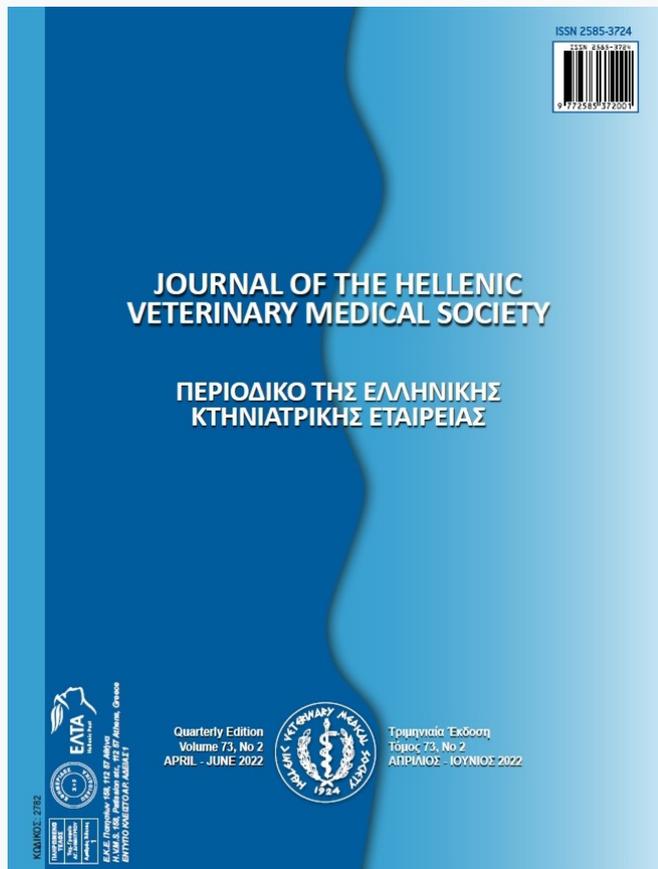


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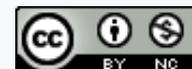


**The contribution of veterinarians to the implementation of legislation on the protection of animals used for scientific purposes in Greece.**

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## The contribution of veterinarians to the implementation of legislation on the protection of animals used for scientific purposes in Greece

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**ABSTRACT:** This article reviews the role of veterinarians in the implementation of Presidential Decree 56/2013, in harmonization to the European Directive 2010/63/EU, on the protection of animals used for scientific purposes in Greece. Veterinarians contribute to the implementation of the legislation as civil servants of the competent central and regional Veterinary Authorities, Designated Veterinarians of the breeder, supplier and user establishments, members of the Animal Welfare Bodies and Project Evaluation Committees, facility managers, researchers, teachers and trainers in laboratory animal science courses, and supervisors of competence of the personnel performing animal care and use procedures. Equally important is the participation of veterinarians as members of the National Committee for the Welfare of Animals Used for Scientific Purposes.

**Keywords:** designated veterinarian; Directive 2010/63/EU; Presidential Decree 56/2013; laboratory animals; animal use

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## INTRODUCTION

The use of animals for scientific purposes within the European Union is regulated by Directive 2010/63/EU, which was issued during 2010 by the European Parliament and Council. This Directive lays down the rules that regulate the care and use of animals used for scientific purposes and the authorization and inspection procedures related to animal experimentation. Many duties arise for the personnel and scientists involved in laboratory animal science. The significant contribution of veterinarians to the care of animals used for scientific purposes is raised in different parts of the Directive. In recital 30 it is clearly stated that *“to ensure the ongoing monitoring of animal-welfare needs, appropriate veterinary care should be available at all times and a staff member should be made responsible for the care and welfare of animals in each establishment”*. Veterinary examination and advice shall be provided in case of injury of animals captured from the wild (article 9), before any reuse of animals (article 16) and for the final decision either to keep or to euthanize an animal at the end of a procedure (article 17). Veterinary input shall be provided to the Animal Welfare Body (article 26) and the Project Evaluation Committee (article 38). Article 38 point 3 describes that *“the competent authority carrying out the project evaluation shall consider expertise in ... veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate”*. The discrete role of the veterinarian as “Designated Veterinarian” is mentioned in article 25, according to which: *“Member States shall ensure that each breeder, supplier and user establishment has a designated veterinarian with expertise in laboratory animal medicine or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals”* (Anonymous 2010a).

Member States had the obligation to adopt European Directive 2010/63 into their national legal framework until 2013. In Greece the European Directive was adopted by Presidential Decree (P.D.) 56 that was published in Greece at the Governmental Gazette A' 106 on April 30<sup>th</sup>, 2013 under the title “Adjustment of Hellenic legislation to the Directive 2010/63/EU of the European Parliament and Council of the 22<sup>nd</sup> September 2010 (L. 276/33/20.10.2010) on the protection of animals used for scientific purposes” (Anonymous 2013b).

This paper aims to present and analyze the different ways veterinarians are contributing to the imple-

mentation of the national law that regulates the protection of animals used for scientific purposes.

## COMPETENT VETERINARY AUTHORITIES

In Greece, the competent authorities for the implementation of P.D. 56/2013 are public veterinary authorities under the domain of the Ministry of Rural Development and Food and Regional Veterinary Departments.

In the central administrative level, the Division of Farm and Laboratory Animals' Welfare of the Directorate of Animal Welfare, Veterinary Drugs and Veterinary Applications (P.D. 56/2013) of the General Directorate for Veterinary Services of the Ministry of Rural Development and Food manages all issues related to animals used for scientific purposes. More specifically, the veterinarians of the above mentioned Division are charged (a) with the composition, completion, amendment and communication of all legal and administrative acts which concern the welfare of animals used for scientific purposes; (b) with the provision of scientific input and support to ensure the protection of animals bred, supplied or used for scientific purposes; (c) with the enactment of inspections, and (d) the resolution of any issues that arise from the implementation of the relevant legislation. They are responsible to ensure that regional veterinary services are updated, trained and equipped to enforce the subsequent duties and inspections, and to contribute to designing applications for data entry and support of the official inspections. Furthermore, they are competent for liaising with the European Commission and other international organizations and communicating relevant statistics and information (Anonymous 2017).

In the regional administrative level, the Departments for Veterinary Care, Drugs and Veterinary Applications of the Directorates of Agricultural and Veterinary Policy under the General Directorates of Agricultural Economy, Veterinary Medicine and Fishery of each Region, is charged with the support of the implementation of the legislation for the protection of animals used for scientific purposes. The veterinarians of the Departments have the competency for the authorization and registration of breeder, supplier and user establishments, the authorization of the research projects as well as the relevant inspections under P.D. 56/2013 (Anonymous 2018, 2013b, 2010b).

Each breeder, supplier or user establishment per-

taining to the Region must be authorized and registered by the Regional competent authority. The veterinarian of the Department receives the supporting documents, performs inspections of the establishments and issues the authorization of the establishment. The supporting documents consist of an application with information about the architectural design, the equipment, the animal species to be used and the provisions for their care, the way of record-keeping, the personnel, the designated veterinarian and the person responsible for the compliance to the legislation. Also, the members of the establishment's Project Evaluation Committee and Animal Welfare Body are stated, and the Department authorizes both committees. Following the authorization procedures, the state veterinarian is responsible for performing regular inspection visits - with or without prior warning. The establishment authorization should be renewed every five years (Anonymous 2013a, 2013b).

The competent authority must authorize each experimental project separately. The veterinarian of the regional Department receives the supporting documents and issues the project authorization. Before the authorization procedure, the establishment's Project Evaluation Committee evaluates each project. The veterinarian of the Department is a *de jure* member of this Committee (Anonymous 2013b).

Because of the crucial role of the competent veterinary authorities in the implementation of P.D. 56/2013 it is especially important to ensure veterinary staff is properly educated and trained. The Directorate of Animal Welfare, Veterinary Drugs and Veterinary Applications of the General Directorate for Veterinary Services of the Ministry of Rural Development and Food issues specific guidelines for the regional veterinary inspectors on how to perform an inspection of the breeder, supplier and user establishments highlighting critical points, which need to be checked. Either as legislators, or inspectors the state veterinarians need to be familiar with the principles of Good Laboratory Animal Practice.

### THE DESIGNATED VETERINARIANS

The duties and competencies of the designated veterinarian are clearly stated in P.D. 56/2013. Each breeder, supplier or user establishment is required to employ a designated veterinarian with expertise in laboratory animal medicine. The designated veterinarian is charged with advisory duties in relation to the well-being and treatment of the animals. The

expertise of the designated veterinarian should be proven by the possession of a master's degree of at least one year duration in laboratory animal science or laboratory animal medicine, a Ph.D. degree on a relevant subject, at least three years of experience on the subject or by the fulfillment of the minimum requirements of education and training for the personnel involved in animal experiments as described in article 22§3 and Annex V of the P.D.

The designated veterinarian usually assumes additional roles within the establishment, including veterinary and administrative duties arising from the care and use of animals, as well as technical procedures. According to P.D. 56/2013, the veterinarian is asked to examine animals injured during their capture from the wild, to decide whether an animal shall be kept alive at the end of procedures and to provide written veterinary input on the reuse of animals in procedures - which is decided by the competent authority. He/She may also be the responsible person (equivalent to manager) of the establishment, without prejudice to any conflict of interest.

The designated veterinarian of each establishment is the person assigned to supervise the veterinary care of the animals in the facility and to undertake duties in the Project Evaluation Committee and Animal Welfare Body as mandated by P.D. 56/2013. In Greece, the designated veterinarian and his/her deputy usually cover veterinary care of the animals. However, in large establishments, veterinary care may be provided by a team of laboratory animal veterinarians whose main task is the clinical veterinary care of laboratory animals (Hasenau 2021). In the future, the demand for specialized laboratory animal veterinarians will increase due to the rapid development of biomedical research in our country.

### VETERINARIANS AS MEMBERS OF THE ANIMAL WELFARE BODY AND PROJECT EVALUATION COMMITTEE

All breeder, supplier and user establishments must set up an Animal Welfare Body, a committee that has advisory duties on animal welfare and overlooks the animal procedures. The designated veterinarian of the establishment is a *de jure* member of the Animal Welfare Body according to P.D. 56/2013. Additionally, the designated veterinarian is recognized as the individual who will disseminate the necessary information to the other members of the Animal Welfare Body. The designated veterinarian as a member of the Animal

Welfare Body supervises the performance of animal experimentations. He/she also has the power and the duty to terminate any procedures causing unexpected pain, suffering or distress to the animals. The role of veterinarians in the Animal Welfare Body is also very important for the development of a Culture of Care program within the establishment (European Commission 2014b, Robinson *et al.* 2020).

All user establishments have to establish a Project Evaluation Committee, which reviews all project applications in compliance to the criteria set by the legislation. A favorable report by the Project Evaluation Committee is necessary to be submitted along with the application for project authorization to the competent authority. Both the designated veterinarian and the state veterinarian of the regional Department *are de jure* members of the Project Evaluation Committee according to P.D. 56/2013. As a result, at least two veterinarians participate in the project evaluation process.

As clarified in the “Commentary Circular 2215/117550 of 01/10/2013 on the implementation of P.D. 56/2013 on the protection of animals used for scientific purposes”, the members of the Project Evaluation Committee must not participate in any way in the scientific work produced by the projects they evaluate, to avoid any conflicts of interest. Therefore, when the designated veterinarian participates in the Project Evaluation Committee, he/she cannot be part of any publications of the specific project. For this reason, a substitute veterinarian may participate in the Project Evaluation Committee in such cases, or when the designated veterinarian is unavailable (Anonymous 2013a).

It has to be underlined that the contribution of both the designated veterinarian and the state veterinarian, as members of the Project Evaluation Committee, is very important for compliance with the requirements for the refinement of procedures. Veterinary input is necessary for the evaluation of the adequacy of anesthetic and analgesic protocols, the selection of refined methods for all procedures according to good veterinary practice, the selection of appropriate humane endpoints and the severity assessment of experimental procedures for the harm-benefit evaluation of projects.

## **VETERINARIANS AS BIOMEDICAL RESEARCHERS**

Veterinary medicine and science have a broad

spectrum of disciplines and equip their graduates with expertise, which allows them to take key roles in research. Many veterinary graduates seek alternative career paths, one of which is research-oriented. Veterinarians are employed as researchers in public or private institutions on a wide range of subjects. They participate in research groups or conduct animal research as part of their post-graduate studies. Veterinarians may be involved in all aspects of biomedical research. A veterinary degree is acceptable as a qualification enabling individuals to perform any of the four functions of research personnel described in the legislation: (a) carrying out procedures on animals, (b) designing procedures and projects, (c) taking care of animals, and (d) killing animals (European Commission 2014a, Anonymous 2013b).

P.D. 56/2013 defines three responsible people for each project: the person responsible for the overall project (equivalent to project manager, or principal investigator), the person responsible for the implementation of the project, and the person responsible for the compliance of the project to the terms of its authorization. A veterinarian may assume one or all of the above roles, since he/she may fulfill the prerequisites of being a university graduate of a relevant discipline, with knowledge of animal biology and experimental design. The P.D. 56/2013 further clarifies the competencies of people who will conduct experiments involving surgical procedures. Those researchers must hold a degree in biomedical sciences, and specifically, a degree of Medicine, Dentistry, Pharmacy, Veterinary Medicine, or Biology and they must either be responsible for the overall project or responsible for the implementation of the project (Anonymous 2013a, 2013b).

The Veterinary Consortium for Research Animal Care and Welfare suggests the term “research veterinarians” for those veterinarians whose main job includes conducting research (Hasenau 2021). Veterinarians seeking a career in research are increasing in Greece.

## **VETERINARIANS IN EDUCATION AND TRAINING**

The importance of adequate education and training of all involved in the care and use of laboratory animals is underlined throughout P.D. 56/2013.

As described in Article 22 of the P.D., “*the staff shall be adequately educated and trained before they*

*perform the four functions: (a) carrying out procedures on animals; (b) designing procedures and projects; (c) taking care of animals; or (d) killing animals. Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge. Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence".* Laboratory animal veterinarians due to their knowledge of the above subjects and the requirements described in Annex V, take the lead in organizing and delivering continuing education courses on the care and use of laboratory animals. Such courses are necessary for personnel and researchers to meet the education and training requirements of the P.D. 56/2013. Furthermore, designated veterinarians undertake the subsequent supervisory roles due to their status in the establishments.

According to Article 23, the person responsible for the establishment must ensure that the staff dealing with animals have access to information specific to the species housed in the establishment; and that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence. Designated veterinarians are usually assigned to undertake and/or coordinate these trainer and supervisor roles within the establishment.

In Article 24, the designated veterinarian is charged with advisory duties on issues regarding animal welfare and veterinary treatments. Additionally, the designated veterinarian takes a key advisory role as a member of the Animal Welfare Body and Project Evaluation Committee. These roles imply a direct and indirect role of the designated veterinarian in supervising all aspects of laboratory animal care and use and providing his/her professional consultation.

Furthermore, laboratory animal veterinarians employed in University establishments and institutions participate in the teaching of laboratory animal science and medicine lessons. Subjects of laboratory animal care and use, laboratory animal medicine and experimental surgery are taught as part of the graduate and post-graduate curriculum in Faculties of Medicine, Veterinary Medicine, Biology, Animal Technology, Medical Laboratory Technology and other biomedical sciences.

A background in veterinary studies allows veterinarians to have a deep understanding of animal-related topics, making them ideal candidates for being instructors or lecturers in laboratory animal science and medicine. A veterinarian specialized in laboratory animal medicine is competent to teach and train students, personnel and researchers in procedures related to animal use.

### **VETERINARIANS AS MEMBERS OF THE NATIONAL COMMITTEE FOR THE WELFARE OF ANIMALS USED FOR SCIENTIFIC PURPOSES**

According to Article 47 of P.D. 56/2013 (article 49 of the Directive 2010/63/EU), the Ministry of Rural Development and Food founds a National Committee for the Welfare of Animals Used for Scientific Purposes. The National Committee acts as an advisory board to the competent authorities, establishments, project evaluation committees and animal welfare bodies and reinforces the exchange of expertise and information. The Greek National Committee was introduced by Ministerial Decision (Anonymous 2016).

Scientists from different scientific fields including biology, medicine, veterinary science and law compose the National Committee. This allows to the members to have interesting discussions on different issues or problems related to the implementation of P.D. 56/2013 or the use of animals for scientific purposes in general. The National Committee comprises the President, ordinary members substitute members and serves for two years. One of the ordinary members is the state veterinarian of the central competent authority - who is, therefore, a *de jure* member of the national committee. In the first three appointments of the national committee, the President and an extensive proportion of the members were veterinarians with expertise in laboratory animal medicine (4/7 ordinary members and 4/6 substitute members for 2016 and 2018 appointments, 6/9 ordinary members and 5/8 substitute members for 2020 appointment) (Anonymous 2020, 2018, 2016, 2013b, 2010a).

Veterinarians are an integral part of the National Committee. Their role in this Committee is crucial as they facilitate the other scientists-members of the Committee to understand animal welfare and health issues. Many National Committee recommendations refer to issues of care and use of laboratory animals, for which veterinary input is necessary.

## COMPARING THE ROLE OF VETERINARIANS IN P.D. 56/2013, DIRECTIVE 2010/63/EU AND OTHER EUROPEAN GUIDELINES

A synopsis of veterinary roles as presented in the P.D.56/2013 and the Directive 2010/63/EU “on the protection of animals used for scientific purposes” is presented in Table 1. This comparison unveils that the P.D. adopts stricter provisions than the Directive regarding the role of the designated veterinarian, as it does not allow for other “suitably qualified experts” to undertake advisory duties in relation to the well-being and treatment of the animals in the establishments. Therefore, in Greece, all establishments must have a working relationship with a qualified designated veterinarian. Furthermore, the P.D. 56/2013 places designated veterinarians both in the Animal Welfare Body and Project Evaluation Committee, while the Directive allows as the minimum for their input to be considered. Additionally, the P.D. 56/2013 mentions specifically that the designated veterinarian may also be the person responsible for the facility. Also, it imposes stricter provisions for persons performing surgical procedures and recognizes veterinarians as one of the specialties equipped with adequate qualifications for this function. In other aspects when veterinary consultation is required for the care and accommodation of animals, for the veterinary treatment of injured animals, the reuse and end of procedures, the P.D. and Directive have the same provisions.

Further guidance for the role of veterinarians under Directive 2010/63/EU is summarized in the ESLAV/ECLAM/LAVA/EVERI working party report, which was invited by the European Commission (Poirier *et al.* 2015). In this document, the roles and responsibilities of veterinarians under the Directive 2010/63/EU are analyzed in more detail as providing: expert advice in laboratory animal medicine, input to the Animal Welfare Body, involvement in project evaluation, comprehensive veterinary care and health monitoring programme for the establishment, training, supervision and assessment of competences of other persons and advice regarding compliance to other veterinary regulations. Additional roles may include facility management, implementation of research projects, involvement in occupational health and safety programmes, ensuring access to information and compliance to the Directive. (Poirier *et al.* 2015) The additional roles described in this publication are undertaken by several of designated veterinarians of Greek establishments, although these are not formal-

ly mandated by the national legislation. Furthermore, veterinarians are involved in ensuring compliance with other aspects of veterinary legislation including animal health, animal byproducts and welfare during transport provisions.

The ESLAV/ECLAM/LAVA/EVERI recommendations underline that “veterinarians have professional, legal and ethical obligations to protect animal health and welfare and share the mission of ensuring high standards for the care and use of laboratory animals, through the continuing education, training, and postgraduate qualification of laboratory animal veterinarians” and suggest a specialized continuing education pathway for veterinarians involved in the field (Poirier *et al.* 2015). Veterinarians are encouraged to form their own continuous education goals (European Commission 2014a). The P.D. 56/2013 lists qualifications a veterinarian must have in order to be considered for a designated veterinarian position. The minimum standard is a continuous education laboratory animal science course with defined learning objectives, which may optionally be enhanced by 3 years of professional experience, and/or a master’s and/or Ph.D. degree in laboratory animal science and/or medicine. At the moment, there are no veterinary specialty qualifications on laboratory animal medicine recognized by the Greek state, although the European veterinary community endorses the Diploma of the European College of Laboratory Animal Medicine (ECLAM) which offers the title for European Veterinary Specialist™ in Laboratory Animal Medicine as recognized by the European Board of Veterinary Specialization (EBVS®). Nowadays, it is suggested that laboratory animal veterinarians attend a designated veterinarian introductory course, and subsequently seek specialized continuous education in laboratory animal science and medicine (European Commission 2014a, Poirier *et al.* 2015). Overall, veterinarians involved in laboratory animal science in Greece are active in networking and advancing their expertise and continuous education and most of them seek further specialization as described above.

## CONCLUDING REMARKS

Veterinarians take a variety of roles in the implementation of the national legislation on the protection of animals used for scientific purposes in Greece. P.D. 56/2013 has established a legal basis for the effective veterinary consultation in the care and use of laboratory animals thus recognizing the importance of veterinary input for the achievement of refinement. Fur-

**TABLE 1.** Synopsis of veterinary roles as presented in Presidential Decree (P.D.) 56/2013 and Directive 2010/63/EU “on the protection of animals used for scientific purposes”

Article of P.D.56/2013	Article of Directive 2010/63/EU	Content of the P.D. 56/2013 in contrast with the content of the Directive 2010/63/EU regarding veterinarians.
	Recital 30	Recital 30 of the Directive mentions “To ensure the ongoing monitoring of animal-welfare needs, appropriate veterinary care should be available at all times and a staff member should be made responsible for the care and welfare of animals in each establishment.” Recitals are not included in the P.D..
2 (§2)	59	<b>Competent authorities</b> The competent authorities for the implementation of the P.D. in Greece are a) the Directorate for Veterinary Care, Drugs and Veterinary Applications of the General Directorate for Veterinary Services of the Ministry of Rural Development and Food, as the central competent authority and b) the Peripheral Directorates of Veterinary Services and the Veterinary Services of the respective Region, as regional competent authorities. The Directive describes only general provisions, as competent authorities are designated by each member state.
8, 15, 16	9, 16, 17	<b>Animals taken from the wild, Reuse, End of the procedure</b> A veterinarian examines animals injured during their capture from the wild, provides written veterinary input regarding the reuse of animals in procedures, and decides whether an animal shall be kept alive at the end of a procedure. The veterinarian is the only competent person mentioned in the P.D. for those actions, whereas the Directive also recognizes other competent people.
23	24	<b>Specific requirements for personnel</b> The responsible person for the breeder, supplier or user establishment may be the designated veterinarian, without prejudice to any conflict of interest. This is clarified only in the P.D..
24	25	<b>Designated veterinarian</b> Each breeder, supplier and user has a designated veterinarian with expertise in laboratory animal medicine, charged with advisory duties in relation to the well-being and treatment of the animals. The expertise of the veterinarian in laboratory animal medicine is proven by the possession of a master’s degree of at least one 1 year duration in laboratory animal science and medicine, a Ph.D. on a subject related to laboratory animal medicine, at least 3 years of professional experience or fulfillment of the minimum requirements of training presented in the PD in article 22§3 and Annex V. A veterinarian is the only qualified expert recognized in the P.D. where as the Directive includes other competent people, and the above expertise criteria clarified only in the P.D.
25	26	<b>Animal Welfare Body</b> The designated veterinarian is a <i>de jure</i> member of the Animal Welfare Body and provides all necessary information to the other members. In the Directive, only his/her input is mandated.
37	38	<b>Project evaluation</b> The designated veterinarian is a <i>de jure</i> member of the Project Evaluation Committee of the establishment. This committee is not mentioned in the Directive. The Directive acknowledges that the competent authority carrying out the project evaluation shall consider expertise in veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate.
39	40	<b>Granting of project authorization</b> The person responsible for a project including surgical procedures may be a graduate of Veterinary Medicine (amongst other biomedical specialties). This is clarified only in the P.D..
Annex III	Annex III	<b>Requirements for establishments and the care and accommodation of animals</b> Animal enclosures may vary from the Directive or P.D. specifications when justified for veterinary reasons in consultation by veterinary staff.

ther empowerment of the roles of veterinarians will hopefully be implemented in the future.

Biomedical research is a sensitive and highly competitive scientific discipline. The involvement of veterinary professionals who are specialized in laboratory animal medicine is crucial both for the appropriate

care and use of these species and for the quality of the obtained experimental results.

## CONFLICT OF INTEREST STATEMENT

The authors report no conflict of interest.

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