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INSTITUTO DE CIÊNCIAS BIOMÉDICAS ABEL SALAZAR
UNIVERSIDADE DO PORTO

Relatório Final de Estágio
Mestrado Integrado em Medicina Veterinária

**OIE's Zoning, review of the concept and proposal of a conceptual
model and an information system to report zones**

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Orientador(es)

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Abstract

Zoning is a concept, promoted by OIE, which recognizes that there can be different subpopulations with distinct health status in regards to a specific disease(s) within a country or region. Zoning allows the establishment of a zone, which is a geographical area containing a subpopulation with a distinct health status, proven through surveillance, maintained through a biosecurity plan, for the purpose of disease control and/or international trade. Even though the OIE is renowned for its ability to disseminate information about animal health issues and for promoting transparency, there is currently no database related to Zoning which has spatial and other relevant information available in a reliable way. To address that problem this work tried to do two main things. Develop a conceptual model in order to understand the main components of Zoning and the relationships between them and create a system, based on the conceptual model, capable of resolving the existing problem. As a basis for the development of the conceptual model, a comprehensive bibliography review was made followed by the development of a conceptual model. After the completion of the model it was used to create an information system to define and to report zones. To test both the model and the system, three case-studies and three use-cases were used. The case-studies evaluated both the conceptual model and the system while also served as the basis for creating the use-cases. The use-cases were needed to stress the system and, additionally, their outcome, maps with other related-zone data were used to show a typical output of the system. Both the conceptual model and the reporting system demonstrated good results and showed great potential in addressing the problem of transparency. Important to mention is the way the model and the system treat spatial information as well as the user-friendly aspect of the system.

Resumo

Zoning é um conceito promovido pela OIE, e que reconhece que podem haver dentro do mesmo país ou região várias subpopulações diferentes. Por subpopulações diferentes subentende-se que diferem em termos de estatuto sanitário em relação a uma determinada doença(s). Zoning permite o estabelecimento de uma zona para o controlo de doenças e/ou facilitar o comércio internacional. Uma zona é uma área geográfica que contém uma subpopulação com um estatuto sanitário distinto e que é mantido através de um plano de biossegurança. Apesar de a OIE promover a disseminação de informação sobre assuntos relacionados com a sanidade animal e transparência nas acções dos seus Países-Membros, a verdade é que não existe neste momento nenhuma base de dados relacionada com Zoning que seja capaz de providenciar informação espacial, entre outras relevantes, de forma eficiente. Este trabalho tenta abordar esse problema da seguinte maneira. Primeiro, desenvolver um modelo conceptual que demonstre os componentes que formam o conceito de Zoning e as relações entre si. Segundo, criar um sistema para reportar informação sobre zonas. Para desenvolver o modelo, foi feita uma revisão da literatura sobre Zoning. Depois o modelo conceptual foi desenvolvido e foi criado o sistema de informação. Três estudos de caso e três casos-de-uso foram usados para testar o modelo e o sistema. Os estudos de caso serviram para avaliar o modelo e o sistema, além de base para criar os casos-de-uso. Esses foram usados para testar a integridade do sistema e, também, para providenciarem um resultado concreto do sistema. Tanto o modelo conceptual como o sistema mostraram bons resultados em geral, e mostraram grande potencial para atacar o problema levantado neste trabalho. A maneira como o modelo e o sistema tratam a informação espacial e o carácter user-friendly do sistema são as características mais relevantes e fortes dos resultados deste trabalho.

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Introduction

According to the OIE Terrestrial Code, Zoning or regionalisation, is a procedure implemented by a Member Country under the provisions of the relevant chapters of the Terrestrial Code with a view to define subpopulations, on a geographical basis, of distinct health status within its territory for the purpose of disease control and/or international trade (OIE, 2013). In other words, it is a concept based on the separation of the animals within a defined area from the animals outside of it due to a difference of the health status between them regarding a specific disease(s). This is achieved by defining a geographical area, and its boundaries, and also by developing and applying a biosecurity plan. The procedure will always be slightly different depending on the relevant disease(s) and the particular situation of the zone and country (Bruschke & Vallat, 2008).

This concept was introduced, by OIE, because of the difficulties that many Member Countries had to eradicate disease from the whole country or to maintain the free-status even if they achieve the eradication of the disease. This happened because the country was viewed as a single area with one global health status (Bruschke & Vallat, 2008). Zoning is a concept that allows for more dynamism when evaluating the animal health status of a country, permitting it to be fairer and less punitive because it considers the possibility of the existence of different health status in the same country. It is also important to notice that it is closely related to Compartmentalisation because both concepts are tools that increase the flexibility of the OIE guidelines and recommendations regarding the country's health status (Bruckner, 2013).

The use of Zoning in Veterinarian Public Health is widespread. For instance, in the European Union because it is extensively applied, and with different objectives. It is employed as the basis for the EU common market for live animals and animal-based products, in which each country functions as an independent zone albeit it is single economic market. Zoning is present in the EU legislation as a control measure for several diseases (Gemmeke et al.2008), i.e. the establishment of a restriction area in an outbreak of avian influenza (EC, 2005), and it is also applied in various disease eradication programmes (Bruschke & Vallat, 2008). It is important to notice that the concept of Zoning was already used before the OIE adopted and refined it for international trade. Although in an informal way, it was applied as a tool in the control and eradication of diseases in order to allocate limited funds for control and eradication programmes on certain zones, depending on their epidemiological situation or economic importance, (Saraiva-Vieira, 2003) and to tailor the programmes to fit the different challenges posed by each zone within a country (Livingstone et al., 2006). Zoning is essentially a disease control tool, but it is used for international trade due to its capacity to provide the necessary trust needed to import animals and animal products safely from the sanitary point of view.

In order to understand this concept one needs to see the context in which it is involved, which includes, the OIE and the Sanitary and Phytosanitary agreement (WTO, 2014). The SPS agreement was one of several agreements created when the World Trade Organization (WTO) was formed on 1st January 1995(WTO, 2014). The SPS agreement has the objective of making all decisions regarding agricultural products science-based as to avoid needless trade barriers. It also advocates the use of international standards and, in regards to animal health, it is OIE the chosen organization for it, without neglecting safety (Thiermann, 2011; Zepeda et al., 2005). The SPS agreement makes reference to Zoning in article 6 (Adaptation of regional conditions, including pest- or disease-free areas), point 1 (Zoning and regionalisation), and the most important idea to retain is that Members of the WTO should recognize the concept of areas with distinct health status. In other words, they should recognize the concept of Zoning(WTO, 2014).

The SPS agreement also refers to other important aspects, namely the harmonisation of the sanitary measures and the transparency of the sanitary information (Thiermann, 2004). Both OIE and WTO, through the SPS agreement, consider harmonisation and transparency essential values to be upheld by Member-Countries. The OIE, in particular due to its task of collecting and then providing international information about animal health through information systems, is a great promoter of those values that are essential to the task (OIE, 2013; WTO, 2014). Those information systems are dependent on those values discussed above because there is a need of harmonisation to input the data in the system and due to the need of transparency to have reliable information on the database (Blajan & Chillaud, 1991). For Zoning there are some issues with harmonisation, like the terminology problem that is addressed later in this work, but primarily transparency problems due to the inexistence of a database with spatial and other relevant information, about the zones created, maintained, changed or terminated within the Member-Countries. The development of a reporting system addresses the problem of the transparency because it creates a database with reliable and easily accessed information.

This work was done during a four-month internship at the Istituto Zooprofilattico Sperimentale delle Venezie which is a national public health institute with the following missions assigned: (i) diagnosis of animal zoonotic diseases; (ii) epidemiological surveillance; (iii) research; (iv) support and assistance in animal disease control and improvement in animal production. Its context in Italian veterinary services can be seen in Figure9 on Annex II. It is also an OIE collaborating centre and it was this role that was the driving force for this work.

The objective of this work is to create an information framework to address the transparency problems resultant of the lack of relevant information and its dissemination in the context of zoning. In order to achieve this goal three things were done. The concept was reviewed and

clarified, a conceptual model was developed and, finally, the prototype of an information system was created.

This work starts with an introduction, followed by the following chapters: material and methods, the results achieved and the discussion. It also contains two annexes, the first with the case-studies and the second with a diagram of the veterinary services organization in Italy.

Material and Methods

Procedure to produce a comprehensive review the concept of Zoning

The collection of bibliographical references included the OIE Terrestrial Code 2013 and relevant scientific publications found in Web of Science™ and in OIE-related publications. The method of collection and selection of relevant articles differed between Web of Science™ and OIE-related publications.

In regards to Web of Science™, the search terms used were “zoning”, “regionalisation”, “protection zone”, “containment zone”, “surveillance zone”, “restriction zone” and “buffer zone”. Each search term was then complemented by filtering only the articles associated to Veterinary Sciences. Additionally the search terms “zoning” and “regionalisation” were refined by adding the term “OIE” in order to discard the great quantity of irrelevant publication presented by the search.

The OIE-related publications were searched manually through the repository of articles in the OIE website.

All articles found were selected after an evaluation of their relevance first by the title then by the abstract and finally by reading the full article. Articles were included in the review either if they mentioned Zoning in an unequivocal way or if they reported an application of the concept to real-life situations.

The OIE Terrestrial Code 2013 and the articles were then used to understand the concept and identify the components that are part of it and how do they relate to each other. That information was then used to feed the conceptual model.

The procedure to develop the Conceptual Model

Spatial information has the purpose to communicate knowledge about “where” a thing is and “what” is at some location. In the veterinary domain, spatial components are usually defined with only a couple of coordinates (Durr & Froggatt, 2002). One of the techniques used to create efficient and consistent spatial information is conceptual modelling (Kuhn, 2005). The

conceptual model applied in a spatial information context improves the clarity of the concept and problems related, it provides a formal model which can be used to communicate in a harmonised way and also allows the easy upgrade and management of the system and database. Last but not least, the model created can be used in other systems.(Nativi & Federeci, 1994).

A conceptual modelling approach was used to define two different models: an Essential Model, and an Abstract Model. The Essential model provides a description of how the system is conceptualized, and allows the establishment of a conceptual linkage between the system design and the real world. The Abstract model takes into consideration the objectives, inputs, outputs, content, and assumptions to complete the conceptual model (Kotiadis & Robinson, 2008; Kottman & Reed, 2009).

The essential model was developed using the results of the bibliographical review on Zoning. It consisted in a description, in natural language, of the phenomenon (i.e. Zoning). The Abstract Model is a description of how the phenomenon will be represented and structured in the information system. To develop the Abstract model tools such as the UML, E-R schema and GIS software were used (see below).

Unified Modeling Language

Unified Modeling Language (UML) is a standard language for specifying, visualizing, constructing and documenting a conceptual model. In particular with the UML it is possible to capture the important concepts (represented by classes) and relationships (represented by associations) in some domain.

The building of the conceptual model was based on the UML meta-model as specified in the UML reference manual (Booch, 1999). The Class Diagram was not only used for visualizing, describing and documenting different aspects of a system but also for building the database structure. The Class Diagram allows the description of the attributes and operations of a class and also the constraints imposed on the system.

The expected outcome is a UML meta- model to be used to define the Entity-Relationship schema.

Entity-Relationship Schema

An Entity-Relationship (ER) schema is a representation of data within a domain. The ER schema allows the definition of the logical model of a process, by describing how entities relate

to each other. In ER modeling, the term entity can also be described as "table", "database table", "entity-type". Each entity consists of a set of columns (attributes), which describes the properties of the entity itself. Relationships are essentially links between different entities. Examples of relationships include: one-to-one, one to many, and many to many (Elmasri & Navathe, 2000). A one to one relationship means that an entity refers to another entity, and to each object of the former corresponds a single object of the second entity. In a one to many relationships to each object of the first entity may correspond more than one object in the second entity. Finally a relationship is considered as many to many when more objects of the first entity may be connected to more than objects in the second entity (Elmasri & Navathe, 2000).

Using UML to describe the conceptual model of the Zone and then the ER process one can create the logical model of the zone. The next step is transforming the logical model defined with the ER schema into an initial physical data model upon which it is possible to elaborate and build the Geodatabase into a GIS software.

Geographic Information Systems

The term Geographic Information Systems (GIS) is applied to systems that perform a computational analysis of geographic data. The main difference between GIS and a conventional information system is the ability of GIS to store both the descriptive attributes and the geometries of different types of spatial data. The use of GIS has grown and continues to grow rapidly throughout the world due to advances in hardware and software, and to the increasingly easier access to these technologies. The main component of a GIS is the geographic database, which allows to structure and store data in order to analyse spatial data. Applications developed with GIS are highly complex and a major problem in developing these applications has been designing the spatial data structure (Foote & Lynch, 2000).

The conceptual model developed was used to create coherent and efficient spatial information, allowing the extraction of information related to different type of Zones in a public health context.

The QGIS open-source software ver. 2.2.0 (QGIS Development Team, 2014) was used for the analysis of the Zoning geographical information.

Case-studies and Use-Cases

Three case studies were chosen to test the response of the conceptual model under real-life circumstances. These events were extracted from experiences that Italy had in dealing with infectious diseases and in international trade. A case-study is essentially a descriptive analysis

of an event, which may have various aims such as to test and/or explain a method or a concept(Yin, 2009).

In the context of this study the main targets were: (i) to understand if the conceptual model, and by consequence the system, permitted and handled the input of information; (ii) to provide a reference to compare the output of the system with the information contained in the source; and (iii) provide the base for a simplified use-case to stress and evaluate the system.

A use-case describes the interactions that occur between a system and an actor, to reach a particular goal. A complete set of use cases specifies all the possible uses of the system, defining how the system would reply to the different queries, ultimately determining the scope of the system(Cockburn, 2001). The use-cases created to evaluate the system are simple because they are conditioned by the objectives of the case-studies and because a complex set of use-cases is essential from a technical point of view but not from a conceptual one, for that, simple queries to the system are enough.

The considered use-cases were structured as follows:

- Use case identifier: Each use case was provided of a unique name suggesting its purpose
- Context: An imaginary context, inspired by real-world situations, in which the query could be asked
- Actors: A list of the actors involved in the use case
- Description of the goal: brief definition of the goal to be reached
- Output: A description of the result of the query
- Description: A brief description of the steps of the use-case

The case studies are reported in Annex I, where all the relevant information, the considered scenario and the type of zone implemented are described. The use-cases considered to obtain information from the conceptual model are provided in the results.

Results

Review of Zoning

Results of the Web of Science™ search can be seen in Table 1. Those publications were then analysed, except the ones discarded which are underlined in the table, and 17 of them were considered relevant, and included in the review. As to the results on the OIE-related

publications the search provided 14 articles. Out of all the publications retrieved, 31 were considered to be of interest for the review: 17 were classified as theoretical or general approaches to the concept, and 14 publications were considered as practical examples of Zoning (Table 2). In order to simplify the reporting of the results, publications found in both searches were only classified as OIE-related.

Search term	Filter 1 - Veterinary Sciences	Filter 2 - OIE	No. of articles
<u>“Zoning”</u>	yes	no	4129
“Zoning” 2	yes	yes	8
<u>“Regionalisation”</u>	yes	no	36
“Regionalisation” 2	yes	yes	2
“Protection zone”	yes	no	20
“Containment zone”	yes	no	1
“Surveillance zone”	yes	no	8
“Restriction zone”	yes	no	5
“Buffer zone”	yes	no	28

Table 1 Search terms used in Web of Science™, the filters applied and the number of articles retrieved (The search terms underlined are present only to understand why they were discarded)

	OIE-related publications	Web of Science™
General approach to Zoning	9	8
Practical example	5	9

Table 2 - Articles considered relevant and why, and the search engine that provided them

The analysis of the relevant bibliography allowed the identification of the components of Zoning and, in doing so, permitted the construction of the conceptual model.

Zoning

There are three main steps to be considered regarding the procedure to establish a zone:(i) the definition of the subpopulation;(ii) the definition of the geographical area;(iii) the planning and establishment of a biosecurity plan. Those steps are going to be described in the text below.

Then other related aspects of Zoning will be discussed in order to understand everything Zoning encompasses and the context in which it works.(OIE, 2013)

Definition of the Subpopulation

Subpopulation is stated in the OIE Terrestrial Code as a distinct part of a population identifiable according to specific common animal health characteristics (OIE, 2013).

The questions that should be answered when defining a subpopulation are: its geographic location, the reasons why it was chosen (i.e. the health status), and what are the individuals that are part of it. Geographical area, surveillance and identification are what provide the answers (OIE, 2013).In Zoning the definition of the geographical area is the key element to determine the subpopulation, and its extent and boundaries are of particular importance (Bruschke & Vallat, 2008). Nevertheless also the other factors are important to define the subpopulation(OIE, 2013). In the following pages each of those components will be discussed and examples will be given to understand their relationship with Zoning.

- Identification and Traceability

According to the Terrestrial Code, traceability is the ability to follow an animal or group of animals during all stages of its life(OIE, 2013). To achieve that purpose a system of unique and secure identification is fundamental, based on tamper-proof/tamper-evident identifiers which are linked to a database (McGrann & Wiseman, 2001). This should consist in the combination of the identification and registration of either each individual animal, with a unique identifier, or collectively by its epidemiological unit or group, with a unique group identifier (OIE, 2013).

Both animal identification and animal traceability are tools that help to deal with animal health and food safety problems. They are fundamental for proper action planning, being it related to surveillance, vaccination programmes or movement restrictions among others (Caporale & Giovannini, 2001). Traceability and animal identification system are paramount in animal health, public health, and quality assurance programs (Barcos, 2001), as they allow Veterinary Services to consult data in a fast and reliable way, therefore permitting prompt actions. In the case of Zoning, it plays an important part in defining the subpopulation, guaranteeing a reliable system for movement control, helping the implementation and smooth running of surveillance and to prove the provenience of live animals and animal products from the specified zone.

- Surveillance

The Terrestrial Code defines surveillance as the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information so that action can be taken(OIE, 2013). The aims of surveillance include: demonstrating the

absence of a disease, determine the presence and/or distribution of a disease, or to detect early the introduction and spreading of exotic or emerging diseases (OIE, 2013). A surveillance system may involve one or more component activities of surveillance that generate information on the health or disease status of animal populations (OIE, 2013); this is the case of an early detection system for Bluetongue implemented in Switzerland, which includes two surveillance activities, passive clinical surveillance and targeted surveillance consisting on bulk milk testing on dairy cattle in high risk areas (Hadorn et al. 2009).

Most of the OIE listed diseases have specific guidelines regarding surveillance (Martin et al. 2007). So when designing a surveillance system for a specific disease, a Member Country should follow the general provisions of the Terrestrial Code and complement them with the specific guidelines contained in the relevant chapter (OIE, 2013).

In this work the word surveillance includes concepts from both surveillance and monitoring. It was done to simplify the terminology and because there is no mention of monitoring on the Zoning chapter, this does not mean that it is not used but probably it was also done to simplify wording as well(OIE, 2013).

Definition of a geographical area

The extent of a zone and its geographical limits should be established by the Veterinary Authority and should be based on natural (e.g. rivers and mountains), artificial (e.g. fences and roads), and/or legal/administrative boundaries (e.g. municipality borders). Moreover, the limits of the zone should be made public through official channels (OIE, 2013). Once established, the border of the area should be considered as biosecurity barriers (Livingstone et al., 2006).

The use of legal boundaries to define the geographical area is widely used, as in the case of the application of zoning in USA as to recognise and maintain the tuberculosis-free status of individual States (Livingstone et al., 2006). The reduced need for geographical analysis of the terrain and the fact that Veterinary Services are already organized within these boundaries may simplify the management of control measures. In Portugal, a similar approach was used to control and eradicate African Horse Sickness in 1989, when the different subpopulations were separated on the basis of provincial and county boundaries (Portas et al., 1999). Although this is a correct application of Zoning and may be appropriate for many cases, the overall result may be strongly improved when exploiting the geographical features of the area and the knowledge on the disease. In regards to tuberculosis, referenced before as an example of the use of administrative boundaries in USA, there are some cases where wildlife impairs the eradication of the disease and it is essential to acknowledge and analyse geography, relevant wildlife habitat and density and establish epidemiological-derived geographic zones. Even with the

same disease an efficient implementation of Zoning is dependent of different factors in each situation. In New Zealand some zones applied to control tuberculosis have boundaries defined based on the prevalence of tuberculosis in each area (Livingstone et al. 2006).

The outbreak, and following containment and eradication, of Equine Influenza in Australia shows the establishment of zones taking into account several factors. In this case administrative boundaries (e.g. Local Government Areas or Parishes) were used by the Veterinary Service to define the areas, while other geographical features (e.g.as roads, topography, national parks) were used to increase the efficiency of the zone (Scott-Orr, 2011).

Another example is the one of the Equine Disease Free Zone in Guangzhou, China. During the preparation for the Beijing 2008 Olympic Games there was a need to establish and maintain a zone guaranteeing the protection of the sanitary status of the high competition horses that were going to compete there (Murray 2009). The establishment of these areas took into account the geography, human activities located on the area and animal population densities and showed the different types of boundaries that can be used (Murray, 2010). The Equine Disease Free Zone (EDFZ) was based on the establishment of a Core Zone and a Surveillance Zone. The former consisted of a 5 km radius area, was fully fenced or enclosed and delimited by natural geographical features that provided high level of isolation; therefore both artificial natural boundaries were used. The Surveillance Zone occupied all the administrative division of Conghua City except the core zone, and was entirely based on the use of administrative boundaries (Murray, 2010).

The definition of the zone needs to be well-pondered. The epidemiology of the disease must be taken into account when defining an area (Fujita et al., 2004). The process is flexible and permits the use of a myriad of different geographical boundaries to allow for an easy and efficient application of the zone. But to achieve it the Veterinary Services must consider the disease, the ecology and the administrative aspects of the areas involved in the process.

Biosecurity Plan

The Terrestrial Code defines biosecurity plan as a plan that identifies potential pathways for the introduction and spread of disease in a zone or compartment, and describes the measures which are being or will be applied to mitigate the disease risks, if applicable, in accordance with the recommendations in the Terrestrial Code. This definition embraces a wide number of measures. The most important and/or common will be referred here.

- Movement Control

Movement Control is one of the most important components of Zoning. This happens because of the utmost necessity to separate the subpopulation from the rest of the population in order to prevent the introduction or spread of a disease.

Animal movement is one of the most relevant factors in the spread of diseases (Nöremark et al., 2011) and both the movement of livestock and wildlife are relevant. For example, studies in the UK demonstrate the important role that cattle movement has in the long-distance spread of Tuberculosis and the establishment of novel strains in new geographical areas (Fèvre et al., 2006). The same can be exemplified in regards to wildlife movement with the case of introduction of rabies in Mid-Atlantic States of the USA due to the translocation of racoons from Florida to Virginia for hunting purposes (Fèvre et al., 2006).

To implement movement restrictions there must be a legal basis, and to enforce it the Veterinary Services should make use of certification procedures and oversight to make sure it is correctly applied. Also it should be noted that the selection of the geographical boundaries should take into consideration movement restrictions, especially where wildlife is concerned. The most basic example of movement control can be found in the AHS-free zone in Cape Town, South Africa, where entrance of equines from higher risk areas to lower risk areas is prohibited, with the exception of horses that fulfil a number of requisites like identification, veterinary certification, etc(EC(a), 2008). Nevertheless, enforcing the movement restrictions can involve a myriad of things. In the Equine Disease Free Zone in Guangzhou, China, there was signage and three quarantine checkpoints to prevent unauthorised entry (Murray, 2010).

Movement control can also be used to prevent the spread of the disease from the zone, in this case a containment zone. That is the case of an outbreak of African Horse Sickness in Western Cape Province in South Africa. A movement ban was implemented one day after the test results came back positive and was lifted one month after the last confirmed case within the defined containment zone (Grewar et al., 2013).

- Surveillance (in the context of the biosecurity plan)

In this context, surveillance has the objective of detecting changes in the health status of the subpopulation and act accordingly. To do so, the great majority of surveillance activities in this context are non-random surveillance, like disease reporting and post-mortem inspections. One of the most important surveillance systems that may be included in the biosecurity plan of a zone is the early detection system which allows the detection of an exotic or emerging disease. This is particularly important since the extent of an epidemic depends on the period between the introduction of the disease and the moment it is first diagnosed (Backer et al., 2011). The early detection system is defined by the OIE Terrestrial Code as a system for the timely detection and identification of an incursion or emergence of diseases/infections in a country, zone or

compartment(OIE, 2013). An example of it can be found at the African Horse Sickness free-zone in Cape Town, South Africa, there is a surveillance system comprised of a monthly sero-epidemiological testing over the whole AHS free area and the surveillance zone. The death of an equine suspected to be due to an infectious disease are subject to an investigation comprising of an official necropsy and collection and analysis of relevant samples(EC(a), 2008).

- Vaccination

Vaccination is used to prevent the spread of disease in case of introduction of the pathogen (Windsor 2011)and to allow the entrance of an animal from a high risk area to a low risk area in order to prevent the possible spread of the pathogen caused by the introduction of that animal in the zone(EC(a), 2008).

- Biosecurity Measures

Biosecurity measures include an extensive number of different procedures implemented to control the introduction of pathogens into a population (OIE, 2013).

- Awareness Campaigns

These types of activities aim at informing veterinarians, animal health technicians, farmers, and the population about the disease. In doing so there is an improvement of the measures applied in the zone because the actors in the field (farmers, veterinarians, etc.)are more aware and informed. The activities may include technical training, mass media communication, and seminars (Windsor et al., 2011)

Type of Zones

There are several types of zones, which differ in the aim but have always the same final objective, to protect the health status of the subpopulation with lower risk. Table 3 reports the definitions of the different zone types, focusing on the differences between the concepts expressed in the OIE Terrestrial Code (OIE, 2013)and the definition reported in the proposal for the European Animal Health Legislation (EC(c), 2013)

	OIE Terrestrial Code	Animal Health Law
Zone	a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade	a clearly defined part of a Member State, third country or territory containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures

Free zone	a zone in which the absence of the disease under consideration has been demonstrated by the requirements specified in the Terrestrial Code for free status being met. Within the zone and at its borders, appropriate official veterinary control is effectively applied for animals and animal products, and their transportation	Zone that fulfils one or more of the conditions present in Article 36 (Disease-free Member States and zones) of Chapter 4 (Disease-free status)
Containment Zone	a defined zone around and including suspected or infected establishments, taking into account the epidemiological factors and results of investigations, where control measures to prevent the spread of the infection are applied	-
Protection Zone	a zone established to protect the health status of animals in a free country or free zone, from those in a country or zone of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or free zone. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance	a zone with one or more disease cases which is established after the official confirmation of an outbreak, and where disease control measures are applied in order to prevent the spread of the disease from that zone
Surveillance Zone	-	a zone, established after the official confirmation of an outbreak and which is situated around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from that zone and the protection zone
Restriction Zone	-	a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones

Table 3 - Definitions of zones by the OIE and the proposal for the new Animal Health Law

In order to harmonise the terminology used throughout the present study, only the definitions expressed in the OIE Terrestrial Code were considered. In each particular case, zone defined

using different terminology were reported to the OIE definitions. Using the case of OIE vs. European nomenclature: European's surveillance and restriction zones are equivalent to OIE's protection zones; the European's protection zone is equivalent to the OIE's containment zones.

Competent Authority

The responsible for a zone is the Veterinary Authority of the Member-Country. It is defined as the Governmental Authority of a Member Country that has the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code (OIE, 2013). Figure 1 shows how the different government levels work regarding a zone.

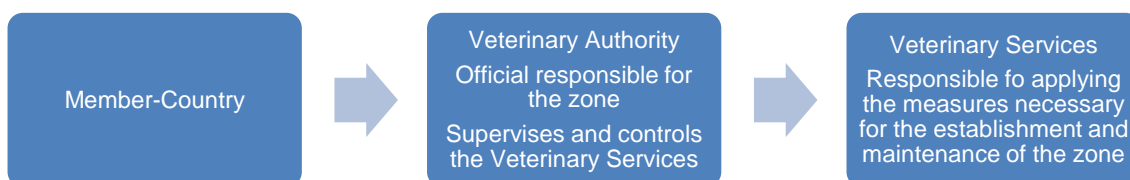


Figure 1 – Diagram of the authorities responsible for a zone and the relationships between them

Legal aspects

There are two levels when trying to understand the involvement of the legal system in a Zone. The first level includes the legal bases that allow the Veterinary Services to create a zone and establish the control measures necessary to maintain the zone. For example, in the case of Avian Influenza the Council Directive 2005/94/EC provides the European legal basis to create the zones and the necessary measures in order to contain outbreaks (EC, 2005). Then there is a need of transposing that Directive to the law of each country. For example, Decreto-Lei nº 110/2007 is the Portuguese transposition of the European Council Directive (Decreto-Lei nº 110/2007). In this work, due to its general approach, the national law was not considered unless it was inevitable. That means for example that in the case of outbreaks of avian influenza the Council Directive 2005/94/EC was considered the legal basis even though the real legal basis is the national law which transposed that Directive to the national legislation.

The second legal level refers to a specific zone, and has two main objectives: (i) it legally binds the authorities to the zone and the activities implemented there, and (ii) it makes the zone and its information available through public channels (OIE, 2013). The Decision Commission 2013/439/EU which defines the protection and surveillance zones in regards to the 1st outbreak of HPAI H7N7 in Emilia-Romagna province, Italy, is a perfect example of this type of legislation. The Decision includes the geographical extent and limits of the zones and the particular

measures which were applied and to whom (EC(b), 2013). It is also important to mention that those two levels may be contained in the same legislation act. This is the case of the AHS-free zone in Cape Town, South Africa, where the Animal Diseases Act 35 of 1984 as both the legal basis for the zone and the legal transposition of the zone (Animal Diseases Act 35 of 1984).

International Trade

The international trade aspect of Zoning is particularly complex, as it involves many non-veterinary related issues, and will not be thoroughly faced in this work.

The OIE Terrestrial Code needs to be as general as possible to encompass the differences between Member-Countries, therefore the measures included in the Code are essentially more recommendations than mandatory actions to be taken. What defines the zones are actually the different agreements between countries. Those treaties need to take into account all the factors involved, adapting general concept like Zoning to the specific conditions present in a particular situation. Nevertheless, the acceptance or rejection of the trade conditions may often take into account economic and/or political factors more than sanitary issues (Thiermann, 2004).

The OIE recommends a procedure for the acceptance of a zone between a importing and an exporting country. The general idea is that the exporting country provides all the relevant information to the importing country with all the detail and transparency needed. In turn the importing country evaluates the exporting country's Veterinary Services and makes a risk assessment based on the information given and finally accepts, rejects or asks for more information (OIE, 2013).

Conceptual Model

Essential Model

Taking into account this definition of the Terrestrial Code and the bibliographical review, it is possible to simplify and clarify the concepts related to Zoning and Zones. A zone is, at the same time, the functional unit and the output of the procedure. It is defined geographically and it contains a subpopulation, which consists of a specific species with a distinct health status regarding a specific disease(s). According to the aim, and the health status of the subpopulation, there are different types of zones (Table 3). Those zones may be related to others, or their type may change (e.g. due to an outbreak occurring in a free-zone). To establish and maintain the zones some activities should be put in place. These measures are applied to a target population, which can be all the subpopulation, part of it or another type of species. A legal framework should encompass all this procedure and activities.

Based on this, the concepts necessary to define a Zone are:

- Disease: the clinical and/or pathological manifestation of infection (OIE, 2013), or diseases that are related to the zone; each zone has to have a subpopulation of a distinct health status to a specific disease(s);
- Geography: location, extent and boundaries of the zone are an essential component of Zoning since it defines the zone itself;
- Subpopulation: is the cause of the procedure, and a key concept; subpopulations must be identified, which specie(s) are part of the subpopulation, and there should be a system for traceability;
- Action: measures which are being or will be applied to mitigate the disease risks; this concept is largely overlapping with the biosecurity plan for the zone;
- Legal framework: it enables the establishment and maintenance of the zone
- Relation with other areas: zones can be overlapping, within and/or adjacent to other zones which is important for their management, but most importantly they can be the result of other zones; for example, a protection zone, in regards to an HPAI outbreak, 21 days after cleansing and disinfection of the infected holding(s) turns to a surveillance zone (EC, 2005);
- Actor: the one who implements the procedure; in a general way it can be referred as the Member Country, but in a more particular way the responsible for the zone is the Veterinary Authority, defined by the Terrestrial Code as the Governmental Authority of a Member Country (OIE, 2013).

Abstract Model

The graphical description of the conceptual model is reported in Figure 2. The boxes represent the different classes which may be classified as: feature-type, data-type and code-list.

“Feature-type” in geographical information systems is intended as an object that can have a geographic location and other properties; on the contrary “data-type” only includes attributes and no geographic traits, while “code-list” represents a set of possible values that a data-type or a feature-type may have(OGC, 2014). In the model, the object Zone is intended as a defined geographic area, and has therefore been managed as a “feature type” to which other attributes are associated.

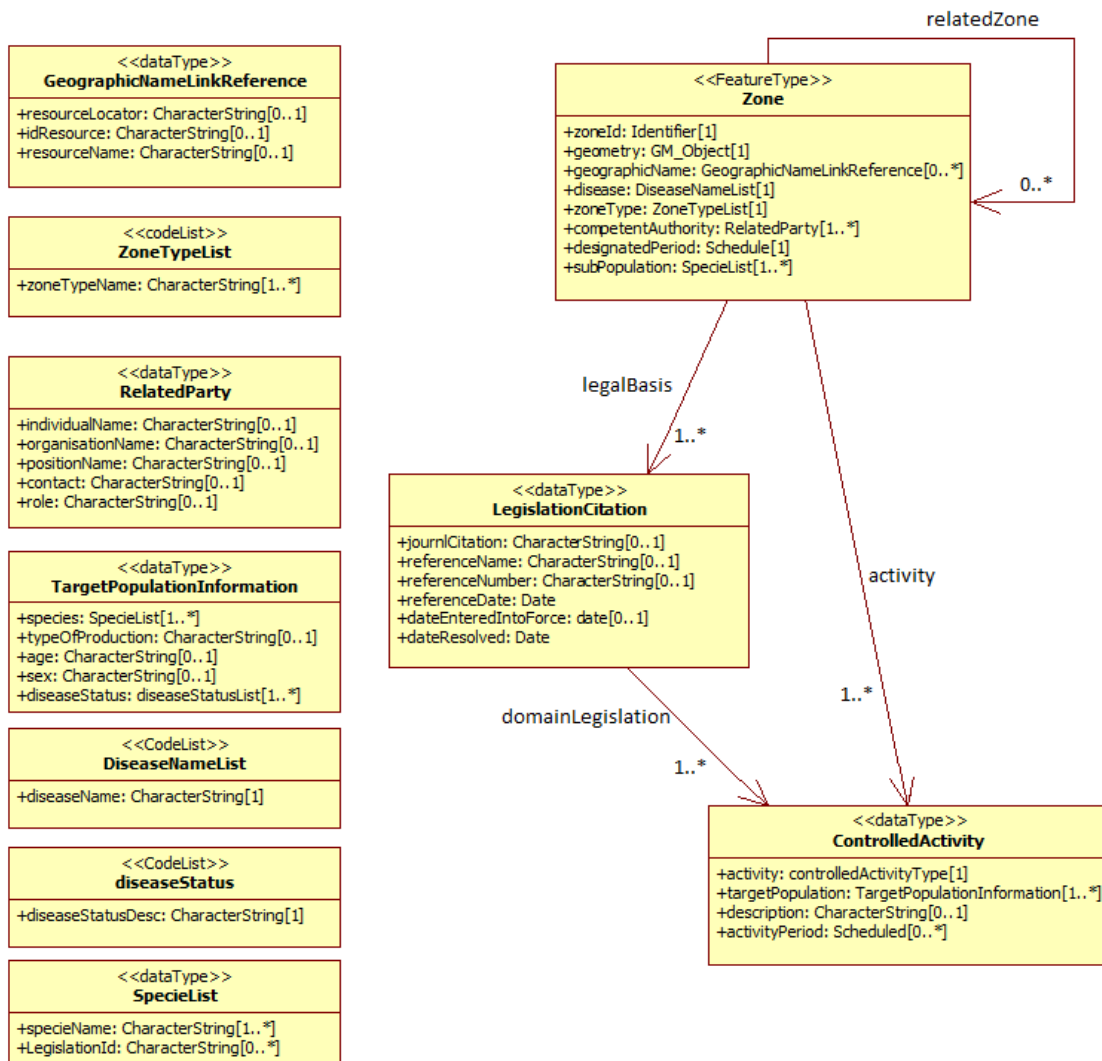


Figure 2 - Graphical description of the conceptual model created for reporting data on the application of zoning.

As shown in the schema, every object has attributes who describe them. Those attributes can be a type of data, like string, date, and gm_object (i.e. geometry object), or they can be expressed as a data-type, which is an object by itself with its own attributes. For example, the object SpeciesList is an example of a data-type and is described by SpeciesName, which is string type, and the attribute LegislationId.

The code-list class can be exemplified by ZoneType, which is the list of the different types zones can be.

The schema also reports the relations between the different classes (Figure 2). Each relation is represented by an arrow and/or a set of characters, which express how the two objects are related. Arrows are used to indicate the relations between Feature-types and another class (either a Feature-type or a Data-type) which is not among the attributes of the feature-types. On the contrary, relationships with attributes represented as data-type or code-list, are usually indicated with numbers and characters within squared brackets. For example the expression [1..1] means that a single element in a class may be related to a single other element in the second class (relation “one to one”), while [1.. *] means that an element of an object may be linked to several elements of the other object (relation “one to many”, e.g.....). If it is not mandatory that an element exists in the first object, the relationship is indicated as, for example, in a [0..*] or a [0..1] relationship, which essentially means that it is not necessary to specify which of the elements of the table is related to the either several ([0..*]) or a single ([0..1]) element of the second object.

Apart from the technical description, it can be observed that the abstract model follows what was achieved with the essential model. All the concepts that were considered crucial for Zoning, and therefore to report a zone, are present in this schema. In a simple and natural language what is shown in the schema is that a zone has attributes used to describe it, like geometry and competent authority, and is embodied in a legal framework in addition to a set of activities that take, or took, place in the zone. These activities are also embodied in a legal framework of their own.

Entity– Relationship schema

In the ER Schema the entities and the relationships between them were defined and can be seen in Figure 3.

For instance, the class Zone in the conceptual model has been translated into a table called “Zone”. The field “Zoneld” is then set as the *primary key* of the table (unequivocally identifying each different zone), which was mandatorily set to be not-null (i.e. if a zone exists, it has to have an unequivocal ID). A field “geometry” has been created to include the geographic details of each zone, as well as fields containing the attributes defined in the conceptual model. To simplify and streamline the operations to be taken on the database, all of the attributed were created as “text” type (i.e. all of them are expressed as character strings), with the exception of the “Schedule” field (showing the range of time in which the zone was enforced) that is defined using two different attributes of the type “date” (zoneFrom, and zoneTo).

All of the other entities were defined in a similar way. After the creation of the entities, the relationships were set, reflecting the restrictions imposed by the conceptual model. For example, considering the relation between Zone and DiseaseList (which is defined as a code-list class in the conceptual model, with its own *primary key* named “diseaseCod”) (Figure 3), a new field is created in the table Zone to manage the relation many to one. This field contains the same elements of the *primary key* of the table DiseaseList, and is called *foreign key*, and it is necessary to relate the entity “disease” to the entity “Zone”. Therefore a foreign key is essentially a column that allows uniquely identifying diseases in the DiseaseList table within a zone in the “Zone” table.

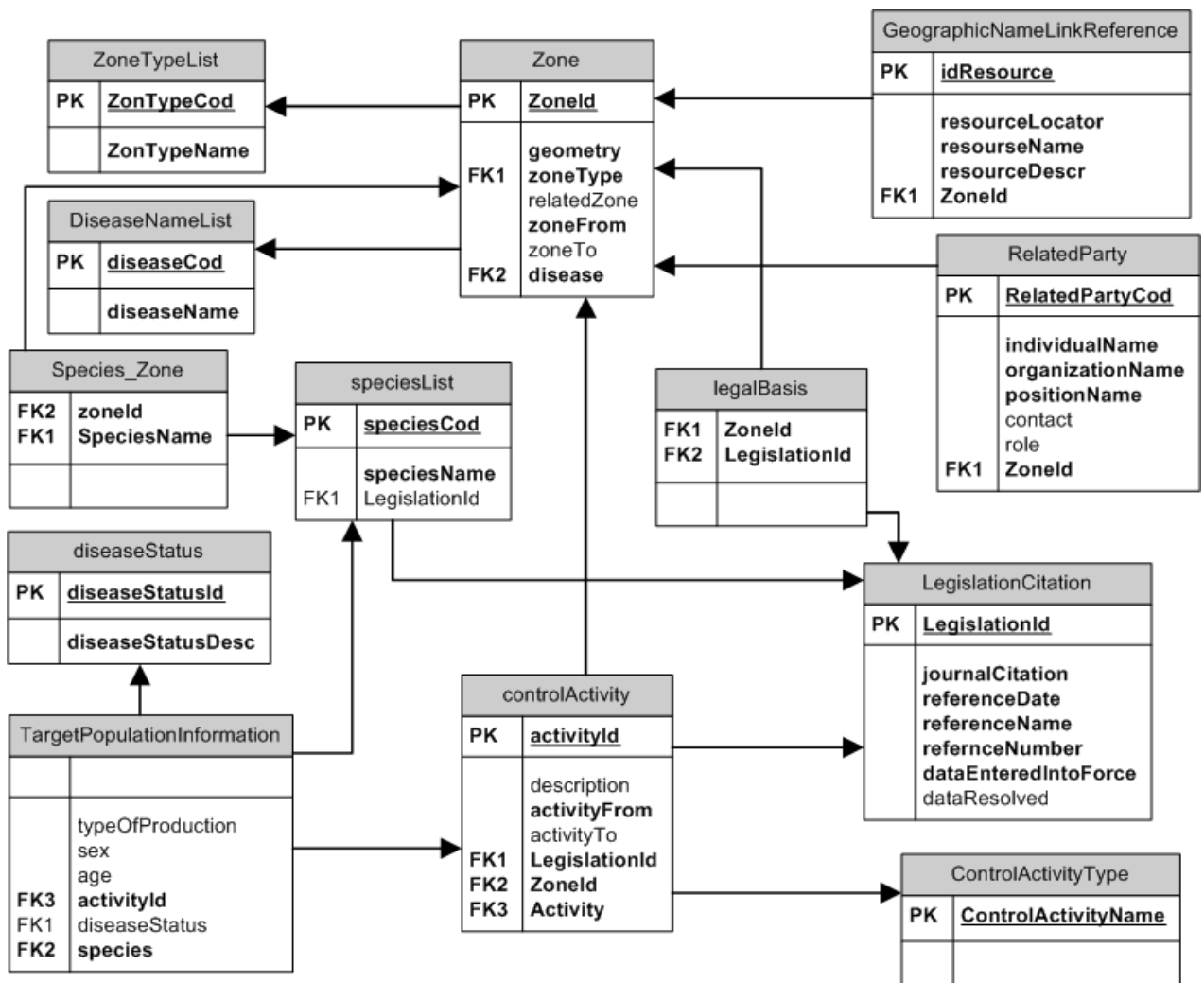


Figure 3 - Graphical representation of the Entity-relationship schema; arrows define the relationship between the entities, bold font represents non-optional fields (i.e. mandatory information). PK stands for Primary Key, and FK are Foreign Keys; the different numbers for the FKs design the use of the field as Foreign Keys in several tables.

Use-cases

In Table 3 it is shown the use-cases that were created.

Name	Primary Actor	Context	Goal	Output	Description
Use-case MR	Stakeholders	A stakeholder of a poultry company wants to have access to information about imposed movement restrictions in a fast and user-friendly way in order to help in its decision-making process	Visualize the zones with movement restrictions to certain species and consult the laws which allow and enforce those restrictions	Map with a visual representation of the zones with movement restrictions imposed on poultry during a specific time and a table with the legal basis which enables them	The user uses GIS to generate a map with a visual representation of the location and extent of the active containment zones in September 2013 and information about the measures applied, their legal basis and to whom
Use-case VA	Competent Authority	A competent authority wants to know if there are established zones in adjoining countries that could affect its country, in order to put measures in place if needed	Visualize the relevant zones of a certain outbreak in order to better manage disease control measures	Map with a visual representation of the zones related to a specific disease during a specific time and in a specific location	The user uses GIS to generate a map with a visual representation of the location and extent of the zones related to rabies in the months of april until june and that are near the Austrian border
Use-case FZ	Academic	An academic wants fast and reliable information about the health status of a country, and its zones	Visualize the active free-zones for a specific disease in order to understand the epidemiological situation of a country related to a specific disease	Map with a visual representation of the active free-zones for a specific disease within a country	The user uses GIS to generate a map with a visual representation of the location and extent of the active free-zones related to SVD in Italy at present time

Table 4 - Use-cases and their description

The case-studies which populated the database are in Annex I. Like it was said before, there are three cases that are very different from each other, with different subpopulations, diseases,

legal framework, etc., in order to provide different issues to the input, analysis and output of the information. The output is always a map in order to show the potentiality of using spatial information.

Use-case MR

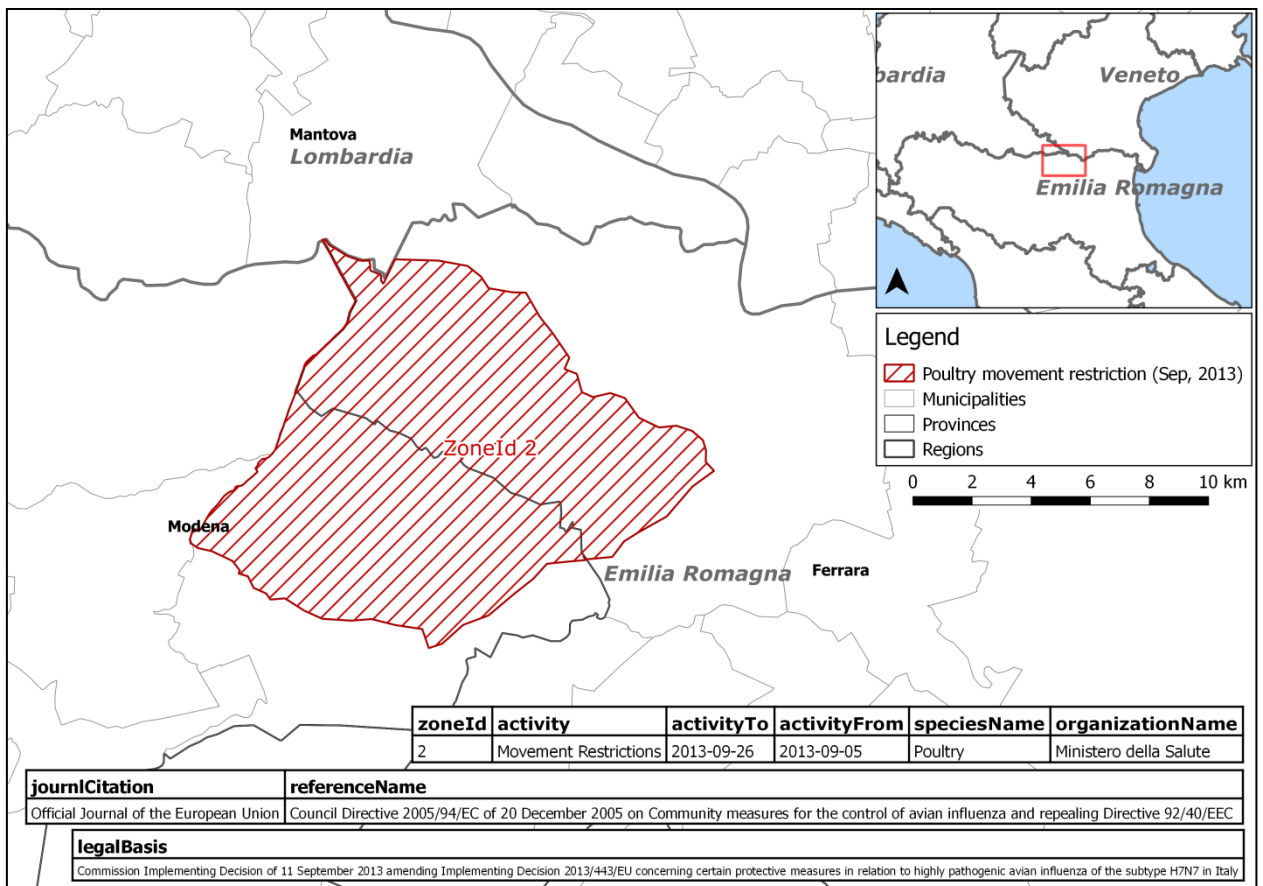


Figure 4 - Output of the system in use-case MR

In use-case MR a query was made to the system to show which zones fulfilled the following requisites: (i) they had to be active during September 2013, and (ii) they had to have any kind of movement restrictions applied to poultry. The system was required to produce a set of information such as the localization of the zones, and the legal bases of the zones and of movement restriction.

The output of the query produced the map in Figure 4, where the Zone 2 is where movement restrictions on poultry were implemented, with the relevant information reported in the tables.

Relating Figure 2 to the conceptual model, we can observe the zone itself, represented by the polygon that is the GM_Object in the conceptual model, the map is provided by the data, contained in the GeographicNameLinkReference in the model (Figure 2), the organizationName is one of the attributes of the competent authority. Then there is the activity performed in the

area (Movement Restriction), the time when it was enforced (2013/09/05 to 2013/09/26), and the target population for that activity (poultry), all of these are attributes of ControlledActivity. Lastly there is the legal framework involved in the activity, with both the journal where it was published (JournalCitation) and the reference name (ReferenceName).

Use-case VA

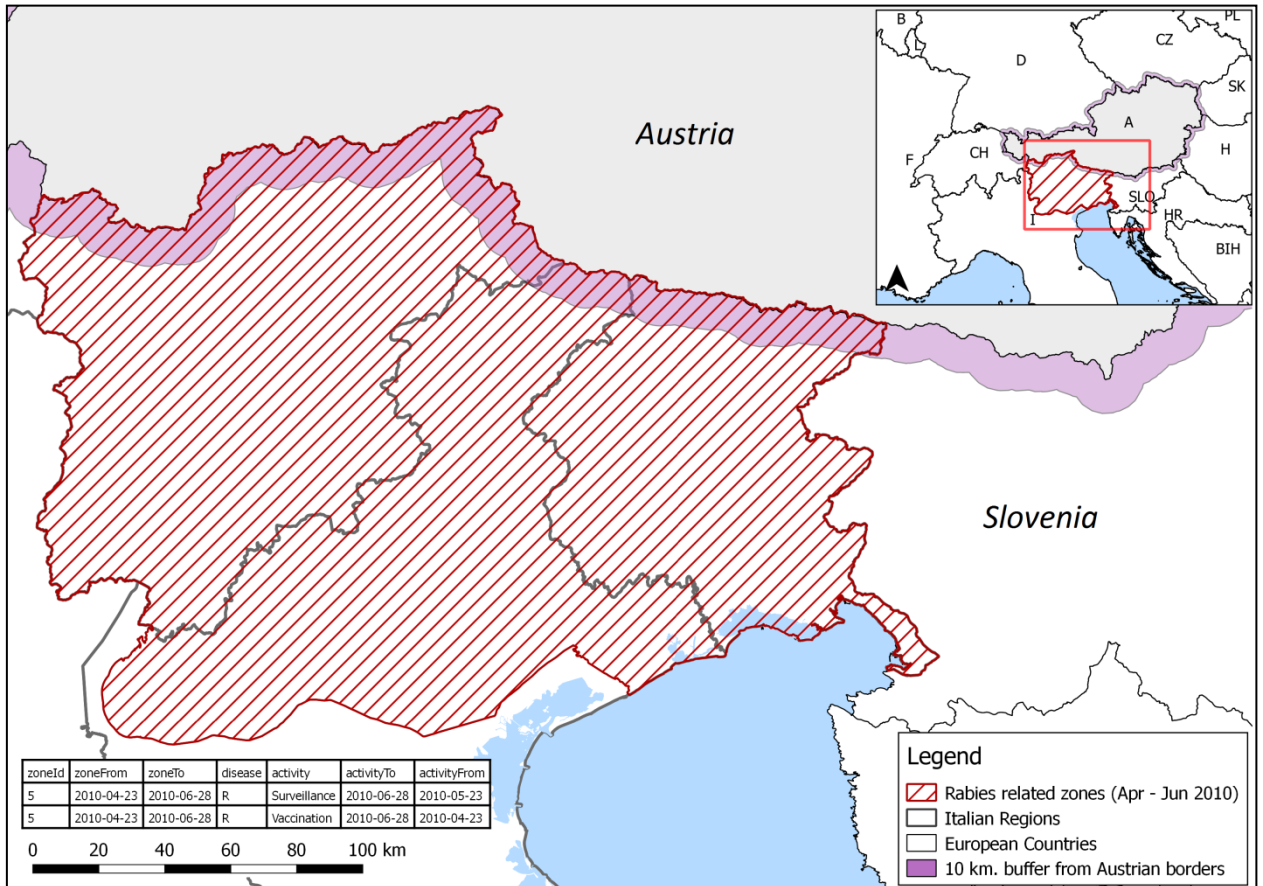


Figure 5 - Output of the system i use-case VA

In use-case VA a query was made to identify the active zones for rabies control in Italy, within 10 km from the Austrian Border between the months of April and June of 2010. The system identified zone 5 from which the following data was retrieved (Figure 5): (i)the time frame of when the zone was active; (ii)the relevant disease to which the zone was created; (iii)the activities applied; (iv)the activities time frame.

Use-case FZ

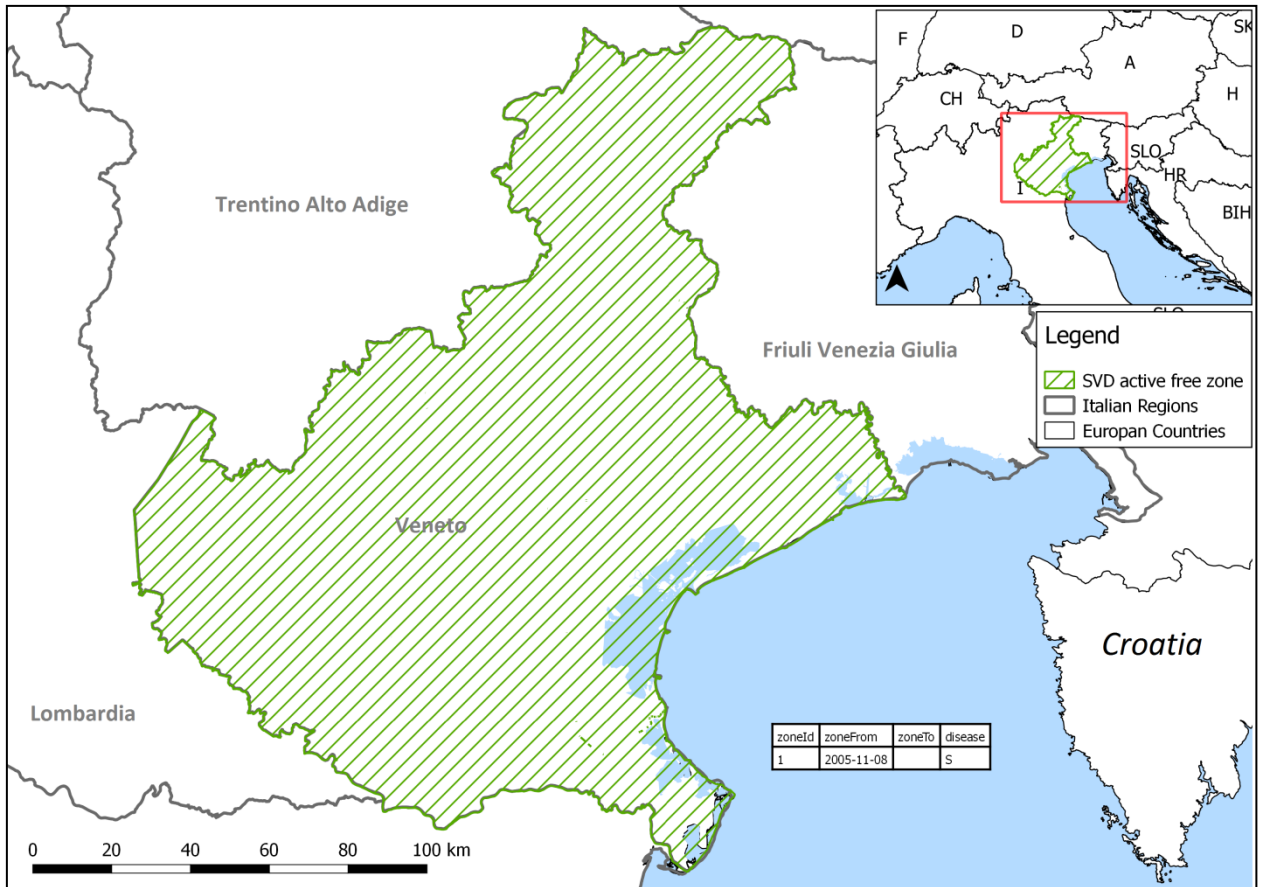


Figure 6 - Output of the system in use-case FZ

In use-case FZ the query made was for the system to identify free from disease zones active at present time, related to a specific disease (in this case Swine Vesicular Disease) and located in a specific country (Italy in this example). The output is seen in Figure 6 and it shows the only free-Swine Vesicular Disease zone in Italy that is active at the present time, considering the data present in the database.

Discussion

The present study dealt with the inexistence of a database, merging spatial and other relevant data, about zones. In order to resolve this absence an approach that included a detailed literature review and technical informatics tools was proposed. A bibliography review was done to understand the concepts and procedures and scopes related to the implementation of a zone. The information collected was then used to build a conceptual model, to understand the components of Zoning and their relationships. Next amore complex system was developed based on that model. Three case-studies were chosen in order to populate the database and test the conceptual model and system. Additionally three case-uses, that were based on the

case-studies, were used to evaluate the stability of the system and also to show the possible outputs of it.

The bibliography review allowed taking into account both the theoretical and the practical aspects of Zoning when developing the conceptual model. It was especially useful to identify and understand each component and its importance. The review was essential to allow the conceptual model to have the most relevant information possible in the simplest way so it could serve as an efficient reporting system. An example is the use of legislation, and its relationship with the zones, to provide less details about some data. In understanding the relationship between legislation and a zone it was possible to understand that the system could have less detailed data on some aspects. That happened because that information had to be contained in the legislation, which was referenced in the system. That fact allowed the user to find it and gather the information if needed. This fact was inferred when reading about real-life Zoning events during the literature review.

Nevertheless also some issues were experienced in the literature review, although they were confined to the searching criteria. One of the main problems was the broad meaning of the terms associated with Zoning. Terms like “Zoning”, “zones”, and “regions” have several meanings, most of them non-veterinarian, and their use is quite common, and for some of them it was very difficult to an easily manageable number of articles to analyse, even applying further filters. Therefore the terms “zones” and “regions” were discarded. Another problem was that some papers focus singular aspects, i.e. Surveillance, without providing basic information about the other aspects related to Zoning slowing down the analysis.

The conceptual model, built on information derived from the review, showed great potential, as it allowed to collect and describe all the components of zoning, their relevant data, and their relationships. With the case-studies it was shown that the final system manages the input of information very well, even with cases that were very different in terms of focus, subpopulation, etc. Also the system contained all the relevant information when comparing to the information gathered in the case-studies. Based on that, the conceptual model may be considered a success, and although the system is not complete, one of the good things of conceptual modelling is the re-usage of the same model for other systems. Moreover, to a concept that is as complex as Zoning conceptual modelling is essential to provide a link between real-life and the informatics world. This happens because it simplifies the concept and transforms it in something that can be transposed to a system. Also a model helps the harmonisation of the concept, at least the part more connected to the system like the input of information.

About the information system created, the use-cases indicated its remarked capacity to handle the inputs, analysis, and outputs. The queries made were answered correctly and the outputs

were very satisfactory, with correct and very informative maps. It is important to notice that one of the greatest strengths of the conceptual model, and consequently the system, is the fact that it contains spatial information and how it delivers that information which is essential in a system about Zoning, where the geographical aspects are the basis for the concept.

Nonetheless, the system could be improved on some technical aspects. The harmonisation of the system could be impaired due to the use of text to input information which is not ideal because each user can use different terminology. This was not a problem in this work because there was only one person inputting the information, but in with an increasing number of users it can become a severe issue if no constraints are imposed. Also the chosen use-cases were simple, as it was said before, and did not heavily stress the system completely. This was because they had to conform to the case-studies and also because they were used mainly to show the potential of the system and not to find any technical problem in it. Therefore testing would be necessary to validate the stability of the system, with more complex queries. Another possible improvement is the creation of a link from the containment zones to OIE's report of the outbreak which prompted the establishment of that zone. The link would allow the user to connect the information about the zone with the information about the relevant outbreak.

The information system developed, as well as the conceptual model, can have several applications, but its potential as a platform for a database containing zone-related data makes it an ideal system to function as an integrating part of the World Animal Health Information System (WAHIS). In doing that the problem with the lack of transparency, due to the absence of a way to consult the spatial and other relevant information in a fast and reliable way, would be closer to resolution. At the moment WAHID [Specify the acronym] is the only official OIE source of information about zones; nevertheless it appears being quite incomplete with limited availability spatial information, and in some occasions it has demonstrated being of difficult use. A possible integration of the system presented in this work, within WAHID, would help in addressing some of the mentioned problems.

Discussing transparency could feel like it is purely theoretical and/or inconsequent but the lack of it when associated with a concept as important for international trade as is Zoning is a relevant issue. There are some political issues that interfere with decisions that should be only sanitary. For example, The Russian ban on the importation of live pigs, fresh pig meat and meat preparations from EU appears to be one of the cases. The ban was imposed after the identification of two cases of African Swine Fever in wild boars in Lithuania. The problem is that even with all the control measures, the zoning of the area and the fact that the African Swine Fever is endemic in some parts of the Russian Federation a ban was imposed in all Member-Countries of the European Union. So there was the rejection of Zoning at two levels. There was

the rejection of the containment zone in Lithuania but also there was the rejection of all European Union disregarding individual countries(Anonymous, 2014). Both OIE and the WTO have processes to handle cases where a country thinks there is a unjustified trade but they are very long and expensive and, because of that, they are not commonly used (OIE, 2013; A. Thiermann, 2004; WTO, 2014). The use of a system like the one developed in this work gives more transparency to the process and, because of it, could help diminish the number of these cases.

Another application for the conceptual model, not for the system, could be the development of a management system. This would mean to change the goal of the model from reporting the application of control measures, to managing those measures, allowing to help both the central and local authorities in establishing and maintaining a zone. This would need a makeover of the conceptual model to address problems like the need for the information to be in real-time and also some information should be a lot more descriptive. For example, the way the conceptual model and system rely on the legislation to provide more detailed information which in turn makes the system much faster, simpler and user-friendly would be impossible in a management system. Nonetheless the basis of the conceptual model would be the same.

Taking what is said above into account, the outcome of this work is very positive. This is because the conceptual model created proved itself and permitted the creation of an efficient information system about Zoning. Furthermore, it can be used in other systems related to Zoning. About the system developed, it showed great potential when tested and it is a valid system to be considered by any organization interested. To summarize the main strengths of the system are: (i) the spatial information it contains and how it is relayed; (ii) the fact that it has all the relevant data while maintaining itself user-friendly; (iii) that its conceptual model describes perfectly Zoning which makes it a good basis for any system related to this concept. The use of this system, or other system based on the conceptual model of this work, should tackle the problem of lack of information, especially geographical one, concerning Zoning. It would provide more clarity and transparency to a process that is sometimes used as a political tool instead of its real objective, which is to facilitate international trade without neglecting sanitary issues.

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Annexes

Annex I

Containment Area for HPAI in Emilia-Romagna province

Avian Influenza is a disease caused by type A influenza viruses. These viruses belong to the Orthomyxoviridae family and can be further classified according to their hemagglutinin (HA) and neuraminidase (NA) surface glycoproteins. These glycoproteins are extremely variable and for the HA glycoproteins 16 subtypes were identified and 9 subtypes for the NA glycoprotein. This is important because the antibodies which are responsible for the protective immune system response are produced against those glycoproteins (Lee & Saif, 2009).

They can also be defined according to their pathogenicity in: Highly Pathogenic (HP) and Low Pathogenicity Avian Influenza (LPAI) viruses. A strain showing an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality) are considered to be HPAI viruses. Also strains belonging to the H5/H7 subtype are considered HPAI due to the ability to mutate from LPAIV to HPAIV causing devastating epidemics (Lee & Saif, 2009).

In regards to the disease itself, there are a multitude of clinical signs that change with the pathogenicity and species affected. The HPAI viruses cause a systemic infection with variable mortality rate depending on the species affected and the LPAI in domestic bird species causes a number of unspecific symptoms, like respiratory problems and decreased production, resulting in a mild disease (Capua & Marangon, 2006).

The Italian poultry production sector is characterised by the presence of a densely populated poultry area (DPPA) in north-eastern Italy (Lombardy, Veneto and Emilia-Romagna region), where the poultry density may be higher than 10,000 birds/ km^2 . This area is also located along the migratory flight paths of a great number of wild birds. Those two characteristics, that several times overlap, make some parts of Italy particularly susceptible to Avian Influenza introduction and spread (Busani et al., 2007).

Since mid 1990s Italy has been involved into several AI outbreaks and epidemics, including the HPAI outbreaks of 1997 (H5N2), 1999-2000 (H7N1) and 2013 (H7N7), and recurrent epidemics of LPAI. The HPAI outbreaks can be related to LPAI outbreaks which is the case of the 1999-2000 HPAI H7N1. This HPAI virus was circulating as an LPAI virus in 1999 before it mutated into an HPAI virus and caused the biggest Avian Influenza outbreak in the history of Italy (Sartore et al., 2010).

At the end of July 2013, a laying hens farm located in Ostellato municipality (Ferrara province, Emilia Romagna) experienced a increase in the mortality rate. Laboratory tests performed

between August 9 and 11, showed that birds were PCR positive for H7; on 13 August a HPAI H7N7 virus was isolated in shed 2 and 5. The conclusion was that a LPAI virus had entered the holding due to contact between wild waterfowl and free-range hens and it spread through the holding mutating into a HPAI virus during August (Bonfanti et al., 2014).

On 13 August, after the confirmation of the outbreak, the measures described in the Directive 2005/94/CE started to be applied. Restriction measures were applied on the same day, including the establishment of a restriction zone, movement restrictions and an intense monitoring programme (Bonfanti et al., 2014).

On August 19, during the checks in a contact holding a new outbreak was discovered in a layer company located in Mordano, province of Bologna, which was from the same company of the first holding. Between August 23 and September 4, three more outbreaks were confirmed, one in a meat turkey holding located close to the first outbreak and the other two in laying hen holdings both epidemiologically linked to the outbreak in Mordano (Bonfanti et al., 2014).

The outbreak chosen as case study was the last confirmed in the HPAI H7N7 epidemic in Emilia-Romagna in 2013. On September 5, the virus was detected in a backyard flock of a rural farm in the municipality of Bondeno, Ferrara province (Bonfanti et al. 2014). The flock was composed of 6 layers from which 3 died in the last week of August. On September 2, one of the carcasses was sent to be tested and on September 5 laboratory tests resulted positive for H7N7 virus. In the same day the depopulation measures were applied and the remaining 3 layers were stamped-out (Bonfanti et al., 2014).

There were no apparent epidemiological links found between this outbreak and the others, which led to the implementation of tests in every dealers and growers on Emilia-Romagna region, with every farm being tested (Bonfanti et al., 2014). Regarding other control measures, the zones created and the limits and extents can be found on table 5.

	Defined area
Protection zone	Part of the territory of the municipality of Bondeno situated south of the state road 496 and west of the river Panaro; Part of the territory of the municipality of Finale Emilia situated north of the state road 468, east of the provincial road 9 and west of the river Panaro
Surveillance zone	Bondeno; Finale Emilia; Mirabello; Sant'Agostino; Cento; Part of the territory of the municipality of Crevalcore situated north of 'via Provanone' and east of the provincial road 9 'via Provane'; Part of the territory of the municipality of Mirandola situated east of the railways Modena – Verona; Part of the territory of the municipality of San FelicesulPanaro situated east of the railways Modena – Verona; Part of the territory of

	the municipality of Sermide situated south of the provincial road 35 'via Pole' and west of the provincial road 37; Part of the territory of the municipality of Felonica situated south of the provincial road 35 'via Pole'
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Table 5 – With the geographical extent of the zone (EC(a)2013)

Inside the protection zone there was one laying hen farm and another grower farm, these holdings were subject to quarantine, intensified surveillance, movement restriction and biosecurity measures. Also the infected holding was depopulated and then cleaned and disinfected (Council Directive 2005/94/EC). The surveillance zone had only one farm, and it was subject to intensified surveillance, movement restriction and biosecurity measures (Bonfanti et al., 2014; EC(b), 2005).

The zone and the control measures implemented were applied according to the Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza. The extent and limits of the zones were then published in the Commission Implementing Decision of 11 September 2013 amending Implementing Decision 2013/443/EU concerning certain protective measures in relation to highly pathogenic avian influenza of the subtype H7N7 in Italy (Bonfanti et al., 2014; EC(a), 2013; EC(b), 2005).

Emergency oral vaccination Area for Rabies in Italy

Rabies virus belongs to genus *lyssavirus* (family: Rhabdoviridae). All mammals are susceptible to the virus, although with different extant, and the disease is considered an important zoonosis. Rabies has two main epidemiological cycles, sylvatic and urban. The first one occurs in wildlife being the foxes the main host in the EU for sylvatic rabies. The urban cycle as the domestic dogs as the main reservoir and it is the one that presents more danger for human infection (Nouvellet et al., 2013).

The case-study describes one of the emergency oral vaccination campaigns that were done to control and eradicate the outbreak of sylvatic rabies in Northern Italy.

The central and southern regions of Italy were affected by sylvatic and urban rabies until 1973, and it is now considered at a lower risk of introduction. Nevertheless, the northern regions had had several experiences with sylvatic rabies mainly due to its borders with other countries which had rabies. After sporadic rabies cases in Trento, Bolzano, and Belluno provinces in the second half of the 1960s, several epidemic waves were observed between mid 1970s and mid 1990s, mainly affecting the region of Friuli-Venezia Giulia (FVG) and the province of Bolzano (Mulatti et

al., 2013). The last case of rabies was detected in 1995 and two years later Italy was declared a free-rabies country (Mulatti et al., 2011).

In October 2008, a rabid fox was detected in FVG, near the border with Slovenia. Phylogenetic analyses showed that the virus likely originated from the West Balkan countries, due to its high similarity with rabies viruses circulating in Slovenia and Croatia (Fusaro et al., 2013). Further surveillance demonstrated the rapid spread of the disease in foxes in FVG leading to the start of oral vaccination campaigns in that region. Starting from November 2009 the disease was identified in the Veneto region, reaching Trento and Bolzano early in 2010 (Figure 7) (Mulatti et al., 2013).

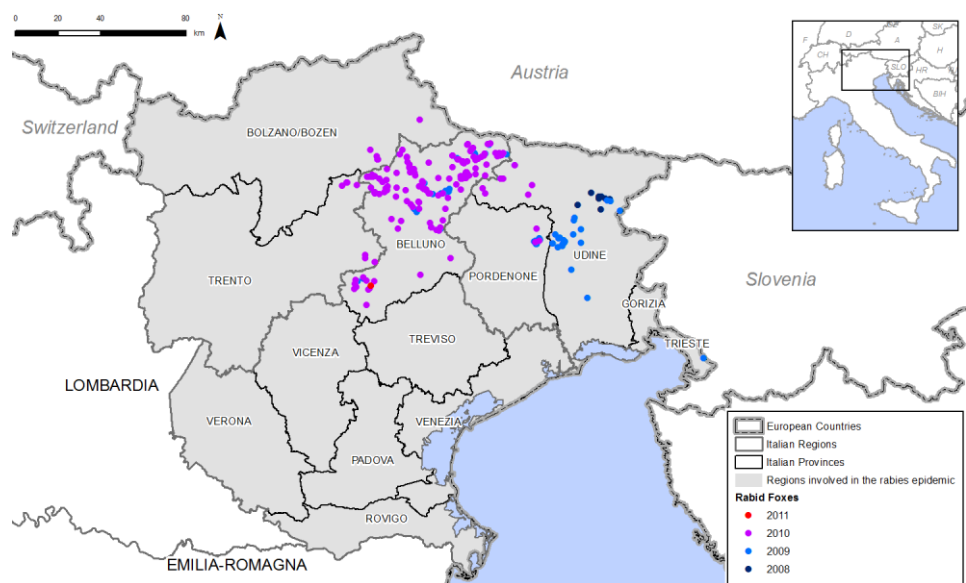


Figure 7 - Geographical distribution of rabid foxes during the 2008-2011 epidemic

Four emergency oral foxes vaccinations (OFV) against rabies by aerial distribution took place between December 2009 and December 2010. In each vaccination campaign a vaccination zone was defined. In this work only the ORV performed between April 23 of 2010 and June 28 of 2010 was considered. The vaccinated area was about 29,700 km², and included part of the Veneto and all of Friuli-Venezia Giulia regions and the whole autonomous provinces of Trento and Bolzano (Figure 8). Besides vaccination there was intensified surveillance with the purpose of monitor the disease (Mulatti & Bonfanti, 2013). Both the vaccination and the surveillance had the foxes as target population even though surveillance was extended to other possible wildlife reservoirs (Italian Ministry of Health, 2009).

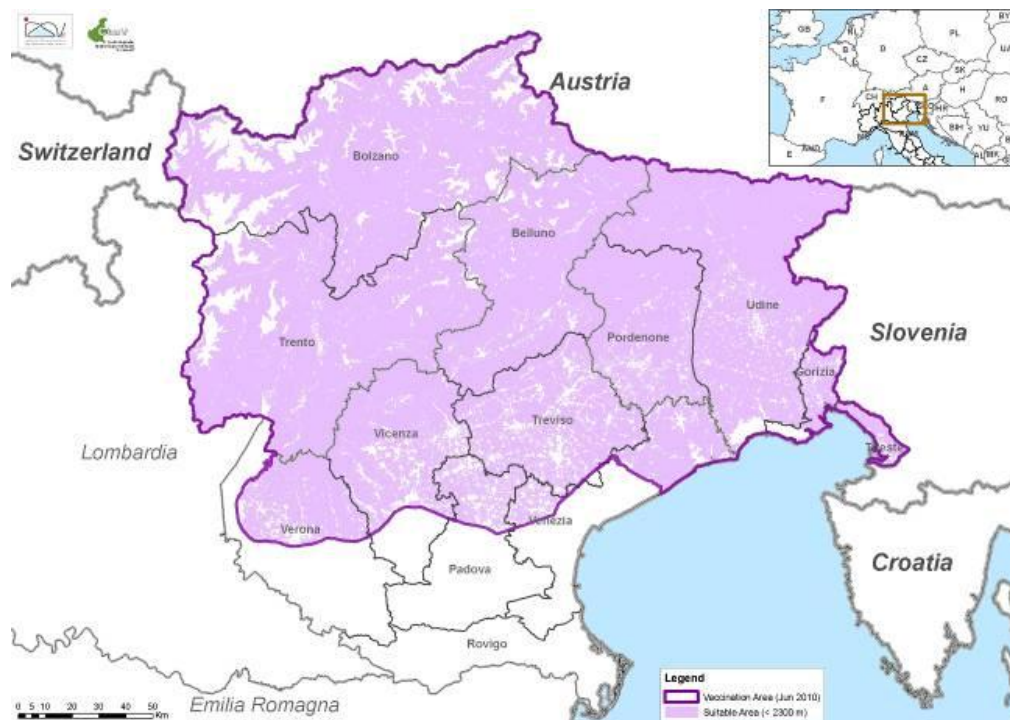


Figure 8 - Geographical extension of the OFV area

This zone and the measures applied were complying with the “Ordinanza ministeriale contingibile e urgent recante misure per prevenire la diffusione della rabbia nelle regioni del nord-est italiano” that entered into force at December 8 of 2009 and was valid until December 8 of 2010. Other control measures applied to avoid the spread to domestic animals included ban on hunting with dogs, and vaccination of dogs and ruminants in pasture (Italian Ministry of Health, 2009; Mulatti & Bonfanti, 2013); but they were not considered to be control measures of the zone but instead general measures applied independently of the protection zone.

Free-Swine Vesicular Disease Zone in Veneto Region

Swine vesicular disease (SVD) is caused by an Enterovirus of the Picornaviridae family. It is a very stable virus, highly resisting in the environment (Bellini et al., 2007) . Its main symptoms include vesicles, present mainly in snout, feet and teats which later become erosions that cause lameness, and fever (APHIS, 2012).

Although generally SVD is not serious and does not implicate great production losses, it can cause disruption in international trade, mainly due to its symptoms being very similar to those of Foot-and-Mouth Disease. This caused also SVD to be included in the OIE list of notifiable diseases. The difficulties that the disease creates at the international trade level, together with

the costs of control and eradication programs, are the main issues related to SVD (Bellini et al., 2007).

In Italy, this disease is present in some regions and sporadic outbreaks occur from time to time. The Commission Decision 2005/779/EC, concerning animal health protection measures against swine vesicular disease in Italy, implements measures more strict than the more general Council Directive 92/119/EEC, introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease, regarding Swine Vesicular Disease in Italy. It also recognizes some zones of Italy free of the disease. One of those zones is the Veneto Region (EC, 2005). Italy published in the Gazzetta Ufficiale the Ordinanza 12 aprile 2008 concerning the sanitary measures for the eradication of the Swine Vesicular Disease. This Ordinanza entered into force at June 27 of 2008 and is in some aspects more strict than the Commission Decision 2005/779/EC (Italian Ministry of Health, 2008).

The north-central area of Italy, including Veneto region, is considered a free-SVD zone not only by the EU but also by the USA, but in this case-study the zone considered takes into account the EU perspective (APHIS, 2012). The measures in place in the Veneto region include Surveillance, Movement Restrictions, stamping-out of infected animals, biosecurity measures (Italian Ministry of Health, 2008).

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VETERINARY and FOOD SAFETY SERVICES IN ITALY STRUCTURE

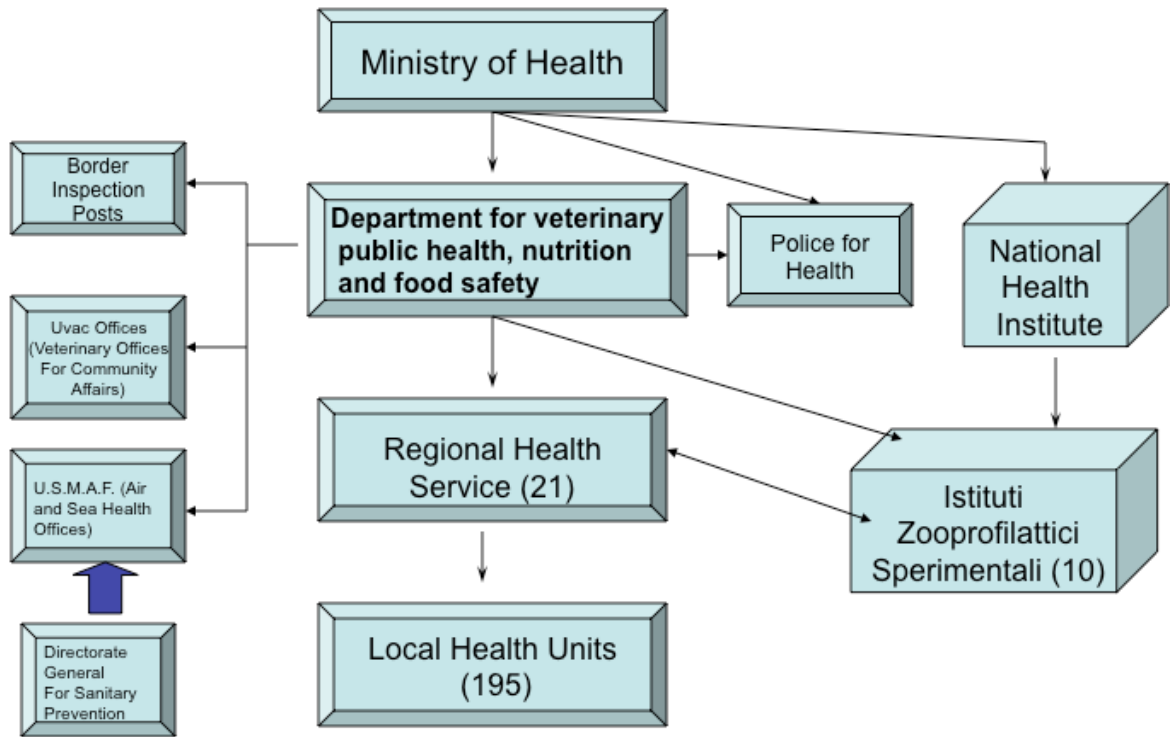


Figure9 - Structure of Veterinary Services in Italy (Source: Ministry of Health)