CHALLENGES OF DEVELOPING AN INTEGRATED FOOD CONTROL SYSTEM FOR SOUTH AFRICA: INSIGHTS FROM THE VETERINARY DRUG AND RESIDUE REGULATORY SYSTEM

By

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ABSTRACT

Food is a complex commodity. Ingredients are farmed and harvested then processed and combined into a variety of foods of different forms and packaged in an equal variety of ways to satisfy a multitude of tastes, textures, colours and smells. The entire food production chain is therefore a means to satisfy a continual demand by the consumer for an essential commodity. Together with the demand of the access to food by consumers is the demand of the assurance that is it safe to consume. This is however the challenge with food production, as by its very nature, food is prone to contamination, whether it is microbial, chemical or physical. Food must also be of adequate quality to impart nutritional value to consumers. To ensure that food is both safe and of sufficient quality requires a regulatory framework from Government which provides for functions and structures within Government to check and ensure adequate safety and quality of foods. This regulation or control is referred to as food control. In essence, food control regulates the food production chain which is a continuous process from the agricultural stage to processing, packaging and finally consumption. Although the food production chain is continuous, food control may always not mirror the continuity of the production chain and functions can be separated between various government authorities. Should this be the case, and when there is no concerted action to make the various parts of the system work together, the system becomes fragmented.

A fragmented system is an oxymoron because a system by definition infers that functions are integrated and coordinated. These two principles of a system are core requirements for the philosophy of systems thinking which is applied in this study. Systems thinking seeks to understand and improve functioning of various systems which include designed systems like food control systems. Application of systems thinking to food control systems infers that each function carried out within the system whether carried out by one authority or many are still part of the same system and therefore must be coordinated and integrated to be regarded as a functioning system. Application of systems thinking to food control systems and in particular the South African food control system is relevant in light of the reported fragmentation of the system and the widespread challenges that fragmentation is purported to cause.

The hypothesis of an internal government report (Bruckner *et al*., 1999) drafted over a decade ago asserted that the South African food control system is burdened with challenges that are caused by its fragmented state. However, there has been limited progress on addressing any of the challenges identified in the report let alone understanding and addressing fragmentation of the system. The lack of response to the report has prompted this research, to determine not only the challenges of fragmentation within the food control system and how to address them, but also to interrogate the characteristic of fragmentation. The aim of the study is therefore to research fragmentation as a characteristic of the South African food control system, and to explore its relationship with challenges that it is associated with. The aim of the study also extends to recommend, based on the findings of this study, how the food control system can be made more effective and efficient. The results of this research are therefore to affect conceptual and ultimately policy changes in South Africa in order to develop an integrated food control system.

The thesis is developed through a series of five papers, two of which are already published in peer reviewed journals. Each paper addresses specific objectives of the overall aims. The papers reflect the use of a variety of methods for the study that include reviews, systematic reviews and questionnaires. Objectives of the study include

defining fragmentation and the scope of the food control system, determining if fragmentation exists within the South African food control system, determining challenges associated with fragmentation as well as the relationship between fragmentation and challenges. Other objectives include determining how fragmentation began as well as providing recommendations on how the system can be integrated. Much of the study was conducted by interrogating one part of food control, namely veterinary drug and residue regulation. This part of the system was used as it became apparent in researching and producing the first journal paper that this part of the system was highly fragmented, plagued with challenges and could act as a window into the issues facing the food control system in its entirety.

The study, through the five papers, determines that:

1. Fragmentation exists within the South African food control system. This fragmentation is structural, functional and legislative in nature.
2. Fragmentation is associated with a variety of challenges which have been classified through this research as fundamental, systemic, functional and policy challenges.
3. The existence of the challenges and fragmentation mean that the current food control system is dysfunctional.
4. The relationship between fragmentation and its associated challenges are not linear, i.e. fragmentation not only causes challenges but these challenges may actually cause fragmentation or exacerbate it.
5. Fragmentation and challenges need to be addressed together through leadership training and drafting of a food control policy that includes a communication policy.
6. The food control policy must integrate the system, structurally, functionally and legislatively.

Based on the findings of the research, the two major interventions for change by the way on integration are determined. These include leadership training and drafting of a food control policy. Training of leaders is required to enhance a systems thinking philosophy in government while including collaborative and collective interaction with a view to enhance inter and intra departmental communication. By training senior managers, the effects of mandate obligations and poor systems conceptualisation can be addressed. A food control policy is required to define the scope of the food control system in South Africa in terms of structures, functions and legislation as well as put in place measures to address each of the identified categories of challenges and frame the integration that trained leaders would have identified.

The food control policy must include a communication strategy that addresses frequency, quality and method of communication as well as strategies for collaboration and interdepartmental interaction. The food control policy must be the overarching framework of food control in South Africa. In terms of a preferred model for integration, the best fit model is considered a system akin to the integrated food control system indicated by the FAO/WHO, (2003b) where the system is functionally integrated and driven by one integrated policy.

The integration of the system is urgently required as continuance of the challenges identified as well as fragmentation of the current system will entrench the dysfunctional nature of the food control system and compromise the safety of foods consumed in the country. In addition, the trust that consumers have in food products and the regulation efforts of Government will also be greatly compromised should the challenges and fragmentation continue.

DECLARATION

I, Renusha Rabichand Chanda declare that:

(i) The research reported in this thesis, except where otherwise indicated, is my original research.

(ii) The thesis has not been submitted for any degree or examination at any other university.

(iii) This thesis does not contain other persons data, pictures, graphs or other information, unless specifically acknowledged as being sourced from other persons.

(iv) This thesis does not contain other persons writing, unless specifically acknowledged as being sourced from other researchers. Where other written sources have been quoted, then:

a. Their words have been re-written but the general information attributed to them has been referenced;
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(v) Where I have reproduced a publication of which I am author, co-author or editor, I have indicated in detail which part of the publication was actually written by myself alone and have fully referenced such publications.

(vi) Where articles/papers comprise this thesis, published or unpublished, these are all works of my own, although, due to their assistance, my supervisor and co-supervisor names appear as co-authors.

(vii) This thesis does not contain text, graphics or tables copied and pasted from the Internet, unless specifically acknowledged, and the source being detailed in the thesis and in the References sections.

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Renusha R Chanda Date

As the candidate's supervisor I have approved /~~not approved~~ this thesis for submission

Signed: Date:

Prof RJ Fincham 26th November 2013

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- To my family and husband, thanks for all the support.

This thesis is dedicated to my late brother Pravesh R. Chanda who taught me to pursue my goals against all adversity

….THANK YOU

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LIST OF ABBREVIATIONS AND ACRONYMS

AC:	Advisory Committee
AMRM:	Antimicrobial Resistance Monitoring
ANOVA:	Analysis of Variance
APHIS:	Animal and Plant Health Inspection Service
APS:	Agricultural Products Standards
ARC:	Agricultural Research Council
AVCASA:	Association for Veterinary and Crop Associations of South Africa
BC:	Biologicals Committee
CAC:	Codex Alimentarius Commission
CCFA:	Codex Committee on Food Additives
CCFL:	Codex Committee on Food Labelling
CCPR:	Codex Committee on Pesticide Residues
CCVDRF:	Codex Committee on Veterinary Drug Residues in Food
CVM:	Center for Veterinary Medicine
CFSAN:	Center for Food Safety and Applied Nutrition
DAFF:	Department of Agriculture, Forestry and Fisheries
DEFRA:	Department for Environment, Food and Rural Affairs
DoA:	Department of Agriculture
DoH:	Department of Health
DPSA:	Department of Public Service and Administration
DTI:	Department of Trade and Industry
EC:	Executive Council (under the GMO Act, 1997)
EHP:	Environmental Health Practitioner
EFSA:	European Food Safety Authority
EPA:	Environmental Protection Agency
EU:	European Union
FAO:	Food and Agriculture Organisation
FBD:	Food Borne Disease
FCD:	Foodstuffs, Cosmetics and Disinfectants
FCS:	Food Control System
FDA:	Food and Drug Authority
FDD:	Food, Drugs and Disinfectants
FLAG:	Food Legislation Advisory Group
FSIS:	Food Safety and Inspection Service
FSQA:	Food Safety and Quality Assurance
GLP:	Good Laboratory Practice
GM:	Genetically Modified
GMO:	Genetically Modified Organism
HACCP:	Hazard Analysis Critical Control Point
IEC:	Information, Education, Communication
IECT:	Information, Education, Communication and Training
IMQAS:	International Meat Quality Assurance Services
JECFA:	Joint FAO/WHO Expert Committee on Food Additives
KFDA:	Korean Food and Drug Authority
MCC:	Medicines Control Council
MEC:	Member of the Executive Council
MoU:	Memorandum of Understanding
MRA:	Medicines Regulatory Authority
MRL:	Maximum Residue Limit
NCRMP:	National Chemical Residue Monitoring Programme
NICD:	National Institute for Communicable Diseases
NHLS:	National Health Laboratory Service
NRCS:	National Regulator for Compulsory Specifications
NSPCA:	National Council of Societies for the Prevention of Cruelty to Animals

OIE:	World Organization for Animal Health
OVI:	Onderstepoort Veterinary Institute
PALAMA:	Public Administration Leadership and Management Academy
PMDS:	Performance Management and Development System
PPECB:	Perishable Products Export Control Board
RA:	Risk analysis
RA:	Risk assessment
rBST:	Recombinant Bovine Somatotrophin
RC:	Risk communication
RM:	Risk management
RSA:	Republic of South Africa
SA:	South Africa
SABS:	South African Bureau of Standards
SAHJ:	South African Historical Journal
SAHPRA:	South African Health Products Regulatory Authority
SANAS:	South African National Accreditation Service
SAVA:	South African Veterinary Association
SPS:	Sanitary and Phytosanitary
STANSA:	Standards South Africa
UK:	United Kingdom
UN:	United Nations
USA:	United States of America
USDA:	United States Department of Agriculture
VCC:	Veterinary Clinical Committee
VMD:	Veterinary Medicine Directorate
WHO:	World Health Organisation
WTO:	World Trade Organisation
ZAR:	Zuid–Afrikaansche Republiek

CHAPTER 1: INTRODUCTION

This thesis is completed through a series of papers rather than the traditional format of theses. This format is preferred considering the limited literature on the subject area and the need to stimulate further research in the field. Making the information produced from this study accessible through peer reviewed journals allows for timeous availability of the research in order to motivate further research in the subject area in South Africa. Two of the five papers are published in international peer reviewed journals while another has been restructured after submission and comments from a peer reviewed journal (see Table 1.1). The ease of publication of papers is greatly enhanced where the papers already comprise the thesis, thereby making the contribution of the study material more accessible. Furthermore, the publication of papers from those comprising a thesis gives credibility to the research conducted as it has been reviewed, read and, where applicable, cited by an international audience.

Table 1.1: Summary of papers comprising the thesis

Paper 1:	Review of the South African Food Control System: Challenges of Fragmentation
Publication status	Published 2010 in Journal: *Food Control*
Citation reference	Chanda, R. R. Fincham, R. J. Venter, P. (2010) Review of the South African Food Control System: Challenges of Fragmentation, *Food Control*, 21: 816-824
Paper 2:	Review of the regulation of veterinary drugs and residues in South Africa
Publication status	Published in 2014 in Journal: *Critical reviews in Food Science and Nutrition*
Citation reference	Chanda, R.R. Fincham, R.J. & P. Venter. (2014) Review of the regulation of veterinary drugs and residues in South Africa, *Critical reviews in Food Science and Nutrition,* 54 (4): 488-494
Paper 3:	Critical influences in the development of veterinary drug and residue regulation in South Africa: Implications for policy change
Publication status	The article was submitted to the South African Historical Journal (SAHJ) in October 2013. *After comments from reviewers and subsequent restructuring of the article, it is now a critical review paper rather than a historical account and therefore the scope of the paper may be outside that of SAHJ. The paper may need to be reformatted and submitted to another journal.
Citation reference	Chanda, R.R. Fincham, R.J. & P. Venter. (unpublished) Critical influences in the development of veterinary drug

	and residue regulation in South Africa: Implications for policy change
Paper 4:	Systems conceptualisation and communication challenges in the South African veterinary drug and residue regulatory system
Publication status	Unpublished. To be submitted to the Journal: Food Control for publication.
Citation reference	Chanda, R.R. & R. J. Fincham. (*unpublished*) Systems conceptualisation and communication challenges in the South African veterinary drug and residue regulatory system
Paper 5:	Fundamental, functional, and policy challenges of creating a successful South African veterinary drug and residue regulatory system
Publication status	Unpublished. To be submitted to the Journal Food Control
Citation reference	Chanda, R.R. & R. J. Fincham. (*unpublished*) Fundamental, functional, and policy challenges of creating a successful South African veterinary drug and residue regulatory system

Since the thesis itself is comprised of 5 papers, each chapter is a paper with its own introduction, content and discussion/conclusion. Each of the papers is in the formats of journals for which they have been submitted to or in which are to be potentially published. The formats of these papers do, therefore, differ as a result of this issue. Prior to presenting the five paper chapters, the first three chapters are introductory by nature. They provide relevant background material for the study including aims and objectives, literature review, including the framework and philosophy on which the study is based, and methods used in obtaining the material and data of the study.

1.1. BACKGROUND

The FAO/WHO (2003b) describes three types of food control agencies or systems. These include multiple agency food control systems, single agency food control systems and integrated agency food control systems. The multiple agency food control systems are generally older and consist of a variety of different government departments that perform functions that are collectively known as a food control system. Single agency food control systems are those where all functions are

performed by one authority and integrated food control systems are those where different agencies or organisations conduct different functions of the system but they are all integrated as they are functioning under one authority or framework. Most fully integrated systems, either single agency systems or integrated systems (FAO/WHO, 2003b) are fairly recent being the result of concerted efforts of governments to integrate their fragmented systems of food control. Examples include the single agency food control systems of Spain and Greece which in the past decade have consolidated their food control functions under the Spanish Agency of Food Controls and the Hellenic Food Safety Authority, respectively (Garcia and Jukes, 2004 & Varszakas *et. al*., 2006). Both these countries have had structurally fragmented food control functions prior to the establishment of the new agencies while with the advent of the new system, food control functions are streamlined to only one government authority. Single agency food control systems therefore are characterised by having all their functions and structures within one authority (FAO/WHO, 2003b).

Integrated food control systems are also possible. In an integrated system, certain functions of the food control system like legislation drafting can be under one authority, inspection and enforcement under another and communication and training under another. This differs from the single agency food control system where all functions are under one authority. An example of the integrated food control system is the Korean Food and Drug Administration which is involved in legislation drafting and enforcement while other bodies within the country look at surveillance and research (Kwak *et. al*., 1999). Aside from single or integrated food control systems, multiple agency systems (FAO/WHO, 2003b) also exist like that of the United States of America (USA) which has three authorities all involved in food control in varying degrees (Chanda *et. al.,* 2010). The multiple agency system differs from the integrated agency in that in the former each involved authority can work in isolation with their own resources whereas

for the latter, each function is still dependant on the others even though they are structurally separated under different authorities.

The South African food control system has already been described as fragmented and riddled with challenges that make it inefficient and unsustainable (Bruckner *et. al*., 1998). In 1998 a task team of officials of the Departments of Health and Agriculture generated a report detailing the fragmented nature of the South African food control system (SA FCS), a report which also included a description of the challenges that were supposedly caused by the fragmented system (Bruckner *et. al*., 1998). Challenges included duplication of resource intense functions such as dual registration for veterinary drugs, unclear jurisdiction of enforcement between the Departments of Health and Agriculture and in-coordination between various parts of the system although similar functions were being conducted across these various parts. This report was preceded by an earlier account of the SA FCS in 1995 by a technical expert of the Food and Agriculture Organization (FAO) upon request of an evaluation of the system by the Department of Health (this earlier report was referenced in the Bruckner *et. al*., 1998 report). Both reports cited fragmentation of the food control system being problematic and associated with a variety of challenges which were evident in the system. In fact, fragmentation was deemed the causal factor responsible for the various challenges that were identified in the FCS. The 1998 report also provided suggestions on how fragmentation could be addressed with a preferred model of integrating related food control activities within a single agency (Bruckner *et. al*., 1998).

The abovementioned Government and FAO reports provided an acknowledgement of challenges in the South African food control system, as well as an indication of the necessity to conceptualise individual food control activities as a coherent system, even though they were never developed as such (Chanda *et. al.,* 2010). These reports also indicate that at least within the task team of officials generating the report, an

integrated approach to the government function of food control was preferred and considered superior to the current fragmented system. However, over a decade later the current SA FCS remains the same as it did in 1998 with the only progress being the completion of a government appointed consultant's report on the scope of the South African food control system (Korsten, 2009), the compilation of a confidential draft document on a food safety policy by the Department of Agriculture, Forestry and Fisheries (DAFF) (DAFF, unpublished) and recently, parliamentary involvement in questioning the fragmented state of the system after media reports of incorrect labelling of meat products (PMG, 2013). However, to date there has been no response as yet to the consultant's report and how and if it will be utilised to address the challenges of the food control system. Furthermore, although the food safety policy of DAFF is one visible action for addressing the needs of the system, it may further entrench fragmentation as it is only being drafted through DAFF and not in interaction with other involved Departments and organisations of the FCS.

The implicit and muted response to a request for change in the SA FCS prompted the desire to better understand why fragmentation and associated challenges of the food control system were not prioritised sufficiently within government. A lack of action on challenges would mean that the dysfunctional nature of the system continues, thus compromising food safety and quality goals. This study therefore seeks to provide a method of addressing challenges and fragmentation, if they exist, to address the dysfunctional nature of the system and to prevent any effectiveness of the current food control system being decimated due to entrenchment of challenges.

Although initial research of this study cited a plausible reason for not addressing fragmentation and challenges after the reports described above, which is the inability of newer food control officials to pursue this issue after staff retired and resigned (Chanda *et. al*., 2010), it is also possible that the inertia for change in the food control system is

related to the poor understanding of fragmentation, how it is associated with the challenges indicated in the reports and therefore how the system could be integrated. This realisation, in turn, required that fragmentation within the food control system needed to be researched in detail in terms of exactly what it is; how it manifests; where it came from and why there are numerous challenges associated with it. In addition, it would need to be understood whether the challenges associated with fragmentation were simply caused by fragmentation, that is, if there was a linear relationship between these two concepts or whether the relationship was more complex. This study therefore went beyond what was generated in the reports to explore and describe the characteristic of fragmentation within the South African food control system, how it is associated with challenges and what challenges existed. This research is required because it would form the basis of the model to integrate the food control system in South Africa for greater efficiency. The relevance of this study is, therefore, to contribute to the literature regarding fragmentation and challenges of the South African food control system and to use that information to determine how the system could be integrated for better efficiency and effectiveness. This study therefore aims to effect policy changes regarding food control in South Africa.

To guide the study, the linear framework of Figure 1.1 was used. This framework encapsulates the thinking around fragmentation of the South African food control system at the beginning of the study but also framed where the research was required in order to better understand and address fragmentation and challenges it is associated with. At the beginning of the study two concepts and one relationship between these concepts was noted. These were fragmentation (of the South African food control system) and challenges with the relationship between them being that fragmentation causes these challenges.

The postulated relationship motivated research of fragmentation and challenges in terms of what they mean, whether they exist and how they are related to one another. Specifically, for fragmentation, research was required in terms of what it is, whether it exists within the South African food control system and why it was initiated. For challenges, the types of challenges of the system needed to be detailed and for the relationship, research was required into whether the relationship was indeed linear. This search for clarification of the relationship between fragmentation and challenges is important in terms of how to address challenges because, if the relationship were indeed linear, simply addressing fragmentation would address all the challenges it is associated with.

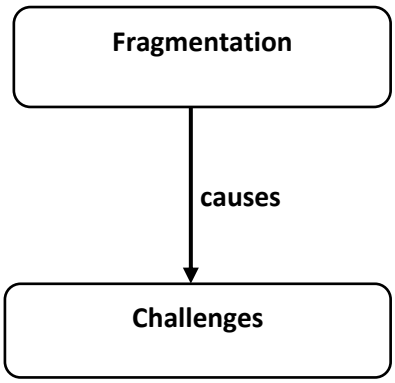

Figure 1.1: Postulating a causal link between fragmentation and challenges for establishing an integrated food control system in South Africa

The above linear framework translated into the specific and defined aims, objectives and research questions below.

1.2. RESEARCH QUESTIONS

To define what was required of the study, as well as to determine what methods could be used in the study; the following research questions were formulated:

a) What is the scope of food control in South Africa? That is, what activities relating to food control are conducted in South Africa and by whom?
b) How is fragmentation defined?
c) Is the South African food control system fragmented?
d) Why did fragmentation begin and why does it continue?
e) What are the current challenges of the South African food control system?
f) How are challenges associated with fragmentation? Is this simply a linear relationship, that is, does fragmentation cause challenges or is the relationship more complex? Can a model be developed to illustrate these linkages?
g) How can fragmentation and identified challenges be addressed to create an integrated and efficient food control system for South Africa?

1.3. AIMS AND OBJECTIVES

Based on the above research questions, the aim of the study is therefore to understand fragmentation and to determine the challenges of the food control system in order to determine how to address these challenges and fragmentation to create an effective and efficient food control system. To achieve this aim requires an understanding of the challenges of the system as well as interrogation of fragmentation itself in terms of what it meant, whether it exists, and if it does exist, why it exists. In terms of challenges, these needed to be determined, categorised and linked to fragmentation in

order to find a way of addressing them for an effective food control system. Understanding the linkage to fragmentation is important as associating all challenges of the food control system to fragmentation as per Figure 1.1 means that addressing fragmentation will address these challenges. If the postulation is incorrect it would mean that there are other causal factors besides fragmentation that need to be addressed in order to create an effective and efficient food control system. The research questions and aim were then translated into the following objectives:

1. To determine the scope of food control in South Africa.
2. To define fragmentation.
3. To determine whether fragmentation exists in the South African food control system based on the specified definition.
4. To determine how and why fragmentation was initiated and why it continues.
5. To determine the challenges of the South African food control system and their relationship to fragmentation. This would lead to developing a model of the association of challenges to fragmentation.
6. To indicate policy changes on food control in South Africa based on recommendations on how to integrate the South African food control system.

1.4 METHODOLOGY

To achieve the aim and objectives of the study, a combination of methods or mixed method research, was used. This included focusing the study on one part of the food control system i.e. veterinary drug and residue regulation. Paper 1 confirmed that the South African food control system is fragmented and also found that veterinary drug

and residue regulation reflects the fragmentation of the larger food control system. Therefore to make the study manageable, veterinary drug and residue regulation, as one aspect of the food control system was considered in detail to understand more fully the nature of fragmentation. Challenges in the veterinary drug and residue regulatory system include duplication of registration functions and in-coordination of registration functions with the function of publication of maximum residue limits of veterinary drugs in foods (Chanda *et. al*. 2014).

Review methodology is also employed extensively in this study in order to consolidate and collate information to substantiate the contention that the system is fragmented. The reviews also acted as the baseline information for primary research. Primary research was conducted through a questionnaire-based survey in order to obtain research results that were never sought nor obtained before. Using a combination of research methods meant that valuable data from a variety of sources was obtained to ensure a holistic view of the food control system and its challenges.

1.5 STRUCTURE OF THE THESIS

The following chapters will provide background to the study particularly on the key concepts of food control and food control systems as well as veterinary drug residues and risk analysis. These are introduced in chapter 2 which constitutes the theory or literature review of the study. Chapter 3 describes the methods employed in the study and how it was employed to achieve the specific objectives.

- Chapters 4 to 8 are individual papers of the study which answer to specific objectives. They are in the format of the respective journals in which they are published or in which they are intended for publication.

- Chapter 4 is the first paper and answers to objectives 1 to 3 of the study which sought to determine the context and scope of the South African food control system, to define fragmentation as well as to determine whether fragmentation of the South African food control system exists.
- Chapter 5 is paper 2 which answers to objectives 3, 5 and 6. Thus it confirms that fragmentation exists by focusing on the structures, functions and legislation related to one part of the food control system, the veterinary drug and residue regulatory system. This paper also identified the key challenges of the system, later termed systemic challenges, which are inadequate communication between government departments and poor conceptualisation of individual functions of food control as being part of a system. It partially addresses objective 6 by indicating that both communication and systems conceptualisation need to be addressed before the reported on challenges of duplication of functions, and in-coordination between functions are addressed.
- Chapter 6 is paper 3 which addresses objective 4 to determine how fragmentation was initiated. Using the focus area of veterinary drugs and residues, article 3 found that fragmentation was initiated by the arbitrary distinction of veterinary drugs from stock remedies based on complexity or simplicity of the drug. Fragmentation continued because of a lack of leadership which was needed for innovation and change.
- Chapter 7 is paper 4, which researches the challenges of poor systems conceptualisation and poor communication thus addressing objective 5. These two challenges are researched in detail because they are considered central to the integration of the system. Paper 4 finds that poor systems conceptualisation is due to a lack of in-depth understanding of related functions rather than awareness of these functions while poor

communication does exist and can be attributed to poor frequency of communication, impractical methods of communication and poor quality of communication.

- Chapter 8 is paper 5 which also addresses objective 5 and looks into determining what other challenges are prevalent in the food control system from results of a questionnaire. Challenges identified were numerous and were categorised as functional, fundamental and policy challenges.

Chapter 9 is the discussion and conclusion chapter of the thesis. Chapter 9 reflects back at the objectives of the study that were set out in chapter 1 and consolidates findings of the study to link to whether objectives identified in Chapter 1 are addressed. Chapter 9 also addresses objective 6 in terms of providing recommendations for integrating the system as well as concludes the study with an overview of the research findings and proposes where further research in this field is urgently required.

CHAPTER 2: LITERATURE REVIEW

The relevance of a literature review is encapsulated in the book by Hart, (1993, p13) which states that a literature review is to '*demonstrate skills in library searching, to show command of the subject area, and understanding, to justify the research topic and methodology of the problem'* (p13). He goes on to indicate that reviews help to narrow down the research topic (Hart, 1993). Other reasons for the relevance of literature reviews are provided by Oliver, (2012) who states that literature reviews are essential for providing a historical perspective of the study area, summarising new and developing knowledge in the area, exploring trends in the literature and identifying gaps in the understanding of the subject (p10-21). All of these reasons are relevant, particularly in each of the review papers, but this chapter also elaborates on theory which underpins the papers and this study as a whole. Therefore this chapter provides the key concepts, subject areas and topics that drive and provide the relevance for the study while also gives the reader the context of the study and where it is placed. The following subject areas are described: systems thinking, food control, food control systems, risk analysis, and the food safety issue and part of the South African food control system that is fragmented and is used for the in depth study, the regulation of veterinary drugs and residues.

2.1. SYSTEMS THINKING

This study is conceptualised against the backdrop of systems thinking. The ability to recognise and understand fragmentation is dependent on the acknowledgement that individual functions are actually part of a system and that an integrated functioning of the system is its key characteristic. In the case of food control systems, the

understanding is that although individual functions do occur, they are all part of a system working towards goals of food safety and quality and facilitation of trade of food. It is the acknowledgement of the common goal and the harmonisation of the functions to achieve that goal that is considered the core requirement of systems thinking. However before systems thinking is applied to food control, understanding what systems mean and therefore what systems thinking is about, is required.

2.1.1. DEFINITION AND TYPES OF SYSTEMS

The Concise Oxford Dictionary (electronic version, 2001) defines a system as a '*complex whole; a set of things working together as a mechanism or interconnecting network'.* Other definitions are similar, with a common premise of complexity and parts, operating in sync to achieve a particular goal (Meadows, 2008, p11; Taylor and Lynham, 2013). This is the fundamental understanding of systems even though current classifications have provided further breakdown of systems into distinct system types. Overarching system types are open systems or closed systems (Haines, 2000, p2; Haines, 2007, p66). Open systems are those susceptible to influences of the environment and as an example could include homeostasis of an organism which is influenced by environmental stimuli like changes in temperature, stock exchange systems that are influenced by global bullion prices, or systems within government systems. Closed systems, although rare are those where environmental influences are negligible. Aside from the open and closed systems, distinct classifications of systems have been identified. Although other classifications exist (e.g. that of Ackoff and Gharajedaghi, 1996), Checkland's, (1981) classification of systems is one of the most straightforward. Checkland's (1981) first classification is of *natural systems*, which is characterised by constancy given a certain set of conditions (including environmental)

such that the system would behave and react in very much the same way should those conditions be met. These refer to ecological and biological systems to a large degree. *Designed physical systems,* on the other hand, are those that are engineered to produce or affect a defined goal. These systems range in complexity and examples include airline transport systems, construction of buildings, a computer system as well as simple systems like knocking a nail into a piece of wood or driving a car. From these examples, a characteristic of *designed physical systems* is not only having a defined goal/s but also; all or part of the system is designed to achieve that particular goal.

Human activity systems or *social systems* are complex in nature with a variety of interactions being a fundamental characteristic. Human activity systems are rarely designed, have no particular goal or objective and are usually open systems. Social clubs, organisations and families are examples of this type of system. It is often difficult to distinguish between specific systems, as characteristics of multiple systems may be present in any one system. This is largely the case for designed physical systems, which are rarely in existence without a human activity system. Indeed since humans perceive and operate within the system, no system can actually be devoid of a human activity system.

Checkland, (1981) indicates that *designed abstract systems* also exist but these are usually the conceptual systems (mental models) that provide the basis for designed physical systems. Therefore designed abstract systems require physical intervention to be considered a concrete system. Ackoff and Gharajedaghi's, (1996) classification of systems compliments that of Checkland's, (1981) and indicates the existence of *deterministic systems* whose parts or whole have no particular purpose. These are for example gaseous cycles like nitrogen or carbon. Neither the parts (various forms of the gas) nor the whole operate towards any goal although the process itself is relevant to

other processes. *Animated systems*, on the other hand, as described by Ackoff and Gharajedaghi, (1996) are those where the parts have no purpose but the system itself is considered purposeful. These are indicative of biological systems like human beings or animals where the bodily processes are not purposeful and operate only to serve the whole, while the whole has a purpose, in this case, survival. These two classifications are essentially a split of Checkland's (1981) classification of natural systems where Ackoff and Gharajedaghi, (1996) substantiate the split of the natural systems classification on parts, wholes and their purposefulness in achieving the goal of the systems itself. Ackoff and Gharajedaghi, (1996) also describe *social systems* or *sub-systems* and this is analogous to Checkland's, (1981) description of human activity systems. Although Ackoff and Gharajedaghi's, (1996) descriptions have their merit, the question of purpose within parts and wholes are complicated to describe and apply, thus for initial application of the systems approach to food control, Checkland's, (1981) classification is favoured. Table 2.1 summarises the classification of systems according to Checkland, (1981).

Table 2.1: Summary of Checkland's, (1981) classification of systems with speculated examples

Type	Characteristics	Example
Natural	Given a set of conditions, the system would emerge and operate similarly Goals are apparent but not always	Ecological and biological systems
Designed physical	One or more parts of the system are designed or engineered therefore system can be changed or adapted. Heavily goal orientated	Transport systems, printing a document
Human activity	No real designed parts or wholes Goals are elusive	Families, social clubs
Designed abstract	Abstract, requires physical intervention to achieve goals	Concept mapping of any designed physical system

It should also be noted that where Checkland, (1981) and Ackoff and Gharajedaghi's, (1996) classification includes references to parts and wholes, other authors like Senge,

(2006) describe systems as wholes within wholes or as Meadows, (2008) indicates, systems within systems. Perhaps the more contemporary view in its applications to organisations, Senge's (2006) explanation stretches the understanding of systems. Whichever terminology and understanding is preferred, where parts are being referred to, they will be termed as such although they can be thought as wholes on their own.

2.1.2. SYSTEMS THINKING VERSUS REDUCTIONIST THINKING

Understanding systems is fundamental to systems thinking and ultimately applying systems thinking to comprehend any system. However, current and dominant routes of understanding systems must also be described such that a contrast can expose primary differences between systems thinking approaches and current reductionist approaches.

It is human nature to seek understanding, particularly of the world around us and it is our attainment of knowledge for this understanding that inculcated the dominant route of understanding all systems. It is acknowledged that the power of knowledge can only be harnessed should there be appropriate methods of firstly attaining it and then understanding it. For the greater part of our history, scientific or reductionist thinking approaches has been largely responsible for any knowledge attained (Haines, 2000, p6; Taylor & Lynham, 2013). This school of thought is *characterised by separating complex systems into elements to understand the system itself*; and was successful for understanding physical phenomena at the onset of its application. Reductionist thinking was largely initiated and incited by the great philosophers of Europe who used scientific approaches as a method of understanding their surroundings (for an elaboration of this see Checkland, 1981, 23-50).

Scientific or reductionist thinking, although invaluable in providing knowledge whose application is still utilised today, becomes less reliable as systems become increasingly complex (Checkland, 1981, p59). As Checkland, (1981, p59) writes, '*the principle most central to scientific practice-assumes that this division* [separation into parts] *will not distort the phenomenon being studied. It assumes that the components of the whole are the same when examined singly as when they are playing their part in the whole, or that the principles governing the components into the whole are themselves straightforward*.' Scientific thinking, therefore, reduces systems to their most elemental forms and describes largely linear interactions and makes assumptions of the system based on these interactions. However, results of linear interactions are fallible, when interactions are varied, numerous and complex. In addition, the understanding of the culmination of the interactions cannot be explained by the understanding of the behaviour of the most elemental forms.

For example, the activity of atoms can be explained by the activity of electrons and neutrons, the activity of chemicals can also be explained by the characteristics of atoms and their constituents. However, when simpler molecules interact to form biological entities like cells, and cells interact to form organisms, the activity of that organism cannot be explained by the activity of the atoms that constitute it. An appropriate example is provided by Checkland, (1981, p77) where he quotes Bertalanffy, the biologist whose earlier works encompassed within the text of *Modern Theories of Development: An Introduction to Theoretical Biology* in conjunction with the work of other authors, really set the stage for systems thinking. The example provided is of metabolism where a definite organisation of the organism is required to achieve the end point. Although physio-chemical processes that operate to achieve metabolism can explain some characteristics of the system, the state required to induce the process cannot be explained by linear interactions. Thus, complexity complicates the

understanding and explanation of systems from the reductionist view and eventually results in the inability to comprehend the system or deter any problems the system is likely to encounter. These problems are more apparent in designed physical systems where problems in the functioning of the system result in poor achievement of goals and more often than not, collapse of the system itself.

2.1.3. THE APPLICATION OF SYSTEMS THINKING

Systems thinking has evolved as a meta-discipline to provide an alternate understanding of systems and to ultimately solve inherent vulnerabilities of systems for optimising functioning. Systems thinkers have applied various definitions, classifications, and principles of systems thinking. Of the disciplines most embracing of systems thinking approaches, is management studies. Senge's (2006) and Mella's (2012) application of systems thinking to large organisations and Haines's, (1999) publication aptly utilises systems thinking for management. Haines, (1999) provides definitions, concepts, and benefits of a systems thinking approach to management of a large organisation, but also explains his '*backwards thinking'* which he considers a synonym for systems thinking within the context of management of organisations. Backwards thinking allows for understanding the output, the environmental influences and the process of the system before the current activities are envisaged. This is similar to Senge's (2006) indication of having the goal in mind at all times.

Senge, (2006), considers systems thinking approaches in an organisation as an organisations ability to continuously learn. Senge, (2006, 383-387) also provides concise essences, principles and practices of systems thinking and cites personal

mastery, use of mental models and building shared vision as fundamental to creating and sustaining a learning organisation. Senge's, (2006) book also combines numerous case studies of organisations around the world that have successfully implemented the strategies he cites and the successes that are wrought from implementing these strategies. He concurs with other authors on the essence of systems thinking centring on holism and interconnectedness. Senge's (2006) work helps organisations deal with vulnerabilities, assumptions and lack of innovation. His case studies indicate successes of applying systems thinking and importantly never really prescribing a set route of attaining success in an organisation but more so prescribing the principles that guide systems thinking application. His work has therefore been widely accepted as an important tool in contemporary management and a basis on which other works like Mella's (2012) have built on.

Using the systems thinking paradigm for this study firstly gives credence to the 'system' in food control system by bringing the aspects of coordination and integration as core features of the system. Secondly, it acknowledges that food control functions are part of a system and that when they are viewed and understood as such, the system has a greater chance of functioning more efficiently and effectively. Finally, viewing current food control functions as an integrated system also means that we can '*learn how to look for leverage points for change*' (Meadows, 2008, p6). This is important because where the South African food control system is fragmented, plagued with challenges and dysfunctional, the systems needs to change for better efficiency and effectiveness and there is an urgent need to know where and how to start the change .

Food control systems are open systems as they are susceptible to influences like political change and resource availability but they are also designed physical systems (Checkland, 1981). Being a designed physical system means that at some stage it

would have to be a designed abstract system and this is manifested in legislation that authorises the existence of the physical system. Where the abstract system is fragmented, which manifests in fragmented legislation, the food control system itself becomes fragmented. This is important because it brings to the fore an important requirement for integration in any system, including food control systems, that the conceptualisation of functions as a system is fundamental to integrating a system.

2.2. FOOD SAFETY AND TRADE OF FOOD

Food safety is the fundamental reason why food control systems are developed and considered relevant and why this study is considered pertinent. Safety of foods is non-negotiable; a trait that all foods produced must adhere to (FAO/WHO, 2003b). According to the FAO/WHO, (2003b, p: 3) food safety is referred to as '…*all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer*.' Hazards can be chemical and include substances such as pesticide residues, veterinary drug residues, colourants, and preservatives. Biological hazards include the presence of bacteria and viruses while those of a physical nature include, for instance, stones, hair and glass chips. In addition, hazards in food could be a result of new technologies in food manufacture or processing like genetic engineering or irradiation (WHO, 2002). Any one of the physical, chemical or biological hazards if not controlled can contribute to illness in the population, and is referred to as food-borne disease (FBD). However, most of the hazards in food that manifests in acute disease are microbiological or chemical, largely because the pathogens or substances are not visible and consumers cannot immediately identify the hazard. In most cases microbiological hazards usually manifest as acute disease while chemical contaminants, if not controlled are able to exhibit chronic effects on consumers.

The impact of consuming unsafe foods is illustrated by the occurrence of FBD where it is estimated that in the United States of America (USA) alone, food borne disease causes approximately 76 million illness, 325 000 hospitalisations and 5000 deaths per year (Rocourt *et. al*., 2003). If the above data is applied to the latest census data of the US population as indicated in the 2010 census (US Census Bureau, 2010), food borne disease is responsible for 25.6 % of the total population of 308.7 million being ill, 0.1 % of the population being hospitalised and 0.002 % of that population dying as a result of food borne disease. In terms of the economy, this equates to estimated costs of $35 billion per year for lost productivity and medical costs (WHO, 2011). In England and Wales, these incidences are 2 366 000 cases of illness, 21 138 hospitalisations and 718 deaths per year (Rocourt *et. al.*, 2003). In South Africa although food-borne illness, identified as food poisoning, is a notifiable disease if two or more cases are identified, the surveillance system for reporting of FBD is not robust (NICD/NHLS, 2010; Weber, 2007). However, if statistics for diarrhoea in children are used as an indicator, then 219 cases per 1000 children (DoH, 2009) is indicative of a 22 % incidence of diarrhoeal disease in South Africa. Although the causative agent for these incidences of diarrhoeal disease is not all food-borne, the statistics provides an indicator of the severity of the problem. Considering the burden of disease on governments, ensuring food safety becomes a highly relevant function (WHO, 2002).

International trade of foodstuffs has, over recent years, become another reason for developing and maintaining efficient food control systems (FAO/WHO, 2003b). With the volume increase of food trade, which is estimated to have increased by 800 percent from 1945 to 1995 (Kastner & Pawsey, 2002), the need to assure food safety to importing countries has become a priority to ensure sustainable trade of foods (WHO, 2002). Doubts on the safety (as well as quality) of foods produced by a country could

impact on whether those foods could be successfully exported and the reputation of the exporting country as an unsafe producer would translate into major losses in food trade income for that exporting country.

Considering the increase in global food trade over the past decades, together with the possibility of differences between food legislation of different countries, it was necessary to develop an international organisation aimed at harmonising standards related to safety for the fair trade of foodstuffs. Differences in legislation arise mainly because of the different exposure of risks in food in various countries as consumption of certain foods varies. For example, contaminants such as heavy metals in fish may be more of a concern for populations living in coastal regions rather than a landlocked country where fish availability and consumption is more limited. Because of the increased consumption, the exposure of the contaminant to that population is greater and therefore that country may set more conservative maximum limits of heavy metals than the landlocked country. In such cases, where exposure to a particular contaminant is a concern, the differing limits of the contaminant between countries are justified. However, exposure is not the only factor when there are differences in legislation and socio-economic factors may become important. For example, the use of hormones like recombinant Bovine Somatotrophin (rBST) in dairy farming for increased milk production is not allowed in the European Union (EU) as its use is against the principles of animal welfare of those countries as indicated in Council Directive 98/58/EC, 1998, p.23 (Brinckman, 2000). This ban exists on most hormones and hormone-like substances and includes the beta-agonist ractopamine which is not permitted for use in animals in the EU but is legislated for use in animals reared in the United States of America (USA) and other parts of the world, including South Africa.

Considering the differences in legislation, the United Nations (UN) FAO and WHO created the Codex Alimentarius Commission (CAC), a body overseeing various committees dealing with specific food safety issues (CAC, 1999). These included committees on Veterinary Drug Residues in Foods (CCVDRF), Pesticide Residues (CCPR), Food Additives (CCFA) and the Codex *ad hoc* Task Force on Foods Derived from Biotechnology, to name a few. Each of these committees drafts standards specific to each food safety issue with an aim of promoting harmonisation between standards of different countries (CAC, 1999). It also aimed to assist developing countries in developing their own food standards where it was lacking, based on the scientific principles on which Codex standards are drafted. Standards developed under each committee are drafted on the basis of the risk analysis framework which is rooted in scientific-based principles (CAC, 1999). Thus food standards developed are based on sciences related to toxicology, nutrition and agriculture. However although a majority of Codex standards deal with safety aspects, Codex acknowledged the role that it plays in consumer protection (CAC, 1999) and this provided the basis on which Committees like the Codex Committee on Food Labelling (CCFL) were established, for the prevention of misleading consumers.

Reference to Codex standards in World Trade Organization (WTO), Sanitary and Phytosanitary (SPS) international agreements has placed an emphasis on the role of Codex standards as the benchmark for safety of foods moving in international trade (WHO, 2002). South Africa became a member of the CAC in 1994, and the status of the CAC standards led to the country not only participating in Codex meetings but also adopting and utilising Codex standards for legislation. Adoption of Codex standards into South African legislation was conducted in one of two ways, the first being where regulations specifically referred to Codex standards and the second being the utilisation of the content of Codex standards to draft regulations. Examples of the

former include Regulations No. R. 246 of 1994 which sets maximum residue limits (MRLs) for pesticide residues and Regulation No. R. 1809 of 1992 which sets MRLs for veterinary drug residues in food, both of which indicate that compliance with Codex MRLs for imported food is permitted rather than compliance to in-country MRLs. Regulations No. R. 718 of 2006 relating to standards for bottled waters and Regulation No. R. 908 of 2003, which sets standards for use of Hazard Analysis Critical Control Point (HACCP) in food manufacturing premises, includes content of the Codex General standard for bottled waters and the Codex HACCP guidelines, respectively and this is the second way of incorporating Codex standards into local legislation, i.e. by use of Codex text in regulations.

2.3. FOOD CONTROL AND FOOD CONTROL SYSTEMS

The need to ensure food safety, trade of foodstuffs and consumer protection regarding foods indicates the need for a structural regulatory entity or entities to carry out functions to achieve those goals. The legislation mandating the regulatory control, as well as functions conducted thereafter, is referred to as food control. Specific definitions provided by the FAO/WHO include the food control system as '….*a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law* (FAO/WHO, 2003b, p:3) as well as '*the integration of a mandatory regulatory approach with preventative and educational strategies that protect the whole food chain*' (FAO/WHO, 2003b, p:3).

The two definitions above provide an indication of what food control comprises and also what it intends to achieve. It is comprised of compulsory laws and regulations which provides the basis for functions related to the enforcement of these laws. Therefore, legislation and enforcement of regulation are core elements of food control. However since function is rarely aloof from structure, this too is inherently included in the elements of food control. With regards to what food control intends to achieve, that is indicated as the requirement to ensure that all foods that are produced at whatever stage of processing or storage are safe to consume. Safety of foods consumed is a fundamental goal of food control but the need for facilitating trade of foodstuffs based on safety is also a prominent requirement of food control. Although not indicated specifically in the definitions provided above, the global authority on food safety, the Codex Alimentarius Commission (CAC) cites its reasons for developing food standards (equivalent to national legislation) as firstly aiming to maintain a safe food supply and then facilitate trade of foodstuffs in international markets (CAC, 2011).

If food control consists of legislation, function and structure and has the goal of ensuring safe food for human consumption as well as a goal of facilitating trade of foodstuffs, a food control system would then give rise to a coordinated effort or organisation in which to perform these functions. Definitions of food control system includes the '*integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain*' (FAO/WHO, 2003b, p: 3) and '*national food control systems are a group of elements organised and arranged in such a way that they can act as a whole to protect consumers health*,' (Neeliah and Goburdhun, 2007). Rightly so, the 'elements' of which can be understood to be legislation, and enforcement amongst others, need to be 'organised' and 'arranged'. This indicates a requirement for coordination, communication and systematic functioning to allow those elements described by Neeliah and Goburdhun, (2007) to

collectively contribute to protecting the health of consumers. All of these attributes of the system, which is, coordination, organisation and systematic functioning are related to integration of the system, a key attribute for this study.

Considering the definition of food control and food control systems, the FAO/WHO, (2003b) has described different types of food control systems or agencies. The first is multiple agency food control systems where structures and functions related to food control are separated, usually into different government departments or ministries; while single agency food control systems usually have their functions and structures of food control consolidated under one parastatal authority or under one Government ministry. The third type of food control agency is the integrated food control agency where distinct functions are carried out by different organisational bodies like enforcement by one body and legislative drafting by one body although these are functionally integrated and co-dependent functions.

2.4. THE FOOD CONTROL SYSTEM IN SOUTH AFRICA

If the FAO/WHO, (2003b) categorisation is applied to the South African situation the food control system can be classified as multiple agency with different departments being involved in various functions based on their overall mandate (Chanda *et.al.*, 2010). Thus the term of system is used loosely to describe the aggregate of functions rather than coordinated and organised functions (Chanda *et. al.,* 2010). When the task team of the Departments of Health and Agriculture referred to earlier was created and they generated the report in 1998, their frustrations were focused on the incoherence of functions that were co-dependent but instead were isolated. This incoherence resulted in incidences were legislation previously drafted was not compatible to other legislation,

while duplication of functions or no functions being undertaken because of lack of understanding of mandates and jurisdiction of Departments was also noted. Thus the challenges noted were largely functional or operational in nature.

The elements of a food control system already exist within the SA FCS (Figure 2.1.). Legislation, enforcement consisting of inspection and analyses, and structural components for drafting legislation and conducting enforcement all exist (Chanda *et. al.,* 2010). Legislation that controls food manufacture, sale and import under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 as well as requirements for raw agricultural product quality under the Agricultural Products Standards Act, 1990 and meat safety under the Meat Safety Act, 2000 are in place. In addition to specific Acts, other legislation controlling production and manufacture like use of veterinary drugs, pesticides and additives as well contaminants all exist. Prevention of misleading consumers is equally valued in legislation with the Foodstuffs, Cosmetics and Disinfectants Act, 1972 as well as the fairly recent Consumer Protection Act, 2008 containing stipulations that accurate food labels are required for informing consumers on the contents and quality of their food. Enforcement of legislation also exists with the Departments of Health and Agriculture, Forestry and Fisheries, which administer majority of the food related legislation, having enforcement arms in provinces and municipalities or even at the national level (Chanda *et. al.,* 2010). Laboratories also exist under the Department of Health and the Department of Agriculture, Forestry and Fisheries.

However, even though structures and functions related to legislation and enforcement exist, they may not be functioning efficiently due to a variety of reported constraints like resource constraints. Resource constraints are applicable, for example, to laboratories under the Department of Health that are constrained in terms of equipment, financial

and human resources (Chanda *et. al.,* 2010). In addition other constraints include inadequate expertise on methodology used for analyses. Aside from constraints in performing duties due to human or financial requirements, functions are inefficient because they are not coordinated between the two major regulatory authorities or with the National Regulator for Compulsory Specifications (NRCS), another arm of the food control system (Chanda *et. al*., 2010; Bruckner *et. al*., 1998). In-coordination between functions typically results in duplication of functions even though resources are limited. Challenges of in-coordination are indicated by FAO/WHO texts as common in multiple agency food control systems with other challenges of this type of system including confusion over jurisdiction, differences in levels of expertise and resources between the different parts of the system, and lack of coherence between the various parts of the system (FAO/WHO, 2003b).

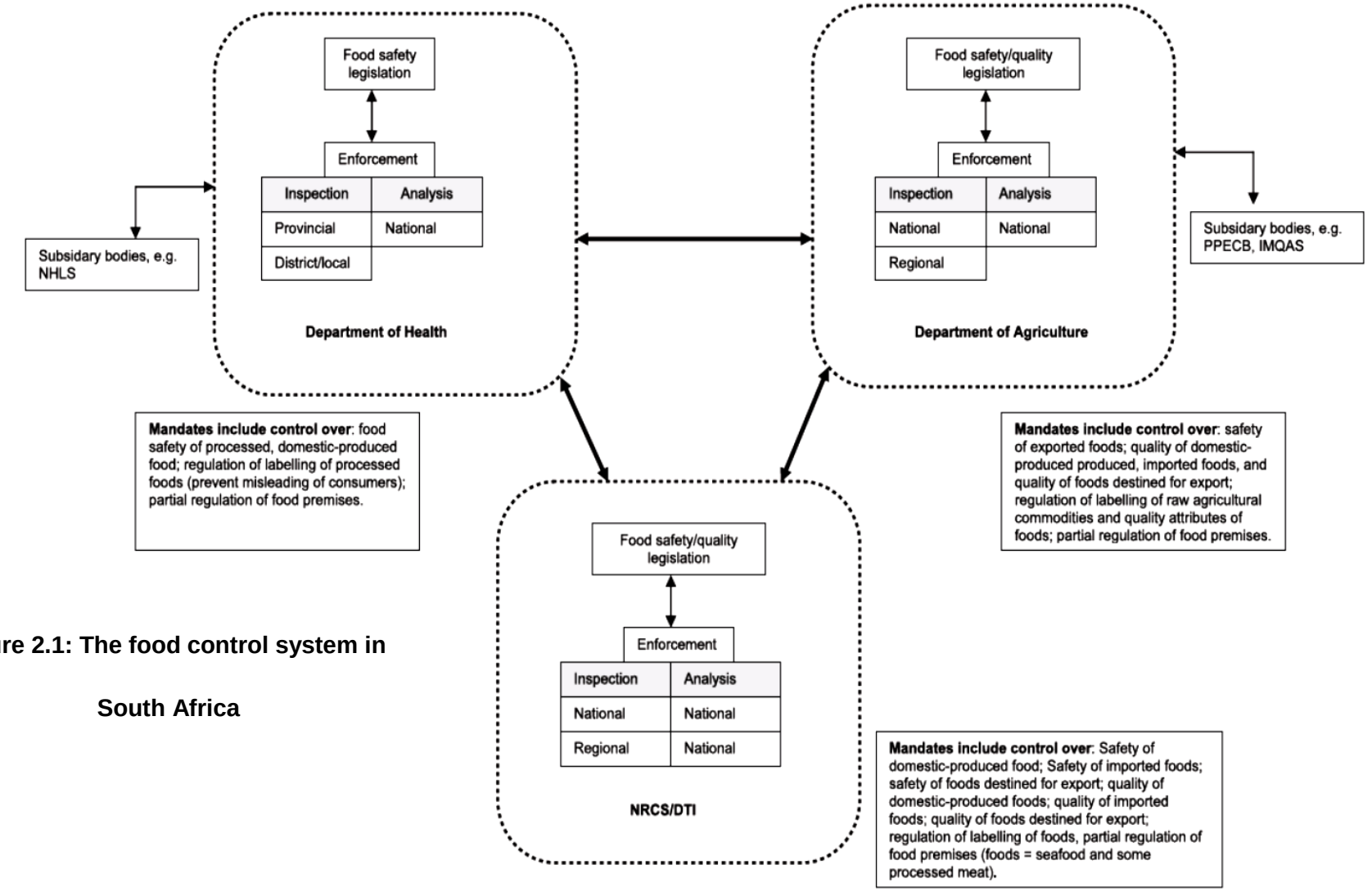

Figure 2.1: The food control system in South Africa

2.5. VETERINARY DRUG RESIDUES

As indicated previously, the objectives of the study require that detailed and contextualised research needed to be conducted on the food control system in order to achieve the objectives of the study. As the food control system is large, the in-depth research required was best obtained from studying one part of the food control system in detail and then to use results obtained from that research to affect changes in the greater food control system. Veterinary drug and residue regulation was chosen because the initial review of the South African food control system indicated that veterinary drug and residue regulation had fragmented structures, functions and legislation and that at least one challenge of duplication was evident within this system (Chanda *et. al*., 2010). Since the regulation of veterinary drug residues becomes a food safety risk only after use of veterinary drugs in food producing animals, the interrelated regulation of veterinary drugs and veterinary drug residues must be considered together. In this way, the entire food supply chain is considered which includes both veterinary drugs and residues and their regulation.

Veterinary drugs, like drugs for humans, are used for the well-being of animals. However in the rearing of food-producing animals where yield is very important, and there are expenses incurred in the rearing of animals, veterinary drugs are used to sustain and increase growth of animals for production. The use of veterinary drugs has not only yielded benefits in ensuring the provision of animal-derived food products from healthy animals but also sustainable production of livestock for economic gains (National Research Council, 1999; Morley *et. al.,* 2005). However, with the benefits related to use of veterinary drugs in animals, their use may also be cause for concern due to effects that the residues of these drugs could have on consumers.

Concerns regarding veterinary drug residues in foods differ based on the type or category of drug used in the animal. The National Research Council of the United States of America (USA) categorises veterinary drugs into: topical antiseptics, ionophores, hormone and hormone-like drugs, antiparasitic drugs and antibiotics or antimicrobials (National Research Council, 1999). Of these categories indicated by either the National Research Council or the CAC, the two most widely debated for their use in food animals is antimicrobials and hormone/hormone-like drugs. Use of antimicrobials in food producing animals has sparked the concern of the possible build-up of resistance of bacteria found in humans because of exposure to antimicrobials in animal-source foods. This could mean that treatment methods with similar if not the same antimicrobials in humans for illness could be rendered less effective. Antimicrobial resistance is of concern because antimicrobials are not only used for therapeutic purposes via dose controlled administration to protect animals against pathogenic bacteria; but are also used sub-therapeutically (when administered through feed) to increase efficiency in food uptake and utilization in animals (Doyle, 2006; National Research Council, 1999).

A further concern of the use and misuse of antimicrobials, as well as other types of veterinary drugs is exposing susceptible human populations to increased concentrations of these drugs thus exacerbating allergic and/or toxic responses (National Research Council, 1999). Other veterinary drugs, particularly growth promoting chemicals that have corresponding hormones in humans have also received much attention as it has been postulated that it could have effects on humans. The rBST case between the USA and the European Union (EU) indicates the controversy in the use of this hormone (Brinckman, 2000; Collier, 2000) whether it is for effects on humans or animal welfare reasons. Other hormones like oestrogens are also in the spotlight because studies indicate that even minute amounts of exogenous oestrogens could potentially alter

reproductive ability and development particularly in young children (Aksglaede *et. al.,* 2006; Andersson & Skakkebaek, 1999; Partsch & Sippell, 2001).

The understanding that residues of veterinary drugs could be a likely food safety and public health concern prompted the need for various countries to control the administration of veterinary drugs to food producing animals. Countries developed a regulatory system of legislation, structures and function for controlling veterinary drugs and their residues. In South Africa, the regulatory system was initiated as far back as 1947 when veterinary drugs were registered as stock remedies under the Department of Agriculture (Act 36 of 1947). After this initial regulation, the control of veterinary drugs and veterinary drug residues has evolved considerably. It is this evolution that has resulted in a fragmented regulatory system of veterinary drug and residue control and which was used for focused research. The elaboration of the current state of the regulation of veterinary drugs and residues is provided in paper 2 while the evolution of the development of this regulation is provided in paper 3.

2.6. SUMMARY

This chapter discussed and reviewed key concepts of this study from food safety, food control, food control systems and veterinary drugs and residues. These topics are interrelated and not isolated. For example food control systems are in place to conduct the function of food control which is required to achieve food safety. The in-depth research of veterinary drugs and residues is a specific food safety issue and this requires control, in the form of regulation, which is conducted within a food control system. Food control systems in turn must be understood from the perspective of the definition of *system* which acknowledges coordination and integration as being core principles for any system.

The key outcome of this chapter is that food safety and food control are imperative as they are key governmental functions required to protect the population from unsafe and poor quality food. This is also true of the individual food safety issue of veterinary drug residues in food as it is with other food safety issues regulated within a food control system. The concepts of food control, food safety, food control function, and veterinary drug and residue regulation, explored in this chapter, will again be used in the papers of the study, in chapters 4-8. Food control and food control systems are looked at in detail in paper 1 where the scope of the South African food control system is discussed, while veterinary drug residue regulation is looked in papers 2-5 (chapters 5-8) where it is used for the in-depth study to determine challenges of the food control system as well as why and how fragmentation was initiated and continues.

Before the papers are introduced, the following chapter will provide an indication of the methods employed in this study, why they were used and which objectives they have satisfied.

CHAPTER 3: METHODS

South Africa's social, political and economic history is mired in fragmentation, the most visible being the manifestations of the apartheid regime, the name of which refers to segregation. During apartheid, the South African population was geographically segregated based on race due to social and economic policies of the country. The white minority governed the country and created a system of elitism for that minority while the black majority was subjugated and marginalized (Beinart and Dubow, 1995). What transpired during this time was that each segregated community developed in isolation socially and economically under seperationist policies. After the first democratic elections in 1994, these segregated communities had to learn to integrate while the economy needed to sustain a larger amount of people with limited resources (Thornhill, 2005). To drive this integration required policies that had to be implemented by the democratically elected government to address the ills of the past.

Implementing policies to address segregation has not been without challenges as the advent of service delivery protests has indicated (Mubangizi, 2005). At the onset, the post-apartheid government had to reallocate functions between the previous four provinces into the current nine provinces while reallocating resources to reach the greater population was cumbersome (Mubangizi, 2005). In addition the previous service delivery model was centralized and the new government needed to make services accessible to all and this required a decentralized government. The work required to conclude these tasks was indeed monumental. Aside from the amount of work required to change service delivery in post-apartheid South Africa, the skills challenges, particularly leadership, for transforming the public sector where scarce (Mothae and Sindane, 2007).

Against this context is where the current health and food control policies of South Africa arise. Health care was segregated as were other social services while food safety and agricultural input control were controlled only to aid food production and prevent illness. Considering that the post-apartheid Government had to address more pertinent human rights transgressions, food safety and agricultural input control was consigned for later evaluation. Thus the current system of fragmented legislation, spurred by a segregationist framework, is what food control policy currently comprises. Therefore to change the food control system means a change in the food control policy of the country and in order to integrate the system, policy must be integrated as well. The end goal of this thesis is therefore to affect changes to policy by understanding what challenges there are on the road to integration.

To determine the challenges of the current food control system as well as to address other goals of the study, a variety of methods were employed, a methodology often referred to as mixed methods research. This mixed method approach is widely established (Creswell & Plano Clark, 2011; Teddlie & Tashakkori, 2010; Johnson *et. al*. 2007) and deemed necessary for this study because literature on the scope and fragmented state of the South African food control system was limited and a variety of methods was needed to firstly obtain information and then to verify it.

Some of the objectives of the study aimed to contribute to developing this literature base while other objectives required application of derived information for recommending changes to develop an integrated food control system. Thus reviews remained an integral part of the methodology used. A description of data collection methods employed in the study is also provided. Data collection methods of reviews, interviews and personal communication and questionnaires will be described. In addition to the above, a brief description of the use of specific tools like the food safety risk analysis

framework which was applied in paper 2 in conjunction with a review will also be provided.

3.1. FOCUSED RESEARCH

As previously indicated, this study used the individual food safety issue, which is the regulation of veterinary drug residues in food, for in-depth research of the entire food control system. This methodology provided for achieving the majority of the objectives of this study. Using one part of the system for focused research is similar to the use of a case study, as the aim is similar. Case research is described as a '*method of intensely studying a phenomenon over time in its natural setting in one or more sites'* (Battacherjee, 2012) or '*a systematic enquiry into an event or set of related events which aims to describe and explain the phenomenon of interest*', (Bromley, 1990 in Zucker, 2009) or '*a case study is an empirical enquiry within its real life context, especially when the boundaries between phenomenon and context are not clearly evident*' (Yin, 1994 in Woodside, 2010). The description of case research reiterates what is desired from the use of researching veterinary drug and residue regulation, importantly that it is generally used to obtain 'deep understanding' and appropriate description of a phenomenon, explanation of a phenomenon or prediction (Woodside, 2010). Therefore studying veterinary drug and residue regulation is like making use of case research where an in-depth understanding of fragmentation and challenges it is associated with is desired.

The use of the focused area of research of veterinary drug and residue regulation was used to address objectives 4 and 5 of this study which looked in detail at challenges of the food control system and how and why fragmentation was initiated and continues.

3.2. DATA COLLECTION METHODS

Battacherjee, (2012) and Zucker, (2009) indicate that data collection methods may be varied and can be obtained from literature reviews, surveys that include interviews, personal communication, literature reviews and observations. As a variety of data collection methods exist for studies many of them were used in this study in order to maximise the information derived. As a result, reviews, questionnaire-based surveys, personal communication and interviews were used in the study and will be briefly described in the following sub-chapters. The food safety risk analysis framework will also be described as it was applied in paper 2 in order to produce a systematic review of the regulation of veterinary drug residues in food in South Africa.

3.2.1. REVIEWS

Literature reviews are important to contextualise a study as well as to determine what has already been written on the study subject (Kumar, 2011) while they are also considered important methods to a) to survey the current state of knowledge in the area of inquiry b) to identify key authors, papers, theories, and findings in that area, and c) to identify gaps in knowledge in that research area (Battacherjee, 2012). For this study reviews were used both to contextualise and understand what had already been written about the food control system but also to address specific objectives of the study in terms of defining the scope of food control and definitions of food control systems and fragmentation. Therefore for this study, reviews were also instrumental for linking ideas, concepts and interactions occurring within the food control system. For example, to obtain objectives 1, 2 and 3 which are to determine the scope of food control in South

Africa, to define fragmentation and to determine whether fragmentation exists in the South African food control system respectively, an integrative review was used which is described as '*an attempt to integrate empirical research for the purposes of creating generalisations'* (Cooper and Hedges, 1994). To obtain objective 4 which is to determine how fragmentation evolved, a critical review was used which reviewed the development of the regulation of veterinary drugs and residues with an aim to determining the influences behind the initiation of fragmentation. To achieve objective 5 which is to determine the challenges of the South African food control system, and to determine the relationship between fragmentation and challenges, review methodology was also employed, amongst other methods.

3.2.2. QUESTIONNAIRE-BASED SURVEY

Survey research is considered a research method for obtaining data in a systematic manner (Battacherjee, 2012). The survey can be conducted through structured interviews or through questionnaires. For this study structured questionnaires were used for the survey. The questionnaires were based on eight risk management (RM) strategies identified in paper 2 and participants were asked to provide their understanding of what each strategy entailed, who conducted it and how well they conducted it. Participants were also asked to indicate whether the RM strategies were considered relevant and if indicated as inefficient, how they could be bettered. Aside from the RM strategies, participants were also asked to respond to questions on the efficiency of communication within the departments they belonged to, with other government departments and with non-governmental stakeholders. The results of the questionnaires were integral in understanding if and why poor systems

conceptualisations and poor horizontal communication were prevalent as well as what other challenges were identified in the system (contents of papers 4 and 5, respectively). It provided an insight to what non-governmental stakeholders thought of the system and what challenges they identified. The use of a questionnaire-based survey also provided the first primary research in South Africa on the veterinary drug and residue regulatory system as a focused area of research for the South African food control system.

3.2.3. INTERVIEWS AND PERSONAL COMMUNICATION

As data on the scope and functioning of the South African food control system were not reported on in detail previously, obtaining this information required acquiring it from knowledgeable and experienced persons within the system in order to report the findings. Interviews are a recognized form of data collection (Fox, 2009; Battacherjee, 2012) and therefore considered valuable for this study. As a result, face-to-face interviews were conducted with key personnel of the Department of Health or outside organisations like the National Society for Prevention of Cruelty to Animals (NSPCA), to obtain information. Interviews were either semi--structured or structured and used to obtain information on the functions of the food control system or the regulation of veterinary drugs and residues, where literature was lacking. Similarly, personal communication to obtain information was used and this was either semi-structured or unstructured. Personal communication was used more often than interviews particularly at the beginning of the study in order to contextualise the study and understand the scope and functioning of the South African food control system.

3.2.4. FOOD SAFETY RISK ANALYSIS

The framework of food safety risk analysis was used in paper 2 to review the South African regulatory system of veterinary drug residues. This framework was used against food control legislation, functions and structures in order to determine if challenges were present within the system. Use of this framework allowed for a systematic review (Victor, 2008) of the veterinary drug residue regulatory system and also provided the risk management strategies for veterinary drug residues which were used as the basis of the questionnaire of this study.

Food safety risk analysis is best described by the FAO in their text of 2006 entitled '*Food safety risk analysis. A guide for national food safety authorities*' (FAO, 2006). This is a framework used to assess, manage and communicate risks in food and allows for consistent decision-making on the risks in food (FAO, 2006). It is also vital as the basis for standard development for individual food safety issues (FAO, 2006). Considering its purpose, risk analysis consists of three parts, risk assessment, risk management and risk communication (Figure 3.1.: FAO, 2006). With risk assessment, the focus is on hazard identification, hazard characterisation, exposure assessment and risk characterisation and is considered the 'science-based' component of the framework. This component utilises scientific methods to quantify the risk in foods and this quantification is used in the next component of risk management, the decision-making part of the framework. Although the risk management component considers risk assessment outcomes, decisions are rarely based on those outcomes alone, and therefore also consider social, ethical, economic and environmental factors amongst others (FAO, 2006).

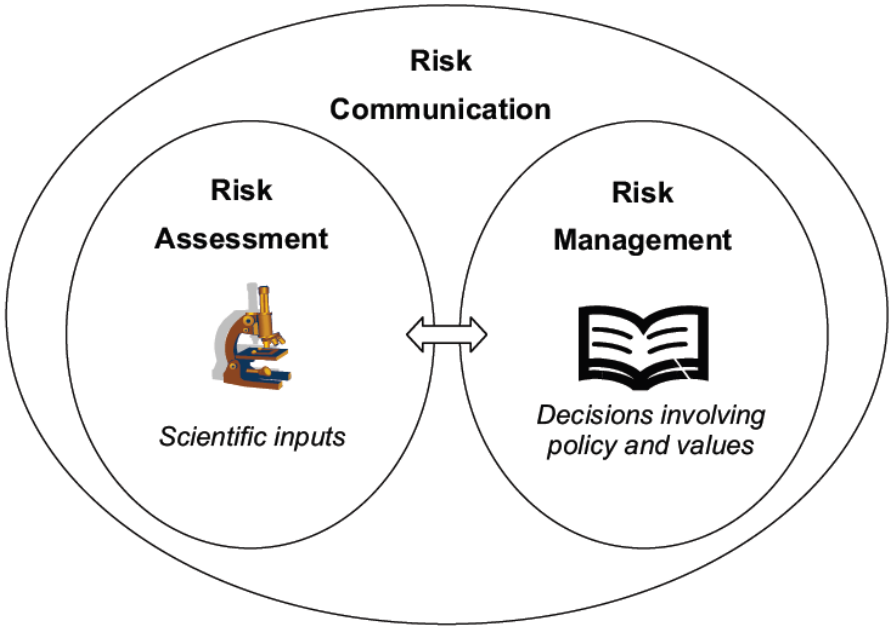

Figure 3.1: Food safety risk analysis framework (from FAO, 2006)

Risk communication is essentially communication between risk assessors, risk managers, risk communicators and other stakeholders like the public, food industry, consumer groups and other organisations about risks in food. The aim of this component of the system is to ensure all stakeholders are aware of the risks in order to make sound decisions to manage risk in food and even to prevent hazards from becoming risks.

The food safety risk analysis framework indicates the functions that are required for assessing, managing and communicating risks in food. Since the functions can be contrasted to those already existing within the South African veterinary drug and residue regulatory system, gaps in functions and corresponding functions and legislation can be identified. The application of this framework therefore provides for a systematic review of the veterinary drug and residue regulatory system.

CHAPTER 4: PAPER 1

Table 4.1: Summary of details of Paper 1

Title	Review of the South African Food Control System: Challenges of Fragmentation
Publication status	Published 2010 in Journal: *Food Control*
Journal website	http://www.journals.elsevier.com/food-control/
Citation reference	Chanda, R. R. Fincham, R. J. Venter, P. (2010) Review of the South African Food Control System: Challenges of Fragmentation, *Food Control*, 21: 816-824
Address objectives	This paper addresses objectives 1-3 of the study which sought to determine the context and scope of the South African food control system, to define fragmentation, to as well as to determine whether fragmentation of the South African food control exists. The paper also provided an initial review of challenges of the South African food control system.
Methods used	The objectives of this paper and study were achieved primarily through reviews where literature on country-specific information from internal government documents; published FAO/WHO documents and journal articles were reviewed. Other methodology used included interviews and personal communication with relevant and knowledgeable persons involved in the food control system, particularly where literature was lacking.
Key outcomes of the paper	The definition of fragmentation and its application to the South African food control system produced the first published, peer reviewed piece of literature on the fragmented state of the South African food control system and the challenges that are evident in the system.

A Review of the South African Food Control System: Challenges of Fragmentation

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Abstract

South Africa's food control system is a typical multiple agency food control system where fragmentation of legislation, structure and functions result in operational challenges. These challenges include lack of coordination of functions as well as duplication and unclear jurisdiction of functions between involved Government Departments. Examples of fragmentation in structure, legislation and function of the South African food control system are presented while descriptions of the abovementioned challenges are also described. In addition, previous and on-going attempts by Government to address these challenges as well as fragmentation as a whole are also provided while brief suggestions on hastening these attempts to integrate the system are also included.

Keywords: food control system; fragmentation

1. Introduction

South African food control activities have previously been reported on although only in either internal documents of Government Departments (Brückner, van de Venter, Rademeyer, Malan, Jansen van Rijssen, & Wolhuter, 1998; DoA, 2005) or through publication of Food and Agriculture Organisation (FAO) reviews or reports (FAO/WHO, 2003a; FAO/WHO, 2005; FAO/WHO, 2004). However, even though the food control activities of South Africa are reported on as part of a system, the literature indicated above describes the system as distinct parts that undertake discrete and isolated activities. In fact many of these documents emphasise the fragmentation in legislation, structure and function.

The concept of fragmentation forms the core of this paper and builds on earlier references to this phenomenon in the South African food control system as well as references to segregation as described by the FAO/WHO (2003b: 13) in their description of multiple agency food control systems. Here it is defined as a situation where '*legislation, structure and functions of a defined food control system are allocated to different government departments (or agencies) or different spheres of government due to policy or mandate obligations.* This definition also infers the rendering of food control legislation, structure and function of a system as merely an accumulation of legislation and activities that operate in isolation and out of synchrony.

The definition, which specifically speaks of legislation, functions and structure related to food control systems, will be applied to the review and discussion of the South African food control system. The discussion will encompass a description of challenges related to fragmentation of the South African food control system while the main texts will provide brief introductions to food control systems as well as the South African food control system under relevant sections.

2. Food control systems

Food control systems have been described by the Food and Agriculture Organisation (FAO)/World Health Organisation (WHO) and later by various researchers (Neeliah and Goburdhun, 2007; Whitehead, 1995; Anyanwu and Jukes, 1990; Nguz, 2007) many of whom have also documented the food control systems within their or other countries. However, before the goals and components of such a system are described, an appropriate definition of food control systems must be provided. In keeping with the authority of the FAO/WHO on food control systems, the definition, which describes these

systems as '*the mandatory regulatory activity of the enforcement of food laws and regulations by national or local authorities'* (FAO/WHO, 2003b: p3) is acknowledged and employed here. According to this definition, the food control system is reliant on food related legislation and the adequate enforcement of these laws, the former of which is drafted as a result of pressures of particular goals of the system. These goals have been identified as the need to provide consumer protection by ensuring that food produced during the handling, storage, processing and distribution stages are safe for consumption (FAO/WHO, 2003b: p3), thus satisfying public health goals. Consumer protection also extends to ensuring quality of foods intended for consumption as well as food that is honestly labelled (FAO/WHO, 2003b: p3). A further goal is the facilitation of the trade of foodstuffs for economic development (FAO/WHO, 2003b: p3-4), a goal emphasised of late due to the global increase in trade of foodstuffs.

The goals of a food control system are achieved via functions of various components of the food control system that work together. In the FAO/WHO (2003b) document the components are indicated to comprise of personnel dealing with food laws; enforcement of food laws (inspection and analytical services); Information, Education, Communication and Training (IECT) as well as food management and administration (FAO/WHO, 2003b: p7). Food laws provide the mandate for government to perform activities related to food control while inspection and analytical services are required to determine compliance of manufacturers, producers or importers to laws published. IECT refers to training of officials within the system, communication of decisions of government as well as communication between various agencies/components of the system and stakeholders of the system (FAO/WHO, 2003b: p9). IECT also refers to the government responsibility to adequately educate consumers and other stakeholders (including manufacturers) about the functions of the food control system as well as the need for safety and quality of foods within the country.

Food control systems can vary in structure and the FAO/WHO (2003b: p13) has provided three categories of these systems where the first type is characterised by structure and functions of the food control system being segregated, usually into different Government Departments or levels of Government (FAO/WHO, 2003b: p13). This is referred to as a multiple agency food control system and segregation can be both horizontal and vertical where food law drafting, inspection and analytical services and IECT are physically and functionally separated into different departments of the same government. An example of this type of food control system is that of the United States of America (USA) where the Department of Health and Human Services, the United States Department of Agriculture (USDA) and the Department of Treasury's Customs Services are all involved in aspects of food control. The Department of Health and Human Services conducts food control activities via the Food and Drug Administration (FDA) and particularly via the Center for Food Safety and Applied Nutrition (CFSAN). The CFSAN is therefore the relevant authority on administering legislation protecting against unsafe and impure food as well as food that is fraudulently labelled (FDA/USDA, 2000). The USDA has within it the Food Safety and Inspection Service (FSIS) and the Animal and Plant Health Service (APHIS) as well as the Environmental Protection Agency (EPA) (FDA/USDA, 2000), the first two of which are responsible for ensuring safety and adequate labelling of meat, poultry and egg products while the EPA is responsible for protecting the public from risks associated with pesticides and for advising on adequate pest management systems (FDA/USDA, 2000). In addition, the Department of Treasury Customs Service provides an enforcement service by assisting the various involved Departments to check and detain imports of food (FDA/USDA, 2000).

In contrast to the above some food control systems have their functions consolidated under a single authority, not necessarily within a single Government Department but

could include a parastatal body that answers to one Government Department (FAO/WHO, 2003b: p15). Thus in this type of system, categorised as a single agency food control system, food law drafting, inspection, analytical and IECT functions are integrated under one body with the same objective and mandate. Examples include The Spanish Agency of Food Controls, a recently developed agency under the leadership of Spain's Ministry of Health and Consumer Affairs (Garcia and Jukes, 2004). This agency consolidates previous food control activities of a multiple agency food control system, consisting of the Ministries of Health and Consumer Affairs, The Ministry of Agriculture, Fisheries and Food and the Ministry of Economic Affairs and Housing as well as individual control systems of 'autonomous communities' (Garcia and Jukes, 2004). Greece has also established the Hellenic Food Safety Authority which consolidates functions of the five national Ministries, viz., Ministry of Agricultural Development and Food, Ministry of Health and Social Welfare, Ministry of Economy and Finance, Ministry of Development and the Ministry of Public Order (Varzakas, Tsigarida, Apostolopoulos, Kalogridou-Vassiliadou D, & Jukes, 2006) and now reports to the Ministry of Development.

The third type of food control system, an integrated agency food control system, is characterised by coordination of various activities of the system by different agencies or departments, for example, food law drafting, inspection, analytical and IECT are coordinated independently. The monitoring of the system could also be coordinated by a separate section (FAO/WHO, 2003b: p15). An example of an integrated agency is the Korean Food and Drug Administration (KFDA), situated in Seoul with regional offices in various other cities (Kwak, Jukes, & Shin, 1999). This Administration is the head of food safety issues and is responsible for enforcing food laws and conducting research on risks in food (Kwak *et. al*., 1999). The Food Safety Bureau, Office of Safety Evaluation and National Institute of Toxicological Research are other agencies that look at

surveillance and field operations and/or toxicological evaluation and research (Kwak *et. al*., 1999).

It is also worth noting that at the international level, although not a food control system the Codex Alimentarius Commission (CAC) a joint body commissioned by both the FAO and WHO of the United Nations (UN) is the most notable of international food standard setting bodies. Developed to provide standards and guidelines for foodstuffs to ensure safety of foods traded, it also plays an enhanced role in foods moving in international trade via the Sanitary and Phyto-Sanitary (SPS) Agreement of the World Trade Organisation (WTO) which has named Codex Standards the international benchmark for foods in trade (WHO/FAO, 2005: p29-32; FAO/WHO, 2003b: p4). Although Codex standards do not infer the change of national legislation, many countries, particularly developing countries, utilise Codex standards and guidelines to draft their own national legislation. Therefore although this body is not a food control system it has numerous characteristics of a food control system at the international level.

3. The food control system in South Africa

South Africa has the fundamentals of a food control system, but legislation and functions are not confined to a single Government Department. Rather laws, regulations, standards, enforcement and analytical services are scattered and control or administration of these is a shared responsibility by three main national Departments (Brückner *et. al*., 1998; DoA, 2005). In addition, Provincial and Local authorities are also involved in food control for enforcement of legislation drafted at the national level (Brückner et. al., 1998; DoA, 2005). Control of import and export destined foods, safety

and quality aspects of foods as well as unprocessed and processed foods are segregated.

The segregated functions of the South African food control system are better understood if the context in which the food control system operates, i.e. the structure and function of the public service and Government in general in South Africa is explained. In Government Departments, legislation and functions are departmental-based with the majority of departments having definite mandates based on Acts and regulations to administer and carry out definite functions. Because government structure in general so heavily influences the activities and structure of the food control system, a brief description of Government structure will be provided to illustrate the framework in which the food control system activities operate.

3.1. The structure of Government in South Africa

National Government Departments are administrative centres for the public service and are mainly involved in policy drafting, research generation, monitoring and evaluation and sometimes enforcement of legislation drafted. National departments are headed by Minister's, Deputy Ministers (both are members of parliament), and Director-Generals, the last of which are considered the administrative heads of the Department (DPSA, 2003: p16). The Director-General heads numerous branches, each of which is managed by Deputy Director-Generals, that deal with specific technical activities. Management below the Deputy Director-General comprises of Chief Directors/Cluster Managers, Directors and Technical Staff.

The Ministers of respective Departments have jurisdiction on all aspects relating to the mandate of their activities but the nine provinces of the country, being statutory bodies under the Constitution of South Africa (van Niekerk, van der Waldt, & Jonker, 2001: p74; DPSA, 2003: p17) have similar Departments to those of the national office and are also therefore recognised Government entities. These provincial departments are headed by MECs (members of the Executive Council) and are authorised to conduct certain activities by the National Ministry under sections 99 and 100 of the Constitution (van Niekerk *et. al*., 2001: p75) but operate also under the budget, structure and direction of the provincial head, the Premier of the respective province (DPSA, 2003: p17). Thus agreements regarding authorisation and assigning of activities of Acts of Parliament between Ministers of Departments and the relevant Premier or MEC must be forged to ensure legal authorisation (van Niekerk, *et. al.*, 2001: p73). Many national departments have delegated their enforcement and implementation of legislation to provincial and local authorities, the latter of which are supervised by Provincial authorities but are still considered distinctive components of government. Local authorities comprise of municipalities which are either metropolitan, district or local and are distinguished by size and authority of the municipality (DPSA, 2003: p19). It should be noted, however, that although provincial and local Departments exist, functions are not automatically delegated and therefore the National Department may still be responsible for enforcement. This is seen in the case of the Department of Agriculture, where although Provincial Departments of Agriculture exist, in the case of regulation of genetically modified organisms (GMOs), and quality of foodstuffs under the Agricultural Products Standards Act, 1990 inspection and enforcement is still a national responsibility.

3.2. Structural fragmentation

As discussed before, three national departments are mainly responsible for the regulation of most of the foodstuffs consumed, produced, manufactured, imported or exported into/via the country. These are the Departments of Health (DoH), Agriculture, Forestry and Fisheries (previously the Department of Agriculture and Land Affairs although only the Department of Agriculture (DoA) is of importance here) and the Department of Trade and Industry (DTI) (Brückner et. al., 1998). The Department of Water and Environment Affairs (previously the Department of Water Affairs and Forestry) is also a relevant authority on water safety but is not discussed in detail here.

The operative unit in the DoH is the Directorate: Food Control (the Directorates: Nutrition, Environmental Health as well as the Cluster: Medicines Regulatory Affairs are also involved in food issues but largely only for fortification, environmental health practitioner support and registration of veterinary drugs in food producing animals, respectively). Operative units in the DoA are numerous and include the Directorates, Food Safety and Quality Assurance, Veterinary Services, Animal Health, Biosafety, Genetic Resources, Plant Health and Agricultural Inspectorate Services. The Department of Trade and Industry administers the Standards Act, 1993 (Act 29 of 1993), which authorises the continued establishment of the South African Bureau of Standards (SABS), which was created approximately 60 years ago primarily for determining safety of food exports to Europe (SABS, 2005). The standards setting division of SABS, the previously known STANSA was the authority on setting compulsory standards for certain foodstuffs, amongst other commodities. In 2008, the National Regulator for Compulsory Services (NRCS) was created after the National Regulator for Compulsory Services Act (Act 8 of 2008) was promulgated. The NRCS is now the authority of compulsory

standards in South Africa, functions of which were previously conducted by the Standards Division of SABS. The NRCS receives funding from the parent Government body, the Department of Trade and Industry (DTI). The NRCS has complete (import and export) regulatory control of frozen and canned fish, molluscs and crustaceans as well as canned meats and meat products (NRCS 2008), Since the NRCS is under authority of the DTI, the DTI becomes part of the food control system as a national regulator.

3.3. Fragmentation of legislation

The chief Act relating directly to food control is the Foodstuffs, Cosmetics and Disinfectants Act (FCD Act), 1972 (Act 54 of 1972) administered by the DoH. The Act addresses the control of safety aspects of foods and specifically makes provision for the sale, manufacture and importation of certain foodstuffs. In addition, the Act regulates the use of processes, methods, appliances, containers or objects in food production and also regulates the description of food papers and responsibilities and liabilities of the importer, manufacturer or packer, inspectors and analysts. Regulations under this act include those relating to additives, sweeteners, marine biotoxins, pesticide residues in foodstuffs, labelling of foodstuffs, microbiological specifications, veterinary drug residues in foodstuffs, metals in foodstuffs and milk and milk products, to name a few. In addition to these, regulations under the repealed Food, Drugs and Disinfectants Act, 1929 are also enforceable although some of these regulations address quality aspects of foods. The FCD Act also makes provision for SABS (could be changed to read NRCS) to inspect foodstuffs and premises under section 10 (3e).

Another principal Act, the Agricultural Products Standards Act (APS Act), 1990 (Act 119 of 1990) administered by the Department of Agriculture deals largely with quality issues

(composition of juices and claims in terms of labelling etc.) and controls the sale and export of a variety of foodstuffs. The Act also makes provision for partial marketing of foodstuffs in relation to quality issues (marketing is controlled under the Marketing Act, 1968 (Act 59 of 1968) and more specifically the Marketing of Agricultural Products Act, 1996 (Act 47 of 1996) and subsequent amendments). Regulations under this Act include, amongst others, the grading, packing and marking of maize products as well as the control of the sale of mayonnaise and salad dressings. Many of the regulations under this Act are vertical with specifications for specific types of foodstuffs. In comparison, vertical regulations are fewer under the Foodstuffs, Cosmetics and Disinfectants Act, 1972. Horizontal regulations under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 provide blanket control over foodstuffs and include as examples, control of preservatives, antioxidants, emulsifiers, sweeteners and colourants for all foodstuffs. Vertical regulations under this Act include regulations relating to bottled waters, milk and milk products and salt.

The Perishable Products Export Control Board Act, 1983 (Act 9 of 1983) authorises the continued existence of the Perishable Products Export Control Board (PPECB) which is a parastatal body that has been assigned by the Department of Agriculture to conduct audits and analysis of perishable foods destined for the export market under the Agricultural Products Standards Act, 1990 (de Beer, Patterson & Olivier, 2003: p82).

The Meat Safety Act, 2000 (Act 40 of 2000), a relatively recent consolidated Act makes provision for hygiene requirements of meat and abattoirs. This Act, administered by the DoA also makes provisions for the export and import of meat and repeals the earlier Abattoir Hygiene Act, 1992 (Act 121 of 1992). Other Acts of importance are the Genetically Modified Organisms Act, 1997 (Act 15 of 1997), The Fertilizers, Farm Feeds,

Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), and the Liquor Products Act, 1989 (Act 60 of 1989) all administered by the Department of Agriculture although via different Directorates (sections). These Acts have broad regulatory mandates and extend control over other commodities and substances that aren't considered food. However, their influence over foodstuffs is vital. The Genetically Modified Organisms Act, 1997 controls the import, general release and field trials of all genetically modified foods. This Act indicates a different ideology in legislation drafting as it makes provision for six Government Departments to be represented at an Executive Council (EC) where final decisions on applications for activities with genetically modified organisms are taken. In addition this Act makes provision for a centralised Advisory Committee (AC) that conducts the risk assessment of genetically modified organisms (including food). With the legal requirement of both an EC and AC, this Act overcomes mandate isolation and allows for decision-making with the parallel inputs of six relevant Government Departments (Departments responsible for Health, Agriculture, Science and Technology, Environment Affairs, Labour, Trade and Industry). The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 is relevant to foodstuffs due to the registration of pesticides and stock remedies (veterinary drugs) that are used on food crops and food producing animals, respectively, while the Liquor Products Act, 1989 controls all aspects of liquor production and labelling.

The Department of Health also administers other Acts that have relevance to food safety and include the Health Act, 1977 (Act 63 of 1977), although repealed by the National Health Act, 2003 (Act 61 of 2003) has standing regulations relating to hygiene requirements for food premises and the transport of food; regulations relating to milking sheds and the transport of milk; regulations relating to food and water vessels and regulations relating to inspections and investigations. The International Health

Regulations Act, 1974 (Act 28 of 1974) has relevance to movement of foodstuffs through ports of entry while regulations under the repealed Food, Drugs and Disinfectants (FDD) Act, 1929 (Act 13 of 1929) include regulation of coffee, chicory and edible gelatine, amongst others, although these regulations are essentially quality standards. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) has relevance to food control via the registration and labelling of veterinary drugs, which are utilized in food producing animals. These Acts are administered by various Directorates of the Department of Health, similar to those Acts administered by various Directorates within the Department of Agriculture.

The Department of Agriculture administers other Acts like the Animal Diseases Act, 1984 (Act 35 of 1984), Plant Breeders Rights Act, 1976 (Act 15 of 1976), Agricultural Pests Act, 1983 (Act 36 of 1983), and Plant Improvement Act, 1976 (Act 53 of 1976) which are relevant in terms of the cultivation and farming of crops and animals produced for human consumption.

As mentioned earlier, the DTI also administers the National Regulator for Compulsory Standards Act, 2008 which is of relevance due to the Act commissioning the existence of the NRCS, which is now the regulatory authority of fresh and frozen fish and canned meat and their products. The NRCS, in turn, produce compulsory standards (regulatory standards) that regulate the commodities over which they have been mandated.

South Africa thus has an array of legislation for food regulation (Table: 4.2), which is drafted, administered, and enforced, through a variety of sections within relevant Government Departments. While drafting and administration is a function of respective national departments, enforcement may also be a function of the parent department as

well as provincial and local authorities where they have been assigned to enforce. The following section details enforcement of relevant food legislation but also recaps on the broad functions (borne of the mandate) of each national department.

3.4. Functional fragmentation

3.4.1. National Departments

As indicated earlier, the three national departments have a split responsibility in the regulation and control of food. The DoH is involved in regulation of safety aspects of all foodstuffs, except raw agricultural products, intended for the domestic market (like fresh fruit and vegetables and carcasses). Thus imports and domestic production for domestic use are under the control of the DoH although quality aspects of imported and domestic crops are regulated under the DoA. In addition, most processed foods are regulated by the DoH. The DoH is therefore a regulatory department whose activities are dedicated to ensuring food safety rather than food quality but only for foods destined for the local market. Food quality aspects are regulated by the DoA. This Department is also the authority on matters relating to export of foodstuffs and subsequent auditing of export commodities are conducted by this department (via the parastatal body, the Perishable Products Export Control Board, PPECB). The DTI/NRCS regulatory arm is responsible for, as mentioned earlier, only certain food products. These include the regulation of canned and certain seafood products (Brückner, *et al*., 1998; SABS, 2005; NRCS, 2009) although safety standards like maximum limits of heavy metals in marine food are under DoH regulation but enforced by the NRCS. The regulation of these products under the NRCS is via agreement by the DoA, DoH and NRCS (DTI) thus allowing the DTI/NRCS regulatory arm to regulate these food products for Ministers of other Government Departments (in this case, the Ministers of Health and Agriculture). The Department of

Health also authorises NRCS inspectors (although the regulation still indicates SABS regulators and would need to be amended) as food safety inspectors for the determination of food safety (FCD Act, 1972, Section 10 [3e]) and therefore also incorporates the NRCS and DTI regulatory arm into the system.

3.4.2. Enforcement

The three main national Departments enforce their respective mandates according to their own Acts, internal procedures, structures and budgets. The Department of Agriculture has an entire directorate dedicated to inspectorate services which service, inclusive of other directorates, the activities of the Directorate: Food Safety and Quality Assurance. In addition, this Directorate also has dedicated laboratories for food analysis although they are largely export orientated, test quality aspects of foodstuffs and analyse raw agricultural products (as opposed to processed foods). In addition, the Department of Agriculture, Directorate: Food Safety and Quality Assurance has assigned the Perishable Products Export Control Board (PPECB) to ensure compliance to food safety and quality standards under the APS Act, 1990 (de Beer *et. al*. 2003: 82). Other subsidiary bodies include the International Meat Quality Assurance Services (IMQAS) to ensure compliance of carcasses according to the Meat Safety Act, 2000. The Directorate: Biosafety which administers the GMO Act, 1997 utilises inspectors of the APS Act, 1990 and these are responsible for determining compliance to the conditions of the permits provided under approval of each application (GMO Act, 1997 (Section 16). Therefore although many provincial authorities have been assigned responsibility of certain Acts of the DoA regarding food, majority of the Acts are both administered and enforced at the national level. A similar structure for enforcement is apparent for the Department of Trade and Industry, where existing laboratories within the NRCS under

the Food and Associated Industries (FAI) section, accredited by the South African National Accreditation Services (SANAS), had standardised methods for analysis and where inspection and analysis were controlled nationally (SABS, 2005).

The Department of Health Acts, however, in contrast to many of the DoA Acts, authorise Provincial and local authorities to enforce them. The FCD Act, 1972 authorises local municipalities to enforce its regulations and appropriate notices in the official Government Gazette legitimise the authorisation (Section 23 of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 and Section 25 of the National Health Act, 2003). In addition, the National Health Act, 2003 delegates public health enforcement to Provinces and Districts/metro municipalities. However, with enforcement of regulations under the FCD Act, 1972, although samples are collected by personnel of the provincial, district or local authorities, these samples are analysed by two forensic chemistry laboratories of the National DoH. They are not dedicated food analyses laboratories as they serve the entire Department of Health and also analyse, for example, alcohol in blood samples (FCL, 2008). Thus, the food analytical aspect is just a portion of the entire laboratory. The control of these laboratories is regulated by the Directorate: Forensic Pathology Services, situated within the national DoH. Thus, the function of food sampling, analysis and enforcement is a segregated function with the involvement of the national Department of Health as well as the nine provinces constituting the country. In addition, district municipalities are also involved with inspectors employed by these authorities usually enforcing the laws promulgated at the national level. District municipalities allow for wall-to-wall municipalities in South Africa such that previously marginalised lands and communities are now integrated into at least one municipality.

3.4.3. IECT

Information, education, communication and training, if referring to informing, educating and communicating to the public and other stakeholders as well as training of officials usually occurs in separate sections or directorates of national Government Departments. In the Department of Health, the Directorate: Health Promotion is primarily responsible for all departmental IEC work but the Directorate: Food Control is quite unique in that it has an appointed official dealing with IEC issues. Training of provincial and local government officials specifically on regulations drafted at the national level are also conducted through the Directorate: Food Control as this Directorate has a sub-directorate (where the IEC officer is situated) that deals with programme support in relation to supporting the Provinces and district and local municipalities. The IEC officer is also responsible for a food safety newsletter dealing with issues of food safety and legislation that is used as a communication tool. The Department of Agriculture has a separate unit called the Directorate: Education, Training and Extension Services for issues of IECT with no dedicated unit within the Directorates involved in food safety conducting IECT work. The mentioned IECT Directorate however, works with food safety directorates in use of exhibitions for communicating to the public and stakeholders. The NRCS makes extensive use of its website as a communication tool but IECT efforts and tools are not specific to the food regulatory section.

From the above, it is apparent that the drafting of legislation, enforcement of legislation and other aspects of food control by the various departments are unique to the operation of the National Department rather than unique to a food control system. This means that Department mandates and structure influence food control activities such that there is no uniformity in the structure and functions of food control activities across the three

National Departments. Figure 4.1 provides a graphical representation of the food control system in South Africa indicating mandates, levels of enforcement and some indication of the subsidiary bodies affiliated to each national Department.

4. Discussion

The above review of the structure, legislation and functional aspects of the South African food control system describes a system that relies on legislation and activities drafted and undertaken by different Government Departments, adequately corresponding to the multiple agency food control system (FAO/WHO, 2003b:13). In addition, an emphasis on both import and export functions is witnessed within the system (as described by Neeliah and Goburdhun, 2007) as control of these functions are specifically segregated. Thus there is no dispute in stating that the South African food control system is fragmented.

However, multiple agency food control systems are common globally and the mere fragmentation of a food control system does not necessarily constitute a challenge. However, if not managed properly, multiple agency food control systems have the highest probability of challenges to food control goals. These challenges include duplication of services, loopholes in service delivery, lack of coordination of functions and confusion in jurisdiction or mandates to name a few (FAO/WHO, 2003b: 13). Some of these challenges are witnessed in the South African food control system.

4.1. Examples of challenges associated with fragmentation

One of the most evident challenges of fragmentation within the South African food control system is the duplication of regulation in foods and/or duplication of functions.

Examples include the Department of Agriculture and the Department of Health both having separate Acts to control identical aspects of regulation related to food. The registration of veterinary drugs and stock remedies which are conducted through two different Acts (Act 101 of 1965 of the Department of Health and Act 36 of 1947 of the Department of Agriculture) when the same function could be carried out by one authority. The case of the separate registration and evaluation of veterinary drugs and stock remedies in South Africa is also indicative that Government did not synchronise legislation after new developments in policy relating to veterinary drugs. Act 36 of 1947 was drafted before veterinary medicines were regulated in South Africa, but this Act and Act 101 of 1965 of the Department of Health were never synchronised after publication of Act 101 of 1965. As a result of the lack of integration of provisions in the Acts, an ill-defined dual regulatory system has been created for registration of veterinary medicines in South Africa. The resultant procedures attached to registration of either veterinary medicines or stock remedies although segregated are also not similar where veterinary drugs under Act 101 of 1965 are evaluated in detail under a defined peer review structure called the Medicines Control Council, or MCC (specifically the Veterinary Clinical Committee or VCC. This body will change as indicated by an amendment to Act 101 of 1965 to the South African Health Products Regulatory Authority or SAHPRA); while stock remedies are evaluated in-house by the Department of Agriculture staff with no defined peer review structure.

Therefore if the risk analysis framework is applied to this example (FAO/WHO, 2006) risk assessment and risk management is conducted by the same authority for stock remedies while for veterinary drugs, the risk assessment and risk management are distinct. Furthermore since no criteria are provided for exclusive registration under either of these Acts, applicants can register drugs as stock remedies, forego the defined, peer reviewed risk assessment conducted by the MCC and potentially allow over-the-counter

access to normally scheduled medicines (where access is controlled). Differences in access to veterinary medicines and stock remedies as a result of dual-registration are indicative of vast lack of coordination in the procedures related to registration of veterinary medicines in South Africa. This lack of coordination results in dissimilar criteria for accessing veterinary medicines and if access of veterinary drugs is not coordinated and controlled; the potential of off-label, illegal and improper use increases. This ultimately compromises the safety of meat and animal products consumed by people as the acceptable daily intakes may be exceeded resulting in manifestation of toxicological effects. Also in the case of antimicrobials, the potential of transfer of antibiotic resistance from bacteria in animal tissues to those in humans through misuse of antimicrobial veterinary medicines (a public health concern) could also occur. In addition, since the Department of Health Forensic Laboratories have resource constraints in testing for veterinary drug residues in foodstuffs, the enforcement of published MRLs is not conducted routinely. This further emphasises the compromise to food safety goals regarding veterinary drug residues and thus to the overall food control system.

Duplication of enforcement functions related to legislation is also evident although duplication of functions may not always be dependent on a dual regulatory system. For example, the analysis of food samples in the Department of Agriculture where testing of unprocessed foods for export markets is the mandate; while the Department of Health has the mandate to test for the same contaminants only on processed foods for the domestic market. A dedicated laboratory analysing for all food samples, processed or unprocessed, export and import-destined could better utilise resources rather than trying to achieve testing by separate laboratories because of the distinction of processed and unprocessed foods, domestic and export markets. Cases in point include the testing for pesticide residues in foods as well as mycotoxins in food. Both the DoH and DoA have

laboratories for testing because departmental mandates indicate that testing for the DoH is limited to processed foods for domestic consumption, while testing by the DoA is only for unprocessed, raw agricultural products destined for export. The DoA laboratories are better equipped to test than the DoH laboratories in the case of pesticides (more active ingredients can be tested for than the DoH laboratories) but division of resources for the same goal is ultimately compromising the overall systems testing capability for pesticide residues and mycotoxins. Regarding mycotoxins, if the product is considered unprocessed like peanuts for testing for limits of aflatoxins, the Department of Agriculture has the mandate to test but if the product is processed like peanut butter, the responsibility lies with the DoH.

Aside from the duplication of functions which contributes to poor resource utilisation, fragmenting a continuous production chain because of mandates of processed vs. unprocessed and domestic market vs. export market, ultimately makes enforcement more difficult. For example, raw agricultural products are regulated by the DoA but as they reach retail level or are packaged, they are the responsibility of the DoH. Processed/unprocessed distinctions interfere with sampling for and testing commodities that will be consumed in the domestic market. For example testing for heavy metals and pesticides in foods are easier to conduct at point of production rather than at retail level because if there are instances of non-compliance, risk management is easier to conduct. Similarly, for animal products, where carcasses at abattoirs should ideally be sampled for veterinary drug residues rather than at retail level but because they are considered unprocessed the DoA has jurisdiction on the carcass up until it leaves the abattoir so the DoH would only sample when it reaches retail level. Therefore staggered mandates of control between Departments for foodstuffs at different points on the food supply and processing chain ultimately convolutes the sampling and analytical aspect of food

regulation, particularly when jurisdiction of control is not specifically defined. This convoluted system indicates lack of coordination of mandates and functions.

Lack of coordination of activities created out of unclear legislation could be addressed through the application of the thinking behind some of the newer Acts drafted, like the Genetically Modified Organisms Act, 1997 that allows for input from six Governments at the same time to make decisions on an application relating to activities of genetically modified organisms (GMOs). This integrated approach could yield a greater understanding of integrated functions in a situation where mandates play enhanced roles in Government activity. For example, if one risk assessment authority like the VCC of the MCC is used for assessment of veterinary drugs (like the Advisory Committee of the GMO Act, 1997) and input is received from both the Departments of Agriculture and Health at the risk management stage (similar to the EC), the risk assessment becomes centralised, is peer reviewed and the process becomes consistent while risk management is conducted with all viewpoints in mind.

Regarding analytical testing, should more money be pooled into development of one highly equipped, accredited laboratory, shared by both Departments of Agriculture and Health, financial and human resources could be better utilised. In addition, different laboratories for different expertise could be developed where for example; the DoA tests for pesticides in all food products while the DoH tests for all mycotoxins or heavy metals. These Government ‘expert labs’ in terms of analytical testing could overcome challenges of accreditation of many laboratories for the same purpose and human resource constraints where expertise could be pooled into one well equipped and well-staffed laboratory.

Regarding IECT, efforts currently are conducted separately in all three National Departments with staggered information and communication being received by the public. This is a form of duplication of functions but more importantly it indicates the lack of coordination in information dissemination of the food control system to the public who does not necessarily distinguish processed and unprocessed foods as well as safety and quality of foods.

4.2. Previous and on-going efforts to address fragmentation

From legislation, to structure and functions that include IECT, enforcement and analytical testing it is clear that each Government Department involved in food control has its own strategic objectives which are extended to the strategic objectives of specific Directorates or sections of that Department. Acts are also Department-specific relating to mandates of the specific Departments. However, over the past decade or so, there has been effort in determining the feasibility of consolidating functions of the food control system into an agency, aloof from Government, so effects of mandates and departmental-based legislation are minimised (DoA 2005; Brückner *et. al.* 1998). Consolidation of legislation, structure and some functions into an integrated food control agency was the most favoured option of a working group assigned after the then Directors-General of Agriculture and Health met to discuss ways of collaboration regarding food control (Brückner *et. al*. 1998). The stimulus for this meeting and the subsequent task group was borne out of a need to align the South African food control system with principles recommended by the FAO after South Africa's admission into the World Trade Organisation (WTO), as well as to provide for a more efficient service regarding food control. In addition, the increased trade of foodstuffs required streamlined

inspection services which also provided a stimulus for discussing the ways forward for a revised food control system (Brückner *et. al.* 1998).

Other recommendations of the Brückner *et. al.* (1998) report included developing a single agency food control system where enforcement as well as drafting of legislation would be included as functions of the single agency (DoA, 2005; Brückner *et. al.* 1998). This option was less favoured as it would require changes to the Provincial and Local Governments constitutional obligation to render enforcement (inspection and sampling) of food control. Also a single agency food control system would combine functions of risk assessment and risk management and the separation of these functions was preferred in line with risk analysis principles that separates the risk assessment from risk management (FAO/WHO, 2006). Thus, from the options available in the Brückner *et. al.,* (1998) report, the integrated food control system was the favoured option where drafting of laws would still remain the function of Government and risk assessment would be the main function of the agency (DoA 2005; Brückner *et. al*. 1998). Many of these recommendations also came from a report of a technical expert assigned from the FAO after request by the Department of Health in 1995 to evaluate the South African food control system (Brückner *et. al*. 1998).

Since these reports and their recommendations, little has been done to facilitate the process of creating an integrated food control system. However, a consultant had been employed by the then Department of Agriculture (now Department of Agriculture, Forestry and Fisheries) to conduct a country profile of food control activities in South Africa, which was to begin on the 3 April 2007 (based on the terms of reference of the consultant). Although no report has yet been generated, and no specific timeline for completion is known, such a report would aid in determining the scope of the current

food control system. This report would therefore aid in deciding whether the consolidation of functions into an agency is feasible and which Government Department becomes the authority of the new agency. This report could also be used as the basis on which to brief Ministers of the respective Departments on the challenges of fragmentation and the possible options where functions, structure and legislation can be integrated. This briefing is essential because it is ultimately Ministers of Departments that would take the request for consolidation of food control activities and functions to the parliamentary level.

There have also been numerous changes in Government since these (DoA, 2005 and Brückner *et. al*. 1998) reports were generated and the re-briefing of senior managers as well as turnover of technical officers driving the process is thought to stall the facilitation. In understanding that staff turnover and changes in Government may be one the reasons behind the slow implementation, it is suggested that current officers revisit the reports and their recommendations and initiate the briefing of the new senior managers in their respective Departments. It is also suggested that the officials of both Departments reconstitute a version of the task team (originally constituted by officials who created the Brückner *et. al*., 1998 report) to develop a current report based on the previous ones for briefing of their senior managers.

5. Conclusion

The above discussion indicates that not only does fragmentation in the South African food control system exist, but also that challenges related to fragmentation are evident. These views have been encapsulated in internal reports of both the then Department of Agriculture (now Department of Agriculture, Forestry and Fisheries) and the Department

of Health. These reports were as a result of stimuli that include streamlining inspection services for facilitating trade of foodstuffs; aligning food control functions, structure and legislation to recommendations of the FAO and incorporating recommendations by an FAO official tasked to evaluate the South African food control system. Since these reports, a consultant has been appointed to determine a country profile of the food control system which would provide greater insight into the scope of the current food control system and feasibility into the integration of activities and structure. Possible reasons for slow progress in implementing an integrated system include change in Government in the years since the initial internal reports were generated and staff turnover where officials involved in initiating change of the current food control system into a more integrated one have since retired or left Government for other employment. In light of these it is recommended that current officials should re-visit the two mentioned internal reports (Brückner et. al., 1998 & DoA, 2005) and brief new senior managers on the recommendations of these reports. In addition, the work of the consultant must be hastened and the report of the country profile be completed in order to provide evidence to senior managers of the fragmentation that exists and the recommendations to change the situation.

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References

1. Anyanwu R. C., & Jukes, D. J. (1990). Food safety control systems for developing countries, Food Control (January), 17-26
2. Brückner G. K., van de Venter T., Rademeyer E., Malan D., Jansen van Rijssen F. W., & Wolhuter M. (1998). A structural-functional analysis of the food control services in South Africa, Report on the findings of the joint working group on food of the national departments of Agriculture and of Health. Pretoria (South Africa) Government of the RSA
3. de Beer G., Paterson A., & Olivier H. (2003). 160 years of export: The history of the perishable products export control board. Available from: http://www.ppecb.com
4. DoA [Department of Agriculture], (2005). Food control strategy for South Africa. Report of the Directorate: Food Safety and Quality Assurance, Department of Agriculture, Government of the RSA, Pretoria.
5. DPSA [Department of Public Service and Administration], (2003). Machinery of Government. Government of the RSA, Pretoria
6. FAO/WHO [Food and Agriculture Organisation/World Health Organisation], (2003a). Report of the FAO/WHO Workshop: Food control systems-practical approaches in the Southern African region, 1 September 2003, Pretoria, South Africa
7. FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2003b). Guidelines for developing an effective food control system, FAO/WHO,
8. FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2004). Second FAO/WHO Global Forum of Food Safety Regulators, Bangkok, Thailand, 12-14 October 2004: Legal Basis for Food Safety Official and non-Official Control-"Strengthening official food safety control services'
9. FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2005). FAO/WHO Regional Conference on Food Safety for Africa. International, Regional, Sub-regional and National cooperation in food safety in Africa, 3-6 October 2005, Harare, Zimbabwe
10. FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2006). Food Safety Risk Analysis-A Guide for Food Safety National Authorities, FAO Food and Nutrition Paper No, 87. FAO/WHO, Rome
11. FCL [Food Chemistry Laboratories]. (2008). Forensic Chemistry Laboratories, Department of Health, Government of the RSA, South Africa. Available from: http://www.doh.gov.za/department/forensic_lab-f.html

12. FDA/USDA [Food and Drug Administration/ United States Department of Agriculture], (2000). United States Food Safety System. Washington (USA) [2009] Government of the United States of America. Available from: http://www.foodsafety.gov/~fsg/fssyst2.html
13. Kwak N. S., Jukes D., & Shin S. G. (1999). Food safety control in the Republic of Korea, Critical Reviews in Food Science and Nutrition, 39 (6), 539-549
14. Garcia R., & Jukes, D. (2004). The Spanish system of food controls-its administration and enforcement, Food Control, 15, 51-59
15. Neeliah S. A. & Goburdhun D. (2007). National food control systems: A review, Food Reviews International 23: 35-51
16. Nguz K. (2007). Assessing food safety system in sub-Saharan countries: An overview of key issues, Food Control 18, 131-134
17. NRCS [National Regulator for Compulsory Specifications]. (2008). Services-Services to Government Available from: http://www.nrcs.org.za/content.asp?subID=19
18. SABS [South African Bureau of Standards]. (2005). Food and Health Division. Available from: https://www.sabs.co.za/Sectors/Food_and_Health/index.aspx
19. van Niekerk D., van der Waldt G., & Jonker A. 2001. Governance, Politics and Policy in South Africa. Cape Town (South Africa): Oxford University Press
20. Varzakas T.H. , Tsigarida E. T., Apostolopoulos C., Kalogridou-Vassiliadou D., & Jukes D.L. (2006). The Role of the Hellenic Food Safety Authority in Greece-Implementation Strategies, Food Control, 17, 957-965
21. Whitehead A. J. (1995). Elements of a national food control system, Food Control 6 (5), 247-251
22. WHO/FAO [World Health Organization/Food and Agriculture Organization]. (2005). Understanding the Codex Alimentarius, Joint FAO/WHO Food Safety Programme, WHO/FAO, Rome

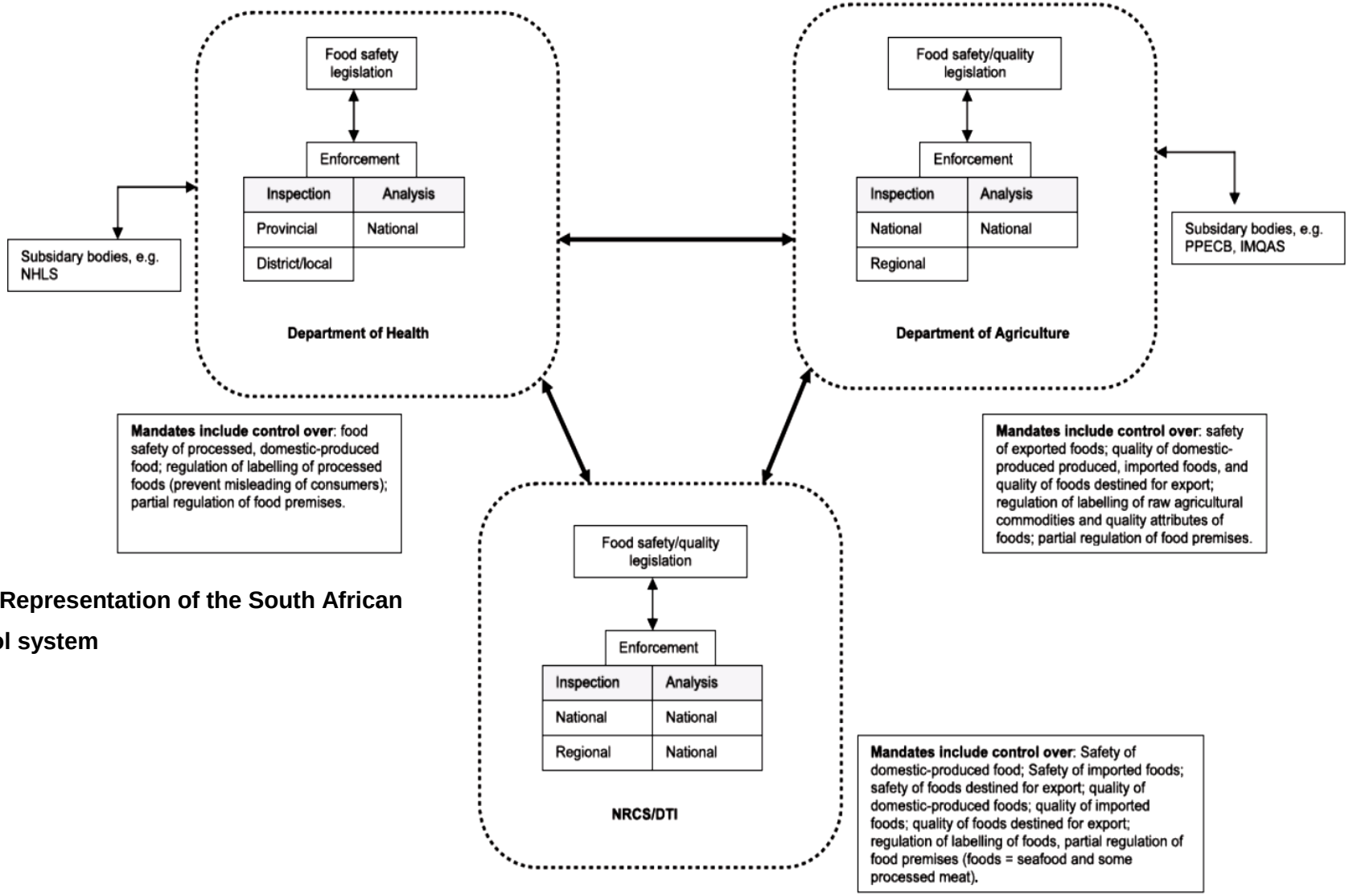

Figure 4.1: Representation of the South African food control system

Table 4.2: Relevant food related Acts in South Africa

Act	Year promulgated	Administered		Enforced	Summary
		Dept.	Directorate/Cluster		
Agricultural Products Standards Act	Act 119 of 1990	Agriculture	FSQA	National	Provides control over the sale and export of certain agricultural products
Animal Diseases Act	Act 35 of 1984	Agriculture	Animal Health	National	Provides for the control of animal diseases and parasites and provides measures for the promotion of animal health"
Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act	Act 36 of 1947	Agriculture	FSQA	National	Provides for the registration of fertilizers, farm feeds, agricultural remedies, stock remedies, sterilizing plants and pest control operators amongst others
Foodstuffs, Cosmetics and Disinfectants Act	Act 54 of 1972	Health	Food Control	Provincial/local	Controls the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants
Genetically Modified Organisms Act	Act 15 of 1997	Agriculture	Genetic Resources	National	Provides for measures to promote the responsible development, production, use and application of genetically modified organisms
Health Act/ National Health Act	Act 63 of 1977 Act 32 of 2003	Health	Food Control	Provincial/district	Provides for measures for the promotion of the health of persons in South Africa. Regarding food has provisions for food equipment and premises. National health Act also delegates enforcement of Health functions to district and metro municipalities
International Health Regulations Act	Act 28 of 1974	Health	Food Control	Provincial/port authorities	Provides for the approval by the Department of Health of the source of food for consumption at ports, airports, on vessels and on aircraft, as well as for the inspection of such premises and the sampling of food by local authorities
Liquor Products Act	Act 60 of 1989	Agriculture	FSQA	National	Provides for the control over the sale and production for sale of certain alcoholic products
Meat Safety Act	Act 40 of 2000	Agriculture	Animal Health/Veterinary Services	National	Provides for measures to promote meat safety and the safety of animal products. Also provides standards for abattoirs.
Medicines and Related Substances Act	Act 101 of 1965	Health	Medicines Regulatory Affairs	National	Provides for the registration of medicines intended for human and for animal use
Plant Breeders Rights Act	Act 15 of 1976	Agriculture	Genetic Resources	National	Provides for registration of varieties of plants which may include plants destined for food production.
Perishable Products Exports Control Board Act	Act 9 of 1983	-	-	National	To provide for the control of perishable products destined for export from South Africa
National Regulator for Compulsory Specifications Act	Act 8 of 2008	Trade and Industry	-	National	Provides for the existence of the NRCS, which is responsible for compulsory standards regarding certain forms of meat and fish foods.

* Key:
DoH: Department of Health
APS: Agricultural Products Standards Act
BS: Directorate: Biosafety
DoA: Department of Agriculture
DTI: Department of Trade and Industry
EH: Directorate: Environmental Health
FAI: Food and Associated Industries
FC: Directorate: Food control
FCD: Foodstuffs, Cosmetics and Disinfectants Act
FSQA: Directorate: Food Safety and Quality Assurance
GMO: Genetically Modified Organism Act, 1997
GR: Directorate: Genetic Resources
PPECB: Perishable Products Export Control Board
MRA: Cluster: Medicines Regulatory Affairs
V: Various Directorates: Department of Health

#: Acts not reflecting scope indicates the Act provides supplementary regulation to foods.

CHAPTER 5: PAPER 2

Table 5.1: Summary of details of Paper 2

Title	Review of the regulation of veterinary drugs and residues in South Africa
Publication status	Published in the journal: *Critical reviews in Food Science and Nutrition*
Journal website	http://www.tandfonline.com/toc/bfsn20/current
Citation reference	Chanda, R.R. Fincham, R.J. & P. Venter. (2014) Review of the regulation of veterinary drugs and residues in South Africa, *Critical reviews in Food Science and Nutrition,* 54 (4), 488-494
Objectives addressed	This paper sought to primarily address objectives 3, 5 and 6 of the study but also contributed to objective 7. Thus it reinforced that fragmentation does exist in the South African food control system, by determining that fragmentation occurs in the veterinary drug and residue regulatory system. Through this research on this system, it also noted a variety of challenges associated with the fragmented system and also discovered a more complex relationship between fragmentation and challenges than originally postulated in Figure 1.1. By answering to objective 7, it also provided key recommendations on how to address challenges of the food control system.
Methods used	Review methodology was employed for this paper and more specifically systematic review. The paper utilised the concepts of the food safety risk analysis framework against the key concepts of structure, function and legislation which were identified in the definition of fragmentation as reported on in paper 1.
Key outcomes	First peer reviewed literature on this topic.

Review of the regulation of veterinary drugs and residues in South Africa

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Abstract

The food safety risk analysis framework of the FAO/WHO is used in the review of veterinary drug and residue regulation in South Africa to determine possible inefficiencies within this system. Results indicate that a variety of challenges relating to the processes of risk assessment, management and communication do exist although these occur within a fragmented system of legislation, functions and structures. Addressing these challenges therefore requires a change to a more collaborative and integrated system. It is indicated that for such a change, the underlying challenges of inadequate horizontal communication, poor conceptualisation and awareness of functions of the system are required to be dealt with.

Keywords: veterinary drug residues, risk analysis, food

1. Introduction

The use of veterinary drugs on food-producing animals has yielded many benefits, from increased quality of life of animals and therefore production of quality food as well as economic gains related to fewer losses in livestock rearing (National Research Council, 1999; Morley *et. al.,* 2005). Veterinary drugs used in food producing animals have therefore been useful to sustain animal food production. However, with the benefits related to use of veterinary drugs in animals, their use may also be cause for concern due to effects that the residues of these drugs could have on consumers.

Concerns regarding veterinary drug residues in foods differ based on the type or category of drug used in the animal. The Codex Alimentarius Commission (CAC) lists

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on their website eleven functional classes of veterinary drugs. However, these can be combined into the five categories of veterinary drugs as described by the National Research Council of the United States of America (USA). These include: topical antiseptics, ionophores, hormone and hormone-like drugs, antiparasitic drugs and antibiotics or antimicrobials (National Research Council, 1999). The first category refers to all drugs used on the surface on the animal to prevent or combat infection like iodine in solution while the second category refers to drugs that alter stomach microorganisms for enhanced nutrient uptake efficiency like monensin (also considered an antimicrobial). Antiparasitic drugs like abamectin are used for treatment of parasites in animals while hormone/hormone-like drugs are generally used for faster growth of animals through efficient feed conversion of which examples include recombinant bovine somatotrophin (rBST) and ractopamine. Antibiotics are perhaps the most well-known and are used for treatment against microorganisms that create or exacerbate infection. Examples include tetracycline or gentamycin.

However, of these categories indicated by either the National Research Council or the CAC, the two most widely debated for their use in food animals is antimicrobials and hormone/hormone-like drugs. Use of antimicrobials in food producing animals has sparked the concern of the possible build-up of resistance of bacteria found in humans because of exposure to antimicrobials in animal-source foods. This could mean that treatment methods with similar if not the same antimicrobials in humans for illness could be rendered less effective. Antimicrobial resistance is of concern because antimicrobials are not only used for therapeutic purposes via dose controlled administration to protect animals against pathogenic bacteria; but are also used sub-therapeutically (when administered through feed) to increase efficiency in food uptake and utilization in animals (Doyle, 2006; National Research Council, 1999). Off-label use, where a specific veterinary drug has not been tested for and used on different

animals and/or changes in dose, has also increased the concern of build-up of resistance by bacteria in humans (Doyle, 2006; Catry, 2003; National Research Council, 1999). A further concern of the use and misuse of antimicrobials, as well as other types of veterinary drugs is exposing susceptible human populations to increased concentrations of these drugs thus exacerbating allergic and/or toxic responses (National Research Council, 1999). Antimicrobials can also interfere with the intestinal microbial balance (Cerniglia & Kotarski, 2005) which can allow for the overgrowth of exogenous pathogens (Jeong *et. al.,* 2009) allowing for increased illness related to the digestive system.

Other veterinary drugs, particularly growth promoting chemicals that have corresponding hormones in humans have also received much attention as it has been postulated that it could have effects on humans. The rBST case between the USA and the European Union (EU) indicates the controversy in the use of this hormone (Brinckman, 2000; Collier, 2000) whether it is for effects on humans or animal welfare reasons. Other hormones like oestrogens are also in the spotlight because studies indicate that even minute amounts of exogenous oestrogens could potentially alter reproductive ability and development particularly in young children (Aksglaede *et. al.,* 2006; Andersson & Skakkebaek, 1999; Partsch & Sippell, 2001). Beyond the risks to human health, veterinary drug residues in excreta of livestock may affect ecosystems and have toxicity concerns for specific organisms in the environment (Yoshimura and Endoh, 2005).

The understanding that residues of veterinary drugs could be a likely food safety and public health concern prompted the need for various countries to control the administration of veterinary drugs to food producing animals. Countries developed regulatory systems of legislation, structures and function for controlling veterinary drugs and their residues. In South Africa, the regulatory system was initiated as far back as

1947 when veterinary drugs were registered as stock remedies under the Department of Agriculture (Act 36 of 1947). After this initial regulation, the control of veterinary drugs and veterinary drug residues has evolved considerably. The current regulatory system is the focus of this paper.

The review of the regulation of veterinary drug residues is conducted under the framework of food safety risk analysis as described by FAO/WHO, (2006) although the existing system was never modelled on this framework. The application of this framework is for insight into the possible inefficiencies and/or challenges of the veterinary drug residue regulatory system as it is a recommended model by the global authorities on food control systems, the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) (FAO/WHO, 2006). This review categorises the legislation, structures and functions relevant to the regulation of veterinary drug residues as it occurs in South Africa based on risk assessment (RA), risk management (RM) and risk communication (RC) (FAO/WHO, 2006). The regulatory system is also discussed to define the challenges that are present and to determine whether and how they can be addressed.

2. Risk analysis and the regulation of veterinary drug residues

South Africa's registration of veterinary drugs is conducted under two different Acts, the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). These two Acts separate drugs for animal use into veterinary drugs (Act 101 of 1965) and stock remedies (Act 36 of 1947). Because of these two pieces of legislation, risk analysis functions are conducted for both Acts. Table 5.2 provides a summary of the

structures, legislation and functions of the regulatory system of veterinary drug residues under the categories of risk assessment, risk management and risk communication. The following sections are based on the information provided in Table 5.2.

2.1. Risk assessment

Act 101 of 1965 is administered by the Department of Health (DoH) where risk assessments are conducted by technical sub-committees of a specialist Council called the Medicines Control Council (MCC). Specific to veterinary drugs, the Veterinary Clinical Committee (VCC) of the MCC conducts the risk assessment of all veterinary drugs requesting registration under Act 101 of 1965. In addition, the Biologicals Committee (BC) conducts risk assessment on biological-based veterinary medicines like vaccines. The VCC, BC and MCC are composed of academics as well as government representatives. The Registrar: Act 101 of 1965 is a senior manager in the DoH, in the section of Pharmaceutical and Related Product Regulation and Management. The registrar holds the register of drugs (including veterinary drugs) and heads the secretariat support to the MCC. Amendments to Act 101 of 1965 in 2008 have made provision for the South African Health Products Regulatory Authority (SAHPRA) which will replace the MCC (The Medicines and Related Substances Amendment Act, Act 72 of 2008; Chanda *et al*., 2010). This change was legislated after a task team compiled recommendations to improve the efficiency of the registration of medicines under Act 101 of 1965 (DoH, 2008).

The four parts of risk assessment as described in by FAO/WHO, (2006) can be identified in existing functions under Act 101 of 1965. This includes hazard identification where risk managers do not commission a risk assessment as the current

process allows for the compulsory assessment of all veterinary drugs (includes food safety assessment). Hazard characterisation is conducted by the VCC (and BC where applicable) where safety, efficacy and toxicology are assessed. Food safety toxicology and exposure assessment is also conducted at this level as the Directorate: Food Control (representing the mandate for food safety) is represented at the VCC meetings. Exposure assessments require a food basket for the various tissues of food producing animals that are consumed as foods. Since South Africa does not have its own food basket, the international values based on those utilised by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are used in the exposure assessment by the VCC. The resultant maximum residue limit (MRL) which is recommended for publication under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 is also determined at this time although there has been lack of capacity for the calculation and extrapolation for MRLs. Risk characterisation, the last of the 4 components of risk assessment, is encapsulated in the recommendations that the VCC (and or BC) puts forward to the MCC for final decision on a veterinary drug. The MCC, after final decision (risk management stage), will route these conclusions back to the Office of the Registrar: Act 101 of 1965 for communication to the applicant. The risk assessment system under Act 101 of 1965 makes use of a peer review system for evaluation of veterinary drugs and its risk assessments are separated both structurally and functionally from those of risk management (Chanda *et. al*., 2010), a favoured separation to distinguish between science and policy issues (FAO/WHO, 2006, 49).

The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) regulates veterinary drugs as stock remedies and was created to provide easy over-the-counter access to veterinary drugs by farmers. Under this Act, an applicant needs to register their stock remedy by submitting an application to the Registrar: Act 36 of 1947 of the Department of Agriculture, Forestry and Fisheries

(DAFF). Risk assessment is conducted in-house by officials of the office of the Registrar as well as the DoH, Directorate: Food Control, either in-house or through expert consultants. In comparison to processes under Act 101 of 1965, risk assessment and risk management functions are not separated and assessments under Act 36 of 1947 do not make use of a defined peer review system (Chanda *et. al*, 2010). Therefore although risk assessments are conducted by both registration Acts, the process of assessment under these two Acts is inconsistent.

Similar to risk assessment under Act 101 of 1965, hazard identification is encapsulated in the process of registration where all stock remedies applying for registration need to undergo a risk assessment. Hazard characterisation is conducted by officials of both DAFF and DoH (Directorate: Food Control) where efficacy, safety and toxicology assessment are conducted. Exposure assessment is a function of the DoH, Directorate: Food Control where food basket values of JECFA are also used to determine approximate exposure but because of the lack of capacity to calculate and extrapolate MRLs, this function does not occur routinely. This is therefore also the reason why the risk management strategy of publication of MRLs has a poor record of being updated. Risk characterisation is conducted by both the DoH and DAFF although the process is not distinct as the risk assessment and risk management processes are not separated.

2.2. Risk management

A variety of risk management strategies have been identified although they may not have been specifically intended for management of veterinary drug residues. They do however contribute or have the potential to contribute to the control of veterinary drug residues and are categorised in Table 5.2. The two registration Acts as well as Act 54

of 1972 legislate the majority of risk management strategies although specific structures for risk management strategies are really only evident under Act 101 of 1965 with the MCC as the risk management body. In addition, the office of the Registrar: Act 101 of 1965 supports this risk management body due to its secretariat responsibilities. For both Act 54 of 1972 and Act 36 of 1947 risk management decisions are conducted together with risk assessments. Some risk management strategies like extension services and residue monitoring are not specifically legislated but are conducted by respective Departments under their overall mandate.

2.2.1. Registration of veterinary drugs and control of access

The registration of veterinary drugs is probably the first aspect of regulation of veterinary drugs and thus regulation of residues of these drugs. Registration of drugs is also the initial regulation for the control of animal health, animal production and public health concerns (Fingleton, 2004) and is therefore wider than the public health concern of exposure to veterinary drug residues via foods. Many countries employ registration of drugs, including veterinary drugs as a risk management strategy. These include Zimbabwe under the Medicines and Allied Substance Control Act, 1969; New Zealand under the Agricultural Compounds and Veterinary Medicines Act, 1997; Taiwan under the Veterinary Drugs Control Act, 1971; and the United States of America under the Federal Food, Drugs and Cosmetics Act, to name a few.

In South Africa, as was indicated previously, both Acts 101 of 1965 and 36 of 1947 are registration authorities with designated Registrars' that administer these Acts. However for control of access of veterinary drugs, only Act 101 of 1965 has a scheduling requirement where drugs are scheduled according to their safety profile and their access is controlled either over-the-counter or through prescription from a qualified

veterinarian. Act 36 of 1947 allows over-the-counter access for all registered stock remedies, which includes antimicrobials. This is problematic because misuse of antimicrobials in animals elevates the risk of development of resistance.

2.2.2. Commissioning a risk assessment

Since this task is conducted by risk managers (FAO/WHO, 2006, 37), it is considered a risk management function. However it has been discussed earlier under risk assessment for both pieces of legislation that require registration of veterinary drugs/stock remedies.

2.2.3. Publication of MRLs

One of the most prominent RM strategies specifically for veterinary drug residues in food is the publication of MRLs of veterinary drug residues in foods of animal origin. This includes MRLs for meat and organs of animals as well as secondary products like eggs of fish and poultry, and milk from cattle and goats. In addition, for veterinary drugs that accumulate in fatty tissue (fat soluble), an MRL specific to fatty portions of the animal are also provided. This RM strategy is heavily dependent on the risk assessment of the veterinary drug for toxicity as well as the withdrawal period (withholding period) in specific animals.

Many countries employ this RM strategy, Australia under standard 1.4.2 of the Food Standards Code; the USA where MRLs are known as tolerances under the Food, Drug and Cosmetic Act, 1938; the European Union under the Council Regulations EEC 2377/90; Japan under the Food Sanitation Law, 1947 and the Positive List of Maximum Residue Limits for Agricultural and Veterinary Chemicals (brought into effect on the 29

May 2006) and the Philippines under the Philippine National Standard /BAFPS 48:2007 ICS 11.220: Veterinary Drug Residues in Food: Maximum Residue Limits. Even countries that don't specifically publish MRLs of their own, and use Codex Alimentarius Commission (CAC) standards as references (CAC/MRL 02/2008) inadvertently utilise this RM strategy as the CAC standards set MRLs for veterinary drug residues in foodstuffs. In South Africa MRLs should be extrapolated from data after the risk assessment has been conducted under both registration Acts but MRLs included in Regulations No. R. 1089 of 1992 were also based on limits of the Codex Alimentarius Commission (CAC). However, Regulation No. R. 1089 of 1992 has only been amended once in 1999 to include new MRLs and the poor updating of this publication can be attributed to a lack of capacity in calculating withdrawal periods and extrapolating for MRLs. The enforcement of published MRLs is delegated to the provinces and local municipalities of the country and is addressed in the following section.

2.2.4. Compliance monitoring

Compliance monitoring involves the requirement to determine and react to exceeding limits of published MRLs. The function of compliance monitoring requires specific activities that are resource intensive. For example, inspectors are required for sampling of meat and animal source foodstuffs, while laboratories are required for the analysis of residues in these foodstuffs. For sampling, sampling methods and number of samples play an important role in sampling validity while for the analysis the requirements usually are highly qualified personnel and expensive laboratory equipment and test material. In addition, methods of analysis need to be accredited internationally to have integrity as a reliable method (Serratosa *et. al.,* 2006). Other specific activities like fines for con-compliance, destroying non-compliant foods and/or prosecuting of the responsible person/s is also required for compliance monitoring. Therefore although

the publication of MRLs does exist in certain countries, the compliance to the published MRLs is often not policed because of resource constraints, constraints in the knowledge and skill of inspectors and analysts and poor credibility of state laboratories, if these laboratories exist.

In South Africa, compliance monitoring related to the publication of MRLs is inferred because Environmental Health Practitioners (EHP's) of the Provinces and Districts are authorised to enforce regulations of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 including that of Regulations No. R. 1089 of 1992. In addition, the National Health Act, 2003 (Act 61 of 2003) indicates under its definitions that food control enforcement is a responsibility of local municipalities. EHPs of provinces and local municipalities collect samples and submit to forensic chemistry laboratories that are managed by the National Department of Health. In addition, provinces and local authorities must budget for collecting and courier of samples to laboratories which adds extra burden on the budget of the particular Department of the provincial or local authority.

However, compliance monitoring of veterinary drug MRLs by the Department of Health (as conducted by Provinces or local municipalities) is not routinely conducted except for testing of antimicrobials in honey, a recent requirement (Campbell, 2009), and this could be attributed to, amongst other reasons, the lack of analytical testing capability by the Department of Health laboratories (Campbell, 2009; Tholo, 2009).

Other specific activities within this risk management strategy like issuing of fines, ban, seizure and destruction of foodstuffs and/or refusal to allow entry of the foodstuff into the country if it is not compliant are addressed in the Foodstuffs, Cosmetics and Disinfectants Act, 1972. The Act allows for fining manufacturers (with no stipulation of maximum fine) for non-compliant foodstuffs as well as destruction of the condemned foodstuffs. Foodstuffs not compliant and presenting at ports of entry are also refused

entry if not compliant or of poor quality. However, even though these stipulations do exist, since sampling and analyses are rarely conducted these are not currently applicable for veterinary drug residues.

2.2.5. Residue monitoring

Residue monitoring involves the sampling of foodstuffs to determine trends in use of veterinary drugs and to identify areas for further and directed monitoring (WHO/FAO, 2009). Residue monitoring also provides information on whether veterinary drugs have been used according to the label or whether off-label use is prevalent in the country. Usually only one, or a few veterinary drugs are chosen and these are tested for in meat and meat products. No enforcement or follow-up actions are typically carried out in residue monitoring. The WHO/FAO, (2009) indicates further that monitoring and sampling relating to residues like directed sampling, special or pilot surveys and targeted sampling. These are either for determining trends of residues in foodstuffs or to investigate in detail the accumulated levels of residue in a combination of foods, after preparation. Sometimes there is little distinction between residue monitoring and compliance monitoring and the two can be combined. Countries that have indicated programmes include mainly developed countries like the EC under Directive EC 90/23; Canada through the National Chemical Residue Monitoring Programme, or NCRMP; the USA through the National Residue Program of the Food Safety and Inspection Service and New Zealand under the Food Residues Surveillance Program, whereas it is less common in developing countries.

The Department of Agriculture, Forestry and Fisheries (DAFF) has a National Residue Export Control Programme which tests for residues of chemicals (including veterinary drugs) in carcasses intended for export as well as a small, very limited, residue

monitoring programme for animal products consumed in South Africa due to financial constraints of analysing large samples. However, residue monitoring is conducted by private retail and manufacturing companies, particularly for substances like antibiotics in milk since antibiotics may hamper production of cheese and yoghurts that require start up cultures (Cogan, 1972).

2.2.6. Extension or outreach services

Extension or outreach services within the context of veterinary drug and residue regulation is discussed here as a RM strategy largely because the FAO/WHO, (2003) indicates that Information, Education, Communication and Training (IECT) functions should be a part of a food control system where various stakeholders are informed, educated and trained on food control issues. IECT functions of Government particularly to rural and small-holder farmers of developing countries allows for encouragement and/or specific training for the establishment of animal health management strategies which are fundamental for controlled use of veterinary drugs.

Due to the existence of parallel subsistence and commercial farming in South Africa, the former of which usually exist as small-holder or rural-based farmers (Gehring *et. al.,* 2002), awareness is much more important. Subsistence farmers are typically poor, live in rural areas away from resource centres, have high levels of illiteracy and have generally limited access to resources for the rearing of their livestock (Gehring *et. al.,* 2002; Keyyu *et. al.,* 2003; Jones, 2009). Bearing in mind the existence of subsistence farming together with the understanding of Government requirements for enhancing rural or small-holder farmers in South Africa, outreach, communication and education is an important RM strategy for enhancing these farmers awareness on animal food

production techniques, use of veterinary drugs and impact of residues on human health.

In South Africa DAFF conducts extension services through extension officers who typically provide information on animal production while animal health technicians together with regional veterinary practitioners provide information and assistance on animal health including use of veterinary drugs. However, because these outreach services are provided by DAFF, they are limited to information of agricultural legislation and techniques and the impact of veterinary drug residues to human health is not extended to farmers. Outreach activities are also conducted by the Farm Unit of the National Council of Societies for the prevention of Cruelty to Animals (NSPCA) (Jones, 2009) with some veterinary drug manufacturing companies also having outreach programmes. Although the Directorate: Food Control has a designated official for IECT functions little has been done on communication and education regarding veterinary drug regulation and residues as compared to IECT material for general food hygiene and food preparation.

2.3. Risk communication

Risk communication is not specifically legislated under any one of the three Acts but aspects of compulsory communication for example, between the Medicines Control Council (MCC) and the applicant are legislated in Act 101 of 1965. The Section that administers the Act, called the pharmaceutical and related product regulation and management, is actually a communication structure although largely for communication between applicants and the MCC. Similarly Act 36 of 1947 legislates communication between applicant and Registrar as well as other individuals or bodies constituted in terms of the Act like appeal boards. Communication for other stakeholders, particularly

the public, is however not legislated nor a constant function under either of these Acts. However, the Department of Agriculture, Forestry and Fisheries (DAFF) has extension services which are a part of risk communication although this is limited to communication to farmers and to communication of only agricultural based knowledge and techniques.

Act 54 of 1972 also has no legislated communication requirements and existing communication is limited to provinces and local authorities who enforce regulations of the Foodstuffs, Cosmetics and Disinfectants Act, 1972. However, information on the function and services provided by both registration authorities and Act 54 of 1972 are available on their respective Departmental websites.

3. Discussion

The application of the risk analysis framework to the overall structural-functional relationship of the veterinary drug and residue system provides insight into the various challenges of the system. These include inconsistent risk assessment processes between the two registration Acts, lack of, or poor compliance monitoring (due to inability of laboratories to analyse samples), limited residue monitoring under the national residue programme, limited extension services, poor updating of MRLs due to human capacity constraints and no-defined risk communication strategies, particularly to the public. Although challenges like the updating of MRLs and analyses capability of the DoH laboratories can be attributed to lack of technical, financial or human capacity which can be addressed through training and adequate budget allocations, the majority of challenges can still be addressed through collaboration and communication to structure resources for better functioning. The inability to communicate and collaborate on common issues highlights the results of the review of the system under the risk

analysis framework which show the presence of fragmented structures (between DAFF and DoH), functions (duplicated or similar functions of the DAFF, DoH and local authorities) and legislation (Acts 36 of 1947, 54 of 1972 and 101 of 1965), a characteristic previously described for the entire food control system (Chanda *et. al*., 2010).

Considering the fragmented structure, function and legislation through which risk assessment, management and communication occur, collaborative integration will form the basis for suggestions to address challenges not limited to capacity constraints.

3.1. Risk assessment

Risk assessments between the VCC, Directorate: Food Control and Department of Agriculture, Forestry and Fisheries (DAFF) are rarely collaborative which sometimes results in registration of the same products under two different registration Acts. Regarding structures, only the Department of Health has a defined risk assessment body, the VCC (or BC) to conduct risk assessment. In both DAFF and the Directorate: Food Control there are no defined risk assessment structures which is expected as they are not legislated under Acts 36 of 1947 and 54 of 1972. For risk assessment structures and functions to be carried out efficiently as per guidelines of the FAO/WHO, (2003), the first step needs to be the legislating or documenting of collaborative risk assessment, if they are not combined altogether. It is suggested that this could be initially legitimised through signing of memoranda of understanding (MoU) which are currently utilised agreements in government for specific shared functions. This would also address the inconsistency in risk assessments conducted by both DAFF and DoH in terms of peer reviews, control of access of drugs by scheduling and separation of both risk assessment and risk management. For registration and control of access of

veterinary drugs, these too can be made more collaborative across the two registration Acts so as to streamline resource-intense functions.

3.2. Risk management

The processes of risk management in terms of both structures and functions are also fragmented between the two registration Acts and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 that mandates each Department or section to conduct their own risk management (RM) functions. These RM strategies are, like the risk assessments, not collaborative which means that where resources could be pooled they are distributed so that they are not efficiently utilised. For example, inadequate compliance monitoring of veterinary drug MRLs by the Department of Health (as conducted by Provinces or local municipalities) and the limited residue monitoring for the country conducted by DAFF could be addressed by pooling sampling and analyses resources (use of the parastatal laboratory, at the Onderstepoort Veterinary Institute (OVI) and utilisation of EHPs and agricultural inspectors for sampling). It is suggested that this too could be done through memoranda of understanding. In addition, the DoH and DAFF should obtain information from the many food retailers and manufacturers of the country that routinely conduct monitoring on foods, sold or produced. This will provide valuable data that is required to determine usage of veterinary drugs and compliance to published MRLs of foodstuffs.

Pooling of resources where fragmentation in both structures and functions exist can also be conducted in the RM strategy of extension or outreach services. Since extension services do exist through DAFF, the Directorate: Food Control should request that information on the risks of animal production and animal health techniques to human health are also included in information material. Therefore information to

farmers would be holistic with impact of improper use and/or misuse of veterinary drugs being understood.

Lack of collaboration is also a limiting factor for risk management strategies that need to be implemented but are not. Monitoring for antimicrobial resistance is one of the biggest concerns regarding use of not only veterinary antimicrobials but also antimicrobials used in human medicine. Internationally this issue has been addressed by the World Health Organisation (WHO); World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC) under the WHO Global Principles for Containment of Antimicrobial Resistance in Animals Intended for Food; the OIE International Standards on Antimicrobial Resistance and the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005). In South Africa, it has only been considered at the academic level (Nel *et. al*., 2004). However, antimicrobial resistance monitoring occurs at medical facilities and through private facilities largely for human medicines. Based on this situation a streamlined programme between the Departments of Health and Agriculture, Forestry and Fisheries together with private sector units that are already conducting resistance monitoring should be initiated to address this RM function.

3.3. Risk communication

As indicated in Table: 5.2, the communication of risk relating to veterinary drug residues does not occur through formal channels except from registration authority to the Directorate: Food Control and *vice versa* (for record purposes and eventual publication of the residue limit in regulations) as well through publication of MRLs as regulations in the Government Gazette. However, regulations are scientific and it is not known what reach the Government Gazette has on the public. In an effort to pool

resources, the Departments of Agriculture, Forestry and Fisheries and Health as well as other stakeholders like retailers and food manufacturers should collaborate on the development and financing of a holistic communication package to the public and farmers. This consolidates communication material and reinforces the message of risks related to veterinary drug residues to the public. To some extent, although not directly involving the public, collaborative risk communication does occur between food associations, retailers the Directorate: Food Control and the Department of Agriculture, Forestry and Fisheries through meetings of the Food Legislation Advisory Group (FLAG) hosted by the Department of Health.

4. Conclusion

The variety of challenges in the system of veterinary drug and residue regulation is linked by the fragmentation of structures, functions and legislation which are prohibitive to communication and collaboration, essential aspects for a functioning system. The presence of inadequate horizontal communication is indicative of poor awareness and conceptualisation of how the various legislation, structures and functions for veterinary drug and residue control function as a system. This is limiting as without the understanding of shared functions, departments and sections tend to isolate their functions, which is apparent within the veterinary drug and residue regulatory system. This in turn deepens fragmentation and poor communication which results in a cycle of poor communication, poor collaboration and fragmentation. Thus as identified challenges are being considered the recommendation is that collaboration should be the basis for change within the system and this requires that communication, awareness and conceptualisation of the system are addressed first.

Therefore the risk analysis framework has proved an applicable instrument in defining the challenges related to the South African regulation of veterinary drug residues. It has also assisted in exposing underlying challenges of poor horizontal communication between structures and functions of the system and poor conceptualisation and awareness of the system; highly relevant issues that may sometimes be too subtle to identify as fundamental challenges.

References

1. Aksglaede, L. Juul, A. Leffers, H. Skakkebaek, N. E., and Andersson, A.M. (2006) The sensitivity of the child to sex steroids: possible impact of exogenous estrogens, *Human Reproduction Update*. *12* (4): 341-349
2. Andersson, A.M., and Skakkebaek, N. E. (1999) Exposure to exogenous estrogens in food: possible impact on human development and health, *European Journal of Endocrinology*. *140*: 477-485
3. Brinckman, D. (2000) The regulation of rBST: The European Case, *AgBioForum; 3* (2 & 3): 164-172
4. Campbell, P. (2009) Department of Health, *personal communication.*
5. Catry, B. Laevens, H. Devriesse, L. A. Opsomer, G., and de Kruif, A. (2003) Antimicrobial resistance in livestock, *Journal of Veterinary Pharmacology and Therapy*. *26:* 81-93
6. Cerniglia, C. E. Kotarski, S. (2005) Approaches in the safety evaluations of veterinary antimicrobial agents in food to determine the effects on the human intestinal microflora, *J. Vet Pharmacol. Therap*. *28*: 3-20
7. Chanda, R. R. Fincham, R. J. Venter, P. (2010) Review of the South African Food Control System: Challenges of Fragmentation, *Food Control, 21*: 816-824
8. Cogan, T. M. (1972) Susceptibility of cheese and yoghurt starter bacteria to antibiotics, *Applied Microbiology*. *23* (5): 960-965
9. Collier, R. (2000) Regulation of rBST in the US, AgBioForum, *3* (2 & 3): 156-163
10. DoH [Department of Health], (2008) Report of the Ministerial Task Team on the restructuring of the medicines and regulatory affairs and Medicines Control Council

and recommendations for the new regulatory authority for health products in South Africa. Department of Health (Pretoria).

11. Doyle, M. E. (2006) Veterinary drug residues in processed meats-potential health risk, A review of the scientific literature, Food Research Institute Briefings, University of Wisconsin, Available at: www.wisc.edu/fri/
12. FAO/WHO, (2003) 854 Guidelines for developing an effective food control system. FAO/WHO (Rome).
13. FAO/WHO, (2006) Food safety risk analysis. A guide for national food safety authorities, FAO Food and Nutrition Paper, FAO (Rome).
14. Fingleton, J. (2004) Legislation for Veterinary Drugs Control. FAO Legal Papers Online #38, FAO: Rome.
15. Gehring, R. Swan, G. E., and Sykes, R. D. (2002) Supply of veterinary medicinal products to an emerging framing community in the north West Province of South Africa, *Journal of the South African Veterinary Association*. *73* (4): 185-189
16. Jeong, S.H. Song, Y.K., and Cho, J. H. (2009) Risk assessment of ciprofloxacin, flavomycin, loaquindox and colistin sulphate based on microbiological impact on human gut biota, *Regulatory Toxicology and Pharmacology*. *53*: 209-216
17. Jones, D. (2009) National Council of the Society of the Prevention of Cruelty to animals, *personal communication*.
18. Keyyu, J. D, Kyvsgaard, N. C. Kassuke, A.A., and Willingham, A. L. (2003) Worm control practices and anti-helminthic usage in traditional and dairy cattle farms in the southern highlands of Tanzania*, Veterinary Parasitiology*. *114* (1): 51-61
19. Morley, P. S. Apley, M. D. Besser, T. E. Burney, D. P. Fedorka-Cray, P. J. Papich, M. G. Traub-Dargatz, J. L., and Weese, J. S. (2005) Antimicrobial drug use in veterinary medicine, *J Vet. Intern Med*. *19*: 617-629
20. Tholo, K. (2009) Department of Health, *personal communication.*
21. National Research Council. (1999) The Use of Drugs in Food Animals: Benefits and Risks, pp. 1, 19 & 71-73, 22-26 & 69 &76, 83-85. National Academy Press (Oxon)
22. Nel, H., Vuuren, M. van, and Swan, G. E. (2004). Towards the establishment and standardization of a veterinary antimicrobial resistance surveillance and monitoring programme in South Africa, *Onderstepoort Journal of Veterinary Research*. *71* (3): 239-246
23. Partsch, C. J., and Sippell, (2001) W. G. Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens, *Human Reproduction Update*. *7* (3): 292-302

24. Serratosa, J. Blass, A. Rigau, B. Mongrell, B. Rigau, T. Tortadés, M. Tlosa, E. Aguilar, C. Ribó, O., and Balagué, J. (2006) Residues from veterinary medicinal products, growth promoters and performance enhancers in food-producing animals: a European Union perspective, *Rev. sci. tech. Off. Int. Epiz*. *25* (2): 637-653
25. WHO/FAO, (2009). Monitoring for chemicals in food. INFOSAN Information Note No. 1/2009 - Monitoring for Chemicals in Foods. Available at: http://www.who.int/foodsafety/fs_management/No_01_Chem_Mar09_en.pdf
26. Yoshimura, H., and Endoh, Y. S. (2005) Acute toxicity to freshwater organisms of antiparasitic drugs for veterinary use, *Environmental Toxicology*. *20*

Table 5.2: Categorisation of existing legislation, structure and function under risk analysis terminology

	Risk assessment	Risk management	Risk communication
Legislation	***Act 36 of 1947:*** Registration Act although risk assessment process not specifically mandated in legislation	***Act 36 of 1965:*** Following RM strategies legislated: • Registration	• Public participation is required when legislation is amended. Amendments in legislation could result in structural-functional changes. Occurs through publication in the Government Gazette and indication of a specified period in which comments can be received. • Changes in legislation also indicated on respective Departments websites.
	Act 101 of 1965: Registration Act although risk assessment process not specifically mandated in legislation	***Act 101 of 1965:*** Following RM strategies legislated: • Registration • Control of access	
	Act 54 of 1972: Risk assessment process not specifically mandated in legislation. This Act just controls the sale, manufacture, import and export of foods based on safety. Broad mandate extended to risk assessment of veterinary drug residues in foods.	***Act 54 of 1972:*** Following RM strategies legislated: • Publication of MRLs • Compliance monitoring (although delegated to provincial local authorities)	
Structure	***Act 101 of 1965:*** Risk assessment structure: Veterinary clinical committee (VCC) and Biologicals Committee (BC)	Risk management structure: Medicines control council (MCC), to be changed to South African Health Products Regulatory Authority (SAHPRA)	• Major changes to structure need to be indicated in legislation. Legislation requires inputs from public during comment period after publication of draft amendment. E.g. structure of MCC to be changed to SAHPRA was legislated in the Medicines and Related substances Amendment Act, 2008 (Act 72 of 2008).
	Act 36 of 1947: No defined structure for risk assessment functions (not mandated for in the Act). Conducted by officials the office of the Registrar: Act 36 of 1947	Risk management structure: No defined structure for risk management functions, conducted officials in the Office of the Registrar: Act 36 of 1947	• Major changes to structure need to be indicated in legislation. Legislation requires inputs from public during comment period after publication of draft amendment.
	Act 54 of 1972: No defined structure for risk assessment functions (not mandated for in the Act). Conducted by officials of the Directorate: Food Control and/or expert consultants.	Risk management structure: No defined structure for risk management functions, conducted by officials in the Directorate: Food Control	
Function	***Act 101 of 1965:*** Evaluation of dossiers conducted: efficacy, toxicity, dosage etc. Peer review system in place	No reported framework for risk management although the following RM strategies have been identified: • Registration • Commissioning of a risk assessment • Control of access of veterinary drugs	• No reported formal communication to public on functions, accept for communication between registration authority and applicant. • Promotion of Access to Information Act, 2000 (Act 2 of 2000) does allow for interested parties to obtain information on registrations • Communication between Directorate: Food Control and VCC on veterinary drug residues
	Hazard identification: All veterinary drugs for requesting registration identified as hazards. All require assessment.		
	Hazard characterisation: Conducted by VCC reviewers (evaluation of data submitted by applicant)		

	Exposure assessment: Joint FAO/WHO Expert Committee on Food Additives (JECFA) food basket values used. Conducted at VCC (Directorate: Food Control present for this purpose). Withholding/withdrawal periods also determined at VCC meetings. Risk characterisation: Conducted during peer review discussions at VCC meetings. Risk characterisation sent to MCC together with recommendations on a particular veterinary drug.		and withdrawal periods.
	Act 36 of 1947: Evaluation of dossiers conducted efficacy, toxicity, dosage etc. No defined peer review system in place. Hazard identification: All stock remedies for food producing animals requesting registration identified as hazards. All require assessment. Hazard characterisation: Conducted by officials of the Office of the Registrar. Risk characterisation: Conducted by officials of the office of the Registrar	No reported framework for risk management although the following have been identified: • Registration of stock remedies • Commissioning of a risk assessment	• No reported formal communication to public. • Communication between registration authority and applicant. • Promotion of Access to Information Act, 2000 (Act 2 of 2000) does allow for interested parties to obtain information on registrations • Communication between the Directorate: Food Control and Registrar's Office: Act 36 of 1947 for risk assessment for human safety and withdrawal periods.
	Act 54 of 1972: Evaluation of toxicity, publication of MRL, advise on withdrawal period Hazard characterisation***:*** Only for Act 36 of 1947. Limited to human safety. Exposure assessment: Conducted at VCC meetings for Act 101 registrations. Conducted by officials of the Directorate: Food Control and/or expert consultants for Act 36 of 1947. Risk characterisation: Conducted by officials of the Directorate: Food Control and/or expert consultants for Act 36 of 1947. Limited to human safety.	No risk management framework although the following RM strategies have been identified: Publication of MRLs Under the No. R. 1089 of 1992. Includes MRLs for both stock remedies and veterinary drugs as registered under Act 36 of 1947 and Act 101 of 1965, respectively. Compliance monitoring Delegated to provincial and local authorities although not routinely conducted as capacity is lacking, particularly in laboratories.	• Formal communication to public on functions, limited to publication of MRLs in the Government Gazette. Also, communication between registration authority and Directorate: Food Control. • Information, Education, Communication and Training (IECT) functions conducted by Directorate: Food Control but limited to enforcement personnel (provinces and municipalities). Also communication material regarding veterinary drug residues is limited. • Platform for risk communication through Food Legislation Advisory Group (FLAG)
	Other: Department of Agriculture, Forestry and Fisheries	Residue monitoring Conducted by a separate section of the Department of Agriculture called veterinary public health in conjunction with the laboratories of the Onderstepoort Veterinary Institute (OVI). Called the National Export Residue Control Programme and National Residue Monitoring Programme. The latter programme is very limited. Veterinary Extension services Conducted by animal health technicians and veterinarians.	• No reported communication by authorities of the residue monitoring programme to public, except for those companies submitting samples for analysis and where specifically requested by a member of the public. • Extension services limited to farmers.

CHAPTER 6: PAPER 3

Table 6.1: Summary of details of Paper 3

Title	Critical influences in the development of veterinary drug and residue regulation in South Africa: Implications for policy change
Publication status	Submitted to the South African Historical Journal (SAHJ). *After comments from reviewers and subsequent restructuring of the paper, it is now a critical review paper rather than a historical account and therefore the scope of the paper may be outside that of SAHJ. The paper may need to be reformatted and submitted to another journal.
Journal website	http://www.tandfonline.com/toc/rshj20/current
Citation reference	Chanda, R.R. & Fincham, R.J. (unpublished) Critical influences in the development of veterinary drug and residue regulation in South Africa: Implications for policy change
Objectives addressed	This paper primarily addressed objective 4 to determine how fragmentation was initiated and how it evolved. This was achieved by critically reviewing the development of veterinary drugs and residues in South Africa to determine influences that initiated fragmentation as well as influences that allowed fragmentation to continue. The paper also addresses objective 6 by providing policy actions on how to address the influences of fragmentation.
Methods used	Methods used for this paper also took the form of a review.
Key outcomes	This paper presented the first critical review of the development of veterinary drug and residue regulation with an aim to determine influences and reasons for the introduction of fragmentation of the system.

Critical influences in the development of veterinary drug and residue regulation in South Africa: Implications for policy change

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Keywords: veterinary drug regulation, veterinary drug residues

Abstract

Previous reviews demonstrate that veterinary drug and residue regulation in South Africa is fragmented and associated with a variety of challenges[1,2]. In order to address fragmentation and its challenges, concerted action and policy shifts are needed. To identify where and what these actions should be in order to change policy, the critical influences for the initiation and continuation of fragmentation of the South African veterinary drug and residue regulatory system are determined. What emerges from the research is that the veterinary drug and residue regulatory system is not integrated as the system has disjointed legislation, structures and functions between the Departments of Health and Agriculture, Forestry and Fisheries. The fragmented state of the system is due to influences that include conceptual distinction between stock remedies and veterinary drugs, mandate obligations of existing governmental departments as well as poor leadership that allowed for the other aforementioned influences to continue. The lack of leadership, substantiated by the lack of collaboration and collective action to drive integration, as well as allowing mandate obligations and poor conceptualisation to influence the system is really the key influence and needs to be addressed at the onset. This is preferably done by revitalising leadership training within the public service which is focused on collaboration, collective action and systems thinking. What is also critical is that veterinary drug registration is integrated through appropriate policies under the Department of Agriculture as the agricultural sector in South Africa is the user of veterinary drugs while regulation of veterinary drug residues should remain with the Department of Health as it is related to the safety of food.

[1] RR Chanda, RJ Fincham & P Venter. '*Review of the South African food control system: Challenges of Fragmentation'*, Food Control, (2010), 21, 813-824

[2] RR Chanda, RJ Fincham & P Venter '*Review of the regulation of veterinary drugs and residues in South Africa*' Critical Reviews in Food science and Nutrition, (2014), 54 (4), 488-494

1. Introduction

Veterinary drug and residue regulation refers to the regulation of the use of drugs in animals as well as the regulation of maximum limits of residues of those drugs that can be left over in the tissues of food producing animals after a drug has been administered[3'4]. Therefore the veterinary drug and residue regulatory system, although applicable to all types of animals, is highly relevant and particular to food producing animals. Veterinary drugs are pharmaceutically active chemical or biological compounds that are used to alleviate, prevent or treat diseases in animals[5,6]. Veterinary drugs are diverse and include antimicrobials, hormones and hormone like substances[7] and biological drugs like vaccines[8]. Some veterinary drugs are also be used at sub-therapeutic levels for purposes other than disease treatment or prevention and include use of antimicrobials in animal feed for increased nutrient uptake in food producing animals[9,10].

Veterinary drug and residue regulation exists in South Africa but it is fragmented[1,2]. This fragmentation is structural, functional and legislative in nature where three pieces of legislation, two national Government Departments, nine provincial authorities and numerous local authorities interact for registration of veterinary drugs, publication of residue limits and enforcement of published legislation[11]. Fragmentation of the veterinary drug and residue regulatory system is associated with various adverse challenges like duplication of functions, an example of which is the dual registration of veterinary drugs under the

[3] A Anadón & AR Martínez Larrañaga. '*Residues of antimicrobial drugs and feed additives in animal products: regulatory aspects*. Livestock Production Science (1999). 59 (2-3), 183-198
[4] NRC [National Research Council]. The Use of Drugs in Food Animals: Benefits and Risks, (1999), 1-4. *National Academy Press:* Oxon
[5] NRC. *The Use of Drugs in Food Animals: Benefits and Risks.* (1999), 2
[6] ES Mitema. '*Improved management of drugs, hormones and pesticides in Africa*'. Onderstepoort Journal of Veterinary Research, (2009), 7: 155-159
[7] I*bid*
[8] NRC. *The Use of Drugs in Food Animals: Benefits and Risks.* (1999), 2
[9] ME Doyle. '*Veterinary drug residues in processed meats-potential health risk. A review of the scientific literature'*, Food Research Institute Briefings, University of Wisconsin, (2006). www.wisc.edu/fri/
[10] NRC. *The Use of Drugs in Food Animals: Benefits and Risks.* (1999), 2
[11] Chanda *et al*. *Review of the regulation of veterinary drugs and residues in South Africa* (2014)

Departments of Agriculture, Forestry and Fisheries and the Department of Health. Duplication of functions results in wastage of valuable resources and in-coordination between functions which compromise food safety goals of the system[12,13]. The link between fragmentation and challenges is generally that fragmentation causes these challenges and therefore understanding the inception and evolution of fragmentation is critical in addressing the phenomenon and the challenges it is purported to cause. To gain an understanding of why fragmentation occurred and continued in the development of the veterinary drug and residue regulatory system, a critical review of the development of this system is provided in this paper. This review aims to uncover the reasons or influences behind the fragmented veterinary drug and residue regulatory system in order to provide the basis of actions required, particularly through a change of policy, to integrate the system.

2. Veterinary drug and residue regulation

Fingleton, (2004) indicates that the scope of veterinary drug control includes safety, quality and efficacy[14]. Indeed veterinary drugs are usually required to be registered before use and during this registration process drug safety is usually assessed, the efficacy or effectiveness is assessed as well as quality, which affects both safety and efficacy of the drug. In assessing safety, quality and efficacy of a drug, regulators address many combined concerns. These include animal health concerns whereby the drug must ensure good health of food producing animals, as well as public health and human health concerns where the foodstuffs derived from an animal are considered safe to consume. Therefore where residues are well regulated, there should be little concern on the health of humans

[12] Chanda *et. al. Review of the South African food control system: Challenges of Fragmentation*, (2010)
[13] FAO/WHO. *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*, FAO Food and Nutrition Paper 76, (2003) FAO/WHO: Rome
[14] J Fingleton. *Legislation for veterinary drugs control*. FAO Legal Papers Online #38. (2004) FAO (Rome)

who consume drug treated animals and if animals are healthy before slaughter they will ensure a safe supply of meat products. In addition, ensuring good animal health also assists in managing zoonotic disease where animal diseases also cause infection and disease in humans[15].

Within any regulatory system, are functions for assessment of safety, efficacy and quality, and in the case of residues, determination of exposure to the human population and calculation of withdrawal periods. Withdrawal periods refer to the time required for a drug to be depleted from an animal during which it cannot be slaughtered. Maximum residues of drugs are usually published as law for animal derived food or feed. In addition to the above functions of assessing safety, quality, efficacy and determination and publication of maximum residue limits, enforcement of maximum residue limits is required. This means that animal derived products are tested for residues and where exceeded, the relevant food manufacturer or producer is liable. All of the above functions are generally encapsulated in law and this becomes the veterinary drug and residue regulatory system.

Veterinary drug and residue regulation is common globally and is currently conducted by numerous countries that include New Zealand under their Agricultural Compounds and Veterinary Medicine Act, 1997[16]; Australia under the Agricultural and Veterinary Chemicals Act, 1994[17]; the USA under the Federal Food, Drug and Cosmetic Act, 1938[18], the EU member states under the Veterinary Medicinal Products Directive 2001/82/EC and the UK under the EU Directive 2001/82/EC and veterinary medicines regulations 2011 (SI 2159)[19].

[15] FAO [Food and Agriculture Organization], OIE [World Organization on Animal Health], WHO [World Health Organization]. *High level technical meeting to address health risks at the human-animal ecosystems interface*. (2012) FAO/OIE/WHO. http://www.who.int/zoonoses/hltm_2011/en/index.html
[16] New Zealand Ministry for Primary Industries: Veterinary compounds (undated). http://www.foodsafety.govt.nz/industry/acvm/vet-medicines/index.htm
[17] APVMA [Australian Pesticides and Veterinary Medicines Authority] (2011) http://www.apvma.gov.au/about/legislation/index.php
[18] FDA [US Food and Drug Administration], (2012) http://www.fda.gov/RegulatoryInformation/Legislation/default.htm
[19] VMD [Veterinary Medicines Directorate], (2011) http://www.vmd.defra.gov.uk/

In the UK the veterinary medicines regulations consolidated previous veterinary drug control which was under the Medicines Act, 1968[20]. Veterinary drug and residue laws are not limited to developed countries and developing countries also have similar veterinary laws which include India's Drugs and Cosmetics Act, 1940 (also includes human drugs); Sri Lanka's Animal Diseases Act, 1992; Malawi's Pharmacy Medicines and Poisons Act, 1988 and Zimbabwe's Medicines and Allied Substances Control Act, 1969[21].

Although many countries have legislation on veterinary drug regulation, the functions and structures established by these laws they differ. For example in the United States, the relevant government section for veterinary drug registration and residue setting is the US Department of Health and Human Services[22]. The specific structures under this Department is the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA) which is responsible for regulating all additives, including veterinary chemical drugs, that will be used in animal feed or used in an animal (FDA, 2013)[23]. Food producing animals as well as all other animals are included in the regulation. However, use of veterinary vaccines in animals is regulated by the United States Department of Agriculture (USDA)[24]. In the UK, the Veterinary Medicines Directorate (VMD) under the Department of Environmental, Food and Rural Affairs (DEFRA) conducts all registrations related to veterinary drugs which include biological drugs like vaccines, and also sets and enforces maximum residue limits for animal derived foodstuffs[25]. The Australian regulatory system is similar to the UK where the Australian Pesticides and Veterinary Medicines Authority registers all veterinary drugs for all animals and sets maximum limits for residues[26]. However the same authority also

[20] *Ibid*
[21] J Fingleton. *Legislation for veterinary drugs control*. (2004)
[22] FDA [US Food and Drug Administration] (2013) Center for Veterinary Medicine (CVM) http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm
[23] FDA [US Food and Drug Administration], (2013) http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm
[24] *Ibid*
[25] VMD [Veterinary Medicines Directorate], (2011) http://www.vmd.defra.gov.uk/
[26] APVMA [Australian Pesticides and Veterinary Medicine Authority], (2011) http://www.apvma.gov.au

registers agricultural compounds like pesticides which is unlike the UK authority where only veterinary drugs are registered under the designated authority. The differences in how regulation occurs in terms of differing structure and functions are due to the history of the regulation and therefore how legislation developed in that country. This development of laws for veterinary drugs, like other laws, is highly dependent on the country context and is also affected by public input, availability of resources like adequate personnel and expertise as well as political will to ensure the development and application of a particular law. Some accounts of how veterinary related laws developed within individual countries are provided in the book 'Healing the herds: Disease, livestock economies, and the globalization of veterinary medicine' (Brown & Gilfoyle, 2010)[27].

In South Africa, the context at the time of the initiation of veterinary drug regulation included colonisation, the separation of the country into three parts and differing rule in these three parts, and the system of apartheid. Although this paper will not go into detail regarding the above factors that contextualise South Africa, the next section will provide some detail on the impetus for development of veterinary medicine and consequently veterinary drugs which preceded veterinary drug regulation in South Africa.

3. Animal diseases and the need for veterinary drugs

The demand for veterinary services in South Africa, which included veterinary drugs, was initiated by the need to combat diseases affecting livestock in order to protect and sustain livestock production because it was (and still is) an important economic industry[28]. Aside from food producing animals, the need to sustain the health of horses used for transport

[27] K Brown & D Gilfoyle (eds.). '*Healing the herds*: *Disease, livestock economies, and the globalization of veterinary medicine*' (2010) Ohio University Press (Athens, Ohio)
[28] A Paterson. Chapter 18: *Veterinary skills.* In: A Kraak & K Press (eds.) *Human resources development review 2008. Education, Employment and Skills in South Africa*. (2008) HSRC Press: Cape Town

was also of interest and therefore produced a demand for veterinary research and drug interventions[29]. In addition, although wildlife is not the focus this paper, the incidence of animal diseases in wildlife was also a concern, largely because they acted as reservoirs for disease that affected livestock[30]. In the years preceding the formal development of a veterinary research facility in South Africa, disease outbreaks were numerous and devastating. Outbreaks of babeosis in cattle in Natal in 1870, foot and mouth disease in parts of the Cape in 1892 (and later other parts of the country)[31], east coast fever in 1902 and African horse sickness in the late 1880s to early 1900s[32], to name a few, established the need for some form of veterinary service in the country that could arrest, treat and prevent the spread of disease in livestock[33,34]. However, the prioritisation of the veterinary health function only really came after the Rinderpest outbreak post 1896 when the epidemic ravaged South Africa[35,36,37,] after introduction to Africa by the movement of cattle from Asia and Europe to the northern parts of the continent[38,39]. Rinderpest is a contagious, viral disease that causes symptoms of fever, diarrhoea, necrosis and emaciation in animals, especially cattle[40].

Rinderpest eradicated vast populations of cattle and considering the economic value of cattle for food security and trade, this stimulated research into eradicating the disease[41]. The then three parts of what is now South Africa (Zuid Afrikaanse Republiek (ZAR), Natal

[29] S vandenBergh .'*The story of a disease: African horsesickness and its direct influence on the necessary development of veterinary science in South Africa, c. 1890s-1920s'*. Historia, (2010) , 55 (2), 243-262
[30] RG Bengis & JM Erasmus. *'Wildlife diseases in South Africa: A review'*. Rev. sci. tech. Off. Int. Epiz.,.(1988) 7(4), 807-821
[31] GK Brückner. W Vosloo. BJA du Plessis. PELG Kloeck. L Connoway. M Ekron. DB Weaver. CJ Dickason. FJ Schreuder. T Marais & ME Mogajane., '*Foot and Mouth Disease: The Experience in South Africa'*, Rev. Sci. Tech. Off. Int. Epiz*., (2002),* 21 (3), 751-764
[32] S. vandenBergh .*'The story of a disease'. (*2010) ,
[33] DoA [Department of Agriculture], 'The development of veterinary services in South Africa', (2009) http://www.nda.agric.za/vetweb/History/H_History_Main_Initual.htm
[34] K Brown & D Gilfoyle. *'Livestock diseases and veterinary science in Southern Africa'*. South African Historical Journal, (2007) 58, 2-16
[35] DW Verwoed,'*A brief historical review of research achievements by the OVI during the 20th century against the backdrop of socioeconomic and political developments in South Africa*'. Journal of the South African Veterinary Association, (2000) 71 (4), 210–214
[36] L Blumberg, '*Robert Koch and the rinderpest'*, South African Medical Journal, 76 (1989), 438-440
[37] Brown & Gilfoyle, *Livestock diseases and veterinary science in Southern Africa* (2007)
[38] CA Spinage. *Cattle plague: a history*. (2003) Kluwer Academic/Plenum Publishers (New York), 3-5
[39] L Blumberg, '*Robert Koch and the rinderpest'*, (1989)
[40] Spinage*. Cattle plague: a history*. (2003), 5-7
[41] South African Veterinary Association: Timeline of veterinary development: www.sava.co.za

and Cape Colony) appointed different researchers for this disease and included Sir Arnold Theiler, a Swiss veterinarian, for the ZAR, Herbert Watkins-Pitchford for Natal[42,43] and Robert Koch for the Cape Colony[44]. In 1897, Robert Koch announced that injecting bile from infected cows allowed for lasting immunity in susceptible populations while prior to this Theiler and Watkins-Pitchford utilised serum for injection into sick animals[45,46]. Concerted efforts lead to the demise of Rinderpest in South Africa in 1898[47] but the loss in livestock numbers meant that more cattle had to be imported from other areas in Africa. This migration of cattle led to further disease which required efforts to control and meant that continued research and treatment methods were required in order to protect livestock, equine and even wildlife populations.

The need to continue research into veterinary diseases was motivated by Arnold Theiler who convinced the then Prime Minister, Louis Botha, and the Parliament to fund the Onderstepoort research laboratory in 1908 in Pretoria[48,49]. Research at this laboratory resulted in identification of infective agents as well as production of early vaccines[50]. Onderstepoort expanded after 1910 and today it is known as the Onderstepoort Veterinary Institute (OVI) under the Agricultural Research Council (ARC)[51], a parastatal body of the Department of Agriculture dedicated to research. Today, the OVI hosts six laboratories for viral diseases: African horse sickness, bluetongue, lumpy skin disease, Rift Valley fever, rabies and African swine fever[52] which are used in identification of infectious agents and vaccine production. As Onderstepoort grew to accommodate the demand for research into

[42] *Ibid*
[43] DW Verwoed. '*A brief historical review of research achievements by the OVI during the 20th century against the backdrop of socioeconomic and political developments in South Africa*'. Journal of the South African Veterinary Association , (2000), 71(4), 210–214
[44] *Ibid*
[45] Blumberg, *Robert Koch and the Rinderpest*, (1989)
[46] RD Bigalke, '*Theiler and the spirit of Onderstepoort*'. Onderstepoort Journal of Veterinary Research (2009), 76, 3- 7
[47] Verwoed, *Historical review of research*, (2000)
[48] Bigalke .*Theiler and the spirit of Onderstepoort* (2009)
[49] Verwoed, *Historical review of research*, (2000)
[50] *Ibid*
[51] Verwoed, *Historical review of research*, (2000)
[52] ARC, [Agricultural Research Council] (2010) ARC-OVI; http://www.arc.agric.za/home.asp?pid=2564

animal diseases it also incorporated training facilities in 1921 under the Transvaal University College with the first eight students of veterinary science qualifying in 1924[53]. The training faculty was later incorporated into the University of Pretoria which now trains veterinarians amongst other veterinary professionals, which include veterinary technicians and veterinary nurses.

With research and training facilities established in South Africa, veterinary drugs (largely biological drugs like vaccines) and veterinary practitioners continued to grow and this provided and sustained the momentum for development of veterinary drugs. Over time, as further veterinary drugs were imported or made in the country by other drug manufacturers, it became necessary to control these drugs for optimal use and application. This situation saw the initiation of veterinary drug and residue regulation.

a. Veterinary drug regulation

Veterinary drug regulation in South Africa only began in 1947, decades after the development of veterinary drugs (largely biological vaccines) at Onderstepoort and earlier at Daspoort[54]. In 1947, the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), administered by the then Department of Agriculture, began the registration of veterinary drugs. This Act required that veterinary drugs, termed stock remedies, be registered in order to make it easier for farmers to access stock remedies[55]. Many farmers were knowledgeable about common diseases of animals and were able to treat many illnesses of their own animals without assistance from veterinary professionals. Therefore, the categorisation of drugs with a description of use and

[53]University of Pretoria, History of veterinary Science (undated) http://web.up.ac.za
[54] Verwoed, *Historical review of research* (2000)
[55]Hela, M. Regulation and control of veterinary pharmaceuticals in South Africa. The role of the national Department of Health. *Presentation to the Portfolio Committee: Agriculture and Land Affairs, 19 September 2006,* Available at: www.pmg.org.za

application was aided by the registration of the drugs. As a result, all drugs registered under Act 36 of 1947 were available over the counter in an effort to facilitate easy access. The facilitation of agricultural production is prominent in the Act itself which regulates fertilizers, farm feeds or animal feed for farm animals as well as pesticides, termed agricultural remedies. All of these are agricultural inputs, regulated to assist better application and use in order to promote agriculture, food security and trade of foodstuffs, all of which are objectives of the Department of Agriculture, Forestry and Fisheries[56].

Thirty two years later in 1979, the already enacted Medicines and Related Substances Act, 1965 (Act 101 of 1965), administered by the Department of Health, was amended (Amendment Act 17 of 1979) to include registration of veterinary drugs. This amendment to Act 101 of 1965 and subsequent registration of veterinary drugs was as a result of the development of new drugs that were not registered under Act 36 of 1947, as they were intended for treatment of complex animal health conditions which required veterinarians to diagnose[57]. Therefore, registration of veterinary drugs was duplicated due to a conceptual distinction of veterinary drugs being different to stock remedies (as registered under Act 36 of 1947) because Act 36 of 1947 only registered 'simple' drugs while it was argued that more complex drugs needed a different system of registration. Therefore, the dual registration system was justified based on the understanding that stock remedies are less complex than veterinary drugs and therefore needed to be accessed and registered differently. Act 101 of 1965 implemented a scheduling status to both human and veterinary drugs based on their toxicity and complexity in order to control how it was accessed, i.e. whether they available over the counter or through a registered veterinary professional. In contrast all drugs registered under Act 36 of 1947 were available over the counter for easy

[56] Department of Agriculture, Forestry and Fisheries (DAFF), 2011. Mission and Vision. www.nda.agric.za
[57] Hela. *Regulation and control of veterinary pharmaceuticals,* 2006

access to farmers. Therefore the conceptual understanding of stock remedies being different from veterinary drugs greatly influenced the separation of registration of veterinary drugs from stock remedies.

The inability of the Department of Agriculture to continue registration of all veterinary drugs, complex or not, is indicative of the separation of functions due to mandate obligations of individual Government Departments. The evaluation of 'complex' drugs which needed evaluation of its risk is a proactive, risk-based function, a function not consistent with the promotion of agriculture. Therefore the Department of Agriculture could not regulate the agricultural input required to sustain agriculture although it is the agricultural sector that are users of the agricultural inputs. The risk-based versus production based mandates were at odds while the risk based approach was compatible to the Department of Health functions as the risk-based approach to human drugs was already a function of the Department of Health with existing expertise to evaluate and register drugs. The evaluation of human medicines and subsequent registration is a proactive, risk based process because it legislated the existence of the Medicines Control Council (MCC), a scientific body that was responsible for the evaluation of human medicines. As a result, the obligation to mandates as well the convenience of existing functions is highly relevant as to why registration was separated and therefore why fragmentation of the registration of veterinary drugs was initiated.

Nineteen years after the dual registration system originated, there was a legislative attempt to consolidate registration of veterinary drugs and stock remedies in addition to changing the registration of human drugs. In 1998, the Department of Health published the South African Medicines and Medical Devices Regulatory Authority Act, 1998 (Act 132 of 1998)

which repealed the earlier Act 101 of 1965 and amendments and parts of Act 36 of 1947 that dealt with stock remedies. The Act also established the South African Medicines and Medical Devices Regulatory Authority to replace the current Medicines Control Council (MCC). Act 132 of 1998 indicated that the conceptual understanding of veterinary drugs and stock remedies had improved since 1979 when their registration was separated. The act also implied that the dual registration was not efficient and hence its integration was sought. This realisation of the need for an integrated registration of veterinary drugs was perhaps more prominent at the time of the publication of Act 132 of 1998 because the definition of simple medicines versus more complex drugs was not clear. In fact complex molecules like antimicrobials were being registered under Act 36 of 1947 both for use in animal treatment but also in feed to increase nutrient uptake efficiency. The registration of complex molecules under Act 36 of 1947 blurred the lines between simple stock remedies and complex veterinary drugs and opened the registration system to exploitation by registrants of drugs as there was no definition of when a medicine was a stock remedy or when it was a veterinary drug. This unclear distinction between the simple drugs and the more complex ones as well as increased awareness of global registration practices allowed for an evaluation system of prospective drugs prior to registration. The evaluation system then introduced a risk based function to the registration of stock remedies under Act 36 of 1947.

Although the attempt to consolidate legislation, structures and functions of the registration of veterinary drugs, was initiated, the South African medicines and medical devices authority did not materialise and four years later an Amendment to the Medicines and Related Substances Act, 2002 (Act 59 of 2002) repealed Act 132 of 1998 and excluded registration of stock remedies as defined under Act 36 of 1947. The revert to the dual

registration system showed the influence of a variety of factors that allowed fragmentation to continue. The first factor is that of poor leadership. Since the system needed change in the way of innovation, the inability to innovate means that leaders were inadequate[58] as they could not support and implement the change. A description of leadership remains elusive but often refers to leaders embracing collaboration[59] and inviting change[60,61] rather than improving existing structures and functions of a system, the latter of which speaks to management rather than change[62]. Because Act 132 of 1998 was drafted and published, it showed that the strategy behind integration was not lacking and so leadership was not altogether lacking but the inability to implement the Act in terms if structures and functions shows leaders that could not collaborate, leaders that had no collective drive to integrate the system and leaders that preferred the dual registration system or *status quo* rather than implementing change.

There are various factors that could have influenced the decision of leaders to revert to the dual registration system and one of them is mandate obligations, similar to the initial separation of veterinary drugs and stock remedies. Regarding mandates, the total registration of veterinary drugs under the Department of Health meant that the previous stock remedies, which were available over the counter to ease access to drugs by farmers, would now be under the Department of Health. However the Department of Health had no mandate in the promotion of agriculture and was also not a caretaker of animal health but rather had a mandate to ensure safety of human health through risk based policies and procedures. Therefore the uneasy context proposed by the Act 132 of 1998 was perhaps why the Act was repealed and the dual registration system maintained. Another reason for

[58] S Borins. '*Leadership and innovation in the public sector*'. (2002) Leadership and Organization development Journal, 23 (8), 467-476
[59] AM Sindane. '*Values and ethics enter the real world: a framework for public leadership and governance'* (2011). Koers. 76 (4), 751-769
[60] G Vinger & F Cilliers. '*Effective transformation leadership behaviours for managing change'* (2006). South African Journal of Human Resource Management, 4 (2), 1-9
[61] RF Callahan. '*The future of public sector leadership*'. (Undated). Available at: http://www.ipa.udel.edu/3tad/papers/workshop3/Callahan.pdf
[62] Callahan. '*The future of public sector leadership'*.

the revert to the dual registration system was that the distinction between stock remedies and veterinary drugs was still not well understood thus it was easier to continue with dual registration than unify the system and deal with the complexity of understanding differences if there were any as well as deal will staff consolidation, consolidation of functions and unifying of structures across the Departments of Health and Agriculture. The above influences on the decision making of leaders shows that the leadership, in terms of innovation and change, collaboration and collective action, was lacking and that there was no attempt to address the factors that affected the decision to revert to the dual registration system.

The system still remains separated today with the only development in function and structure been legislated under the Department of Health in 2008, where Act 101 of 1965 was amended (Act 72 of 2008) to establish the South African Health Products Regulatory Authority (SAHPRA). The amendment to the act, also excludes stock remedies as registered under Act 36 of 1947. With the amendment of the Act to create SAHPRA, the Department of Health entrenches its mandate to control in a proactive risk-based manner, as the body will not only evaluate and register human and veterinary drugs but food and medical devices as well.

b. Veterinary drug residue regulation

Veterinary drug residue regulation was initiated much later than the regulation of veterinary drugs with the implementation of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) of the Department of Health. This Act provided the mandate for safety of foods and was conducted through another section of the Department of Health than the

medicines authority. The section was the Directorate: Food Control which was a small section compared to the medicines registration authority and had limited resources in veterinary drug evaluation and residue calculation. However considering that this section of the Department of Health had a mandate to regulate residues of veterinary drugs in foods, they published regulations with maximum limits (MRLs) for veterinary drug residues in food, No. R. 1089 of 1992. Due to the lack of expertise in veterinary drug evaluation and calculation of withdrawal periods and MRLs, the publication of MRLs in regulation No. R. 1089 of 1992 was not initially linked to registration of stock remedies or veterinary drugs under Act 36 of 1947 and Act 101 of 1965, respectively. In fact, many of the MRLs published in No. R. 1089 of 1992 were taken from global standards related to veterinary drugs, primarily from those of the Codex Alimentarius Commission[63] (CAC) ('Codex') rather than determined from an evaluation of registered drugs and stock remedies. The need to publish MRLs and use of the Codex standards were prompted by the increase in trade of foods[64,65], particularly to Europe where veterinary residue regulation already existed as well as that in 1994, South Africa joined the Codex Alimentarius Commission[66] and started participating in the development of global food safety standards, including the Codex Committee on Veterinary Drug Residues in Food (CCVDRF). This participation allowed officials to understand the importance of publishing veterinary drug residue limits within national legislation.

When registration under Act 36 of 1947 started including proactive risk assessment of stock remedies, this risk assessment for food safety was requested of the Directorate: Food Control although the section had limited resources and risk assessment was conducted by

[63] CAC [Codex Alimentarius Commission].(1999) http://www.codexalimentarius.org
[64] JF Kirsten, J van Zyl & J van Rooyen. '*South African Agriculture during the 1980's'*. South African Journal of Economic History, (1994) 9 (2), 19-48
[65] N Vink. '*South African Agriculture in the 1970s'*. South African Journal of Economic History (1999), 14 (90-113)
[66] CAC [Codex Alimentarius Commission] (2011): List of members. Available at: http://www.codexalimentarius.org/members-observers/members/en/?no_cache=1

MCC, another section of the Department of Health. The isolation of Regulation 1089 of 1992 from the registration process of veterinary drugs in South Africa meant that drugs used in South African food producing animals did not have corresponding MRLs and this created a disjuncture between the registration process and publication of veterinary drug MRLs. The regulation was only amended once in 1999 after its original publication for the inclusion of MRLs of veterinary drugs, indicating an inability to update the MRL list, probably given its lack of support by the in-country veterinary drug registration process and constraints in human resources and expertise regarding veterinary drug residue calculation.

The separation of MRL determination from registration demonstrates the silo-mentality that was (and still is) prevalent within Government and even within the same Department. The Directorate: Food Control saw the need to establish MRLs for veterinary drug residues as per their mandate to ensure safe food but there was no linkage between the MRLs and veterinary drug registration, either from the same Department administering Act 101 of 1965 or the Department of Agriculture administering Act 36 of 1947. Therefore mandate obligations is influential in the initiation and continuation of fragmentation but this is actually exacerbated by silo-mentality or a lack of conceptualisation of individual functions as part of a system.

4. Discussion

From the initial development of the fragmented system in the 70's , to its continuance and the fragmented system that it is today, there a number of influences whose dominance caused and still contributes to the fragmentation of the veterinary drug and residue regulatory system. The first influence is the conceptual distinction between stock remedies

and veterinary drugs. This distinction initiated the separation of the registration of veterinary drugs as a whole and was perhaps justified at the time of separation, because the complexity of some veterinary drugs was not well understood and neither was the need to evaluate the risk associated with seemingly simple drugs. Another influence is mandate obligations, which refers to the fragmentation of an otherwise integrated system into different departments because certain functions fall within the mandate of these departments. In the initiation of the separation of registration of veterinary drugs, the evaluation of risk was seen as a function of the Department of Health and inconsistent with the promotion of agriculture, therefore any risk based functions were taken over by the Department of Health. This differentiation of mandates was also strengthened by the fact that the Department of Health already had existing legislation, structure and functions dedicated to the evaluation of human drugs. Therefore the regulation of complex veterinary drugs which required evaluation was more convenient under the Department of Health. Mandate obligations also influenced the regulation of veterinary drug residues. Since drug residues were of concern in food, the obligation was seen as that of the Directorate: Food Control and it was not conducted by the section of the Department of Health that registered veterinary drugs, but was conducted under a different Act, under a different section of the Department of Health. Even after the Department of Agriculture started including risk assessment of stock remedies as part of their functions, risk assessment for food safety related issues like determination of withdrawal periods and MRLs were requested of the Directorate: Food Control of the Department of Health even though this section had limited staff numbers and expertise in the field of veterinary drug evaluation.

Although conceptualisation constraints and mandate obligations were prominent at the initiation of fragmentation, the revert to the dual registration system after the South African

Medicines and Medical Devices Regulatory Authority Act, 1998 was repealed, indicated that at that stage, conceptualisation of veterinary drugs and stock remedies as distinct products was not the cause of the continuation of fragmentation of veterinary drug regulation. Rather another influence, that of poor leadership; was prominent. Poor leadership refers to managers of different departments within Government who instead of collaborating and driving change[67] collectively[68,69] continued within the fragmented system thus succumbing to the mandates of each department and the everyday running of the system.

The lack of proper leadership is the key factor in the continuance of the fragmented veterinary drug and residue system as it is through suitable leaders that are willing to change the system and innovate where necessary so that the system can be integrated. Good leaders will take into consideration the difficulties of staff consolidation, staff morale and enthusiasm during the consolidation process, and mandate obligations. There will of necessity be a strategy to deal with these issues to make successful change a reality. Good leaders will also cooperate and collaborate for a common and required goal while the collective action[70,71] for integrating a system currently controlled by two different national departments would be essential for integration.

The influences discussed above are indicated in Figure 6.1.

[67] Callahan. '*The future of public sector leadership*'. (Undated).
[68] M Olson, Jr. *The Logic of Collective Action: Public Goods and the Theory of Groups*. (1971) Schocken books: New York
[69] E Ostrom. '*The evolution of institutions for collective action'*. Cambridge University Press (1990)
[70] Olson. *The Logic of Collective Action: Public Goods and the Theory of Groups*.
[71] Ostrom. '*The evolution of institutions for collective action'*

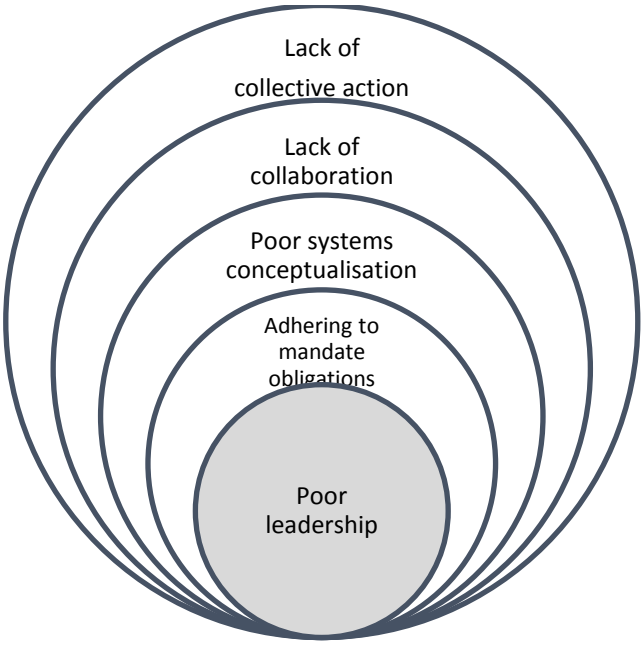

Figure 6.1: Influences on the regulation of veterinary drug and residue development which result in fragmentation showing the key influence of poor leadership.

5. Actions and policy implications

Since the key influence of Figure 6.1 is leadership, the training and mentoring of leaders within the veterinary drug and residue regulatory system is required. However the lack of training is prevalent within the public service in general and the need for training is not a new suggestion[72]. This training must occur in the context of public service where goals of the country, resource constraints and government prioritisation are taken into consideration when leaders are trained. The existing organisation in government addressing leadership is the Public Administration Leadership and Management Academy (PALAMA) and this can function as the base where leaders are trained and mentored. The training of leaders must

[72] G Naidoo. '*Strengthening senior management skills in the South African public service: a rationale for strategic leadership*' (2009). Journal of Public Administration, 44 (1), 3-14

incorporate systems thinking[73,74] for the understanding of linkages between functions in order to dispel silo-mentality, encourage collaboration and collective action. Training must also include understanding that structural fragmentation due to mandates must not influence function, particularly as new functions are created and older ones evolve. Training of leaders must instil collaboration and cooperation rather than silo-mentality and fragmentation as well as the power of collective action[75], particularly in innovation and change. Importantly, training must also include the steps necessary to implement change[76] as strategizing for change is not lacking (evidenced by Act 132 of 1998) but implementing change is. In order to carry out the outcomes of training, the need for innovation must be linked to the performance management and development system (PMDS), a system within Government for incentivising performance[77].

For the above training and mentoring to occur there needs to be some initial collaboration between various government departments and the Department of Public Service and Administration (DPSA). There must be policy from DPSA that states that all managers of Government Departments must be part of the training and mentoring programme and the DPSA must endorse and adopt the systems thinking approach to compulsory training programmes. This policy action will ensure that managers within the public service have consistent training in terms of innovation and change for the better of the Department. However, not only is having the training and mentoring programme in place but the public service must reward innovation and change for the better within Government. In this way the culture of the public service changes to one that calls for and embraces innovation and also creates an enabling environment for change and innovation.

[73] Senge, P. M. (2006) The fifth discipline, The art and practice of the learning organisation, *Doubleday Publishing*: New York
[74] Mella, P. (2012) *Systems thinking: intelligence in action*. Springer: Italy
[75] Olson. *The Logic of Collective Action: Public Goods and the Theory of Groups*.
[76] S. Fernandez & HG Rainey. '*Managing successful organizational change in the public* sector'. (2006). Public Administration Review, March/April, 168-176
[77] E Schwella & A. Rossouw. '*Competencies for the senior management service in the South African public service: an evaluative assessment*' (2005) Journal of Public Administration, 40 (4), 761-779

While DPSA policy will address the calibre and consistency of leadership in public service in the long run, including the veterinary drug and regulatory system, the specific policy actions required for integrating the system must also be discussed. Like the DPSA policy for leadership and training incorporating systems thinking and change management, an agricultural input policy incorporating veterinary drugs needs to be drafted. This policy must look at the entirety of the system including current regulation under the Departments of Health and Agriculture, Forestry and Fisheries and propose the integration of that system under one Department, namely the Department responsible for agriculture. Consolidating veterinary drug registration under the Department of Agriculture means that the same Department using the agricultural input of veterinary drugs is responsible for its management, similar to pesticides, or use of animal feeds. However the access to veterinary drugs under the Department of Agriculture needs to adopt a scheduling system or access control system, similar to the Department of Health's system, so that not all drugs are available over the counter. The movement of the registration of veterinary drugs to the Department of Agriculture means that the Department of Health will focus entirely on the registration of human medicines, giving that registration authority more time and resources to deal with an already ailing human medicines registration system[78,79].

All of the changes indicated above must be agreed upon by both the registration authorities and the integration must be a collective action. The amendment of legislation like Act 101 of 1965 and Act 36 of 1947 must follow the publication of the policy in order to reflect these changes. Regarding veterinary drug residues, these must still be published under the Department of Health as it is related to the safety of food, a mandate of the Department of

[78] Izindaba. *Dysfunctional MCC under legal threat*. (2010) South African Medical Journal, 100 (5), 274-276
[79] DJ Ncayiyana. *Misplaced trust? Gaping flaws in drug approval and licensing*. (2010). South African Medical Journal, 100 (7), 399

Health but the publication must be linked to the registration under the single registration authority, the latter of which must provide the calculation of withdrawal periods in order for the Department of Health to make a decision on the exposure of the drugs to humans. The collaboration between the registration authority under the Department of Agriculture and the Directorate: Food Control of the Department of Health must be formalised through a memorandum of understanding (MoU) or similar in order to ensure that the publication of maximum residue limits is linked to the registration of veterinary drugs.

Even though the above steps to integration are noted, like the Rinderpest outbreak that drove veterinary services in South Africa, a stimulus is needed for the two registration authorities to initiate integration. The stimulus need not be a devastating one but needs to be powerful enough to initiate a shift in policy by attracting the attention of politicians and senior managers[80]. This stimulus is best achieved through the private sector industry. As the industry being regulated, veterinary drug manufacturers through their industry organisations such as the Association of Veterinary and Crop Associations of South Africa (AVCASA) must provide part of the stimulus for change of the system. This could involve parliamentary lobbying, lobbying of senior Government managers like Ministers and spreading awareness of the inefficiency of the current system with the media and consumer unions. The lobbying by various industries involved in veterinary drug use and manufacture is also collective action, a critical factor that is also required from the public sector in order to affect change. Although leadership in Government is ultimately required to initiate and follow through with the change, stimulus and pressure by the regulated industry will prompt the change.

[80] S. Borins. '*Leadership and innovation in the public sector*'

Once changes are initiated, the integration must be managed as a large scale project with timelines for completion and specified goals, the latter of which, when not met, should attract penalties for the leaders of the integration. The change of the system to an integrated one must be monitored periodically to check progress that should be publicly reported and thus available to industry and consumers.

References

1. Anadón A. & A. R. Martínez Larrañaga. (1999) Residues of antimicrobial drugs and feed additives in animal products: regulatory aspects*. Livestock Production Science*. 59 (2-3), 183-198
2. APVMA [Australian Pesticides and Veterinary Medicine Authority], (2011) http://www.apvma.gov.au
3. ARC, [Agricultural Research Council] (2010) ARC-OVI. http://www.arc.agric.za/home.asp?pid=2564
4. Bengis, R. G. & J. M. Erasmus. (1988) Wildlife diseases in South Africa: A review. *Rev. sci. tech. Off. Int. Epiz.,* 7(4), 807-821
5. Bigalke, R. D. (2009) Theiler and the spirit of Onderstepoort. Onderstepoort Journal of Veterinary Research. 76, 3- 7
6. Blumberg, L. (1989).Robert Koch and the Rinderpest. *South African Medical Journal*, 76, 438-440
7. Borins. S. (2002) Leadership and innovation in the public sector*. Leadership and Organization Development Journal*, 23 (8), 467-476
8. Brown, K. & D. Gilfoyle. (2007) Livestock diseases and veterinary science in Southern Africa. *South African Historical Journal*, 58, 2-16
9. Brown K. & D. Gilfoyle (eds) (2010). Healing the herds: Disease, livestock economies, and the globalization of veterinary medicine. Ohio University Press (Athens)
10. Brückner, G. K. Vosloo, W. du Plessis, B. J. A. Kloeck, P. E. L. G. Connoway, L. Ekron, M. . Weaver, D. B. Dickason, C. J. Schreuder, F. J. Marais, T. & M. E. Mogajane. (2002) Foot and Mouth disease: The Experience in South Africa, *Rev. sci. tech. Off. Int. Epiz.,* 21 (3), 751-764

11. CAC [Codex Alimentarius Commission] (1999). Available at: www.codexalimentarius.org
12. CAC [Codex Alimentarius Commission] (2011): List of members. http://www.codexalimentarius.org/members-observers/members/en/?no_cache=1
13. Callahan, R. F. (undated). The future of public sector leadership. Available at: http://www.ipa.udel.edu/3tad/papers/workshop3/Callahan.pdf
14. Chanda, R. R. Fincham R. J. & P. Venter. (2010) Review of the South African food control system: Challenges of Fragmentation, *Food Control*, 21, 813-824
15. Chanda, R.R. Fincham, R.J. & P. Venter. (2014) Review of the regulation of veterinary drugs and residues in South Africa, *Critical reviews in Food Science and Nutrition,* 54 (4), 488-494*.*
16. DoA [Department of Agriculture] (2009), 'The development of veterinary services in South Africa'. http://www.nda.agric.za/vetweb/History/H_History_Main_Initual.htm
17. Doyle, 2006 Doyle, M. E. (2006) Veterinary drug residues in processed meats-potential health risk. A review of the scientific literature, Food Research Institute Briefings, University of Wisconsin. www.wisc.edu/fri/
18. FAO [Food and Agriculture Organization], OIE [World Organization on Animal Health], WHO [World Health Organization], (2012) High level technical meeting to address health risks at the human-animal ecosystems interface. FAO/OIE/WHO. http://www.who.int/zoonoses/hltm_2011/en/index.html
19. FAO/WHO, (2003) *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*, FAO Food and Nutrition Paper 76, FAO/WHO: Rome
20. FDA [Food and Drug Administration] (2013) http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm
21. Fernandez, S. & Rainey, H. G. (2006). Managing successful organizational change in the public sector. *Public Administration Review*, March/April, 168-176
22. Fingleton, J. (2004) Legislation for veterinary drugs control. FAO Legal Papers Online #38. FAO (Rome)
23. Hela, M. (2006) 'Regulation and control of veterinary pharmaceuticals in South Africa: The role of the National Department of Health'. Presentation to the Portfolio Committee on Agriculture and Land Affairs, 19 September 2006
24. Izindaba. (2010) Dysfunctional MCC under legal threat. *South African Medical Journal*, 100 (5), 274-276

25. Kirsten, J. F. van Zyl J. & J. van Rooyen. (1994). South African Agriculture during the 1980's. *South African Journal of Economic History*, 9 (2), 19-48
26. Mella, P. (2012) *Systems thinking: intelligence in action*. Springer: Italy
27. Mitema, E. S. (2009) Improved management of drugs, hormones and pesticides in Africa. *Onderstepoort Journal of Veterinary Research*, 7, 155-159
28. Naidoo, G. (2009). Strengthening senior management skills in the South African public service: a rationale for strategic leadership. *Journal of Public Administration*, 44 (1), 3-14
29. National Research Council. (1999). The Use of Drugs in Food Animals: Benefits and Risks, pp. 1, 19 & 71-73, 22-26 & 69 &76, 83-85. National Academy Press (Oxon) (Tropical Agriculture Association) and http://post.queemsu.ca/~forsdyke/rinderpst0.htm
30. Ncayiyana, D. J. (2010) Misplaced trust? Gaping flaws in drug approval and licensing. *South African Medical Journal*, 100 (7), 399
31. Olson, M. Jr. (1971). *The Logic of Collective Action: Public Goods and the Theory of Groups*. Schocken books: New York
32. Ostrom, E. (1990) Governing the commons. The evolution of institutions for collective action. *Cambridge University Press*.
33. Paterson, A. (2008) Veterinary skills. In: Kraak, A. & Press, K. (eds) (2008) Human resources development review 2008. Education, Employment and Skills in South Africa. HSRC Press: Cape Town
34. SAVA [South African Veterinary Association] (2012) South African Veterinary Association: Timeline of veterinary development. www.sava.co.za
35. Schwella, E. & Rossouw, A. (2005). Competencies for the senior management service in the South African public service: an evaluative assessment. *Journal of Public Administration*, 40 (4), 761-779
36. Senge, P. M. (2006) The fifth discipline, The art and practice of the learning organisation, *Doubleday Publishing*: New York
37. Sindane, A. M. (2011) Values and ethics enter the real world: a framework for public leadership and governance. *Koers* 76 (4), 751-769
38. Spinage, C. A. (2003) *Cattle plague: a history*. Kluwer Academic/Plenum Publishers (New York), 3-5
39. UP [University of Pretoria]. History of Veterinary Science(undated) http://web.up.ac.za

40. vandenBergh, S. (2010). The story of a disease: African horsesickness and its direct influence on the necessary development of veterinary science in South Africa, c. 1890s-1920s. *Historia*, 55 (2), 243-262
41. Verwoed, D. W. (2000) A brief historical review of research achievements by the OVI during the 20th century against the backdrop of socioeconomic and political developments in South Africa. *Journal of the South African Veterinary Association* 71(4), 210–214
42. Vinger, G & F. Cilliers. (2006). Effective transformation leadership behaviours for managing change. *South African Journal of Human Resource Management*, 4 (2), 1-9
43. Vink, N. (1999) South African Agriculture in the 1970s. *South African Journal of Economic History*, 14 (90-113)
44. VMD [Veterinary Medicines Directorate], (2011). http://www.vmd.defra.gov.uk/

CHAPTER 7: PAPER 4

Table 7.1: Summary of details of Paper 4

Title	Systems conceptualisation and communication challenges in the South African veterinary drug and residue regulatory system
Publication status	Unpublished. To be submitted to the Journal Food Control for publication.
Journal website	http://www.journals.elsevier.com/food-control/
Citation reference	Chanda, R.R. & R. J. Fincham. (*unpublished*) Systems conceptualisation and communication challenges in the South African veterinary drug and residue regulatory system
Objectives addressed	This paper reports further on the challenges of the veterinary drug and residue regulatory system and therefore answers to objective 5. It provides a deeper understanding of the two challenges of poor systems conceptualisation and lack of communication.
Methods used	This paper used a questionnaire-based survey as the principal method.
Key outcomes	First in-depth analysis of communication and systems conceptualisation within the food control system through the in-depth study of the veterinary drug and residue system. Establishes that horizontal communication between departments is poor while poor systems conceptualisation is likely due to a lack of in depth understanding of related function which participants are not really aware of. Also establishes that the two challenges are interrelated and exacerbate one another or conversely relieve one another. These two challenges need to be addressed at the onset of dealing with the fragmented food control system.

Systems conceptualisation and communication challenges in the South African veterinary drug and residue regulatory system

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Abstract

Previous reviews have indicated that the regulation of veterinary drugs and residues, like the larger food control system in South Africa, is highly fragmented, a phenomenon that manifests as fragmented structures, functions and legislation (Brückner, 1998; FAO/WHO, 2003a; Chanda *et. al*, 2010; Chanda *et.al.* 2014). These reviews have also reported that fragmentation is associated with and even causes challenges which include poor communication within, between and outside government as well as poor systems conceptualisation of individual functions of the veterinary drug and residue regulatory system. This paper reports on findings of a questionnaire-based survey on whether and why conceptualisation and communication are prominent challenges, based on responses from government and non-government stakeholders of the veterinary drug and residue system. Results indicate that poor systems conceptualisation is due to lack of in-depth understanding of related risk management strategies even though awareness of these RM strategies may not be lacking. Poor communication is also prominent in the system and is due to poor frequency of communication, poor quality of communication and use of limited and impractical methods of communication. Based on these findings, poor communication needs to be addressed through a communication model that addresses frequency, methods and quality of communication. Systems conceptualisation poses a greater challenge and requires a change in mind-set which is most effectively achieved through training of personnel at the policy level thereafter affecting changes in organisational structure, function and legislation governing the system.

Keywords: veterinary drug residues, systems conceptualisation, communication

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1. Introduction

The regulation of veterinary drugs and residues is a functionally integrated system (Serratosa *et. al*., 2006) and part of a larger government strategy of veterinary public health (WHO, 1999) and animal production (Fingleton, 2004). In this system veterinary drugs used for animal welfare or for animal production are assessed for risk, registered and included in a database of drugs that can be used within a country. This system also evaluates the risk of use of those drugs to human consumers if residues of veterinary drugs remain in the animal products. The maximum amounts of residues in a particular food producing species are legislated such that exceeded limits are considered illegal and potentially unsafe to consumers.

As integrated as such a system may be required, parts of that system can be fragmented where registration and risk assessment of drugs are conducted by one authority, publication of maximum residue limits (MRLs) conducted by another authority and checking whether amounts of residues do not exceed legislated limits (enforcement) are conducted by another authority. This is the case with the South African regulatory system of veterinary drugs and residues where structures, functions and legislation of the system are fragmented. This fragmentation is a mirror of the food control system of South Africa which displays the same attributes, i.e. fragmented structures, functions and legislation (Brückner *et. al*. 1998; FAO/WHO, 2003a; 2004 & 2005, Chanda *et. al*., 2010) which are typical characteristics of a multiple agency food control system (FAO/WHO, 2003b; Neeliah & Goburdhun, 2007).

Research and reviews of the fragmented food control system and regulatory system of veterinary drugs and residues indicate that not only is fragmentation a phenomenon of the system, but that fragmentation is associated with a variety of challenges which compromise the ability of the system to function effectively (Brückner *et. al*. 1998; FAO/WHO, 2003b; 2004 & 2005; Chanda *et. al*., 2010). The ineffective functioning of the system translates into compromises in food safety which has potentially negative impacts on the health of citizens and poor use of limited resources which results in ineffective use of public resources. Challenges identified include, amongst others, poor conceptualisation of individual functions, structures and legislation as part of a system and poor communication between various parts of the system termed poor horizontal communication (Chanda *et. al*., 2010; Chanda *et. al*. 2014). Considering the identification of these challenges in reviews, it is important to confirm if they exist and also to understand why and how they occur. This paper therefore reports on whether these challenges exist as well as why and how they occur from results of primary research conducted through a questionnaire-based survey where participants are asked to respond on their awareness and understanding of various risk management strategies related to veterinary drugs and residues as well as their communication to other stakeholders of the system. Identification of the reasons as to why communication and conceptualisation are poor is relevant in determining how these challenges can be addressed.

2. Methodology

2.1. Framework of questionnaire

A structured but flexible-format questionnaire was used to obtain responses from participants who were either government personnel or employees of non-governmental organisations directly involved in the regulation of veterinary drugs and residues. The questionnaire was based on seven risk management (RM) strategies of veterinary drug and residue regulation that should be conducted by government. These RM strategies are actually functions of government that are in place to manage the risk associated with use of veterinary drugs in food producing animals. As these strategies may have already been in place within the South African veterinary drug and residue regulatory system, their use as the basis of the questionnaire was to determine whether participants were aware of these them and whether they understood their purpose. Understanding whether participants were aware of RM strategies and whether they understood their purpose would provide insight into whether poor systems conceptualisation was due to a lack of awareness and understanding of these strategies. The questionnaire also requested responses from participants regarding how they communicated to other stakeholders within the veterinary drug and residue regulatory system to determine if communication is a challenge within the system as previously reported on (Chanda *et. al*. 2014).

The seven risk management strategies used were previously identified in reviews of the veterinary drug and residue regulatory system (Chanda *et. al*., 2014) and included risk assessment or commissioning of a risk assessment; registration of drugs; control of access (scheduling); publication of maximum residue limits (MRLs); compliance monitoring to

published MRLs; extension or outreach services (largely risk communication), residue monitoring and antimicrobial resistance monitoring. Table 7.2 lists and summarises each of the identified RM strategies that were used as the basis of the questionnaire as well as indicates who conducts that strategy within the system.

2.1. Population and respondent group

Both government and non-government personnel participated in the survey and categories of the questionnaire were therefore called ‘government’ and ‘other’. The former included government officials from the national, provincial or local sphere who were involved in any of the risk management strategies and the latter included non-governmental stakeholders also involved in each of the identified RM strategies. For example, for the RM strategy of compliance monitoring, government participants included persons from the Department of Health who legislate residue limits and the officials of the provinces and municipalities who enforced the limits (sampling and analyses). Participants from the ‘other’ category for compliance monitoring included food retailers and manufacturers for compliance monitoring.

For both groups, participants were not specifically chosen based on their personal capacity but were included in the population and sample if their job function allowed for involvement in any of the RM strategies. This meant that there were no criteria for age, gender or qualifications of participants as long as they were appointed by their employers to conduct a particular function. However as the subject area of veterinary drugs is generally a very technical one, this generally meant that participants from both groups were knowledgeable on the subject, had professional qualifications either directly related to veterinary drugs and

residues or to public service and had at least some experience in conducting their functions. This was verified in questionnaires when participants were asked to record their qualifications and years of experience. The lowest number of years of experience was indicated as four years for government participants with an overall average of 10 years (10 respondents) while participants from the 'other' category averaged 14 years of experience with the lowest being a few months (14 respondents). Qualifications of participants were varied but very much in line with their individual functions with a strong basis in natural and veterinary science. The types of qualifications as well as averages of years of experience suggest that participants are not deficient in their technical understanding of veterinary drug and residue functions.

Based on the criteria of involvement in RM strategies, 48 participants for both 'government' and 'other' categories were identified and requested to participate. This however did not mean an equal number of participants for each strategy as there were more participants involved in one RM strategy compared to others. Table 7.3 provides a summary of participants per category as well an indication of which risk management strategy they were most involved in and therefore which was prioritised for responses within the questionnaire. For most of the strategies of the questionnaire the population was so small that the entire population was sampled and therefore requested to participate. Using the example of publication of MRLs, the government population was only two people and both these were requested to participate. For the 'other' category the population was based on criteria like whether the organisation was involved in the RM strategy (applicability) and had expertise on the RM strategy. For example, for participation from veterinary drug manufacturers, criteria for inclusion related to whether the manufacturing company produced any veterinary drugs at all and whether they had submitted requests for registration through either of the registration authorities. Criteria for food retailers and manufacturers included whether they

had regulatory offices and whether they sold or manufactured animal derived foodstuffs. Criteria for academics included those involved in veterinary drug residue extrapolation and MRL determination, those involved in industry or determination of veterinary drug residues.

Requests for participation in the questionnaire were either telephonic or via email. Depending on the geographical distance of participants to the main researcher, questionnaires were also completed through one-on-one interaction. Although this was the favoured method for completion of questionnaires as responses were more in-depth this interaction was limited to only four participants all within the government category due to how far participants were from the researcher, the availability of participants for one-on-one interactions and the willingness of participants to complete the questionnaires in this way. In addition, financial resources and time constraints for meeting each participant were also limiting factors in completing questionnaires one-on-one. Where questionnaires were not completed through face-to-face interaction, participants completed questionnaires on their own and either emailed them back or posted them back.

2.2. Systems conceptualisation and awareness

Systems conceptualisation is derived from systems thinking (Senge, 2006) where questions of the survey were used to determine if participants understood their own functions to be part of the greater food control and safety system, termed ‘vertical systems conceptualisation’ and if participants could conceptually link their own functions to other similar and related functions termed ‘horizontal systems conceptualisation’. The latter was determined through finding out if participants were aware of related functions within the greater veterinary drug and residue system. In the questionnaire this was researched by assessing if participants were aware of a particular RM strategy, whether they were

involved in it or not (RM involved or RM not involved, respectively), whether they could pick the correct authority/ies who conducted the RM strategy and also rate how the strategy was conducted.

Awareness and conceptualisation responses were only requested from the 'government' category as the aim of the questionnaire was to determine whether awareness and conceptualisation were inherent within the system which was not easily determined from outside, non-governmental stakeholders.

2.3. Communication

In this study communication refers to communication between government departments, within government departments and between outside stakeholders and government. For the government category, participants were asked if they communicated, between, within and outside their organisation and why they communicated, i.e. only for discussion, to update and discuss or only to update. From these three options, update and discuss was considered the closest to ideal communication and therefore communication was looked at to determine how close actual communication was from the ideal. Participants were also asked whether they thought they should communicate to more people within and outside their departments. These questions provided an understanding of the quality of communication within a government department, between government departments and government departments and non-governmental stakeholders. The questions therefore sought to determine if communication was a challenge whether the quality of communication was the reason it is a challenge.

The ‘other’ category was asked which communication methods existed between the two departments and three authorities, that is the authorities administering Act 101 of 1965 of the Department of Health (‘Act 101 of 1965’), Act 36 of 1947 of the Department of Agriculture, Forestry and Fisheries (‘Act 36 of 1947’) and Act 54 of 1972 of the Department of Health (‘Act 54 of 1972’). They were also asked whether they considered these forms of communication sufficient and which methods of communication was considered the best and worst. This information was required to determine if the methods of communication used were robust in order to determine why and how communication becomes a challenge.

3. Statistical Analysis

Data was analysed using the statistical program GenStat® *for Windows*™ 14th Edition Introduction. (Payne *et. al*., 2011). This program, like other similar statistical programs is useful for both descriptive and analytical statistics which were used to analyse data in this study. Although elaborated on in section 4, where analytical statistics could not be used due to limitations of the study, the descriptive statistics obtained provided valuable understanding of trends in the data which assisted in understanding whether poor systems conceptualisations and poor communication were indeed challenges and why they exist. The GenStat® statistical program was also easily accessible to the research team and proved valuable in its application.

4. Limitations of the study

The population for this study, particularly for the Government category, was limited and sometimes participants who were approached indicated that they were had insufficient

knowledge on the subject area and therefore declined to participate. This was indicated, for example, for one participant involved in extension services in the Department of Agriculture, Forestry and Fisheries. Indicating non-participation in the survey due to insufficient knowledge may have impacted the size of the population and the response rate, but was relevant as it indicated that the requested participant/s is unable to link identified risk management strategies to their own job functions which in turn provided valuable understanding of the limitation of systems conceptualisation in the particular Department that the participant belonged to.

Since response rates were low, this impacted on the ability to utilise statistical methods to determine for example statistical significance in trends of responses through use of chi-square analysis, t-tests or ANOVA. Nonetheless, valuable data was gathered via the questionnaire process to understand the challenges of poor systems conceptualisation and poor communication as well as acting as the foundation for further research.

5. Results and discussion

Forty eight participants were requested to participate with 17 from government and 31 from the other category. Ten participants from the government category responded (59%) and 14 (45%) for the ‘other’ category responded which yielded an overall response rate of 50 %. The questionnaires were also analysed according to the categories of ‘government’ and ‘other’ and whether participants were directly involved in the RM strategy (RM involved) or not (RM not involved).

5.1. Conceptualisation and awareness

5.1.1. Linkage and association for RM involved

For RM strategies that participants were directly involved in (RM involved), 21 of 26 responses (81 %) showed that participants could link the RM strategies they are involved in to the use and regulation of veterinary drugs and residues. Examples of responses that showed ability to link RM strategies they are involved in to the greater veterinary drug residue system included for extension services: '*adverse effects of veterinary drug residues in foods on humans needs to be known. Safety is non-negotiable*. *Its [extension services] important as extension services provides awareness to consumers'* while for compliance monitoring responses showing the participants ability to link included: '*MRLs are published for veterinary drug residues in foods. Compliance monitoring is to determine whether these foods comply to those limits*.' For publication of MRLs and compliance monitoring, responses showing ability to link these RM strategies to the greater veterinary drug and residue system included: '*process of evaluation of veterinary drugs for regulation (DAFF and DoH) eventually result in determination/publication of MRLs which are intended to ensure that through compliance monitoring (relevant authorities) consumers are protected from affects associated with presence of too high levels of vet drugs in foods*'.

The remaining four responses that showed that participants could not link RM strategies they were directly involved in to the veterinary drug and residue system were indicated as not applicable which is a relevant finding as participants were meant to be directly involved in these RM strategies but they indicated them as not applicable. This firstly meant that they cannot conceptualise their own functions as part of a system or that they didn't conduct the

function at all even though they were supposed to. This is a lack of the ability to conceptualise their own functions as being part of the veterinary drug and residue system.

5.1.2. Linkage and association for RM not involved

For RM strategies that participants were not directly involved in, 30 responses of the 44, (68 %) showed that participants could link the RM strategy to veterinary drug residues while 11 of the remaining 14 responses only indicated partial linkage. The remaining 5 responses showed no understanding and included responses of '*don't know'* or '*not sure'*.

For risk assessment answers indicating full ability to link included '*risk assessments are important to determine withdrawal periods, the maximum residue limit (MRL) and other aspects like efficacy'*. For partial understanding for risk assessment participants responses included was '*protects consumers*' which didn't show how the participant linked the function of risk assessment to protecting consumers. Responses that showed ability to link a particular RM strategy to the greater system included for example, for extension services, '*its important for stakeholders to understand the implications of residues in food and the impact it would have regarding resistance and safety*' and '*knowledge is power. If people are trained and understand the usage, application and risks associated with veterinary drugs, they can make informed choices and manage the risks'*. For partial linkage for extension services, an example of responses included, '*educate the people and then they can use antibiotics responsibly*' which is limited to the understanding that only antimicrobials are veterinary drugs even though there are a variety of veterinary drugs whose functions extend beyond antimicrobials and include hormones, biological drugs like vaccines and even topical drugs.

For the RM strategy of control of access responses showing ability to adequately link to veterinary drugs and residues included '*the control of access of drugs is important to curb abuse of drugs but also ensure that drugs are easily accessed where required. Act 36 of 1947 was the first Act for registration of stock remedies and its purpose was to provide drugs to farmers that were easily accessible. These drugs for common livestock (and other animals) diseases and was introduced as there was a lack of veterinary personnel to diagnose and dispense these drugs. As a result, farmers were able to access these drugs through pharmacies to treatment their own animals. Over time Act 36 of 1947 began to register antimicrobials and these too were over-the-counter access according to the orientation of the Act. This requires change as use of some antimicrobials may lead to resistance development and abuse'.* For partial understanding responses included *'could possibly prevent unauthorized use that can contaminate food supplies'* which only addresses unauthorized use but not misuse or misapplication of veterinary drugs.

For registration, responses indicating ability to link the RM strategy to the greater system included *'registration of a product requires a lot of research and all this information can be used to ensure that no residues are left in products before consumption. It also requires a depletion study to be done. In this way the country is ensured that a testing facility exists as well as a validated method'*. Responses indicating partial linkage for registration included '*the registration of drugs only occurs for MRL determination'* which is not entirely true as registration considers other aspects of veterinary drugs like the quality in terms of efficacy and stability and not only for MRL determination. For compliance monitoring, responses for ability to link included '*drugs must be used according to the registered label claims only*

and samples must be collected to ensure that the drug meets specifications'. No partial responses were noted for compliance monitoring.

5.1.3. Summary for linkage and association

For 'RM involved' the responses indicate that in a majority of cases participants could link RM strategies that they were involved in to the veterinary drugs and residue system. This in turn indicates that 'vertical' system conceptualisation for RM strategies that participants are involved in is not lacking and that participants can link individual functions to the greater system. For 'RM not involved' responses indicated that participants are still able to link RM strategies they are not directly involved in to veterinary drug residues. However responses indicating partial understanding and no understanding meant that for RM strategies they were not directly involved in, vertical association to the greater system may still be of concern.

5.1.4. Awareness

To determine participants awareness of RM strategies they were asked to identify authorities who conducted each of the seven RM strategies regardless of whether they were directly involved in (RM involved) them or not (RM not involved). Participants were asked to also rate the effectiveness of those strategies. Responses were then assessed on whether they could pick an authority, whether it was the correct authority and whether they could rate the effectiveness of that strategy, that is, if they had deeper knowledge of the strategy. For example for publication of MRLs, participants could pick from a variety of authorities like Department of Health, Department of Agriculture, Forestry and Fisheries,

provincial and municipal health and agriculture departments and other, although the correct authority was the National Department of Health.

Of the 10 responses from government participants, 26 replies were for 'RM involved in' and 44 for 'RM not involved'. 23 of the 26 (88 %) responses showed that participants could effectively identify an authority for risk management strategies they were involved in while 33 of the 44 response (75 %) showed that participants could effectively pick a structure for risk management strategies they were not involved in (Figure 7.1). Although 23 of the 26 responses showed that participants could pick an authority of a RM strategy they were involved in, only 18 of the 26 (69 %) responses showed that a correct authority that conducted that strategy could be picked. For RM strategies not involved in, only 23 of the 44 (52 %) responses showed that participants could identify the correct authority conducting that strategy (see Figure 7.1). Questions aimed at checking whether participants could rate the function of the strategy by authorities showed that 16 of the 26 (61 %) responses indicated an ability to rate the risk management strategy that participants were involved in while only 7 of the 44 (16 %) responses could rate a risk management strategy that they were not involved in. These trends suggest that participants are able to pick authorities, pick the correct authorities and rate those strategies correct authority better for RM strategies they are directly involved in versus those that they are not. However chi-square analysis indicated no significant difference in responses for picking an authority between RM involved and RM not involved ($\chi^2 = 1.85$; $p = 0.174$; degrees of freedom = 1) and picking the correct structure between RM involved and RM not involved ($\chi^2 = 1.94$; $p = 0.164$; degrees of freedom = 1). However chi square tests indicated a highly significant difference in responses between RM involved versus RM not involved for the ability to rate the effectiveness of a function conducted by an authority ($\chi^2 = 15.42$; $p < 0.001$; degrees of

freedom = 1). This indicates that participants find it difficult to rate strategies they are not directly involved in versus those they are involved in which indicates that for RM strategies they are not involved in they only have superficial understanding of these strategies and how they operate. This will limit the linkage of these strategies to those they are involved in. This is indicative and a consequence of silo mentality (Cilliers and Greyvenstein, 2012) where isolation of functions limits awareness and interaction within a system.

Data trends also indicate that for both 'RM involved' and 'RM not involved' participants could better pick authorities than pick the correct ones than rate them. As knowledge required of the RM strategy is greater for rating versus picking the correct authority, the data trend indicates that participants may only be superficially aware of RM strategies and may not have enough understanding of RM strategies in order to associate them to their own functions.

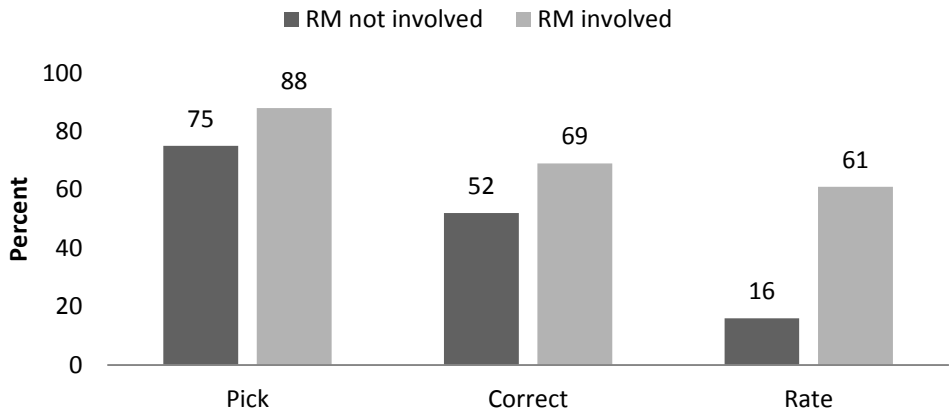

Figure 7.1: Percentage frequencies of responses for ability to pick an authority (pick), picking the correct authority (correct) and ability to rate the effectiveness of conducting the strategy by an authority (rate).

These findings are relevant because they show that awareness is not the only factor involved in conceptualisation of the veterinary drug and residue system but also that

understanding of a RM strategy, particularly how well an RM is understood, can affect the conceptualisation of those RM strategies as part of a system. Therefore a lack of understanding of a RM strategy limits association of that strategy to one's own function or strategy and that limits systems conceptualisation.

5.2. Communication

5.2.1. Government

Government participants were requested to respond to questions that aimed to evaluate and determine effectiveness of communication within their respective departments, with other government departments and with the private sector or outside government (Figure 7.2). For communication within government, all 10 participants (100 %) indicated they already communicate to other personnel of their respective department while for communication between other government departments (other government) only 5 of the 10 participants (50 %) indicated they already communicate. For communication with non-government stakeholders 8 of the 10 (80 %) government participants said they already communicate. Results indicate that although communication occurs within Departments, across Departments and with outside stakeholders, the lowest frequency of communication occurs between departments. This is an indication of poor horizontal communication.

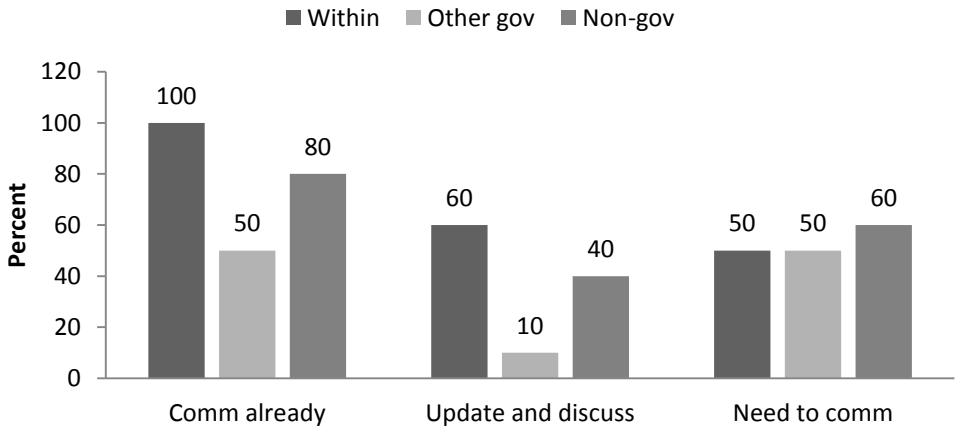

Figure 7.2: Percentage frequencies of responses for government respondents indicating they communicate already (comm already), whether they communicate appropriately (update and discuss) and whether they still need to communicate within their departments, between sister departments and outside government (within, other gov and non-gov)

To determine quality of communication within and across departments as well as with non-government stakeholders, participants were also asked why they communicated and they were provided with the choices of 'update only', 'discuss only' and 'update and discuss' with the last option being considered the ideal form of communication, compared to only discussing or only updating. Results indicate that for communication within respective government departments only 6 of the 10 participants (60 %) communicate to update and discuss, for communication with other government departments only 1 of the 10 participants (10 %) communicate for updating and discussing and for communication to non-governmental stakeholders only 4 of the 10 (40 %) communicate for updating and discussing (Figure 7.2). Another interesting result is that for communication across departments, 4 of the 10 (40 %) participants indicated that communicating to other departments was not applicable while 2 of 10 (20 %) participants indicated communication to outside stakeholders as not applicable. No participants indicated that communication

within their department was not applicable. These results indicate that communication across all three groups is not ideal but that ideal communication is severely limited between government departments perhaps because communication is seen as not required or important. This is a key finding as communication and quality of communication is limited between government departments and this affects the linkage between RM strategies of the system.

Participants were also asked whether they still needed to communicate to persons within their department, persons in other government departments and with non-governmental stakeholders. Five of the 10 participants (50 %) indicated they still need to communicate within their department and to other departments, while 6 of the 10 (60 %) said they need to communicate to non-governmental stakeholders. These results were similar across all three groups even though communication and quality of communication is poorer between government departments than within departments or outside stakeholders. The lack of a higher percentage of participants still needing to communicate to other departments suggests that they are not aware of the need to communicate more with other departments. However, the results do indicate that with half of participants saying they still need to communicate to various governmental and non-governmental stakeholders, there is understanding that current communication is not ideal.

5.2.2. Other

Participants of the 'other' category were also asked to indicate whether communication with the three authorities, those that administer Act 101 of 1965, Act 46 of 1947 and Act 54 of 1972, was sufficient, which methods they used to communicate and which they considered

to be the most effective. This information was used to assess sufficiency of communication as perceived by outside stakeholders and to determine whether current communication methods are ideal. Responses to the question on sufficiency of communication (do you consider communication with this particular authority sufficient), across all three authorities indicated that the majority of respondents responses considered communication to be insufficient (Figure 7.3).

Participants were also asked to indicate what communication methods were available to them for communication to the three government authorities and they chose from physical meetings (PM), website (W), letters (L), email (E), telephone (T) and other (O). The most prevalent communication types indicated below with the three authorities were through emails, letters and telephones while communication through websites and physical meetings were less prevalent (Figure 7.4).

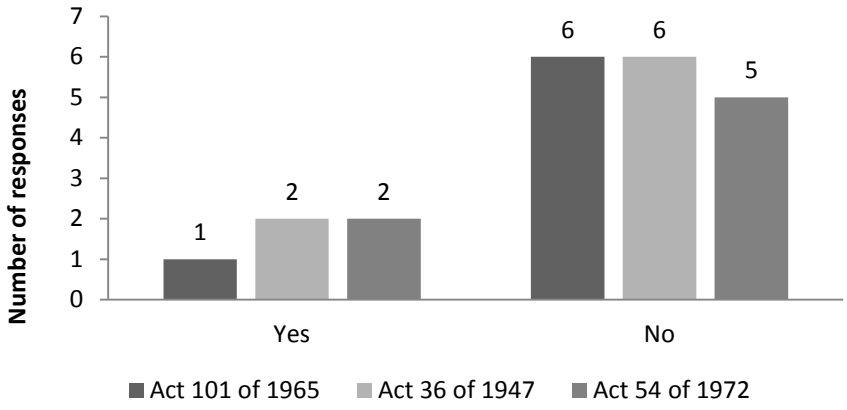

Figure 7.3: Frequencies of responses on the sufficiency of communication between government and outside stakeholders for the three authorities administering Act 101 of 1965, Act 36 of 1947 and Act 54 of 1972.

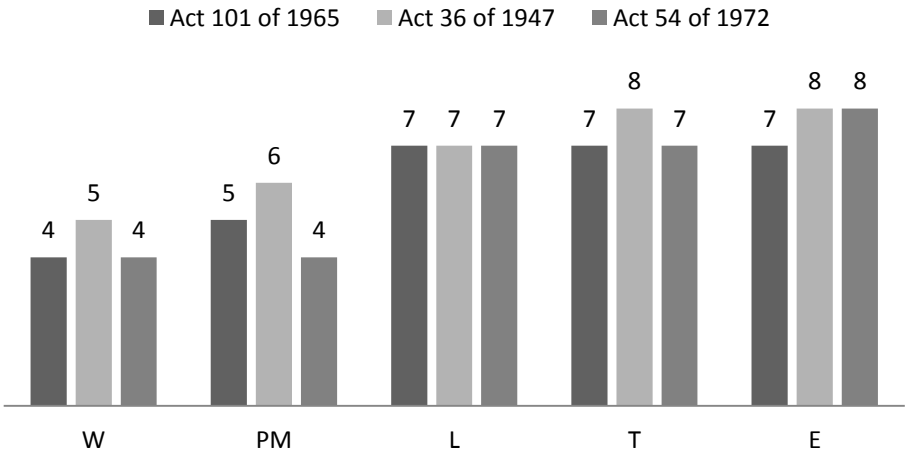

Figure 7.4: Frequencies of responses on most prevalent types of communication between government and outside stakeholders for the three authorities administering Act 101 of 1965, Act 36 of 1947 and Act 54 of 1972. W=website, PM=physical meetings, L=letters, T=telephone, E=emails

However some of the less prevalent communication types were noted as the most effective when participants were also asked to rate the effectiveness of the communication methods they used to communicate across the three authorities. Results indicated that letters and telephones were the most effective communication method for Act 36 of 1947, physical meetings for Act 101 of 1965 and physical meetings and other for Act 54 of 1972 (Figure 7.5). This indication by non-governmental stakeholders on the effectiveness of communication reinforces that current communication is insufficient.

From the effectiveness of methods as indicated by participants, it is understood that the three authorities administering Act 101 of 1965, Act 36 of 1947 and Act 54 of 1972 have not embraced newer forms of communication like through websites and social media and this limits effective communication to physical meetings which is dependent on physical availability of the officials and industry and may not always be practical.

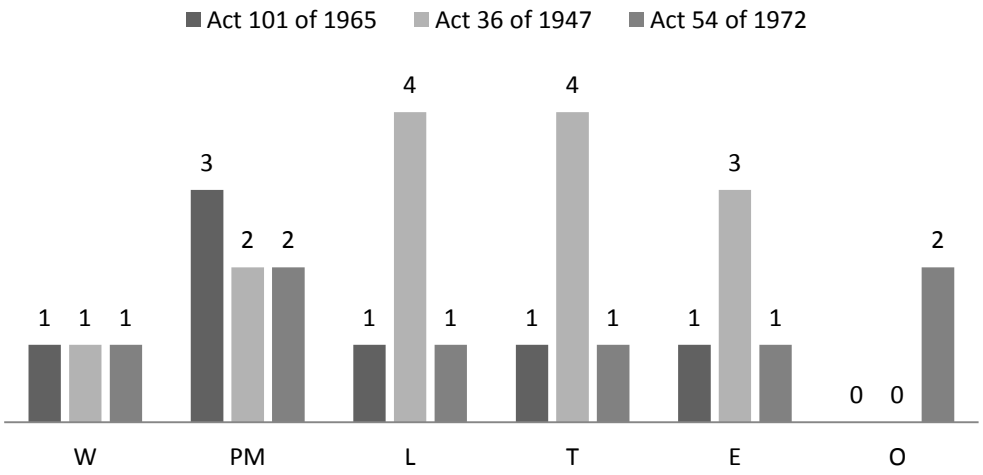

Figure 7.5: Frequencies of responses on most efficient types of communication between government and outside stakeholders for the three authorities administering Act 101 of 1965, Act 36 of 1947 and Act 54 of 1972. W=website, PM=physical meetings, L=letters, T=telephone, E=email, O=other

An effective communication model is therefore required for communication within and between departments as well as with outside stakeholders. This would need to ensure that communication occurs regularly, is of acceptable quality in terms of not only updating but also to discuss, and make decisions jointly and to reassess through which routes communication occurs in order to maximise communication. It is suggested that electronic forms of communication needs to be integrated into the communication model in order to rapidly make information available to stakeholders.

6. Conclusion and recommendations

There are three key findings of this study. One is that poor communication and poor systems conceptualisation are indeed challenges of the South African veterinary drug and residue regulatory system. The second key finding is that communication within the system

is poor, and in particular communication between government departments, so called horizontal communication. Poor horizontal communication limits the ability to engage and therefore address common issues within a system like registration between the two registration authorities of Act 101 of 1965 and Act 36 of 1947 or residue monitoring and compliance monitoring between the Departments of Health and Agriculture, Forestry and Fisheries. Non-government stakeholders also indicate that communication with authorities is not sufficient primarily because it is limited to face-to-face interaction which may not always be practical. The third key finding is that systems conceptualisation is also a challenge as indicated by findings that respondents do not have the in-depth knowledge of related functions which in turn limits the ability of people within the system to associate their functions to similar functions conducted under different RM strategies or different government departments.

Although communication and poor systems conceptualisation are researched separately in this paper, they also interconnect with poor systems conceptualisation affecting poor communication between departments while poor communication entrenches the silo mentality within the system and leads to poor systems conceptualisation. This is relevant as any attempt to address these challenges requires that they are addressed together. Understanding the existence of a relationship between systems conceptualisation and communication requires that communication models are which are introduced address communication methods, frequency of communication and quality of communication while considering the influence this has on systems conceptualisation. The conceptualisation challenge is more difficult to address as it requires change in mind-sets and this is best achieved through training of policy makers where changes regarding intergovernmental

relations (Reddy, 2001), organisational structure (van der Heijden & Mlandi, 2005), function and legislation are affected.

References

1. Chanda, R. R. Fincham, R. J. Venter, P. (2010) Review of the South African Food Control System: Challenges of Fragmentation, *Food Control, 21*: 816-824
2. Chanda, R.R. Fincham, R.J. & Venter, P. (2014) Review of the regulation of veterinary drugs and residues in South Africa, *Critical reviews in Food Science and Nutrition,* 54 (4), 488-494
3. Cilliers, F., & Greyvenstein, H. (2012). The impact of silo mentality on team identity: An organisational case study. *SA Journal of Industrial Psychology.* Vol. 38(2), Art. #993, 9 pages.
4. FAO/WHO [Food and Agriculture Organisation/World Health Organisation 2003a]. Report of the FAO/WHO Workshop: Food control systems-practical approaches in the Southern African region, 1 September 2003, Pretoria, South Africa, Rome
5. FAO/WHO [Food and Agriculture Organisation/World Health Organisation 2003b]. Guidelines for developing an effective food control system, FAO/WHO, Rome (1/1)
6. FAO/WHO [Food and Agriculture Organisation/World Health Organisation] (2004). Second FAO/WHO Global Forum of Food Safety Regulators, Bangkok, Thailand, 12-14 October 2004: Legal Basis for Food Safety Official and non-Official Control- "Strengthening official food safety control services', Rome
7. FAO/WHO [Food and Agriculture Organisation/World Health Organisation] 2005. FAO/WHO Regional Conference on Food Safety for Africa. International, Regional, Sub-regional and National cooperation in food safety in Africa, 3-6 October 2005, Harare, Zimbabwe, Rome
8. Fingleton, J. (2004). Legislation for Veterinary Drugs Control. FAO Legal Papers Online #38, FAO: Rome
9. Neeliah S.A., Goburdhun D. 2007. National food control systems: A review, Food Reviews International 23: 35-51
10. Payne, R. W. Murray, D.A. Harding, S. A. Baird, D. B. Soutar, D. M. (2011) Genstat® for Windows™ 14th Edition Introduction. VSN International, UK.

11. Reddy, P. S. (2001) Intergovernmental relations in South Africa, *Politeia*, Vol. 20 (1), 21-39
12. Senge, P. M. (1990, 2006) The fifth discipline, The art and practice of the learning organisation, Doubleday Publishing: New York
13. Siegel, S. (1956) Non-parametric statistics for the behavioural sciences. New York: McGraw-Hill Book Co. Inc.
14. van der Heijden, T. Mlandi, M. (2005) Organisational performance, success and failure in the public sector, *Journal of Public Administration*, Conference Proceedings, October 2005
15. WHO (1999) Study Group on Future Trends in Veterinary Public Health.
16. Future trends in veterinary public health: report of a WHO study group (Teramo, Italy)

Table 7.2: Risk management strategies and their definitions

	Identified risk management strategies						
	Risk assessment	**Registration**	**Control of access**	**Publication of MRLs**	**Compliance monitoring**	**Extension services**	**Residue monitoring**
Definition: Refers to…	A scientifically based process where the theoretical risk of a veterinary drug is assessed. This involves assessing toxicity and exposure of the veterinary drug to the human population.	The system whereby pharmaceutical companies apply to a Government Department to have their drug assessed so that it can be used in the country.	The process of how drugs of different toxicity and specialisation are accessed. In South Africa medicines are scheduled according to their toxicity if registered under the Medicines and Related Substances Act, 1965. This means that some drugs are accessed over-the-counter while others need prescriptions.	Legislation that states the maximum residue limits (MRLs) of specific veterinary drugs for specific foods.	Monitoring of foods by Government to determine if they comply with published MRLs as per legislation of a country. Also infers follow-up action is foods are non-compliant like destruction of foods or prevention of sale of foods.	Government initiated services that inform, educate and communicate to farmers and other stakeholders on use of veterinary drugs, animal production and animal health.	Monitoring programme that tests various foods to determine amounts of veterinary residues in them. Is different to compliance monitoring, as no follow-up actions (like fining the manufacturer), are conducted. It is mainly for determining trends in usage veterinary drugs.
	Authority that conducts the strategy						
	-Department of Agriculture, Forestry and Fisheries: Act 36 of 1947 -Department of Health: Act 101 of 1965 -Department of Health: Act 54 of 1972	-Department of Agriculture, Forestry and Fisheries: Act 36 of 1947 -Department of Health: Act 101 of 1965	-Department of Agriculture, Forestry and Fisheries: Act 36 of 1947. Although all drugs are over the counter access -Department of Health: Act 101 of 1965	-Department of Health: Act 54 of 1972	-52 municipalities of the country. 9 provinces of the country.	-Department of Agriculture, Forestry and Fisheries: Section of extension services although limited function –Department of Health: Act 54 of 1972. Although no extension to public or farmers on veterinary drug residues	-Department of Agriculture, Forestry and Fisheries: Section of residue monitoring

Table 7.3: List of categories of participants with criteria for inclusion and RM strategies 'involved in'

Category			
Government	**Criteria for inclusion**	**RM involved**	**RM not involved**
Sub-category: Department of Health			
Registration authority	Direct involvement in RM strategy/ies	Risk assessment, registration, control of access	Publication of MRLs, compliance monitoring, extension services, residue monitoring.
DoH-policy	Direct involvement in RM strategy/ies	Risk assessment, registration, control of access , publication of MRLs, compliance monitoring	Extension services, residue monitoring
DoH-analyst	Direct involvement in RM strategy/ies	Publication of MRLs, compliance monitoring	Risk assessment, registration, control of access, extension services, residue monitoring.
DoH-inspector	Direct involvement in RM strategy/ies	Publication of MRLs, compliance monitoring	Risk assessment, registration, control of access, extension services, residue monitoring.
Sub-category: Department of Agriculture, Forestry and Fisheries			
DAFF-analyst	Direct involvement in RM strategy/ies	Residue monitoring	Extension services, publication of MRLs, compliance monitoring, registration, risk assessment, control of access
DAFF-extension	Direct involvement in RM strategy/ies	Extension services	Residue monitoring, publication of MRLs, compliance monitoring, registration, risk assessment, control of access
DAFF-residue	Direct involvement in RM strategy/ies	Residue monitoring	Extension services, publication of MRLs, compliance monitoring, registration, risk assessment, control of access

CHAPTER 8: PAPER 5

Table 8.1: Summary of details of Paper 5

Title	Fundamental, functional, and policy challenges of creating a successful South African veterinary drug and residue regulatory system
Publication status	Unpublished. To be submitted to the Journal Food Control
Journal website	http://www.journals.elsevier.com/food-control/
Citation reference	Chanda, R.R. & R. J. Fincham. (*unpublished*) Fundamental, functional, and policy challenges of creating a successful South African veterinary drug and residue regulatory system
Objectives addressed	As with paper 4 also addressed objective 5 to determine challenges of the system.
Methods used	As this paper reports challenges identified from the questionnaire indicated in paper 4, the methods used are also consistent with those of paper 4.
Key outcomes	Challenges were categorised into policy challenges, functional challenges and fundamental challenges. Policy challenges included a lack of policy or strategy direction while functional challenges were specific to functions of the system and included in coordination, unclear jurisdiction of functions, and duplication of functions. Fundamental challenges are those that are not specific to the food control services and have been reported on previously in public service. These included human and financial resources and skills shortages.

Fundamental, functional, and policy challenges of creating a successful South African veterinary drug and residue regulatory system

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(Received; final version received)

Abstract

The South African veterinary drug and residue regulatory system is fragmented with a variety of challenges which are thought to be caused by fragmentation. (Chanda *et. al.,* 2010; Chanda *et. al*., 2014). In order to determine whether challenges of the veterinary drug and residue regulatory system can be attributed to fragmentation, the different types of challenges of this system required exploration. Responses on challenges were sought from government and non-governmental personnel involved in the regulatory system from results obtained from a questionnaire. The questionnaire was based on eight risk management strategies of the veterinary drug and residue regulation where respondents had to indicate what challenges were present per risk management strategy. Challenges identified were categorised into fundamental, functional and policy challenges where fundamental challenges were non-specific to the veterinary drug and residue system and included inadequate staff, inadequate skilled staff and inadequate financial resources. Policy challenges included insufficient policies and poor prioritisation of functions of this system while functional challenges included in-coordination, either to affect functions or in-coordination between two similar functions and are operational or process based. The identification of fundamental challenges indicated that not all challenges associated fragmentation are caused by fragmentation. This understanding is relevant because is disproves the linear relationship between fragmentation and challenges and shows instead that a complex interaction between challenges and fragmentation exists. Acknowledging the complex relationship affords the application of that knowledge to addressing the fragmented and inefficient state where inefficiency cannot be attributed solely to fragmentation. What is required then to improve the system is to address fragmentation as well as challenges that are not directly linked to it.

Keywords: veterinary drugs, veterinary drug residues, personnel shortages, skills and inadequate financial resources

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1. Introduction

The South African veterinary drug and residue system is fragmented and is plagued with a variety of challenges (Chanda *et. al.,* 2010; Chanda *et. al*., 2014). The challenges are generally understood to be caused by fragmentation and these results in an inefficient and ineffective system. This linear relationship between fragmentation and challenges infers that since fragmentation causes challenges, addressing fragmentation will address challenges which will make the system more efficient and effective. However this theory needs to be tested as application of the understanding of the relationship between fragmentation and challenges will determine if the system can be effectively improved. Testing the theory requires that challenges need to be determined both in the scope of challenges and types of challenges of the veterinary drug and residue regulatory system. In order to identify the types of challenges within the veterinary drug and residue system, responses from personnel involved in the system were sought through a questionnaire. The questionnaire requested responses on challenges of eight risk management strategies or functions of the veterinary drug and residue regulatory system from both government and non-governmental personnel and results are reported in this paper as identified per risk management strategy. The following sections will provide a description of the questionnaire and respondent group as well as the results obtained. The last two sections will discuss the results and provide a way forward for improving the veterinary drug and residue system.

2. Methodology

2.1. Framework of questionnaire

A structured but flexible-format questionnaire was used to obtain responses from participants in terms of challenges of the South African veterinary drug and residue system. The questionnaires used eight risk management strategies of veterinary drug and residue regulation as its basis although only seven were currently being conducted by government. Risk management strategies are functions conducted by government to manage the risk associated with use of veterinary drugs in food producing animals. The risk management strategies included risk assessment or commissioning of a risk assessment; registration of drugs; control of access of (scheduling); publication of maximum residue limits (MRLs); compliance monitoring to published MRLs; extension or outreach services (largely risk communication) and residue monitoring. The eighth risk management strategy, antimicrobial resistance, which is not an operational strategy of Government, was also included to determine why it was not conducted or considered in the current regulatory framework and therefore to determine what challenges are preventing the implementation of this strategy. Table 8.2 lists and summarises each of the identified RM strategies.

The aim of the questionnaire was to obtain responses on whether these RM strategies were being effectively conducted and if they weren't, what challenges were prominent and what can be done to address those challenges. Therefore where challenges were noted, it was an indication of the ineffective functioning of that strategy of the veterinary drug and residue system.

2.2. Population and respondent group

Both government and non-government personnel participated in the survey and categories of the questionnaire were therefore called ‘government’ and ‘other’. The former included government officials from the national, provincial or local sphere who were involved in any of the risk management strategies and the latter included non-governmental stakeholders also involved in each of the identified RM strategies. For example, for the RM strategy of compliance monitoring, government participants included persons from the Department of Health who legislate residue limits and the officials of the provinces and municipalities who enforced the limits (sampling and analyses). Participants from the ‘other’ category for compliance monitoring included food retailers and manufacturers for compliance monitoring.

For both groups, participants were not specifically chosen based on their personal capacity but were included in the population and sample if their job function allowed for involvement in any of the RM strategies. This meant that there were no criteria for age, gender or qualifications of participants as long as they were appointed by their employers to conduct a particular function. However as the subject area of veterinary drugs is generally a very technical one, this generally meant that participants from both groups were knowledgeable on the subject, had professional qualifications either directly related to veterinary drugs and residues or to public service and had at least some experience in conducting their functions. This was verified in questionnaires when participants were asked to record their qualifications and years of experience. The lowest number of years of experience was indicated as four years for government participants with an overall average of 10 years (10 respondents) while participants from the ‘other’ category averaged 14 years of experience with the lowest being a few months (14 respondents). Qualifications of participants were varied but very much in

line with their individual functions with a strong basis in natural and veterinary science. The types of qualifications as well as averages of years of experience suggest that participants are not deficient in their technical understanding of veterinary drug and residue functions.

Based on the criteria of involvement in RM strategies, 48 participants for both 'government' and 'other' categories were identified and requested to participate. For most of the strategies of the questionnaire the population was so small that the entire population was sampled and therefore requested to participate. Using the example of publication of MRLs, the government population was only two people and both these were requested to participate. For the 'other' category the population was based on criteria like whether the organisation was involved in the RM strategy (applicability) and had expertise on the RM strategy. For example, for participation from veterinary drug manufacturers, criteria for inclusion related to whether the manufacturing company produced any veterinary drugs at all and whether they had submitted requests for registration through either of the registration authorities. Criteria for food retailers and manufacturers included whether they had regulatory offices and whether they sold or manufactured animal derived foodstuffs. Criteria for academics included those involved in veterinary drug residue extrapolation and MRL determination, those involved in industry or determination of veterinary drug residues.

Requests for participation in the questionnaire were either telephonic or via email. Depending on the geographical distance of participants to the main researcher, questionnaires were also completed through one-on-one interaction. Although this was the favoured method for completion of questionnaires as responses were more in-depth this interaction was limited to only four participants all within the government category due to how far participants were from the researcher, the availability of participants for one-on-one interactions and the willingness of participants to complete

the questionnaires in this way. In addition, financial resources and time constraints for meeting each participant were also limiting factors in completing questionnaires one-on-one. Where questionnaires were not completed through face-to-face interaction, participants completed questionnaires on their own and either emailed them back or posted them back.

3. Statistical Analysis

Although this paper is largely qualitative in nature, where possible, data was analysed using the statistical program GenStat® *for Windows*™ 14th Edition Introduction. (Payne *et. al*., 2011) This program, like other similar statistical programs is useful for both descriptive and analytical statistics which were used to analyse data in this study. Where analytical statistics could not be used due to limitations of the study, the descriptive statistics obtained provided valuable understanding of trends in the data. The GenStat® statistical program was also easily accessible to the research team and proved valuable in its application.

4. Results

Twenty four out of a possible 48 responses were received which yielded a response rate of 50 %. 10 of 17 (59 %) responses were received for the 'government' category while 14 of the 28 (50 %) participants for the 'other' category responded. In the government category, 70 % of the responses were from the Department of Health while only 30 % of the responses were from the Department of Agriculture. This response rate was however expected as the sample included 12 of the 17 participants from the Department of Health while the only possible 5 participant responses were sought from the Department of Agriculture. The questionnaires were analysed according to the two

major categories of ‘government’ and ‘other’. With ‘government’ and the ‘other’ category, the aim was to determine what challenges and solutions per risk management strategy were identified and how they could be categorised.

4.1. Government

Respondents involved in each of the RM strategies were asked to indicate what challenges they encountered in their everyday functions as well as what other challenges they were aware of in other RM strategies.

4.1.1. Challenges of risk assessment, registration and control of access

Challenges of the risk management strategies of risk assessment, registration and control of access were provided by both personnel of the Departments of Agriculture, Forestry and Fisheries (DAFF) and Health (DoH). The most prominent challenge was identified as a skills shortage. For example, within DAFF it was indicated that technical advisors being veterinarians did not have the skills required to evaluate certain part of the registration dossiers (information submitted to the registration authority for evaluation of the veterinary drug) that were submitted for evaluation by industry. Some parts of these dossiers required the expertise of pharmacists rather than veterinarians although only veterinarians were employed by DAFF for registration evaluation functions. The lack of a peer review was also indicated as problematic for DAFF because the staff complement for evaluators was inadequate. Responses of challenges included that there are few experts in the country to get second opinions for evaluation of registration dossiers therefore the skills shortage for veterinary drug evaluation in South Africa also impacts the ability to affectively evaluate dossiers by registration authorities. Respondents also indicated that for DAFF the amount of staff

was too little for the registration function (risk assessment, registration and control of access strategies) and that resulted in a work overload for current technical staff. Solutions offered by respondents to the questionnaire were that employing sufficient staff was required while for the skills shortage, training was essential.

Other prominent challenges identified for risk assessment, registration and control of access of veterinary drugs was that traceability and record keeping of the evaluation of veterinary drugs, particularly for food safety related aspects, like withdrawal periods and MRLs, was lacking. This meant that although evaluation, risk assessment and thereafter registration was a continuous process, parts of the process not considered the mandate of the registration authority function were not included in records of the evaluation of a drug. This is regrettable as it prevented traceability of decisions taken regarding food safety aspects of veterinary drugs. Another identified challenge is that the decision making processes which is imperative for a transparent understanding of what criteria was used for drug evaluation and therefore how the drug was evaluated, is lacking. The lack of such a process allows for inconsistency in decision making for registration of veterinary drugs.

Other challenges included that it was difficult for the two registration authorities to resolve the duplication issues of the dual registration system although no reasons to why it was considered difficult were provided. Solutions offered were to harmonise registration and to define functions that are currently compounded by mandate obligations. It was noted that this could possibly be done through the new health authority SAHPRA or South African Health Products Regulatory Authority. The integration of registration could also assist in pooling resources which could assist in the skills and staff shortage.

4.1.2. Challenges of publication of MRLs

Responses were received from all categories of government participants. A lack of staff as well as a lack of staff skills was identified where for the latter; a lack of suitably qualified or available persons to conduct toxicological assessments and MRL determination for veterinary drugs was indicated by respondents. Solutions offered for the lack of expertise in MRL determination were to research methods of MRL determination like the food basket concept although the skills and staff shortage required to be addressed as the research function for MRL determination could not be realised without it. A lack of financial resources was also prominently identified as a challenge for this risk management strategy.

Other challenges identified included bottlenecks in publication of MRLs due to slow internal processes within the Department of Health while the inadequate prioritisation of MRLs and food safety by managers within the Department of Health was also identified as a challenge. Respondents also indicated that the lack of progress with the implementation of an integrated food control system, the latter of which was identified in reports of 1998 (Chanda *et. al*. 2010) is still a challenge.

4.1.3. Challenges of compliance monitoring

Responses on challenges of compliance monitoring were received from all categories of government participants. Challenges included inadequate staff and insufficient budget, the latter of which is likely related to another identified challenge of lack of equipment for analyses of samples. It was indicated in some responses that the major challenge of this RM strategy was that it was not currently conducted and this needed to be addressed. However other challenges that compounded this were that the

number of current inspectors for sampling for compliance monitoring is few and had too much to do besides food sampling and that poor knowledge of sampling and follow up was also a challenge. Respondents also indicated that sampling and subsequent analytical testing by laboratories was not coordinated and occurred *ad hoc*. For challenges of analytical testing, unavailability and prohibitive price of analytical standards which made proper analyses unfeasible was identified.

Solutions offered for the above challenges included that national government needs to initiate programmes and offer guidance on how to conduct compliance monitoring. Staff education was indicated as critical and the shortage of staff needed to be addressed. It was also indicated that sampling should be coordinated and statistically sound and that samples should be taken randomly to get the true indication of residues in affected products. Solutions for laboratories included prioritising the laboratory function particularly within the Department of Health and then ensuring that budget, staff and equipment are provided for. It was noted that this was had already been initiated by utilising a consultant to evaluate the current situation of laboratories but that this needs to continue in order to determine the way forward. Respondents also proposed that within the Department of Health, the laboratory testing should be moved to the National Health Laboratory services (NHLS) if the in-house labs were not feasible as the NHLS was independent and currently operated more robustly than the in-house laboratories. The collaboration with tertiary institutions and international laboratories for analyses and standards on analyses was also indicated as a possible solution while better salary packages to retain personnel was indicated for staff shortages. Technical standards on analyses could also be sought from industry and expensive equipment could be hired rather than bought and external funding could be sought for equipment.

The challenge of lack of prioritisation was also identified for compliance monitoring where sampling and subsequent testing was not coordinated because the Department

of Health did not include this in its key priorities. Other challenges like the lack of conceptual understanding of food safety in relation to health issues by senior officials, the fragmented nature of food control, and thinking in isolation were also noted as challenges. A lack of coordination between the Department of Agriculture, Forestry and Fisheries (DAFF) and the Department of Health (DoH), and the other tiers of government was also indicated as a challenge. Solutions to this were that the lack of coordination needed to be strategically approached while conceptualisation of the wider food control system is required, and internal process of organisational structure within the departments needs to be finalised.

4.1.4. Challenges of residue monitoring

Responses for this RM strategy were received from government officials directly involved in the risk management strategy as well as Department of Health officials involved in compliance monitoring. Other respondents either were not aware of the function or were aware but could not provide an indication of challenges or solutions. Once again, the challenges indicated were a lack of finances and a lack of technical and human capacity. Another challenge was also noted and that is that the current residue monitoring function is geared for export not for national residue monitoring and this was because there is no funding for the national function.

The solution to the challenge of funding was collaboration where the Department of Health, through its compliance monitoring function and the Department of Agriculture, Forestry and Fisheries through its function of residue monitoring collaborated for compliance and residue monitoring. Collaboration would be in terms of sampling and analytical testing so that they could work smarter by pooling resources. Suggestions were also that drug manufacturers and other role players in industry should pay levies

for testing to address the lack of funding. A solution for in-coordination of residue monitoring and compliance monitoring is that compliance should be done at municipal level but that residue testing and funding of residue monitoring and compliance should be done at national level. It was also suggested that since the drug registration authorities are not taking leadership of residue monitoring, they should draft guidelines for retailers and manufacturers for sampling and testing of MRLs in foods. Solutions to challenges of skills shortage in personnel were to train personnel for a better skilled staff base.

4.1.5. Challenges of extension services

Responses of challenges to this RM strategy were only from officials involved in extension within the Department of Health as participants requested to complete the survey from the Department of Agriculture, Forestry and Fisheries indicated that they were not involved in such a strategy and therefore were not knowledgeable on the subject area and therefore could not participate. Therefore from both the responses of the Department of Health and DAFF, it was noted that this RM strategy was not conducted. However challenges regarding extension in general included the fact that support from provinces is lacking in order to conduct such services and this could be due to communication challenges between the three layers of government, particularly provinces to municipalities. Challenges could also be due to lack of inspector resources, or lack of finances.

Solutions were to prioritise the extension function in general including veterinary drug residues and that more awareness on the subject needs to be created with senior managers. Budget constraints also need to be addressed for this RM strategy.

4.1.6. Constraints inhibiting the implementation of anti-microbial resistance monitoring (AMRM)

Since this was not an existing risk management strategy within the system, the question to participants was what challenges they thought would hamper the implementation of such a strategy. Responses on challenges were received from all categories of government participants and once again included challenges of a lack of human and financial resources, lack of knowledgeable staff to undertake the strategy, lack of facilities and funding of laboratory services. In addition to the above, a lack of understanding by senior managers of the need to implement this strategy and a lack of a policy or strategy for such a programme were indicated as challenges while cooperation between the two registration authorities, Act 101 and Act 36, would also likely be a challenge. It was also noted that the culture of reactive responses as opposed to proactive response by the veterinary drug and residue system authorities would likely be a key challenge while a lack of will power to continue the implementation of this strategy due to food safety issues not being prioritised in South Africa would also hamper the implementation of this strategy.

One solution to the above constraints included allowing for a proactive planned process to address resource constraints like financial and human resources. This could include determining key priorities and making senior managers and even parliamentarians aware of the need for this RM strategy. For awareness to senior managers of the need of antimicrobial resistance monitoring, comparisons to other countries could be done. Streamlining legislation must also be done while industry must also be communicated to and involved in the programme of AMRM. Reporting on the system must also be required with suggestions of a database being used to allow reporting. Commitment is

noted as key to successful implementation of the programme as well as collaboration, locally and internationally.

4.2. Other

4.2.1. Challenges of risk assessment, registration and control of access

Responses to challenges in this section were from drug manufacturers and industry experts as they were directly involved in these RM strategies. Retailers and food manufactures were not really aware of these functions or if they were aware, could not provide challenges or solutions.

Participants were initially also asked to indicate whether the current dual regulatory system was considered efficient. Only one of the 10 responses indicated it was while the remaining indicated it was inefficient. Chi-square analysis indicated a significant difference in these responses ((χ^2 = 15.47; p <0.001, 2 d.f,) indicating that the system is indeed inefficient as considered by non-governmental users of the system. Responses to the question of challenges and solutions yielded a variety of responses. The table below summarises the challenges and solutions that were provided by individual respondents.

Table 8.2: Summary of challenges and solutions for risk assessment, registration and control of access by the 'Other' category.

Participant	Challenge	Solution	Predominant challenges
1	• No cooperation with registrar. • Act 101: service orientation is lacking.	No solutions noted	1. Lack of staff, particularly for Act 36 of 1947 2. Act 101:
2	• Act 101: Emphasis on human medicine and staff don't have an understanding of unique aspect of veterinary drugs. • Act 101 and Act 36: Insufficient	• Act 101: More staff, trained for understanding veterinary drugs. • Act 36: increased technical evaluators. ○ Appoint more external	

	personnel capacity.	evaluators. ○ Better consistency in evaluations.	Influence of human drug evaluation without considering complexity of veterinary drug evaluation
3	• Act 36: Understaffed	• Registration should be moved to Act 101 with proper scheduling of drugs. • Vaccines can continue to be registered under Act 36, personnel to specialise in this registration.	
4	• Act 101: shortage of evaluators • Act 36: shortage of personnel	• Better salaries are required for personnel	
5	• Registration takes too long for both authorities • Act 101: influence of human drug evaluation	• Act 101: More staff, better control of dossiers, more meetings • Act 36: more staff. • Ultimately, better if registration is under one Act	
6	• No challenges noted although solutions provided for challenges	• Act 101: retention strategy for staff, electronic database and tracking system for drugs sent to be registered. • Act 36: more staff paid fairly. • For the whole system: revamp the whole system. Separate from government bureaucracy.	
7	• Act 101 designed for human medicine therefore lack of understanding of veterinary drugs, communication issues, • Act 36: small pool of evaluators, overworked. Lack of acknowledgement by the registrar of the amount of work the Department of Agriculture carries out. • Staff complement is low. • Bottleneck at technical advisors. • Lack of adequate systems.	• One registration body under the Dept of Agriculture. Must be veterinary focussed and more stringent than Act 36 systems. • Improve evaluation of withdrawal periods. • Look to act 101 for systems.	

Challenges that were strongly indicated for both registration authorities were staff shortages while other challenges differed between the two authorities and included better control of dossiers for registration under Act 101 of 1965 and better consistency in evaluations. Importantly, although the system of Act 101 of 1965 was preferred, the emphasis placed on the evaluation of veterinary drugs similar to that of human drugs was a concern to drug manufacturers. This was not noted for registration under Act 36 of 1947. Interestingly having two registration authorities was identified as a challenge with the suggestion that the registration system needs to be consolidated into one system.

Drug manufacturer respondents were also asked to rate various functions of registration and risk assessment strategies in a Likert scale to determine their opinions on the system they utilised. For risk assessment this included rating of the following functions on a scale of 1 to 5: toxicology assessment, efficacy assessment, determination of withdrawal period, evaluation of the package insert, and evaluation of the formulation and scheduling of the drug or control of access. For registration the following functions were rated: turnaround time, getting dossiers to evaluators, traceability and record of dossiers and decisions submitted, database of registered drugs, staff knowledge of the registration process and number of staff for the registration process.

In order to determine the most frequent rating for each of the functions under risk assessment and registration, the mode was determined as per Figures 8.1 and 8.2.

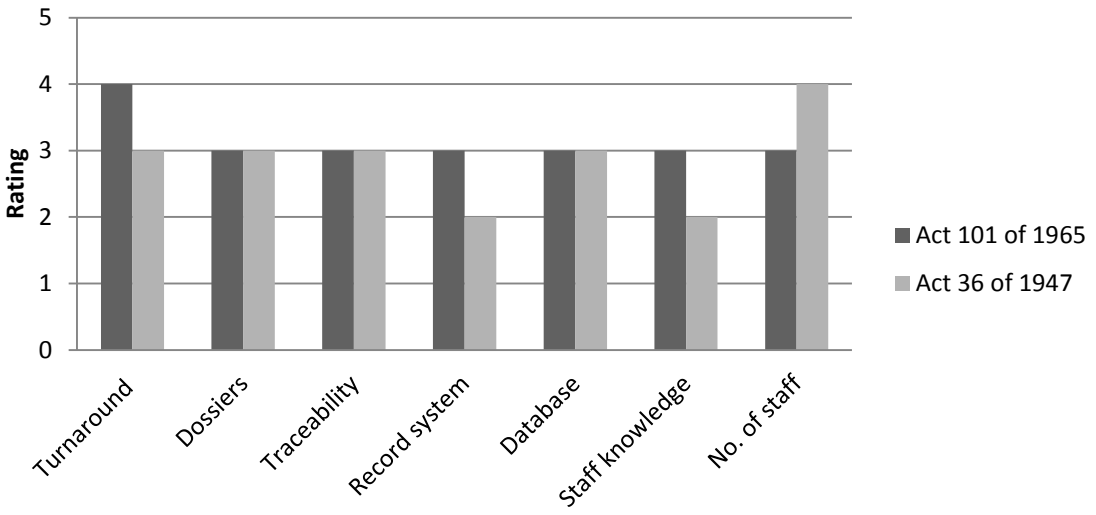

Figure 8.1.: Summary of ratings of functions under the registration strategy. 1= excellent, 2=good, 3=average and 4=poor. 0=don't know

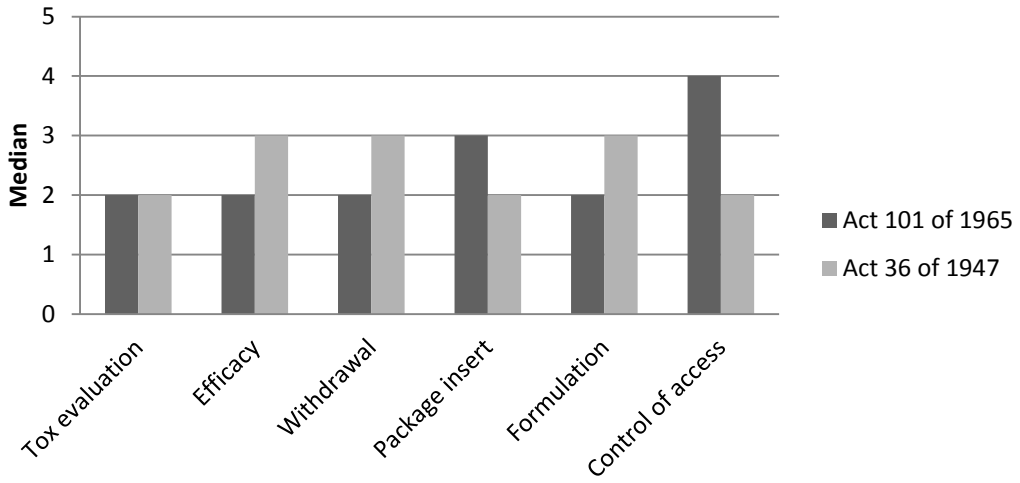

Figure 8.2: Summary of ratings of functions under the risk assessment strategy. 1= excellent, 2=good, 3=average and 4=poor. 0=don't know

The most frequent rating for registration under Act 101 of 1965 showed scores that were clustered centrally indicating responses of average and good. For registration under Act 36 of 1947 scores were also centrally clustered but with larger responses for average. For risk assessment under Act 101 of 1965 scores were clustered around 2 for good or average but for Act 36 of 1947 scores were clustered at average. Therefore, based on results, registration and risk assessment of both authorities is considered inefficient by drug manufacturers using the veterinary drug system for registration. To determine whether there was a difference in efficiencies between the two registration authorities, Mann-Whitney U tests were conducted to determine whether there were significant differences in responses for each of the functions under registration for Act 101 and Act 36. All tests indicated no significant difference which indicates that that functions do not differ significantly in efficiency of function and that inefficiency is not more or less under either authority.

4.2.2. Challenges of publication of MRLs

Drug manufacturers and industry academics indicated challenges as the lengthy time taken to update MRLs in regulation, and lack of a proper review process and accountability within the system. Related challenges included that an indication of how MRLs were determined are not easily accessible. The challenges of lack of knowledgeable staff and inadequate service from staff were also identified. Solutions were to have adequate and motivated staff, have the same authorities that register drugs to update and publish MRLs and to use international standards for MRLs.

Responses of food retailers were varied with some indicating that the MRL lists provided by the Department of Health were good and they used that for testing. Others indicated that they don't test and rely on suppliers to ensure that MRLs are within specification. Some retailers indicated that samples are taken by the Department of Agriculture, and no responses are received to inform them of the results. Solutions were to legislate monitoring for companies and to appoint officials to only conduct veterinary drug residue testing.

4.2.3. Challenges of compliance monitoring

Three of the 6 drug manufacturers that responded indicated they did not know of compliance monitoring or it was not applicable to them while the remaining three indicated that it was conducted by both the Departments of Health and Agriculture. Challenges indicated were:

- A lack of funds
- A lack of staff

- Residue testing was only geared for export and not in-country
- Sampling and testing was infrequent and not enough samples were tested for

Only one of the four food retailers and manufacturers indicated that compliance monitoring was good, the others rated it as poor or that they were unaware of compliance monitoring. Other challenges that were identified were that samples were taken but no feedback was received, and that the lack of law enforcement was a problem and that samples were infrequent. Industry experts indicated that the monitoring programme needed to be better managed and better laboratory infrastructure was required.

4.2.4. Challenges of residue monitoring

Many drug manufacturers indicated this RM strategy as not applicable to them although from responses received and, similar to compliance monitoring, challenges included that too little samples were taken and that the turnaround time was too long from the time samples were taken to publication of results. Retailers and manufacturers indicated that results of surveillance needs to be published or made available and that monitoring should be conducted more regularly. The challenge of inadequate staff was identified. Solutions offered were to increase staff, to integrate legislation and to follow up on violations.

4.2.5. Challenges of extension services

Drug manufacturers either indicated this RM strategy as not applicable or they were not aware of any extension services. However drug manufacturer respondents indicated that an extension service is important and that registration authorities need to take

ownership of this RM strategy. However they also indicated that both industry and government should be involved for a dedicated programme while community involvement should also be a key factor in the implementation of such a strategy. None of the retailers or manufacturers who responded were aware of extension services and therefore could not provide any challenges or solutions.

4.2.6. Constraints on the implementation of AMRM

Retailers provided challenges that could hinder the implementation of such a strategy and this included a lack of current enforcement infrastructure, lack of staff and funding, and inability to interpret and respond to results. The high cost of testing and the huge amount of informal trade were also noted as possible impediments. Therefore challenges were varied and similar to responses from drug manufacturers who indicated constraints as lack of funding, inadequate communication, importation of antimicrobials which is not controlled, lack of Good Laboratory Practice (GLP) accreditation for laboratories, inadequate sampling, antimicrobials in feed, staff and resource constraints, skills shortages, lack of political will and inability of government to prioritise this RM strategy.

Solutions offered are to create a separate section that deals with this, take ownership of the strategy, integrate legislation and employ more people.

4.3. Summary of challenges

From the results received, a variety of challenges were provided by respondents. Three main categories of challenges were noted, i.e., those that are apply to the operation of the risk management (RM) strategy or functioning within the strategy; those that are

applicable to wider issues like food safety and frameworks and contexts and those that are not specific to the veterinary drug and residue system and are intrinsic challenges of public service or systems in general. Based on the types of challenges identified, they are categorised into *fundamental challenges, functional challenges* and *policy or strategy challenges*. Fundamental challenges can be described as those not specific to the veterinary drug and residue system but are intrinsic and basic challenges that can occur in most systems. They include lack of human and financial resources and a lack of skills as examples. Functional challenges are operational in nature and are specific to functions or strategies of the veterinary drug and residue system and include in-coordination between sampling and analyses, duplication of functions and no traceability of evaluation of registration dossiers of drugs, as examples. Policy or strategy challenges can be described as those linked to the framework of veterinary drugs and residues like inadequate prioritisation of functions related to veterinary drugs and residues, and no policies for conducting a function as examples.

Based on the categorisation of challenges above, the most common challenges identified were fundamental challenges and included, for almost all RM strategies from both the 'Government' and 'Other' category, lack of staff , lack of finances and a lack of skilled staff. The indication of skills constraints as a challenge is not a new one as has been reported on for the greater public service system (Chelechele, 2009; Kroukamp, 2002; Nengwekhulu, 2009). Some of these reports also indicates that although a skills shortage is increasingly purported as the key challenge, it is often not the only challenge and addressing only the skills constraint fails to take into account the multifaceted approached that is required to address challenges in the South African public service (Nengwekhulu, 2009). Nevertheless, the constant indication of a lack of skills by respondents indicates that this is indeed a challenge which needs to be addressed in order to improve the system, particularly because understanding and

therefore regulating veterinary drugs and residues is a highly skilled subject area. Tertiary institutions in South Africa do not currently specifically train in subject areas like toxicology from a food safety perspective and specialists in the subject area are scarce. More so, the Veterinary Clinical Committee (VCC) is academic with the evaluation function being secondary to the academic role so the skills do not reside within Government. Therefore even within the challenge of skills constraints there are many factors like not having adequate technical skills in the country, no plan for skills development in the country through tertiary institutions as well as no plan to allow for skills development within Government rather than outside it. Therefore the skills challenge is complex to address but still a very pertinent fundamental challenge as it has the potential to restrict the proper functioning of any strategy regardless of whether other functions are addressed.

The second most common challenge identified was that of staff shortages and this was indicated strongly by the 'other' category as well. It is likely that staff shortages are impacted by, if not caused by, skills shortage but the challenge of staff shortages is also multifaceted. The inability to recruit more staff is not only because there are no skilled persons to occupy the position but also because of financial constraints or decisions within the departments on recruitment and staff numbers. Staff numbers are also linked to the organisational structure within a department such that if a vacancy does not exist within an existing organisational structure, it is difficult to include more staff to that structure. The inability to change the structure of government departments in South Africa is also a likely consequence of the Weberian model on which the South African public service is modelled (Nengwekhulu, 2009). This model is centred on hierarchy, command, control and bureaucracy (Nengwekhulu, 2009) which makes it difficult to make decisions at the lower levels of the hierarchy without involving the upper echelons of managers. Staff shortage is also likely a result of inability to retain

staff as public servants may leave for better salaries in the private sector (Masibigiri & Nienaber, 2011).

Inadequate or lack of financial resources was also identified by respondents, particularly by government respondents as a key fundamental challenge. This is perhaps so as they are aware of the budgets within their respective departments. Finances in government are always scarce as government managers must decide on what is a priority for the country. As South Africa is a developmental state, challenges like inadequate housing, inadequate healthcare and education also need to be addressed and resources are most often channelled to these as they affect people directly but to the detriment of other less known functions of Government like regulation of veterinary drugs and residues. The reason that subjects like regulation of veterinary drugs and residues are less well known is because it is less well understood particularly by politicians and senior government managers whose will and action are required to initiate change in the system. However the lack of financial resources requires to be strategically addressed if the challenges of regulation of veterinary drugs and residues are attended to.

Although fundamental challenges dominated the responses of challenges across the eight RM strategies related to veterinary drugs, policy challenges were also noted. This included poor prioritisation of RM strategies by senior managers of Departments and as a result those RM strategies were underfunded, had inadequate staff and generally could not function optimally. Poor prioritisation could be due to a myriad of reasons like inadequate awareness of any particular strategy by senior managers of Government, lack of finances or poor understanding of the need to have these functions in light of more prominent public health issues. It could also be caused by poor leadership of senior and political managers in terms having the skill, will and drive to innovate and

change the system. Other policy issues were that there are no strategies or policies within government and this was also indicated as a constraint prohibiting implementation of antimicrobial resistance monitoring (AMRM) in South Africa. Functional challenges are specific to each risk management strategy and included lack of traceability in registration of veterinary drugs and determination of withdrawal periods and MRLs; as well as duplication of registration and in coordination between functions like sampling and analysis in compliance monitoring. Although not identified as a predominant challenge, particularly by government stakeholders, functional challenges are present within the system.

5. Discussion

With the categorisation of the challenges of the South African veterinary drug and residue system, the interaction of challenges with fragmentation is brought into focus. Functional challenges can be directly linked to fragmentation in that fragmentation can cause these challenges. In other words fragmentation can cause in-coordination of functions and duplication of functions but it is unlikely that fragmentation can cause skills shortages, financial shortages or inadequate strategies for food control, or policy and fundamental challenges. At the very least fragmentation can influence these challenges but not cause them entirely. What is more likely is that fragmentation influences the interaction of the three types of challenges while these challenges may also influence fragmentation. Therefore the three types of challenges identified interact with one another and cannot be considered isolated. For example, policy challenges describe challenges that lay the foundation on which other challenges are allowed to develop like not having a policy or framework for the regulatory function of veterinary drugs and residues. This in turn will affect the budget allocated to the function and the staff contingent for the function (fundamental challenges) and therefore how well the

function operates (functional challenges). This interactive relationship between the three types of challenges is represented in Figure 8.3 where each of these challenges usually do not exist in isolation but can exacerbate or even cause other challenges. This interaction of challenges or 'challenge system' is what is influenced by fragmentation and what can also influence fragmentation.

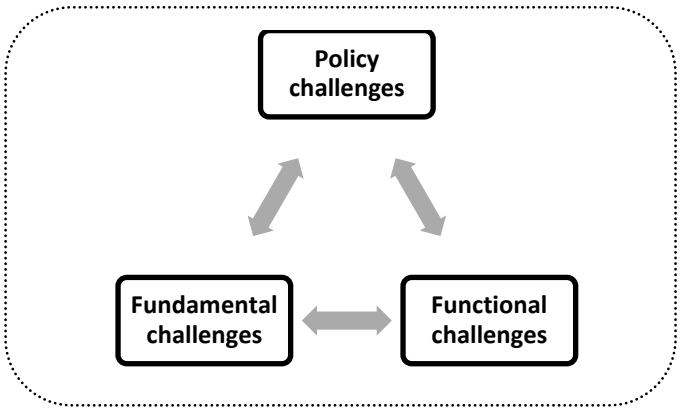

Figure 8.3: Representation of the three types of challenges associated with the fragmented South African veterinary drug and residue system and their interaction with one another

The existence of different types of challenges is relevant because it indicates that the linear relationship between fragmentation and challenges is not correct and perhaps only correct if certain types of functional challenges are considered, like in-coordination of functions. Other challenges are not directly linked to fragmentation and this means that the complexity of interactions between fragmentation and challenges as well as between challenges must be considered before the poor effectiveness and inefficiency of the system are addressed. Therefore merely addressing fragmentation will not address all challenges and the veterinary drug and residue regulatory system would not be entirely improved.

6. Conclusion

The eight risk management strategies used in the questionnaire provided a basis on which the challenges of the veterinary drug and residue system could be identified and categorised. The challenges that were provided by respondents were categorised into functional, policy and fundamental challenges although fundamental challenges were predominant in responses. To summarise what is required from respondents to improve the South African veterinary drug and residue regulatory system: sufficient and well trained personnel, governance by an enabling policy, legislative framework, and financial backing, as these are all inadequate in the current system. This effective and improved system is not possible by only addressing fragmentation with a view to addressing challenges as not all challenges of the veterinary drug and residue regulatory system are directly caused by fragmentation. In fact some challenges may even entrench fragmentation. What is required then is to understand each of the types of challenges, their interaction with one another and with fragmentation and apply that knowledge to address the veterinary drug and residue regulatory system. This means that fragmentation should be addressed for functional challenges while policy and fundamental challenges should not be arbitrarily linked to fragmentation and therefore should be addressed as critical deficiencies in the system.

References

1. Chanda, R. R. Fincham, R. J. & Venter, P. (2010) Review of the South African Food Control System: Challenges of Fragmentation, *Food Control, 21*: 816-824
2. Chanda, R.R. Fincham, R.J. & P. Venter. (2014) Review of the regulation of veterinary drugs and residues in South Africa, *Critical reviews in Food Science and Nutrition*
3. Chelechele, T. I. (2009) Skills development in the South African public service: problems and solutions, *Journal of Public Administration*, Vol. 44 (1), 44-57

4. Kroukamp, H. (2002) Skills training: a prerequisite for the changing position and status of public servants in South Africa, *Journal of Public Administration*, Vol. 37 (4), 453-474
5. Masibigiri, V. & Nienaber, H. (2011). Factors affecting the retention of Generation X public servants: An exploratory study. *SA Journal of Human Resource Management/ Vol. 9*(1), 318-320
6. Nengwekhulu, R.H. (2009) Public service delivery challenges facing the South African public service, *Journal of Public Administration*, Vol. 44 (2), 341-365
7. Payne, R. W. Murray, D.A. Harding, S. A. Baird, D. B. Soutar, D. M. (2011) Genstat® for Windows™ 14th Edition Introduction. VSN International, UK.

Table 8.3: Risk management (RM) strategies and their definitions

	Identified risk management strategies						
	Risk assessment	**Registration**	**Control of access**	**Publication of MRLs**	**Compliance monitoring**	**Extension services**	**Residue monitoring**
Definition: Refers to…	A scientifically based process where the theoretical risk of a veterinary drug is assessed. This involves assessing toxicity and exposure of the veterinary drug to the human population.	The system whereby pharmaceutical companies apply to a Government Department to have their drug assessed so that it can be used in the country.	The process of how drugs of different toxicity and specialisation are accessed. In South Africa medicines are scheduled according to their toxicity if registered under the Medicines and Related Substances Act, 1965. This means that some drugs are accessed over-the-counter while others need prescriptions.	Legislation that states the maximum residue limits (MRLs) of specific veterinary drugs for specific foods.	Monitoring of foods by Government to determine if they comply with published MRLs as per legislation of a country. Also infers follow-up action is foods are non-compliant like destruction of foods or prevention of sale of foods.	Government initiated services that inform, educate and communicate to farmers and other stakeholders on use of veterinary drugs, animal production and animal health.	Monitoring programme that tests various foods to determine amounts of veterinary residues in them. Is different to compliance monitoring, as no follow-up actions (like fining the manufacturer), are conducted. It is mainly for determining trends in usage veterinary drugs.
	Authority that conducts the strategy						
	-Department of Agriculture, Forestry and Fisheries: Act 36 of 1947 -Department of Health: Act 101 of 1965 -Department of Health: Act 54 of 1972	-Department of Agriculture, Forestry and Fisheries: Act 36 of 1947 -Department of Health: Act 101 of 1965	-Department of Agriculture, Forestry and Fisheries: Act 36 of 1947. Although all drugs are over the counter access -Department of Health: Act 101 of 1965	-Department of Health: Act 54 of 1972	-52 municipalities of the country. 9 provinces of the country.	-Department of Agriculture, Forestry and Fisheries: Section of extension services although limited function –Department of Health: Act 54 of 1972. Although no extension to public or farmers on veterinary drug residues	-Department of Agriculture, Forestry and Fisheries: Section of residue monitoring

CHAPTER 9: DISCUSSION, POLICY IMPLICATIONS AND CONCLUSION

The research results of this thesis, in the form of a series of papers for publication in journals, have uncovered a wide range on information and data. In order to consolidate the findings from each of the papers, interpret the results against the objectives set out at the beginning of this study and apply what was learnt from the veterinary drug and residue regulatory system to the larger food control system, this chapter will provide an overview of the findings and also address objective 6, which is to provide where and how policy needs to be changed to integrate the system. This chapter will initially recap on the intention and context of the study and then discuss findings and recommendations that could be policy relevant.

9.1. CONCEPTUALISATION OF THE STUDY

In previous chapters, the format, literature background, key concepts and methods were described as well as the reason why this study was considered relevant. In essence the study was borne of a need to understand why the South African food control system was reportedly plagued by challenges caused by fragmentation, a phenomenon that was neither defined nor understood in much detail. A casual link of fragmentation causing challenges was used as the framework for the study based on the content of internal government reports of the food control system. The framework was applied to studying the two concepts of fragmentation and challenges as well as the relationship between these two concepts. Fragmentation was researched in terms of what it is, how it manifests and how and why it started and continues while challenges were addressed in terms of what types exist and how they interact with each other and fragmentation. The interaction between various challenges and

fragmentation is more complex but understanding this relationship is relevant in order to make recommendations for integrating the system.

9.2. THESIS FORMAT, PAPERS AND OBJECTIVES

This study was conceptualised and brought to fruition through a series of five papers that address specific objectives of the study either singly or in combination. In order to contextualise the papers, the thesis consisted of an introduction, literature review, and a methods section. These chapters were followed by the papers and the discussion and concluding chapter 9.

The five papers of the study are found in chapters 4-8. The first paper addresses objectives 1, 2 and 3 of the study, which were to determine the scope of the South African food control system, define fragmentation and determine whether or not the South African food control system is fragmented. The results indicate that fragmentation can be defined as separation of structural, functional and legislative aspects of food control because of mandate obligations of government departments; while food control is a conglomeration of functions separated between the Departments of Health, Agriculture, Forestry and Fisheries and the Department of Trade and Industry, in particular, the National Regulator for Compulsory Specifications (NRCS). With the definition of fragmentation and the scope of the food control system, it established that the South African food control system is indeed fragmented. Paper 1 also provides an initial review of the challenges noted in the food control system and therefore contributed to objective 5. Challenges noted were largely functional challenges and included in-coordination between related functions, unclear jurisdiction between parts of the system and duplication of functions. The first paper also identified

the regulation of veterinary drugs and residues as being highly fragmented and fraught with challenges. The key recommendation of this first paper was that processes that were initiated previously to investigate the state of the system, which included a consultant's report on the state of the system, must be expedited in order to address challenges.

The objective of the second paper was to determine challenges of the food control system or objective 5 of the study. Since an in-depth understanding of challenges was required, only a part of the food control system was focused on. The focus area is the regulation of veterinary drugs and residues which was identified as fragmented and burdened with challenges in paper 1. In order to systematically determine challenges, the framework of food safety risk analysis was introduced and its concepts of risk assessment, risk management and risk communication were applied to the three concepts in the definition of fragmentation developed in the first article. Therefore, risk assessment, risk management and risk communication were applied to structures, functions and legislation related to the regulation of veterinary drugs and residues. This systematic review identified the challenges of the regulation of veterinary drugs and residues which included in-coordination and duplication of functions but more importantly identified systemic challenges that were not considered previously in any detail. These systemic challenges included a lack of systems conceptualisation and poor horizontal communication which is poor communication between various parts of the food control system. The paper concludes by indicating that before functional challenges like in-coordination are addressed, systems conceptualisation and horizontal communication need to be improved. This paper brought to attention that although fragmentation is purported as the cause of various challenges, the casual link of fragmentation causing challenges is not as clear cut or linear as initially proposed. In fact, the systemic challenges of poor horizontal communication and poor systems

conceptualisation are also likely to influence and cause challenges generally associated with fragmentation such as unclear jurisdiction of functions, duplication of functions and in-coordination of functions. This in turn means that fragmentation can be viewed as a challenge itself rather than simply a cause of other challenges.

Paper 3 sought to determine how and why fragmentation was initiated as well as why it continues, the central issue of objective 4. This paper also focused on veterinary drugs and residue regulation and found that poor leadership, adherence to mandate obligations and conceptual distinction between stock remedies and veterinary drugs are critical influences of the initiation and continuation of fragmentation. The arbitrary conceptual distinction of stock remedies and veterinary drugs separated the registration of veterinary drugs while mandate obligations also contributed to separation. Poor leadership at the senior management level was also found to be a critical influence as it allows for the conceptual distinction and influence of mandates. Poor leadership is also substantiated by the inability to follow through on plans to integrate the system through Act 132 of 1998. Paper 3 indicates that policy action is required to affect proper leadership and fragmentation of the veterinary drug and residue system which entails training programmes for senior managers of the system as well as an agricultural input control policy that provides for registration of veterinary drugs under the Department of Agriculture while residue regulation remains within the Department of Health.

Paper 4 interrogated the two systemic challenges of poor systems conceptualisation and poor communication by reporting on responses of participants involved in a questionnaire based survey. These two challenges were looked at in detail because paper 2 indicated that they should be addressed before functional challenges like in-coordination and duplication of functions are addressed. In addition, poor systems conceptualisation means that there will be a fragmented designed abstract system

which will affect the physical system. Therefore in-depth research into conceptualisation of the system was considered highly relevant. This primary research of paper 4 confirmed the results of the reviews that systems conceptualisation is poor and that horizontal communication is lacking and therefore contributed to objective 5 of the study, namely to provide insight on challenges and how it is related to fragmentation. More importantly, it indicated that systems conceptualisation is not lacking due to the lack of awareness of related risk management functions by government officials of the food control system but because personnel of the system do not have an in-depth understanding of related risk management functions in order to determine the importance of the related function to their own functions. This is indicative of silo-mentality, an already acknowledged constraint in Government (Cilliers and Greyvenstein, 2012). For communication, paper 4 underlined the fact that horizontal communication between government departments involved in food control is poor, so much so that communication is better between individual government departments and outside stakeholders than between departments. In addition, even though communication is poor there is no realisation that communication needs to be drastically improved compared to improving communication with outside stakeholders. Both bettering horizontal communication and addressing the lack of in-depth understanding of related functions are relevant for integrating the system as these need to be addressed.

The research underpinning paper 5 also provides findings from the questionnaire-based survey. It also reports on challenges identified by participants, which is a contribution to objective 5. This paper aimed to identify the different types of challenges of the system with a view to understanding whether these are directly linked to fragmentation. This paper introduces three categories of challenges: policy, functional and fundamental challenges. Policy challenges are a lack of strategies or policies for

an integrated food control system while functional challenges include in-coordination and duplication of functions and are, as the name suggests, functional in nature. Fundamental challenges are not specific to food control and have been reported on previously, particularly as challenges of the public service as a whole. These include lack of staff and financial resources as well as a lack of skills. Paper 5 reported that a lack of skilled staff is very prominent in the regulation of veterinary drugs and residues and this is a significant fundamental challenge as it will require a concerted plan to address before an integrated system can emerge.

With the above results of the articles, objectives 1 to 5 of the study were achieved with only objective 6 being discussed within papers but not in totality. Objective 6 is to provide recommendations for policy change in order to integrate the South African food control system for greater effectiveness and efficiency. This is provided in the following section where results of the research into the veterinary drug and residue regulatory system are consolidated and applied to the entire food control system to indicate what they mean for the system and how it can be integrated.

9.3. DISCUSSING THE FINDINGS

The study revealed that the South African food control system is a multiple agency food control system; it is fragmented and is plagued by many functional challenges. This in turn makes the current food control system a dysfunctional one because functions can be duplicated, in-coordinated or functional jurisdictions are unclear and most disconcerting of all, functions are not conducted at all. The study, through research into the veterinary drug and residue regulatory system, also determined that fragmentation is not a phenomenon in isolation and it is not the sole cause of functional challenges. In

fact, fragmentation can be viewed as a challenge as well, and the challenges of the system extend to systemic, policy and fundamental challenges, not only functional challenges (Figure 9.1).

Figure 9.1: Categorisation of the challenges of the food control system

Also highly relevant is the fact that these challenges are interrelated, entrenching and exacerbating one another while also causing and being caused by fragmentation. For example, within the focus study area of veterinary drug and residue regulation, although fragmentation was initiated by a conceptual distinction of stock remedies and veterinary drugs and mandate obligations, poor leadership by senior management in both the Departments of Health and Agriculture, Forestry and Fisheries, a fundamental challenge, entrenched fragmentation as leaders did not innovate or change the system even though they had opportunities to do so (through Act 132 of 1998). Also, functional challenges like in-coordination exacerbates systemic challenges like poor systems conceptualisation while poor systems conceptualisation affects the physical structures, functions and legislation of the food control system. In other words, the designed abstract system affects the designed physical system (Checkland, 1981). This complex interaction between challenges and challenges and challenges and fragmentation can be illustrated in Figure 9.2.

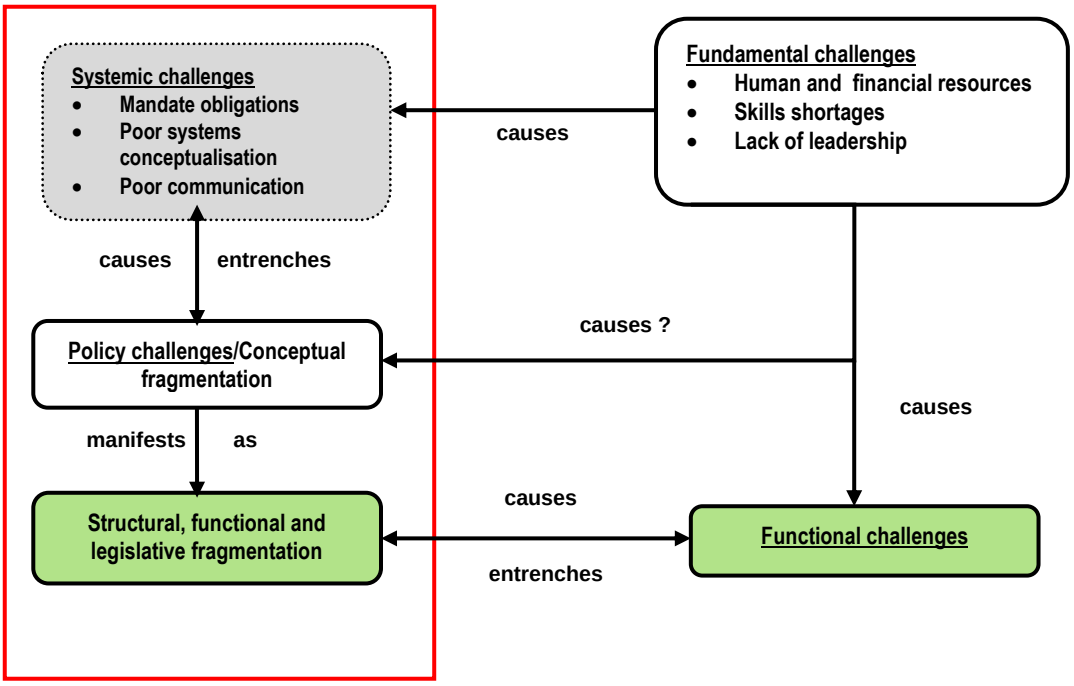

Figure 9.2: Model of the association of challenges with fragmentation: Revisiting the initial linear framework of the study

Figure 9.2 underlines the fact that challenges such as mandate obligations of government departments; poor systems conceptualisation and poor communication between departments are systemic and cause conceptual fragmentation. However the interaction of mandate obligations, poor systems conceptualisation and poor communication, are elaborated on in Figure 9.3 which depicts these three systemic challenges as dependent on each other such that they entrench one another. In addition, and as per the results of paper 4, another factor, which is the lack of in-depth understanding of related food control functions, can also influence this interaction and is therefore also an important factor to be considered when addressing systemic challenges. Figure 9.2 also shows that systemic challenges cause conceptual fragmentation which in turn manifest as fragmented structures, functions and

legislation. The interaction of the systemic challenges, conceptual fragmentation and physical fragmentation (structural, functional and legislative fragmentation) cause functional challenges like in-coordination and duplication of functions. However figure 9.2 also indicates that functional challenges also entrench fragmentation, if they are not attended to. Fundamental challenges like human and financial resources and skills constraints also affect functional challenges. Their relationship to systemic challenges is not fully explored in this study but paper 3 found that poor leadership is a critical fundamental challenge and therefore must be addressed if fragmentation and its associated challenges are to be addressed.

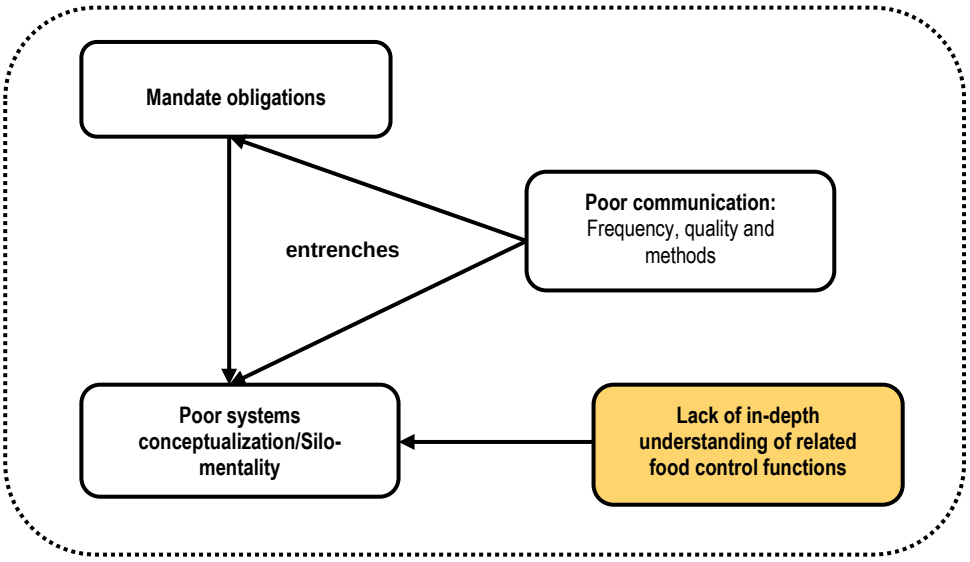

Figure 9.3 Systemic challenges: elaboration of the interaction between mandate obligations, poor communication and poor systems conceptualisation

The green boxes of Figure 9.2., refer to physical fragmentation and the link to functional challenges such as in-coordination and duplication of functions. The reason for highlighting these is that they were the basis of the initial linear framework of Figure 1.1 (page 7). The complexity exemplified in Figure 9.2 can then be contrasted with what was postulated at the outset of the study, which is far from the simple linear

framework. The study has therefore provided an insight into the complexity of challenges associated with fragmentation as well as their interaction with the phenomenon of fragmentation. It has therefore been determined that the phenomenon of fragmentation itself is complex as it is in constant interaction with challenges that either exacerbate its existence or even cause it. This understanding is crucial as it provides the evidence for interventions required to address the challenges and fragmentation that have been identified in this research.

9.4. POLICY INTERVENTIONS FOR ADDRESSING CHALLENGES

Research into the veterinary drug and residue regulatory system found two important policy interventions for addressing challenges. These interventions are therefore also highly relevant and urgently required to address challenges of the entire food control system. The first intervention is training. Training is of paramount importance but it needs to be institutionalised within the public service. This means that all senior and middle managers within the public service must attend compulsory training on leadership and change management. This is perhaps best done through the Department of Public Service and Administration's (DPSA) leadership academy called PALAMA (Public Administration Leadership and Management Academy) as it already exists. Training programmes must however be entrenched in systems thinking that embraces change and adaptability, communication and collaboration. Training cannot be construed as just another programme in Government, and Government policies must create an enabling environment for trained leaders to exercise their learned skills. In fact, change and innovation, hallmarks of true leadership (Borins, 2002), must be awarded through existing performance systems in government, like the (performance

management and development system or PMDS) and through other forms of recognition like monetary or recognition awards.

The other intervention for addressing challenges is the drafting of an overarching policy which takes into account challenges and puts in place measures to address the risks of those challenges. For the veterinary drug and residue regulatory system, an agricultural input policy is required which addresses registration of all veterinary drugs, pesticides and other inputs used for sustaining agriculture. For the food control system, a food control policy for South Africa is required. As with the agricultural input policy recommended in paper 3, the food control policy needs to be drafted by trained leaders, who have been through the abovementioned training programme. This food control policy must define the scope of the food control system in terms of the structures, functions and legislation that is required and most importantly what model is used to integrate the food control system. This policy must also address the fundamental challenges of financial and skills resource constraints as well as inter-departmental collaboration that include communication and training. Figure 9.4 shows the interventions of training and a food control policy for addressing challenges and fragmentation, namely those categorised as systemic, fundamental, policy and fundamental challenges.

Training:	**Food control policy:**
• Based on systems thinking • Entrenches systems conceptualization, collaboration and communication • Must be part of the larger public service • Public service policies must encourage change and innovation to create an enabling environment for leaders.	• Developed by trained leaders. • Must define scope of food control system as well as structures, functions and legislation. • Must legislate inter-departmental collaboration and communication. • Must address fundamental challenges related to financial and skills resources.

Figure 9.4. Potential of training and food control policy interventions to address all systemic, fundamental, policy and fundamental challenges

The above interventions on specific challenges can be applied to the food control system as per the process depicted in Figure 9.5 which illustrates that the critical systemic challenges need to be addressed at the onset in order to affect change. This is regarded as step 1 of the process of change. In this step the three systemic challenges of poor systems conceptualisation, poor communication and mandate obligations are addressed. However to address poor systems conceptualisation requires adequately informed and educated leaders who understand the systems thinking philosophy both in terms of viewing current isolated functions as part of a system as well as embracing innovation and change. In fact, the leaders for the new system must integrate the ability to change and adapt within the system and acknowledge that continuously learning must accompany system development. As previously indicated, leadership training is a key requirement, either through specified programmes within government or where lacking because of initial scarcity of leadership trainers and programmes in government, through private sector or international organisations like the Food and Agriculture Organization (FAO). However, government must capacitate itself to provide this leadership training itself because it can tailor programmes to specific public sector management styles and goals. The key aspect of this training must be that systems thinking, collaboration, collective action and communication are entrenched in leaders and their ability to utilise their skills must be linked to key performance areas. In this way, leaders are not only trained but provided with an enabling environment in which to conduct change.

The leaders that will change the system must be able to determine the scope of food control thereby defining what the system is and isn't and where there might be overlaps, and the jurisdiction of functions need to be clarified. For example, if the registration of veterinary drugs is conducted by the Department of Agriculture as recommended in paper 3 and the MRL publication and enforcement conducted by the

Department of Health, the penalty for improper use of a veterinary drug that results in an MRL exceedance must be defined in terms of whether the food control enforcement will issue a penalty or the registration authority or both. It is important that the scope of the food control system is done without influence of mandate obligations such that the integrated nature is kept intact and mandates are only considered when the physical system is deliberated. Once the overall conceptualisation of the integrated system is complete, together with the scope of the system, there must be a decision on which Government Department is the authority overseeing this agency or system.

In step 1, the poor communication identified in paper 2 and elaborated on in paper 4 needs to be dealt with at the designed abstract phase, even before the system is physically changed. In paper 4, the frequency, type and quality of communication were identified as problematic and these all need to be considered in developing a communication strategy for the system. Therefore during step 1's development of a communication strategy, the methods and frequency of communication need to be defined like physical meetings once a month between the various parts of the system, or continuous communication with non-governmental stakeholders via twitter or face book or emails or newsletters. In addition the quality of communication needs to be addressed in terms of what is communicated. Is communication only for updating or for discussion in terms of getting inputs into how certain functions are conducted? This communication strategy must be a fundamental requirement of the food control system and must be put into policy or legislation in subsequent steps of the change process for an integrated system.

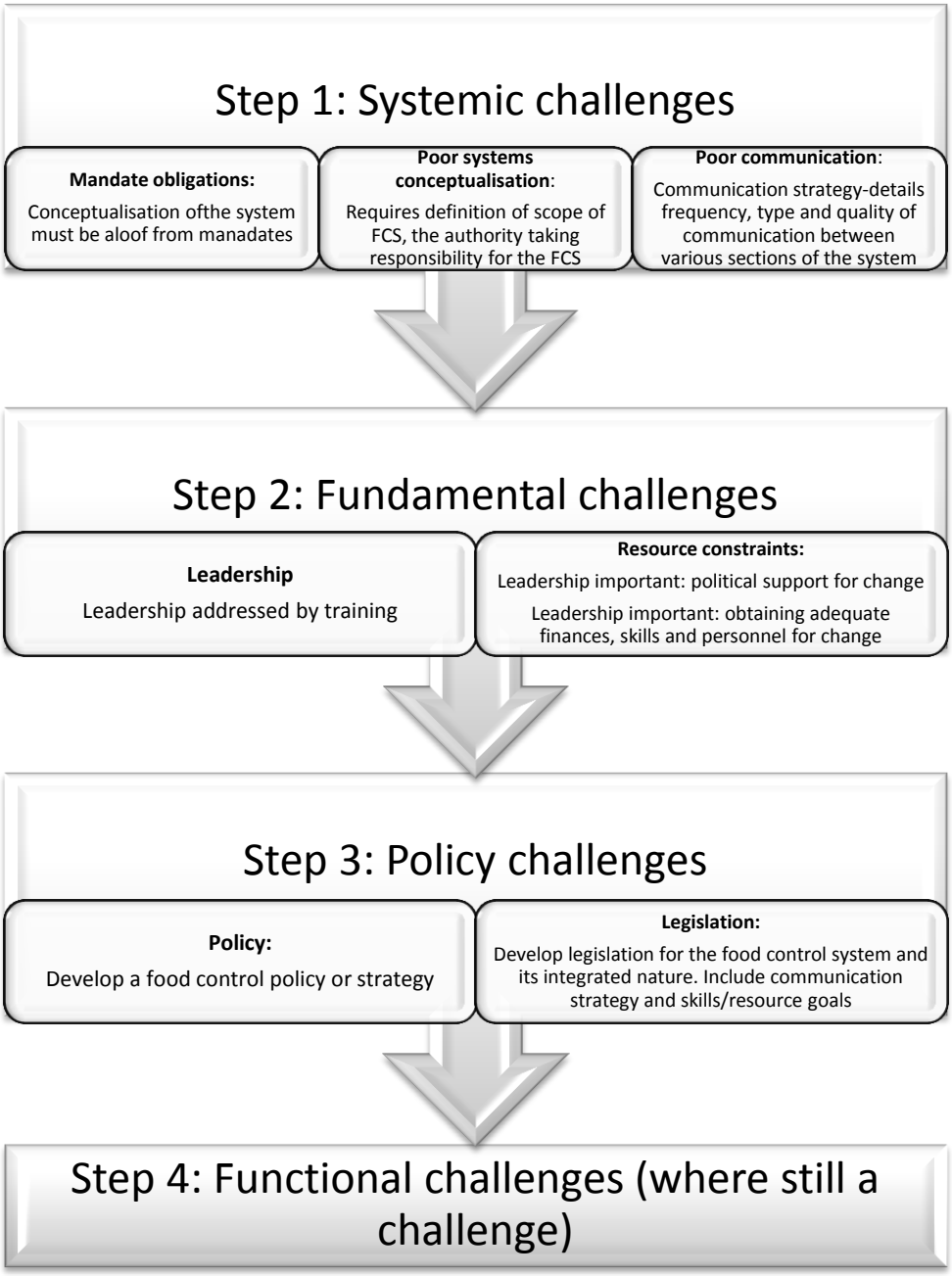

Figure 9.5: Concept map indicating the steps required to integrate the food control system based on the four identified challenges

The next step is to look at fundamental challenges as they will affect the functioning of the system regardless of whether the system is fragmented or not. Leadership is integral to addressing not only fundamental changes but all other challenges as well. Proper leadership, will ensure the system remains continually poised for change thus

allowing it to adapt and mature as a system. Leadership however has been discussed in previous paragraphs as without it the systemic challenges cannot be overcome. Step 2 must also outline what skills are required for the various parts of the food control system and what the skills deficits are. This can be translated into financial requirements for the system.

Step 3 is perhaps the most difficult because it encapsulates the thinking of step 1 and 2 into a formal policy and thereafter legislation. This step will require review of existing legislation and policies and will indicate the changes that are required to formalise the South African food control system. It will require changes to existing legislation like the National Health Act, 2000 where food control functions are delegated to the municipalities. What is needed from this step is the development of a food control policy and subsequent legislation, the latter of which will take a substantial amount of time considering the legislative process. The culmination of this step will indicate structures, functions and legislation of the system.

Step 4 is addressing functional challenges like in-coordination, unclear jurisdiction and duplication. Although most of these challenges will be addressed in the ‘design phases’ of steps 1,2 and 3, the actual functioning of the system might reveal areas of duplication or unclear jurisdictions and this will need to be addressed at the operational level.

9.5. MODELS OF INTEGRATION

Although the steps in section 9.4 outline the process in integrating the food control system, the model for integration, which should be finalised in step 3, has not yet been discussed. This next section will discuss models that are applicable as well as the recommended. Models for food control systems do exist as well as models used outside the food control arena and these can be explored in terms of their applicability to integrating the South African food control system based on the requirements provided through this study. One model is macrostructure forming policy within already existing structure, legislation and function. Such policy already exists with the biotechnology strategy of South Africa and the Genetically Modified Organisms Act, 1997 (Act 15 of 1997) which legislates a semi-permanent macrostructure called the Executive Council (EC), tasked to combine the mandates of different government departments to collectively make decisions on use of genetically modified organisms. The EC is currently made up of nominated representatives of the Department of Agriculture, Forestry and Fisheries, Health, Science and Technology, Environmental Affairs, Labour, and Trade and Industry. It legislates approximately 6 meetings a year for all these representatives where decisions on use of GMOs are made. This legislation and therefore structure overcomes mandate obligations by legislating that representatives represent their respective mandates but make decisions collectively and by consensus thereby balancing mandate obligations with obligations to the Act and decision making. It also considers structural and functional fragmentation by legislating one body and one administration which is not served by a new isolated function but by existing functions within these departments. It therefore addresses functional challenges like in-coordination, unclear jurisdiction and duplication as the administration lies within the Department of Agriculture, Forestry and Fisheries. This model also legislates communication between representative departments as meetings

are legislated and therefore face-to-face communication is mandatory. Fundamental challenges may also be addressed as skills, staff and finances are pooled from existing departments into the administration relating to regulation of genetically modified organisms.

However there are challenges to use of the above model because it has only been used on one specific food safety issue that is also considered wider than food safety encompassing animal safety, environmental safety and trade protection. Therefore applying such a model to the entire food control system will be challenging as will the decision on who administers the policy and macrostructure. In addition, even though such a structure may overcome poor systems conceptualisation and mandate obligations, poor communication may still be the *modus operandi* as the macro-structure is not permanent.

Considering the constraints of the macro-structure model, two other models, previously reported on, are the single agency food control system and the integrated food control system. Both of these systems have been reported on by the FAO/WHO, (2003b) with the single agency system being entirely consolidated with functions that include policy and standards development, monitoring, enforcement and education and training (FAO/WHO, 2003b). The FAO/WHO, (2003b) text considers this system as effective as it allows for uniformity in functions, better reaction time to non-conformance and food safety issues, harmonisation of food standards and legislation, better integration and coordination between functions, and streamlined services. However it is also pointed out that this system is often difficult to develop because in-country situations need to be taken into account and these often hinders the total consolidation of functions. This is so because at the initiation of such a system, food control functions already exist within a country and these cannot be simply removed to make way for a consolidated system.

More favoured by some countries is the integrated food control system (FAO/WHO, 2003). This system is actually composed of more than one structure but these operate in sync as they are governed by one strategy. In the integrated model, policy and standard or legislation development occurs within one system or section while enforcement and training occur in another. Alternatively, enforcement occurs on its own and education is conducted by another system or section. These differences are generally related to the country situation in terms of what funding is available, what the country prioritizes and what goals are set. There is also a need to understand how different functions work within the existing legislation structures and functions of the country.

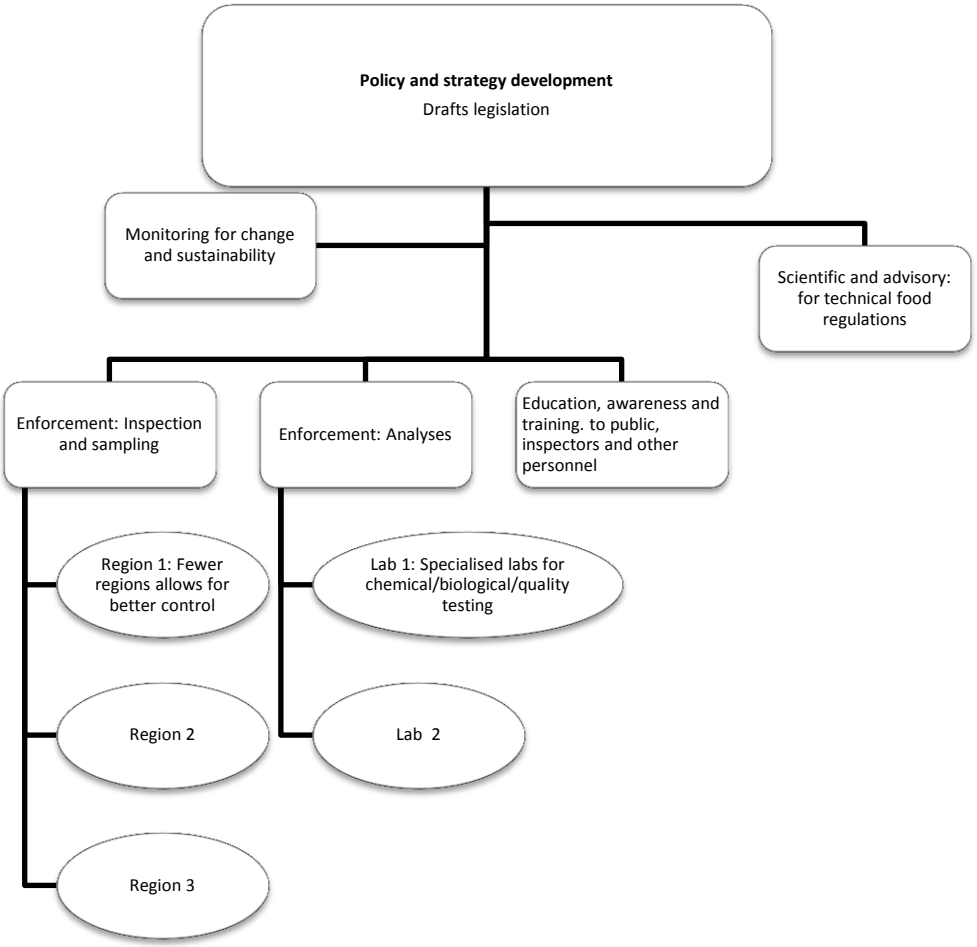

Figure 9.6: Recommended structural/functional model for the South African food control system

The FAO/WHO, (2003b) integrated food control system is considered a workable model for the South African food control system because the structural separation of the parts of the system is less important compared to the conceptual integration of all of the parts as a functioning system. Figure 9.6 is a recommended structural/functional model of an integrated food control system for South Africa based on the integrated food control system of the FAO/WHO, (2003b) and its recommended organisational structure of a food control agency (Figure 9.7.) as well as taking into consideration the key findings of this study.

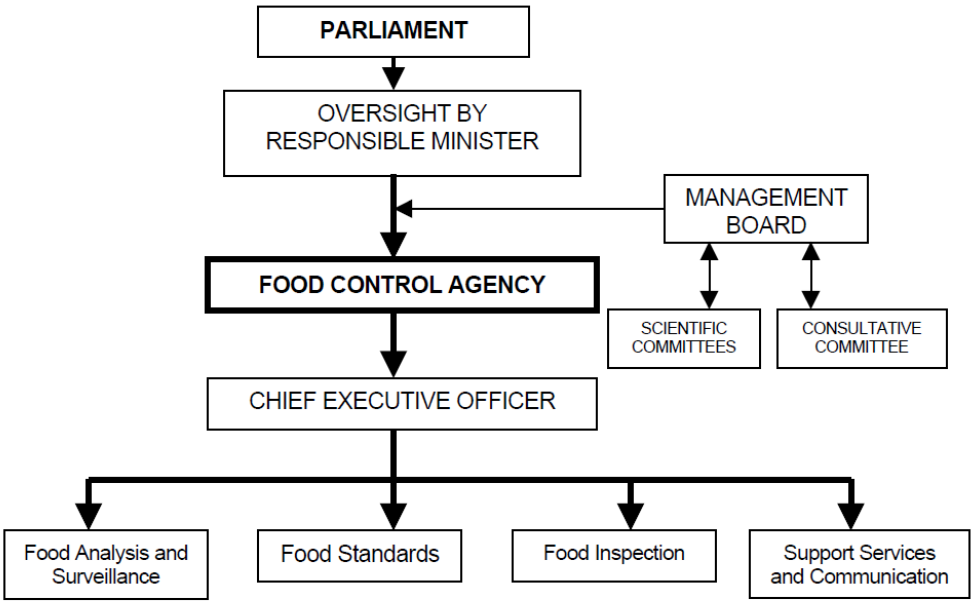

Figure 9.7. Recommended organisational structure of a food control agency by the FAO/WHO (FAO/WHO, 2003b)

The most important aspect of the system is that policy or legislation (which is step 3 of the framework of Figure 9.5) that is drafted must be considered as part of the system and they must be interrelated and operated in sync. Practically the structural and functional manifestation of the system would be a parastatal body answering to one government department but not constrained in terms of that department's mandate.

The policy section will draft legislation from the initial food control policy and chief legislation relating to food safety and quality. Since much of this secondary legislation drafting is technical in nature, the policy section should be supported by a scientific and advisory section or group. This section, also a key feature in the FAO/WHO, (2003b) recommended organisational structure, would provide the supporting substantiation for technical regulation but also provide advice on strategies and policies. This can be similar to the European Food Safety Authority (EFSA) that advises relevant government departments on technical standards development.

The monitoring of the system is also highly relevant as this indicates how the system is performing and whether it needs to change or adapt, another key systems thinking requirement (Senge, 2006, Mella, 2012). This monitoring must occur independently but must be part of the policy process in that section. The monitoring of the system must be able to provide areas of improvement, integration gaps and methods of how to improve. The remaining sections of the system are dedicated to enforcement of regulations, both for sampling and analyses as well as education, awareness and training or food related health promotion, all of which are indicated in the FAO/WHO, (2003b) recommended structure as well. Enforcement should ideally be regional compared to provincial as regional offices are better controlled and because provincial control requires consideration of the authority of provincial authorities as described in paper 1. Analyses can be outsourced or in-house depending on budget availability and availability of human resources but because of the variety and scope of analytical requirements, laboratories should specialised for two or three types of food analyses. This too must be structured as per budgets and ease of analyses. Therefore, pesticide residues, drug residues and environmental contaminants can be done at one laboratory while additives like colourants and preservatives can be done at another. Another laboratory can specialise in microbiology. The organisation of laboratories

requires a lot of thought as it is an expensive undertaking and weighing the outsourcing of analyses versus administration and maintenance of in-house laboratories needs to be carefully considered.

Education, awareness and training are indicated as separate from enforcement only to illustrate that the function needs to be catered for and prioritised. However these functions can be separate or combined where inspectors inform the public of regulation, food related health issues and other similar topics. Education and awareness is also linked to education to health care providers, and food manufacturers in order to inform them of regulations and the risks of food borne illness.

The recommended model of Figure 9.6 is flexible in terms of the lower hierarchical functions. There could be differences on the functionality, such as chemical laboratories being outsourced while the in-house laboratory only focuses on microbiology or that enforcement is provincial rather than regional. However there are key principles which the model should not deviate from:

1. The food control policy must be the legal framework that allows for the existence of the food control system.
2. The legal framework and policy must ensure that all functions are integrated.
3. The policy or legal drafting section of the system must always be incorporated in the system.
4. The monitoring section is imperative and must be included in legislation.
5. The functions of enforcement (sampling and analyses), IECT and reporting must always be present.

9.6. CONCLUSION

This study was initiated to determine whether the South African food control system is fragmented, why it is fragmented and why this state of the food control system is so problematic. This was conducted by studying one part of the food control system in detail, the veterinary drug and residue regulatory system. It is found that the South African food control system is fragmented at the structural, functional and legislative levels and, through research into the veterinary drug and residue regulatory system, it was also determined that fragmentation occurred and continues to do so due to the inability of leaders to conceptualise the individual functions as part of a system. The study also found that the fragmented system of food control system, as seen in the fragmentation of the veterinary drug and residue regulatory system, is associated with four types of challenges: systemic, fundamental, functional and policy challenges and the relationship between the challenges and between fragmentation and challenges is not linear. This means that fragmentation does not necessarily cause all these challenges but these challenges can actually cause or exacerbate fragmentation while some challenges actually cause and exacerbate one another. Based on the categorisation of challenges, a process framework is developed which indicates the steps required to integrate the food control system as well as two policy interventions that are required for integration. Models for the integration are also discussed with a recommendation for a system as described in Figure 9.6. This system comprises of a policy or legalisation drafting unit guided by a food control policy and different sections that look at sampling and analyses, IECT, technical advice and monitoring. Within this model though and as described in Figure 9.5, systems conceptualisation, a strategy for horizontal communication and capacitated leaders to drive the change are imperative. The following are essential to integrating the South African food control system:

- Capacitated and motivated leaders willing to innovate and change for the betterment of the system. These leaders must also work collectively to obtain the goal of the integrated system.
- Systems conceptualisation: Ability to conceptualise beyond mandate obligations
- Food control policy based on systems conceptualisation of the food control system
- Horizontal communication strategy that addresses methods, quality and frequency of communication
- In-built ability of the system to adapt to change. This includes continually updating staff or training staff on related functions such that silo-mentality is addressed.

9.7. LIMITATIONS AND FURTHER RESEARCH

As all studies are finite, this one too is restricted. This study looked at fragmentation of the South African food control system, its associated challenges and linkages between fragmentation and challenges by researching the veterinary drug and residue regulatory system. In doing so it categorised challenges and focused on systemic challenges as they are considered pivotal in integrating the system. Therefore for further research, functional and fundamental challenges (although poor leadership is superficially explored in this study), needs to be explored in detail as it will supplement the stepwise process of integrating the system.

In addition to the above, in-depth research of other parts of the food control system are also required so that it builds the body of research of food control system challenges and how to address them.

REFERENCES

N.B. References in this section are consolidated references of each of the five papers as well as references of the introduction and conclusion chapters. Each paper (chapters 4-8) also has its own references at the end of the chapter/paper.

Ackoff, R. L. Gharajedaghi, J. (1996) Reflections on Systems and their Models, *Systems Research*. 13 (1), 13-23

Aksglaede, L. Juul, A. Leffers, H. Skakkebaek, N. E. and Andersson, A.M. (2006). The sensitivity of the child to sex steroids: possible impact of exogenous estrogens, *Human Reproduction Update*. 12 (4), 341-349

Anadón A. & A. R. Martínez Larrañaga. (1999) Residues of antimicrobial drugs and feed additives in animal products: regulatory aspects*. Livestock Production Science*. 59 (2-3), 183-198

Andersson, A.M. Skakkebaek, N. E. (1999) Exposure to exogenous estrogens in food: possible impact on human development and health, *European Journal of Endocrinology*. 140, 477-485

Anyanwu R. C. Jukes, D. J. (1990). Food safety control systems for developing countries, *Food Control*, January, 17-26

APVMA [Australian Pesticides and Veterinary Medicine Authority], (2011) http://www.apvma.gov.au

ARC [Agricultural Research Council] (2010) ARC-OVI. Available at: http://www.arc.agric.za/home.asp?pid=2564

Battacherjee, A. (2012). *Social Science Research: Principles, Methods and Practices*. USF Open Access Textbooks Collection. Available at: http://scholarcommons.usf.edu/oa_textbooks/3

Beinart, W. & S Dubow. (eds) (1995). Segregation and apartheid in 20th century South Africa. Routledge (London)

Bengis, R. G. & J. M. Erasmus. (1988) Wildlife diseases in South Africa: A review. *Rev. sci. tech. Off. Int. Epiz.,* 7(4), 807-821

Bigalke, R. D. (2009) Theiler and the spirit of Onderstepoort. *Onderstepoort Journal of Veterinary Research*. 76, 3- 7

Blumberg, L. (1989). Robert Koch and the Rinderpest. *South African Medical Journal*, 76, 438-440

Borins. S. (2002) Leadership and innovation in the public sector*. Leadership and Organization Development Journal*, 23 (8), 467-476

Brinckman, D. (2000) The regulation of rBST: The European Case, *AgBioForum;* 3 (2 & 3), 164-172

Brown K. & D. Gilfoyle (eds) (2010). Healing the herds: Disease, livestock economies, and the globalization of veterinary medicine. Ohio University Press (Athens)

Brown, K. Gilfoyle, D. (2007) Livestock diseases and veterinary science in Southern Africa. *South African Historical Journal*, 58, 2-16

Brückner G. K. van de Venter T. Rademeyer E. Malan D. Jansen van Rijssen F. W. Wolhuter M. (1998). A structural-functional analysis of the food control services in South Africa: Report on the findings of the joint working group on food of the national Departments of Agriculture and of Health. Pretoria (South Africa)

Brückner, G. K. Vosloo, W. du Plessis, B. J. A. Kloeck, P. E. L. G. Connoway, L. Ekron, M. . Weaver, D. B. Dickason, C. J. Schreuder, F. J. Marais, T. Mogajane, M. E. (2002) Foot and Mouth disease: The Experience in South Africa, *Rev. sci. tech. Off. Int. Epiz.,* 21 (3), 751-764

CAC [Codex Alimentarius Commission] (1999) Understanding the Codex Alimentarius. Available at: http://www.codexalimentarius.org/about-codex/understanding-codex/en/
CAC [Codex Alimentarius Commission] (1999). Available at: www.codexalimentarius.org

CAC [Codex Alimentarius Commission] (2011). Codex Alimentarius Commission: List of members. Available at: http://www.codexalimentarius.org/members-observers/members/en/?no_cache=1

Callahan, R. F. (undated). The future of public sector leadership. Available at: http://www.ipa.udel.edu/3tad/papers/workshop3/Callahan.pdf

Campbell, P. (2009) Department of Health, *personal communication.*
Catry, B. Laevens, H. Devriesse, L. A. Opsomer, G. de Kruif, A. (2003) Antimicrobial resistance in livestock, *Journal of Veterinary Pharmacology and Therapy*. 26*,* 81-93

Cerniglia, C. E. Kotarski, S. (2005) Approaches in the safety evaluations of veterinary antimicrobial agents in food to determine the effects on the human intestinal microflora, *J. Vet Pharmacol. Therap*. 28, 3-20

Chanda, R. R. Fincham R. J. & P. Venter. (2010) Review of the South African food control system: Challenges of Fragmentation, *Food Control*, 21, 813-824

Chanda, R.R. Fincham, R.J. Venter, P. (2014) Review of the regulation of veterinary drugs and residues in South Africa, *Critical reviews in Food Science and Nutrition,* 54 (4), 488-494

Checkland, P. (1981) *Systems Thinking, Systems Practice*, John Wiley and Sons: Chichester, UK

Chelechele, T. I. (2009) Skills development in the South African public service: problems and solutions, *Journal of Public Administration*, 44 (1), 44-57

Cilliers, F. Greyvenstein, H. (2012). The impact of silo mentality on team identity: An organisational case study. *SA Journal of Industrial Psychology.* 38(2), Art. #993, 9 pages.

Cogan, T. M. (1972) Susceptibility of cheese and yoghurt starter bacteria to antibiotics, *Applied Microbiology*. 23 (5), 960-965

Collier, R. (2000) Regulation of rBST in the US, *AgBioForum*, 3 (2 & 3), 156-163
Cooper H. Hedges, L. V. (eds) (1994). *The handbook of research synthesis*. Russell Sage Foundation: New York

Creswell, J. W. Plano Clark, V. L. (2011) *Designing and conducting mixed methods research (2nd ed).* SAGE Publications (Thousand Oaks: California)

DAFF [Department of Agriculture, Forestry and Fisheries], (unpublished). Draft food safety policy Version 2.

de Beer G., Paterson A. Olivier H. (2003). 160 years of export: The history of the perishable products export control board. Available at: http://www.ppecb.com
DoA [Department of Agriculture] (2009), 'The development of veterinary services in South Africa'. http://www.nda.agric.za/vetweb/History/H_History_Main_Initual.htm

DoA [Department of Agriculture], (2005). Food control strategy for South Africa. Report of the Directorate: Food Safety and Quality Assurance, Department of Agriculture, Government of the RSA, Pretoria.

DoH [Department of Health], (2008) Report of the Ministerial Task Team on the restructuring of the medicines and regulatory affairs and Medicines Control Council and recommendations for the new regulatory authority for health products in South Africa. Department of Health (Pretoria).

Doyle, M. E. (2006) *Veterinary drug residues in processed meats-potential health risk. A review of the scientific literature.* Food Research Institute Briefings. University of Wisconsin, Available at: www.wisc.edu/fri/

DPSA [Department of Public Service and Administration], (2003). Machinery of Government. Government of the RSA, Pretoria

FAO [Food and Agriculture Organization], OIE [World Organization on Animal Health], WHO [World Health Organization], (2012) High level technical meeting to address health risks at the human-animal ecosystems interface. FAO/OIE/WHO. http://www.who.int/zoonoses/hltm_2011/en/index.html

FAO/WHO [Food and Agriculture Organisation/World Health Organisation], (2003a). Report of the FAO/WHO Workshop: *Food control systems-practical approaches in the Southern African region,* 1 September 2003, Pretoria, South Africa
FAO/WHO, (2003b) *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*, FAO Food and Nutrition Paper 76, FAO/WHO: Rome
FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2004). Second FAO/WHO Global Forum of Food Safety Regulators, Bangkok, Thailand, 12-14 October 2004: *Legal Basis for Food Safety Official and non-Official Control-"Strengthening official food safety control services'*

FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2005). FAO/WHO Regional Conference on Food Safety for Africa. International, Regional, Sub-regional and National cooperation in food safety in Africa, 3-6 October 2005, Harare, Zimbabwe

FAO/WHO [Food and Agriculture Organisation/World Health Organisation]. (2006). *Food Safety Risk Analysis-A Guide for Food Safety National Authorities*, FAO Food and Nutrition Paper No, 87. FAO/WHO: Rome

FCL [Food Chemistry Laboratories]. (2008). Forensic Chemistry Laboratories, Department of Health, Government of the RSA, South Africa. Available from: http://www.doh.gov.za/department/forensic_lab-f.html

FDA [Food and Drug Administration] (2013) http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm

FDA/USDA [Food and Drug Administration/ United States Department of Agriculture], (2000). United States Food Safety System. Washington (USA) [2009] Government of the United States of America. Available from: http://www.foodsafety.gov/~fsg/fssyst2.html

Fernandez, S. & Rainey, H. G. (2006). Managing successful organizational change in the public sector. *Public Administration Review*, March/April, 168-176

Fingleton, J. (2004) Legislation for veterinary drugs control. FAO Legal Papers Online #38. FAO (Rome)

Fox, N. (2009) Using Interviews in a Research Project. The NIHR RDS for the East Midlands / Yorkshire & the Humber 2006. Available at: www.rds-eastmidlands.nihr.ac.uk

Garcia R. Jukes, D. (2004). The Spanish system of food controls-its administration and enforcement, *Food Control*, 15, 51-59

Gehring, R. Swan, G. E. Sykes, R. D. (2002) Supply of veterinary medicinal products to an emerging framing community in the north West Province of South Africa, *Journal of the South African Veterinary Association*. *73* (4): 185-189

Haines, S. G. (1999).*The managers pocket guide to strategic and business planning. The systems thinking approach*. HRD Press: Canada

Haines, S. G. (2000). *The complete guide to systems thinking and learning.* HRD Press: Amherst

Haines, S. G. (2007) *Strategic and systems thinking: The winning formula*. Systems Thinking Press: San Diego

Hart, C. (1998) Doing a literature review. Sage Publications: London

Hela, M. (2006) Regulation and control of veterinary pharmaceuticals in South Africa: The role of the National Department of Health. Presentation to the Portfolio Committee on Agriculture and Land Affairs: 19 September 2006

Izindaba. (2010) Dysfunctional MCC under legal threat. *South African Medical Journal*, 100 (5), 274-276

Jeong, S.H. Song, Y.K. Cho, J. H. (2009) Risk assessment of ciprofloxacin, flavomycin, loaquindox and colistin sulphate based on microbiological impact on human gut biota, *Regulatory Toxicology and Pharmacology*. 53, 209-216

Johnson, R. B. Onwuegbuzie, A. J & L. A. Turner (2007) Towards a definition of mixed methods research, *Journal of Mixed Methods Research*, 1 (2), 112-133

Jones, D. (2009) National Council of the Society of the Prevention of Cruelty to animals, *personal communication*.

Kastner, J. J. Pawsey, R. K. (2002) Harmonising sanitary measures and resolving trade disputes through the WTO-SPS framework: Part I: A case study of the US-EU hormone treated beef dispute, *Food Control*, 13, 49-55

Keyyu, J. D, Kyvsgaard, N. C. Kassuke, A.A., Willingham, A. L. (2003) Worm control practices and anti-helminthic usage in traditional and dairy cattle farms in the southern highlands of Tanzania*, Veterinary Parasitiology*. *114* (1): 51-61

Kirsten, J. F. van Zyl J. & J. van Rooyen. (1994). South African Agriculture during the 1980's. *South African Journal of Economic History*, 9 (2), 19-48

Korsten, L. (2009) *Synopsis of the country profile study*. University of Pretoria: Pretoria

Kroukamp, H. (2002) Skills training: a prerequisite for the changing position and status of public servants in South Africa, *Journal of Public Administration*, 37 (4), 453-474

Kumar, R. (2011). *Research methodology: A step-by-step guide for beginners*. Sage Publications: London

Kwak N. S. Jukes D. Shin S. G. (1999). Food safety control in the Republic of Korea, *Critical Reviews in Food Science and Nutrition*, 39 (6), 539-549

Masibigiri, V. Nienaber, H. (2011). Factors affecting the retention of Generation X public servants: An exploratory study. *SA Journal of Human Resource Management.* 9(1), 318-320

Meadows, D. H, (2008) *Thinking in systems. A Primer.* Earthscan: Abingdon, Oxon

Mella, P. (2012) *Systems thinking: intelligence in action*. Springer: Italy

Mitema, E. S. (2009) Improved management of drugs, hormones and pesticides in Africa. *Onderstepoort Journal of Veterinary Research*, 7, 155-159

Morley, P. S. Apley, M. D. Besser, T. E. Burney, D. P. Fedorka-Cray, P. J. Papich, M. G. Traub-Dargatz, J. L. Weese, J. S. (2005) Antimicrobial drug use in veterinary medicine, *J Vet. Intern Med*. 19: 617-629

Mothae, L. Sindane, M. (2007) A strategy focused leadership for improving public policy implementation and improving good governance. *Journal of Public Administration*. 42 (5), 143-157

Mubangizi, B. C. (2005) Improving public service delivery in the new South Africa: some reflections. *Journal of Public Administration*. 40 (4.1), 633-648

Naidoo, G. (2009). Strengthening senior management skills in the South African public service: a rationale for strategic leadership. *Journal of Public Administration*, 44 (1), 3-14

National Research Council. (1999). The Use of Drugs in Food Animals: Benefits and Risks, pp. 1, 19 & 71-73, 22-26 & 69 &76, 83-85. National Academy Press (Oxon) (Tropical Agriculture Association) and http://post.queemsu.ca/~forsdyke/rinderpst0.htm

Ncayiyana, D. J. (2010) Misplaced trust? Gaping flaws in drug approval and licensing. *South African Medical Journal*, 100 (7), 399

Neeliah, S. A. Goburdhun, D. (2007) National Food Control Systems: A Review, *Food Reviews International*, 23 (1), 35-51

Nel, H. van Vuuren, M. Swan, G. E. (2004). Towards the establishment and standardization of a veterinary antimicrobial resistance surveillance and monitoring programme in South Africa, *Onderstepoort Journal of Veterinary Research*. 71 (3), 239-246

Nengwekhulu, R.H. (2009) Public service delivery challenges facing the South African public service, *Journal of Public Administration*, 44 (2), 341-365

Nguz, K. (2007). Assessing food safety system in sub-Saharan countries: An overview of key issues, *Food Control,* 18, 131-134

NICD/NHLS [National Institute of Communicable Diseases/National Health Laboratory Services] (2010) Communicable Diseases Surveillance Bulletin: Foreword, 8 (4), 1. Available at: http://www.nicd.ac.za

NRC [National Research Council] (1999). *The Use of Drugs in Food Animals: Benefits and Risks*, pp. 1, 19 & 71-73, 22-26 & 69 &76, 83-85. *National Academy Press:* Oxon

NRCS [National Regulator for Compulsory Specifications]. (2009). Services to Government. Available at: http://www.nrcs.org.za/content.asp?subID=19

Oliver, P. (2012). Succeeding with your literature review. A handbook for students. Open University Press: London

Olson, M. Jr. (1971). *The Logic of Collective Action: Public Goods and the Theory of Groups*. Schocken books: New York

Ostrom, E. (1990) Governing the commons. The evolution of institutions for collective action. *Cambridge University Press*.

Partsch, C. J. Sippell, W. G (2001) Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens, *Human Reproduction Update*. *7* (3), 292-302

Paterson, A. (2008) Veterinary skills. In: Kraak, A. & Press, K. (eds) (2008) Human resources development review 2008. Education, Employment and Skills in South Africa. HSRC Press: Cape Town

Payne, R. W. Murray, D.A. Harding, S. A. Baird, D. B. Soutar, D. M. (2011) *Genstat® for Windows™ 14th Edition Introduction*. VSN International, UK.

PMG [Parliamentary Monitoring Group]. (2013) Report back from Departments of Health, Trade and Industry, and Agriculture, Forestry and Fisheries on meat inspection services and labelling in South Africa. 21 June 2013. http://www.pmg.org.za/report/20130621-report-back-from-departments-health-trade-and-industry-and-agriculture-forestry-and-fisheries-meat-inspection

Reddy, P. S. (2001) Intergovernmental relations in South Africa, *Politeia*, Vol. 20 (1), 21-39

Rocourt, J. Moy, G. Vierk, K. Schlundt, J. (2003). *The present state of foodborne disease in OECD countries.* World Health Organization (WHO)

SABS [South African Bureau of Standards]. (2005). Food and Health Division. Available at: https://www.sabs.co.za/Sectors/Food_and_Health/index.aspx

SAVA [South African Veterinary Association] (2011): Timeline of veterinary development. Available at: www.sava.co.za

SAVA [South African Veterinary Association] (2012) South African Veterinary Association: Timeline of veterinary development. www.sava.co.za

Schwella, E. & Rossouw, A. (2005). Competencies for the senior management service in the South African public service: an evaluative assessment. *Journal of Public Administration*, 40 (4), 761-779

Senge, P. M. (2006) The fifth discipline, The art and practice of the learning organisation, *Doubleday Publishing*: New York

Serratosa, J. Blass, A. Rigau, B. Mongrell, B. Rigau, T. Tortadés, M. Tlosa, E. Aguilar, C. Ribó, O. Balagué, J. (2006) Residues from veterinary medicinal products, growth promoters and performance enhancers in food-producing animals: a European Union perspective, *Rev. sci. tech. Off. Int. Epiz*. 25 (2), 637-653

Sindane, A. M. (2011) Values and ethics enter the real world: a framework for public leadership and governance. *Koers* 76 (4), 751-769

Spinage, C. A. (2003) *Cattle plague: a history*. Kluwer Academic/Plenum Publishers (New York), 3-5

Tashakorri A. & C. Teddlie (2010) (eds.) *Handbook of mixed methods in social and behavioural research. SAGE Publications* (Thousand Oaks: California)

Taylor, R. G. Lynham, S. A. (2013) Systemic leadership for socio-political leadership. *South African Journal of Business Management*. 44 (1)

Tholo, K. (2009) Department of Health, *personal communication.*
Thornhill. C. (2005). A decade of transformation: An overview. *Journal of Public Administration*. 40 (4.1), 575-589

UP [University of Pretoria], (2011) History of veterinary science. Available at: http://web.up.ac.za/default.asp?ipkCategoryID=1132&sub=1&parentid=50&subid=1127&ipklookid=13

US [United States] Census Bureau, (2010) 2010 Census Briefs: Population Distribution and Change: 2000-2010. Available at: www.census.gov

van der Heijden, T. Mlandi, M. (2005) Organisational performance, success and failure in the public sector, *Journal of Public Administration*, Conference Proceedings, October 2005

van Niekerk, D. van der Waldt, G. Jonker, A. 2001. *Governance, Politics and Policy in South Africa*. Oxford University Press: Cape Town (South Africa)

vandenBergh, S. (2010). The story of a disease: African horsesickness and its direct influence on the necessary development of veterinary science in South Africa, c. 1890s-1920s. *Historia*, 55 (2), 243-262

Varzakas T.H. Tsigarida E. T. Apostolopoulos C., Kalogridou-Vassiliadou D. Jukes D.L. (2006). The Role of the Hellenic Food Safety Authority in Greece-Implementation Strategies, *Food Control*, 17, 957-965

Verwoed, D. W. (2000) A brief historical review of research achievements by the OVI during the 20th century against the backdrop of socioeconomic and political developments in South Africa. *Journal of the South African Veterinary Association,* 71(4), 210–214

Victor, L. (2008) Systematic reviewing. Social Research Update: University of Surrey. Available at: http://www.soc.surrey.ac.uk/sru/

Vink, N. (1999) South African Agriculture in the 1970s. *South African Journal of Economic History*, 14, 90-113

Vinger, G. & F. Cilliers. (2006). Effective transformation leadership behaviours for managing change. *South African Journal of Human Resource Management*, 4 (2), 1-9

VMD [Veterinary Medicines Directorate], (2011). http://www.vmd.defra.gov.uk/

Weber I. B. (2007) *Evaluation of the notifiable disease surveillance system in Gauteng Province, South Africa.* MMed (Community Health) thesis, University of Pretoria.

Whitehead, A. J. (1995) Elements of an effective national food control system, *Food Control*, 6(5), 247-251

WHO [World Health Organization] (2011) Food Borne Disease. Available at: http://www.who.int/mediacentre/factsheets/fs237/en/index.html food borne illness).

WHO [World Health Organization], (2002) WHO Global strategy for Food Safety, Food Safety Programme, World Health Organization

WHO [World Health Organization]. (1999) Study Group on Future Trends in Veterinary Public Health. Future trends in veterinary public health: report of a WHO study group (Teramo, Italy)

WHO/FAO [World Health Organization/Food and Agriculture Organization]. (2005). Understanding the Codex Alimentarius, Joint FAO/WHO Food Safety Programme, WHO/FAO, Rome

WHO/FAO [World Health Organization/Food and Agriculture Organization]. (2009). Monitoring for chemicals in food. INFOSAN Information Note No. 1/2009 - Monitoring for Chemicals in Foods. Available at: http://www.who.int/foodsafety/fs_management/No_01_Chem_Mar09_en.pdf

Woodside, A. G. (2010) *Case study research: Theory, Methods, Practice*. Emerald Group Publishing Limited: United Kingdom

Yoshimura, H. Endoh, Y. S. (2005). Acute toxicity to freshwater organisms of antiparasitic drugs for veterinary use, *Environmental Toxicology*. 20, 60-66

Zucker, D. M. (2009) *How to Do Case Study Research*. School of Nursing Faculty Publication Series. Paper 2

APPENDICES

I. QUESTIONNAIRE EXAMPLE

Targeted to participants involved in registration of veterinary drugs

GOV 7: REG AUTH

Questionnaire on risk management of veterinary drug residues in food

This questionnaire aims to obtain your views on the various risk management strategies OF GOVERNMENT identified in South Africa related to veterinary drug residues. Risk management is defined as: **The process in Government that identifies and implements measures to control risks in food usually after a risk assessment.**

You are requested to provide information on your key performance areas (job functions), your interactions and communication to stakeholders and other Government Departments as well as your understanding of the challenges related to your job functions.

Figure 1 shows all the identified risk management strategies related to veterinary drug residues in foods that will be used as the framework for this questionnaire.

Since you may only be involved in a few of the RM strategies which have been identified below, Section C will be of greatest relevance to you. However, section D, which relates to RM strategies outside of those with which you are directly involved, also requires your attention and answers as they allow the researcher to determine your awareness and opinion on the effectiveness of these strategies. Section E is also of relevance as it addresses general communication.

Please note that the answers requested in this questionnaire should be based on your personal experience and understanding.

SECTION A:

PERSONAL DETAILS

Please provide the following information (place an X where required):

Age		**Gender (place an x in the relevant box)**	**M**	**F**
Years of experience in veterinary drug activities				
Qualification/s				

Date on which questionnaire completed	

SECTION B:

RISK MANAGEMENT STRATEGIES FOR VETERINARY DRUG RESIDUES

Veterinary drug residues in South Africa:

The Department of Health and the Department of Agriculture, Forestry and Fisheries are key role-players in the regulation of veterinary drugs and their residues. Between the two Departments, the risk management strategies employed or considered in South Africa are those indicated in Figure 1 below. Definitions of each strategy are provided in each section. This diagram will be used as a reference framework for the questionnaire.

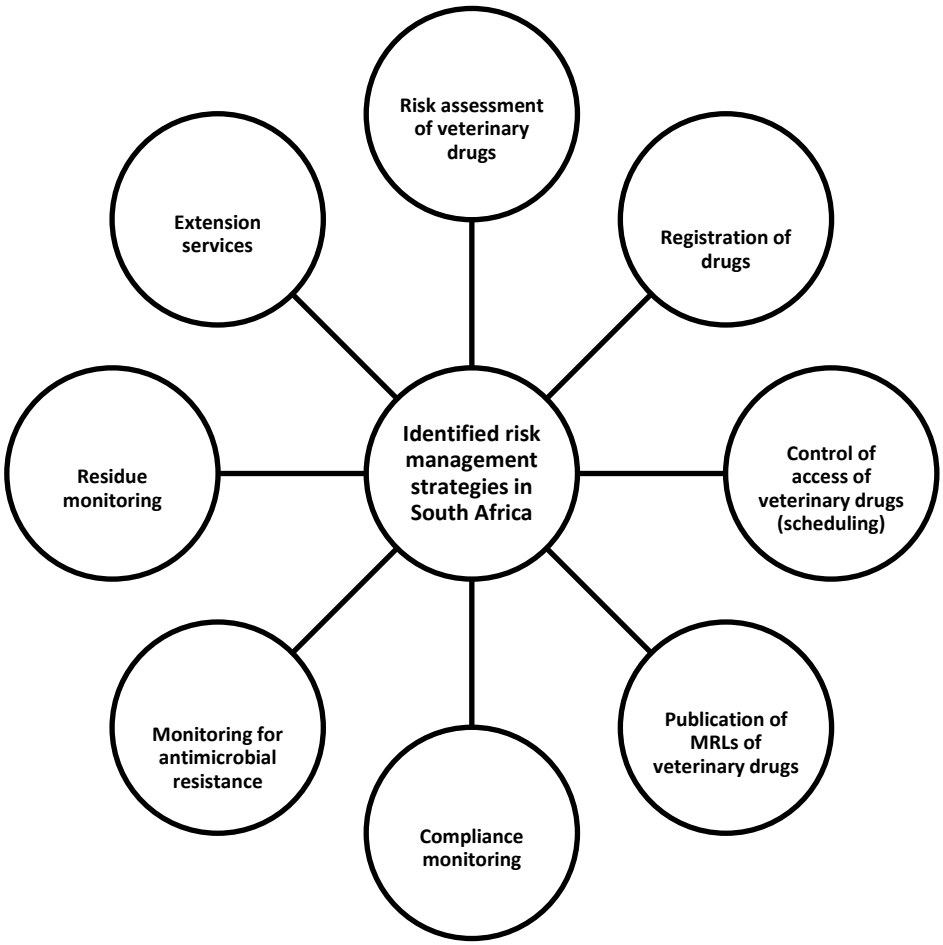

Figure 1: Risk management strategies of veterinary drug residues in foodstuffs in South Africa

SECTION C:

You have been identified as being involved in the following risk management strategies regarding veterinary drugs indicated in figure 1 above:

- **Risk assessment**
- **Registration**
- **Control of access (scheduling)**

Please answer the following:

1. Describe your key performance areas/job functions.	

2. Which legislation provides for your job functions?
3. Why do you think your job is relevant?

4. Veterinary drug residues in food is a relevant food safety issue? Do you (place an in x to indicate your choice):				
1. Strongly agree	**2. Agree**	**3. Don't know**	**4. Disagree**	**5. Strongly disagree** **6.**

5. Are there any challenges in performing your duties? Please describe these in detail.		
Challenge		**Description/examples**
a.		
b.		
c.		
d.		

6. How could these challenges be overcome or lessened?	
Challenge	**Possible solution**
a.	
b.	
c.	
d.	

RISK ASSESSMENT

A scientifically based process where the theoretical risk of a veterinary drug is assessed. This involves assessing toxicity and exposure of the veterinary drug to the human population.

Please answer the following:

1. Describe how RISK ASSESSMENT of veterinary drugs/stock remedies is related to drug residues in foods.

2. Describe (a) how and (b) by whom RISK ASSESSMENTS for veterinary drugs/stock remedies are conducted in South Africa.	
(a) How	**(b) By whom**

3. How efficient do you think your office is in terms of:					
	1. Excellent	**2. Good**	**3. Don't know**	**4. Average**	**5. Poor**
Turnaround time (from applicant to assessment to decision)					
Getting dossiers to risk assessors for evaluation					
Traceability (of applications and decisions)					
Record system of applications					
Database of registered veterinary medicines					
Knowledge of staff					
Number of staff					
4. If you answered average or poor, please explain why you think this is the case. Please provide examples where possible.					
Turnaround time (from applicant-assessment-decision)					
Getting dossiers to risk assessors for evaluation					
Traceability (of applications and					

decisions)	
Record system of applications	
Database of registered veterinary medicines	
Knowledge of staff	
Number of staff	

5. How do you propose the inefficiencies of your office could be overcome or lessened:	
	Proposals
Turnaround time (from applicant-assessment-decision)	
Getting dossiers to risk assessors for evaluation	
Traceability (of applications and decisions)	
Record system of applications	
Database of registered veterinary medicines	
Knowledge of staff	
Number of staff	

6. How does South Africa's RISK ASSESSMENT for veterinary drugs, compares to that of other countries? What do you think are the major differences and similarities in the following categories?		
Don't know		
	Differences	**Similarities**
Knowledge of staff		
Knowledge of evaluators		
Number of staff		
Number of evaluators		
Method of conducting risk assessment		
Scope of risk assessment		
Number of risk assessment authorities		
Other		

REGISTRATION

Refers to the system whereby pharmaceutical companies apply to a Government Department to have their drug assessed so that it can be used in the country.

Please answer the following:

1. Describe how you think REGISTRATION of veterinary drugs/stock remedies are related to veterinary drug residues in foods.

2. Describe (a) how and (b) by whom REGISTRATION of veterinary drugs/stock remedies are conducted in South Africa.	
(a) How	**(b) By whom**

3. How does South Africa's REGISTRATION of veterinary drugs compares to that of other countries? What do you think are the major differences and similarities in the following categories?		
Don't know		
	Differences	**Similarities**
Time it takes to register		
Database of registrations		
Re-evaluation of registration		
Number of registration authorities		
Other		

CONTROL OF ACCESS

Refers to the process of how drugs of different toxicity and specialisation are accessed. In South Africa medicines are scheduled according to their toxicity if registered under the Medicines and Related Substances Act, 1965. This means that some drugs are accessed over-the-counter while others need prescriptions.

Please answer the following:

1. Describe how you think the CONTROL OF ACCESS of veterinary drugs/stock remedies is related to veterinary drug residues in foods.

2. Describe (a) how and (b) by who CONTROL OF ACCESS of veterinary drugs/stock remedies are conducted in South Africa.	
(a) How	**(b) By whom**

3. How do you think South Africa's CONTROL OF ACCESS of veterinary drugs/stock remedies compares to that of other countries? What do you think are the major

differences and similarities in the following categories?		
Don't know		
	Differences	**Similarities**
Method of controlling access		
Revaluation of scheduling status		
Monitoring of scheduling post market		
Other		

SECTION D:

REMAINING RISK MANAGEMENT STRATEGIES

PUBLICATION OF MRLS

This refers to legislation that states the maximum residue limits (MRLs) of specific veterinary drugs for specific foods.

Please answer the following:

1. Do you think PUBLICATION OF MRLs of veterinary drug residues is an important strategy? Please place an x in the relevant box.			
Yes		**No**	
2. How do you think PUBLICATION OF MRLs relates to veterinary drugs in general?			

3. By whom do you think PUBLICATION OF MRLs of drugs is conducted in South Africa? Place an x to indicate your choice. You can choose more than 1. **4. Also rate the UPDATING/AMENDMENT OF MRLS on the scale next to your choice.**						
	Place an x for your choice/s	**1. Excellent**	**2. Good**	**3. Don't know**	**4. Average**	**5. Poor**
National Department of Health						
National Department of Agriculture						
Other Government Departments						
Provincial Health Departments						
District/local Health Departments						
Provincial/Regional Agriculture Departments						
Other						
Don't know						
5. If you rated average or poor please indicate what can be done to increase the efficiency of UPDATING/AMENDING MRLs.						

COMPLIANCE MONITORING

This refers to monitoring of foods by Government to determine if they comply with published MRLs as per legislation of a country. Also infers follow-up action if foods are non-compliant like destruction of foods or prevention of sale of foods.

Please answer the following:

1. Do you think COMPLIANCE MONITORING of veterinary drug residues is an important strategy? Please place an x in the relevant box.	
Yes	**No**
2. How do you think COMPLIANCE MONITORING relates to veterinary drugs in general?	

3. By whom do you think COMPLIANCE MONITORING of drugs is conducted in South Africa? Place an x to indicate your choice. You can choose more than 1.
4. Also rate the efficiency of COMPLIANCE MONITORING on the scale next to your choice.

	Place an x for your choice/s	**1. Excellent**	**2. Good**	**3. Don't know**	**4. Average**	**5. Poor**
National Department of Health						
National Department of Agriculture						
Other Government Departments						
Provincial Health Departments						
District/local Health Departments						
Provincial/Regional Agriculture Departments						
Other						
Don't know						

5. If you rated average or poor please indicate what can be done to increase the efficiency of COMPLIANCE MONITORING.

ANTIMICROBIAL RESISTANCE MONITORING

This refers to a programme that continually tests whether microbes in humans or foods are resistant to antibiotics. In this context it refers to a programme initiated by Government).

Monitoring for antimicrobial resistance is not a functional RM strategy in South Africa by Government. It is not exclusively an RM strategy for determining resistance caused by veterinary drug usage in livestock and could include resistance caused by use in the medical field. This risk management strategy has up until now only been considered at the academic level.

Based on this, please answer the following:

1. Describe what (a) ANTIMICROBIAL RESISTANCE is and (b) how it relates to veterinary drugs/stock remedies in food?	
(a) What is antimicrobial resistance?	**(b) How does it relate to veterinary drug residues in food**

2. Do you think monitoring for ANTIMICROBIAL RESISTANCE is an important risk management strategy? Please place an x in the relevant box.			
Yes		**No**	
Why?			

3. ANTIMICROBIAL RESISTANCE is feasible in South Africa. Do you:				
1. Strongly agree	**2. Agree**	**3. Don't know**	**4. Disagree**	**5. Strongly disagree**
4. Explain your choice.				

5. Do you think your current key performance areas could integrate ANTIMICROBIAL RESISTANCE monitoring? (please mark with a tick)				
1. Strongly agree	**2. Agree**	**3. Don't know**	**4. Disagree**	**5. Strongly disagree**
6. Why?				

7. Who do you think should be involved in ANTIMICROBIAL RESISTANCE monitoring?			
Government		**Other stakeholders**	
Name	**Reason for being**	**Name**	**Reason for being**

	involved		involved

8. Describe any existing challenges in Government that you think could hamper implementation of an ANTIMICROBIAL RESISTANCE programme by Government?	
Challenge	**Description**

RESIDUE MONITORING

This refers to a monitoring programme that tests various foods to determine amounts of veterinary residues in them. Is different to compliance monitoring, as no follow-up actions (like fining the manufacturer), are conducted. It is mainly for determining trends in usage veterinary drugs.

Please answer the following:

1. Do you think RESIDUE MONITORING of veterinary drug residues is an important strategy? Please place an x in the relevant box.	

2. How do you think RESIDUE MONITORING relates to veterinary drug residues in food?

3. Are you aware of any Government activities regarding RESIDUE MONITORING: Please place an x in the relevant box.	
Yes	**No**

4. If yes, by whom do you think RESIDUE MONITORING of drugs is conducted in South Africa? Place an x to indicate your choice. You can choose more than 1.
5. Also rate the efficiency of the RESIDUE MONITORING on the scale next to your choice.

	Place an x for your choice/s	1.Excellent	2. Good	3. Don't know	4.Average	5. Poor
National Department of Health						
National Department of Agriculture						
Other Government Departments						
Provincial Health						

Departments						
District/local Health Departments						
Provincial/Regional Agriculture Departments						
Other						
Don't know						

6. If you rated average or poor please indicate what can be done to increase the efficiency of RESIDUE MONITORING.

EXTENSION/OUTREACH SERVICES

Refers to Government initiated services that inform, educate and communicate to farmers and other stakeholders on use of veterinary drugs, animal production and animal health.

Please answer the following:

1. Do you think EXTENSION/OUTREACH SERVICES of veterinary drug residues is an important strategy? Please place an x in the relevant box.	
Yes	**No**
2. How do you think EXTENSION/OUTREACH SERVICES relates to veterinary drugs in general?	

3. Are you aware of any Government activities regarding EXTENSION/OUTREACH SERVICES? Please place an x in the relevant box.	
Yes	**No**

4. If yes, by whom do you think EXTENSION/OUTREACH SERVICES of drugs is conducted in South Africa? Place an x to indicate your choice. You can choose more than 1.

5. Also rate the efficiency of the EXTENSION/OUTREACH SERVICES on the scale next to your choice.

	Place an x for your choice/s	**1. Excellent**	**2. Good**	**3. Don't know**	**4. Average**	**5. Poor**
National Department of Health						
National Department of Agriculture						
Other Government Departments						
Provincial Health Departments						
District/local Health Departments						
Provincial/Regional Agriculture Departments						

Other						
Don't know						

7. If you rated average or poor please indicate what can be done to increase the efficiency of EXTENSION/OUTREACH SERVICES.

SECTION E:

GENERAL: COMMUNICATION

1. Who do you interact with WITHIN THE DEPARTMENT OF HEALTH (national, provincial, district, and local) on a frequent basis and why (regarding veterinary drugs/stock remedies)?	
Name of section	**Reason for interaction**

2. When do you interact?		
No.	**Interaction requirement**	**Choose (you can choose more than one option)**
1	Only when there is an issue to discuss	
2	Only when input is required	
3	Only for updating other sections within the Department	
4	Other	

3. Which of the following formal communication channels exist through which you communicate to sections WITHIN THE DEPARTMENT OF HEALTH (at all levels-national, provincial, district, local)? Please also rate which you think are the most effective (where 1 is the most effective and 5 the most ineffective).			
No.	**Communication channel**	**Channels used. (Place an x in the relevant boxes)**	**Rate (1 to 5)**
1.	Physical meetings		
2.	Through website		
3.	Letters		
4.	Email		
5.	Telephone		
6.	Other		

4. Do you think you (or your section) should be communicating with any other sections WITHIN THE DEPARTMENT OF HEALTH (at all levels-national, provincial, district, local)? Please place an x in the relevant box.			
Yes		**No**	

Which other sections?	
Why?	

5. Which OTHER GOVERNMENT DEPARTMENTS do you interact with on a frequent basis (regarding veterinary drugs/stock remedies)?	
Name of Department	**Reason for interaction**

6. When do you interact?		
No.	**Interaction requirement**	**Choose (you can choose more than one option)**
1	Only when there is an issue to discuss	
2	Only when input is required	
3	Only for updating other sections within the Department	
4	Other	

7. Which of the following formal communication channels exist through which you communicate to OTHER GOVERNMENT DEPARTMENTS (at all levels-national, provincial, district, local)? Please also rate which you think are the most effective (where 1 is the most effective and 5 the most ineffective).			
No.	**Communication channel**	**Channels used. (Place an x in the relevant boxes)**	**Rate (1 to 5)**
7.	Physical meetings		
8.	Through website		
9.	Letters		
10.	Email		
11.	Telephone		
12.	Other		

8. Do you think you should be communicating with OTHER GOVERNMENT DEPARTMENTS? Why? Please place an x in the relevant box.			
Yes		**No**	
Which other Departments?			
Why?			

9. Which STAKEHOLDERS (NOT GOVERNMENT) do you interact with on a frequent basis (regarding veterinary drugs/stock remedies)?	
Name of Stakeholder	**Reason for interaction**

10. When do you interact?		
No.	**Interaction requirement**	**Choose (you can choose more than one option)**
1.	Only when there is an issue to discuss	
2.	Only when input is required	
3.	Only for updating stakeholders	
4.	Other	

11. Which of the following formal communication channels exist through which you communicate to sections STAKEHOLDERS (NOT GOVERNMENT)? Please also rate which you think are the most effective (where 1 is the most effective and 5 the most ineffective).			
No.	**Communication channel**	**Channels used. (Place an x in the relevant boxes)**	**Rate (1 to 5)**
13.	Physical meetings		
14.	Through website		
15.	Letters		
16.	Email		
17.	Telephone		
18.	Other		

12. Do you think you should be communicating with OTHER STAKEHOLDERS (NOT GOVERNMENT)? Why? Please place an x in the relevant box.			
Yes		**No**	
Which other stakeholders?			
Why?			