

Xenotransplants

Is it possible that in the future laboratories may create genetically engineered animals with the purpose of being used in xenotransplants?

Law Report (having as grounds the European legislation for the protection of animals)

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1. Xenotransplant: notion

The *European Medicines Agency* defines a *xenogeneic cell therapy medical* as “the use of viable animal somatic cell preparations suitably adapted for: (a) the transplantation/ implantation/ infusion into a human recipient or (b) extracorporeal treatment through bringing (non-human) animal cells into contact with human body fluids, tissues or organs”.

There we find, in that preliminary document for what will be the *Specific Guidelines on Xenotransplantation* or more broadly speaking the *Specific Guidelines on Xenopharma*¹, the exact notion of the new therapeutic method that combines the use of animals with the implementation of genetic materials, recovered from those same animals, in human beings².

2. Importance of the resort to xenotransplant

a. Problems it seeks to suppress

The growing medical needs of organs for transplantation are not always followed by their immediate availability for that purpose.

In Portugal, the National Ethics Committee for Life Sciences suggests that the main reasons are “the legislative restrictions for the harvesting from existing corpses in some countries, vitality changes in the organ to be transplanted, with deterioration in the ante-mortem period, the great demands of the immunological compatibility systems”³.

The creation of several solutions, capable of making viable the obtaining of scarce organs, becomes, therefore, necessary, emerging the idea of the resort to animal donors, as well as the “development of research programs within the scope of genetic engineering with the purpose of creating transgenic animals, in such a manner that their genome may contain human genetic material in order to reduce the intensity of the reaction of immunological rejection”^{4 5}.

¹ cf. point 5 of the document: *it is anticipated that the draft revised guideline will be adopted and released for 6 months consultation in the first quarter of 2008.*

² cf. *Report of the national committee of ethics for life sciences regarding bill n° 65/x (alteration of law n.º 12/93, of April 22 – harvest and transplant of human tissue), 50/cnecv/06, December of 2006, http://www.cneecv.gov.pt/NR/rdonlyres/868B3E3B-3FE2-42FC-9322-4F624843D30D/0/P050_ParecerTransplantes.pdf, p. 3, where we find the characterization of the types of transplants contemplated in medical science: autotransplant, homotransplant or allotransplant and xenotransplant. The first refers to grafting one's tissues into himself; allotransplant implicates the transfer of tissue, organs or cells from one individual to another, within the same species, regardless of the donor being alive or not; xenotransplantation or heterotransplantation refers to the transplantation of organs among different species (e.g. from pig to man) [cf. p. 4].*

³ cf. *Report... cit.*, p. 5

⁴ cf. *Report... cit.*, p. 4.

⁵ cf., also, DAMIAN KÖNIG, DOMINIQUE SPRUMONT, *La xénotransplantation dans l'ordre juridique suisse*

The purpose is to resolve some of the main problems associated with xenogenetics, from a medical and human point of view.

b. State of scientific search regarding xenotransplants

The first clinical trials with xenotransplants date back to the 1960s. However, and unlike what happens with the xenotransplant of cells, one cannot consider successful the efforts of the scientific community regarding this matter. To this day, the implantation of animal genetic products in man is in an embryonic stage. It has been successfully registered the use of pig valves in human transplants. However, all the cases of xenotransplantation that involved full organs were temporary: transplantation of a baboon's heart in a newborn and a liver, of an animal of the same species, in an adult human that survived 70 days^{6 7}.

c. Problems it engenders

i. Medical-scientific problems

Several problems emerge when resorting to xenotransplant, both from a medical and scientific point of view.

Among the most important, we find the danger of immunological rejection on part of the human organism that receives the animal organ or tissue, and the risk of transmitting known or unknown pathologies. Namely, the *European Agency of Medicine* underlines that, subjacent to this practice, there is the potential risk of introducing new infectious diseases⁸ and studies show that some of the most deadly virus existent nowadays result from the transmission from animals to humans⁹.

More than the individual consideration of each difficulty, it will be the combination that will result in an increased problematic. In fact, according to the medical literature on the matter, one either reduces the immunological response of the recipient, leaving him vulnerable to infections, or the risk of rejection increases exponentially.

Among the examples mentioned by the medical community, the more prominent are the transmission of pathogenic elements, the risk of infection, the risk of tumors, and the risk of

<http://www2.unine.ch/webdav/site/ids/shared/documents/rapportxenotransplantation.pdf>.

It is considered that the great interest of xenotransplants can be justified, nowadays, due to scarce number of organs available for allotransplants.

⁶ cf. *Report...* cit., p. 4

⁷ Currently, is under testing the possibility of creating transgenic pigs. The experiment, as mentioned by the Higher Council for Life Sciences, consists of introduction a human gene in the embryo of the animal, in order to avoid such an intense immunological reaction on part of the human. However, the technique has not yet been tested on humans.

⁸ cf. Point 1 of the quoted document. Basically, if the human does not reject the transplant, he becomes a potential carrier of an unknown virus, with all the dangers it represents for public health. In other words, he would be a door for a new epidemic threat.

⁹ The World Health Organization issued an alert regarding the risk of contamination that xenotransplant involves, recommending rigid procedures that the research on this matter should follow.

rejection. If some are also common to allotransplants, it is certain that this mixture of species enhances them, especially regarding, due to the continuous presence of proviral cells, the effective transmission of viruses¹⁰.

ii. Ethical problems

Here come into play all the questions regarding the limits of science from an ethical point of view. To what point is it legitimate to genetically manipulate reality?

iii. Problems regarding animal ethics

Among the main questions that the resort to xenotransplant raises is the question regarding the protection of animals. Frequently appear protective voices that claim the statute of co-creatures for those beings, although not truly subjects with rights, thus shedding over the question at hand a thread of ethical devalue or, at least, the suspicion that is almost deadly harmful.

And, regarding the concerns revealed, two emerge recurrently. On the one hand, it is invoked the “right” of animals to their own existence, free from pain and suffering; on the other hand, it is questioned to what degree may humans legitimately create species of animals in laboratories, with the sole purpose of submitting them to experiments and being used by humans.

The answer to such questions will depend on the vision that each one has of the relation between person and animal; ultimately, it will be co-determined by the ethic-axiological presupposition of the human being. And inevitably carries with it a structural duplicity. In other words, it is not the same structure of values than the one regarding the use of already existent animals or transgenic animals.

3. Legal framework of such problems¹¹

a. Public health protection

Foremost, xenotransplants, due to the risks involved, are subjected to the same restrictions as genetic engineered organisms, and to all the restrictions that have as specific purpose the protection of public health.

It is not only the recipient of the animal organ, but also all the people that come in contact with it, and the population in general, that are subjected to the epidemic risks that such practices convey, therefore it is not strange that the rules implemented or recommended at

¹⁰ cf. Virtually, there are two possible paths for xenotransplant. The resort to transgenic pigs or the use of non-human primates. However, the second as been refused by the scientific community because of the risks involved. Among those risks there are: long periods of incubation, reduced number of animals, small sized organs, high costs and high risk of virus transmission. cf. DAMIAN KÖNIG, DOMINIQUE SPRUMONT, *La xénotransplantation...cit.*, p. 11. Cf., and, COUNCIL OF EUROPE, *Report from the working party on xenotransplantation*, 7th July 2000, Strasbourg, p. 7.

¹¹ cf. DAMIAN KÖNIG, DOMINIQUE SPRUMONT, *La xénotransplantation...cit.*, p. 5 and following.

several levels, impose the monitoring of procedures and their subjection to previous state approval.

b. Patient/organ recipient protection

The legislation regarding health and medicine law, transplants, clinical trials, drugs and pharmaceutical law is, changeable, and still virtually applicable.

From this point of view, is highly important the full comprehension of medical intervention, in its duplicity between medical practice and research in that area.

In fact, only a well based division between both realities may be able to achieve a solid normative frame, in order to deal with questions such as the validity or not of the consent that the organ recipient may give, authorizing the transplant.

c. Animal protection

The legislation, result of the legal relevance denoted, regarding the protection of animals is also applicable. Originating from several sources, it becomes particularly important the analysis of the legislation that specifically deals with the use of living creatures in scientific experiments.

Apparently, we can assert that two lines of force arise from the frame designed. On the one hand, the limitation of experiments to the absolute essential; on the other hand, the interdiction of abuse in terms of genetics¹².

However, some rectifications are required.

On the one hand, it is important to retain that, according to the normative relations, the assimilation of the scope of relevance of the cases by the legislation regarding the use of animals in scientific experiments is subsidiary, only being resorted to when something is not specifically stipulated, in relation to xenotransplants.

On the other hand, we must underline that, far from a literal interpretation of the legal provisions, since it is not viable, the comprehension of the rule may only be obtained through the very ethic-axiological principles that are the basis of the entire system. Which means that the solution found to our problem depends upon their intellect and, ultimately, upon the way we perceive the ethical statute of animals.

To do so, we will start by outlining a slight frame of how their rights can be understood, in light of distinct philosophical positions. And by observing in parallel the juridical statute of animals in the same territorial space, we will try to determine which of these points of view may have been object of projection or refraction.

¹² cf. DAMIAN KÖNIG, DOMINIQUE SPRUMONT, *La xénotransplantation...cit.*, p. 10.

Now we enter the particular, so that in possession of international, transnational and national legislative data, we may look into the regulation in force regarding the use of those living beings in scientific experimentation. With which we try to achieve the basic rules that must be followed, and also become fit to grasp their ultimate intention. The note, far from being exhausted in a simple theoretical interest, will make viable, in absence of a specific discipline that approaches genetic creation for use in xenotransplant, the comprehension of the teleological-axiological aspects that will assure the answer to question that guides us.

It is important to mention that, and advancing some conclusions that we will reach, some of the rules imposed in the problematic horizon already identified, in name of the protection of animals must be interpreted according to the defense of the human being himself. In that way, the temporary answer regarding the (il)legitimacy that we seek to establish will always suffer from an incompleteness justified by the delimitation here stated. In fact, the same comparative effort should be done regarding the regulation of genetic engineered organisms, as well as organ donation and homotransplants.

However, we must give independence to each niche in order to make a specific profound analysis of one of them.

4. How to conceive animal rights?

There have been debates regarding the two adopted philosophical perspectives that approach the way we should consider animal rights¹³.

On one side, some authors support that animals have rights since they possess an intrinsic value that cannot be denied. Among the defenders of such position we find TOM REAGAN. To this author, placed at one of the ends of the discussion, animals have value as individuals and cannot be used as means to an end. The basis of this perception would be the consideration of cognitive abilities as a feature that justifies the dignity of the human being, therefore, and also being present in some animals, they would also be carriers of respect aspirations. Not all, certainly, but at least some, among which would stand out mammals over one year old¹⁴.

From here would result, in a normative projection of the claimed, the impossibility of consuming animals in human food, of creating them for experimental scientific use or for recreational human activities.

¹³ For a reference regarding the perspective that considers animals as people, cf. <http://www.aamc.org/newsroom/reporter/oct03/animalrights.htm> (*Personhood' Redefined: Animal Rights Strategy Gets at the Essence of Being Human*)

¹⁴ TOM REAGAN, *The case for animal rights*, University of California Press, Berkeley, 1983. cf., and, J. RIECHMANN, "La experimentación con animales", in M. CASADO, (Coord.), *Bioética, derecho y sociedad*, Editorial Trotta, S. A., Valladolid, 1998, p. 221-254.

With a different line of arguments, appears frequently PETER SINGER as one of fathers of the animal protection movement. However, the conclusions he reaches are far from those presented by REAGAN, even considering animal experimentation¹⁵.

In the basis of the division is the different presupposition of the author philosophically speaking. It does not based on the value of the individual himself, category in which animals are included¹⁶, but on an utilitarian and consequential position, for which he defends the equal consideration of the interests of all living beings sensible to pain¹⁷.

Beyond the differences, the categorization of the two thinkers in a common group is not unreasonable. All we have to do is think that both put man and irrational animal in the same dialogic level. In the outlining of the contours of personality does not appear as common denominator humanity, but they seek a characteristic that draws to itself the seal of *dignitas*. The division between them comes from the focus presented by each one: the cognitive ability and the sensitivity to pain. The deontological matrix opposing the utilitarian perspective does the rest.

That said, any of them distances itself from the authors that refuse species equality, and persist in the higher position occupied by the human being, the only one capable of integrating the ethical-axiological category of person, therefore being the only one that can manifest his dignity, openly communicate with others, and thus establishing a community of equals, in a responsible self-determination, without whom it would be impossible.

The perspective is no longer biocentric, but anthropocentric. And it seems to be the only one susceptible of ever really being adopted, especially as long as our perspective remains juridical and is contaminated by the law in force.

There are three reasons that, apparently, can be used to justify the statement.

Not only the legal system may find in the idea of dignity of the human being as person the anchorage point, but it will also see how the comparison between human and irrational animals questions the ethical-axiological dimension of legality, since its two predicative notes are lost – liberty and responsibility – once animals are not susceptible of making that mentioned self-determination.

If it is so, especially regarding consequential utilitarianism, it slides into rationality incompatible with the ethic matrix of law. Since the same logic that considers animals carriers of respect aspirations and then sacrifices them in name of the maximization of the well-being of others may, referenced in other contexts, mean the sacrifice of human beings in view of the

¹⁵ cf. <http://www.timesonline.co.uk/tol/news/uk/article650168.ece> It refers to statements by PETER SINGER, regarding a specific case of animal experimentation. The author accepts it according to the consequential and utilitarian logic that heads, as it can, the confrontation of equal interests, may be justified when it involves benefits much greater than the pain inflicted.

¹⁶ cf. E. ENGELS, “El estatuto moral de los animales en la discusión del xenotrasplante”, in C. M. ROMEO CASABONA (Coord.), *Los xenotrasplantes. Aspectos científicos, éticos y jurídicos*, Comares, S. L., Granada, 2002, p. 71-108, p. 98.

¹⁷ A current philosophical trend considers that, in the post-Darwin era, it becomes inevitable to defend the species equality, and therefore human rights should be extended to all beings that may feel pain.

utility obtained. Or, and moreover, lead to the depersonalization of others since they do not feel pain. In fact, the conclusions are not ours, but explicitly asserted by SINGER¹⁸.

In the same way, the position stated by REAGAN does not receive our approval. Even disregarding the reservations caused by the fact that dignity is built-in the subject's cognitive ability, we would always have to consider the inconsistency of such position from a practical-normative point of view. From where we conclude that even if it could, which we doubt, be considered ethically valuable, the radical position from which we have started would be, from a juridical point of view, condemned to be nothing more than a statement of principles. It would lack efficiency, and in that way would not be binding.

This means that, since methodologically it is impossible to look upon positive law without mentioning the normative principles in which it is based, once that is our only assurance of reaching the normative intentionality of the rules when confronted with any normative discipline that establishes animal rights, it must be seen in light of the ultimate individuality observed in the dignity of the human being.

Of what was said it is possible to draw two preliminary conclusions.

Does not the refusal of a biocentric position means the confirmation of the inexistence of protection regarding animals? We simply do not look at it as trying to make them subjective, not even from the point of view of attribution of co-creatures statute, but from the ethics that emerges from the insertion of a person in the surrounding world.

The problem has doctrinal repercussions. A great part of the discussion, in the juridical context, taking place regards the qualification of animals: things, as they have always been seen by law, especially civil law, or subjects with rights^{19 20}?

This is the alternative with which we are confronted nowadays, and that has received an answer in some positive legal systems, among which we underline, due to the original character of the position, the Austrian and the German²¹.

¹⁸ cf. PETER SINGER, *Animal Liberation. A New Ethics for the Treatment of Animals*, New York, 1975

¹⁹ cf. MENEZES CORDEIRO, *Tratado de Direito Civil Português, Parte Geral, Tomo 2, Coisas*, Coimbra, 2nd edition, 2002, p. 32 and p. 211 following.

²⁰ For a historical analysis of juridical evolution regarding the protection of animals, cf. JOHANNA FILIP-FRÖSCHL, "O estatuto jurídico dos animais: Coisas ou co-criaturas?", +++++

The author considers that "the real legislation regarding this matter only began in the nineteenth century and limited to domestic animals". Among us and for all, FERNANDO ARAÚJO, *A hora dos direitos dos animais chegou*, Coimbra, 2003

²¹ cf. JOHANNA FILIP-FRÖSCHL, "O estatuto jurídico dos animais: Coisas ou co-criaturas?",

The author underlines that the Austrian Civil Code now considers, since 1988 (*Bundesgesetz über die Rechtsstellung von Tieren vom 10. 3. 1988, in force since July 1 of 1988 – Federal law regarding the juridical statute of animals in civil law of March 1 of 1988*), that animals are not things and in 1990 the German BGB follows the same footsteps (*Gesetz zur Verbesserung der Rechtsstellung des Tieres im Bürgerlichen Recht vom 20. 8. 1990 – Law for the improvement of the juridical position of animals in civil law of August 20 of 1990*)

See also, p. +++ : "To complete this rule was introduced at the same time a new article within the scope of compensation regarding the treatment expenses of an injured animal, the § 1332a ABGB. § 1332a. Wird ein Tier verletzt, so gebühren die tatsächlich aufgewendeten Kosten der Heilung oder der versuchten

In 1988, was introduced in the ABGB the § 285 a. that considers “*Tiere sind keine Sachen; sie werden durch besondere Gesetze geschützt. Die für Sachen geltenden Vorschriften sind auf Tiere nur insoweit anzuwenden, als keine abweichenden Regelungen bestehen*“ [Animals are not things; there are protected according to special laws. The rules in force regarding things are applicable only if there are no divergent dispositions].

Notice that what could be considered a step forward regarding the equitableness of animals and human beings, is nothing more than the clarification of their juridical statute, they have rights but are not subjects, and so are protected by specific dispositions. And with this is shown the legislative modification in perfect accord with the previously mentioned perspective. In fact, JOHANNA FILIP-FRÖSCHL when analyzing the problem emphasizes precisely that²². The author states that “animals should no longer be things, but the dispositions regarding things apply. Obviously, this means that here nothing is said regarding the juridical position of animals” and she adds that “the conclusion of the doctrine regarding the value of the law, almost unanimously considers it to be more of a *cosmetic modification* of the law of things, which now should be designated, the law of things and animals”²³.

And the same is confirmed in BGB, where the § 90 a. stipulates that *Tiere sind keine Sachen. Sie werden durch besondere Gesetze geschützt. Auf sie sind die für Sachen geltenden Vorschriften entsprechend anzuwenden, soweit nicht etwas anderes bestimmt ist.* [Animals are not things; there are protected according to special laws. The rules regarding things are applicable to animals, unless otherwise estipulated] and the § 903 adds that *Der Eigentümer eines Tieres hat bei der Ausübung seiner Befugnisse die besonderen Vorschriften zum Schutz der Tiere zu beachten* [The owner of an animal must comply, in the exercise of his powers, with the special rules of animal protection].

This means that, and without forgetting the discipline communicated by other rules contained in that and other laws, to animals is not – nor could be – granted the statute of subjects with rights. Their protection, as undeniable as it may be, is based in another set of values than the intrinsic recognition of their dignity, since it is impossible to match that of human beings.

Therefore, we witness, in the legal systems, its structural dependence regarding the human interests that are connected to it. From a civil law point of view, it is the notion of

Heilung auch dann, wenn sie den Wert des Tieres übersteigen, soweit auch ein verständiger Tierhalter in der Lage des Geschädigten die Kosten aufgewendet hätte“.

§ 1332a. In case of an injured animal, the treatment expenses or effective healing attempt are refundable, even if exciding the animal's value, since a reasonable animal owner, if in the situation of the other party, would also have carried them out”.

²² Cf. JOHANNA FILIP-FRÖSCHL, cit., p. +++ . From there results the criticism with which the new rule was received. Its declarative, more than constitutive, sense does not seem to satisfy the radical defenders of animals, since even monuments and some plants are object of special protection.

²³ Inclusively, animals continue to integrate the subject's heritage, they are objects of juridical commerce, they can be sacrificed in order for people, true subjects with rights, to satisfy their numerous needs.

property that supports the mentioned protection, resulting from the limitations that are imposed to the holder of those rights, numerous times in name of public interest, which is inflated within some dogmatic niches, such as the penal and the administrative, thus transmitting the uncovering of biodiversity as juridical asset worthy of protection²⁴.

It is not harmless the division experienced between the protection of domestic animals and all the others that are used in industrial and commercial explorations, and other activities. It shows that, apart from the radical pretensions that may have been the source of this discussion, all protection is established by man, for man²⁵.

Stating that animals possess an individual intrinsic dignity leads, without a doubt, to the impossibility of using them in human food. Simply, if do not want to create an ethical community in fact inexistent, we are confronted with the biological fact of the food chain. Reaching the paradox of prohibiting man to use animals for his survival, when animals themselves kill each other for instinct. Then, it would be objected that man has the ability to practice self-determination by an axiological referential, and that in his positive liberty, has the ability to fulfill his responsible existence. However, by doing so we are already recognizing the inevitable leading position of man and stating the distinctive mark of his personality, which, ultimately, makes legitimate his domination over other beings.

Such does not mean, obviously, that man can proudly flaunt his aggressive behaviors towards them. There is a dimension that must be assured, out of respect for nature, place of cosmological integration of each individual, and out of respect for what connects us to future generations. In other words, animal protection is still seen as the protection of the essential conditions necessary for the free development of each one's personality.

Focused in property, the claim becomes unequivocal; it comes in these terms, stained by publicist notes, in every situation in which human interests gain added value, as is the case with animal experimentation regulation and xenotransplants.

Other understandings regarding the subject, depending on the notion of world from which we start, may confirm the non-neutrality of the juridically established speech.

There are simply two notes that support our understanding.

On one side, it is the methodological consideration of the need to transcend the criteria of positive law for the reference to the foundations of all juridical things and we find them, as we know, in the undeniable ethic dignity of the human person

²⁴ cf. MENEZES CORDEIRO, *op. cit.*, p. 211 and following.

²⁵ cf. JOHANNA FILIP-FRÖSCHL, *cit.*, p. the reforms consider foremost human interests, and in a much smaller scale animal interests, especially focused on domestic animals. This results in a somewhat exaggerated appraisal of domestic animals, meanwhile society remains indifferent before other animals, whom I call "useful animals" or "economically used animals".
We believe the author's tone is, without being justified, judgmental.

On the other side, are the criteria established in the legislation regarding the matter, which after the clarification provided earlier, can only be interpreted in that light.

Basically, we are stating once more, on another dimension – juridically denser – the anthropocentric notion of animal rights. With all the consequences it bears regarding the possibility of using living beings in scientific experimentation.

So, we can, without fear of making a mistake, expose the non-binding character of the Universal Declaration of Animal Rights. It is formally and materially non-binding – since it is only directed at animal protection associations and their associates. It could even be said that the rules there contained are not binding, once they have no effectiveness or validity. In fact, their radicalness turns them into something ignored or a mere statement of principle, unsusceptible of being included in the several legal systems. The human person that is their basis is completely erased from the regulation, thus placing the irrational animal in the same dialogical level of humans, with all the harmful considerations that may arise.

Therefore, the stipulated in article 8 of the referred declaration²⁶ does not constitute an impediment for animal experimentation, which means, *mutatis mutandi*, it can be carried out without any restrictions.

5. Animal protection within the scope of scientific research

a. Xenotransplants

Specifically regarding xenotransplants, it is important to consider the recommendation [Rec \(2003\)10 of the Committee of Ministers to Member States on xenotransplantation of 19 June 2003](#)²⁷.

²⁶ Article 8

- a) Experiments on animals that cause physical and mental pain, are incompatible with animal rights, even if it is for medical, scientific, commercial or any other kind of experiment.
- b) A substitute technique must be investigated and developed

²⁷ Regarding the matter, see also:

[Recommendation 1399 \(1999\) on xenotransplantation, of 29 January 1999](#)

1. The advancement of transplantation technology has allowed considerable success in human-to-human organ transplants (allotransplantation) and is promising a radical breakthrough for the transplantation of animal cells, tissues, and organs into humans (xenotransplantation).
2. Whereas rejection problems and the transfer of diseases can be satisfactorily controlled in allotransplantation, these risks remain today uncontrollable for xenotransplantations. Research to solve these problems should be stepped up prior to any clinical trial.
3. The transmission of animal retroviruses and prions into humans through xenotransplants may cause diseases which, if transmitted to other humans, may cause major pandemics.
4. The health risks of xenotransplantation must therefore be weighed up against their estimated benefits and methods must be found to eliminate any such risks.
5. There are considerable scientific, medical, ethical, social and legal problems that should be answered before clinical xenotransplantations proceed. The ethical problems include the acceptability of xenotransplantations as regards both humans and animals.
6. The Assembly, noting Recommendation No. R (97) 15 of the Committee of Ministers to member states on xenotransplantation, recommends that the Committee of Ministers:

If there were any doubts regarding the anthropocentric character of animal protection, they will certainly disappear by looking at the quoted law. It has two main goals: *to protect, in both the short and long term, public health, patients, their close personal contacts and the professional staff involved in xenotransplantation, and to provide adequate protection for the animals used in xenotransplantation.*

In other words, not only animals are affected by the technique, but also human beings, therefore, results the combination of specific measures to protect humans and the same measures that are applied to the scientific use of irrational animals.

a) Restrictions to xenotransplant:

- a. No xenotransplantation should be carried out in a member state that does not provide regulation for xenotransplantation activities in conformity with the provisions of this recommendation – article 4
- b. No xenotransplantation activity should be carried out in a member state unless authorization is given by a body officially recognized as competent for this purpose – article 5 (*Authorisation for clinical xenotransplantation research should only be given if: a. pre-clinical research has demonstrated, in accordance with internationally accepted scientific standards, that: i. in the light of current scientific knowledge it is highly probable that there is no risk, in particular of infection, for public health; ii. the potential level of efficacy and safety for the patient may justify the intervention having regard to the risks incurred; b. all substantive and procedural conditions generally*

i. work for the rapid introduction in all member states of a legally-binding moratorium on all clinical xenotransplantations, and consider the feasibility of elaborating a second protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (European Treaty Series No. 164), on xenotransplantation;

ii. take steps to make this moratorium a worldwide legal agreement;

iii. ask its European Health Committee and Steering Committee on Bioethics to work out, in co-operation with the World Health Organisation, a strategy for balancing the ethical, medical, scientific, legal, social and public health aspects of xenotransplantation, before the scientific and medical establishment is permitted to proceed with clinical trials on humans

[Recommendation No \(97\) 15, on xenotransplantation, of 30 September 1997](#)

Considering that xenotransplantation, that is, the use of living organs, tissues and/or cells from animals, whether genetically modified or not, for transplantation into humans, may become a practicable therapeutic intervention in the very near future.

Aware that there is a risk of transmission of disease as a result of xenotransplantation procedures, Recommends that Governments of member States should establish a mechanism for the registration and regulation of the following aspects of xenotransplantation with a view to minimising the risk of transmission of known or unknown diseases and infections to either the human or animal population:

- i. basic research and clinical trials;
- ii. the source and care of animals for use in xenotransplantation;
- iii. xenotransplantation programmes;
- iv. long term follow-up and review of xenograft recipients and the xenograft source animals.

applicable to clinical research are fulfilled. Xenotransplantation should not be authorised other than in clinical research unless, on the basis of clinical data: i. there is adequate evidence, in accordance with internationally accepted scientific standards, that no risks, in particular of infection, to the general population exist, and ii. the therapeutic benefit of the xenotransplantation has been established.)

- c. No xenotransplantation should be carried out unless by an accredited team in an authorized centre undertakes it – article 6
- d. Non-human primates should not be used as source animals for xenotransplantation – article 11. Strangely, and reinforcing the previously stated, the rule integrates the recommendation regarding the protection of public health²⁸.
- e. No xenotransplantation should be carried out unless the following specific conditions are fulfilled: i. There is no other appropriate therapeutic method of comparable effectiveness available for the patient. ii. The data resulting from pre-clinical research suggest or, where appropriate, the data resulting from prior clinical research indicate a clear therapeutic benefit for the xenotransplantation patient. In particular these data should: - have demonstrated an adequate function of the xenotransplant in relevant models for an appropriate period of time through a clinically applicable methodology, - provide sufficient reasons to believe that rejection can be overcome and that the xenotransplant can function adequately in humans. iii. The risks which may be incurred by the patient are not disproportionate to the potential therapeutic benefit of the procedure. In particular, the evaluation through pre-clinical research of the risks for adverse events and transmission of infectious agents to the recipient, as based on international standards for laboratory results and diagnostic assays, should have demonstrated sufficient safety – article 12.

- b) Public health protection: certain rules are imposed in order to guard public health. Once more, it is the dignity of the human person that is at stake:

²⁸ See number 2 of article 11:

- 2. Exceptionally, authorisation for the xenotransplantation of cell lines obtained from non-human primates may be given if:
 - the conditions under Article 5 are fulfilled, and
 - specific protective measures for these animals have been addressed. This implies that Great Apes should not be used as source animals in xenotransplantation.

- a. There should be a contingency plan to guard public health: *Member states should have a plan in place to address any events, in particular of infection, possibly related to a xenotransplantation which could compromise public health – article 7²⁹*
 - b. Long-term monitoring – article 8th (*Information and biological samples concerning the source animals used in xenotransplantation and the recipients should be collected and stored in order to ensure traceability and long-term monitoring*)
 - c. Preventive measures of contamination risk – article 10th *All appropriate measures, in accordance with internationally recognised criteria, should be taken to prevent the risk of transmission of infectious agents from source animals.*
- c) Patient protection (organ recipient and the people that are close to him). It is absolutely necessary that the organ recipient states his consent, after being properly informed³⁰. In order to do so, some clarifications are essential. They should also be

²⁹ Article 7:

(...)In particular, public authorities should take appropriate measures, in conformity with the principles of necessity and proportionality, to respond to events of transmissible or previously unknown illness related to xenotransplantation. These measures, if exceptional circumstances so require, might include isolation

³⁰ Article 13 – Information to be given to patients:

1. Patients participating in a xenotransplantation should be adequately informed in a comprehensible manner of the nature, objectives, possible benefits, potential risks and consequences of the procedure, as well as of any constraints that may be linked to it.
2. In particular patients should also be made aware of the constraints of monitoring and precautionary measures that may become necessary subsequent to xenotransplantation. Such measures will, according to the principles of necessity and proportionality, be adapted to the circumstances and adjusted in accordance with the assessment, based on current scientific and medical knowledge, of the risks generated by each of the procedures involved, and may in particular include:
 - a. the collection of personal data and inclusion in a register;
 - b. the provision by the medical team, in accordance with Article 14, of information concerning the risks of infection and the constraints associated thereto;
 - c. long-term medical monitoring including repeated biological samples being taken and archived;
 - d. reporting any significant unexplained symptoms or illness that may arise after the xenotransplantation;
 - e. maintaining contact with the medical team;
 - f. taking precautions with respect to sexual activity;
 - g. the need for the patient to agree that information is provided by a medical team to any future close personal contacts, in accordance with Article 14, concerning the risks of infection and the constraints associated thereto;
 - h. the other constraints which might be applicable if circumstances so require, in particular the possibility of isolation which may become necessary in the event of a contagious or previously unknown illness occurring.
3. Patients should be informed that, in accordance with Article 21, constraints mentioned hereinabove may be imposed if the person concerned refuses to comply with them.

Article 16 – Consent to xenotransplantation

provided to the people that are in direct and close contact with the patient³¹ and healthcare professionals³². The freedom manifested by the patient when stating his consent, should not in any case be subjected, in case of refusal, to any penalty³³, and for the need of having the ability to carry out such act, without which self-determination would be excluded³⁴. It is also stipulated a compensation for the damages that may occur³⁵.

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1. No xenotransplantation should be carried out without:
 - i. the documented, specific, free and informed consent of the patient to the procedure and any necessary specific constraints; and
 - ii. the provision by the patient to the medical team of the necessary information concerning his or her current close personal contacts and the acceptance by the patient that his or her current and future close personal contacts be given information in accordance with Article 14.
 2. Prior to xenotransplantation, the consent to carry out the intervention may be freely withdrawn at any time.

Article 17 - Counselling and support

The patients and their close personal contacts should be given proper information and have access to counselling and support by experts outside the team both before and after the xenotransplantation. This informing and counselling process should include the biomedical, ethical, psychological and social aspects of xenotransplantation.

³¹ See Article 14

To protect close personal contacts and warn of the possible risks they might pose to the general public, the patient's close personal contacts should, with his or her consent, be informed by the medical team of the patient's envisaged participation in a xenotransplantation, of the risks of infection and of the consequences for them of such participation, and in particular, of the constraints which may be applicable.

The patient should also ensure that such information is provided to any future close personal contacts.

³² Article 15 – Information to be given to the professional staff involved in xenotransplantation

Professional staff involved in xenotransplantation should be fully aware of the risks of infection as well as the possible consequences and constraints which may derive from their participation in xenotransplantation.

³³ Article 18: A refusal to participate, or a withdrawal of consent prior to the xenotransplantation, should not prejudice the patient's right to receive all other appropriate medical care in due course. The patient's consent to participate in a xenotransplantation should not prejudice his or her right to benefit from an allotransplant that becomes available while awaiting xenotransplantation, if medically indicated.

³⁴ In case the patient is unable to consent, article 19 stipulates the following:

1. Where xenotransplantation has been authorized for use other than in clinical research according to Article 5 paragraph 2, it may be carried out on a person not able to consent only if the following conditions are fulfilled:

- there is no therapeutic alternative of comparable effectiveness available to the patient,
- taking into account the constraints and conditions to which the person will or may be subjected according to Articles 13 and 14, the intervention is expected to result in a direct and important benefit for the patient, and
- the representative or an authority or a person or body provided for by law, after receiving the information referred to in Article 13, has authorized both the intervention and the provision of the necessary information to the present and future close personal contacts of the patient.

2. Patients unable to consent should not undergo clinical xenotransplantation research as referred to in Article 5, paragraph 1.

Exceptionally, a patient unable to consent may participate in a clinical xenotransplantation research intervention if the following specific conditions are fulfilled:

- there is adequate indication, on the basis of prior clinical research, that the xenotransplantation might be lifesaving,
- there is no alternative means of saving the life of the patient,

- d) Animal protection: the recommendation establishes that animal protection should be carried out as established by the quoted and analyzed European convention (article 22). Some special dispositions are stipulated:
- a. Minimize the suffering and pain of animals [article 23]^{36 37}
 - b. Animal transport: *Transport of animals for xenotransplantation should be kept to a minimum. If transportation is necessary, adequate arrangements should be made for the dispatch, receipt, acclimatisation and quarantine of animals in order to minimise the associated stress.* (article 26)³⁸
 - c. Genetic intervention in animals: *Surgical derivation and segregated/medicated early weaning production techniques should only be used where essential to produce animals of appropriate health status for use in xenotransplantation* – article 25
 - d. Gathering information regarding the animal: *Detailed records should be maintained of the derivation, source, use and final disposal of all animals bred for or used in xenotransplantation. Any unusual or unexpected traits or events should be recorded.*

In conclusion, we can state that regarding xenotransplants the communitarian protection of animals represents only a small share of the communitarian legislator worries.

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- taking into account the constraints and conditions to which the person will or may be subjected according to Articles 13 and 14, the intervention is expected to result in a direct and important benefit for the patient, and
 - the representative or an authority or a person or body provided for by law, after receiving the information referred to in Article 13, has authorised both the patient's participation in the clinical xenotransplantation research and the provision of the necessary information to the present and future close personal contacts of the patient.

³⁵ Article 33 - Compensation for undue damage

The person who has suffered undue damage resulting from a xenotransplantation is entitled to fair compensation according to the conditions and procedures prescribed by law.

³⁶ Article 23 – Husbandry, care, use and requirements of animals

The husbandry and care for all animals used in xenotransplantation should take account of their physiological, social and behavioural needs and should be designed to ensure their well being, particularly where breeding animals are maintained for long periods. The pain, suffering or distress and the number of animals used should be minimised.

³⁷ In that way, article 27 stipulates

Article 27 – Organ and tissue procurement from animals

Analgesia or anaesthesia should be used for the procurement of organs, tissues and cells for xenotransplantation, where it is necessary to minimise pain, suffering and distress of the animals.

If, as a result of the procurement, the subsequent health and welfare of the animals would be compromised, the animals should be killed by an appropriate method.

Sequential harvest of solid organs from individual animals should not be permitted

³⁸ The rules stipulated by the European Union Directive 95/29/EEC modified Directive 91/628/EEC regarding the protection of animals during transport, and the European Convention for the Protection of Animals During International Transport are considered applicable.

In the same way can be interpreted other normative structures that have emerged. Example of that is the Swiss regulation, especially directed for the protection of the human being, although it does not forget the interests of animals. Namely, it is considered applicable the Federal Law for the Protection of Animals, of March 9 of 1978, with the modifications of the Federal Law for the Protection of the Environment, having as consequence the admissibility of genetic mutation in animals, as long as carried out after consideration of all interests^{39 40}.

b. Animal experimentation

Regarding animal experimentation, there is at an European level an abundance of legislation containing specific rules that aim to protect animal life from aggressive human intrusion.

Curiously, we seem to be able to announce the convergence of the discipline in the several European legal systems. As so, it will not be inconsequential the wish of the communitarian law regarding that matter, seeking by its own means the harmony in the internal systems of each State-member.

Thus, it is important to consider the **European Convention regarding the Protection of Vertebrate Animals used for experiments or for other scientific purposes**, of March 18 of 1986 (Strasbourg)⁴¹.

From the start, it is important to emphasize the species restriction stipulated by article 1. When it mentions the scope of the directive, it states that the dispositions only concern vertebrate animals.

And regarding the scope of relevance, we must underline the notion of procedure that is provided: *any experimental or other scientific use of an animal which may cause it pain, suffering, distress or lasting harm, including any course of action intended to, or liable to, result in the birth of an animal in any such conditions, but excluding the least painful methods accepted in modern practice (that is "humane" methods) of killing or marking an animal.*

It can take place with determined purposes. Regarding the dispositions of the same rule:

a

³⁹ Cf. www.admin.ch/buwal/press/2000/f0001191.htm

⁴⁰ See also, the Recommendation of WHO of 1998. It considers the therapeutic potential of xenotransplants, but does not ignore that it bears risk of transmission of infectious agents, known or unknown. It emphasizes the need to contain the risk within acceptable measures, suggesting precaution. As guidelines it proposes measures of animal selection and control, vigilance programs and long-term monitoring, and the reach of a consensus regarding the matter, so that risks and uses are properly considered.

Cf. Xenotransplantation: Guidance on Infection Disease Prevention and Management: World Health Organization, Emerging and Other Communicable Disease Survey and Control, 1998

⁴¹ The Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (No. 170) has been opened for signature by the signatories to Treaty ETS 123. It was opened for signature in Strasbourg on 22 June 1998. Since its entry into force, this Protocol forms an integral part of ETS123.

- i avoidance or prevention of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants, including the production and the quality, efficacy and safety testing of drugs, substances or products;*
- ii diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, vertebrate or invertebrate animals or plants;*
- b detection, assessment, regulation or modification of physiological conditions in man, vertebrate and invertebrate animals or plants;*
- c protection of the environment;*
- d scientific research;*
- e education and training;*
- f forensic inquiries.*

We verify, now as before, that the use of animals in scientific experiments or in therapeutic interventions is possible. However, some limitations are imposed:

- a) Regarding usable animals, fetal and embryonic forms are excluded. As a general rule, only animals supplied from registered breeding or supplying establishments shall be used, unless a general or special exemption has been obtained (art. 22)⁴².
- b) There is a general prohibition on the use of stray animals of a domesticated species (art. 21.3), except for a stray dog or cat that has a special exemption (as the only which prohibits this article is the general exemption)⁴³.

The question can be asked as to whether the stray animals that are made reference to in this article are solely those that are listed in number 1 (rabbit, dog or cat) or, on the contrary, whether this limitation is extended to all possible domesticated animals. In accordance with a systematic interpretation, it seems to be limited only to those domesticated strays that are listed in this article, although, as previously mentioned, this list is open, in accordance to what is stated in section two of the article. In any case, to admit a special exemption for a stray dog or cat, but not for the rest of the domesticated animals, least linked to man seems curious, always when this is the basis that justifies the restriction of the exemption (only special, excluding the general exemption). Therefore, I believe that the interpretation of the precepts must be another: First. As a general rule, only domesticated animals from breeding establishments shall be used. Second. Only on an exceptional basis, if there is a concurrence with a general or special exemption, will it be possible to use domesticated animals that don't come from breeding establishments and therefore, domesticated stray animals. Third. Except when dealing with dogs and cats, in which case it will only be possible with a special exemption.

⁴² Each dog or cat must be duly identified either marked, before its weaning, or by keeping documentary records (art. 17 of the Convention).

⁴³ See Article 4 of the directive, which stipulates that it is not permitted to use animals of endangered species, unless the experiment has as purpose the protection of that species or unless proven that it is the only species capable of satisfying the scientific needs in question [*research aimed at preservation of the species in question, or essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.*]

Therefore these animals have the general exemptions excluded. The reason for this limitation is justified, as mentioned, in that we are dealing with two species of domesticated animals that have very strong ties to man^{44 45}.

- c) Animal experimentation must only be used when there are no other scientific alternatives that can be undertaken without the use of animals (art. 6.1). And in a choice between procedures, that which uses the least number of animals, which is least harmful and that is most likely to provide satisfactory results shall be used should be the selected one.
- d) Except for express authorization, every experimental or scientific procedure must be performed in a registered establishment (art. 23) that complies with a series of conditions (art. 18)⁴⁶.

In parallel, determined rules must be followed:

- a) Article 8 of the Convention states that a procedure shall be performed under general anesthesia or analgesia in order to eliminate as far as practicable suffering of an animal, unless it is incompatible with the aim of the procedure or the well-being of the animal⁴⁷.

⁴⁴ Cf. *Draft Report*, p. 41

⁴⁵ See [Resolution on the acquisition and transport of laboratory animals \(adopted by the Multilateral Consultation on 30 May 1997\)](#)

Acquisition of laboratory animals

The following criteria shall be taken into consideration when deciding whether or not to grant a general or special exemption from Article 21 of the Convention:

. There should be a justifiable need for the animals for experimental or laboratory animal breeding purposes.

. Reasonable efforts should be made to establish that suitable animals are not available from registered breeders and suppliers. Elements relevant to suitability could relate to the following: species and strain, quantity, quality, time aspects.

. Assurances should be sought concerning the adequacy of the care and accommodation at the breeding or supplying establishment.

. None of the above must take precedence over the requirement concerning stray animals provided in Article 21, paragraph 3.

⁴⁶The directive prescribes that the procedure shall be performed by authorised people, or under their direct supervision (art. 21).

⁴⁷ See article 8 of the Directive:

Article 8

1. All experiments shall be carried out under general or local anaesthesia.

2. Paragraph 1 above does not apply when:

(a) anaesthesia is judged to be more traumatic to the animal than the experiment itself;

(b) anaesthesia is incompatible with the object of the experiment. In such cases appropriate legislative and/or administrative measures shall be taken to ensure that no such experiment is carried out unnecessarily.

Anaesthesia should be used in the case of serious injuries which may cause severe pain.

3. If anaesthesia is not possible, analgesics or other appropriate methods should be used in order to ensure as far as possible that pain, suffering, distress or harm are limited and that in any event the animal is not subject to severe pain, distress or suffering.

4. Provided such action is compatible with the object of the experiment, an anaesthetized animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.

- b) Any animal used or intended for use in a procedure shall be provided with accommodation, an environment, at least a minimum degree of freedom of movement, food, water and care, appropriate to its health and well-being. Any restriction on the extent to which an animal can satisfy its physiological and ethological needs shall be limited as far as practicable. (art. 5). The well-being and state of health of animals shall be observed sufficiently closely and frequently to prevent pain or avoidable suffering, distress or lasting harm. (see also art.10)^{48 49 50}

⁴⁸ See article 5 of the Directive:

Article 5

Member States shall ensure that, as far as the general care and accommodation of animals is concerned:

- (a) all experimental animals shall be provided with housing, an environment, at least some freedom of movement, food, water and care which are appropriate to their health and well-being;
- (b) any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited to the absolute minimum;
- (c) the environmental conditions in which experimental animals are bred, kept or used must be checked daily;
- (d) the well-being and state of health of experimental animals shall be observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm;
- (e) arrangements are made to ensure that any defect or suffering discovered is eliminated as quickly as possible.

⁴⁹ See also [Resolution on the acquisition and transport of laboratory animals \(adopted by the Multilateral Consultation on 30 May 1997\)](#)

Transport of laboratory animals

The Parties shall:

- * ensure that the principles of best practice in the packing and transport of laboratory animals contained in the Appendix to this Resolution are circulated among the persons concerned with the transport of laboratory animals;
- * encourage these persons to follow these principles complementing Appendix A.
- * encourage the insertion of those principles in any education or training programme intended for persons concerned with the transport of laboratory animals

⁵⁰ See also [Resolution on the accommodation and care of laboratory animals \(adopted by the Multilateral Consultation on 30 May 1997\)](#):

The responsibility of the establishment and persons carrying out scientific procedures on animals is to maximise the overall benefit for "animals" as "individuals" and as a "group", with the 3R principle as a permanent concern and considering that the relevance and high quality of scientific results will facilitate the achievement of this rule.

Therefore group-housing, even pair-housing, is preferable to individual housing for all gregarious species normally manifesting social behaviour, as long as the groups are stable and harmonious. Where for behavioural or inescapable requirements of a scientific protocol group-housing is not possible, consideration should be given to accommodating conspecifics within sight, sound or smell of one another.

(...)

General recommendations and comments

Ventilation

- ventilation rate in the animal room should be appropriate to stocking density in accordance with the total caloric output of the animals. Additional attention should be paid to the ventilation within the cage with respect to different caging systems.

Contact

- Animals should be handled or be in social contact with humans on a regular basis, with particular attention to the socialization period in species such as cats and dogs.

(...)

Recommendations and comments on different groups of species:

With respect to individual species - the following recommendations and comments should be taken into consideration:

Rodents

- Rodents should be kept in cages rather than pens, guinea-pigs excepted. The cages should be made of easy to clean material and their design should allow proper inspection of the animals without unnecessarily disturbing them.

- They should be provided with solid floors with bedding instead of grid floors, special circumstances excepted.

- Gregarious species should be group-housed, as long as the group are stable and harmonious, which can be achieved with difficulty in male rats and mice, and female hamsters. Where the experimental procedures or welfare requirements make it impossible, consideration should be given to accommodating conspecifics within sight, sound or smell of one another.

- Encouragement should be given to break up the interior space of a cage by introducing objects such as platforms, tubes, boxes, etc. and attempts should be made to provide environmental enrichment with objects to explore, carry or transform, unless negative effects are observed on welfare or on the intended scientific use.

- High hygiene standards should be maintained. However, it may be advisable to maintain odour patterns left by the animals.

- Special attention should be paid to ensuring that the lighting intensity particularly on the top row of cages is not too high. Maximum light intensity should not exceed 350 Lux measured 1 metre from the floor. Provision should be made for shaded areas within the cage to allow the animals to withdraw.

Rabbits

- Young and female rabbits should be housed in socially harmonious groups, unless the experimental procedure or welfare requirements make this impossible.

- Wire floors without the provision of a solid resting area should not be used for rabbits. The materials, design and construction of slatted or perforated floors should provide surfaces which do not produce welfare problems.

- Pens as well as cages should include environmental enrichment material e.g. roughage, sticks, an area for withdrawal and nesting material.

Cats

- Cats should be housed in pens in socially harmonious groups unless the experimental procedures or welfare requirements make this impossible. There should be 0.8 sq. m. floor area per weaned cat for group-housed animals. The minimum height should be 1.5 m. and pens should be so equipped that the three dimensions can be used.

- Pens should provide semi-closed structures for privacy, clawing substrate, objects to play with and enough places for feeding, drinking, urination, defecation and lying down to avoid competition.

- If cages have to be used and exercise is not possible for experimental reasons, cage heights should allow the animal to stand up at full stretch.

Dogs

- Dogs should be housed in socially harmonious groups, unless the experimental procedures or welfare requirements make this impossible.

- Dogs should be exercised at least daily. Under no circumstances should dogs be caged without exercise for more than 14 days. Preferably, dogs should be exercised with other dogs.

- Dog pens should allow some privacy for the animals. They should include playthings and structures, including elevated platforms.

- Solid floors should be used for dogs. The materials, design and construction of slatted or perforated floors should provide surfaces which do not produce welfare problems, and should supply a solid resting area.

Pigs (including minipigs)

- Pigs should be housed in stable, socially harmonious groups, adult boars excepted.

- Preferably they should be housed in pens, unless experimental procedures or welfare requirements make it impossible.

- They should be provided with enrichment such as straw, chains, balls, etc.

Poultry

- Various structural elements such as perches and nesting sites, and the possibility of dustbathing, should be provided in the cages or pens whenever possible and appropriate.

Non-human primates

- The volume of cages (floor area, height) should take into account the specific needs of the different species, the social composition of the group, the age of the individuals, the use of animals (breeding, stock, research and the nature and duration of the scientific procedure), and the need for enrichment.

- Primate cages should have environmental enrichment.

- c) Where it is necessary for the legitimate purposes of the procedure and with previous authorization by the responsible authority, the animals shall be set free provided that it is satisfied that the maximum practicable care has been taken to safeguard to animal's well-being (Art. 12)

The convention stipulates rules that must be followed after the scientific procedure. The debate regards the fate of the animal:

At the end of the procedure, the responsible person, the veterinarian, the person responsible for the experiment or whomever has performed it, shall decide the future of the animal, whether to be kept alive or be killed (art. 11.1 and 11.2 of the Convention). Therefore, the person responsible shall freely choose, except for some exceptions in which the killing is mandatory. *The mandatory sacrifice* shall be performed when: a) the animal is likely to remain in lasting pain or distress, though it has been restored to normal health (art. 11.1); b) when, due to its state of being, the animal can't benefit from the legally established provision (accommodation, food, etc) (art. 11.3.b).

If there is any decision in keeping the animal alive, it shall be placed under the supervision of a veterinarian or other competent person, thus receiving the minimum care of housing, food, cleaning, etc, aforementioned, as well as those that are in conformance with its health, if necessary (art. 11.3a).

In accordance with article 11.4 of the Convention, no animal which has been used in a procedure entailing severe or enduring pain or suffering can be used in a further procedure. Nonetheless, this possibility exists if the animal has returned to good health and the further

- *Primates should be kept in stable social groups of compatible animals while taking into account the diversity of social structure between species. Single caging should be avoided unless a specific scientific justification is provided.*

Research shall be encouraged in the areas where scientific evidence is lacking on the biological requirements of the animals, considering also the changes in the use of animals for scientific purpose. To make the best use of available resources to determine the optimum housing conditions for laboratory animals, taking into account species, strains, current and future research needs, priority shall be given to the following areas:

- *scientific validation of minimum cage sizes for rodents, as well as of minimal space per individual animal, taking into account social structure and role (sex, age, hierarchy...), cage structure etc;*

- *scientific validation of floor areas and cage heights for non-human primates, taking especially into account the biological and social differences between species and the purpose of housing (stock, breeding, use in procedures);*

- *the welfare impact of group housing compared to individual housing and the impact on the group of removing individuals or splitting up the group of animals after a period of time for experimental purposes;*

- *the impact of different cage structures on the welfare of rodents and non-human primates;*

- *the effect of introducing objects and structural elements into cages as environmental enrichment;*

- *the space requirements and environmental enrichment needs of dogs.*

See also, *Commission Recommendation of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes*. It also stipulates rules regarding Ventilation, Temperature, Humidity, Lighting, noise, health, care, capture from the wild, transport, quarantine, housing, feeding, watering, cleaning, human killing, paying special attention to the analysis of the conditions those same must follow considering every species contemplated.

procedures involve minor interventions or if the animal is subject to general anaesthesia throughout the procedure, which shall be maintained until the animal is killed⁵¹.

It is not far from the discipline provided by the **86/609/CEE Directive of November 24 of 1986, of the Committee**⁵², regarding the proximity of the internal law of the several State-members when it comes to the protection of animals, used in scientific experiments or for other scientific purposes.

The aim of this Directive is to ensure that where animals are used for experimental or other scientific purposes the provisions laid down by law, regulation or administrative provisions in the Member States for their protection are approximated so as to avoid affecting the establishment and functioning of the common market, in particular by distortions of competition or barriers to trade (art. 1).

It is important to note the infiltration of the specific aspiration of communitarian law in the regulation. The concern does not regard only animal protection, but also the elimination of barriers for free competition, without which a common market cannot be established.

Without obstacles, the frame of values provided is not far from the one mentioned before. Here are the points of divergence:

- a) It is not permitted to use animals of endangered species (Article 4), unless the experiment has as purpose the protection of that species or unless proven that it is the only species capable of satisfying the scientific needs in question [*research aimed at preservation of the species in question, or essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.*]

⁵¹ See Article 9 of the Directive:
Article 9

1. At the end of any experiment, it shall be decided whether the animal shall be kept alive or killed by a humane method, subject to the condition that it shall not be kept alive if, even though it has been restored to normal health in all other respects, it is likely to remain in lasting pain or distress.

2. The decisions referred to in paragraph 1 shall be taken by a competent person, preferably a veterinarian.

3. Where, at the end of an experiment:

(a) an animal is to be kept alive, it shall receive the care appropriate to its state of health, be placed under the supervision of a veterinarian or other competent person and shall be kept under conditions conforming to the requirements of Article 5. The conditions laid down in this subparagraph may, however, be waived where, in the opinion of a veterinarian, the animal would not suffer as a consequence of such exemption;

(b) an animal is not to be kept alive or cannot benefit from the provisions of Article 5 concerning its well-being, it shall be killed by a humane method as soon as possible.

⁵² Cf. [Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC 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](#)

- b) It is more detailed in determined aspects, especially regarding the choice of the several species that might be subjected to experimentation – article 7, no.3: In a choice between experiments, those which use the minimum number of animals, involve animals with the lowest degree of neurophysiologic sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected. Experiments on animals taken from the wild may not be carried out unless experiments on other animals would not suffice for the aims of the experiment.]

The Spanish legislation regarding the protection of animal rights is not very different from the European regulation on the matter.

- [Royal Decree 1201/2005, of 10 October, on the protection of animals used for experimentation and other scientific purposes](#)

a) Conditions of animal use:

- a. The use of animals is restricted to specific purposes: scientific research, including aspects such as the prevention of diseases, health changes and other anomalies and their effects, as well as their diagnosis and treatment in humans, animals and plants; the development and production of pharmaceutical products, food, or other substances and products, as well as the procedures of quality, efficiency and safety verification; the assessment, detection, regulation or modification physiological conditions in humans, animals or plants; the protection of environment, in the interest of human or animal health and well-being and the conservation of biodiversity; education and training; medical-forensic research.
- b. The use of animals is subjected to the three R rule: reduction, refinement and replacement⁵³.
- c. No animals from endangered species may be used (Article 17).

b) Animal accommodation⁵⁴:

⁵³ 1. Reduction: strategy that aims to use the minimum possible number of animals necessary to achieve the objective of the procedure.

2. Refinement: includes most of the procedures that affect the life of the animal and allow the relief or reduction of the pain or discomfort.

3. Replacement: use of alternative techniques that may provide the same level of information obtained through procedures that involve animals but that do not resort to their use.

⁵⁴ See also [Project of Law, of 10 July 2007, on basic norms relating to operation, transport, experimentation and sacrifice for the care of animals.](#)

- a. The animals must be provided with suitable conditions to assure their well-being (especially, assure proper feeding, freedom of movements and care considered necessary for the comfort of the animals).
 - b. The level of well-being of the animals must be controlled daily.
 - c. All measures that are not necessary and endanger the well-being of the animals must be avoided⁵⁵.
- c) Animal transportation⁵⁶
- a. The existing rules regarding animal transportation must be followed.
 - b. The transport containers must assure the minimum freedom of movements.
 - c. The animals should, in the transport, be accompanied by a document, provided by an animal health expert, containing determined information⁵⁷.
- d) Compulsory animal identification⁵⁸.
- e) The person in charge of the center should assure that the rules are followed and should have the proper training to do so⁵⁹.
- f) Centers obligations⁶⁰: they may only obtain animals from breeding centers,

⁵⁵ Article 4: General conditions of handling and accommodation

⁵⁶ Regarding animal transportation, cf. [Project of Law, of 10 July 2007, on basic norms relating to operation, transport, experimentation and sacrifice for the care of animals.](#)

The law contemplates the transportation of animals which are object to scientific research.

See article 5: Public bodies will adopt the necessary measures to assure that only animals who are in condition to travel are transported, so that the transportation is carried out without causing them injuries or unnecessary suffering, and to reduce as much as possible the duration of the transport and to satisfy the needs of the animals during that same transportation..

The well-being of animals and their security should be guaranteed. That's why all unnecessary or unjustified injuries and suffering should be proscribed.

See also article 8: The animal carriers, their vehicles, containers or means of transportation must have the proper authorization and be registered, according to the dispositions stipulated.

⁵⁷ Article 5

⁵⁸ Article 6

Animal identification

1. All animals belonging to species with already stipulated identification systems should be identified according to the binding normative. The identification method is designed in order to be unforgeable, easily read throughout the animal's life, not reusable and that does affect the animal's well-being.

2. Namely, dogs, cats and non-human primates must be individually identified, preferably before their ablation, with a permanent system that causes the minimum pain possible. When dogs, cats or non-human primates are transferred from one center to another before ablation and before being properly identified, the receiving center must maintain a complete record, especially, information regarding the mother and should proceed to the identification of the animal as soon as possible.

3. When the identification system used may inflict pain to the animal should be provided with the proper anesthesia or analgesia.

⁵⁹ cf. Article 9

The centers must have a person in charge of the animals' health and well-being (veterinarian).

⁶⁰ See also [Project of Law, of 10 July 2007, on basic rules regarding the operation, transportation experimentation and sacrifice for the care of animals.](#), article 7 The centers or establishments destined to breed, supply or use of animals for experimentation or other scientific purposes, including teaching, must be authorized or registered in the correspondent administrative record, before the beginning of activity.

unless legally imported. The use of stray or abandoned animals is prohibited.

g) Conditions of procedures: (article 16)

- a. The use of animals is subjected to the idea of subsidiarity. Only if there is no other procedure available will the resort to animal experimentation be acceptable.
- b. Unnecessary pain and suffering of the animals must be avoided.
- c. It should be chosen the procedure that involves a fewer animals and less suffering for the animal; among the species selected, it should be chosen the one that presents less neurosensitive sensibility.
- d. Each procedure must have someone in charge.
- e. The procedures must be performed by skilled personnel.
- f. It is not allowed to perform procedures that involve animals of endangered species or of protected fauna. As well as, procedures with stray animals.
- g. All procedures must be communicated to the competent authorities (article 18).
- h. The procedures must be performed with the animals under local or general anesthesia, unless it is more traumatic to the animal than the procedure itself or if it contrary to the research developed. In the latter, an authorization should be requested to the competent authorities (article 20).
- i. The same animal may never be used more than once in procedures that inflict great pain or sacrifice (article 20).
- j. After the procedure, it must be decided if the animal is to be kept alive or put to death, through a humanitarian method (article 21).
- k. In case the animal is kept alive, all healthcare necessary to his state must be provided, which must be followed by a veterinarian (article 21).

In **Portugal**, the solutions stipulated regarding the protection of animals are not very different from its communitarian correspondents.

Law no. 92/95, of September 12, with the modifications introduced by law no. 19/2002, of July 21, stipulates the general regime for the protection of animal rights. However, it does not specify any rules regarding their use for scientific purposes.

Regarding that matter the **Cabinet Order 1005/92, of October 23, changed by Cabinet Order 466/95, of May 17 and by Cabinet Order 1131/97, of November 7.**

- a) Scope of the law: it applies to the use of animals in experiments with one of the following purposes: a) Development, production and quality, efficiency and safety control of drugs, food and other substances or products destined to i) avoid, prevent, diagnose or treat diseases, unstable health conditions or abnormal situations, or their effects on man, animals or plants; ii) assess, detect, regulate or change the physiological conditions of man, animals or plants; b) the protection of environment, in the interest of the health or well-being of man or animals.
- b) Restrictions:
- a. It is forbidden the use of animals of endangered species. (article 5)
 - b. No animals may be used when the same scientific purpose may be reached through other means. (article 9)
 - c. Among the several experiments available should be chosen the ones that a) require the lower number of animals; b) involve animals with the lower degree of neurophysiologic sensibility; c) cause less pain, suffering, anguish or permanent damages; d) offer greater probabilities of fulfilling results. (article 11)
 - d. The use of wild animals is only permitted when the purposes of the experiment cannot be reached through the use of other animals (article 12).
 - e. The same animal cannot be used in more than one experiment that causes violent pain or suffering. (article 21)
- c) Rules to follow regarding the procedure:
- a. Regarding animal accommodation, they must be accommodated in a suitable environment that assures the minimum freedom of movements. Their feeding, well-being, and water necessary to their sustenance must also be assured. Such well-being conditions must be daily controlled. (article 6)
 - b. The suffering of the animal must be eliminated as soon as possible. (article 6)
 - c. Scientific projects must be authorized by the competent body and experiments may only be performed by properly skilled people and under their direct responsibility. (article 8)
 - d. The choice of the species used must be thoughtful and, if necessary, justified before the competent authority.
 - e. All experiments must be performed under local or general anesthesia, especially in serious injuries that may inflict violent pain, unless the anesthesia is more traumatic than the experiment itself or unless it is

incompatible with the experiment's purpose, in that case there should be taken measures to assure that such experiments are not unnecessarily performed. (article 14)⁶¹

- f. At the end of each experiment should be decided if the animal is to be kept alive or out to death, through a humanitarian method, namely, if even having recovered his normal health condition regarding all other aspects, he is likely to remain in permanent pain or suffering. (article 17)
- d) Rules that the centers must follow:
 - a. The breeding centers and suppliers must register the number and species of animals sold or provided, the name and address of the recipient and the number and species of animals that die in the centers in question. (article 30)
 - b. The establishments must have a permit provided by DGP, in order to obtain it they must: a) have facilities and equipments suitable for the animals species used and the experiments carried out; b) have a planning, construction and functioning that assures that the experiments are carried out with the purposes of obtaining solid results with the minimum number of animals and the minimum pain, suffering, affliction or lasting damages. (article 36)
 - c. The establishments of use must maintain records of all used animals and make them available to the central authorities, whenever requested (article 41).

Also in the Italian legal system the solutions are not very different from the mentioned. Resulting from the modification of the communitarian directive already mentioned, the Legislative Decree no. n. 116 of 27.01.1992 almost totally reproduces the rules there organized.

Therefore, we will only underline certain innovating points.

- a) It is specified that the Health Ministry may authorize *esperimenti su primati non umani, sui cani e sui gatti soltanto quando obiettivo siano verifiche medicobiologiche essenziali previste dalla Farmacopea Ufficiale, da linee guida validate da organismi tecnico scientifici nazionali o internazionali, limitatamente ad attività di ricerca di rilevante ed urgente interesse socio-sanitario e qualora altri animali non rispondano agli scopi dell'esperimento.*(article 8)
- b) Experiments with didactic-demonstrative purposes are prohibited.

⁶¹ cf. also article 15 *If it not possible to administrate anesthesia, there should be used anesthetic or other suitable methods to assure that the suffering, affliction or damage are as limited as possible and that the animal, in any case, is subjected to violent pain, affliction or suffering.*

- c) The establishments and the animals used in them must be registered (*Il responsabile di stabilimenti di allevamento e di stabilimenti fornitori è tenuto a registrare il numero e le specie di animali venduti o forniti, la data in cui sono stati venduti o forniti, il nome e l'indirizzo del destinatario, nonché il numero e la specie degli animali morti negli stabilimenti stessi.*) [article 11]. At the same time, and as confirmed in other systems, the functioning of these establishments must be previously authorized, and such authorization will depend upon the compliance with the requirements necessary to provide animals the minimum conditions. (article 12)

In **France**, Decree-law no. 87-848 of 19/10/1987 regarding experiments with vertebrate animals is the basis of the regime in that matter. Changed by Decree-law of 295.2001, it presents a structure different from the laws analyzed so far, without meaning the resort to totally different solutions.

1. Animal experiments are lawful when confirmed necessary and unable to be replaced by alternative methods, and as long as they have as purpose:

a) *Le diagnostic, la prévention et le traitement des maladies ou d'autres anomalies de l'homme, des animaux ou des plantes ;*

b) *Les essais d'activité, d'efficacité et de toxicité des médicaments et des autres substances biologiques et chimiques et de leurs compositions, y compris les radioéléments, ainsi que les essais des matériels à usage thérapeutique pour l'homme et les animaux ;*

c) *Le contrôle et l'évaluation des paramètres physiologiques chez l'homme et les animaux ;*

d) *Le contrôle de la qualité des denrées alimentaires ;*

e) *La recherche fondamentale et la recherche appliquée ;*

f) *L'enseignement supérieur ;*

g) *L'enseignement technique et la formation professionnelle conduisant à des métiers qui comportent la réalisation d'expériences sur des animaux ou le traitement et l'entretien des animaux ;*

h) *La protection de l'environnement.* [article 1]

2. Are not considered experiments:

a) *Celles qui sont faites sur des animaux invertébrés et sur les formes embryonnaires des vertébrés ovipares ;*

b) *Celles qui consistent en l'observation d'animaux placés dans des conditions n'entraînant aucune souffrance ;*

c) *Les actes vétérinaires liés à la pratique agricole ou vétérinaire à des fins non expérimentales.*

[Article 2: this means that whenever these animals are used, or others in the same conditions, the constraints of the law do not apply]

3. Conditions of the procedures:

- a. The experiments must be performed under anesthesia, as long as possible. The procedures in which it is impossible must be reduced to a minimum, and the ones that inflict great suffering to the animals must be previously authorized. [article 3]
- b. After the experiment, the animal must not be kept alive if the suffering is permanent or long-lasting. Otherwise, the animal must receive the proper healthcare. [article 4]
- c. The experiments must be authorized by the competent body (all people carrying out experiments are holders of a generic or special authorization) [article 5].

4. Restrictions regarding the use of animals

- a. No wild animals may be used.
- b. No animals other than the ones stipulated in the legal list may be used⁶².

⁶² Art. 7 (modifié par le décret n° 2001-464 du 29 mai 2001). - Les animaux utilisés ou destinés à être utilisés dans des expérimentations ne peuvent provenir que d'établissements d'élevage ou fournisseurs déclarés selon les modalités prévues à l'article 18.

Pour les animaux des espèces dont la liste est fixée conjointement par le ministre chargé de la recherche, le ministre chargé de la protection de la nature et le ministre chargé de l'agriculture, les établissements d'expérimentation animale sont tenus de se les procurer dans des établissements d'élevage spécialisé tels que définis à l'article 1^{er}-1 du présent décret.

L'utilisation, pour des expériences, d'animaux appartenant à des espèces figurant à l'annexe A du règlement du Conseil n° 338/97 du 9 décembre 1996 ne peut être autorisée que pour :

- la recherche en vue de la conservation des espèces concernées ;
- un objectif biomédical, lorsque l'espèce concernée se révèle exceptionnellement être la seule pouvant convenir à cet objectif.

Les expériences sur des animaux qui ont été capturés dans la nature ne peuvent être effectuées que si des expériences sur d'autres animaux ne suffisent pas aux fins de l'expérience.

Art. 8 (modifié par le décret n° 2001-464 du 29 mai 2001). - Lorsque l'application du deuxième alinéa de l'article 7 ne permet pas à un établissement d'expérimentation animale de se procurer les animaux nécessaires aux besoins de l'expérience auprès d'un établissement d'élevage spécialisé, il peut :

- soit recourir à un établissement fournisseur déclaré répondant aux conditions fixées à l'article 18. Pour les chiens, les chats et les primates, cet établissement fournisseur ne peut se procurer les animaux qu'auprès d'établissements d'élevage spécialisés. Lorsque les animaux proviennent d'États autres que la France, le responsable de l'établissement fournisseur ou, le cas échéant, de l'établissement d'expérimentation animale destinataire s'assure que les conditions d'élevage et de production des animaux sont au moins équivalentes à celles prévues par le présent décret et les textes pris pour son application pour ces établissements ;
- soit recourir à un fournisseur occasionnel à la condition d'y avoir été préalablement autorisé, sur justification, par le préfet du lieu où les expériences doivent être réalisées.

In the *Common Law* frame, the animals' scientific procedures act (1986) stipulates new dispositions for the protection of animals used in experiments or for other scientific purposes.

For the purpose of this act, an animal means *any living vertebrate other than man and any invertebrate of the species Octopus vulgaris from the stage of its development when it becomes capable of independent feeding* (article 1). It also concerns *any vertebrate in its fetal, larval or embryonic form when in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed and in any other case, it becomes capable of independent feeding*.

No person shall apply a regulated procedure to an animal unless he holds a personal license qualifying him to apply a regulated procedure of that description to an animal of that description, the procedure is applied as part of a work program specified in a project license authorizing the application, as part of that program, of a regulated procedure of that description to an animal of that description; and the place where the procedure is carried out is a place specified in the personal license and the project license (article 3).

No personal license shall be granted to a person under the age of eighteen (article 4) and if he hasn't the appropriate education and training (including instruction in a relevant scientific discipline) for the purpose of applying the regulated procedures to be specified in the license and isn't competent to apply those procedures in accordance with the conditions which are to be included in the license and to handle and take care of laboratory animals.

As it comes defined in article 5, a project license is a license granted by the Secretary of State specifying a program of work and authorizing the application, as part of that program, of specified regulated procedures to animals of specified descriptions at a specified place or specified places.

The project shouldn't be licensed except if its purpose cannot be achieved satisfactorily by any other reasonably practicable method not entailing the use of protected animals.

When the responsible one has chosen the adequate procedure he should decide for those which use the minimum number of animals, involve animals with the lowest degree of neurophysiologic sensitivity, cause the least pain, suffering, distress or lasting harm, and are most likely to produce satisfactory results.

It's not possible using dogs, cats and primates, unless animals of no other species are suitable for the purposes of the program to be specified in the license or that it is not practicable to obtain animals of any other species that are suitable for those purposes.

Where a protected animal has been subjected to a series of regulated procedures for a particular purpose; and any of those procedures has caused severe pain or distress to that animal, that animal shall not be used for any further regulated procedures which will entail severe pain or distress (article 14)

Where a protected animal has been subjected to a series of regulated procedures for a particular purpose and has been given a general anesthetic for any of those procedures and been allowed to recover consciousness, that animal shall not be used for any further regulated procedures unless the Secretary of State has given his consent to such further use and the procedure, or each procedure, for which the anesthetic was given consisted only of surgical preparation essential for a subsequent procedure; or the anesthetic was administered solely to immobilize the animal; or the animal will be under general anesthesia throughout the further procedures and will not be allowed to recover consciousness.

Where a protected animal has been subjected to a series of regulated procedures for a particular purpose; and at the conclusion of the series is suffering or likely to suffer adverse effects, the person who applied those procedures, or the last of them, shall cause the animal to be immediately killed by a method appropriate to the animal (article 15).

Also in **Germany**, the solutions stipulated by Tierschutzgesetz vom 24. July of 1972, BGBl I 1972, 1277, Neufassung vom 25.5.1998, I,1105, 1818, zuletzt geändert durch Artikel 7b G. v. 21.6.2005, I 1666 and by Tierzuchtgesetz vom 22. December of 1989, BGBl I 1989, 2493; Neufassung vom 22.1.1998 I 145, zuletzt geändert durch Artikel 2 Absatz 4 G. v. 7.7.2005 I 1954 are not very far from the ones presented in the previous legislation.

6. Summary of the stipulated solutions

a. Experimental use of animals – conditioned model.

After the brief analysis of the several national, international and transnational regimes regarding the use of animals in laboratory experiments, *maxime* clinical experiments, we are in condition of emphasizing the admissibility of the resort to such living beings with that intent.

But we are also in condition to dare classify the model drawn as conditioned model. In other words, the susceptibility mentioned is not unrestricted.

Now, we will synoptically outline the frame of conditioning to which we were referring. Not from a nationalist perspective, but macroscopically summarizing the common characteristics regarding this matter.

Legal System	<u>Usable/Non-usable Animals</u>	
	Usable Animals	Non-usable Animals
European Community	<ul style="list-style-type: none"> ◆ Registered animals or property of authorized and registered establishments ◆ Preferably animals with a less developed neurosensitive system ◆ Animals obtained in 	<ul style="list-style-type: none"> ◆ Domestic animals ◆ Endangered animals ◆ Endangered animals

Spain	breeding centers ◆ Preferably animals with less developed neurosensitive system ◆ Thoughtful choice of species	◆ Animals from protected fauna ◆ Stray animals
Portugal	◆ Preferably animals with less neurophysiologic sensibility	◆ Endangered animals ◆ Wild animals (unless absolutely necessary for the purpose at hand)
France	◆ Animals stipulated in the legal list	◆ Wild animals
Italy		◆ Non-human primates, cats and dogs, unless otherwise authorized by the Health Ministry
United Kingdom	◆ Vertebrate and invertebrate ◆ Fetal and embryonic forms, when half the gestation time as passed	◆ Dogs ◆ Cats ◆ Non-human primates [unless only those fit the purposes at hand]
Germany		

Methods and principles

Legal System	Principles/Methods	Feeding, transportation, accommodation
European Community	<ul style="list-style-type: none"> ◆ Principle of subsidiarity ◆ Preferably methods using fewer animals. ◆ Preferably less invasive and painful methods. ◆ Mandatory anesthesia, unless impossible or harmful for the results. ◆ No animal may be used more than once. ◆ Decision after the experiment regarding either the animal should be kept alive or not. ◆ The animal must be put to death when survival causes great suffering, when he cannot recover his health condition or benefit from legal support. ◆ Being the animal kept alive, a veterinarian must be responsible for his recovery. ◆ Three R rule. ◆ Subsidiarity. 	<ul style="list-style-type: none"> ◆ Proper accommodation, to assure some comfort and the minimum freedom of movements ◆ Water and food supply ◆ Transportation subjected to minimum conditions,

Spain	<ul style="list-style-type: none"> ◆ Preferably methods that avoid pain and suffering. ◆ Preferably methods using fewer animals. ◆ Anesthesia ◆ Free decision regarding either the animal should be kept alive or not, after the experiment. ◆ Being the animal kept alive, a veterinarian must be responsible for his recovery. 	<ul style="list-style-type: none"> ◆ which assure freedom of movements. ◆ Transportation of animals accompanied by identifying documents with the necessary information regarding each animal. ◆ Accommodation in conditions that assure the well-being, comfort and freedom of movements of the animal. ◆ Daily control of the well-being levels.
Portugal	<ul style="list-style-type: none"> ◆ Preferably procedures that do not involve animals or involve fewer animals. ◆ Elimination of suffering as soon as possible. ◆ Anesthesia, unless incompatible with the experiment's purpose or more traumatic. ◆ The animal must be put to death if the suffering or affliction is permanent. 	<ul style="list-style-type: none"> ◆ Accommodation in suitable environment, assuring the minimum freedom of movements. ◆ Feeding and water necessary to assure his sustenance. ◆ Daily control of well-being conditions.
France	<ul style="list-style-type: none"> ◆ Principle of subsidiarity ◆ Anesthesia ◆ Previous authorization, when it is not possible and the experiment causes great suffering to the animal. ◆ Authorization from the competent authorities for the experiment. ◆ The animal must be put to death after the experiment, if the suffering becomes permanent. 	
Italy		
United Kingdom	<ul style="list-style-type: none"> ◆ Preferably methods that use fewer animals. ◆ Preferably methods that inflict less pain, suffering and stress to the animal. ◆ Anesthesia 	
Germany		

Requirements of the experiment/establishment

Legal System	Experiment/Project	Establishment
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European Community		<ul style="list-style-type: none"> ◆ Mandatory registration, pending upon the compliance with determined requirements. ◆ Appointment of an establishment responsible.
Spain	<ul style="list-style-type: none"> ◆ Appointment of an experiment responsible. ◆ Communication to the competent authorities of any project. 	
Portugal	<ul style="list-style-type: none"> ◆ Subjected to authorization by the competent body. ◆ Performed by a skilled person or under direct responsibility. ◆ Registration of all used animals [breeding and supplying centers must also register the number of animals, name, address of the recipient, and animals that died]. 	<ul style="list-style-type: none"> ◆ Authorized functioning according to permit pending upon the compliance with minimal conditions regarding equipments and methods.
France	<ul style="list-style-type: none"> ◆ Granted a generic or special authorization to the person that performs the experiment. 	
Italy	<ul style="list-style-type: none"> ◆ Registration of the number of animals sold, date, name and address of the recipient. 	<ul style="list-style-type: none"> ◆ Functioning authorized according to requirements.
United Kingdom	<ul style="list-style-type: none"> ◆ Licensed project ◆ Animal description. ◆ No authorization will be granted to people aged under 18 or not skilled in the matter. 	<ul style="list-style-type: none"> ◆ Permit
Germany		

b. Intentions of the stipulated solutions

The solutions organized have a specific intention. If we are directed by the unifying basis of all that is juridical, any doubt left vanishes in face of the comparison between that basis and the legal discipline created by the several legal systems.

Therefore, there are three points that must underlined.

On the one hand, the human being, presented with an ethical way of being, has towards the surrounding environment certain duties that make him preserve the environmental and zoological conditions of integration in the cosmos, thus protecting himself and future generations. In that way, a share of the duties he has towards animals is interpreted in light of the respect for biodiversity.

Without it being, in its asserting and valuable unity, the only line of intelligibility in the legal frames presented, since we witness that whenever research interests based in scientific

needs at the service of human beings dictates the so called rights – more duties of the subject towards them – of animals are put aside in face of the urgency of search for innovating solutions.

Finally, and this is the third point of reference that we cannot forget, it is still and always in the name of human protection, its dignity and safeguard that many solutions are thought through. In more direct words, many of the solutions only make sense because they aim to safeguard the protection condition of the human being regarding the risks animal contact may hold.

c. Feasibility of the use of transgenic animals in xenotransplants in light of animal protection

In light of the previous considerations, and considering the data regarding the recommendations of several bodies and entities, we do not see anything that may prevent the manipulation of animals for use in xenotransplants.

Instead, if there was any obstacle regarding the matter it would not be from the perspective of animal rights or better yet their protection regarding the legal system, but from the point of view of public health or patient's health protection.

It would only be necessary to have a procedure that would comply with the minimum requirements, assuring the respect for biodiversity so that the protection we plunge ourselves in would be reached.