA
Faculty of medicine and surgery	41100 Modena	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	41100 Modena	YES	NA	NA	NA
Faculty of Pharmacy	43100 Parma	YES	YES	NO	YES

Faculty of medicine and surgery	43100 Parma	YES	NO	NO	NO
Faculty of veterinary medicine	43100 Parma	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	43100 Parma	YES	YES	NO	NA
Faculty of Pharmacy	34127 Trieste	YES	YES	NO	NA
Faculty of medicine and surgery	34149 Trieste	YES	YES	NO	NA
Faculty of medicine and surgery	33100 Udine	YES	NA	NA	NA
Faculty of veterinary medicine	33100 Udine	YES	YES	NO	NO
Faculty of mathematical, physical and natural sciences	33100 Udine	YES	NO	NO	NA
Faculty of medicine and surgery “biomedical campus”	00128 Rome	YES	NA	NA	NA
Faculty of mathematical, physical and natural sciences	01100 Viterbo	YES	YES	NO	NA
Faculty of Pharmacy	00185 Rome	YES	YES	NO	YES
Faculty of medicine and surgery	00161 Rome	YES	YES	NO	NA
Second faculty of medicine and surgery	00189 Rome	YES	YES	NO	YES
Faculty of mathematical, physical and natural sciences	00185 Rome	YES	YES	4 or 5	YES
Faculty of medicine and surgery – Tor Vergata University	00133 Rome	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	00133 Rome	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences – Roma Tre University	00146 Rome	YES	YES	NO	YES
Faculty of Pharmacy	16132 Genova	YES	YES	NO	YES
Faculty of medicine and surgery	16132 Genova	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	16132 Genova	YES	YES	NO	NA
Faculty of medicine and surgery “A. Gemelli”	00168 Roma	YES	YES	NO	NA
Faculty of mathematical, physical and natural sciences	25121 Brescia	YES	NA	NA	NA
Faculty of medicine and surgery	21100 Varese	YES	NA	NA	NA
Faculty of mathematical, physical and natural sciences – Como	22100 Como	YES	NA	NA	NA
Faculty of medicine and surgery	25123 Brescia	YES	YES	NO	NA
Faculty of Pharmacy	20133 Milan	YES	YES	NO	N/A
Faculty of medicine and surgery	20122 Milan	YES	YES	1	YES
Faculty of veterinary medicine	20133 Milan	YES	YES	4	YES
Faculty of mathematical, physical and natural sciences	20133 Milan	YES	YES	Very rarely	YES
Faculty of medicine and surgery – Milano Bicocca University	20050 Monza	YES	NO	NO	YES
Faculty of Pharmacy	27100 Pavia	YES	YES	NO	N/A

Faculty of medicine and surgery	27100 Pavia	YES	YES	NO	N/A
Faculty of mathematical, physical and natural sciences	27100 Pavia	YES	YES	NO	N/A
Faculty of medicine and surgery Vita San Raffaele University	20132 Milan	YES	N/A	N/A	N/A
Faculty of medicine and surgery	60020 Torrette di Ancona	YES	YES	YES	YES
Faculty of mathematical, physical and natural sciences	60131 Ancona	YES	YES	YES	YES
Faculty of Pharmacy	62032 Camerino (MC)	YES	N/A	N/A	N/A
Faculty of veterinary medicine	62024 Matelica (MC)	YES	YES	NO	YES
Faculty of sciences and technologies	62032 Camerino	YES	YES	NO	N/A
Faculty of Pharmacy	61029 Urbino	YES	YES	NO	N/A
Faculty of mathematical, physical and natural sciences	61029 Urbino	YES	YES	10	N/A
Faculty of mathematical, physical and natural sciences	86170 Isernia	YES	NO	NO	YES
Faculty of Pharmacy	28100 Novara	YES	N/A	N/A	N/A
Faculty of medicine and surgery	28100 Novara	YES	YES	NO	N/A
Faculty of Pharmacy	10126 Turin	YES	YES	NO	N/A
Faculty of medicine and surgery	10126 Turin	YES	YES	NO	N/A
Faculty of veterinary medicine	10095 Grugliasco (TO)	YES	YES	NO	N/A
Faculty of mathematical, physical and natural sciences	10125 Turin	YES	YES	N/A	N/A
Faculty of Pharmacy	70126 Bari	YES	YES	NO	N/A
Faculty of medicine and surgery	70124 Bari	YES	YES	NO	N/A
Faculty of veterinary medicine	70010 Valenzano (BA)	YES	YES	NO	NO
Faculty of biotechnological sciences	70126 Bari	YES	N/A	N/A	N/A
Faculty of mathematical, physical and natural sciences	70125 Bari	YES	YES	NO	N/A
Faculty of medicine and surgery	71100 Foggia	YES	YES	NO	N/A
Faculty of mathematical, physical and natural sciences	73100 Lecce	YES	YES	Rare cases	N/A
Faculty of pharmacy	09126 Cagliari	YES	YES	NO	YES
Faculty of medicine and surgery	09124 Cagliari	YES	YES	NO	N/A
Faculty of mathematical, physical and natural sciences	09126 Monserrato (Ca)	YES	YES	NO	NO
Faculty of pharmacy	07100 Sassari	YES	YES	NO	N/A
Faculty of medicine and surgery	07100 Sassari	YES	NO	NO	N/A
Faculty of veterinary medicine	07100 Sassari	YES	YES	YES	NO
Faculty of mathematical, physical and natural sciences	07100 Sassari	YES	N/A	N/A	N/A
Faculty of pharmacy	95125 Catania	YES	YES	NO	N/A
Faculty of medicine and surgery	95125 Catania	YES	YES	NO	NO

Faculty of mathematical, physical and natural sciences	95123 Catania	YES	NO	NO	N O
Faculty of pharmacy	98168 Messina	YES	YES	NO	N/A
Faculty of medicine and surgery	98125 Messina	YES	YES	NO	N/A
Faculty of veterinary medicine	98123 Messina	YES	NO	NO	NO
Faculty of mathematical, physical and natural sciences	Sant'Agata – 98166 Messina	YES	YES	NO	N/A
Faculty of pharmacy	90123 Palermo	YES	YES	NO	N/A
Faculty of medicine and surgery	90127 Palermo	YES	YES	NO	N/A
Class of mathematical, physical and natural sciences	56126 Pisa	YES	YES	NO	N/A
Scuola Superiore di studi universitari di perfezionamento Sant'Anna	56127 Pisa	YES	YES	NO	N/A
Faculty of pharmacy	50134 Florence	YES	YES	NO	YES
Faculty of medicine and surgery	50134 Florence	YES	N/A	N/A	N/A
Faculty of mathematical, physical and natural sciences	50121 Florence	YES	N/A	N/A	N/A
Faculty of pharmacy	56124 Pisa	YES	YES	YES	NO
Faculty of medicine and surgery	56126 Pisa	YES	N/A	N/A	N/A
Faculty of veterinary medicine	56124 Pisa	YES	N/A	NO	Ethics Committee
Faculty of mathematical, physical and natural sciences	56126 Pisa	YES	YES	NO	N/A
Faculty of pharmacy	53100 Siena	YES	YES	NO	YES
Faculty of medicine and surgery	53100 Siena	YES	N/A	N/A	N/A
Faculty of mathematical, physical and natural sciences	53100 Siena	YES	YES	NO	N/A
Faculty of mathematical, physical and natural sciences	38050 Trento	YES	NO	NO	N/A
Faculty of pharmacy	06126 Montebello (PG)	YES	YES	NO	YES
Faculty of medicine and surgery	06126 Montebello (PG)	YES	YES	NO	NO
Faculty of veterinary medicine	06126 Montebello (PG)	YES	YES	NO	YES
Faculty of mathematical, physical and natural sciences	06123 Perugia	YES	YES	NO	YES
Faculty of mathematical, physical and natural sciences	30123 Venice	YES	YES	YES	YES
Faculty of pharmacy	35131 Padova	YES	N/A	N/A	N/A
Faculty of medicine and surgery	351281 Padova	YES	YES	NO	N/A
Faculty of veterinary medicine	35020 Legnano (PD)	YES	NO	NO	N/A
Faculty of mathematical, physical and natural sciences	35121 Padova	YES	N/A	N/A	YES
Faculty of medicine and surgery	37134 Verona	YES	NO	NO	N/A
Faculty of mathematical, physical and natural sciences	37134 Verona	YES	N/A	N/A	N/A

Regarding conscientious objection supported by L.413/1993

Personal remark by Prof. Francesco D'Agostino

I believe that the *National Bioethics Committee* did well to dedicate its attention to the problem of methodologies alternative to animal testing and to draw up a document in which we take note with satisfaction of the existence in our legislation of a law, the 413/1993, with which the right to conscientious objection (CO) for every act linked to animal testing. I also feel that it is commendable that the NBC has stigmatised the fact that still in some ways two fundamental obligations contemplated by law as duties of the competent establishments, are not met, that of making known to all employees and students their right to exercise CO to animal testing and that of putting in place a form to formalise this declaration.

I believe however that it would have been appropriate for the NBC to go a step further, recalling its readers' attention to its document on the *paradoxical* character of Law n° 413/1993. Article 1 of this Law, in fact, bases the right of CO to animal testing on the due respect our legislation gives to citizens who, *in obedience to their conscience, in the exercise of their freedom of thought, conscience and religion recognised by the Universal Declaration of Human Rights, by the Convention for the Protection of Human Rights and Fundamental Freedoms and by the International Covenant on Civil and Political Rights, oppose violence on all living beings*. Now, what is the paradox? This: there is no doubt that, like all other animals, man is also a living being; it seems therefore unjustified the fact that the law – *starting with the premises abovementioned* – does not anticipate that the right to CO can be exercised also towards any kind of experimentation involving living human beings as well as towards animal testing. It is a fact that the text of the law, as well as its explicit title (*Regulations on conscientious objection to animal testing*), although it takes *violence on all living beings* seriously, does not make any reference to the relevant bioethical problems raised by practices of experimentation on man and to the indubitable problems of conscience that can arise in those carrying out the experiments.

The paradox highlighted, like any paradox, needs to be resolved or in any case requires adequate reflection. There are no other regulations, in our legislation, that explicitly (the way Law n° 413/1993 is explicit) guarantee CO to experimentation on man and we don't understand why. Therefore I think that a *bioethical* reflection on this *absence* is indispensable, as it has been going on *scandalously* now for more than fifteen years, also in order to verify if it is possible to give a convincing answer to the malicious, but almost irresistible observation, repeated by many, that *some* supporters of animal bioethics (in particular those who at the time were the promoters of Law n° 413/1993) suffer from a serious ideological short-sightedness, which would lead them to give very little attention to "human animals", in comparison to "non-human animals". I feel that it is this short-sightedness affecting, as

already stated, *some, but not all animalists*, that makes their bioethics fragile and supports the idea, wrong in itself, but consolidated by the media, that they are in fact a sect.

Effectively, this document could have been a good opportunity to recall attention to the fact that CO towards experimental practices of bioethical relevance is a value of the outmost importance that must be rigorously protected and that must not be confined to spheres that are relevant, but restricted, like animalism. In the plenary meeting of the 18th of December 2009 I pressed the Committee to include in the document some reflections, although quick, along these lines, but I was left pretty much isolated (something that obviously I don't mind at all, seen as, with regards to moral issues, the opinion of the majority is only a fact, certainly not an argument). This fact however, seemed pretty curious, seen as I did not propose to cut even a line from the text, but to simply integrate it. We know that experimentation on man is regulated by directives that are much more defensive and binding than animal testing, but we have reason to believe that, at least in some cases, there are experimental practices (e.g. on newborns, mentally ill patients, extremely elderly subjects) able to raise relevant ethical dilemmas on experimenters, dilemmas that deserve attention and are certainly similar to those that have been taken seriously in Law n° 413/1993.