

Sanitary Surveillance of veterinary facilities: an area in need of sanitary laws

Vigilância Sanitária de estabelecimentos veterinários: uma área carente de legislação sanitária

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ABSTRACT

Introduction: Veterinary facilities are those places where medical-veterinary procedures are performed. They are subject to sanitary surveillance actions. **Objective:** To discuss the lack of sanitary laws applicable to veterinary facilities, seeking to reflect upon the importance of such laws in the context of a Unified Health perspective. **Method:** This is a documental analysis study, whereby a set of documents has been selected and analyzed, particularly those arising from the Unified Health System and the National System of Sanitary Surveillance. **Results:** The activities carried out at veterinary facilities involve risks to the human health, animal health and environmental health. A legal framework, particularly at a federal level, is required to support the sanitary surveillance actions carried out at said facilities, which are not even regarded as health care centers according to the Ministry of Health. **Conclusions:** One can easily notice the lack and the need of a nationwide regulatory framework that understands and regards veterinary facilities as health care centers and that regulates and combines the sanitary surveillance actions performed thereat. Additionally, we understand that the mentioned said rules should be prepared under the Unified Health perspective, aiming at encompassing human health, environmental health and the animal health.

KEYWORDS: Sanitary Surveillance; Veterinary Medicine; Health Care Surveillance; Health Laws

RESUMO

Introdução: Estabelecimentos veterinários são aqueles onde são realizadas intervenções médico-veterinárias, sendo sujeitos às ações de vigilância sanitária. **Objetivo:** Discutir a carência de legislação sanitária incidente sobre esses estabelecimentos, buscando refletir sobre a importância da existência da mesma no contexto da Saúde Única. **Método:** Trata-se de estudo de análise documental em que foi selecionado e analisado um conjunto de documentos, com prioridade para os oriundos do Sistema Único de Saúde e do Sistema Nacional de Vigilância Sanitária. **Resultados:** As atividades desenvolvidas nos estabelecimentos veterinários envolvem riscos à saúde humana, animal e ambiental. Há carência de arcabouço jurídico, principalmente em nível federal, que dê suporte às ações da vigilância sanitária em relação a esses estabelecimentos, que sequer são considerados estabelecimentos de saúde, à luz do Ministério da Saúde. **Conclusões:** Tornam-se muito perceptíveis a carência e a necessidade de um arcabouço normativo em nível nacional que entenda e preveja esses estabelecimentos como estabelecimentos de saúde e normatize e homogeneíze as ações de vigilância sanitária realizadas em relação a eles. Além disso, entende-se que tais normas devam ser elaboradas sob a perspectiva da Saúde Única, visando contemplar tanto a saúde humana, como a ambiental e dos animais.

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INTRODUCTION

The act of caring for animals has always existed throughout the history of mankind, as stated in the oldest historical records ever found. The professional responsible for this activity has received several names throughout history, such as *mariscal*, *mulomedicus*, *farrier*, *maréchal*, *albeytar*, hipologist, animal healer, and veterinarian¹. The term veterinarian, which ended up denominating the profession until the present day, would have been used for the first time in the first century AD by the Roman Lucio Columela to designate the shepherds who cured animal diseases².

The epistemological rupture of the ancient practices of healing, which occurred even in colonial Brazil, for veterinary medicine, occurred with the Enlightenment and the adoption of the principles of rationality, when the first higher courses of veterinary medicine were created¹. In Brazil, the first appeared late, only in the beginning of the 20th century, in Olinda, Pernambuco, and in Rio de Janeiro³.

If, in the beginning and most of the time, veterinary medicine was dedicated to horses, as they were the most important animals for society in times past for their use for transport and in battles^{1,4}, it is increasingly specializing in the care of companion animals, such as dogs, cats, and domesticated wild animals.

Several studies around the world have shown these animals as family members, with people seeing them as their children, including them in social rituals, such as birthday celebrations. Another situation that deserves to be highlighted is the processes that run in the family courts regarding the custody of companion animals when their guardians are separated. Thus, they play significant roles in people's lives, invoking an ethic of care and responsibility, which is a characteristic feature of family relationships, and the social recognition of the multispecies family in postmodern family entities is irrefutable⁵.

Since 1932, under the Getúlio Vargas government, the practice of veterinary medicine has been regulated in Brazil⁶ and, since 1993, veterinary medicine has been recognized in Brazil as a health profession⁷. But veterinary establishments, even though they are on the list of establishments supervised by the Sanitary Surveillance, lack a legal framework that allows for harmonious action at the national level, especially in a One Health context, that is, with the inclusion of animals in the dimension that is due to them, from the epidemiological point of view and in relation to humans.

One Health can be understood as an approach in which human, environmental and other animal health are considered in an integrated manner, since they are, by nature, interconnected and inseparable⁸.

Such standardization becomes even more important when one considers that studies have demonstrated the failure to comply

with basic biosafety rules^{9,10} and sanitary surveillance rules by veterinary establishments in Brazil¹¹.

In the meantime, it is essential to highlight the importance of zoonoses, as diseases transmitted between vertebrate animals and humans, in the current health scenario. They represent an important part of the number of emerging and reemerging infectious diseases that have been affecting humans in recent years, delaying the epidemiological-demographic transition in emerging countries such as Brazil. In addition, they can have drastic long-term livelihood and economic effects^{12,13,14}.

Thus, the present work aimed to discuss the lack of a federal legal framework, seeking to reflect on the importance of the existence of these norms for veterinary establishments in the context of One Health.

METHOD

It is a work based on the methodology of document analysis. This method consists of a first phase, in which the location of sources and the selection of documents must be provided, and a second phase, in which the information collected must be treated and analyzed¹⁵. Therefore, a set of documents was selected with information on the issue to be discussed, namely, the lack of sanitary legislation on veterinary establishments, based on documents from the Unified Health System (SUS) and its National Health Surveillance System (SNVS), as well as the system formed by the Federal Council of Veterinary Medicine (CFMV) and the Regional Councils of Veterinary Medicine (CRMV).

Initially, a consultation was carried out on the legislation portal of the Brazilian Health Regulatory Agency - Anvisa (<http://portal.anvisa.gov.br/legislacao/>) in order to identify resolutions and ordinances related to health services that contemplated, formally excluded, or ignored veterinary establishments.

Then, a search was carried out on the CFMV and CRMV sites, seeking norms and documents that could provide tools for the discussion.

Finally, a survey was carried out using Google Scholar and the Regional Portal of the Virtual Health Library (VHL) as databases. The terms “vigilância sanitária” (sanitary surveillance) AND “estabelecimentos veterinários” (veterinary establishments) and “legislação sanitária” (sanitary legislation) AND “estabelecimentos veterinários” (veterinary establishments) were used. The search time was not established because it was considered that the subject is poorly researched.

In the VHL Regional Portal, no results were obtained with the search terms. In Google Scholar, 91 results were found, but only one that addressed the issue of health legislation itself.

Based on these key documents, a discussion was prepared on the weaknesses found and the lack of legislation at the national level on the subject, focusing on the issue of One Health.



RESULTS AND DISCUSSION

Veterinary establishments are those where medical-veterinary interventions are carried out¹⁶.

The National Classification of Economic Activities (CNAE) aims to standardize economic information and tax control in the three spheres of government, seeking to improve the quality of information systems that serve as a basis for decisions and actions by the Government. According to the CNAE, all veterinary establishments (outpatient clinic, office, clinic, hospital, laboratory, and veterinary transport unit) receive the same code: Veterinary Activities CNAE 7500-1/00¹⁷.

According to Anvisa, veterinary activities (CNAE 7500-1/00) are classified as risk-dependent, but the norm classifies as high risk those establishments where there is use of controlled drugs, the existence of diagnostic imaging equipment and invasive procedures, for example¹⁸. In many veterinary establishments such realities can be found.

According to the Ministry of Health, veterinary establishments are not classified as health establishments, since they would only encompass those where human health actions and services are developed¹⁹. This situation persists even though, since 2018, there has been a recommendation by the National Health Council (CNS) for these establishments to be classified as health establishments in the federal regulations that regulate these establishments, as well as to be included in the National Registry of Health Establishments (CNES). The document also recommends that the Tripartite Inter-Management Commission (CIT) and Anvisa regulate the situation of veterinary establishments within the scope of the SNVS²⁰.

In this system, Anvisa is responsible, at the national level, for regulating the establishment and operation of services of interest to health, as well as regulating services that involve a risk to public health²¹.

Even so, Anvisa never established rules for the operation of veterinary establishments. According to the Agency, the role of Sanitary Surveillance in relation to these establishments would not be pacified at the national level, with different types of approaches in different federative entities²².

In fact, the inspection of medicines for veterinary use only, from a legal point of view, is the exclusive responsibility of the Ministry of Agriculture, Livestock and Supply (MAPA) and the state and district secretariats of agriculture²² and the state and district secretariats of agriculture and the supervision of the professional exercise is the responsibility of the professional councils of veterinary medicine²³.

But, according to Anvisa, the competence to inspect the structure of veterinary establishments would also fall to these councils, since there is a rule created by the CFMV with minimum requirements for their functioning, and agreements, covenants, or legislation can be made proposing alternative solutions, by mutual agreement between the institutions, redefining roles and

attributions and unifying the competence for the inspection of these establishments¹⁷.

The CFMV conceptualizes and establishes operating conditions, according to the complexity, of the different types of care establishments for small pets, namely: office, outpatient, clinic, and veterinary hospital. Among these conditions are listed the environments, physical structure, and minimum mandatory equipment in each type of establishment. In addition, it provides for the good practices necessary for the operation of establishments, involving: storage conditions for medicines, vaccines, antigens, and other biological materials; the storage conditions of food for humans and animals; waste management; dirty and clean, critical and non-critical area flows; the storage and writing management of controlled medicines for animal or human use; the conditions of conservation, safety, organization, comfort, and cleanliness of the physical, internal, and external facilities; suitable furniture covering materials; the disinfection and sterilization processes of materials and equipment; vector control actions and synanthropic animals; the packaging and handling of expired, violated or suspected alteration or adulteration products¹.

It should be noted that this CFMV Resolution does not define or establish operating conditions for other veterinary establishments, such as laboratories, diagnostic imaging establishments, semen and blood banks, and veterinary transport units.

Therefore, some CRMV have been legislating on the subject. São Paulo's CRMV, for example, standardized the criteria for the installation and operation of mobile veterinary medical services (in vehicles and containers) in programmatic, emergency, or social actions, on which the federal regulation is silent²⁴. Rio de Janeiro's CRMV, on the other hand, created a resolution that deals with the functioning and proper functioning of veterinary establishments in the state, with structural and documentary requirements. The resolution also emphasizes its objective of guiding the actions of sanitary surveillance by the municipalities, seeking isonomy in the performance within the state²⁵. In addition, the CRMV-RJ regulated by resolution the installation and operation of the so-called Specialized Veterinary Services in the state, which involve diagnostic imaging, laboratory analyses, blood banks, and semen banks²⁶.

In 2009, a technical reference was published, in which it is printed in large letters and in red color "without legal value" and whose objective would only be to serve as guidance for state and municipal governments in the implementation of inspection actions of veterinary services, if they were not already working. The references would serve as suggestions and not as pre-conditions and would be based on the legislation in force at the time¹⁷.

According to the aforementioned technical reference, in veterinary establishments, it would be up to the Sanitary Surveillance, mainly, to act in relation to legal sanitary aspects that involve the prevention of injuries and risks to human health. This would encompass waste management, water supply, cleaning and



hygiene of the site, environmental protection, worker health, and the conditions of medicines of the human line¹⁷.

Anvisa outlined a series of recommendations to be observed by the Sanitary Surveillance licensors of veterinary establishments, such as the requirement of a sanitary permit consistent with the area of operation; issues related to radiation protection and worker health (Environmental Risk Prevention Program - PPR, Occupational Health Examination Program - PCMSO, and compliance with NR-32, for example); on the hygienic-sanitary conditions of the establishment, involving the state of conservation and cleanliness of the property, furniture, and equipment, as well as some structural details¹⁷.

These structural details included: ceiling, wall, and floor coverings; requirement for waterproof and intact furniture; presence of washbasins, liquid soap, and paper towels dispensers; bins without manual operation and with plastic bags; technical environments not serving as access to other technical environments; absence of fans in technical areas; compliance with legislation on operation, maintenance, and cleaning in air-conditioned environments; elaboration of Standard Operating Procedures (SOP) covering the activities performed and available to health professionals and inspectors; covered access to technical areas and environments; characteristics and frequency of cleaning of water reservoirs; and waste management. In several situations, the Resolution of the Collegiate Board of Directors (RDC) of Anvisa n° 50, of February 22, 2002, was cited as a reference for the recommendations in this Anvisa¹⁷ document.

RDC Anvisa n° 50/2002 deals with physical health care projects and provides that all health care establishments must comply with it, but at no time does it deal directly with veterinary establishments²⁷. However, if federal legislation emphasizes that, despite being subject to the action of sanitary surveillance, animal health establishments should not be considered health establishments¹⁹, there is no justification for using this resolution for veterinary establishments. Despite this, it is mentioned in Anvisa's technical reference for veterinary establishments¹⁷ and in several other standards.

Minas Gerais' CRMV, for example, in its Technical Responsibility Manual informs that the technicians responsible for veterinary establishments must make them comply with the legislation pertinent to the area, referring, also among them, to RDC Anvisa n° 50/2002²⁸.

The city of São Paulo also has a technical regulation on hygienic-sanitary conditions and good practices in veterinary establishments, involving the minimum requirements of facilities, the use of radiation, the use of medicines, zoonosis control, and operation. In its Art. the Ordinance of the São Paulo city hall makes it clear that sanitary surveillance actions deal especially with aspects of human health (workers, clientele, and population), having as a reference, once again, the RDC Anvisa n° 50/2002²⁹.

Regarding veterinary establishments that have diagnostic imaging services involving radioactivity, Anvisa advises that the prior

presentation of an architectural project to the municipal sanitary surveillance agency, as well as the Radioprotection Project, is required. These establishments must have included in their location permits the diagnostic imaging service code using ionizing radiation, except tomography CNAE 8640-2/05¹⁷.

In 2019, Anvisa published RDC n° 330, of December 20, which regulates these radiology services, including regarding the control of occupational and public exposure to radiological technologies³⁰. Unlike the previous regulation (Ordinance No. 453, of June 1, 1998), which also dealt with the subject, but was restricted to medical and dental purposes³¹ and was revoked, this includes veterinary radiology services (diagnostic or interventional) in the list of establishments that must comply with it, but making it clear that compliance with the norm must occur with regard to the protection of the health of workers and the public, without any mention of animal patients³⁰.

Regarding the use of medicines, it is known that in veterinary medicine, especially in the small animal clinic, both human and veterinary medicines are used, either for treatment or for sedation and anesthesia. According to Anvisa, it would be up to the Sanitary Surveillance to inspect the origin, expiration date, and storage and conservation conditions, as well as the requirements set out in the legislation for medicines and drugs for human use subject to special control, such as a restricted and keyed room or locker, proof of disposal and movement records. Despite the competence of agricultural agencies in relation to the inspection of medicines for veterinary use only, Anvisa recommends the action of the Sanitary Surveillance in relation to poor packaging and validity of products¹⁷.

The Ministry of Health empowers the health authorities of states, municipalities, and the Federal District to supervise the production, commercialization, and use of controlled medicines for human use, therefore, there are no doubts in this area³². But, regarding the issue of dispensing human medicines in veterinary establishments, the understanding is not pacified in the country.

Federal Law No. 13,021, of August 8, 2014, provides that the operation of pharmacies of any nature requires, mandatorily, the assistance and technical responsibility of a qualified pharmacist³³. The Sanitary Surveillance of some federative entities has been requiring this presence in veterinary establishments, but in the CFMV's understanding, such a requirement is not appropriate since the veterinary establishments would already have a veterinarian as the technical responsible. Thus, this situation has been raising questions on the part of the CFMV and establishments in Anvisa and in justice^{34,35}.

Also in this context, to pacify the understanding, the CFMV created a resolution, in 2020, aiming to regulate the actions and services related to the use of products intended for use in animals and delegating to the technical responsible veterinarian the responsibility for the custody, storage, distribution, prescription, fractionation, preparation, dilution, handling, and use of these products. In addition, there is a requirement for an appropriate location (restricted access, without exposure to the



public, and a locked environment), segregation and adequate destination for expired products and the bookkeeping and control of these products in accordance with the determinations of the Sanitary Surveillance and MAPA, according to the nature of the products³⁶. Even so, it is necessary to highlight the hierarchy of norms, in which a professional council resolution, as it is an infralegal norm, cannot, in theory, contradict a federal law, a primary norm³⁷.

Regarding waste management, RDC Anvisa n° 222, of March 28, 2018, is quite consistent and makes it very clear that veterinary establishments must comply with the requirements, as it applies to all health service waste generators, without differentiating administrative sphere or nature, regardless of whether or not it is a health service, but provided that it generates waste similar to those generated in these establishments. The Resolution goes further and classifies as generators of waste from health services all services that develop activities related to health care, whether human or animal³⁸.

Although Anvisa regulates good practices for the processing of health products, involving the Material and Sterilization Centers, once again, the standard excludes veterinary care services from the scope of application of the resolution³⁹.

Some federative entities have been regulating regarding veterinary establishments. The state of São Paulo has, since 1995, a Decree that provides for the minimum requirements for the installation of veterinary establishments, also involving the use of radiation, medicines, animal transit, and the control of zoonoses. It is a comprehensive standard that determines, for example, mandatory environments and their minimum dimensions, the conditions and materials used for covering floors and walls, devices for preventing synanthropic animals, sterilization equipment, devices to avoid noise and odor exhalation, among others. The Decree emphasizes the need for facilities to provide hygiene, comfort, and safety to animals and people⁴⁰.

In the new Sanitary Code of the city of Rio de Janeiro, there is a classification of activities subject to Sanitary Surveillance and veterinary establishments, including diagnostic establishments, classified as “establishments of interest in zoonosis surveillance” (chapter III) and not as “establishments of interest to sanitary surveillance” (chapter II), which includes establishments related to human health. This code delegates to the head of the sub-secretariat responsible for sanitary surveillance and zoonoses control actions the issue of regulations with the requirements foreseen for each type of establishment, in view of their particularities⁴¹.

When, in 2018, the CNS recommended the inclusion of veterinary establishments in the list of health establishments and their regulation by Anvisa, it outlined very well a rationale that justifies such inclusion, involving the risk of zoonoses (including the high percentage of mandatory notification); the use of ionizing radiation, chemotherapeutics, contrasts, and controlled drugs of the human line and the environmental and occupational risk of the use of certain types of drugs such as

antineoplastics that can cause neoplasms, genetic mutation, and fetal malformation²⁰.

According to RDC Anvisa n° 153, of April 26, 2017, all economic activities of sanitary interest must be subject to risk management and application of good sanitary practices⁴², but how to fulfill such requirements in the absence of specific legislation?

Cordeiro et al.⁴³ reported exactly the difficulties that can arise in the actions of sanitary surveillance in view of the myriad of existing laws and regulations, which may not cover all the necessary aspects, as well as in relation to the possible contradiction between them.

In addition, a paradigm shift in the SNVS is important in order to recognize the importance of companion animals as part of the family nucleus, adapting the actions to the concept of One Health.

In the contemporary multispecies family, what permeates the relationship between humans and other animals is no longer the heritage element, but affection, which enables this union around a nucleus, forming the family. Companion animals are already recognized as members of the multispecies family in the national legal system⁴⁴. They began to function in the symbolic order of the family, and in this multispecies relationship, humans must take care of animals, contemplating their real needs⁴⁵, since this family configuration involves a relationship of protection, trust, and well-being and, in this context, humans, as animals endowed with greater “rationality”, must be responsible for protecting the interests of companion animals. Thus, the principle of responsible parenting, *mutatis mutandis*, can be applied to the duty of care between guardians and their companion animals⁴⁶.

Pastori⁴⁷ states that tutors seek to extend the lives of their companion animals, given the affectionate relationship between them, even though this requires significant expenses. This new conformation and new way of relating in itself would justify the Sanitary Surveillance acting with the same vision in relation to the protection of human life and other animals.

But in a One Health approach, which is even proposed and encouraged by the World Health Organization, the inseparability of environmental, human and other animal health is considered, unifying health care⁴⁸. In this aspect, Couto and Brandespim⁸ defended the importance that public health policies should be based on a legal framework that contemplates the One Health perspective. This aspect would ratify the need to be concerned with the health of animals from the perspective of sanitary surveillance legislation in relation to veterinary establishments.

CONCLUSIONS

In view of what has been presented and discussed, the lack of a national regulatory framework that understands and foresees veterinary establishments as health establishments and that



regulates and homogenizes the sanitary surveillance actions carried out by the different federative entities in relation to them, respecting, obviously, possible loco-regional peculiarities.

In addition, it is understood that such a normative framework must be built from the perspective of One Health, aiming to

contemplate both human, environmental, and animal health. Not that the requirements demanded in human and animal health establishments should be the same, but that there is a federal health legislation that also covers veterinary establishments, protecting their peculiarities, but contemplating everyone, and protecting everyone.

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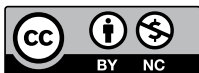
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Author's Contributions

Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. The author approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.



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