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DRAFT

CRITICAL UPDATED REPORT ON THE MORAL AND LEGAL STATUS OF ANIMALS

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1. INTRODUCTION

Any discussion on the moral problems derived from the use of animals in research or experimentation undoubtedly leads us to the controversial matter of the ethical consideration of animals. The aim of this essay is not to enter into a deep analysis of this matter. Nonetheless, we must leave evidence of some of the main trends of thought on it and about some of its possible ethical consequences.

Throughout many centuries, the treatment of animals by man has been influenced by the story of Creation in chapter 1 of the Book of Genesis, which states:

“And God said, Let us make man in our image, after our likeness: and let them have dominion over the fish of the sea, and over the fowl of the air, and over the cattle, and over all the earth, and over every creeping thing that crept upon the earth”.

Starting from this premise, the idea that only the human being is important, that is, the most extreme form of anthropocentrism comes as no surprise and has dominated western philosophical tradition. As a matter of fact, and with numbered exceptions of isolated individuals such as Saint Francis of Assisi, one had to wait until Modernity to find the first manifestations of a new way of dealing with animals. In this regard, the following may be the most famous text:

“The day may come, when the rest of the animal creation may acquire those rights which never could have been with olden from them but by the hand of tyranny. The French have already discovered that the blackness of the skin is no reason why a human being should be abandoned without redress to the caprice of a tormentor. It may come one day to be recognized, that the number of the legs, the fluffiness of the skin, or the termination of theism sacrum, are reasons equally insufficient for abandoning a sensitive being to the same fate. What else is it that should trace the insuperable line? Is it the faculty of reason, or, perhaps, the faculty of discourse? But a full-grown horse or dog is beyond comparison a more rational, as well as a more conversable animal, than an infant of a day, or a week, or even a month, old. But suppose the case were otherwise, what would it avail? The question is not, Can they reason? Nor, Can they talk? But, Can they suffer?”¹

The aforementioned quote is the work of philosopher Jeremy Bentham, among his many achievements, he contributed to the founding of one of the most important ethical movements of all-time, *utilitarianism*, whose basic principle is that of

¹ Cfr: BENTHAM, J., *Introduction to the Principles of Morals and Legislation*, Oxford: Clarendon, Edited by J. H. Burns and H. L. A. Hart, 1996, p. 283.

maximising pleasure and minimising pain. Obviously based on this, the utilitarian movement should awaken the debate on whether we should take animals, that is, beings capable of feeling pleasure and pain, into account when making moral decisions. It is uncontested that many animals are capable of feeling pain. Equally, it is uncontested that to cause pain is morally problematic and so needs to be taken into account in moral reasoning. This is the case whether the pain is suffered by a human or by any other sentient being.

As has been said above, utilitarianism, in its simplest form, establishes a social duty to maximize the balance of pleasure over pain. Utilitarianism requires careful consideration of the capacity of all beings capable of suffering, and permits animal (or human) suffering if, in general terms, it causes more pleasure than pain. Where this is the case, the ends would justify the means. Thus, from the utilitarian view, the capacity for pain and suffering does not constitute an absolute constraint, prohibiting any negative interference. The approach does not usually associate inviolable rights with sentience. This is why contemporary utilitarians, such as Peter Singer, do not talk of ‘animal rights’ but of ‘animal liberation’. In his book *Animal liberation*, Singer focused on cases of research that caused grave suffering to animals and had little discernible benefit. He did not explore in detail the question of whether medical research involving animals can be justified in utilitarian terms. However, this seems likely in at least some cases, provided the overall costs in terms of pain, suffering and distress caused by research are outweighed by the overall benefits in terms of alleviating and preventing pain, suffering and distress.

From this utilitarian viewpoint there is, in principle, no restriction of the goals of research, whether it be health benefits, idle curiosity or cruel pleasure, as long as the overall sum of pleasure outweighs the overall sum of pain. Within the current debate, this extreme view, though often mentioned and theoretically possible, is probably not held. Most commentators appear to accept at least some restrictions on the acceptable goals of research; for instance, there must be some health or scientific benefit.

According to this utilitarian view, some argue that the human experience of pain is in some relevant sense different from that of animals. It may be more intense because of a greater facility of humans to anticipate pain, or because of the disruption to social relationships that humans can suffer, for example if one member of a family suffers chronic pain. This is sometimes seen to lead to the conclusion that it might be more justifiable to use animals rather than non-consenting humans in harmful research. An

alternative argument might be that humans are far more able than animals to cope with pain and suffering, especially when they understand the underlying reasons or purposes. This could suggest that beings with less-developed rational capacities are not necessarily suffering less, but more, since they are not in a position to conceptualize pain or suffering as means to ends.

Nevertheless, before this, centuries of oblivion would go by, in which, with the notable exception of Henri S. Salt,² almost no one spoke of the rights of animals. However, the 1970's saw the strong resurgence of the debate of this matter due to two basic texts, *Should Trees Have Standing*, by Christopher Stone (1974)³, and *Animal Liberation*, a work of Australian philosopher Peter Singer (1975)⁴. From that moment, the movement favouring the recognition of a duty of respect towards animals has increased in importance, this debate being nowadays one of the most important in academia. Among those authors who have supported this movement, we can find Tom Regan and Ted Benton⁵, Robin Attfield⁶, Alasdair MacIntyre⁷, Ursula Wolf⁸, Angelika Krebs⁹, Ángel Pelayo González Torre¹⁰, etc.

The denouncements by these authors have made the current philosophical thinking to look at the issue of animal rights from two different perspectives. On the one hand, there are those who uphold the traditional moral anthropocentrism, either in its strongest version or in more moderate ones which introduce elements in favour of animals. On the other, there are those who follow the directives introduced by the aforementioned authors, denouncing anthropocentrism in order to place themselves in one of the alternative trends, biocentrism, zoocentrism, sensocentrism, etc. In the

²who published in 1892, in London and New York, a book entitled *Animals' Rights: Considered in Relation to Social Progress*, which is considered the first monograph aimed at establishing some type of rights for non-human life forms. In this text, the author argues that, given that animals are possessed of a distinctive individuality, sensible and intelligent, and, therefore, "are in justice entitled to live their lives with a due measure of that "restricted freedom" (Cfr: SALT, H. S., *Los derechos de los animales*, Madrid: La Catarata, 1999, p. 34).

³ Cfr: STONE, C., *Should Trees Have Standing?, Toward Legal Rights for Natural Objects*, Los Altos (California), 1974.

⁴The author had already put forward a majority of his arguments in an article published a year earlier (Cfr: SINGER, P., "All Animals are Equal"; *Philosophical Exchange*, vol. 1, n° 5, 1974). However, the publishing of his book decisively promoted the dissemination of his thinking.

⁵ Cfr: BENTON, T., *Natural Relations, Ecology, Animal Rights and Social Justice*, Londres: Verso, 1993.

⁶ Cfr: ATTFIELD, R., *Value, Obligation and Meta-Ethics*, Amsterdam-Atlanta: Editions Rodopi, 1995.

⁷ Cfr: MACINTYRE, A., *Animales racionales y dependientes*, Barcelona: Paidós, 2001.

⁸ Cfr: WOLF, U., *Das Tier in der Moral*, Frankfurt am Main, 1990.

⁹ Cfr: KREBS, A., "Haben wir moralische Pflichten gegenüber Tieren? Das pathozentrische Argument in der Naturethik", *Deutsche Zeitschrift für Philosophie*, n° 41/6, 1993, pp. 997 ff.

¹⁰ Cfr: PELAYO TORRE, A. P., "Sobre los Derechos de los Animales", *Anuario de Filosofía del Derecho*, n° VII, 1990.

following, we explore the soundness of these stances, beginning with those most novel, that is, those which consider that we have basic moral obligations towards animals. However, we will not analyse each and every one of the different approaches of the aforementioned authors, especially because the greater part, belong, in one way or another, to one of the three main schools. These are *Deep Ecology*, Peter Singer's Utilitarianism or the ethical proposal of Tom Regan. Let us look at these three main models.

2. THREE MODELS OF ANIMAL RIGHTS DEFENSE MOVEMENTS *DEEP ECOLOGY*, PETER SINGER'S UTILITARIANISM AND TOM REGAN'S PROPOSAL

2.1. Biocentrism and Deep Ecology

One of the most interesting philosophical movements¹¹ from among all those that have flourished in these last years is that known as *deep ecology*. *Deep ecology* emerged in 1973 due to the work of Norwegian mountaineer, philosopher and Oslo University professor, Arne Naess, who coined this term in one of his best known articles¹². This text was published in order to create a new type of ecological movement that was capable of overcoming what he considered the shallowness of the existing activism of the time.¹³

¹¹See: NAESS, A., *Ecology, Community and Lifestyle: Outline to an Ecosophy*, Cambridge: Cambridge University Press, 1989, p. 51.

¹² In this article, the author drew a distinction between two types of ecological movements, " long-range deep ecology movement" and the "shallow ecology". In it, he would later demonstrate why he thought that the first should prevail (See: NAESS, A., "The Shallow and the Deep. Long-Range Ecology Movement", *Inquiry*, nº 16, 1973, pp. 95-100).

¹³ By far, *Deep Ecology* is not the only radical ecologist trend. The most popular, together with it, is that known as *Land Ethic*. The origins of this philosophical movement can be traced to the works of American forestry engineer and ecologist Aldo LEOPOLDA *Sand County Almanac* which was written in 1948 and posthumously published in 1949 and later made popular by Lynn WHITE in an article published in *Science Magazine* (Cfr: WHITE, L, "The Historic Roots of Our Ecologic Crisis", *Science*, nº 155, 1967, pp. 1203-1208). In the original work of LEOPOLD, he defends the concept that the Land is at the same time a dynamic ecological system as well as a moral community which belongs to all beings that are part of it. Curiously, the author included inanimate elements such as rocks, air, water among its inhabitants. All of which are also worthy of our respect. As ALEDO & DOMÍNGUEZ correctly state, the main difference with the deep ethic which has been looked at earlier is that it doesn't try to make nature sacred, but rather denounce the risks of a lifestyle centred solely in an economic interest and what this means for the survival of nature and even for the human being. In view of this, he proposes a redrafting of our thinking, a new ecologic ethics that allows the human to see themselves as a member of the natural community with full responsibility over it. This is possible only if the all of nature is afforded the character as a moral entity through the attribution of intrinsic values which entail rights that must be respected. (Cfr: ALEDO, A. y J. A. DOMÍNGUEZ, *Arqueología de la Sociología Ambiental*, text available in the internet at the following University address:

The essential principle which is the starting point of this movement is that the only truly worthy thing in our world is life. This is understood in the same way as teleological centres of life understand it, life organised towards a purpose, irrespective of its holder. Life in itself has an intrinsic value that goes beyond our acknowledgment. It is a value that, despite that which is upheld by the majority of the habitual ethical proposals that surround us, does not arise from the acknowledgment by a conscious living being, but rather it is directly linked to the mere act of living. In this sense, a human being is valuable due to the fact that he is alive and is so even if he is not capable of acknowledging the value of his own life. The value comes from an act, the act of living that is completely independent, as an act, of human judgment. This motive, in turn, is why subjective judgments that are made on our lives are not meaningful at all.

The consequence of this starting point is that, given that a human being is alive, he is undoubtedly worthy, but not more so than an animal, in so far as the latter is also alive. The act itself of being alive is what is valuable, regardless of the quality of life and nobody can be more alive than another, thus it is senseless to establish value differences among beings: all share the same dignity. Along these lines, Naess mentions that the right of all life forms to live *is a universal right that cannot be quantified*. Hence and according to the advocates of this movement, of course, we can also deduce that any attempt to establish a hierarchy among the different living beings based on specific qualities that each of them possess is nothing but an attempt to take away the true value of life in order to favour human beings.

Deep ecology, as a philosophy, proposes eight essential principles which have been elucidated from within the eco-philosophical movement¹⁴:

1. The well-being and flourishing of human and non-human life on Earth have value in themselves (synonyms: intrinsic value, inherent worth). These values are independent of the usefulness of the non-human world for human purposes.

www.ua.es/personal/antonio.aledo/docs/libro/libro.pdf, p. 153. Last visited: 29 December 2007). A very complete study of all types of ecological ethics can be found in: BARTOLOMMEI, S., *Ética e Natura*, Roma-Bari: Laterza, 1995. On the development and importance of the work of LEOPOLD, see: NASH, R. F., *The Rights of Nature. A history of environmental ethics*, Madison: The University of Wisconsin Press, Madison, 1989, pp. 5-7.

¹⁴In fact, these are the work of Arne NAESS and George SESSIONS, after a long stay of the former in *Death Valley* (California).

2. Richness and diversity of life forms contribute to the realization of these values and are also values in themselves.
3. Humans have no right to reduce this richness and diversity except to satisfy vital needs.
4. The flourishing of human life and cultures is compatible with a substantially smaller human population. The flourishing of non-human life *requires* a smaller human population.
5. Present human interference with the non-human world is excessive, and the situation is rapidly worsening.
6. Policies must therefore be changed. These policies affect basic economic, technological, and ideological structures. The resulting state of affairs will be deeply different from the present.
7. The ideological change will be mainly that of appreciating life quality (dwelling in situations of inherent value) rather than adhering to an increasingly higher standard of living. There will be a profound awareness of the difference between bigness and greatness.
8. Those who subscribe to the foregoing points have an obligation directly or indirectly to try to implement the necessary changes.

The obvious problem of this movement is that the idea of life is complex in itself. A tumour is a set of living cells, but nobody would claim that to extract it from our body is an immoral act. Similarly, there are great differences between vegetables and animals within the different types of organised life forms and even within the latter. In fact, not even the most steadfast defenders of this movement would dare to say that the life of a human being is equivalent to that of a lettuce or a cod, to name two examples. On the other hand, we must take into account that the preference granted to the ecosystem by the theorists of *deep ecology* can be dangerous, in so far as it can condition the life of individuals in favour of the survival of the species or the environment¹⁵. Hence, it doesn't seem morally reasonable to sustain this type of biocentric stance.

¹⁵ Regarding this issue, VIOLA has stated that this outlook bears disturbing issues, and that in any case, it is ethically debatable. From the viewpoint of the species, abortion, infanticide, involuntary euthanasia, war and all that can be used to eliminate those least adapted can be admitted as the ecosystem requires it” (Cfr: VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, Granada: Comares, 1998, translation by Vicente Bellver, p. 173).

2.2. Peter Singer's Preference Utilitarianism

The utilitarian stance in favor of granting moral dignity to animals is no less problematic than the earlier stances. Its main postulate is based on the fact that animals, in so far as they may suffer, have interests that must be respected. One of the most important representatives of modern utilitarianism, Peter Singer believes that “whichever the nature of the being, the principle of equality requires that the suffering be considerate in the same manner as the suffering of any other being”¹⁶. For him, to privilege the interests of human beings, solely because they are human, is to incur in an unacceptable speciesism. Singer accepts that “normal adult human beings have a mental capacity that, in certain circumstances, makes them suffer more than animals in the same circumstances”¹⁷, reason why, from his utilitarian perspective, it seems acceptable that in a situation where there is no other alternative but to choose between the interests of the animals and the adult human beings, the choice is made in favor of humans, given that there is a greater avoidance of the quantity of suffering.

However, we must take into account that although set in the utilitarian tradition, Peter Singer is substantially different from the founders of the movement in so far as that from his point of view, what must be maximised is not so much pleasure or pain but rather the preferences and interests of the different living beings. The difference between both concepts is essential, as it allows us to resolve some of the flaws of classical utilitarianism. This way, for example, Bentham was never able to provide a direct reason for not killing a person when the murder was painless, as in such case, it would not have altered the pleasure/pain relation.¹⁸ Nonetheless, Singer's stance is capable of meaningfully altering the terms of the dilemma, noting that killing is something morally reproachable as it goes against the desires, preferences or interests of the murdered person.

The problem that Peter Singer must immediately face is that of establishing which beings are capable of possessing those preferences or interests. Obviously, not all sentient beings are endowed with that quality. This way, for example, insects do not seem to be endowed with it. In this way and though he may not want to, the Australian

¹⁶ SINGER, P., *Ética práctica, op. cit.*, p. 72.

¹⁷ *Ibid.*, p. 74

¹⁸ Obviously, killing could break the desire of the deceased to continue living, but given that the breaking of these desires would only cause pain to the subject in case of continuing alive to notice it, it would be very difficult to argue that one shouldn't kill in order to minimise pain or maximise pleasure.

author breaks the association which Bentham had greatly fancied between sentient beings and beings subject to morality, substituting it with another that ties morality to those beings capable of expressing preferences. But, who makes up this particular community? According to Singer's reasoning, only self-conscious beings, as only these can possess preferences on their future. However, conscious beings, but not aware of themselves are more similar to the image of receptacles of happy or painful experiences as their preferences are more immediate. They don't have desires which project their image of their own existence towards the future¹⁹. Obviously, with this he provides greater consistency to his theory, but on account of distancing himself to a great extent of the classical utilitarian paradigm, making its maxim useless at the expense of those beings that although are sentient beings, do not possess self-consciousness²⁰.

However, the greatest handicap of his moral theories comes from their consequences. Taking his utilitarian idea to its conclusion, he argues that small children and humans with serious disabilities do not have the same attributes as adult humans and are in the same categories as many animal species, at least many species of mammals. His conclusion is that animals as well as children and the seriously disabled should have the same moral consideration and should be treated in the same manner. Although he clarifies that he doesn't want to morally reduce these categories of human beings, but rather to elevate animals in order to have a worthy treatment, his stance entails moral implications that, from my point of view, are completely unacceptable. Among them, the justification of infanticide in certain circumstances within the first month of life²¹ or the assessment that "non-human animals, children and humans with serious intellectual disabilities are in the same category"²², reason why killing a chimpanzee, for example, is no worse than killing a human being, who, due to a congenital intellectual disability, isn't or will never be able to become a person.

Obviously, most of us would have trouble agreeing with these conclusions, which do not come from an erroneous development of the suppositions which are the basis, but rather from assumptions which are the starting point. Making self-consciousness the maximum parameter for granting value to beings is rather a random

¹⁹ SINGER, P., *Ética Práctica*, Madrid: Cambridge University Press, 2ª edición, 1995, p. 156.

²⁰ As VIOLA writes, Singer has betrayed the original utilitarian attempt of total equality of sentient beings of type A with those of type B, sentient beings that are mere means of pleasure and pain and sentient beings who have the value of their self-consciousness" (Cfr: VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, cit., p. 190).

²¹ RUPHY, S., "Peter Singer: la ética vuelta a visitar" (interview with Peter Singer), *Mundo Científico*, 218, December 2000, p. 98.

²² SINGER, P., *Ética práctica, op. cit.*, p. 75.

assumption which we don't have to share, especially due to its consequences being so counterintuitive. In accordance with this, I consider that Singer's ethic cannot be the starting point from which to defend a more respectful treatment of animals.

2.3. Tom Regan's model

Focusing our attention on the thinking of Tom Regan and his supporters²³, I will begin by saying that the basic starting point of this group of authors is that there are some beings, subjects-of-a-life, that have the greatest value we can think of, an inherent value²⁴. The subjects-of-a-life are defined as those individuals “*whose life is characterized by those features explored in the opening chapters of the present work: that is, individuals are subject-of-a-life if they have beliefs and desires; perception, memory, and a sense of the future, including their own future; an emotional life together with feelings of pleasure and pain; preference- and welfare-interests; the ability to initiate action in pursuit of their desires and goals; a psychophysical identity over time; and an individual welfare in the sense that their experiential life fares well or ill for them, logically independently of their utility for others and logically independently of their being the object of anyone else's interests*”²⁵.

According to Regan, we must not make great differences between subjects-of-a-life and others based on their different qualities: all have the same value and must bear the same moral values. Only when a conflict arises between the rights of two must we override the scale in favour of humans and only when based on some principles which opponents consider deeply incongruous with the starting basis of the author: the miniride principle and the worse-off principle. The miniride principle states that “special considerations aside, when we must choose between overriding the rights of few who are innocent, and when each affected individual will be harmed in a prima facie comparable way, then we ought to choose to override the rights of the few in preference to overriding the rights of the many”. The worse-off principle, on the other hand, states that “special considerations aside, when we must decide to override the rights of the many or the rights of the few who are innocent, and when the harm faced

²³ An excellent summary of REGAN's reasoning can be found in: TORRES ALDAVE, M., “La teoría de los derecho de los animales de Tom Regan”, *biTARTE*, N° 47, pp. 5-24.

²⁴ REGAN has said to this effect that those who satisfy the criteria of subject-of-a-life bear a specific type of value- an inherent right- and cannot be considered or treated as mere means (Cfr: REGAN, T., *The Case for Animal Rights*, Berkeley: University of California Press, 1983. Translation by V. BELLVER in: VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, cit., p. 192).

²⁵See: REGAN, T., *The Case for Animal Rights*, Berkeley: University of California Press, 1983.

by the few would make them worse-off than any of the many would be if any other option were chosen, then we ought to override the rights of the many”.

Regan uses both principles in the famous example of a raft²⁶, which upholds that the rights of one type of beings can be placed before those of another without this implying that the former are superior in value to the latter. Nevertheless, several authors have manifested that this stance seems incoherent in that if the rights of a being prevail over those of another due to the mere fact of being that type of being and not another, then it does not make sense to uphold that there exists an inherent value to life for all subjects that is immeasurable.²⁷ Regan’s conclusion reflects that there is always room to establish a comparison between different types of beings in which one will always prevail over the other. This invalidates the assumption he originally started from.

This same stance but in more consistent way has been held by Eve-Marie Engels when stating that “we must admit that animals have a moral status as an inherent value, not instrumental, in which their protection is based and which should exclude them from being used as mere instruments for human purposes [...] The term “dignity of an animal” is but another way of admitting that animals have an inherent value, that constitute an end in itself”²⁸. However, this statement can hardly be accepted. If we accept a formulation of this type and we seriously look at its consequences, the use of animals for research should disappear, as it would have to be in conformance by the same criteria that we use for experimentation with human beings. In that case, the use of animals would be limited, almost exclusively, to those interventions that would be directly beneficial for those animals used in the research.

Another obstacle of great importance that must be overcome by those who defend the need to grant animals rights similar to those of humans is that if we admit to having a moral obligation to treat equal beings in the same manner, regardless of the species, then one cannot understand why we should only have to defend animals from aggressions coming from members of the human species, although these advocates try

²⁶Where there are four adult humans and a dog in a sinking life raft, the humans would do nothing wrong by throwing the dog overboard instead of drawing lots to see who should be thrown overboard. Where there is a clash of rights of this nature, those of humans must prevail (Cfr: REGAN, T., *The Case for Animal Rights*, cit., p. 324).

²⁷ See: VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, cit., p. 214 ff. TORRES ALDAVE, M., “La teoría de los derechos de los animales de Tom Regan”, *biTARTE*, nº 47, pp. 19 ff.

²⁸ ENGELS, E., “El estatuto moral de los animales en la discusión del xenotrasplante”, in C. M. ROMEO CASABONA (Coord.), *Los xenotrasplantes. Aspectos científicos, éticos y jurídicos*, op. cit., p. 98.

to limit their rights to this²⁹. On the contrary, they should be protected against any harm, no matter its origin, be it animal or human, and furthermore, assistance in case of need should be guaranteed³⁰. Otherwise, different rights would be granted depending on the species: to humans against all (*erga omnes*) and to animals only versus humans. Isn't this another type of refined speciesism?

In our judgment, it is obviously so. In order to be coherent with the arguments in favour of the recognition of rights for animals, a problem would arise and would lead to a situation that would be difficult to uphold from the perspective of the survival of human beings. This would make us become some sort of super police of nature that would prevent, for example, lions attacking chimpanzees or to aid dolphins in their fight against sharks.³¹, which would make our life completely unfeasible. The conclusion which we can draw from all the above is that a detailed analysis of the consequence of the paradigm that we criticize provides the surprising paradox of falling in the same vice as it denounces: speciesism. If the purpose of the denouncement is the deep injustice of treating in a different manner equal beings due to the mere fact of belonging to different species, it is hard to understand why their demand falls in the denounced vice, suggesting the relevance of establishing different rights for animals and humans which share a similar ontological condition³². In order to be coherent with their own principles, those who uphold this hypothesis should defend the equality of all quasi-persons, regardless of the species and should be granted the same rights, not variable rights based on the species to which the victim and the aggressor belong to. By not doing it in this manner, this entails a great difficulty, not in the argument itself, but rather on the drawn conclusion by its supporters.

²⁹ Along these lines, see: CAVALIERI, P., *The Animal Question*, cit., pp. 139-140 DE GRAZIA, D., *Taking Animals Seriously. Mental Life and Moral Status*, Nueva York: Cambridge University Press, 1996, pp. 273, 277

³⁰ In this matter, see: WARREN, M. A., *Moral Status. Obligations to persons and other living things*, Oxford: Oxford University Press, 1997, pp. 112-113; SAPONTZIS, S. F., *Moral, Reason and Animals*, Philadelphia: Temple University Press, 1987, p. 230; DE LORA, P., *Justicia para los animales. La ética más allá de la humanidad*, op. cit., p. 261.

³¹ As early as the 19th century, RITCHIE became aware of this circumstance, which led him to consider that the attribution of rights to animals was absurd. See: RITCHIE, D. G., *Natural Rights. A Criticism of Some Political and Ethical Conceptions*, Londres: George Allen y Unwin, 1895, p. 109. Cited by DE LORA in: DE LORA, P., *Justicia para los animales. La ética más allá de la humanidad*, cit., p. 260. In more modern times, these type of arguments can be found in: McCLOSKEY, H. J., "Moral Rights and Animals", *Inquiry*, nº 22, 1979, pp. 52-53; SAPONTZIS, S. F., *Moral, Reason and Animals*, cit., p. 230.

³² This paradox has been skilfully denounced by D'Agostino. See: D'AGOSTINO, F., "Los derechos de los animales", in D'AGOSTINO, F., *Bioética. Estudios de Filosofía del Derecho*, Madrid: Ediciones Internacionales Universitarias, 1998, p. 194.

3. ANTHROPOCENTRISM

3.1. General overview

Moral anthropocentrism may be defined as paradigm which supports the idea that the interests of human beings must take preference over those of other individuals is justified. Its justification can substantially vary, as noted by Óscar Horta³³. There are also meaningful differences between strict anthropocentrists, that is, those who defend the notion that every human being is particularly valuable and those that do not include embryos, foetuses, anencephalous, etc. among that group of beings as they do not consider them equal to humans born with normal conditions.

Anthropocentrism does not necessarily imply an attitude of loathing of those animals that are not members of the species we have chosen as particularly significant. Therefore, it cannot be identified with what Mason has called misothery, which, in his

³³ In order to consider this matter it is first necessary to distinguish the various ways in which this position can be defended. These are the following ones: II.1) *Defenses of anthropocentrism as a universally valid view*. Some approaches have defended that anthropocentrism is relevant in a universal and neutral way, i.e. independently of our particular situation. They defend that if a moral agent from a different planet landed on Earth, she would have to accept humans' interests as more important than those of other animals. There are two ways in which this idea can be maintained: II.1.1) *Defenses of anthropocentrism that allude to individual abilities*. Several views have defended anthropocentrism by arguing that only humans have certain abilities that are necessary in order to be morally considerable. Examples of these are complex intellectual capacities, linguistic command, freedom, moral agency or the possibility of having positive and negative experiences, among others (defenders of this view include Descartes, Frey, Leahy, Ferry and Narveson). II.1.2) *Defenses of species-linked discrimination that allude to metaphysical reasons that are not open to corroboration*. Other views have rested on the idea that humans' interests are more important than those of others for reasons that have to do with certain metaphysical assumptions regarding their ontological status. Some of these are based on religious beliefs (as the ones held by Reichmann, Vidal or Harrison), others are grounded on the idea that there is an axiological order in the universe in which humans occupy a place higher than the one in which other animals belong (as it has been defended by Aristotle, Ferré or Machan). According to these views having such status does not necessarily entail the display of certain capacities. For this very same reason, the question of whether humans actually possess it remains open. II.2) *Defenses of species-linked discrimination that allude to relational factors*. Finally, some positions have not been based on the idea that human interests are in themselves more valuable than others'. They have rather defended that we have reasons to give priority to the satisfaction of human interests because of the relation that we, as humans, have with other fellow humans. This is sometimes defended by claiming that we are emotionally tied to humans in a way in which we cannot be tied to other animals. Other examples of this kind of view appeal to possibilities for interaction, biological relations, social reproduction or our situation in the web of power relationships (as defended by Whewell, Becker, Scanlon, Gray, Benson, Wenz, Petrinovich, Goldman, Williams, or Hume).⁸ An interesting instance of this position is the one that defends the relevance of belonging to a species whose members usually have certain individual capacities (although this criterion appears to refer to individual capacities, it is ultimately defined by a certain relation: mere species membership –as defended by Scruton, White or Bookchin). See: HORTA, O., "Animal Experimentation and Bias in Bioethics", in *Proceedings of the III International Conference on Technoethics: Ethical Subjects Related to Science, Technology and Their Social Applications* (Barcelona: Instituto de Tecnoética, Fundación Epson, Universitat de Barcelona, 2008), pp. 199-210.

own words, would mean “hatred and contempt for animals”³⁴. Nowadays, there are many who make their anthropocentrism, that is, the idea that the human being is superior to animals, compatible with the defense of the welfare of the latter, in what has often been labelled as “weak anthropocentrism”. Contrary to this, “strong anthropocentrism” is that which places animals as mere objects at the service of the human being and which he can freely dispose of. Weak anthropocentrism is in our time the dominant ethical point of view and it is what we shall defend in this text. However, before continuing from this basis, it is necessary to face the most important criticism against anthropocentrism, the argument from marginal cases.

3.2. A general objection to anthropocentrism: the argument from marginal cases.

The biggest and most consistent objection to anthropocentrism is that known as “argument from marginal cases”³⁵. The argument can be stated in many ways. The simplest manner is the following: firstly, one must establish the general principle that it is unjust to treat those who are similar in a different manner; secondly, one must accept that human beings who are unable to cast moral judgments do not possess different qualities to those of superior animals³⁶. From these two premises, one can deduce that if one accepts that those human beings who show no greater capacity to that of animals possess rights, or that their interests should be protected in the same manner as ours, then we should grant the same importance to those animals.³⁷ The contrary would be a clear example of *speciesism*, a term which in the eyes of the members of the movement in defence of animals is similar to others such as racism, sexism, etc.

³⁴See: Mason, J., *An Unnatural Order: Why We Are Destroying the Planet and Each Other*, New York: Continuum, 1998, p. 163.

³⁵ The origin or at least, the conception of the original argument is object of discussion. DE LORA implicitly points to German philosopher Wilhelm DIETLER as its author (See: DE LORA, P., *Justicia para los animales. La ética más allá de la humanidad*, cit., p. 235). The name, certainly, is the work of Canadian Jan NARVENSON (See: NARVENSON, J., “Animal Rights”, *Canadian Journal of Philosophy*, n. 7, 1977, p. 164).

³⁶ As can be seen, the argument's name come from the fact that it uses a fact, the existence of human and non-human beings who are placed in the extreme of both kingdoms, in order to justify the rights of the latter. Apes are the pinnacle of the animal kingdom, at least in reference to the qualities that are of interest in this discussion, while embryos, foetuses, elderly with Alzheimer, etc, are those human beings least endowed. In fact, their endowment is so small that if one forgot which species either of them belong to, it would be complicated to decide which is most similar to a person. Altogether, the classification seems very confusing and as Óscar HORTA has asserted, it should probably be abandoned (See: HORTA, O., “Términos básicos para el análisis del especismo”, press article, p. 8).

³⁷ See: HUTHER, C., *Can speciesism be defended? A discussion of the traditional approach to the moral status of animals*, p. 55. The text is available in Internet at the following address: [http://www.constanzehuther.de/philosophie/Huther%20\(2005\)%20Magisterarbeit%20Speziesismus.pdf](http://www.constanzehuther.de/philosophie/Huther%20(2005)%20Magisterarbeit%20Speziesismus.pdf).

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Certainly, some people argue that the way many animals are treated in contemporary societies is morally objectionable. They draw an analogy to unjustified discrimination and exploitation in cases of racism and sexism, and argue that making membership of the moral community dependent on specific human traits alone amounts to 'speciesism'³⁸. Rejecting this view, they argue that a much wider circle of beings deserve to have their interests considered for their own sake, usually meaning all those beings that are able to suffer. Some of those who share the belief that society's current treatment of animals amounts to speciesism take the view that overcoming this form of discrimination requires that rights are ascribed to all animals. The criterion for whether or not a being deserves rights is frequently seen to depend on whether or not it is 'the subject of a life'. If, the argument runs, it makes sense to say of a being that it is conscious of its own existence, and that its own life is important to itself, it has intrinsic moral value. This moral value should then be recognized by the same rights accorded to humans, as, for example, set out in the United Nation's *Universal Declaration on Human Rights*. This raises the question of which animals are capable of being the subject of a life. Some argue that this is the case in animals such as the great apes, but others would draw a much wider circle, including all animals capable of being sentient.

As previously stated, this argument is particularly convincing when appealing to universally recognised moral principles such as the principle of equality before the law, which requires equal treatment for those who are equal. However, we think that there are sufficiently important flaws in it so as to reject it. The main flaw lies in that a moral principle must only be abided when dealing with valuable beings, or if one prefers, when they possess a morally relevant condition, according to Bernstein's terminology³⁹ or when they have a moral significance, according to Pluhar⁴⁰. In absence of this consideration, certainly its application lacks sense.

³⁸ However, many people reject the analogy between the humane treatment of animals on the one hand and racism and sexism on the other. They emphasize what might be called a 'psychological truth' which states that in cases where a choice has to be made, protecting the life or welfare of a human is a greater priority than a similar protection for an animal, just as one might also protect a family member rather than a distant stranger. A vital question is whether such preferences for humans in general, or those who are close to us, are strictly speaking immoral, and should be over-ridden by a comprehensive and all-inclusive moral system, or whether they are morally justified, as other philosophers have argued. There are powerful arguments on both sides, and no universally agreed answer.

³⁹ Cfr: BERNSTEIN, M., "Marginal Cases and Moral Relevance", *Journal of Social Philosophy*, n° 33 (4), 2002, p. 531.

⁴⁰ Cfr: PLUHAR, E. B., *Beyond Prejudice. The Moral Significance of Human and Nonhuman Animals*, Durham-Londres: Duke University Press, 1995, p. 1.

Therefore, the issue is to know which beings have the necessary value in order to apply this principle of justice. This is where we deeply differ with the stance of those who defend animal rights. Let us remember that the basis on which this philosophical stance is built, by Regan and his followers, is that those beings that are subjects-of-a-life are intrinsically valuable, that is, beings with a value regardless of the opinion of human beings. Depending on the validity of this starting point, one must necessarily apply the aforementioned principle of justice, as if these beings do not have value, then we would automatically stop feeling the obligation to act in accordance with it. It is precisely here where the problems arise, as the same idea of an intrinsic value is truly complex. The acceptance that something or someone has an intrinsic value that human beings can only but recognise amounts to saying that the value of a good does not depend on the subject who evaluates it.

This idea in itself is absurd for the simple reason that in the absence of an evaluating subject there cannot be an evaluated object.⁴¹ In fact, this is so much so, that the question of whether values that cannot be understood by man as such would continue to be values is completely absurd. To value, as such, entails an action, which in turn, needs a subject to commit the act and an object to receive it⁴².

Bearing this in mind, it seems impossible not to reach the conclusion that animals, as such, do not have intrinsic value and therefore there are no real reasons why we should feel obliged to grant them rights. The fact that a chimpanzee or a gorilla are subjects-of-a-life, as Regan states, or self-conscious beings, as Singer notes, does not necessarily mean that it is morally reproachable to do away with their lives. In fact, this type of behaviour would only be contrary to morality if there is a subject, a source of morality, that is, a human being who dictates that it is so. However, if this affirmation is true, then there seems to be no reason why we should grant rights to animals or to have a direct moral obligation towards them⁴³ unless we outline these obligations in a conventional manner. Therefore, the conclusion must be that we don't have a moral

⁴¹ Cfr: MOSTERÍN, J., "Prólogo", DE LORA, P., *Justicia para los animales. La ética más allá de la humanidad*, cit., p. 22; VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, cit., p. 213; ECHEVERRÍA, J., *Ciencia y valores*, Barcelona: Destino, 2002, p. 64; BUNGE, M., *Ética y Ciencia*, Buenos Aires: Siglo XX, 1962, pp. 96, 97).

⁴² As BILBENY has noted, values only exist *in* and *for* man Cfr: BILBENY, N., *Humana dignidad*, Madrid: Tecnos, 1990, p. 78. Also see: FRONDIZI, D., *¿Qué son los valores?*, México: Fondo de Cultura Económica, 3rd edition, 1972, p. 28).

⁴³ Nonetheless, there can be indirect moral obligations, of a KANTIAN nature, that is, obligations derived from the fondness that specific human beings can have towards animals. But obviously, the animal rights advocates do not speak of this type of obligations.

obligation to treat animals with justice or to grant them rights unless we are the ones who outline them. The reasons of such stance have been briefly and admirably pointed out by Victoria Camps, when she states that *“if animal suffering or the degradation of the planet are-as I believe it is- inadmissible” For whom are they inadmissible? Don’t they continue to irremediably be this way for humans? Who else judges and complains over animal suffering but us humans? Though I have extended the ambit of compassion, solidarity, even justice to non-human beings this does mean that we –the only ones who can do so, us humans- are those who have decided so as indisputable subjects that we are of some rights”*⁴⁴. Further along, she returns to the same idea when highlighting that *“we think and worry, in the short and long term, about the other living beings as beings that deserve help and protection, but the thinking is done by us, the only ones who are capable of thought, this is not done by animals or forests. It is us, in the end, who constructs the ethic or the legislation that will have to protect them”*⁴⁵.

Some of the advocates of the argument for marginal cases could nonetheless argue that if we are consequent with what is stated above, then we would also have to recognise that we also don't have the obligation to recognise any rights to human beings incapable of making a moral evaluation, which is indeed true. However, what is not true is that we would be doing something unjust if we decided to provide rights to all human beings and, in turn, denied them to animals. The key issue here is to understand that the fact that we have no obligation does not exclude that we deem granting it, either because we think some day we might become one, due to charity or empathy towards members of the human species or for any other motive⁴⁶. Where a previous moral obligation does not exist, it is not necessary to provide moral reasons: if I want to treat well all human beings simply because they are members of our species, then I am not doing anything wrong. Where there are no moral obligations, liberty reigns. If I wish to treat an embryo as a person, then nobody can say that in this way I am unfairly treating animals: I have no obligation towards either of them, but I can conventionally establish all that I want. In other words, the fact that I don't have to grant rights does not mean

⁴⁴ *Ibid.*, p. 66.

⁴⁵ *Ibid.*, p. 69

⁴⁶ Tom REGAN makes a serious mistake when he puts forth the idea that if one only considers that inevitably people are those beings who have qualities of free-will and rationality, then we would be leaving small children without rights (See: REGAN, T., “Poniendo a las personas en su sitio”, en TAFALLA, M. (Ed.), *Los derechos de los animales*, cit., p. 61). That the former undoubtedly possess the status of persons does not entail, at all, that the latter cannot have it, if the former agree to grant it. The same handicap can be found, in our judgment, with the reasoning of Oscar HORTA. See: HORTA, O., “Términos básicos para el análisis del especismo”, press publication, p. 7.

that I can't grant them, and certainly if I grant them in a discretionary manner, I am not being unfair⁴⁷. As a consequence, if I desire to grant humans the same rights as those of persons and on the other hand, not grant any right to animals, I am not doing anything morally reproachable.

This, of course, does not mean that we should not defend the need to adopt reasonable stances in this issue. To be reasonable, for example, means to reach similar conclusions to those who advocate the granting of rights to animals, that is, provide them with certain rights versus human beings. As has been splendidly pointed out by Victoria Camps, although “*ethics must open in a way to provide fitting to other beings different to humans [...] it must be done without mistaking the perspective and without rejecting from the outset the existing ethical paradigm, which until now is anthropocentric*”⁴⁸. According to her perspective, which I share, “*one thing is to think that the subject of ethics is solely the human being, and something quite different is to say that ethics deals or must deal solely with human life. The responsibility towards others must be made extensive to all living beings, human or not, although to a different extent and in different forms. To deduce from this that animal or nature in general is also the subject of ethics or of fundamental rights is to extrapolate things without too much basis and with rather absurd consequences*”⁴⁹.

Whoever has read this last phrase maybe has thought that in the end, we are subscribing to the principles of animal rights advocates. Let us differ. The fact, that to a great extent, there is a coincidence with the claims of Regan does not entail, at all, that we share his reasoning. Where he speaks of previous moral obligations, we speak of unconditional liberty. Hence, we can be fully coherent where he encounters serious difficulties. From this, the consistency of the argument as a whole is improved with this change. Obviously, there are some who might say that eliminating either the concept of a previous moral obligation, of the intrinsic value of animals or the need for respect weakens the claim. In our opinion, we truly believe that the opposite occurs: if I think I am responsible for animals and that nothing or no one but I can provide value to their

⁴⁷Think of the following example: if I decide to donate part of my salary to the poor people of a region, let us say La Mancha, would it make sense that I am being seriously discriminatory with the other poor people of the country? From our point of view it would not. As I have no obligation to donate, that is, the donation is not due to a previous obligation, then I don't have to justify why I give to some and not to others. Where a previous obligation does not exist, there can be no unfair discrimination.

⁴⁸ CAMPS, V., *Una vida de calidad. Reflexiones sobre bioética*, Editorial Crítica, S. L., Barcelona, 2001, p. 67.

⁴⁹ *Ibid.*, pp. 67-68.

lives, it is more probable that they will take this issue seriously. On the contrary, to find shelter in what is necessary is nothing but to provide reasons to those who ridicule the possibility of granting rights to animals.

4. SUMMARY OF THE MORAL VALUE OF ANIMALS

Before looking at some criteria that must guide the use of animals in research, we are going to summarize our point of view on the ethical value of animals in general and on their use for scientific experimentation in particular.

1. All human beings are equal in their dignity. Therefore, all should be treated not according to their real qualities, whichever these may be, but rather in accordance with the qualities that we recognize as proper of normal individuals of our species.
2. Though seriously mentally disabled humans may not possess capacities superior to some animals, they are, in spite of all, living beings and as such, we maintain special relations with them that we don't with other animals.
3. We need a clear line to divide those beings with whom I can experiment and those that I can't. The belonging to our species constitutes a clear and well-defined division line.
4. The level of self-consciousness or the category of a sensible being, though it doesn't make animals equal to humans, is morally important when valuing the different animal species and the use that can be made of such. From this point of view, mammals deserve a greater consideration than other groups of animals. Primates, and particularly the great apes, due to their mental development and the level of self-consciousness, hold a special position that imposes stricter limits in their use for research.
5. We have the moral duty to respect and protect non-human animals and to impede, so far as it is possible, the pain, suffering, distress or harms that they may suffer.
6. Taking into account the aforementioned clarifications, the use of animal for scientific experiments is ethically acceptable, always when undertaken with an evaluation that will weigh the suffering inflicted on the animals versus the benefits of research that can be provided to improve the health and quality of life of human beings.

7. Research projects that involve the use of animals must be supervised by ethics committees and must be subject to the legally adopted regulations on the matter.

In spite of a critical perspective with the more clearly zoocentric stances, we must admit that they have had an important positive role in the reporting of the degrading treatment to animals and the abusive, indiscriminate and often times superfluous use of animals in scientific research. The development of a social awareness and a greater ethical sensibility in the consideration of the importance of the animal well-being are in great part due to the attitude of the protectors of animals in their different versions. If we exclude the extreme postures, contrary to any type of research with animals, the proposals of conduct of many of its defenders are reasonable and perfectly acceptable in the majority of the cases and coincide with the normative criteria established in the different regulations that have been approved in these last years in order to regulate the use of animals in research.

5. PROS AND CONS OF THE USE OF ANIMALS IN RESEARCH

One of the reasons given for using animals in research is to ensure scientific progress in basic and applied biological and medical science. Few people would deny that science is an important and powerful way of understanding the natural world. Methodical observations of evidence produced in carefully designed experiments have helped us to understand, for example, a great number of physical and chemical principles that govern biological processes. Many scientists argue that research involving animals is crucial in continuing progress. On the basis of these views, it might appear that animal research does not require justification. But, there are also people who assert that the use for harmful purposes of one species by another, without consent, is fundamentally unethical, regardless of any possible benefits, and that all forms of animal research must therefore be abandoned. Instead, they argue that more effort should be made to find alternative ways of obtaining the required information, for example by undertaking research on human volunteers or on human tissue. Those who disagree assert that there are many significant research questions which can only be answered by using animals and that they are only used when absolutely necessary. They also question whether an abandonment of animal research, and the implied consequences, would be acceptable to all members of society. This situation leads us to more specific questions... How important is the alleviation of human and animal

suffering, in view of the fact that it may cause pain, suffering and distress to animals involved in research?; Why should the use of animals in research be acceptable in cases in which it would be unacceptable to use humans?... When we consider a type of cost that both humans and animals are capable of bearing, such as the experience of suffering, do they count the same? If not, what is the justification for counting animals' interest less –and how can this be done without begging the question against the growing ranks of people involved in this area who believe that the comparable interests of humans and animals are equally important?...

Those who accept the use of animals in research where the use of non-consenting human participants would be unacceptable could seek to develop and set forth a number of arguments supporting their case. For example, they could argue that animals are somehow morally less important than humans; that, when compared to humans, it matters less to animals to be used in research in certain ways; or that, although it would be preferable for animals to be free to live their lives, some research questions are so significant that the use of animals can be justified. Nevertheless, it could be also argued that the justification of animal research is more difficult when the disease, for instance, could be avoided by appropriate human behavior. It may be more straightforward where diseases emerge spontaneously and are independent of human behavior.

These options require us to consider a wide range of issues, ranging from abstract discussions about the moral status of humans and animals to more concrete comparisons of how animals are treated in other contexts. It could easily be assumed that the justification for using animals for research depends entirely on the question of the relative moral status of humans and animals. Then the defense of animal use would be the same task as showing that only humans have moral status, or that their status is in some way 'higher' than that of animals. But this assumption might be too simplistic. Yet, this is not enough to show that animals can properly be sacrificed for human purposes. As has been said by some authors: "The greater power of humans over other species bring with it a duty of care and compassion, no a license to abuse" (A. St. John).

It could be suggested, as has been said before, that the proper moral treatment of a being depends on the characteristics it possesses, rather than simply on the species to which it belongs. In this regard, we can focus on sentience, higher cognitive capacities, sociability, etc. Each feature provides reasons for moral concern, and hence it can plausibly be argued that animals in possession of one, or several, of these features are

moral subjects, and that any treatment infringing on one of the features requires careful justification.

We have not yet considered what weight the individual morally relevant features should have in deciding the acceptability of research. To anticipate the discussion, let us consider the capacity to feel pain. There is little disagreement that this provides a clear moral constraint on how a being may be treated. But is it merely one factor to be taken into account, which is to be weighed against others? Or does it create an absolute protection on how the being may be treated, in the form of an inviolable right? These two possibilities are reflective of different philosophical approaches which are summarized. Someone arguing from a consequentialist view, where the moral value of individual actions is based primarily on their outcome, would emphasize the first possibility, and accept a ‘weighing’ of different goods. A proponent of a rights-based or deontological view might argue in terms of the second possibility, asserting that certain factors establish absolute constraints, which ‘trump’ or ‘outweigh’ other factors. We now explore briefly the three principal options of how to consider the morally relevant features in relation to animal research: the weighing of consequences (consequentialism); the setting of absolute prohibitions (rights-based) or incorporating elements of both in a hybrid approach.

5.1. Two paradigms of normative ethics: Consequentialism and Deontology

Normative theory is a branch of philosophical ethic which seeks to develop theoretical frameworks that can help to determine whether actions are right or wrong. There are several approaches with regard to this aspect but we are going to focus on two of them: consequentialism and deontology. According to the first one, the moral value of individual actions, or rules for such actions, is determined primarily by their outcome. Such approaches do not usually put strong emphasis on the inviolable rights of moral agents or moral subjects. One important type of consequentialism is utilitarianism as has been mentioned before. Contrary to this approach, deontology is a theory which supports that actions are right or wrong independent of their outcome. Instead, their rightness or wrongness is defined by a formal system, which defines certain actions as intrinsically right or wrong. Moral agents have a duty to respect the principles derived from this system and to act according to it. Rights of other moral agents or subjects can be violated if they are not treated accordingly. Historically, deontology is associated

with the work of the philosopher Immanuel Kant. A separate form of deontology advocates the concept of animal rights.

5.1.1. *Consequentialism approach*

In any approach that seeks to weigh consequences, a number of more detailed questions need to be considered, to establish whether justification of a particular form of animal research is possible. These are as follows:

A) The cost or price of the ends of research:

Research may be undertaken to achieve several objectives, for example to advance basic biological knowledge, or to directly improve medical practice. In evaluating research, it is important to ask: how valuable is the aim and for whom?

With regard to the value of the aims of research, some people argue that a major distinction should be made between two types of research. The note that there is a research that has the aim of benefiting human health, animals or the environment in a direct and immediate way, for instance, by assessing the safety of a new medicine; and there is another one –basic research- which is just called curiosity research. The primary aim of the latter is to increase knowledge rather than directly to decrease human suffering, but with the possibility that eventually the research could produce health-related benefits.

Consequentialism reasoning requires, at least, an identification of the harms and benefits considered relevant to moral justification and, on the other hand, a calculation of whether the course of action envisaged produces a higher balance of benefit over harm than any alternative feasible option. It is necessary to have an estimate of the probability of success (be this the generation of knowledge or the development of a new medicine), which will need to outweigh, in some sense, the estimated harm that the experiment will cause, if an experiment is to be justified on consequentialist grounds. Any such calculation will need to allow a way of comparing distinct costs and benefits in order to calculate what level of health benefit for humans would outweigh, for example, a particular pain experienced by animals involved in research.

B) The harm experienced by animals:

This is dependent on the number of animals used, and their capacity to experience pain, suffering or distress or other adverse effects. The degree of harm relates, where applicable, to conditions referred, for instance, to research-related

procedures. The question posed is: what harm could animals suffer in pursuit of the research goals?

C) The availability of alternatives to research involving animals:

It is important to know if there are non-animal alternatives that could achieve the same research goal. If alternatives are not available, it would appear crucial to be able to assess the reasons why: are alternatives logically or conceptually unavailable? Are these alternatives unavailable because of political, financial or other practical reasons?

5.1.2. *Deontological approach*

Those arguing within a deontological framework assert that at least some uses of humans and animals are absolutely prohibited. For example, according to an argument frequently set forth by theorists and campaigning organizations the capacity for sentience is not merely an input into a utilitarian calculus, but the basis of a *right* not to be subjected to pain and suffering, whatever the wider benefits. According to this view, any sentient being has a right not to be used purely as a means to the ends of others if to do so would cause it pain or suffering. Such an approach combines a utilitarian theory of value with deontological (duty-based) constraints on action and would appear to rule out all research involving animals that causes any degree of pain.

We must take into account that not all experiences of pain are the same. Where to draw the line may be very difficult, but there could be room for a complex view in which different types of pain call for different types of moral response, in which some pains are permitted and others not, involving some weighing and some absolute prohibitions. Such an approach is found in what can be called a crossbreed theory.

1.5.3. Crossbreed theory

This theory contains some elements of the consequentialist theory, and some of the deontological approach. Most views in the current debate are of this form, even if there is great disagreement about the details. For instance, the current legislations combine deontological and consequentialist elements: there is a ban on the use of specific species, the prohibition of causing some forms of pain and certain types of research is based, for instance, on some relevant features such as sentience, higher cognitive capacities, sociability, etc. Within the “acceptable” or “permitted” circle, where reasons are weighed and balanced, the regulations are, somehow,

consequentialist but not utilitarian, placing restrictions on the type of goals that may be pursued. It is important to know how valuable the goal of the research is and for whom. Licenses are thus granted on a case by case basis where weighing of animal suffering in relation to the research goal is one aspect of the cost-benefit assessment, and where other considerations, such as deontological constraints, are taking into account.

To sum up, it is critically important to consider the worthiness of the goal of the research, the suffering of the animals involved in it and the availability of alternative ways of achieving that goal for which animals are used. If we are well informed, such comparisons can be instructive in establishing the basis of justifications given for the use of animals. However, each of the uses requires individual consideration and justification. We must take into account what is the appropriate role or way of regulation for research involving animals. In this regard, it is also important to consider the terms of the debate of this subject⁵⁰.

With regard to the opinion of the European citizens, we observe, in general terms, that they think that more needs to be done to improve the level of welfare /protection of animals used in experiments. In recent years, it has become increasingly apparent that the existing legislation for the protection of animals used in experiments (Directive 86/609/EEC) needs to be revised in order to promote improvements in the welfare of laboratory animals and to further foster the development of alternative methods. The UE citizens' consultation received the third largest number of responses to a Commission Internet consultation ever. Since 1986 important progress has been made in science and new techniques have become available, such as use of transgenic animals, xenotransplantation and cloning. These require specific attention, which the current Directive does not provide for. Nor is the use of animals with a higher degree of neurophysiological sensitivity specifically regulated, such as in the case of non-human primates and transgenic animals from the perspective of the institutional European ethics.

There is a recent Action Plan on the Protection and Welfare of Animals 2006-2010 which has been the subject of a wide public consultation in accordance with the

⁵⁰ Nuffield Council on Bioethics, *The Ethics of Research Involving Animals*, Nuffield Council on Bioethics, London, 2005. In this report are described the types of research involving animals: to advance scientific knowledge (Chapter 5); to study disease and develop medicines (Chapters 6-8); and to assess the safety of chemicals (Chapter 9)

European Commission's Interactive Policy Making⁵¹. It is accompanied by an Impact Assessment and also provides for individual impact assessments for future legislative initiatives. Lastly, a Commission Working Paper has been produced to serve as basis for the follow-up work of the Action Plan.

The primary objectives that the Commission wishes to achieve with the elaboration of this Action Plan are to: Define more clearly the direction of Community policies on animal protection and welfare for the coming years; Continue to promote high animal welfare standards in the EU and at the international level; Provide greater coordination of existing resources while identifying future needs; Support future trends in animal welfare research and continue to support the 3Rs principle: Replacement, Reduction and Refinement alternative approaches to animal testing; Ensure a more consistent and coordinated approach to animal protection and welfare across Commission policy areas, also taking into account aspects such as the socio-economic impact of any new measures.

These objectives have been identified based on the experience gained by the Commission in planning, preparing and negotiating various animal welfare initiatives both within the Commission, with Member States, the various EU Institutions and the steadily increasing number of stakeholders and international organisations that participate in such discussions. In order to achieve these objectives and to ensure a more structured approach in the different sectors involved, five main areas of action have been identified: upgrading existing minimum standards for animal protection and welfare; Giving a high priority to promoting policy-oriented future research on animal protection and welfare and application of the 3Rs principle; Introducing standardised animal welfare indicators, Ensuring that animal keepers /handlers as well as the general public are more involved and informed on current standards of animal protection and welfare and fully appreciate their role in promoting animal protection and welfare; Continue to support and initiate further international initiatives to raise awareness and create a greater consensus on animal welfare.

⁵¹ Commission Working Document on a Community Action Plan on the Protection and Welfare of Animals 2006-2010, Brussels, 23.01.2006 COM (2006) 14 final. This Action Plan describes the Commission intends to implement between 2006 and 2010 with the aim of developing and guaranteeing animal welfare and protection within the European Union and in other parts of the world. Its objective is to clarify Community legislation and make provisions for proposals in areas where it is insufficient. This Action Plan responds to the principles laid down in the protocol on animal welfare and protection annexed to the Treaty establishing the European Community (EC Treaty) This protocol recognizes that animals are sentient beings and that full regard should be paid to animal welfare concerns when formulating or implementing policies relating research, transport, etc.

In terms of minimum standards, the action plan would reinforce the existing Community regulation in line with latest scientific knowledge, practical experience and progress in international forums. It also suggests that the minimum standards should be extended to cover species and issues currently not adequately provided for under EU legislation.

Despite the fact that many strong advances in the field of animals welfare date from recent years, for generations societies have recognised their obligations with regard to caring for animals under their responsibility and many countries have long-standing legislation on the protection of animals and the prevention of cruelty. The first legislation on animal welfare at EC level was adopted in 1974 and concerned the protection of animals at the time of slaughter⁵².

In the intervening years a growing body of Community legislation on the protection of animals has accumulated. The Commission has important responsibilities to ensure that new legislation regarding animal welfare standards is based on evolving scientific knowledge, expertise and practical experience. In its role as guardian of the EC Treaties the Commission is also responsible for ensuring that Community legislation is properly implemented and enforced and the Commission's inspection service plays an important role in fulfilling this task. The scientific basis of such policies has also been supported by the activity of a succession of advisory bodies such as, Scientific Committee on Animal Health and Animal Welfare, Group of Advisers on the Ethical Implications of Biotechnology (GAEIB), etc.

In the area of the protection of animals used in experiments, the Commission has, as early as 1985, presented a Proposal for a Directive on the protection of animals used for experimental and other scientific purposes. Furthermore, by a Council Decision 1999/5755/EC the Community became party to a Council of Europe Convention ETS 123 on the protection of vertebrate animals used for experimental and other scientific purposes. This further reinforces the commitment to pursue efforts to replace animals used in experiments as well as to improve the welfare of those still being used.

As has been mentioned, animal welfare is a cornerstone of Community policies. Concerning the protection of experimental animals the Commission is currently

⁵² The recitals of this Directive indicate the importance that was already attached to animal welfare and the prevention of unnecessary suffering: "Whereas the Community should also take action to avoid in general all forms of cruelty to animals, whereas it appears desirable, as a first step, that this action should consist in laying down conditions such as to avoid all unnecessary suffering on the part of animals when being slaughtered". Council Directive 74/577/EEC.

preparing a revision of Directive 86/609/EEC. The aim of the revision is to strengthen the legislation in the area of animal experimentation in the EU and to ensure that animals still used in experiments will receive appropriate care and human treatment. The revision will be looking particularly into the requirements for the authorization of experiments, personnel and establishments and the inspection of establishments which breed, supply or use laboratory animals as well as the introduction of an ethical review process.

5.2. Key tasks for promoting animal wellbeing

In line with obligations under the EC Treaty Protocol, Community-funded research policies specifically incorporate the need to take animal welfare and ethical concerns into account in implementing research policies. It is important that, while addressing ethical aspects of new technologies whenever appropriate, developments in the field of animal welfare are based on a firm scientific background. This should be the case where new biotechnologies –such as animal cloning- have the potential to impact on animal welfare. Therefore, policies and recommendations related to animal welfare should take into account the latest available scientific information. Correspondingly, where there is a lack of objective information needed to develop appropriate policies and recommendations this should be used to inform the debate on prioritising new research.

It is necessary to develop guidelines with regard to this subject matter in order to assist not only investigators but also members of AEC to achieve the objectives referred to the wellbeing of animals used for scientific purposes. In this regard, the use of animals in scientific activities should be justified, and AEC must ensure that there are no alternatives to using animals. In addition, for animals that are used, pain and distress must be alleviated or minimized. On the other hand, uncontrolled adverse effects on animal wellbeing directly affect the validity of research results and the number of animals used to achieve a scientific objective. Therefore, an animal's potential to experience pain and distress while it is being used for scientific purposes has ethical, scientific and practical implications.

In addition to the potential effects of specific research procedures on the wellbeing of animals, animals can experience a range of stressors that are part of their daily living conditions and social environment. It is important that investigators

consider the wellbeing of an animal over the whole of its life, whether the animal is bred specifically for research purposes or obtained from other sources.

As has been mentioned in the Action Plan on the Protection and Welfare of Animals, it will be studied the possibility of creating a European Centre or Laboratory for the protection and welfare of animals. This Centre could be entrusted of a number of key tasks related to the rolling-out of the mentioned Action Plan. In particular it could be involved in the standardization/Certification process for new welfare indicators and it could coordinate and stimulate research to upgrade existing standards and promote further investigation of the inherent links between animal health and welfare. The Centre could also serve to host a “centre of excellence” to foster the active exchange of information in all areas of animal welfare. Thereby, the Centre could also facilitate the establishment of a European label for animal welfare by providing for harmonized European set of science-based benchmarks. Finally, the Centre could also be involved in the preparation of socio-economic studies and impact assessments relevant to the implementation of major new animal welfare measures.

5.2.1. The 3Rs principle as a key principle for promoting animal wellbeing

Concerning animal experimentation Directive 86/609/EEC has encouraged the development of alternatives to animal testing and the European Centre for Validation of Alternative Testing Methods (ECVAM) was created in 1991. It directly contributes to animal welfare through the application of the 3R principle (Replacement, Reduction and Refinement) and the validation of alternatives. Alternatives to animal experiments play an increasing role in the implementation of relevant legislation although public and political pressure and the availability of alternatives are very variable in different sectors. In addition to animal welfare benefits alternative methods also have the potential to provide robust information through quality-controlled, state-of-the-art tests which are faster and less cost-intensive than classical animal-based tests. In this context it is important to note that the concept of the 3Rs is already an integral part of the Community’s approach to the use of animals in experiments. The final aim is to replace animal experiments with methods not entailing the use of an animal. For those experiments that still need to be carried out using live animals, the objective is to reduce the numbers of animals and refine the methods so that they cause less pain, suffering and distress.

Concern about the wellbeing of animals used for scientific purposes, and the perception of the levels of pain, distress... endured limit pain in laboratory animals. What is the necessary common framework for ensuring the ethical and humane care of animals used in scientific activities?

It is necessary to outline some of the key principles for promoting the wellbeing of animals. The principle of *Replacement, Reduction and Refinement* (known as the 3Rs) aims to reduce the impact of scientific activities on animal wellbeing⁵³.

The use of animals in biomedical research (or any other research using animals as experimental subjects) entails ethical costs to the animal subjects, which consist mainly in suffering, pain, distress, infringement upon species typical behavior and death. It is mandatory to assess ethical costs before any research project using animals can be carried out. Such an evaluation aims at minimizing costs to animals and at the same time at maximizing benefits (both in terms of scientific knowledge and quality of life) for both humans and animals. In order to carry out this cost-benefit analysis, local animal care and use committees rely on standards that have been referred to as the 3Rs. That is researchers must look for alternatives to animal use in research (i.e., Replacement), they must use the minimum number of animals (i.e., Reduction), and they must minimize the pain inflicted on animals (i.e., Refinement). In other words, decisions regarding animal's wellbeing must be based on this premise. The 3Rs are defined as follows:

- *Replacement*, if a viable alternative method exists that would partly or wholly replace the use of animals in a project, investigators should use that alternative. Examples of alternative methods include in vitro techniques and computer models.
- *Reduction*, A project must be designed to use no more than the minimum number of animals necessary to ensure scientific and statistical validity. However, the principle of reducing the number of animals used should not be implemented at the expense of greater pain and distress for individual animals.
- *Refinement*, Studies must be designed to avoid or minimize both pain and distress in animals, consistent with the scientific objective. Investigators must also be competent in the procedures they perform. Project design must take into account the choice of animals, their housing, management and care and their acclimatization; the choice of techniques and procedures; the appropriate use of sedatives, tranquillizers, analgesics

⁵³ Cfr. RUSSELL, W.M.S., BURCH, R. L, *Principles of Humane Experimental Technique*, London: Methuen & Co, 1959.

and anaesthetics; the choice of appropriate measures for assessing pain and distress; the establishment of early intervention points and humane endpoints; adequate monitoring of the animals; appropriate use of pilot studies.

Other key principles in addition to the 3Rs include *Justification* and *Responsibility*:

- *Justification*, The projects using animals should be performed only after they are justified, weighing the predicted scientific or educational value of the project against the potential effects on the wellbeing of the animals. Thus, the justification must take into account all aspects of the project that may have an adverse impact on the animals.
- *Responsibility*, Investigators who use animals for scientific purposes have personal responsibility for all matters relating to the wellbeing of the animals. They have an obligation to treat the animals with respect and to consider their wellbeing as an essential factor when planning or conducting projects. To meet these responsibilities, it is essential that investigators are knowledgeable about all factors associated with the project that may affect the wellbeing of the animals they use, mechanisms to minimize these effects, the monitoring and assessment of adverse effects on animal wellbeing, and appropriate actions to take if adverse effects are observed.

Even though the 3Rs are widely accepted as ethical standards⁵⁴, and also taking into account the fact that alternative to animal use is an expanding field of research⁵⁵, which undoubtedly underlines the impact of the 3Rs, the ethical status of the 3Rs still remains to be clarified. Actually, the 3Rs were not derived from any ethical theory, but they represented an attempt to increase humanity to animal experimentation, in turn, to improve validity of scientific data. Given the controversy surrounding animal experimentation and the weight given to the 3Rs in animal ethical evaluation, it appears relevant to address the issue of the ethical status of the 3Rs.

The 3Rs define the modern search for alternatives in the experimentation with animals.

⁵⁴ CANADIAN COUNCIL ON ANIMAL CARE GUIDELINES, *Terms of reference for animal care committee*, Ottawa, Ontario, 2000; ORLANS, F. B., BEAUCHAMP, T. M., DRESSER, R., MORTON, D. B., GLUCK, J. P., *The Human Use of Animals: Case Studies in Ethical Choice*, Oxford: Oxford University Press, 1998; TALLACCHINI M., “Commentary: Council of Europe Working Party on Xenotransplantation: state-of-the-art report on xenotransplantation (2000)”, *Xenotransplantation* 8, 2000, pp. 154-156.

⁵⁵ BALLS, M., VAN ZELLER, A.-M., & HALDER, M. E. (Eds), *Progress in the Reduction, Refinement and Replacement of Animal Experimentation, Proceedings of the 3rd World Congress on Alternatives and Animal Use in the Life Sciences*, Development in Animal and Veterinary Sciences, No 31, Amsterdam: Elsevier, 2000.

In reference to the first “r” (*Replacement*), in the last years, there has been a development, in a very important manner, of alternative methods to the use of animals. In some cases, these methods allow us to obtain more precise and reliable results than those obtained with animals, but, unfortunately, it is not always the case. In spite of the advances achieved, we must recognise that it is not possible to completely replace the use of animals, at present, and probably in the future. The following chart contains some of the alternative methods that are being used at present.

Alternative methods to the use of animals in research

In vitro culture of animal or human cells

Research with animal organs

Use of premature stages of development

Use of organisms of a lower phylogenetic scale

Assisted clinical observation instead of laboratory tests

Endoscopic exams and biopsies

Autopsy studies

Mathematical and computer models

Image formation techniques

Activity studies based on the physic-chemical properties of the molecules

Epidemiology studies

From an ethical perspective, it is advisable that in certain areas, there be a complete stop with animal experimentation. Examples of these can be in the military, cosmetic industry or laboratory practices in education. From the perspective of people who believe that the recourse to war is a rejectable and immoral form of resolving conflicts amongst humans, animal experimentation precisely aimed at perfecting methods of destruction and death of human beings doesn't seem justifiable.

In reference to the cosmetic industry, several makers have totally eliminated animal tests by using home substitutions or by using ingredients that had passed the tests in the past. The British cosmetic industry agreed with the Government the suppression of tests on November 1998⁵⁶. Likewise, Directive 93/35 of the European

⁵⁶ RIECHMANN, J., *Un mundo vulnerable. Ensayos sobre ecología, ética y tecnociencia*, op. cit., p. 258.

Union prohibits, since 30 June 2000, to sell cosmetic products that have been tested on animals, though this prohibition was later postponed in all the European Union. In Spain, it was through an order of 3 August, 2000.

As far as education practices are concerned, the total elimination of animals seems more problematic. However, this is a tendency, which began very early. Specifically, in 1876 in Great Britain there was a prohibition for surgeons to practice with animals. Since then, they practice with human cadavers instead. In the United States, approximately one third of the faculties of medicine don't use animals in their ordinary courses. I think that the use of animals in education could disappear without great problems due to the existence at present of audiovisual and computer methods.

Regarding the second "r" (*Reduction*), the reduction in the use of animals has been happening in many countries since the seventies of last century. This way, Great Britain and Switzerland since 1975 and 1980 respectively, until 1992, have had a reduction of 50 percent. Holland and Germany also registered decreases of about 50 percent. Other European countries had smaller reductions, between 20 to 40 percent. The United States doesn't have complete data, but those available also reflect that since 1968, the decrease has also been very pronounced for the greater part of the species used.

The continuation of this tendency of reduction depends on several factors. Among these are, the improvement of statistical methods, which allow the obtaining of reliable results using a smaller sample size, the exchange of information and the exhaustive revision of the bibliography, which avoids the unnecessary repetitions of experiments. A greater degree of sensibility by the research community and the public opinion and the promulgation of growingly more precise legal norms are also important.

The often criticised test of lethal dose 50 is a very meaningful example of the role of statistical methods in the reduction of the number of necessary animals. The recourse to advanced statistical procedures is allowing to drastically reducing the size of the sample used. Recent protocols only require a tenth of the number of animals that were formerly used, with results that attain the same reliability.

Finally, the third criterion of the three "r" (*Refinement*), to refine, has been partially made reference to in the previous criteria when we made reference to the perfecting of statistical tests. We should add all those measures that eliminate or at least

minimise the pain and stress that affect animals throughout the experiments. These measures also include the use of adequate analgesics and anaesthesia and the painless killing of animals when the harm produced remains after the experiment.

Several authors have included in their works the enumeration of behaviour principles. In the following chart, as examples, we compile three of them. Marshall Hall's was one of the first guides of behaviour that was compiled, and though it goes back to 1831 it is still applicable. The other two are more recent and correspond, respectively, to LLuis Montoliu and Asier Urruela-Carlos Romeo. The three coincide in several matters and are complementary in their respective recommendations. Furthermore, although Hall's is much earlier to the publication of the "three r's", it is no less coherent with the orientations of it. The other two are directly or indirectly inspired on it. With different formulations, the three share the ideas to replace, always when possible the use of animals for alternative methods, to reduce their number to the indispensable minimum and to refine the procedures in order to cause the least possible harm to animals.

These same criteria have presided in the drafting of the main existing normative, such as the *European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes* of the Council of Europe, which in turn has been the basis for the drafting of laws and regulation that have been established by the majority of the European States in these last years.

Principles of behaviour in research and experimentation with animals		
Hall (1831) ⁵⁷	Montoliu (2002) ⁵⁸	Urruela y Romeo (2002) ⁵⁹
1. Experimentation mustn't be	1. Guarantee that all animals used for research receive the most humane	1. The recognition of the need to experiment with live and intact animals of diverse species in

⁵⁷ Cited by A. ARANDA, "Ética en la experimentación con animales de laboratorio", in G. M. TOMÁS GARRIDO, (Coord.), *Manual de bioética*, Editorial Ariel, S. A., Barcelona, 2001, p. 314.

⁵⁸ LI. MONTOLIU JOSÉ, "Utilización responsable de animales modificados genéticamente en biología, biomedicina y biotecnología", in J. J. FERRER y J. L. MARTÍNEZ, (Eds.), *Bioética: un diálogo plural. Homenaje a Javier Gafo Fernández, S. J.*, Publicaciones de la Universidad Pontificia Comillas, Madrid, 2002, pp. 290-292.

⁵⁹ A. URRUELA MORA, y C. M. ROMEO CASABONA, "Los dilemas éticos del xenotrasplante", *op. cit.*, p. 64.

<p>undertaken if observation can replace it.</p>	<p>and adequate treatment possible.</p>	<p>order to be able to discover more suitable means to protect human and animal health and to progress in biological knowledge.</p>
<p>2. No experiment must be done without a clear objective.</p>	<p>2. Use of animals for research only when there are no other alternatives or if they are inappropriate.</p>	<p>2. The need to search for substitute biological and non-biological methods.</p>
<p>3. Scientists must be well-informed on the experiments of their colleagues in order to avoid unnecessary repetitions.</p>	<p>3. Use the minimum number of animals possible for research.</p>	<p>3. That those animals that necessarily need to be used are of a quality and species that is appropriate for the experimentation and that their number is limited to an indispensable minimum in order to obtain valid results.</p>
<p>4. The experiments that are justified must be carried out with the least pain possible.</p>	<p>4. Design the experiments in such a manner so that the number of animals used in research is sufficient to guarantee the reproducibility and the statistical validity of the conclusions from the derived data.</p>	<p>4. The assumption that animals are also sensible beings and to reduce to a maximum its discomforts, distress or pain and suffering therefore constitute an ethical duty.</p>
<p>5. Each experiment must be carried out under conditions that give rise to the clearest results and avoid the repetition of</p>	<p>5. Use of anaesthetics and/or analgesics always when possible in order to alleviate and/or limit the possible pain or suffering that the experiment may cause those animals used in research.</p>	<p>5. When those are not going to be temporary or minimal, an intervention must be carried out with sedation, analgesia or anaesthesia in accordance with accredited veterinary methods.</p>
<p>the repetition of</p>	<p>6. All work, surgical and treatment protocols that</p>	<p>When this can't be done, the competent authority must</p>

experiments.	are going to be used with research animals must be approved by specific bioethic and scientific committees and be in accordance and comply with legislation in force.	authorise the experiment. 6. If there are irreparable suffering of disabilities, then the killing of the animal must be carried out by harmless procedures
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5.2.2. *Assessing pain, distress and suffering in animal*

The impact of research on animals and their welfare depends upon the nature of the experiments. However, many factors other than the experiment itself can have an effect, including conditions during breeding, transport, housing, handling and restraint. Although it is impossible to get “inside the mind” of animal, we can make meaningful “approximations” in assessing pain and suffering that they may experience. Observations of animal behavior and evaluation of signs of distress, such as increased levels of specific hormones or weight loss, combined with an awareness of species-specific needs and a critical use of empathy, can lead to useful assessments of animals’ well-being⁶⁰. But, what does the concept of wellbeing mean? And how is it affected by stress, distress and pain?

5.2.2.1. Animal wellbeing

The terms ‘animal wellbeing’ and ‘animal welfare’ are used interchangeably in many publications, but there is considerable debate as to the use and interpretation of these terms in various settings.

The notion of animal welfare encompasses the different ways in which an animal may respond to its circumstances, ranging from a positive state of wellbeing to a negative state of distress. Criteria that define wellbeing and distress provide a basis for the critical evaluation of how an animal is coping in a given situation, and hence also provide evidence that informs our judgment about their welfare.

Animal wellbeing relates to evidence of how an animal is coping with a given situation and a judgment as to how the animal feels in these circumstances. It is

⁶⁰ Using GM animals in research may raise particular problems in assessing welfare. The implications of introducing and deleting specific genes cannot usually be predicted and the effects on welfare can be difficult to detect and measure.

important to know the way in which an animal perceives and experiences internal, external and environmental factors, and how this affects its wellbeing.

Wellbeing is an internal state involving quality of life that is affected by responses to internal and external factors. These factors may be good or bad, positive or negative. Individuals experience wellbeing differently, because of their different needs, goals, motivations and preferences. In addition, wellbeing in one individual can vary from time to time, and changes may or may not be orderly or predictable. As a protective mechanism, departures from optimal wellbeing generally cause normal adaptive coping responses designed to return the animal to its normal state of wellbeing. Ineffective responses may result in distress, disability, disease or death.

There are different factors involved in assessing the animal wellbeing. For instance, animal behavior is an important indicator of how an animal is interacting with its environment:

Changes in patterns of behavior are often the first pointer as to how an animal is responding to and coping with change. Animal behavior can be assessed by observation and during interactions with the researcher or animal carer. A number of factors can influence individual responses. Therefore, knowledge of species-specific behaviors as well as prior history is important. Documentation of the range and level of activities such as eating, drinking, play, grooming, sleeping, resting, interactions with co-specifics and exploration of the environment can be used to describe patterns of behavior indicative of wellbeing. Species-specific differences will be seen in the types and levels of activities. Individual responses within this framework may be modulated by prior experiences.

Indicators of an animal's state of health include general appearance, posture, coat condition, clinical signs (eg. temperature, heart rate, respiratory rate), hematological and biochemical measurements, responses to handling, demeanour, temperament, maintenance of bodyweight or, in immature animals, rate of weight gain, and reproductive performance.

Although requiring sophisticated methods, the pattern of circadian rhythms in the physiological, immunological and neuroendocrine indicators of the stress response is a sensitive indicator of physiological adaptation. Researchers and animal carers must be familiar with species-specific indicators of wellbeing; these are the basis for assessment of evidence of pain and distress. Absence of signs of disease or abnormal behaviors,

together with positive evidence of health status and behavior, indicate that an animal is probably coping with its current situation⁶¹.

It is also important to take into account the effects of an animal's wellbeing on scientific outcomes.

Good experimental design is essential. The aim is to use animals that are in a stable and defined physiological state so that the response to the variable of interest is not confounded by unwanted influences. Studies in animals where there is not a stable baseline for reference can lead to incorrect interpretation of data due to the effects of a treatment being masked or confounded. Given the complexity and range of the physiological and behavioral responses associated with stress, distress and pain, there is a high risk of these effects confounding the collection and interpretation of data.

In addition to the potential effects of specific research procedures on their wellbeing, animals can experience a range of stressors that are part of their daily living conditions and social environment. Animals may experience physiological and behavioral perturbations associated with stress, distress or pain, which are induced as part of the experimental protocol, in which case the magnitude of the effect must be minimized commensurate with the aims of the study. However, when these effects are incidental and not part of the experimental design, factors that cause such perturbations should be eliminated or controlled so as not to confound data collection and interpretation of results. Any response to stressors that results in fluctuations in physiological and behavioral measurements, however transient, may influence the reliability and interpretation of data. If an animal's wellbeing is compromised, the consequences can include: greater variability in the data; a need for increased numbers of animals; reduced credibility of data, etc.

Clearly, in the design and execution of protocols, avoiding unintended effects on animal wellbeing involves much more than the selection of the appropriate anaesthetic or analgesic agent.

It is in the interests of good scientific practice to maintain the wellbeing of animals used in scientific activities and to identify, control and, if possible, eliminate

⁶¹ Cfr. WEARY D. M., NIEL L., FLOWER F. C., and FRASER D., "Identifying and preventing pain in animals", *Applied Animal Behaviour Science* 100, 2006, pp. 64–76; CLARK J. D., RAGER D., and CALPIN J. P., "Animal well-being: an overview of assessment", *Laboratory Animal Science: International Journal of Comparative and Experimental Medicine* vol. 47, No. 6, 1997, pp. 580–585; MOBERG G. P and MENCH J. A (eds), *The Biology of Animal Stress: Basic Principles and Implications for Animal Welfare*, CABI Publishing, 2000; CARSTEN E., and MOBERG G. P., "Recognizing pain and distress in laboratory animals", *ILAR Journal*, vol. 41, No. 2, 2000, pp. 62-71;

factors likely to cause physiological or behavioral responses associated with stress, distress or pain. Reduced variability between animals should lead to reductions in the number of animals needed to achieve statistical significance. When stress, distress or pain is a predicted or unavoidable consequence of a research procedure, strategies to minimize or control these effects are an essential component of good experimental design.

5.2.2.2. General discussion about the benefits and drawbacks that entails the experimentation with animals

There is a disagreement about whether research involving animals is useful for studying human disease and for assessing toxicity of medicines or chemicals.

As has been mentioned, in accordance with the *European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes* of the Council of Europe, later adopted by the European Union, to seek “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”⁶² is a moral duty that can be sanctioned according to several legal regulations.

The discussion on the benefits and drawbacks that, from an ethical point of view, entails the experimentation with animals usually gives rise to opposing conclusions that are respectively drawn by those in favour and those against that use. This discrepancy is focused on three aspects:

- Firstly, there is no agreement when evaluating how much pain and suffering is inflicted to animals with the confinement and experimentation. Franklin Loew has pointed out: “experimentation with laboratory animals causes less pain and suffering than that suggested by its detractors and more than claimed by its proponents”⁶³.
- Secondly, the different value given to the importance of the conclusions that can be drawn from animal research. Critics highlight that the experimentation with animals can lead us to the wrong conclusions, as the physiology of the species used is different from ours and the results of the experiments can be different from those that would be obtained from humans, reason why the tests on humans are always, in all cases, essential before any clinical application.

⁶² COUNCIL OF EUROPE, *European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes*, Strasbourg, 18 March, 1986, art. 5.3.

⁶³ LOEW, F. M., “Los animales en la investigación”, *op. cit.*, p. 327.

On its part, the advocates of the use of animals consider that there are no basic differences between the physiology of laboratory animals and that of humans. They also remind us that a great part of the advances that have been achieved in biomedicine have been backed by a solid base of animal experimentation.

- Thirdly, there is a different value attached to the usefulness of alternative methods to the use of animals. Although there is a broad consensus that we should practise with alternative methods in so far as they become available, there is discrepancy on whether the use of these methods allows doing away with the use of animals now and in the future.

Beside these points of disagreement, groups that are opposed to animal experimentation have expounded other arguments with which they aim to demonstrate that, either animal experimentation is not necessary or is not as important as claimed by the advocates of such. Among these arguments is the need to provide a greater importance to preventive medicine versus the excessive use of healing treatments, as happens at present; the undertaking of more epidemiologic research and the increase of assisted clinical research with laboratory tests⁶⁴. Although these suggestions are acceptable and may reduce, in some cases, having to use animals, they don't eliminate at all the need for their use.

In summary, some say that because of biological differences between humans and animals, results from animal studies cannot reliably be applied to humans. Cases of medical research involving animals where progress has been difficult, such as cancer and HIB/AIDS research are used to support this view. Other people point to the occurrence of adverse drug reactions as evidence that research involving animals is harmful for humans.

Analysis of the scientific literature and the history of medical discovery show in fact that there is clear evidence that specific types of research involving animals have provided benefits to society. For instance, scientists have developed effective preventatives and treatments for diseases such as rheumatoid arthritis, polio and hepatitis C. The results of animal testing have also been used successfully predict the likely harmful effects of chemicals on human health.

We have studied in this document some ethical questions and arguments to try to clarify the debate about if it is morally acceptable to cause pain, suffering and death to

⁶⁴ RIECHMANN, J., "La experimentación con animales", *op. cit.*, pp. 248-249.

animals. We have tried to understand what lies behind remaining disagreement on whether research involving animals is morally justified. As has been explained at the beginning of this document, the question of defining the moral status of humans and animals often arises in the debate on research involving animals. Are humans morally more important than all animals? Is there a sliding scale with humans at the top and the simplest animals at the bottom? Or are humans and animals morally equal? We are not going to repeat what was said before, we suggested, -among other arguments- that the proper moral treatment of a being depends on the characteristics it possesses, rather than simply on the species to which it belongs. But, what weight should be given to each of the morally relevant features in considering whether or not research is acceptable? Are they factors to be weighed against human benefit? Should they be understood as absolute constraints? Should any use of animals that are capable of suffering be prohibited, or only the use of those that have higher cognitive capacities?

With regard to all these questions, it is important to establish not only the criteria and norms of behavior, but also some of the possible strategies that investigators can use to maximize wellbeing and minimize pain and distress in animals. We are going to study them in the next paragraph.

We can conclude, for the moment, that because of biological similarities between animals and humans, in principle, animals can be useful models for studying specific aspects of human biology and disease and the likely effects of chemicals and medicines in humans. However, the usefulness of animal models has to be judged on a case by case basis for each type of research or testing.

From our point of view, it is important that funders in research, animal protection groups, industry associations, etc should consider ways of funding and carrying out reviews on the scientific validity of animal research in specific areas. In response to public concerns, priority should be given to research that causes substantial pain and suffering to animals. Therefore, it should be also important, as has been said, to know the possible criteria and strategies that can be used to maximize wellbeing and minimize pain and distress in animals.

5.3. Criteria and strategies to improve the animal wellbeing

What is the necessary information to help investigators decide if animal experiments are needed to meet the aims of a specific research project? For projects that require the use of animals, information is provided on all stages of the research process, such as

choosing the right animal to use; sourcing, transporting and housing animals; designing the experiment; predicting and minimizing pain and distress; training personnel, etc.

Scientists using animals in scientific procedures have an *ethical* and *legal* obligation to ensure that the principle of 3Rs: *Reduction, Refinement* and *Replacement* are used wherever possible. In other words, if a research project does require the use of animals, investigators should follow the aforementioned principle, *where the minimum number of animals* (or amount of animal tissue) *is used to obtain the maximum amount of scientific information*, and *where methods of using animals are selected for their minimum impact*. In this regard, collaboration between investigators (both intra and inter-institutional) can reduce the number of animals or amount of animal tissue required for a particular research question. Investigators can also collaborate to develop methods of *refinement*, such as standard operating procedures, to promote animal wellbeing and maintain *high ethical research standards*⁶⁵.

Therefore, before developing a new research using animals, the investigator should consider, for instance, if the use of animals is justified; if similar projects have been performed elsewhere; if the same results could be obtained using tissue culture or computer modeling or other alternative to animals. Investigators must weigh up whether the potential benefits of the scientific knowledge gained will outweigh harm to the animal. On the one hand, if animals are required for the research, the necessary information must be considered before submitting a proposal to the AEC. On the other hand, investigators must ensure that the AEC from each institution, -if the research is carried out in more than one institution-, is aware of the proposal, and that appropriate approvals have been obtained for each component of the project⁶⁶.

Before submitting a proposal to the AEC, the investigator must have considered, for instance, the following issues:

- Is it necessary to use animals?
- Has the study been designed to produce valid results?
- Is a pilot study required?
- Have appropriate species/animals been selected?
- Are suitable facilities, equipment and environmental conditions available?

⁶⁵ Cfr. FESTING M. F. W., “Reduction, model development and efficient experimental design”, in: *Progress in Reduction, Refinement and Replacement of Animal Experimentation*, BALLS M., VAN ZELLER A. M and HALDER M. E (eds), Elsevier Science, Amsterdam, 2000, pp. 721–727.

⁶⁶ Another important point that must be taken into account is to know what the right animal for a proposed research is. The most suitable animal to achieve the required outcomes must be used, and the reasons for choosing a particular species must be clear in the proposal.

- Are all personnel involved suitably trained?
- Are there strategies for minimizing and monitoring pain and distress?

After approval has been received from the AEC, investigators must not deviate from the approved protocols without seeking AEC approval. Investigators must also notify the AEC if any adverse or unforeseen events occur, and suspend research until AEC advice has been obtained⁶⁷.

It is also of high importance that research protocols are well designed. However, given the ethical considerations associated with using animals in research, it is particularly essential that studies using animals are well designed. The aim is to use as few animals as possible to get meaningful data, without using too few so that the study needs to be repeated or gives inconclusive results. This is the principle of *Reduction*, one of the 3Rs, along with *Replacement* and *Refinement*. Studies must be designed to ensure that valid data can be obtained⁶⁸. Festing states that good experimental design means that the experiment should be: Unbiased (for example, the treated and control groups have the same environment); Precise (so that the chance of detecting treatment effects is as high as possible). To achieve this, investigators must ensure not only their experimental design but also objectives and hypotheses are thoroughly considered and completed before they start any research involving animals.

Before starting a research project, the experimental design must be approved by the relevant AEC. Festing and Altman recommend that, before starting an experiment, investigators should have protocols (preferably written) that include the following: clearly stated objectives and hypotheses of the research; in the case of animal models, an explanation of why the model was chosen; a good understanding of relevant scientific literature (including similar studies already done and reasons why more

⁶⁷ A proposal to an AEC must have enough information for the committee to be satisfied that the proposed use of the animal in the research project is justified. It should include: the project title; the expected project timeframe; the names, roles and experience of all personnel; the source of animals and required permits; details of housing and procedures to be used; the potential benefits of the project; an overview of the project; how the principles of Reduction, Replacement and Refinement are being applied; how animals will be monitored; justification for the use of animals in the project; any practical considerations, such as special risks to other animals or humans; a declaration that the project complies with the relevant legislation. CANADIAN COUNCIL ON ANIMAL CARE, *Guidelines on Choosing an Appropriate Endpoint in Experiments Using Animals for Research, Teaching and Testing*, 1998; TALLACCHINI M., "Commentary: Regulatory issues in Europe and Canada", *Xenotransplantation* 9 (2002b), pp. 371-373.

⁶⁸ Cfr. FESTING M. F. W., "Reduction, model development...", 2000, pp. 721-727.

research using animals is required); precise details of the study design; precise details of the statistical methods that will be used to analyze the data⁶⁹.

5.3.1. What are the possible strategies for assessing and minimising pain and suffering?

The complexity of an animal's response to stressors makes it difficult to rely on one simple measurement as an indicator of pain or distress. In addition, because animals cannot communicate their experiences directly to humans, their pain and suffering can only be assessed by observing their behavior and physiology. The challenge is to measure or evaluate pain, stress and distress in the animal, and to determine when a stress response develops to a stage at which the response has a harmful effect on the animal's wellbeing and leads to distress. In order to minimize pain and suffering in animals, practical systems must be developed for the prediction, monitoring and assessment of these states.

Once investigators have identified all potential sources of pain and distress associated with a particular project, they should determine those signs that will indicate an animal's wellbeing is compromised. Based on these assessments, a monitoring strategy should be developed for the study, including documentation of the relevant signs, frequency of monitoring, intervention points, and points for regular review.

The clinical signs or observations that will be used to assess an animal's condition must be defined. These include general signs of ill health or abnormality, and signs specific for the procedure. So that appropriate clinical signs can be selected, it is essential that investigators know the normal characteristics of the particular species, damage and individual animal that will be used.

It is also important that the investigators or the persons responsible for making observations of the animals are competent in evaluation the normal physiology, behavior and body condition of the animals. The research group, the AEC and the institution are responsible for providing appropriate training before the project begins. Training should be provided as needed, and should encompass not only techniques but also the responsibilities of the investigators for monitoring the animals. It is also of high importance to gather accurate documentation of the monitoring strategy so as to ensure that all persons involved with the care of the animals are aware of the basis for determining the presence and severity of pain and suffering.

⁶⁹ Cfr. FESTING M. F. W.; ALTMAN D. G., "Guidelines for the design and statistical analysis of experiments using laboratory animals", *ILAR Journal*, No. 43, 2002, pp. 244–258.

5.3.2. *The role of the animal ethics committee (AEC)*

Agreement on the monitoring strategy should form part of the application process to the AEC. This committee can be involved in the fine-tuning of the monitoring criteria and intervention points in consultation with the research team. In this regard, all criteria for monitoring and subsequent actions are documented before the project begins. The AEC must also ensure that the investigators have the appropriate experience and/or training to effectively implement the monitoring strategy⁷⁰.

Therefore, all studies using animals must be approved and monitored by an AEC. This committee is responsible for ensuring, on behalf of institutions, that all care and use of animals complies with the rules established in this field, the use of animals is justified and the principle of 3Rs is followed. Institutions are responsible for ensuring that any use of animals for scientific purposes is approved and monitored by an AEC. Before a project using animals can begin, any new protocols must be approved by the research institution's AEC.

The animal ethics committee (AEC) must be also advised of any problems or adverse events. AEC would view with concern any adverse event that is not reported or any failure to conduct an autopsy when an animal dies unexpectedly. Reporting to the AEC enables the committee to assist with any investigation of the incident, to prevent its recurrence and to prevent any compromise of animal wellbeing and the experimental model. Reporting also educates the AEC by informing it of any problem with a procedure that has been approved. The AEC should be also involved in the review process. At a minimum, AEC approval should be required for any changes to intervention points or humane endpoints. AEC approval must be obtained before the implementation of any amendment to the approved protocol. AEC representatives may be involved in the 'day-to-day' evaluation of the effectiveness of the monitoring criteria, particularly if a project is associated with specific animal wellbeing concerns. The AEC should also be involved with the review of the monitoring strategy following an adverse event or unexpected death. The use and effectiveness of monitoring checklists should be actively reviewed by the committee during its routine inspections of research in progress, when project records are examined.

⁷⁰ Cfr. HAWKINS P., "Recognizing and assessing pain, suffering and distress in laboratory animals: a survey of current practice in the UK with recommendations", *Laboratory Animals*, No.36, 2002, pp. 378–395; Canadian Council on Animal Care, *Guidelines on Choosing an Appropriate Endpoint in Experiments Using Animals for Research, Teaching and Testing*, 1998.

6. Transgenesis, cloning and xenotransplantation

In order to finish, we will briefly make reference to three specific applications: animal transgenesis, cloning and xenotransplantation. The three are inter-related. For example, animals that are the source of organs for xenotransplants must be transgenic, as they have to modify their genes of histocompatibility in order to achieve that the transplanted organ doesn't create any type of rejection on the receptor, as are hyper acute rejection, differed vascular rejection or in the longer term, the retarded and chronic cell rejection. Likewise, the technique of nuclear transplant which is the basis of cloning can be used in order to increase the efficacy of the obtaining of transgenic animals, which has already been tested in some cases.

Undoubtedly, one of the major advantages of the use of pigs as source animals for xenotransplantation products is their excellent breeding capabilities in captivity. These breeding characteristics facilitate genetic engineering and allow the rapid transmission of introduced genetic modifications into the herd, as well as their combination with other genetic modifications. Several human genes have already been introduced into pigs as transgenes, and advances in nuclear transfer techniques have permitted the recent development of pigs that do not express aGal on cell surfaces. It is likely that the optimal pig for xenotransplantation will require multiple genetic manipulations, which could be facilitated by increasing experience with the techniques for porcine genetic modification, developing more efficient techniques for genetic modification, and sharing of proprietary genes or genetically modified pigs to allow their combination in a single animal.

Investigators have also produced several strains of *transgenic pigs* that express human proteins that down-regulate activity of the human complement cascade involved in hyper acute rejection. These human proteins were selected because some of the corresponding proteins in pigs do not fully down-regulate human complement activity. It is thought that the expression of human complement regulatory proteins at higher than physiologic levels might significantly diminish antibody-mediated destruction of the graft. Some of these proteins have been introduced into pigs, and all showed some efficacy. In some cases, the proteins reduced or prevented hyper acute rejection of porcine solid organs that had been transplanted into nonhuman primates⁷¹.

⁷¹ COZZI E., YANNOUTSOS N., LANGFORD G. A., PINO-CHAVEZ G., WALLWORK J., WHITE D. J. G., "Effect of transgenic expression of human decay accelerating factor on the inhibition of

Although these studies have demonstrated the efficacy of the transgenic approach in preclinical models, they have also highlighted the fact that hyper acute rejection is only one of several rejection processes that can rapidly destroy solid-organ xenografts. In this regard, researchers have recently developed a technique of nuclear transfer in which a genetically modified donor cell nucleus can be used to replace the nucleus of a germ cell (an oocyte). This development provides an approach to making site-specific genetic modifications. The technique has been used successfully to generate transgenic animals and may be more efficient than earlier strategies. Additional transgenic strategies are also under consideration or development.

The ethical evaluation of these applications must be done weighing the benefits they provide versus the suffering and harm that the animals employed may suffer.

We can divide the applications of the use of transgenic animals into three categories, which are: basic research, medicine and biotechnology. In relation with the benefits of the latter, Lluís Montoliu has correctly emphasized that “genetic manipulation, applied to animals, has meant a real revolution in biology, medicine and biotechnology”⁷². In biology, transgenic animals are a very valuable tool to know the function of the genes, having contributed to the explanation of the patterns of expression that are characteristic of many of them. Among the applications related with medicine would be the genetic models of human disease, the obtaining of proteins of therapeutic interest, the use of animals as bioreactors and the obtaining of animals as a source of organs for xenotransplants. The biotechnological applications, on their part, would be aimed at the improvement of the quantity and quality of animal production.

Genetic modification is a subject of considerable moral debate. Many members of the scientific community would deny that most cases of genetic modification animals are more ‘unnatural’ than conventionally bred animals. They point to the fact that selective breeding of animals dates back to the beginnings of agriculture and domestication, and that it has been used extensively within scientific research. Proponents of this view also argue that there is no substantial difference in principle between more traditional forms of genetic selection and genetic modification; that any

hyperacute rejection of pig organs”, in Cooper D. K. C., KEMP E., PLATT J. L., WHITE D. J. G., (eds), *Xenotransplantation: The Transplantation of Organs and Tissues Between Species*, Heidelberg, Springer-Verlag; 1997, pp. 650–658. SCHUURMAN H. J., PINO-CHAVEZ G., PHILLIPS M. J., THOMAS L., WHITE D. J., COZZI E., “Incidence of hyperacute rejection in pig-to-primate transplantation using organs from hDAF-transgenic donors”, *Transplantation*, 2002, 73, pp. 1146–1151.

⁷² MONTOLIU JOSÉ, LI., “Utilización responsable de animales modificados genéticamente en biología, biomedicina y biotecnología”, *op. cit.*, p. 286.

animal produced through genetic modification could theoretically also have been created by means of selective breeding; and that the main difference is that genetic modification is faster and more precise.

While some of those who do not share this view might agree that arguments for species integrity are not straightforward, they may challenge the suggestion that no new issues are raised by the genetic modification approach. For example, they may assert that the more gradual processes of selective breeding enable researchers to detect possible welfare-related problems at an earlier stage; as such problems may manifest themselves in smaller increments, and can be assessed against known strains of animals. By contrast, the 'sudden' introduction of a distant gene in a new organism by the genetic modification method may lead to unexpected and unpredictable implications for welfare, especially in mutagenesis. Although most researchers consider that the vast majority of such studies do not have any negative consequences for the animals involved, the evidence so far is inconclusive.

Alternatively, opponents to the genetic modification approach might agree that the technique does not differ fundamentally from some forms of selective breeding, but consider that it amplifies the problem of deliberately interfering with a species' genotype in ways that can cause harm. If these observations are correct, the moral discussion then becomes focused on the extent to which genetic modification, and other forms of selective breeding, can be conducted without causing harm.

Taking as a reference the propositions put forward in the conference on Bioethics organised by the Council of Europe in Oviedo in 1999, Houdebine, in reference to the acceptability of the use of transgenic animals, has proposed some tolerance levels in accordance with the suffering that it entails the animal⁷³. These are the following:

1. High tolerance level: strictly experimental transgenic animals
2. Medium tolerance level: transgenic animals source of organs for transplants or producers of therapeutic proteins.
3. Minimum tolerance level: transgenic animals used in livestock improvement.

The third case seems the most clear. As Houdebine argues "in this case we are dealing with an improvement in production, which is not necessary at all for human populations, already well supplied, and that, on the other hand, would affect a great

⁷³ HOUDEBINE L., *Los transgénicos. Verdades y mentiras sobre los organismos genéticamente modificados*, Salvat Editoriales, S. A., Barcelona, 2001, p. 144.

number of animals that would be destined to suffer with the sole purpose of increasing the benefits of some”⁷⁴.

The problems would acquire a different dimension if this increase in animal production would be based on a need in relation with the food supply to the underdeveloped populations of the Third World. However, we must take into account, that given the low level of biotechnological developments in those countries and the high economic costs to obtain transgenic animals due to the limited efficacy of the technique (the obtaining of a sole transgenic cow costs half a million dollars), it does not seem that the improvement in the animal production through the use of transgenic animals can be, in the short run, a viable alternative for those countries. Furthermore, even surmounting those difficulties, we would have to evaluate up until what point the solution to the food problems would truly need the recourse to transgenic animals, which, certainly, is far from being evident.

The levels of tolerance of the other two cases are less clear. Paradoxically, a smaller level of acceptance is established, at first, for applications that could have a more direct medical application, such as xenotransplants or the obtaining of therapeutic proteins. For these cases, Houdebine deems that the suffering of animals must be studied on a case by case basis and later compared with the benefit that it has for the patients. In the case of the production of therapeutic proteins, the animals usually don't suffer problems derived from the transgenesis, as the transgene is solely expressed in the mammary gland in which it produces milk. This gland “has demonstrated to be the ideal organ for the expression of recombinant proteins due to its high capacity of synthesis, the few risks that it has in the expression of the transgene for the health of the animal and the ease of recollection and purifying of the product”⁷⁵.

Versus the scarcity of problems for animals derived from their use as bioreactors, the potentialities of this technique are enormous, though some time must still go by until they are developed. As Lluís Montoliu has pointed out “theoretically, a sole cow that would produce about ten grams of factor VIII of blood coagulation per litre of milk would satisfy the annual world need for this protein in order to guarantee

⁷⁴ *Ibíd.*

⁷⁵ SÁNCHEZ BONASTRE A., and FOLCH ALBAREDA, J. M., “Transgénesis y mejora animal”, en CASADO M., y GONZÁLEZ-DUARTE R., (Eds.), *Los retos de la genéticas en el siglo XXI: genética y bioética*, Edicions de la Universitat de Barcelona, Barcelona, 1999, p. 199.

the treatment to each and every homophile on the face of the Earth”⁷⁶, though at present, the efficacy is between 10 and 100,000 times less.

The same criterion of evaluation of the benefits and harms for animals should also be used in the first of the mentioned cases, in that of strictly experimental animals. One must keep in mind that among the specific applications of this case would be both the biological research aimed at knowing the function of the genes and its patterns of characteristic expression, as well as, the establishment, from a medical point of view, of animal models that would permit us to study many genetic diseases.

Although the greater part of transgenic animals does not usually suffer any bother, it is not always this way, and in some cases, the transfer of genes can provoke suffering of a diverse degree. This is what happened when transgenic pigs were obtained from the gene of the growth hormone. These had several pathologies that affected, among other organs, the kidney and the liver. Furthermore, they were incapable of staying up due to the low quality of their muscular fibres⁷⁷.

In the case of transgenic animals that are modified in order to serve as a model of human diseases, the aim is precisely for the diseases to become manifest in the animal in order to be able to study the genetic mechanisms that cause it.

The benefit that can be obtained from these procedures, in the form of medical knowledge in order to combat human diseases that nowadays have no cure, can be enormous, but it is no less true, that at times, the manifestation of the disease in animals lead to important suffering for them. An example in the Lesch-Nyhan disease, a recessive illness linked to the X chromosome, the phenotype is characterised, among other manifestations, by mental retardation and compulsive bodily self-mutilation due to the biting of fingers and lips. The obtaining of *knock-out* mice for this disease produced as a result that the phenotype was similar to humans, which highlighted the seriousness of the self mutilations that were produced.

In summary, the use of transgenic animals for diverse purposes is sufficiently justified due to the importance of the benefits that are obtained and a small level of discomfort or suffering in the majority of the cases. However, it is convenient to individually evaluate the different situations that may arise, given that not all are the same, not even from the perspective of the benefits for the health and improvement in

⁷⁶ MONTOLIU JOSÉ LI., “Animales transgénicos”, in GAFO J., (Ed.), *Aspectos científicos, jurídicos y éticos de los transgénicos*, Publicaciones de la Universidad Pontificia Comillas, Madrid, 2001, p. 62.

⁷⁷ *Ibíd.*, pp. 59-60.

the quality of life of human beings or even from the point of view of the suffering and harm that the different procedures could entail for animals.

On its part, animal cloning doesn't present important ethical problems. In any case, they are not different from those already mentioned in the case of transgenesis. From the different methods of cloning, twinning or embryonic splitting is the simplest to evaluate, as it doesn't pose any type of moral reservation in itself. The resulting animals do not suffer any type of harm derived from the procedure and develop as completely normal individuals.

Animal cloning through nuclear transfer can be a little more controversial from the perspective of the harm entailed to animals, due to a lack of safety of the technique and the consequent presence of malformations in some of the cloned animals. However, these problems seem minimised due to the fact that the majority of the defective cloned embryos die before completing their development, and therefore the number of animals that could reach to have some suffering, due to the imperfection in the technique of nuclear transfer is very small. If we would apply the criteria of tolerance that was previously exposed in animal transgenesis, only those cases of livestock applications of cloning would be problematic in light of such, always and when cloning would produce a meaningful harm in a significant number of individuals, a situation that doesn't happen in fact.

The ethical problems of xenotransplantation in relation with the use of animals is in reference to its use as a source of organs and also due to the previous necessary research in order to develop the technique until it can be used on humans with safety and with sufficient guarantees of success⁷⁸.

We can sum up these ethical problems in the following:

- The previous research, for years, with animals for the development and perfecting of methods of transgenesis applicable to xenotransplantation.
- The production and breeding of transgenic pigs as a source of organs for transplants
- The death of transgenic pigs that are the source of organs.
- The experimentation with primates to test transplanted organs from transgenic pigs.
- To consider ethically unacceptable the use of primates as a source of organs.

⁷⁸ ROMEO CASABONA C. M.; MORA URRUELA A.; PEREIRA DE MELO H.; MCGLEENAN, *Xenotransplantation. Ethical, Legal, Economic, Social, Cultural and Scientific Background*, Vol. 4, AVM, 2008; ROMEO CASABONA C. M.; MORA URRUELA A.; "New legal developments in xenotransplantation: the spanish approach", *Revista de Derecho y Genoma Humano*, No. 29, 2008, pp. 111-129

The first three problems mentioned: previous research, as well as the production, breeding and death of transgenic pigs can be evaluated with the same criteria that we have already mentioned for transgenesis. In any case, it is necessary to increase the precautions so that the animals don't suffer as a consequence of the treatment and that their killing must be completely painless. The benefits that could be obtained in the future, if xenotransplants become a reality, would sufficiently justify the use and killing of animals.

The majority of study groups that have dealt with the ethical implications of xenotransplantation, such as the Nuffield Council of Bioethics⁷⁹, The Advisory Group on Ethics of Xenotransplantation⁸⁰, presided by Ian Kennedy or the Report of the Subcommission on Xenotransplantation of the Permanent Commission of Transplants in Spain⁸¹, agree in deeming as acceptable the use of pigs as a source of organs for xenotransplantation. The Spanish Report on Xenotransplantation points out that the creation of transgenic animals would only be acceptable if the transformations carried out don't change the phenotype of the animal, in the sense that the modified animal must be completely similar to the rest of the members of its species and the modification undertaken must solely affect an immunological function⁸².

The other two mentioned problems deal with the use of primates. There is a broad consensus in rejecting their use as a source of organs. This rejection is based in its evolutionary relation with our species and that, as a consequence of such, share certain emotional and cognitive capacities with human beings, including, to a certain extent, the capacity of their own conscience. Its raising and stabling would also be ethically problematic due to the pain and suffering that this may cause them. Another reason for rejection of the use of primates would be the high number of specimens needed, given that their survival would be placed in danger, which is nowadays threatened with extinction.

There are other technical and procedural reasons that are not favourable to the use of primates:

⁷⁹ NUFFIELD COUNCIL ON BIOETHICS, *Animal-to-Human Transplants. The ethics of xenotransplantation*, Nuffield Council on Bioethics, London, 1996.

⁸⁰ THE ADVISORY GROUP ON THE ETHICS OF XENOTRANSPLANTATION, *Report on Animal tissue into humans*, TSO, London, 1997.

⁸¹ MINISTERIO DE SANIDAD Y CONSUMO, *Xenotrasplante. Informe de la Subcomisión de Xenotrasplante de la Comisión Lastinge de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud*, Madrid, 1998.

⁸² *Ibíd.*, p. 55 ff.

The risk of a virus transmission between primates and humans can increase due to the phylogenetic parentage, especially when there is a precedent of the plausible transfer of the AIDS virus from monkeys to humans.

Primates have a very low index of reproduction.

7-10 years are needed in order for their organs to reach a sufficient size.

It would be practically impossible to meet organ demand by only using primates.

On the contrary, there is a trend to accept as a lesser evil, undesired but necessary, the use of primates, though in small numbers, in order to experiment with the transplant of organs from transgenic pigs before proceeding to clinical research on humans (Nuffield Council of Bioethics, The Advisory Group on Ethics of Xenotransplantation, presided by Ian Kennedy or the Report of the Sub commission on Xenotransplantation of the Permanent Commission of Transplants in Spain).

1. Summary of conclusions

Steps that reduce or minimize the magnitude and duration of perturbations associated with stress and postoperative complications support scientific and animal welfare goals and promote the principle of the three Rs. The complexity and range of issues involved in surgical procedures require careful evaluation to identify risks, to develop strategies to minimize or manage those risks and to develop a pain management plan. A pilot study may be necessary to inform this process. Planning should also include an assessment of the availability and suitability of facilities and equipment, and of the skills, knowledge and experience of the people involved. Once a management plan has been formulated, ongoing review will identify opportunities to refine methods and procedures. As part of annual and final reporting to the AEC, the investigator must report whether the wellbeing of the animal was consistent with the predictions in the protocol.

The main reason which supports this statement is our moral duty to respect and protect animals and to avoid, when possible, the pain, suffering, distress and other types of harms that they may suffer. The benefits expected from animal experimentation must be weighed against the harm or suffering that these may suffer. Therefore, it must be weighed up whether the potential benefits of the scientific knowledge gained will outweigh harm to the animal

As has been mentioned in this text, the use of animals in research must be done in accordance with the principle of the 3Rs: *replace*, always when possible, the use of

animals for other alternative methods. This “R” means the use of methods that permit a given scientific purpose to be achieved without conducting experiments or other scientific procedures on living animals; *reduce* the number of animals employed, improving the statistical methods and means of information and consultation in order to avoid unnecessary repetitions. It is important to use the fewer animals in each experiment without compromising scientific output and the quality of biomedical research and testing, and without compromising animal welfare; and *refine* the techniques and methods in the use and management of animals in order to impede, or if this is not possible, to minimize to the utmost, the pain and suffering that these may suffer as a result of research. It is also of high importance to improve all aspects of the lifetime experience of animals to reduce suffering and improve welfare.

The principle of the 3Rs is widely accepted as ethical standards in the majority of societies regarding animal ethical evaluation. This principle is in agreement with ethical values such as reverence for life, dignity, painless treatment and biodiversity.

In addition, we must highlight that these 3Rs should not be regarded as contradicting each other, despite being evaluated separately in the research protocols and by the members of AEC. They verify if each principle has been satisfied; that is, AECs verify each principle separately. Another reason to justify the statement of not considering these principles as contradicting each other is that these 3Rs are basically focused on a single dimension: that is pain. In this regard, they are still valuable tools in evaluating research protocols using animals as experimental subjects. They should not be reduced to “things”. We have the duty to take into account the pain and suffering of animals when applying and practicing any research or experiment. Therefore, these same criteria are applicable for transgenesis, animal cloning and xenotransplantation.

In reference to the latter, the use of primates as sources of organs raises more ethical controversies, given their emotional capacities and their evolutionary parentage with human beings.

For the next future it is necessary to continue with the efforts so as to ensure that Community legislation is drafted in a rational and comprehensible manner. Community animal welfare policies need to be based on the best available scientific evidence as well as taking into account the concerns of civil society, socio-economic consequences and relationships with international organizations. Specific legislative provisions should also be foreseen for species for which minimum protection standards are not currently outlined in Community legislation.

2. Summary of the legal statute: Regulation and policy relating to scientific procedures on animals

The legal protection of animals is relatively recent. The first laws of the 19th century which prohibited abuses to animals were conceived to improve the well being of humans. Domestic animals were only protected against public abuses due to the effects that this cruelty could have on people. The basis of this protection could basically be found in avoiding the bad influence that the exercise of violence towards animals had for society⁸³. Nonetheless, we mustn't forget that the well-being of animals, more specifically, of an animal used in experimentation, was already the object of protection in the *Cruelty to Animals Act of 1876*. This exception was only followed by the rest of the States in the 20th century.

Traditionally, diverse sectors of the legal regulation have made reference of animals as an object of possession, property, obligations, etc. Civil Law, the same as the special legislation on hunting and fishing, considers the animal as an object, personal property and as such can only be the object of rights, but not the titleholder of rights, in the same manner as physical and legal persons⁸⁴. In Criminal Law, the animal is likewise considered as an object of property or possession that must be protected against robberies, defrauding, injuries, etc. The same as in Civil Law, only the person, but here only the physical person, with intellectual and volition capacity, can be the active subject of an offence⁸⁵.

Nonetheless, through the last reform of the Criminal Code⁸⁶, two new criminal infractions are introduced which confirm a new perspective towards the criminal protection of animals based on the well being of the animal: the offence that can be found in article 337, which punishes the abuse with cruelty to domestic animals causing their death or serious physical damage and the misdemeanour in article 631.2, on the abandonment of domestic animals, placing at risk their life or integrity. Added to these,

⁸³ See, RIECHMANN, J., "La dimensión jurídica ¿derechos para los animales?" in *Animales y Ciudadanos*, Jesús Mosterín and Jorge Riechmann, Talasa, Madrid, 1995, p. 198.

⁸⁴ Along these lines, see GONZÁLEZ MORÁN, L., "El derecho frente a los animales" in *Los derechos de los animales*, Juan Ramón Lacadena, Ed., Universidad Pontificia de Comillas y Desclée de Brouwer, Bilbao, 2002, p. 83.

⁸⁵ Nonetheless, both in Antiquity as in the Middle Ages, animals were object of criminal proceedings. See on this matter ANTÓN ONECA, J., *Derecho Penal* (2^a ed.), annotated and updated by J. J. Hernández Guijarro and L. Beneytez Merino, Akal, Madrid, 1986, pp. 173 ff.

⁸⁶ Basic Law 15/2003

there is a misdemeanour in article 632 of the Criminal Code which prohibits the cruel abuse of domestic animals and of animals used in non-authorized shows.⁸⁷

Nonetheless, from the perspective of Kelsen, based on obligations and not on rights, there wouldn't be an obstacle to affirm that animals, including inanimate things, are titleholders of rights from the moment in which there is a subject who is required to follow a specific behaviour in its favour or to avoid one against it, independent of whether it is required or not. This way, the subject rights is but a mere reflection of a legal obligation. Kelsen believes that a subject is only that which is obligated by a norm⁸⁸.

Whether you choose one stance or another, whether you recognise the animal as titleholder of rights or not, whether you talk about the "rights of animals" or of the "legal statue of animals", the truth is that actually, an animal, its well-being, is object of legal protection from diverse perspectives: in relation with the protection of the environment (wild fauna), in the field of military research (chemical weapons), biomedicine, etc.; its use in industry (food, cosmetics, fur, military, chemical) and therefore, as object of production or breeding, sale, transport and sacrifice; its possession or use as a company or domestic animal, for work, its custody in zoos, its use in shows, etc.

If, in the 19th century, the interest of Law in animals was due to being an object of possession, appropriation, etc, the 20th century initiates the concern over its protection versus the action of man. Only when man sees his basic needs satisfied, then appear the first social manifestations for the legal protection of animals versus their worst enemy: man.

In the next paragraphs we summarize some of the important aspects of the international and European framework governing research involving animals. A review of international responses to the issues raised by xenotransplantation in this regard has an important role to play in the ethico-legal assessment of the procedure, particularly because efforts to address the issues associated with this field require some form of international cooperation.

2.1. International regulation

⁸⁷ And also of misdemeanour in article 631 (which shall now be misdemeanour of 631.1) which punishes those responsible for fierce animals who let them loose and whose object of protection are people rather than animals.

⁸⁸ See, KELSEN, H., *Teoría pura del derecho* (2^a ed.), Porrúa/UNAM, Méjico, 1991, pp. 141 ff.

The basic principles that underline the regulation of animal research are very similar in all countries in which animals have legal protection. Regulations specify the conditions under which animals may be used and seek ensure that harms are minimized as far as possible. They are usually implemented through review of proposed research projects, applying the Three Rs where possible and assessment of the general standards of laboratory animal housing and husbandry. However, countries differ in the complexity and detail of regulations, and the manner and strictness with which they are implemented and enforced. Some countries do not have national regulatory systems and use guidelines or policies developed by individual institutions. For instance, Canada relies on a well-developed voluntary system of self-regulation based upon protocol review by Institutional Animal Care Committees, which operate according to guidelines set out by the Canadian Council on Animal Care⁸⁹.

The system of project review by an institutional committee is the most common method of self-regulation in most countries. Committees typically involve scientists with experience in the field and veterinary staff. In some cases, these committees have a broader membership which includes animal technicians, non-technical staff of the institution, external lay members or representatives with an interest in animal welfare.

In many countries, the detailed operation of these committees is controlled by agencies that fund research. The USA has an extensive system of Institutional Animal Care and Use Committees, created by the Animal Welfare Act and its regulations⁹⁰. Australia uses a similar system of Animal Ethics Committees, created under state legislation, but operating in accordance with the code of practice produced by the National Health and Medical Research Council⁹¹.

2.2. European regulation

Within Europe, there are two, almost identical, legal instruments. They are the Council of Europe Convention for the protection of vertebrate animals used for experimental and other scientific purposes (ETS 123, 1986), and the EU Directive EEC 86/609 on the approximation of laws, regulations and administrative provisions of the Members States regarding the protection of animals used for experimental and other

⁸⁹ See Canadian Council on Animal Care, available at <http://www.ccac.ca/>

⁹⁰ US Department of Agriculture Animal Welfare Act and Regulations, available at: <http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>

⁹¹ National Health and Medical Research Council (2004) Australian code of practice for the care and use of animals for scientific purposes, 7th Edition, available at: <http://www.nhmrc.gov.au/publications/pdf/ea16.pdf>

scientific purposes. The legal status of these instruments differs. Member States of the Council of Europe can decide whether or not to ratify the Convention by implementing it in their national legislation. By contrast, Member States of the EU are legally obliged to implement the goals set out in the Directive. All have transposed the Directive in their national or regional legislation, although the European Commission has referred several countries to the European Court of Justice to ensure that their legislation is fully in accordance with the Directive.

The main current provisions of the EU Directive are that:

- Establishments conducting animal experiments must be registered with the authorities and maintain the housing and husbandry of the animals according to a standard set out in an annex to the Directive;
- Experiments must only be conducted by, or under the direct responsibility of, a competent, authorized person, who should have appropriate education and training;
- Animals cannot be used if another, scientifically and satisfactory method is available;
- Experiments must be designed to use the minimum number of animals, the species with the lowest neurophysiological sensitivity and to cause the least pain, suffering, distress or lasting harm, compatible with the purpose of the experiment;
- The experiments to be performed, or the details of the individuals who will perform them, must be notified in advance to the authorities,
- Experiments that may cause severe pain that is likely to be prolonged must be justified in advance and authorized by the authorities;
- Statistical information on the numbers and types of experiments conducted must be collected by the authorities; and
- Breeding and supplying establishments must be registered and comply with the same standards as experimental establishments.

There is significant variation in the national systems for regulating animal research introduced under the Directive. Member States are permitted to adopt stricter measures if they wish. Several countries have done so. For instance, training requirements are more detailed in The Netherlands, and provisions for freedom of information are more liberal in Sweden.

Most EU countries originally implemented the Directive with “external” regulation, which means that authorizations for research projects are given by national or local government officials. Some countries opted for a system in which local or

regional animal ethics committees authorize research involving animals. None of the EU countries have implemented systems of self-regulation.

The system of regulation in most Member States uses either one or two licenses. The main license usually covers the research or testing activities of an institution and serves as the registration of the establishment and the license for research to be conducted. Other countries use separate licenses for the institution and the projects, which may include details of the personnel who will carry out the research.

To fulfill the requirement in the Directive for verifying that the provisions of this Directive are properly carried out, most Member States have established a system of inspection of establishments that conduct animal experiments. This function is usually added to the role of local veterinary inspectors, whose primary role is to inspect agricultural use of animals. Very few countries have statutory systems of inspection dedicated exclusively to animal research. In The Netherlands there are three inspectors for the animals used annually. In the USA, only institutions that conduct research involving certain classes of animal covered by the Animal Welfare Act are subject to inspections from the US Department of Agriculture. Additional levels of inspection operate for institutions that receive federal funds. The non-governmental Association for Assessment and Accreditation of Laboratory Animal Care also carries out inspections of accredited institutions. Accreditation is voluntary but includes most large companies and major universities as accreditation is an important factor for securing contracts and funding.

Since the Directive was adopted in 1986, there has been a trend towards increased and more detailed regulation in many Member States. For instance, France, The Netherlands and some parts of Spain have added a system of local Animal Ethics Committees to their previously existing systems of control; Austria, The Netherlands, Sweden and the UK have abandoned the use of great apes in scientific procedures, although they had not been used in the UK and Sweden for some years; More recently, a ban on the use of animals within the EU for the testing of cosmetics has been passed and is due to come into force in 2009 (and sales within the EU will not be allowed after 2013).

Under the Council of Europe's Convention ETS 123 there are periodic meetings of representatives of the Member States and relevant non-governmental organizations to 'examine the application of this Convention, and the advisability of revising it or extending any of its provisions'. In 1997, the revision of Appendix A to the Convention,

which gives guidelines for the accommodation and care of laboratory animals, was agreed. The revised Appendix A will include details about the husbandry and housing of all the principal laboratory animal species. Since the EU ratified the Convention, Appendix A will be adopted as a revised Annex II to Directive EEC 86/609.

In 2001 the European Commission proposed that Directive EEC 86/609 should itself be revised. This process started in 2003 when the Commission formed four Technical Expert Working Groups (TEWGs) to offer advice on how the existing Directive could be improved. Discussions are currently in progress but it is likely that a revised Directive will not be adopted for several years. The provisions of the new Directive will be transposed into national legislation once the revisions have been agreed.

ANNEX 1: International Declaration on the Rights of Animals

The International League on Animal Rights adopted in 1977, in its third meeting on animal rights (London, 21-27 September 1977) and proclaimed in Paris, 15 October 1978, the Universal Declaration of Animal Rights, later approved by The UNESCO and later by The UN. The adscription of moral and legal rights to animals and their enshrinement in a United Nations Declaration of Animal Rights is a logical and inevitable progression of ethical thinking. It is not an imperative document. But it is as much a statement of intent as it is of principle. We marked the fiftieth anniversary of the original Declaration by announcing our intention to achieve the aim of enshrining the rights of animals in the policy of the United Nations. The challenge facing human society is to redefine our understanding of progress such that our recognition and protection of the rights of animals is as much a barometer of our level of civilisation as our recognition and protection of the rights of human beings. The evolution of human civilisation, its principles as well as its practice, will not end with the twentieth century: the citizens of the coming century, who are the children and young people of today, will not fail to grasp the opportunity to mark the moral progress of their time as we have defined ours. The future is theirs but it begins with us, today...

Preamble: Considering that Life is one, all living beings having a common origin and having diversified in the course of the evolution of the species; Considering that all living beings possess natural rights, and that every animal with a nervous system has specific rights; Considering that the contempt for, and even the simple ignorance of these natural rights cause serious damage to nature and lead man to commit crimes against animals; Considering that the coexistence of species implies a recognition by the human species of the right of other animal species to live; Considering that man commits genocide and threatens to continue; Considering that the respect of humans for animals is inseparable from the respect of man for another man; Considering that an education in the infancy period must provide observance, comprehension, respect and affection towards animals, it is hereby proclaimed:

Article 1

All animals are born equal and they have the same rights to existence.

Article 2

a) Every animal has the right to be respected.

b) Man, like the animal species, cannot assume the right to exterminate other animals or to exploit them, thereby violating this right. He should use his conscience for the service of the animals.

c) Every animal has the right to consideration, good treatment and the protection of man.

Article 3

a) No animal should be submitted to bad treatment or cruel actions.

b) If the death of an animal is necessary, this should be sudden and without fear or pain.

Article 4

a) All animals belonging to a wild species have the right to live free in their natural environment, and have the right to reproduce.

b) Each deprivation of freedom, even for educational purposes, is in opposition to this right.

Article 5

a) Every animal that usually lives in a domestic environment must live and grow to a rhythm natural to his species.

b) Any change to this rhythm and conditions dictated by man for mercantile purpose, is a contradiction of this law.

Article 6

a) All animals selected by man, as companions must have a life corresponding to their natural longevity.

b) To abandon an animal is a cruel and degrading action.

Article 7

Working animals must only work for a limited period and must not be worked to exhaustion. They must have adequate food and rest.

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.

Article 9

In the eventuality of an animal bred for food, it must be fed, managed, transported and killed without it being in fear or pain.

Article 10

- a) No animal should be used for entertainment.
- b) Animal exhibitions and shows that use animals are incompatible with an animal's dignity.

Article 11

Every action that causes the unnecessary death of an animal, is cruel which a crime against life is.

Article 12

- a) Every action that causes the death of a lot of wild animals is genocide that is a crime against the species.
- b) Pollution and destruction leads to the extinction of the species.

Article 13

- a) Dead animals must be treated with respect.
- b) Violent scenes, where animals are the victims, must be forbidden at the cinema and on TV, unless they are for the demonstration of animal rights.

Article 14

- a) Protection and safeguarding associations must be represented at government level.
- b) Animal rights must be defended by law as are human species, cannot assume the right to exterminate other animals or to exploit them, thereby violating this right. He should use his conscience for the service of animals.
- c) Every animal has the right to consideration, good treatment and the protection of man.

Some of these proposals have been compiled in conventions and national legislations, as for example, the prohibition of cruelty (art. 3), sacrifice for humane reasons (art. 3), research when necessary and there are no other alternatives (art. 8), research without suffering (art. 8) and the protection guaranteed by Law and the States (art. 14). Others nowadays continue being a declaration of intentions, such as the guarantee to life (art. 1), freedom (art. 4), respect and protection (art 2 & 5), prohibition of genocide (art 12) and the prohibition of unnecessary sacrifice or biocide (art. 11).

ANNEX 2: International Conventions

Previously, on 3 March 1973, The Convention on International Trade in Endangered Species of Wild Fauna and Flora was signed in Washington.

In Bonn, 23 June 1979, The Convention on the Conservation of Migratory Species of Wild Animals was signed.

In that same year of 1979, the signing of The Convention on the Conservation of European Wildlife and Natural Habitats took place.

European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes of the Council of Europe and 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, whereby there is an establishment of common regulations that incorporate the main principles, objectives and dispositions of this Convention.

In our continent, we have the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes of the Council of Europe of 18 March, 1986.

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 integrant part of ETS123.

On the 24 November, 1986, The Council of the European Communities adopted **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** whereby there is an establishment of common regulations that incorporate the main principles, objectives and dispositions of this Convention.

11.1 Scope of Application

A. Definition of Procedure

It must be applicable to any experimental or scientific procedure capable of causing pain, suffering, distress or permanent harms (art. 1.1). This is understood as “any use of an animal for experimental or other scientific purposes which may cause it pain,

suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition, but excluding the least painful methods accepted in modern practice (i.e. 'humane' methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use and ends when no further observations are to be made for that experiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition.” (art. 1.2 c) Agricultural practices, non-experimental and clinical veterinary practices are excluded (art. 1).

Therefore, this covers any experimental or scientific procedure capable of causing suffering or distress to an animal, always when there is not a use of the humane methods mentioned, independent of whether anaesthesia or analgesia are used. This begins when the animals is being prepared and ends when the last practice is undertaken. If the first condition is not met, that is, the experimental or scientific purpose, then agricultural or non-experimental clinical veterinary practices is excluded.

B. Purpose of the Procedure

The aim of these experimental or scientific procedures are the prevention, diagnosis or treatment of disease in humans, animals or plants; the protection of the environment; scientific research (fundamental or applied); forensic inquiries, education and training (art. 2).

C. Animals object of experimentation

In the experiment, any type of animal that is a live non-human vertebrate, including free-living larval and/or reproducing larval forms, but excluding foetal or embryonic forms (art. 2.1a).

In accordance with the precept, the protection exclusively reaches those animals already born. However, within its ambit we can find “autonomous larval forms and/or with the capacity to reproduce”, that Directive 86/609/EEC labels as “free-living larval and/or reproducing larval forms”.

Absolute limitations - Human, foetal and embryonic forms of the rest of vertebrate animals are excluded.

Relative limitations:

Animals supplied from registered breeding or supplying establishments. 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 ⁹²(art. 22).

This condition in reference to the origin of the animal is reiterated in Article 21.1 when the animal used in procedures is a mouse, rat, guinea pig, golden hamster, rabbit, dog, cat, or quail⁹³, however, this limitation can equally be surmounted by obtaining a general or special exemption (art. 21.1).

Although articles 21 and 22 don't form part of the basic content of the Convention, Directive 86/609/EEC introduces this limitation in its Article 21, making reference to its annex I, which adds the non-human primate to the list of species of the Convention.

In accordance with article 21.2 of the Convention, that establishes the possibility of extending this guarantee to all those species that in the future could be supplied by such establishments, then the obligation to use animals that proceed from these establishments would be extended to the rest of rodents, anthropoids, apes, pro-apes, other carnivores, horses, donkeys and hybrids, pigs, goats, sheep, cows, other mammals, birds, reptiles, amphibians and fish.

Stray animals. 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).

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

⁹² Each dog or cat must be duly identified either marked, before its weaning, or by keeping documentary records (art. 17 of the Convention).

⁹³ This list can be extended to other species, in particular of the order of primates, as soon as there is a reasonable prospect of a sufficient supply of purpose-bred animals of the species concerned (art. 21.2)

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. 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.

The Directive keeps this restriction in article 19.4, which according to article 34 of the Convention, can be the object of reservation by the parties (art.34)

Animals in danger of extinction - Likewise, Article 4 of Directive 86/609/EEC prohibits the use of animals in danger of extinction in accordance with that established in appendix I of The Washington Convention of March 3, 1973 on International Trade in Endangered Species of Wild Fauna and Flora⁹⁴ and in annex C, part 1 of the Regulation of the European Economic Community, 3626/1982⁹⁵.

Animals captured in nature or wild animals.- Article 7 of the Directive equally impedes the possibility to experiment with animals captured in nature (wild animals), except if research with any other animals is not enough for the purpose of the experiment.

Execution of the Experiments

General conditions or requisites of the procedure

Exceptional - 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)⁹⁶.

In order to strengthen the exceptional use of such procedures, the law provides that when *the animal is subject to severe pain*, it shall be necessary to have the express authorisation or at least, to justify its need (art. 9).

Least harmful - 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.

Directive 86/609/EEC adds another criterion: that the experiment affects animals with the least degree of neurophysiologic sensibility (art. 7).

Competent Researchers - The procedure shall be performed by authorised persons, or under their direct supervision (art. 21). In accordance with the meaning of this article, an authorised person must be understood as a competent person.

⁹⁴ Modified on October 22, 1987

⁹⁵ Modified by EEC Regulation 3143/1987.

⁹⁶ Directive 86/609/EEC has a similar prohibition in article 7.2

Article 7.1 of the Directive has a more precise drafting of what is an authorised competent person, which is further developed in article 14.

Registered Establishments - Except for express authorisation, every experimental or scientific procedure must be performed in a registered establishment (art. 23) that complies with a series of conditions (art. 18 ff).

The Convention requires that the establishments:

Be registered;

Have qualified personnel, that is, care takers, veterinarians, advisors for the well-being of animals, etc;

Have appropriate installations and equipment for the animals that are going to be used and for the effective performance of procedures (results with least suffering); and

Have an accommodation that is in accordance with environmental conditions, minimum degree of freedom of movement, sufficient food, water, health-sanitary conditions adequate for its health and well-being and that of the species.⁹⁷⁹⁸

The conditions of the installations must be complemented with the regulation that in the future shall regulate the conditions of laboratories in order to guarantee the safety of the health of the animals.

On an exceptional basis, experiments can be performed outside registered establishments.

Applicable measures during the execution of the procedure

Use of anaesthesia or analgesia - Article 8 of the Convention states that a procedure shall be performed under general anaesthesia 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 animal.

The Directive seems more restrictive on the regulation of this matter, as it establishes such exceptions with the use of anaesthesia (art. 8.2) but not with analgesia (art. 8.3)⁹⁹. However, this greater protection of the animal is only apparent, as it generally doesn't require the use of these substances in a general manner. This way, in article 8.2, there is a recommendation on the use of anaesthesia when serious injuries are caused to an animal which can cause severe pain, while article 8.3 establishes that: "If anaesthesia is

⁹⁷ These conditions are set out in article 5 and developed in annex 5. It deals with the general accommodation conditions (ventilation, noise, temperature, etc) and care (cleaning, health, transportation, sound proofing, fencing, feeding, etc).

⁹⁸ These demands are imposed in article 19 of the Directive.

⁹⁹ Although it doesn't expressly impose it in section 1 of Article 8.

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”. Therefore and although article 7.4 establishes that the experiments must avoid the unnecessary distress and suffering, article 8, section 2 & 3, only recommend the use of anaesthesia and analgesia. The Directive, in article 8.4, only imposes the providing of pain relieving means in good time only after the animal suffers considerable pain after the anaesthesia has worn off, except if such action is incompatible with the object of the experiment. As can be seen, the Directive is much more flexible than the Convention, as it only imposes the use of analgesics when the animal suffers severe pain and always when it has previously been subject to anaesthesia, conditions which will not always be present.

2. *Subject to general care.* - Article 10 of the Convention points out that the animal during the procedure shall be provided of accommodation, food and care, etc., already mentioned, except where those provisions are incompatible with the objectives of the procedure.

3. *To set free.* - Where it is necessary for the legitimate purposes of the procedure and with previous authorisation 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-being¹⁰⁰(art. 12).

The Convention limits this possibility to experiments with lawful ends and always when these are not for training or education. Lawful purpose must be understood as that which is not contrary to the dispositions of the Convention or to the legal regulation of the parties. In any case, as this measure is subject to authorization, the responsible authority always has the possibility to control such purposes.

The Directive establishes two additional restrictions when setting free an animal, that it doesn’t entail a risk for public health and the environment (art.11).

Applicable measures after the execution of the procedure

To be kept alive or to kill 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 & 11.2 of the Convention)¹⁰¹. Therefore, the person responsible shall freely choose, except for some exceptions in which the killing is mandatory.

¹⁰⁰ Supposedly so that the animal can live free.

¹⁰¹ See article 9.1 of Directive 86/609/EEC

Decision in favour of its killing.- The killing must be made in any case by a humane method (art. 11.1), that is, with the minimum physical and mental suffering appropriate to the species (art. 1.2 j) and as soon as possible (art. 11.3b)¹⁰²

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)¹⁰³, but not clarifying which are those states.

Decision in favour of being kept alive.- If this is the case, the animal 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)¹⁰⁴.

Use of an animal in more than one procedure.- 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 procedures involve minor interventions or if the animal is subject to general anaesthesia throughout the procedure, which shall be maintained until the animal is killed.

We can deduce the general rule from the precept which is not expressly mentioned. Any research animal may be used as many times as necessary¹⁰⁵, except in the case that is established in the Convention, its use in procedures that entail severe or lasting suffering; possibly, due to not having applied general anaesthesia or only local anaesthesia, but even if this has been so¹⁰⁶. But even in such situations, one or more interventions would be possible if the animal returns to a state of well-being and the decision are made to be kept alive. In such circumstances a new and sole intervention can occur, if the new procedure is aggressive, therefore applying general anaesthesia, which is to be maintained until the animal is killed, which is only recommended for procedures which are not contrary to the use of that substance. Several interventions can be performed if the new procedure is hardly aggressive.

¹⁰² This is stated in a similar manner in article 9 of the Directive, though it used the term "humane method" instead of humanitarian (art. 2.1)

¹⁰³ See article 9.1 & 9.3 of the Directive.

¹⁰⁴ Similarly, see article 9 of Directive 86/609/EEC

¹⁰⁵ As confirmed by article 10 of Directive 86/609/EEC

¹⁰⁶ As expressly provided in article 16 of the Catalan Law 5/1995

In this case, the Directive is more restrictive than the Convention, establishing in its article 10, a sole use of the animal when the procedure entails severe suffering for the animal¹⁰⁷.

11.3 Recognizing of the practiced procedures, registry and furnishing of the information

The European Economic Community, in its interest for the protection of animals used in experimentation and in order to avoid unnecessary duplication of experiments, as far as possible, establishes in article 22.1 of the Directive, following article 29.1 of the Convention, the recognition of the validity of results generated by experiments for the purposes of complying with the regulation of health and safety in the member States, unless further testing is necessary in order to protect public health and safety.

With this purpose, the member States must report to the European Economic Community, now the European Union¹⁰⁸, on its regulations, requisites for commercializing of products, administrative procedures, undertaken experiments, authorizations, etc, therefore the states must have established the aforementioned registries.

Likewise, the Convention foresees the making publicly available of these statistics that are performed on this type of experiments (numbers and kinds of animals used, purpose of the experiments, etc.) except for cases of confidentiality and secret (art. 27). This information shall be communicated every year to the Council of Europe for its publication (art. 28). Nonetheless, the Council of the European Union excluded this obligation from the signing process (by making a reservation to the precept)¹⁰⁹.

Fostering of alternative techniques

In accordance with article 6.2 of Convention 73, the European Economic Community, in article 22 of its Directive, imposes on itself and the Member States, the obligation to foster the development of *alternative techniques* that offer the same results with the least number of animals and with procedures that are less aggressive for them¹¹⁰.

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.

¹⁰⁷ Along these lines, see article 14 of RD 223/1988

¹⁰⁸ The European Union approved the Convention on a decision dated 23 March, 1998.

¹⁰⁹ Through Decision 1999/575/EC of 23 March 1998.

¹¹⁰ Along these lines, whereas 7 of the Decision of the European Union of 23 March 1998, states that the simulation of models by computer are among the alternative methods to be undertaken by the European Centre for Validation of Alternative Methods

ANNEX 3: Summary of the Action Plan on animal welfare 2006-2010

For the period 2006-2010, the EU is planning general measures aimed at ensuring animal welfare and protection. The measures will focus on improving standards, developing research and indicators, informing professionals and consumers and taking action at international level.

Act

Communication from the Commission to the European Parliament and the Council of 23 January 2006 on a Community Action Plan on the Protection and Welfare of animals 2006-2010 (COM (2006) 13-Official Journal C 49 of 28.02.2006)

Summary

The action plan describes the measures the Commission intends to implement between 2006 and 2010 with the aim of developing and guaranteeing animal welfare and protection within the European Union and in other parts of the world. Its objectives are to clarify Community legislation and make provisions for proposals in areas where it is insufficient.

The Commission would like to achieve the following objectives:

- Define more clearly EU action on animal welfare;
- Continue to promote high standards in this field;
- Provide greater coordination of resource;
- Support research and promote alternatives to animal testing;
- Ensure the coherence and coordination of all EU policies on animal welfare.

The action plan defines five main fields of interlinked action with the aim of achieving the stated objectives:

- Upgrading minimum standards;
- Promoting research and substitute methods for animal testing;
- Introducing welfare indicators;
- Ensuring that professionals and the general public are better informed;
- Supporting international initiatives for animal protection.

In terms of minimum standards, the action plan would reinforce the existing Community regulation in line with latest scientific knowledge, practical experience and progress in international fora. It also suggests that the minimum standards should be extended to cover species and issues currently not adequately provided for under EU legislation. Emphasis will *inter alia* be put on the respect of animal welfare by means of

other policies, especially the Common Agricultural Policy (conditions for assistance, possible help in rural development policy).

The action plan recommends encouraging research projects that fill in the gaps and provide a sound scientific framework upon which future developments of EU policy on animal protection and welfare can be based. In addition, it proposes the creation of a European Centre or laboratory, whose mission would be to collect, coordinate and exchange information on research and activities. The plan also emphasizes the application of the 3Rs Declaration (replacement, reduction and refinement) defined at European level with regard to animal testing.

The action plan is hoping to introduce standardised animal welfare indicators. These indicators would guarantee that the minimum standards or stricter standards have been respected. The action plan also suggests that a Community label be created in order to promote products elaborated under higher animal welfare standards.

The action plan underlines the importance of training professionals, especially in order to disseminate good practice, and of informing consumers to enable them to make more enlightened choices on their purchases.

Under the action plan, the EU will continue to promote animal welfare standards within international fora such as the International Office of Epizootics (IOE) and the European Council. The plan advocates promoting the recognition and importance of these standards within the World Trade Organization. Closer cooperation is also envisaged between the EU and countries that apply high standards and with developing countries.

The measures foreseen in the action plan will be assessed regularly in order to evaluate the progress made and to program complementary action after 2010.

Context

The action plan responds to the principles laid down in the protocol on animal welfare and protection annexed to the Treaty establishing the European Community (EC Treaty). This protocol recognises that animals are sentient beings and that full regard should be paid to animal welfare concerns when formulating or implementing policies relating to agriculture, transport, research and the internal market.

The impact study accompanying the action plan takes stock of the anticipated benefits of the action plan, of the existing legislation and of the research undertaken.

Since 1974, European legislation has been developed with a view to protecting animals and ensuring their well-being on farm holdings, during transport and at the time of slaughter.

REFERENCES

- ABEL I FABRE, Francesc, “Reflexión en torno a los xenotrasplantes”, en FERRER, Jorge José y MARTÍNEZ, Julio Luis (Eds.), *Bioética: un diálogo plural. Homenaje a Javier Gafo Fernández, S. J.*, Publicaciones de la Universidad Pontificia Comillas, Madrid, 2002, pp. 309-321.
- ACTION PLAN ON THE PROTECTION AND WELFARE OF ANIMALS, 2006-2010, Brussels, 23.01.2006 COM (2006)
- ALEDO, A. y J. A. DOMÍNGUEZ, *Arqueología de la Sociología Ambiental*, texto accesible en internet en la siguiente dirección de la universidad autónoma: www.ua.es/personal/antonio.aledo/docs/libro/libro.pdf, pág. 153. Last visit: 29th of December 2007.
- ARANDA, Ana, “Ética en la experimentación con animales de laboratorio”, en TOMÁS GARRIDO, Gloria María (Coord.), *Manual de bioética*, Editorial Ariel, S. A., Barcelona, 2001, pp. 311-322.
- ATTFIELD, R., *Value, Obligation and Meta-Ethics*, Amsterdam-Atlanta: Editions Rodopi, 1995.
- BALLS, M., VAN ZELLER, A.-M., & HALDER, M. E. (Eds), *Progress in the Reduction, Refinement and Replacement of Animal Experimentation, Proceedings of the 3rd World Congress on Alternatives and Animal Use in the Life Sciences*, Development in Animal and Veterinary Sciences, No 31, Amsterdam: Elsevier, 2000.
- BARNARD, Neal D. y KAUFMAN, Stephen R., “Una investigación despilfarradora y engañosa”, *Investigación y Ciencia*, núm. 247, abril de 1997, pp. 66-69.
- BARTOLOMMEI, S., *Ética e Natura*, Roma-Bari: Laterza, 1995.
- BENTHAM, J., *Introduction to the Principles of Morals and Legislation*, Oxford: Clarendon, Edited by J. H. Burns and H. L. A. Hart, 1996, p. 283.
- BENTON, T., *Natural Relations, Ecology, Animal Rights and Social Justice*, Londres: Verso, 1993.
- BENTON, Ted, “Los derechos de los animales y las prácticas sociales”, en THOMAS-MA, David C. y KUSHNER, Thomasine (Eds.), *De la vida a la muerte. Ciencia y Bioética*, Cambridge University Press, Madrid, 1999, pp. 352-365.
- BERNSTEIN, M., “Marginal Cases and Moral Relevance”, *Journal of Social Philosophy*, nº 33 (4), 2002, p. 531.
- BILBENY, N., *Humana dignidad*, Madrid: Tecnos, 1990, p. 78.
- BOTTING, Jack H. y MORRISON, Adrian R., “La experimentación animal, imprescindible para la medicina”, *Investigación y Ciencia*, núm. 247, abril de 1997, pp. 69-72.
- BUNGE, M., *Ética y Ciencia*, Buenos Aires: Siglo XX, 1962, pp. 96 y 97.
- CAMPS, Victoria, *Una vida de calidad. Reflexiones sobre bioética*, Editorial Crítica, S. L., Barcelona, 2001.
- CANADIAN COUNCIL ON ANIMAL CARE GUIDELINES, *Terms of reference for animal care committee*, Ottawa, Ontario, 2000.
- Canadian Council on Animal Care, *Guidelines on Choosing an Appropriate Endpoint in Experiments Using Animals for Research, Teaching and Testing*, 1998.
- CARRUTHERS, Peter, *La cuestión de los animales. Teoría de la moral aplicada*, Cambridge University Press, Cambridge, 1995.
- CARSTEN E., and MOBERG G. P., “Recognizing pain and distress in laboratory animals”, *ILAR Journal*, vol. 41, No. 2, 2000, pp. 62-71.

- CAVALIERI, P., *The Animal Question*. Why nonhuman animals deserve human rights, Oxford University Press, 2001, pp. 139 y 140.
- CLARK J. D, RAGER D., and CALPIN J. P., “Animal well-being: an overview of assessment”, *Laboratory Animal Science: International Journal of Comparative and Experimental Medicine* vol. 47, No. 6, 1997, pp. 580–585.
- CONSEJO DE EUROPA, *Convenio Europeo sobre la protección de los animales vertebrados utilizados para experimentación y otros fines científicos*, Estrasburgo: 18 de marzo de 1986.
- CONSEJO DE LAS COMUNIDADES EUROPEAS, *Directiva 86/609/CEE del Consejo de 24 de noviembre de 1986 relativa a la aproximación de las disposiciones legales, reglamentarias y administrativas de los Estados Miembros respecto a la protección de los animales utilizados para experimentación y otros fines científicos*.
- COZZI E., YANNOUTSOS N., LANGFORD G. A., PINO-CHAVEZ G., WALLWORK J., WHITE D. J. G., “Effect of transgenic expression of human decay accelerating factor on the inhibition of hyperacute rejection of pig organs”, in Cooper D. K. C., KEMP E., PLATT J. L., WHITE D. J. G., (eds), *Xenotransplantation: The Transplantation of Organs and Tissues Between Species*, Heidelberg, Springer-Verlag; 1997, pp. 650–658.
- D’AGOSTINO, F., “Los derechos de los animales”, en D’AGOSTINO, F., *Bioética. Estudios de Filosofía del Derecho*, Madrid: Ediciones Internacionales Universitarias, 1998, p. 194.
- DE GRAZIA, D., *Taking Animals Seriously. Mental Life and Moral Status*, Nueva York: Cambridge University Press, 1996, pp. 273 y 277.
- DE LORA, P., *Justicia para los animales. La ética más allá de la humanidad*, Alianza Editorial, 2003.
- ECHEVERRÍA, J., *Ciencia y valores*, Barcelona: Destino, 2002, p. 64.
- ENGELS E., “El estatuto moral de los animales en la discusión del xenotrasplante”, in C. M. ROMEO CASABONA (Coord.), *Los xenotrasplantes. Aspectos científicos, éticos y jurídicos*, op. cit., p. 98.
- ENGELS, Eve-Marie, “El estatuto moral de los animales en la discusión del xenotrasplante”, en ROMEO CASABONA, Carlos María (Coord.), *Los xenotrasplantes. Aspectos científicos, éticos y jurídicos*, Editorial Comares, S. L., Granada, 2002, pp. 71-108.
- ESPONDA, Pedro, *Seres del futuro. De la fecundación in vitro a los clónicos y transgénicos*, Ediciones Libertarias/Prodhufo, S. A., Madrid, 2000.
- FERNÁNDEZ BUEY, Francisco, *Ética y filosofía política*, Edicions Bellaterra 2000, S. L., Barcelona, 2000.
- FESTING M. F. W., “Reduction, model development and efficient experimental design”, in: *Progress in Reduction, Refinement and Replacement of Animal Experimentation*, BALLS M., VAN ZELLER A. M and HALDER M. E (eds), Elsevier Science, Amsterdam, 2000, pp. 721–727.
- FESTING M. F. W.; ALTMAN D. G., “Guidelines for the design and statistical analysis of experiments using laboratory animals”, *ILAR Journal*, No. 43, 2002, pp. 244–258.
- FRONDIZI, D, *¿Qué son los valores?*, México: Fondo de Cultura Económica, 3ª edición, 1972, p. 28.
- GAFO, Javier, *10 palabras clave en bioética*, Editorial Verbo Divino, Pamplona, 1998.
- GAFO, Javier, *Problemas éticos de la manipulación genética*, San Pablo, Madrid, 1998.
- GOLDBERG, Alan M. y FRAZIER, John M., “Opciones alternativas al uso de animales de laboratorio”, *Investigación y Ciencia*, núm. 157, octubre de 1989, pp. 10-17.

- GOMILA BENEJAM, Antoni, "Personas primates", en G^a GÓMEZ-HERAS, José M^a. (Coord.), *Ética del medio ambiente. Problema, perspectivas, historia*, Editorial Tecnos (Grupo Anaya, S. A.), Madrid, 2001, pp. 191-204.
- GRUEN, Lori, "Los animales", en SINGER, Peter (Ed.), *Compendio de Ética*, Alianza Editorial, S. A., Madrid, 1995, pp. 469-481.
- GUERRA GONZÁLEZ J., "Prevention of the xenogenic Infection Risk and the Spanish and German Constitutions", *Revista de Derecho y Genoma Humano*, No. 20, pp. 123-146.
- GUERRA GONZÁLEZ J., *Xenotransplantation: Prävention des xenogenen Infektionsrisikos. Eine Untersuchung zum deutschen und spanischen Recht*, Peter Lang GmbH, Frankfurt, 2008.
- HAWKINS P., "Recognizing and assessing pain, suffering and distress in laboratory animals: a survey of current practice in the UK with recommendations", *Laboratory Animals*, No. 36, 2002, pp. 378-395.
- HORTA, O., "Animal Experimentation and Bias in Bioethics", in *Proceedings of the III International Conference on Technoethics: Ethical Subjects Related to Science, Technology and Their Social Applications* (Barcelona: Instituto de Tecnoética Fundación Epon, Universitat de Barcelona, 2008), pp. 199-210.
- HOUEBINE, Louis-Marie, *Los transgénicos. Verdades y mentiras sobre los organismos genéticamente modificados*, Salvat Editoriales, S. A., Barcelona, 2001.
- HÜSING, Bärbel y REY, Lucienne, "El xenotrasplante bajo todas sus suturas", *Mundo Científico*, 203, julio/agosto 1999, pp. 45-53.
- HUTHER, C., *Can speciesism be defended? A discussion of the traditional approach to the moral status of animal*: [http://www.constanzehuther.de/philosophie/Huther%20\(2005\)%20Magisterarbeit%20Speziesismus.pdf](http://www.constanzehuther.de/philosophie/Huther%20(2005)%20Magisterarbeit%20Speziesismus.pdf). Last visit: 29th of April 2008.
- KREBS, A., "Haben wir moralische Pflichten gegenüber Tieren? Das pathozentrische Argument in der Naturethik", *Deutsche Zeitschrift für Philosophie*, n° 41/6, 1993, pp. 997 y ss.
- LACADENA, Juan-Ramón, *Genética y bioética*, Universidad Pontificia Comillas / Editorial Desclée De Brouwer, S. A., Bilbao, 2002.
- LOEW, Franklin M., "Los animales en la investigación", en THOMASMA, David C. y KUSHNER, Thomasine (Eds.), *De la vida a la muerte. Ciencia y Bioética*, Cambridge University Press, Madrid, 1999, pp. 325-338.
- LÓPEZ GUERRERO, José Antonio, *¿Qué es un transgénico? (Y las madres que lo parieron...)*, Equipo Sirius, S. A., Madrid, 2001.
- MACITNYRE, A, *Animales racionales y dependientes*, Barcelona: Paidós, 2001.
- MARFANY, Gemma, "Modelos animales de enfermedades hereditarias", en CASADO, María y GONZÁLEZ-DUARTE, Roser (Eds.), *Los retos de la genética en el siglo XXI: genética y bioética*, Edicions de la Universitat de Barcelona, Barcelona, 1999, pp. 181-192.
- Mason, J., *An Unnatural Order: Why We Are Destroying the Planet and Each Other*, New York: Continuum, 1998, p. 163.
- MATESANZ ACEDOS, Rafael, "Los trasplantes de órganos y tejidos: una mirada al futuro", en PALACIOS, Marcelo (Coord.), *Bioética 2000*, Ediciones Nobel, S. A., Oviedo, 2000, pp. 313-324.
- McCLOSKEY, H. J., "Moral Rights and Animals", *Inquiry*, n° 22, 1979, pp. 52-53.
- MILLET, Annette, "¿Humanizar a los cerdos?", *Mundo Científico*, 203, julio/agosto 1999, pp. 54-55.

- MINISTERIO DE SANIDAD Y CONSUMO, *Xenotrasplante. Informe de la Subcomisión de Xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud*, Madrid, 1998.
- MOBERG G. P and MENCH J. A., (eds), *The Biology of Animal Stress: Basic Principles and Implications for Animal Welfare*, CABI Publishing, 2000.
- MONTOLIU JOSÉ, Lluís, “Animales transgénicos”, en GAFO, Javier (Ed.), *Aspectos científicos, jurídicos y éticos de los transgénicos*, Publicaciones de la Universidad Pontificia Comillas, Madrid, 2001, pp. 49-67.
- MONTOLIU JOSÉ, Lluís, “Utilización responsable de animales modificados genéticamente en biología, biomedicina y biotecnología”, en FERRER, Jorge José y MARTÍNEZ, Julio Luis (Eds.), *Bioética: un diálogo plural. Homenaje a Javier Gafo Fernández, S. J.*, Publicaciones de la Universidad Pontificia Comillas, Madrid, 2002, pp. 285-292.
- MOROS, Daniel A., “Tomarse los deberes en serio: experimentación médica, derechos de los animales e incoherencia moral”, en THOMASMA, David C. y KUSHNER, Thomasine (Eds.), *De la vida a la muerte. Ciencia y Bioética*, Cambridge University Press, Madrid, 1999, pp. 339-351.
- MUKERJEE, Madhusree, “Tendencias en la investigación animal”, *Investigación y Ciencia*, núm. 247, abril de 1997, pp. 74-83.
- NAESS A., “The Shallow and the Deep Long-Range Ecology Movement”, *Inquiry*, nº 16, 1973, pp. 95-100.
- NAESS, A., *Ecology, Community and Lifestyle: Outline to an Ecosophy*, Cambridge: Cambridge University Press, 1989, p. 51.
- NARVESON, J., “Animal Rights”, *Canadian Journal of Philosophy*, n. 7, 1977, p. 164.
- NASH, R. F., *The Rights of Nature. A history of environmental ethics*, Madison: The University of Wisconsin Press, Madison, 1989, pp. 5-7.
- NOGUÉS, Ramón M., *Ingeniería genética y manipulación de la vida. Bases para la educación*, Cisspraxis, S. A., Barcelona, 2002.
- NUFFIELD COUNCIL ON BIOETHICS, *The Ethics of Research Involving Animals*, Nuffield Council on Bioethics, London, 2005.
- NUFFIELD COUNCIL ON BIOETHICS, *Animal-to-Human Transplants. The ethics of xenotransplantation*, Nuffield Council on Bioethics, London, 1996.
- ORGANIZACIÓN DE LAS NACIONES UNIDAS, *Declaración Universal de los Derechos del Animal*.
- ORLANS, F. B., BEAUCHAMP, T. M., DRESSER, R., MORTON, D. B., GLUCK, J. P., *The Human Use of Animals: Case Studies in Ethical Choice*, Oxford: Oxford University Press, 1998.
- OSSWALD, Walter, “A experimentação no animal”, en ARCHER, Luís, BISCAIA, Jorge y OSSWALD, Walter (Coords.), *Bioética*, Editorial Verbo, Lisboa, 1996, pp. 329-333.
- PELAYO TORRE, A. P., “Sobre los Derechos de los Animales”, *Anuario de Filosofía del Derecho*, nº VII, 1990.
- PLUHAR, E. B., *Beyond Prejudice. The Moral Significance of Human and Nonhuman Animals*, Durham-Londres: Duke University Press, 1995.
- PORRAS DEL CORRAL, Manuel, “Trasplantes y xenotrasplantes”, en TOMÁS GARRIDO, Gloria María (Coord.), *Manual de bioética*, Editorial Ariel, S. A., Barcelona, 2001, pp. 335-349.
- REGAN, T., *The Case for Animal Rights*, Berkeley: University of California Press, 1983. Traducción de V. BELLVER en: VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, cit., p. 192.

- REGAN, T., *The Case for Animal Rights*, Berkeley: University of California Press, 1983.
- REGAN, Tom, *The case for animal rights*, University of California Press, Berkeley, 1983.
- RIECHMANN, Jorge, “Animales humanos y no humanos en un contexto evolutivo”, en MOSTERÍN, Jesús y RIECHMANN, Jorge, *Animales y ciudadanos. Indagación sobre el lugar de los animales en la moral y el derecho de las sociedades industrializadas*, Talasa Ediciones, S. L., Madrid, 1995, pp. 8-42.
- RIECHMANN, Jorge, “La experimentación con animales”, en CASADO, María (Coord.), *Bioética, derecho y sociedad*, Editorial Trotta, S. A., Valladolid, 1998, pp. 221-254.
- RIECHMANN, Jorge, “Los experimentos con los animales”, en MOSTERÍN, Jesús y RIECHMANN, Jorge, *Animales y ciudadanos. Indagación sobre el lugar de los animales en la moral y el derecho de las sociedades industrializadas*, Talasa Ediciones, S. L., Madrid, 1995, pp. 8-42.
- RIECHMANN, Jorge, “Razones para incluir a los animales en la comunidad moral”, en MOSTERÍN, Jesús y RIECHMANN, Jorge, *Animales y ciudadanos. Indagación sobre el lugar de los animales en la moral y el derecho de las sociedades industrializadas*, Talasa Ediciones, S. L., Madrid, 1995, pp. 151-172.
- RIECHMANN, Jorge, *Un mundo vulnerable. Ensayos sobre ecología, ética y tecnociencia*, Los libros de la Catarata, Madrid, 2000.
- RIFKIN, Jeremy, “¡Lo que podemos aprender de los animales!” , *El País*, 20 de octubre de 2003.
- RITCHIE, D. G., *Natural Rights. A Criticism of Some Political and Ethical Conceptions*, Londres: George Allen y Unwin, 1895, p. 109.
- ROMEO CASABONA C. M.; MORA URRUELA A.; PEREIRA DE MELO H.; MCGLEENAN, Xenotransplantation. Ethical, Legal, Economic, Social, Cultural and Scientific Background, Vol. 4, AVM, 2008.
- ROMEO CASABONA C. M.; MORA URRUELA A.; “New legal developments in xenotransplantation: the spanish approach”, *Revista de Derecho y Genoma Humano*, No. 29, 2008, pp. 111-129.
- ROWAN, Andrew N., “Ética y resultados del empleo de animales en la investigación científica”, *Investigación y Ciencia*, núm. 247, abril de 1997, p. 65.
- ROWAN, Andrew N., “Ética y resultados del empleo de animales en la investigación científica”, *Investigación y Ciencia*, núm. 247, abril de 1997, p. 65.
- RUPHY S., “Peter Singer: la ética vuelta a visitar” (interview with Peter Singer), *Mundo Científico*, 218, December 2000, p. 98.
- RUPHY, Stéphanie, “Peter Singer: la ética vuelta a visitar” (entrevista con Peter Singer), *Mundo Científico*, 218, diciembre 2000, pp. 96-98.
- RUSSELL, W.M.S., BURCH, R. L, *Principles of Humane Experimental Technique*, London: Methuen & Co, 1959
- RUSSELL, William y BURCH, Rex, *The Principles of Humane Experimental Technique*, Methuen, Londres, 1959.
- SALT, H. S., *Los derechos de los animales*, Madrid: La Catarata, 1999, p. 34.
- SÁNCHEZ BONASTRE, Armand y FOLCH ALBAREDA, Josep M., “Transgénesis y mejora animal”, en CASADO, María y GONZÁLEZ-DUARTE, Roser (Eds.), *Los retos de la genética en el siglo XXI: genética y bioética*, Edicions de la Universitat de Barcelona, Barcelona, 1999, pp. 193-201.
- SAPONTZIS, S. F., *Moral, Reason and Animals*, Philadelphia: Temple University Press, 1987, p. 230;

- SARMIENTO, A., RUIZ-PÉREZ, G y MARTÍN, J. C., *Ética y genética. Estudio ético sobre la ingeniería genética*, Ediciones Internacionales Universitarias, Barcelona, 1996.
- SCHUURMAN H. J., PINO-CHAVEZ G., PHILLIPS M. J., THOMAS L, WHITE D. J., COZZI E., “Incidence of hyperacute rejection in pig-to-primate transplantation using organs from hDAF-transgenic donors”, *Transplantation*, 2002, 73, pp. 1146–1151.
- SINGER, P., *Animal liberation*, New York, Harper Collins, 1975.
- SINGER, P., “All Animals are Equal?”, *Philosophical Exchange*, vol. 1, nº 5, 1974.
- SINGER, Peter, *Desacralizar la vida humana. Ensayos sobre ética*, Ediciones Cátedra (Grupo Anaya, S. A.), Madrid, 2003.
- SINGER, Peter, *Ética práctica*, Cambridge University Press, Cambridge, 1995.
- STONE, C., *Should Trees Have Standing?, Toward Legal Rights for Natural Objects*, Los Altos (California), 1974.
- TALLACCHINI M., “Commentary: Council of Europe Working Party on Xenotransplantation: stat-of-the-art report on xenotransplantation (2000)”, *Xenotransplantation* 8, 2000, pp. 154-156.
- TALLACCHINI M., “Commentary: Regulatory issues in Europe and Canada”, *Xenotransplantation* 9 (2002b), pp. 371-373.
- THE ADVISORY GROUP ON THE ETHICS OF XENOTRANSPLANTATION, Report on Animal tissue into humans, TSO, London, 1997.
- TORRES ALDAVE, M., “La teoría de los derecho de los animales de Tom Regan”, *biTARTE*, Nº 47, pp. 5-24.
- URRUELA MORA, Asier y ROMEO CASABONA, Carlos María, “Los dilemas éticos del xenotrasplante”, en ROMEO CASABONA, Carlos María (Coord.), *Los xenotrasplantes. Aspectos científicos, éticos y jurídicos*, Editorial Comares, S. L., Granada, 2002, pp. 43-69.
- VELAYOS CASTELO, Carmen, “La ética y el animal no humano”, en G^a. GÓMEZ-HERAS, José M^a. (Coord.), *Ética en la frontera*, Editorial Biblioteca Nueva, S. L., Madrid, 2000.
- VIOLA, F., *De la naturaleza a los derechos. Los lugares de la ética contemporánea*, Granada: Comares, 1998, traducción de Vicente Bellver, p. 173.
- WARREN, M. A., *Moral Status. Obligations to persons and other living things*, Oxford: Oxford University Press, 1997, pp. 112-113.
- WEARY D. M., NIEL L., FLOWER F. C., FRASER D., “Identifying and preventing pain in animals”, *Applied Animal Behaviour Science* 100, 2006, pp. 64–76.
- WHITE, L., “The Historic Roots of Our Ecologic Crisis”, *Science*, nº 155, 1967, pp. 1203-1208.
- WOLF, U., *Das Tier in der Moral*, Frankfurt am Main, 1990.