Animal testing in the European Union countries: a comparative legal review

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1. - *Introduction.* The term «animal experimentation» refers to any surgical activity carried out on live animals (treated or not with analgesics or anesthesia) devoid of any therapeutic purpose for the animals themselves. This activity aims to promote scientific research through the experimental method and encourage knowledge development in various sectors, such as biomedical sciences, surgical training, and tests for drugs, cosmetics, chemicals, and food substance production[1].

By now, the term «animal testing» has replaced the word «vivisection» both in legislative texts and in the current language, although these are two different practices[2].

Regardless of the different terms used in this field, research on animals has played and continues to play a fundamental role in scientific and medical developments and improves our comprehension of many human and animal diseases. Indeed, animal testing led to a better understanding of how the bodies of animals and humans «work»[3].

However, it must be taken into account, at the same time, that animal welfare is acquiring, especially at the European Union level, ever greater importance, and it has become a priority of EU policies in the last decades. Provisions on animal welfare are in primary (treaties) and secondary (directives, regulations) supranational legislation.

Animal welfare encompasses a broad range of topics, for example, pet care or their exploitation and abuse, and it is related to the overall animal health and well-being. In recent years, the animal welfare concept has become very important, especially following the development of scientific knowledge regarding animal protection[4].

From a legal point of view, while animal welfare was first dealt with by the previous European Community in the 1980s, primarily as part of the harmonization process, this concept is now included in the processing of EU policies within a broader framework that also encompasses social and economic issues. This development shows that opinions regarding the need to lessen needless suffering for animals have changed in the EU society[5].

In addition to what has been said so far, in the last few decades the regard of the relationship between «human beings» and «non-humans» has changed. The animal is increasingly becoming a point of reference in the lives of many people and families. Some animals, including «companion animals», can

[1] G. PELAGATTI, *Profili giuridici della sperimentazione animale*, in *Dirittifondamentali.it*, 1, 2018, 1.

[2] Regarding the difference between «animal experimentation» and «vivisection», see D. CERINI, *Light up: la sperimentazione su animali sotto lente d'ingrandimento*, in *Rivista giuridica dell'ambiente*, 2, 2021, 360 s.; S. MENICALI, *La sperimentazione animale. Aspetti giuridici e sociologici*, in *ADIR - L'altro Diritto*, 2003, *https://www.adir.unifi.it/rivista/2003/menicali/cap2.htm#2*.

[3] M.H. PERRUCHOT - F. DESSAUGE, *Les approches complémentaires à l'expérimentation animale en agronomie et clinique vétérinaire: Solutions et limites*, in *INRAE Productions Animales*, 36, n. 2, 2023, 4.

[4] For more on this matter, see C. BOTTARI - T. DI PAOLO, *La tutela degli animali utilizzati a fini scientifici e il diritto alla ricerca: la delicata valutazione dei danni e dei benefici compiuta dall'autorità competente*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 77.

[5] I.R. PAVONE, *Animal Experimentation and Animal Welfare in the Context of the European Union: Reflections on the Directive 2010/63/EU and Its Transposition in Italy*, in *BioLaw Journal - Rivista di BioDiritto*, 3, 2015, 77.

experience pleasure, pain, and emotions; thus, the relationship between people and animals concerns two psychophysically sensitive beings, the centers of sentient life. Sentience refers to the ability of animals, or at least some of them, to feel and perceive life.
At this point, it is then necessary to ask whether the legislative trend aimed at recognizing animal sentience, found in the European Union and the Member States' legal systems, is compatible with the development of animal testing practices. In particular, during the discussion, three systems that are part of the European Union, the French, the German, and the Italian, will be analyzed to verify how the Member States have implemented the supranational legislation issued on animal testing.
The study will concern not only the legislation issued by the three countries in the field of scientific experimentation on animals but also the judgments that have aroused great interest in the legal world and public opinion.
The final objective of the paper is to understand whether Member States have implemented the European Union legislation taking into account, primarily, the need for scientific research or whether countries have taken into account (and to what extent) the need to protect animals, especially the so-called «laboratory animals».

2. - *Animal testing in the legal context.* Animal testing refers to all kinds of use of animals that involve anatomical lesions or functional alterations, which may also have a bloody character or cause the death of these living beings[6].
The use of animals to acquire and increase knowledge of biological, physiological, and medical processes dates back to antiquity. Indeed, this practice was already in force in ancient Greece for anatomical studies (5th century BC). Around 2000 BC, the Assyrian-Babylonians also performed surgical operations on animals. Since Roman law prohibited the dissection of human corpses, Galeno (130-200 AD) carried out the systematic practice of animal experimentation, primarily on pigs and monkeys[7].
Until the Renaissance period, animal testing was prohibited; in the Middle Ages, it was carried out secretly by a few courageous scholars[8]. Instead, after the Renaissance period, the legislation affirmed the need for animal testing despite many protests of scientific and moral kinds. In particular, since the 17th century, animal experimentation practices have contributed significantly to advancing medicine and scientific research[9].
By now, almost the entire scientific community believes that animal testing is necessary as long as researchers take all appropriate precautions to avoid animal suffering[10].
Currently, the regulations of experiments carried out on animals concern the relationship between science and law, and it constitutes one of the crucial problems of the bioethical debate[11]. According to some, from an ethical point of view, animal testing is unacceptable; therefore, experiments should be banned, while others believe that they are essential to preventing and treating diseases. An intermediate opinion holds that animal testing is acceptable if it produces an advancement in the search for alternative methodologies aimed at replacing in vivo research, as well as an improvement in animal welfare[12].

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[6] G. PELAGATTI, *op. loc. cit.*
[7] A. GUERRINI, *Experimenting with Humans and Animals: From Galen to Animal Rights*, Baltimore, 2003; M.R. MICHELI, *L'impiego degli animali nelle pratiche cliniche sperimentali*, in *Sanità pubblica*, 2002, 1057; V. SFORZA, *Etica nella sperimentazione animale*, Milano, 2000, 273; A.H. MAEHLE - U. TRÖHLER, *Animal experimentation from antiquity to the end of the eighteenth century: Attitudes and arguments*, in N.A. RUPKE (Ed), *Vivisection in Historical Perspective*, London, 1987.
[8] M.R. MICHELI, *op. loc. cit.*
[9] M.R. MICHELI, *op. cit.*, 1057 s.
[10] See M.R. MONTINARI, *La sperimentazione animale dall'antichità al diciannovesimo secolo*, in *Medicina nei secoli, arte e scienza: Journal of History of Medicine*, 29, n. 2, 2017, 477.
[11] L. BATTAGLIA, *La questione della sperimentazione animale in prospettiva bioetica*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 13; M. MORELLI, *Il difficile rapporto tra Scienza e Magistratura*, *ivi*, 2, 2021, 11.
[12] Cf. *amplius* R. FORASTIERO, *La tutela giuridica degli animali da esperimento: riflessioni sull'attuazione in Italia della direttiva 2010/63/UE*, in *Studi sull'integrazione europea*, 9, 2014, 565 s.

Over the years, the European Union and the Member States have enacted specific legislation on scientific animal research.
As can be easily understood, the regulations issued on animal testing, especially those carried out in the pharmacological field, have had to carry out a delicate balancing activity between different, often conflicting, rights[13]. The balance between animal protection and the right to scientific freedom, particularly in the sector of preclinical experimentation, did occur at the jurisprudential and legislative levels. The European Union and Member States legislation aims to reconcile, ex-ante, these opposing rights, thus attempting to reconcile two principles: the principle of the inevitability of experimentation on live animals to obtain the expected results and that of minimizing animal suffering[14].
Indeed, in this sector, it is necessary to find an equilibrium between a variety of goods that are all deserving of protection, such as the advancement of welfare and human health, as well as the progress of scientific research on the one hand, and the avoidance of needless and excessive animal suffering on the other[15].
In reality, according to some, it is not possible to carry out, from a legislative perspective, a balancing activity between the respect for animal welfare on the one hand and the collective interest in experimentation, health protection, and the advancement of technical and scientific knowledge, on the other, since the latter values always prevail at a constitutional level (compared to the value represented by animal protection)[16]. Furthermore, according to others, in addition to evaluating the two interests mentioned, a correct and thoughtful balance between all the constitutional rights involved in this field is necessary[17].
However, as will be seen later, the European Union and Member States legislation pays increasing attention to the animals' needs. Of course, the use of animals in scientific research is still necessary, although this must happen with the highest possible respect for these living beings[18].

3. - *The European Union legislation.* After dealing with the animal testing question, it seems appropriate to focus on the regulatory aspect, starting to analyze the supranational legislation and then the legislation issued by some Member States, especially France, Germany, and Italy. The aim is to understand if and to what extent State regulations have deviated from the objectives set by European Union legislation.
We have already said that the European Union gives great importance to the issue of animal protection and their welfare in various sectors, including that of scientific experimentation. As early as the 1980s, the European Union began a regulatory process to harmonize legislation on animal testing within the Member States.
Attention to the protection of animals used in scientific experiments increased following the signing of the Treaty of Lisbon in 2007. Article 13 of the Treaty on the Functioning of the European Union (TFEU) considers, from a legal point of view, animals as sentient beings, that is, as beings capable of feeling sensations, suffering, and pain; therefore, animals can no longer be qualified as objects[19].

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[13] F. PAVAN, *L'attività di bilanciamento nella sperimentazione farmacologica: condotte che ne possono pregiudicare il risultato*, in *BioLaw Journal - Rivista di BioDiritto*, 1, 2015, 7; A. PASSANTINO - C. DI PIETRO, *L'etica veterinaria e la "liceità" della sperimentazione animale nella cultura contemporanea*, in *Riv. it. medicina legale*, 2, 2006, 339.
[14] G. PELAGATTI, *op. cit.*, 18.
[15] I.R. PAVONE, *op. cit.*, 76.
[16] L. MARIANTONI, *Lo statuto (costituzionale) dell'animale sperimentale. Le prospettive del bilanciamento fra ricerca scientifica e benessere degli animali: ovvero quando gli "oneri" divengono "onori"*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 36.
[17] P. VERONESI, *La scienza secondo la Costituzione italiana (e le sue applicazioni)*, in *BioLaw Journal - Rivista di BioDiritto*, 3, 2021, 160 s.
[18] F. PAVAN, *op. cit.*, 9.
[19] In this regard, Art. 13 of the Treaty on the Functioning of the European Union (TFEU) states that: «In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the EU countries relating in particular to religious rites, cultural traditions and regional heritage».

Subsequently, in 2010, the European Union intervened specifically on animal testing. The European Union tried to answer the ethical concerns linked to animal research through Directive 2010/63/EU (Protection of Animals used for Scientific Purposes)[20], the most relevant supranational legislative act in this field.
The Directive exemplifies the debate on this matter, essentially characterized by two opposing orientations: the position supported by animal rights associations and the idea propagated by the scientific world[21].
Specifically, this legislation, which replaces the former Directive 86/609/EEC, aimed to ensure greater animal welfare, setting up more stringent requirements for animal use in biomedical research to improve their protection[22].
This legislation aimed to harmonize research standards and animal testing practices within the Member States, guarantee the latter access to the same research opportunities, and eliminate disparities between the different State legislations. The Directive aimed to replace, as far as possible, the use of animals with alternative methods and to guarantee their maximum well-being, avoiding lasting damage, pain, suffering, or distress resulting from experimentation.
The European Union legislation considers animal testing necessary in the treatment of diseases. However, the Directive aimed to ensure the highest standard of care for animals used in biomedical research through their replacement, in line with the «3Rs» («3R» System), which means «Replace, Reduce, Refinement» (Recitals 10-13; Articles 4 and 13), a widely accepted ethical framework for conducting scientific experiments using animals humanely[23]: the replacement of animal studies by other methods; the use of methods to reduce the number of animals; the refinement of how animals are used, i.e. the use of methods able to improve animal welfare, including the promotion of alternative systems[24].
An assessment carried out by the competent authorities designated by the Member States guaranteed compliance with minimum standards in the use of animals (Art. 36).
As for the purposes, the provisions of the 2010 Directive aimed to harmonize the internal market in the field of breeding, supplying, and using animals[25]. The EU attempted to uphold the idea of subsidiarity by adopting this supranational legislation to guarantee a balance between the advancement of research, EU competitiveness, and animal welfare inside the internal market[26].
The Directive aimed to determine a uniform application of European Union legislation in all Member States since the implementation of the previous legislation issued on animal testing has produced many doubts of an interpretative kind[27].
Thus, one of the objectives of the supranational legislation was to establish more comprehensive

[20] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, *https://eur-lex.europa.eu/eli/dir/2010/63/oj*.
[21] G. PELAGATTI, *op. cit.*, 11.
[22] F. MEOLA *La tutela degli animali da sperimentazione nel contesto europeo*, in *Dir. pubbl. comp. ed eur.*, 2, 2019, 388 s.; R. FORASTIERO, *op. cit.*, 583.
[23] The creators of the «3R» System are Rex Burch and William Russell. It stands for two of the more divisive topics in animal-based research, education, and testing: the quantity of animals utilized and the suffering these animals go through. On topic see W.M.S. RUSSELL - R.L. BURCH, *The Principles of Humane Experimental Technique*, London, 1959. More in general, on «3Rs» implementation in clinical practice, see J. TANNENBAUM - B.T. BENNETT, *Russell and Burch's 3Rs then and now: the need for clarity in definition and purpose*, in *Journal of the American Association for Laboratory Animal Science*, 54, 2015, 120 ss.; A. ROGIERS, *ECOPA: The European Consensus on Three Rs Alternatives*, in *Alternatives to Laboratory Animals*, 32, 2004, 349 ss.
[24] I.D. MIZIARA et al., *Research ethics in animal models*, in *Brazilian Journal of Otorhinolaryngology*, 78, 2012, 128 ss.; A. PETROIANU, *Aspectos éticos na pesquisa em animais*, in *Acta Cirúrgica Brasileira*, 11, 1996, 157 ss. The term «alternative methods» was introduced in 1978 by Smyth (D.H. SMYTH, *Alternatives to Animal Experiments*, London, 1978). It brings together the methods making it possible to satisfy one or more principles of the «3Rs» (Replace, Reduce, Refine).
[25] Article 114 of the Treaty on the Functioning of the European Union (former Art. 95 of the EC Treaty) represented the legal basis of the Directive.
[26] I.R. PAVONE, *op. cit.*, 81. See also C. BOTTARI - T. DI PAOLO, *op. cit.*, 65.
[27] F. MEOLA *op. cit.*, 384.

guidelines to lessen animal suffering, minimize legislative variations in the European Union regarding the treatment of animals used in research, and guarantee proper operation of the internal European market[28].
The Directive recognized the fundamental role of animals in scientific research; indeed, it did not prohibit the use of animals for this purpose but highlighted some key principles to respect. The ultimate goal of the Directive was to replace, in a complete manner, procedures involving live animals used for scientific and educational purposes (as soon as it becomes scientifically feasible to do so) to balance these opposing moral positions and, at the same time, to ensure the highest protection standard for animals used in scientific research[29].
The European Union legislation has been criticized by all parties involved in animal experimentation (animal welfare groups, scientists, and enterprises); it has determined a delay or irregularities in the transposition of its content into domestic legal order by some States (one of these is Italy)[30].
The Directive 2010/63/EU has been the product of a lengthy and intricate debate between various interests (protection of scientific research and animal welfare), and it reflected an acceptable political compromise despite the criticism leveled by the stakeholders involved in animal experimentation, animal welfare groups, and most scientists[31].
The supranational legislation never states clearly prohibitions of certain practices but always foresees exceptions. For instance, concerning endangered species, the legislation bans the use of some animal species unless some conditions are respected[32].
Thus, experimenting on animals is acceptable if their suffering is minimal and other methods cannot produce the same human benefits. The EU legislation establishes that experiments are banned if alternative methods can contribute equally valid outcomes. The Directive achieved harmonizing the legislation of the Member States at the highest level, preventing them from promoting more stringent laws aimed at protecting animal experimentation[33].

4. - *The position of the French legislator.* At this point, it is interesting to study how the Member States, particularly France, Germany, and Italy, have implemented the supranational legislation. The objective is to understand whether these States have implemented the Directive correctly, i.e., in a manner compliant with the aims and objectives set by the EU institutions.
Before the Directive was issued, many Member States had enacted legislation on animal welfare protection. Among these countries, it is possible to mention France and Germany, although they are currently among the States that mostly use animals in scientific experimentation.
In particular, France was the first State to introduce, in 1850, legislation on this matter (so-called «Loi Grammont»)[34]. Attention towards animals has gradually increased, especially after 1880. During this period, the sensitivity and feelings of human beings towards animals increased, so animal suffering was unacceptable, as well as scientific experimentation practices on live animals[35].

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[28] I.R. PAVONE, *op. cit.*, 82.
[29] According to EU institutions, biomedical research has reached the point where we can reasonably begin to envision a time when it could advance without causing harm to animals. On this topic see I.R. PAVONE, *op. cit.*, 83.
[30] The correct transposition of the directive within the Member States did not occur linearly. Almost all EU countries have been recalled by the European Commission under Art. 258 TFEU, due to the irregularities found within national legislation, which led to various infringement procedures.
[31] C. BOTTARI - T. DI PAOLO, *op. cit.*, 61; I.R. PAVONE, *op. cit.*, 96.
[32] One of these conditions is the existence of scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than those listed in Annex A of the Directive.
[33] I.R. PAVONE, *op. cit.*, 97.
[34] Loi du 2 juillet 1850 relative aux mauvais traitements exercés envers les animaux domestiques («Loi Grammont»), *https://www.animallaw.info/sites/default/files/stfrlawofJuly21850.pdf*. See É. PIERRE, *Réformer les relations entre les hommes et les animaux: fonction et usages de la loi Grammont en France (1850-1914)*, in *Déviance et Société*, 31, 1, 2007, 66 ss.
[35] É. PIERRE, *op. cit.*, 67 s.

The law of 1963[36] and the subsequent implementing decree of 1968 established the crime of «acts of cruelty towards animals», providing for the need to request authorization to carry out experiments on them[37].
Nowadays, animal testing is a controversial and sensitive topic, as it raises many ethical questions[38]. Animal testing is increasingly viewed negatively, so much so that, for example, many cosmetic product companies highlight the absence of tests carried out on animals.
From a legal point of view, in 2013, France implemented a Directive to strengthen the protection of animals used for scientific purposes. Therefore, today, it is possible to carry out animal testing, although it is subject to precise legal regulations, the latter based on compliance with the «3R» principle (Replace, Reduce, and Refinement)[39].
The legal conditions to use animals for experimental purposes are stricter because of the feeling change that people have toward animals.
Specifically, the Charte nationale portant sur l'éthique de l'expérimentation animale[40], drawn up by the Comité national de réflexion éthique sur l'expérimentation animale (CNREEA), establishes the principles about the use of animals for scientific purposes[41].
Firstly, French legislation provides for the monitoring and inspection, by competent authorities, of breeding establishments, research centers, and laboratories.
Secondly, animal testing procedures are legitimate only if they are considered strictly necessary and cannot be replaced by other experimental strategies or methods that, although not using live animals, are nevertheless capable of providing the same level of information (Art. R214-105 code rural et de la pêche maritime). Indeed, experimentation is forbidden if there is a method that does not involve the use of animals but provides scientists with the same level of information.
All vertebrate animals are protected by legislation, while invertebrate animals are not legally protected, except cephalopods. The use of non-human primates (such as macaques) is subject to specific restrictive regulations; it is forbidden to use great apes (such as chimpanzees or gorillas) unless there is authorization, which can only be issued in cases of extreme necessity.
Animals used in experimental procedures must have been bred for this purpose and come from approved breeders or suppliers; wild-caught, domestic, stray, or wild animals cannot be used. However, exceptional exemptions may be granted by the competent authorities based on scientific arguments demonstrating that the use of a farmed animal cannot achieve the objective of the procedure (Art. 214-92 code rural et de la pêche maritime).
All experimental procedures that may cause pain must be performed under general or local anesthesia, using analgesics or another appropriate method, to minimize pain, suffering, and distress (Art. R214-109,

[36] Loi n. 63-1143 du 19 novembre 1963 relative à la protection des animaux, *https://www.legifrance.gouv.fr/download/securePrint?token=cAxBDSL3kEsGSY37qQov&pagePdf=3*.
[37] G. MAHOUY, *Législation et réglementation de l'expérimentation animale*, in *GIRCOR*, *Livre blanc sur l'expérimentation animale*, Paris, 1995.
[38] See J.Y. BORY, *La polémique sur l'expérimentation animale. Le cas d'un laboratoire de la sécurité routière*, in *Ethnologie française*, 38, 3, 2008, 541 ss.; R. LARRERE, *éthique et expérimentation animale*, in *Natures Sciences Sociétés*, 10, n. 1, 2002, 24 ss.
[39] In 2012, OPAL (a French animal association founded in 1968) organized a conference around a 4th R: «Responsibility of all those involved in animal experimentation»; this means that researchers must apply ethical principles to guarantee quality research while best preserving animals. Societal expectations regarding alternative methods in experimentation appear mostly reasoned and consistent with the progress of research, the analysis of issues, and regulatory developments. On this matter see M.H. PERRUCHOT - F. DESSAUGE, *op. cit.*, 5.
[40] Charte nationale portant sur l'éthique de l'expérimentation animale, December 18, 2014, *https://www.enseignementsup-recherche.gouv.fr/sites/default/files/content_migration/document/1_Charte_nationale_portant_sur_l_ethique_de_l_experimentation_animale_243579_1417161.pdf*.
[41] The Comité national de réflexion éthique sur l'expérimentation animale (CNREEA) carries out various activities, the list of which is available at *https://www.enseignementsup-recherche.gouv.fr/fr/comite-national-de-reflexion-ethique-sur-l-experimentation-animale-cnreea-51275*.

code rural et de la pêche maritime).
The Ministry of Research issues authorizations to projects that use animals, subject to a favorable evaluation by the ethical committees for animal testing, which carry out an ethical assessment based on the cost-benefit ratio between the potential benefits that arise from the project and the animal damage[42].
The problem is that these ethics committees have never received approval to issue opinions on the ethical nature of research projects, as confirmed by the ruling recently issued by the Administrative Court of Paris. Indeed, on February 8, 2024, the administrative judges, following a legal action brought by the Transcience Association, canceled ten authorizations to carry out research projects using animals[43].
In France, from 2013 to 2021, more than twenty thousand projects (involving a total of between 16 and 18 million animals) have been authorized based on the opinion of the ethics committees for animal testing, which, however, were never been approved. The Ministry of Research did not check the composition of the committees, their functioning, and resources, in violation of the current legislation[44]. According to the 2010 Directive, Member States must ensure that the authorities responsible for evaluating projects provide all the required guarantees; in particular, the ethics committee must ensure that researchers apply the so-called «3R» rule[45].
The Administrative Court of Paris stated that the research project can only be authorized if it has been subject to a favorable evaluation by an ethics committee approved by the order of the Minister of Research[46]. Therefore, this Minister cannot authorize a project that involves an experimental procedure if the consent of the previously approved ethics committee is missing. The ethics committees, although not legitimized, have authorized thousands of projects; thus, the Administrative Court has canceled the authorizations previously granted to carry out animal experiments[47].

5. - *The German legislation on animal testing.* After having studied the French legal situation on animal testing, it is possible to move on to analyze the German legal system, which presents some peculiarities, especially from a historical point of view.
Indeed, National Socialist Germany ensured high animal protection[48]. Moreover, not only the German government but also the majority of the population was in favor of protecting these living beings. Consider that current legislation on animal rights is composed of amendments to the laws issued during the Third Reich[49].
The National Socialist regime, despite has issued many laws to safeguard animals, did not manage to abolish vivisection since this practice was considered, by some exponents of the government, as necessary for research, even for military purposes; in any case, animal testing practices were fully restored after the fall of the Nazi regime[50].

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[42] M.H. PERRUCHOT - F. DESSAUGE, *op. loc. cit.*; É.F. LHOSTE - B. DE MONTERA, *L'expérimentation animale: une responsabilité à dire et à partager*, in *Natures Sciences Sociétés*, 19, 2, 2011, 170.
[43] Tribunal administratif de Paris, 4e Sec., 1re Ch., February 8, 2024, n. 2219572, *https://www.dalloz.fr/documentation/Document?id=TA_PARIS_2024-02-08_2219572*.
[44] A. PROVENZANO, *Recherche: Pourquoi les expérimentations animales ne sont pas toujours dans les clous en France?*, March 25, 2024, *https://www.20minutes.fr/sciences/4081063-20240325-recherche-pourquoi-experimentations-animales-toujours-clous-france*; Fondation 30 Millions d'Amis, *Expérimentation animale: le ministère de la Recherche rappelé à l'ordre par la justice*, March 6, 2024, *https://www.30millionsdamis.fr/actualites/article/24658-experimentation-animale-le-ministere-de-la-recherche-epingle-par-la-justice/*.
[45] A. PLAYOUST-BRAURE, *Des milliers de recherches sur animaux menées en France «hors cadre réglementaire»*, March 5, 2024, *https://www.lemonde.fr/sciences/article/2024/03/05/des-milliers-de-recherches-sur-animaux-menees-en-france-hors-cadre-reglementaire_6220254_1650684.html*; É.F. LHOSTE - B. DE MONTERA, *op. cit.*, 166.
[46] Tribunal administratif de Paris, 4e Sec., 1re Ch., February 8, 2024, n. 2219572, cit.
[47] Fondation 30 Millions d'Amis, *op. loc. cit.*
[48] A. ARLUKE - C.R. SANDERS, *Regarding Animals*, Temple, 1996, 132; R. THOMAS - R. DE GREGORI, *Bountiful Harvest: Technology, Food Safety, and the Environment*, Washington D.C., 2002, 153.
[49] B. BRAUN - N. CASTREE, *Remaking Reality: Nature at the Millenium*, London, 1998, 92; R. PROCTOR, *The Nazi War on Cancer*, Princeton, 1999, 5.
[50] F. UEKÖTTER, *The Green and the Brown: A History of Conservation in Nazi Germany*, Cambridge, 2006, 55.

In 1933, Nazi leader Hermann Göring, an opponent of animal experimentation, promulgated a law (Tiergschutzgesetz) that completely abolished vivisection. But this legal provision has been criticized, so that same year, just three weeks after the issue of the law, the latter has been modified to allow the Minister of the Interior to grant, on an occasional basis, permits in favor of researchers and university institutes, which could therefore carry out experiments on live animals[51].
Specifically, Par. 1 of the 1933 law prohibited cruelly tormenting or mistreating an animal, except in cases of necessity. Paragraph 5 of this law prohibited vivisection; indeed, it was forbidden to operate or treat live animals for experimental purposes in a way that could cause them significant pain unless there was a special exemption granted by the Ministry of the Interior. This law, with a few changes, is still in force in Germany today[52].
As regards the current legislation, according to the Regulation on the Protection of Laboratory Animals (TierSchVersV), it is not permitted to use abandoned or wild animals of species usually kept in human custody[53].
The Animal Protection Act (TierSchG) allows the killing of dogs, cats, and primates for scientific purposes only if they have been bred for this purpose or, in any case, to be used in animal testing[54]. Furthermore, vertebrate animals and cephalopods can be used if they have been bred for this purpose (Par. 9, cpv. 1, and Par. 19 TierSchVersV)[55].
According to the Regulation on the Protection of Laboratory Animals, the competent authority may grant exemptions from the ban on the use of abandoned specimens of domestic species, provided that two requirements are met: the need to carry out animal health and welfare studies or the existence of the environment or human or animal health serious risks; the purpose of the procedure can only be achieved through the use of one of these animals. However, these are cases that occur very rarely in Germany.
Furthermore, according to TierSchVersV, the competent authority may grant derogations from the obligation to use exclusively vertebrate animals and cephalopods that are specifically bred for this purpose. Think, for example, of therapeutic trials or diagnostic procedures carried out in university or veterinary clinics, using dogs and cats that are «hospitalized» in these facilities[56].
As regards the procedural aspect of animal testing, a recent ruling deserves to be analyzed. This decision was issued recently by the Bremen Administrative Court, which deals with the granting of the authorizations necessary to carry out scientific experiments on animals.
In Germany, some requests to carry out similar experiments on animals have been rejected by the competent authorities, that of Berlin in 2008 and that of Munich in 2006.
Instead, in Bremen, a long-time legal battle began in 2008. Indeed, in October 2008, the Bremen State

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[51] F. UEKÖTTER, *op. cit.*, 56. Some question the Nazi government's protective activity in favor of animals. On this topic see B. BRAUN, N. CASTREE, *op. loc. cit.*

[52] A. CIONCI, *Quelle leggi animaliste dei nazisti che facevano esperimenti sui bambini*, April 26, 2016, *https://www.lastampa.it/cronaca/2016/04/26/news/quelle-leggi-animaliste-dei-nazisti-che-facevano-esperimenti-sui-bambini-1.35014092/*.

[53] Par. 21 Verordnung zum Schutz von zu Versuchszwecken oder zu anderen wissenschaftlichen Zwecken verwendeten Tieren (Tierschutz-Versuchstierverordnung - TierSchVersV), August 1, 2013, *https://www.gesetze-im-internet.de/tierschversv/BJNR312600013.html.*

[54] Par. 4, cpv. 3, co. 2 Tierschutzgesetz (TierSchG), July 24, 1972, *https://www.gesetze-im-internet.de/tierschg/BJNR012770972.html.*

[55] Anyone who purchases unmarked dogs, cats, or primates to sell them or use them in animal testing must, upon request from the competent authority, demonstrate that they are animals bred for these purposes (Par. 9, cpv. 2 TierSchVersV). Instead, anyone who breeds dogs, cats, or primates that will be used in animal testing or whose organs and tissues will be used for scientific purposes must mark them; that is, they must mark the individual animal with a permanent mark so that it is possible to ascertain their identity (Par. 11a, cpv. 3 TierSchG).

[56] Now that these studies are carried out for experimental purposes, using animals that have an «owner» must be authorized by the authorities, but the owners of the dogs and cats in question are not considered laboratory animal breeders; therefore, the authorization also requires a derogation from the obligation to use only vertebrate animals bred for this specific purpose. As regards the legislation, cf. Par. 19 TierSchVersV. In doctrine, see C. BRAUSE, *In Germania è consentito utilizzare cani e gatti randagi, abbandonati o selvatici per sperimentazioni sugli animali? Una sintesi delle basi giuridiche*, July 10, 2020, 7, *https://www.tasso.net/tasso/files/b2/b2aaf0e5-4aac-419f-8064-28b0852e2ba5.pdf.*

government refused the extension of the authorization to carry out animal experiments requested by a researcher at the University of Bremen because the welfare of the animals was more important than the potential benefits arising from the experiment[57].
The researcher proposed legal action. In December 2008, the Bremen Administrative Court decided that the experiment could continue for a maximum of two months after the refusal decision issued by the competent health department[58].
But in October 2009, just before the two-month deadline expired, the Bremen Administrative Court issued a provisional decision authorizing the experiments to continue[59].
Even subsequently, on May 28, 2010, the administrative judges ruled in favor of the University of Bremen, therefore not taking the state objective of animal protection into account but giving exclusive importance to freedom of research[60].
On November 25, 2011, the Higher Administrative Court of Bremen extended the continuation of the experiments by one year, i.e., until November 30, 2012[61]. According to the judges, the interest of the research prevailed over animal protection since these experiments were already authorized; therefore, the interruption of the experimentation could undermine the positive results achieved up to that point[62].
In reality, there was a lack of evidence regarding the benefits of experimenting on monkey brains to develop therapies for humans. However, on December 11, 2012, the Higher Administrative Court of Bremen ruled in favor, once again, of the university researcher[63].
The last extension expired at the end of November 2023. Thus, the University of Bremen again requested permission to carry out this kind of experiment, but the Bremen health authority rejected the request on November 14, 2023[64].
According to this authority, the benefits cannot justify the animals suffering in terms of scientific knowledge; therefore, the experiment was illegitimate from an ethical point of view. The experiment produced «serious» suffering in the macaques, thus violating the provisions of the European Union legislation.
The evaluation of the project in terms of the benefit/risk ratio, as required by the Directive, has been negative because the potential benefits deriving from the experiment are lower than the animal damage[65].

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[57] Indeed, according to the law on animal protection, experimentation can be considered legitimate when it is «essential» and «ethically justifiable». Furthermore, the German Constitution also establishes the animal protection.
[58] VG Bremen, 5 V 3719/08, December 19, 2008. Meanwhile, the authority responsible for issuing authorizations has refused, once again, to issue the authorization necessary to carry out the experiments on primates.
[59] VG Bremen, 5 V 1524/09, October 19, 2009. See C. GERICKE, *Hirnforschung an Affen in Bremen*, April 29, 2024, *https://www.aerzte-gegen-tierversuche.de/de/affen/hirnforschung-an-affen-in-bremen*.
[60] VG Bremen, 5 K 1274/09, May 28, 2010. The Administrative Court of Bremen has annulled the rejection decision issued by the authority responsible for issuing the authorizations and has ordered the latter to justify its refusal to authorize the scientific experiment. This authority has appealed against the ruling.
[61] OVG Bremen, 1 B 272/11, November 25, 2011.
[62] C. GERICKE, *op. loc. cit.*
[63] OVG Bremen, 1 A 180/10; 1 A 367/10, December 11, 2012, *https://www.oberverwaltungsgericht.bremen.de/sixcms/media.php/13/1_A_180_10_URTEIL_00000003_073849Anonym.pdf*. The competent licensing authority has appealed to the Federal Administrative Court against the decision of the Higher Administrative Court of Bremen (BVerwG, 3 B 29.13), but the legal action was dismissed on January 20, 2014, *https://www.bverwg.de/200114B3B29.13.0*. In mid-2021, the researcher applied to continue his research even after November 30, 2021, while the University of Bremen submitted an urgent request to the Bremen Administrative Court. On November 24, 2021, the Court granted the request, stating that experiments on monkey brains have been ongoing for many years (VG Bremen, 5 V 2285/21, *https://www.verwaltungsgericht.bremen.de/sixcms/media.php/13/21_2285_V_5.pdf*). Subsequently, on February 3, 2022, the Bremen Administrative Court approved, through a provisional measure, the continuation of experiments on the monkey brains until November 30, 2022 (VG Bremen, 5 V 2285/21, *https://www.verwaltungsgericht.bremen.de/sixcms/media.php/13/21_2285_V_5.10770.pdf*).
[64] Freie Hansestadt Bremen, Die Senatorin für Gesundheit, Frauen und Verbraucherschutz. Antrag auf Fortsetzung der Primatenversuche abgelehnt, November 14, 2023, *https://www.senatspressestelle.bremen.de/pressemitteilungen/antrag-auf-fortsetzung-der-primatenversuche-abgelehnt-434455?asl=bremen02.c.732.de*.
[65] Oltre la Sperimentazione Animale (OSA), *Germania: respinta la richiesta di una ricerca sul cervello di primati*, November 16, 2023,

The health authority's decision took into consideration the particular characteristics of the animals involved: macaques, or non-human primates, are intelligent animals capable of understanding the reality of their lives; these animals can suffer and hide the pain felt, which is sometimes difficult for humans to understand[66].
However, on April 17, 2024, the Bremen Administrative Court provisionally authorized the testing of monkey brains, provided that the animals do not undergo surgical operations preparatory to testing[67]. Furthermore, the Court has restricted this authorization to only two months after the licensing authority decided on the objection to the rejection of the application to carry out animal testing submitted by the researcher. The judges reasoned that the expertise does not provide a scientifically sound basis, and it is impossible to definitively assess the burden on animals and the importance of the research project. Overall, the Court has concluded that the damage caused by the end of the experiments exceeded the animal stress, which at best has been recognized as only moderate[68].
This ruling seems to be a compromise solution because the administrative judges attempted to balance the interest of scientific research with the need to protect animals. However, in our opinion, this decision gave greater importance to the requests of the researcher and the University of Bremen.

6. - *The Italian legal system: the «LightUp» case.* After studying German legislation and the judicial and administrative dispute concerning the authorization to carry out experiments on the brains of non-human primates, it is possible to examine the Italian legal system.
Italy has intervened in the field of vivisection carried out on warm-blooded vertebrate animals (mammals and birds) as early as 1931 through law No. 924 (modified in 1941) to prevent unnecessary cruelty and unjustified suffering from being inflicted on the animals, even when they have to be sacrificed for a reasonable cause[69].
The experiments permitted by law were those aimed to promote the progress of biology and experimental medicine, as experiments carried out for educational purposes were permitted exclusively in cases of unavoidable necessity, precisely if it was not possible to resort to other demonstration systems (Art. 1 of the Law No. 924 of 1931).
In any case, the use of pets (dogs and cats) is allowed if the nature of the experiment does not allow the use of animals of other species.
Animal testing could be carried out by qualified people, except in some exceptional cases and in any case where there was authorization issued by the Minister of Health.
Furthermore, the 1931 Law established the need to implement measures aimed at preventing or at least limiting the suffering of animals: the obligation to do anesthesia if this was not incompatible with the nature of the experiment; the ban of using the animal already subjected to vivisection for further experiments, except in cases of absolute scientific necessity; the killing of the animal if, following anesthesia, the suffering continued (even) after the experiment and it was not essential to keep it alive for the experiment itself (Art. 1)[70].
As can be seen, this legislation was particularly careful to the welfare of animals, including those used in

https://www.oltrelasperimentazioneanimale.eu/germania-respinta-la-richiesta-di-una-ricerca-sul-cervello-di-pnu/.
[66] This animal species also exhibits the described behavior in the laboratory. On this topic see M.T. GASBARRONE, *In Germania decisione storica contro la sperimentazione su animali in laboratorio*, November 21, 2023, *https://www.ohga.it/in-germania-decisione-storica-contro-la-sperimentazione-su-animali-in-laboratorio/*; Doctors Against Animal Experiments, *German authority rejects application for brain research on non-human primates*, November 15, 2023, *https://www.aerzte-gegen-tierversuche.de/en/news/german-authority-rejects-application-for-brain-research-on-non-human-primates*.
[67] VG Bremen, 5 V 2729/23, April 17, 2024, *https://www.verwaltungsgericht.bremen.de/sixcms/media.php/13/23_2729_V_5.pdf*.
[68] C. Gericke, *op. loc. cit.*
[69] L. 12 giugno 1931, n. 924, Modificazione delle disposizioni che disciplinano la materia della vivisezione sugli animali vertebrati a sangue caldo (mammiferi ed uccelli) (modificata dalla l. 1° maggio 1941, n. 615).
[70] For a comment on the law, see F. COPPI, *Maltrattamento o malgoverno di animali*, in *Enc. dir.*, vol. XXV, Milano, 1975, 265 s.

testing practices. However, the current Italian legislation, as shown after the implementation of the Directive, is even more guaranteed regarding animals used in scientific experimentation[71].
Indeed, in Italy, animal experimentation is regulated by the national law (Law No. 96/2013), which has implemented the EU Directive[72]. In particular, Art. 13 of Law No. 96 has been reproduced then by Legislative Decree No. 26 of 2014[73], which attempted to balance the needs of scientific research with the need to protect the well-being of the animals used in the experiments. However, the Legislative Decree has been criticized because, according to some scientists, its provisions excessively limit the freedom of scientific research[74].
Italian legislation, although very similar to EU legislation, provides higher protection for animals used for scientific purposes. Art. 1, co. 2 of Legislative Decree No. 26/2014 states that animal experimentation is allowed when another model cannot be used. Therefore, if animal testing is considered essential, then it is possible to use animals that have the least capacity to experience pain, suffering, and stress, give the greater possibility of achieving the expected results, and that are capable of providing the right balance between harm and benefit[75].
The Animal Welfare Body submits the animal research projects to the Ministry of Health, which can approve them. The Ministry issues the authorization to carry out the project only after having ascertained that there are no alternative methods to animal models, the benefit to society resulting from the study is potentially high, and the proposed project respects the «3R» principle.
These controls are also carried out by the Animal-Welfare Body, before transmitting the project to the Ministry. The Ministry of Health can carry out control at any time to verify that research activities comply with the law and the authorizations granted.
The implementation of supranational legislation has been criticized by a part of the doctrine since many provisions of the Italian legislation contrasted with the legal content of the 2010 Directive[76]. The State legislator's decision to enact stricter national regulations to safeguard animal welfare is obviously at odds with several of the provisions outlined in this Directive[77].
Legislative Decree No. 26/2014 provides for a series of limitations on scientific research; these limitations have been considered negatively by the European Union, which opened an infringement procedure against Italy[78].
In particular, Italian legislation does not allow the breeding of certain animal species and prohibits research activities in some sectors. Consider that many practices, for example, xenotransplantation and organ transplants across different animal species, are banned; this is a strategic field of research, as it can improve a situation characterized by a strong demand for organ transplants.
Moreover, according to Italian legislation, studies cannot be carried out on drugs that induce addiction in animals, despite the knowledge of the toxic effects, both short-term and long-term, produced by narcotic or psychotropic substances on people would be of considerable scientific interest.
These two bans do not seem to have any rational justification, and they are not in force in the legislation of the other member countries of the European Union. Following the researchers' protests, some

[71] Italy is the only EU country that has concluded the «transposition» phase very late. This delay has caused the beginning of an infringement proceeding by the European Commission against Italy on January 23, 2014, in conformity with Article 258 of the TFEU.
[72] L. 6 agosto 2013, n. 96, Delega al Governo per il recepimento delle direttive europee e l'attuazione di altri atti dell'Unione europea (Legge di delegazione europea 2013).
[73] Decreto legislativo 4 marzo 2014, n. 26, Attuazione della direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici.
[74] L. MARIANTONI, *op. cit.*, 37.
[75] F. PAVAN, *op. loc. cit.*
[76] P. PUOTI, *L'attuazione della direttiva 2010/63/UE sulla protezione degli animali da sperimentazione nel contesto dell'armonizzazione del mercato interno e il futuro della ricerca in Italia*, in *Studi sull'integrazione europea*, 11, 2016, 316 ss.
[77] I.R. PAVONE, *op. cit.*, 96.
[78] M. MORELLI, *op. loc. cit.*

exemptions from the ban on carrying out research in these two sectors have been granted, but the exemptions last for one year; therefore, it is impossible to plan significant research since a long time (six months) is required for the exemption's approval[79].
The Italian legislation contains other severe restrictions on some types of research. Indeed, the breeding or use of cats, dogs, non-human primates, and specimens of species in danger of extinction for basic research is forbidden. Furthermore, animals of any nature previously employed in procedures classified as of moderate severity, mild, or non-recovery within the meaning of Art. 16 of Directive 2010/63/EU cannot be re-used; anesthesia or analgesic agents must be applied in any procedure in which the animal may experience some pain, except in cases where anesthesia or analgesia are the subjects of the study; the use of genetically modified animals is limited. Finally, the breeding of genetically modified animals, such as rodents, will need to take into account the potential risks to human health, animal welfare, and the environment.
The difficulties of carrying out animal testing in our country are well exemplified by a long and intricate legal case, ultimately decided by the Council of State.
The legal case (called «LightUp» or «Tamietto») concerned the use of six animals in an experiment aimed to verify the possibility of recovering induced blindness in monkeys. Two animal rights associations (Lega Antivivisection and Oltre la Sperimentazione Animale) challenged the authorization issued on October 15, 2018, by the Ministry of Health concerning a research project presented by the University of Parma aimed to study anatomical and physiological mechanisms of the recovery of vision in monkeys. The ultimate goal was to evaluate a translatable rehabilitation protocol for humans, especially blind patients.
On November 5, 2019, the Lazio Regional Administrative Court rejected the precautionary request presented by the appellant associations since they have not demonstrated the existence of alternative scientific methods (i.e., those that do not use animals, namely non-human primates) compared to those envisaged from the contested experimentation, which allows the same research results to be achieved[80].
However, on January 23, 2020, the Council of State suspended the previous order issued by the Lazio Regional Administrative Court[81]. According to the Council of State, contrary to what was held by the judge in the first instance, the researcher must prove that there are no alternatives to invasive experimentation on animals. Thus, second-instance administrative judges have affirmed the prevalence of animal protection over the research interest[82].
Subsequently, on June 1, 2020, the Lazio Regional Administrative Court (T.A.R.) rejected the application presented by the appellant associations. This court has ascertained the correctness of the logical procedure implemented by the relevant bodies and the reliability of the technical and evaluation operations, not identifying any violation of the relevant legislation[83].
The animal rights associations have appealed this decision to the Council of State, which accepted, on October 9, 2020, their arguments, thus suspending, until the collegial discussion in a public hearing, the enforceability of the appealed ruling[84].

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[79] S. GARATTINI, *I limiti della sperimentazione con gli animali in Italia*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 15.
[80] T.A.R. Lazio - Roma, Sez. III *quater* ord. November 5, 2019, n. 7130.
[81] Cons. Stato, Sez. III ord. January 23, 2020, n. 230.
[82] Instead, the Council of State, albeit as a precautionary measure, did not consider the evidence provided by the competent authorities as satisfactory for the legitimacy of the authorization, suspending the authorization and requesting a report ascertaining the lack of alternative methods to experimentation. For a comment on the precautionary order, see T. DI PAOLO, *Il sindacato del giudice amministrativo sulle autorizzazioni dei progetti di ricerca sulla sperimentazione animale*, in *Corti supreme e salute*, 3, 2020, 538 s.
[83] T.A.R. Lazio - Roma, Sez. III *quater* June 1, 2020, n. 5771, in *Rep. Foro it.*, 2021, *Animali e vegetali (protezione e tutela penale)*, n. 25; in *www.giustamm.it*, 2020, 6.
[84] Cons. Stato, Sez. III ord. October 9, 2020, n. 5914. According to the judges, there are two opposing interests in the animal testing sector. The first interest is animal welfare, protected at the European Union level by Art. 13 of the TFEU and Directive 2010/63, and at the state level by Legislative Decree No. 26/2014; the second interest is scientific research, which is a universal value and, in general, cannot be limited. In doctrine, see T. DI PAOLO, *op. cit.*, 541 s.

On February 8, 2021, the Council of State ruled on this dispute definitively. Appellate administrative judges have considered that the experiment was legitimate, highlighting that the objective of the project could not be achieved through methodologies carried out directly on humans and that there were no alternative methods or the possibility of carrying out the experimentation on a smaller number of macaques[85].
However, the judges of the second instance specified that the Higher Health Council had issued a favorable but «conditional» opinion, on which the authorization could be issued only on the condition that, every six months, the data relating to the stress conditions detected during the individual phases were sent to the Office of the Directorate General for Animal Health and Veterinary Medicines (DGSAF) of the project, as well as the measures taken to limit adverse effects; indeed, the project could have negative consequences for the non-human primates involved[86].
According to the administrative judges, the reports made were meager and missing, for example, a photograph of the state of the macaques, which also points out the stress monitoring parameters[87]. In other words, it was necessary to record the physical and mental state of the macaques at every single activity, stimulation, or therapy applied to them because the experimentation concerns living, sentient primates, of which blindness is induced, with undoubted suffering.
The experimentation must be conducted with full respect for the guinea pigs, «living beings» with particular neurological sensitivity, minimizing their suffering. Therefore, the University of Parma is obliged to make and file periodic and frequent reports, given that macaques have developed intelligence and relationships that also focus on the stressful conditions of these animals, to respect their well-being, as established by Art. 13 of the TFEU[88].
The «LightUp» judicial case is an example of the need, both for the legislator and the judges, to find a balance between the protection of animals subjected to experimentation and the community interest in carrying out the experimental activities considered indispensable, based on current scientific knowledge[89].
The ruling of the Council of State did not focus so much on the need, or otherwise, to use animals in experiments but rather on the concrete methods of using these living beings. Both the administrative judge of the first instance and the Council of State have highlighted the important role played by experimentation and, therefore, by scientific research, but also, at the same time, the need to protect animal welfare as a key principle of the European Union law[90].
The «LightUp» case confirms a complicated relationship between science and law, particularly in the animal testing sector[91]. Although the judges attempted to reconcile animal welfare with the interest of scientific research, the ruling has been criticized, since the judicial process has slowed down the scientific research for at least twenty months[92].

7. - *Comparative aspects of animal testing legislation.* The implementation of supranational legislation has produced many legal problems, especially concerning the unification of law and freedom of scientific

[85] Cons. Stato, Sez. III February 8, 2021, n. 1186, in *www.osservatorioagromafie.it*. A comment on the ruling is readable in M. LOTTINI, *Il Consiglio di Stato e la sperimentazione tra limiti alla ricerca scientifica e difesa del benessere degli animali*, in *Cultura e diritti*, 1, 2021, 105 ss.
[86] Cons. Stato, Sez. III February 8, 2021, n. 1186, cit.
[87] Indeed, these reports lacked the reaction of the macaques to every action exerted on them by researchers.
[88] Cons. Stato, Sez. III February 8, 2021, n. 1186, cit.
[89] E. MALFATTI, *Modelli sperimentali preclinici in vivo, fra diritto ed etica applicata. Riflessioni "dall'interno" di un organismo preposto al benessere animale (OPBA)*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2023, 431; D. CERINI, *op. cit.*, 367; F.S. FLORIO, *La sperimentazione animale e il confine tra diritti ed etica alla luce dei recenti interventi della giurisprudenza*, in *Sanità pubblica e privata*, 3, 2021, 69 s.
[90] E. MALFATTI, *op. cit.*, 432 s.
[91] L. CHIEFFI, *La sperimentazione animale tra aperture europee e restrizioni statali: una nuova puntata del tormentato rapporto tra scienza e diritto*, in *Nomos*, 1, 2019, 18.
[92] L. CHIEFFI, *op. loc. cit.*, according to which, the judicial decision does not refer, in an extensive manner, to the consolidated scientific evidence existing in the fields of biomedicine, behavioral genetics, and geophysics.

research.
The first issue concerns legislative uniformity, which should characterize the animal testing sector in the context of the European Union.
It has already been said that Directive 2010/63/EU aimed to ensure that all Member States could operate under the same conditions in the field of scientific research. However, Italy has shown an anti-scientific attitude, issuing more restrictive legislation than all other countries[93]. The bans imposed by national legislation can create inequalities compared to the rest of the scientific community, as it is forbidden to carry out some experiments that can be legitimately carried out abroad[94]. Therefore, the restrictions provided by the State legislator will hurt biomedical research in Italy, violating the Directive provisions, which prohibit Member States from introducing more restrictive rules[95].
The State legislation has established further prohibitions and restrictions (compared to those established by supranational legislation), reducing the possibility of carrying out the experiments necessary to develop new medical therapies.
In Italy, animal testing is often hindered[96]. Consider that in recent years, in France and other European Union countries, the number of animals used in experiments has decreased slightly[97].
Instead, in our country, fewer animals are used (less than a third) compared to those used for scientific experiments in other countries, both in Member States, such as France, Germany and in non-EU countries, such as Great Britain and Switzerland, thus confirming the absence in Italy of favorable conditions to carrying out of research projects.
For example, Italian legislation prohibits the breeding of dogs, cats, and non-human primates to be used later for biomedical research, but their use is permitted, which represents a contradiction since the animals are purchased from foreign breeders (which cannot be controlled) and then imported in Italy to be used in experiments. This situation increases the costs of the experiments and discomfort for these animals[98].
The 2010 Directive aimed to bring the legislation of the Member States closer together by overcoming the legal divergences that have characterized the implementation phase of the previous Directive 86/609/EEC[99].
The study of the legislation of the three member countries highlights a common provision: if there is a way to gather the same amount of data without using animals in the experiment, then doing so is prohibited. The problem is that the assessment regarding the presence of this condition is up to the State judges, which implies different applications of European Union legislation.
Furthermore, the choice of the EU institutions in favor of the directive (and not the regulation) as a legal instrument, while allowing the agreement to be reached more easily between all the Member States, has produced both a weakening of the innovative scope of the Directive and legislative divergences, sometimes notable, in the practical implementation of supranational legislation within national legal systems[100].
The different considerations of the relationship between humans and animals in various countries have

[93] S. GARATTINI, *op. loc. cit.*
[94] European Commission, February infringements package: key decisions, February 15, 2017, *https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_17_234*.
[95] See Comitato Nazionale per la Bioetica, *In merito ad alcuni problemi bioetici sollevati dalla Legge 6 agosto 2013, n. 96, art. 13 "Criteri di delega al Governo per il recepimento della Direttiva 2010/63/UE del Parlamento europeo e del Consiglio, del 22 settembre 2010*", *Risposta al quesito posto al Comitato Nazionale per la Bioetica dalla Senatrice Prof. Elena Cattaneo*, January 24, 2014, *https://bioetica.governo.it/media/3470/p114_2014_criteri-delega-recepimento-cattaneo_it.pdf*.
[96] S. GARATTINI, *op. loc. cit.*
[97] Le Mag des Animaux, *L'expérimentation animale est-elle encore autorisée en France?*, April 12, 2023, *https://lemagdesanimaux.ouest-france.fr/dossier-1703-experimentation-animale-france.html*.
[98] I.R. PAVONE, *op. cit.*, 95.
[99] R. FORASTIERO, *op. loc. cit.*
[100] R. FORASTIERO, *op. loc. cit.*

probably influenced the implementation of the EU legislation[101]. At this point, the European Union should evaluate the opportunity to intervene again on this matter, possibly through an EU regulation, to adapt the legislation to the scientific progress that has occurred in recent years, also in the sector of animal testing.
The Directive implementation has produced a second problem of a legal-scientific nature, as some countries, primarily Italy, give fewer possibilities to researchers to carry out experiments on animals, which causes damage to freedom of research and hinders the advancement of knowledge, particularly in the field of medical science. Therefore, it is interesting to question ourselves about the potential conflict of State legislation (Legislative Decree No. 26/2014) with the Italian Constitution. Indeed, the latter promotes scientific research (Articles 9, co. 1, and 33) and protects health as a fundamental right of the individual and the interest of the community (Art. 32) since scientific research has the main (and final) aim of producing an improvement in people's health and living conditions[102].
Of course, the Italian Constitution protects animals (Art. 9, co. 3), but it leaves the possibility of regulating the modalities and kinds of protection of these living beings to the ordinary legislator. Moreover, the Constitutional Charter does not explicitly prohibit animal testing. Therefore, we think that freedom of scientific research should prevail (over animal protection), at least in cases where it aims to improve (and prolong) human life and alleviate its suffering.
However, from a comparative perspective, Italy has implemented supranational legal rules by issuing more stringent regulations; instead, France and Germany have issued legislation more compliant with the spirit and content of the Directive. But, it is necessary to carry out, in addition to a comparison between the different State regulations, also a comparison between the judicial (or administrative) decisions that these three member EU countries have taken on animal experimentation.
In the «LightUp» case, according to judges, the scientific activity must be accurate, transparent, and credible, and it must comply with the legislation on animal testing. The researchers cannot simply claim that animal suffering has been minimal, but they must demonstrate, precisely and accurately, how this objective has been achieved[103]. The Council of State, in the ruling of 2021, has stated that scientific activity cannot be self-referential but must demonstrate the validity of its assertions. Anyway, in the end, the administrative judges have considered animal testing legitimate in this case[104].
In Germany, the ruling of the Bremen Administrative Court also has considered the interest in animal protection to prevail over the possible benefits deriving from the research work. This legal system has implemented supranational legislation in a more «elastic» manner compared to the Italian legal system; however, the decisions of the Italian judges and that of the German ones have been favorable to the researchers.
The ruling of the Council of State and that of the Bremen Administrative Court recognized, but only partially, the appellants' requests. In fact, in both legal cases, the judges, while affirming the obligation of the researchers to carry out the experiments with full respect for the animals, nevertheless authorized the continuation of the experimentation.
Our opinion is that, after project approval, jurisdictional authorities have difficulty suspending research activities. Indeed, these rulings are often issued many years after the start of the testing procedures; therefore, judges must take into account not only the protection of animals, on the one hand, and the needs of scientific research, on the other hand, but also other factors, such as the economic aspects and scientific implications, both for the researchers than for the research itself, linked to the interruption of animal testing. These aspects, although not explicitly mentioned in the European Union legislation, can

[101] C. BOTTARI - T. DI PAOLO, *op. cit.*, 65.
[102] On topic see P. VERONESI, *op. cit.*, 153 ss.
[103] M. TALLACCHINI, *La sperimentazione animale tra scienza, istituzioni e cittadini*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 8 s.
[104] F.S. FLORIO, *op. cit.*, 68 s.

be assessed by the judge when issuing the decision.
In both the Italian and German cases, the research project involved tests on the brains of non-human primates. Therefore, the two controversies concerned a very delicate field of research characterized by many ethical issues but in both cases, the potential benefits for human beings in terms of the development of new therapies to fight diseases seemed to justify, in our opinion, the decisions to authorize the continuation of the experiments.
Instead, the French judicial case is partially different compared to those of Italian and German since the decision of the administrative judges of Paris did not concern the legitimacy or otherwise the scientific experiments but the procedural aspect of the experimentation, affirming the invalidity of the activity carried out by ethics committees, as they had not any legitimacy to evaluate the testing practices. However, this formal flaw also has affected the validity of the research projects carried out for almost ten years despite the absence of a valid assessment regarding their ethical nature.
In the three countries examined, the orientation of the case law is still favorable, generally, to animal testing. The Administrative Court of Paris affirmed the invalidity of the animal testing procedures from a «formal» point of view due to the lack of legitimacy of the ethics committees. However, the ruling did not declare the invalidity of these practices from the point of view of the content of the research projects.
The analysis of the three judicial cases helps to understand the important role of the judicial (and administrative) authorities in the field of animal testing. Each testing procedure is different from the other; therefore, despite the existence of «generally» uniform legislation in the European Union countries, it is up to the national decision-making authorities (and not the legislator) to carry out the delicate balancing activities between the need to guarantee higher protection of animals used for experimental or scientific purposes and the need to allow the development of new knowledge[105].
Moreover, the «3R» System, which is the basis of the supranational legislation, is a significant principle in regulating animal testing; however, the respect of this principle about the grant of the authorization and the implementation of the research project can be interpreted elastically, thus differently by the judges of the member countries.

8. - *Conclusion remarks.* The legal evolution of animal testing has produced legislation aimed at protecting animals, especially laboratory animals, in an ever-stronger manner.
At this point, however, we want to analyze and refute an assertion frequently made when you talk about animal testing. It is often said that legislation has recently changed, following the higher sensitivity of humans towards animals.
In truth, although the legislation on animal testing has become more protective towards animals, especially in recent years, various countries, already many decades ago, have paid considerable attention to the phenomenon under consideration. The comparative analysis carried out so far has highlighted how the three European countries in question, long ago, have issued regulations on animal experiments: France is the country that has intervened in this sector before the other countries, precisely in the mid-1800s; Germany and Italy have intervened later, but, anyway, almost a century ago, i.e., in the 1930s.
Furthermore, although the consideration of animals has changed, especially in recent years, because of the increased sensitivity of people towards these living beings, it must be highlighted that the first Italian and German legislation on animal testing dates back to a particular historical period. Indeed, the decade preceding the Second World War has been characterized, at least at the level of national governments, by a poor consideration of human life, precisely by a widespread hatred towards minorities (of people) due to the belonging of these persons to certain people (think of the Jews), or ethnic group, or a particular political group (minority). Consider, for example, that the German legislation of the 1930s prohibited vivisection, with some exceptions, but the Nazi regime allowed, again in those years, scientific

[105] R. FORASTIERO, *op. loc. cit.*

experiments in the concentration camps on detained people, even children, used without scruple as human guinea pigs[106].
Beyond the historical-legal events just reviewed, the fundamental point of the question is to understand whether experiments on animals are still necessary and whether experimentation on them can be considered legitimate from a legal point of view.
Despite the thesis supported by animal rights associations regarding the uselessness of experimentation on animals, which only produces suffering for them[107], in reality, these practices still represent today a fundamental step in the development of new pharmacological therapies and, more generally, in the advancement of biomedical knowledge, to allow a better understanding of the pathological mechanisms affecting human beings and to offer increasingly modern medical therapies in the fight against diseases, especially those genetic, rare, or new ones[108].
We think that animal testing should always be allowed if it aims to create new drugs or develop more advanced therapies to treat diseases, especially those incurable or seriously disabling[109]. Furthermore, these practices should be permitted, in general, if they aim to ease the advancement of scientific knowledge in new fields of medicine, such as predictive medicine and personalized medicine.
Animal experiments have facilitated the development of various vaccines and many drugs that have made it possible to cure diseases and alleviate people's suffering, thus increasing their lifespan: think, for example, of the usefulness, more precisely the necessity, of animal testing regarding the rapid and effective development of anti-COVID-19 vaccines[110].
In our opinion, animal testing can produce advantages both for humans and animals since some of these practices improve knowledge of the pathological mechanisms of diseases; thus, researchers can develop more modern and effective therapies to treat animal diseases.
Furthermore, artificial intelligence systems and new technologies are used increasingly in animal care[111]. It is presumable that in the coming years, the use of animals will decrease, especially if science manages to develop new techniques and alternatives to those that use these living beings[112]. Some countries, for example, France[113], Germany[114], and Italy[115] have developed projects that use organoids (miniature organs developed in laboratories) as part of scientific experimentation.
However, the best way to avoid using animals in these practices is to exploit the potential made available

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106 Cf. A. CIONCI, *op. loc. cit.*
107 G. RIZZOLATTI, *Sperimentazione animale: un dibattito privo di senso?*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 10.
108 G. GRIGNASCHI, *Sperimentazione animale, l'Italia frena e contraddice le norme UE. Research4Life: «Innovazione paralizzata e il malato resta senza terapie»*, November 21, 2018, *https://www.sanita24.ilsole24ore.com/art/medicina-e-ricerca/2018-11-21/sperimentazione-animale-l-italia-frena-e-contraddice-norme-ue-research4life-innovazione-paralizzata-e-malato-resta-senza-terapie-135827.php?uuid=AEMxRskGc&refresh_ce=1*; M.R. MICHELI, *op. cit.*, 1085.
109 On this matter see I.R. PAVONE, *op. cit.*, 96 s. Cf. A. PASSANTINO - C. DI PIETRO, *op. cit.*, 338.
110 S. GARATTINI, *op. loc. cit.*
111 R. SEIFMAN, *Animal Health: How AI and Drones Make a Big Difference*, January 19, 2024, *https://impakter.com/animal-health-how-ai-and-drones-make-a-big-difference/*; L. ZHANG et al., *Advancements in artificial intelligence technology for improving animal welfare: Current applications and research progress*, in *Animal Research and One Health*, 2, n. 1, 2024, 93 ss.; S. NEETHIRAJAN, *Artificial Intelligence and Sensor Innovations: Enhancing Livestock Welfare with a Human-Centric Approach*, in *Human-Centric Intelligent Systems*, 2023, 1 ss.; D. HERNANDEZ-PATLAN et al., *Editorial: Technological strategies to improve animal health and production*, in *Frontiers in Veterinary Science*, 10, n. 1206170, 2023, 1 ss.; A. GOEL, *Technology Reshapes Animal Health And Well-Being*, March 29, 2021, *https://www.forbes.com/sites/forbesbusinessdevelopmentcouncil/2021/03/29/technology-reshapes-animal-health-and-well-being/*.
112 G. PIRANI, *Sperimentazione animale: perché in Europa è ancora obbligatoria per i farmaci*, May 17, 2023, *https://www.upday.com/it/sperimentazione-animale-perche-in-europa-e-ancora-obbligatoria-per-i-farmaci.*
113 A. PROVENZANO, *op. loc. cit.*
114 Leibniz-Gemeinschaft, *Organoide statt Tierversuche*, May 23, 2023, *https://www.leibniz-gemeinschaft.de/ueber-uns/neues/forschungsnachrichten/forschungsnachrichten-single/newsdetails/hirnforschung-mit-organoiden.*
115 Research4Life, *Non solo modelli animali: organoidi per lo studio del cancro*, January 26, 2022, *https://www.research4life.it/non-solo-modelli-animali-gli-organoidi-per-lo-studio-del-cancro/*.

by artificial intelligence tools[116].
The nexus between animals and artificial intelligence is very complex because they can be used to test the performances of AI applications. Indeed, animals, especially animal brains, play a crucial role in developing artificial intelligence technologies. This development is partly rooted in research results gained in animal experiments and tests of its technologies by comparing them to animal capabilities. Animals are considered mere resources and providers of data; instead, the animals used in this context are often sentient vertebrates that can feel pain and pleasure[117].
Consider that, in the United States of America, Neuralink, a medical device company, is under federal investigation for potential animal welfare violations amid internal staff complaints that its animal testing is being rushed, causing needless suffering and deaths. Neuralink Corporation is developing a brain implant that it hopes will help paralyzed people walk again and cure other neurological ailments. The federal investigation has been opened by the US Department of Agriculture's inspector general, following the request of a federal prosecutor[118]. The inquiry focuses on violations of the Animal Welfare Act, which governs how researchers treat and test some animals[119].
Undoubtedly, over the years, the use of animals for experimental purposes has decreased[120] but it is not yet possible to abolish this practice even because in the European Union, unlike in the United States of America, it is still mandatory to test new drugs on animals. Indeed, in the United States of America, the Food and Drug Administration (FDA) has established that pharmaceutical companies are no longer obliged to test drugs on animals. Instead, in the European Union, it is still mandatory to carry out tests on laboratory animals to verify the safety of the drug and its actual effectiveness, except for particular products[121].
Beyond the ethical and moral aspects of animal experimentation, the European Union legislation raises delicate legal problems, as animal testing practices violate the right to life and well-being of these living beings. The issue is complicated since many European countries, including Germany and Italy, provide for the protection of animals, not only at the ordinary legislation level but also at the constitutional level. At this point, a question arises: is it possible to reconcile the protection of animal rights, especially those sentient, and the need to advance scientific knowledge?
It seems necessary for an act of balance between the opposing interests of living beings (human and non-human), following which animal testing should be justified if there is a superior human interest that cannot be protected in any other way[122].
Moreover, this balancing activity, carried out both at a legislative and judicial level, appears to be increasingly complicated and delicate because, in recent years, the consideration of animals has changed, thus strengthening the legal protection of these living beings, particularly those used in experiments.
In our opinion, although the supranational legislation has been implemented differently in the member countries, the case law could «guarantee» legal uniformity (on this matter), which has failed, both due to the choice of the European Union institutions in favor of the directive (and not of the regulation), and

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[116] E. WALDMAN, *How AI and VR Are Saving Animals From Experiments*, March 24, 2023, *https://www.peta.org/blog/how-ai-and-vr-are-replacing-experiments-on-animals/*.
[117] L. BOSSERT - T. HAGENDORFF, *Animals and AI. The role of animals in AI research and application - An overview and ethical evaluation*, in *Technology in Society*, 67, n. 101678, 2021, 1 ss.
[118] R. LEVY, *Musk's Neuralink faces federal inquiry after killing 1,500 animals in testing. Brain-implant company accused of causing needless suffering and deaths amid pressure from CEO*, December 6, 2022, *https://www.theguardian.com/technology/2022/dec/05/neuralink-animal-testing-elon-musk-investigation*.
[119] Animal Welfare Act (AWA), Public Law 89-544; Approved on August 24, 1966 (As Amended Through P.L. 115-334, Enacted December 20, 2018), *https://www.govinfo.gov/content/pkg/COMPS-10262/pdf/COMPS-10262.pdf*.
[120] M.R. MICHELI, *op. loc. cit.*
[121] G. PIRANI, *op. loc. cit.*
[122] F. RESCIGNO, *Esseri senzienti e sperimentazione: quali frontiere?*, in *BioLaw Journal - Rivista di BioDiritto*, 2, 2021, 6 s. On this topic see also L. COSTATO, *Benessere Animale, tra "misericordia" e giurisprudenza*, in *Riv. dir. alim.*, 3, 2021, 90; M.R. MICHELI, *op. cit.*, 1084.

of the different implementation of EU legislation. Indeed, the judicial cases analysis seems to confirm this trend at a jurisprudential level, overall favorable to animal testing, albeit with respect for animal protection.
In conclusion, it is conceivable that in the coming years, researchers will have more and more difficulty carrying out experiments on animals, as legislation, but above all case law, will give greater importance to the needs of animals than the interests of humans. But, currently, in the European Union, the judges of the Member States are not yet ready to radically modify the orientation substantially favorable to animal testing practices, also because supranational and State legislation leaves them a lot of space regarding balancing the different conflicting interests in this field.