



Veterinary Legislation Support Programme

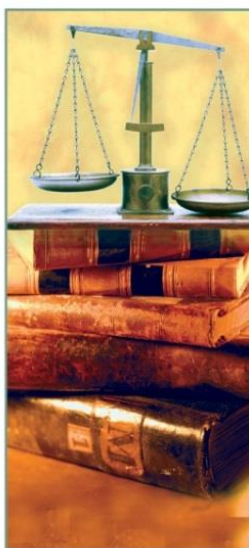
MALAWI

Veterinary Legislation Identification Mission Report

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May
2016

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VETERINARY LEGISLATION SUPPORT PROGRAMME

REPORT OF THE VETERINARY LEGISLATION IDENTIFICATION MISSION

MALAWI

9TH – 13TH May 2016

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Disclaimer

This mission has been conducted by an OIE PVS Team authorised by the OIE. However, the views and the recommendations in this report are not necessarily those of the OIE.

The results of this report remain confidential between the evaluated country and the OIE until such time as the country agrees to release the report and states the terms of such release.

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List of acronyms

ADD	Agriculture Development Division
AHSA	Animal Health Surveillance Assistant
AI	Artificial Insemination
AIDS	Acquired Immune Deficiency Syndrome
ASWAp	Agricultural Sector Wide Approach
AU	African Union
AU-IBAR	African Union – Inter-African Bureau for Animal Resources
CAADP	Comprehensive African Agricultural Development Programme
CDAA	Control and Diseases of Animals Act
CE	Continuing Education
CLC	Chief Legislative Counsel
COMESA	Common Market for Eastern and Southern Africa
CVL	Central Veterinary Laboratory
CVO	Chief Veterinary Officer
DADO	District Agricultural Development Office
DAHLD	Department of Animal Health and Livestock Development
DDRI	Deputy Director for Research and Investigation
DVS	Director of Veterinary Services –CVO
EPA	Extension Planning Area
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FFFA	Fertilisers, Farm Feeds and Remedies Act
FMD	Foot and Mouth Disease
GDP	Gross Domestic Product
HACCP	Hazard Analysis and Critical Control Point
HIV	Human Immunodeficiency Virus
HIPC	Heavily Indebted Poor Countries
LUANAR	Lilongwe University of Agriculture and Natural Resources
MBS	Malawi Bureau of Standards
MGSDII	Malawi Growth and Development Strategy II (2011-2016)
MK	Malawi Kwacha
MLC	Malawi Law Commission
MoAIWD	Ministry of Agriculture, Irrigation and Water Development
MoH	Ministry of Health
MoIT	Ministry of Industry and Trade
MoJCA	Ministry of Justice and Constitutional Affairs
MoNREE	Ministry of Natural Resources, Energy and Environment
MRL	Maximum Residue Level
NGO	Non-governmental Organisation
OIE	World Organisation for Animal Health
OIE-PVS	OIE Performance of Veterinary Services Evaluation Tool

PHA	Public Health Act
PMPA	Pharmacy, Medicines and Poisons Act
PPR	Peste de Petits Ruminants
PS	Permanent Secretary
RVF	Rift Valley Fever
SADC	Southern African Development Community
TAD	Transboundary Animal Disease
TAHC	OIE Terrestrial Animal Health Code (2014)
TB	Tuberculosis
UN	United Nations
VET-GOV	Reinforcing veterinary governance in Africa project (AU-IBAR / EU-funded)
VLIM	Veterinary Legislation Identification Mission
VLSP	Veterinary Legislation Support Programme
VPH	Veterinary Public Health
VPP	Veterinary Para-professional
VPVPA	Veterinary and Para-Veterinary Professionals Act
VS	Veterinary Services
VSF	Veterinary Statutory Body (see OIE Code definition)
WTO	World Trade Organisation

Acknowledgements

The conduct of this OIE PVS (Performance of Veterinary Services) Veterinary Legislation Identification Mission by Dr John Woodford (Team Leader), Dr Tania Thomson (Veterinary Expert) and Ms Jessica Vapnek (Legal Expert), hereinafter called the Team, has been formally authorised by the OIE. The support provided by OIE to this mission is acknowledged with thanks. The Team also acknowledges and gives thanks for the assistance provided by Dr Moetapele Letshwenyo, OIE Regional Commission for Southern Africa, in setting up this legislation mission.

The Team wishes to express its sincere thanks to Ms Erica Maganga, Principal Secretary for the Ministry of Agriculture, Irrigation and Water Development (MoAIWD), who met with the Team on the morning of the penultimate day of the mission. Ms Maganga gave the Team valuable insight into the vision of the Ministry, acknowledging that the livestock sector had not always received the support it deserved, but that this situation was beginning to change as the role that this sector plays in the national economy as well as its importance to small holder farmers was becoming more widely recognised in political circles. Ms Maganga assured the Team that in view of the current potential for export of live poultry and poultry products and other animal products, as well as the potential gains in improved food safety for domestic consumers, she would give priority to supporting the process of legislative reform to bring Malawi's veterinary legislation in line with international standards.

The Team would also like to thank Ms Angela Kaunda, Legislative Counsel at the Ministry of Justice and Constitutional Affairs (MoJCA), who also met with the Team and assisted with clarifications sought on the legislative framework for the veterinary domain in Malawi.

The Team would like to give thanks to Dr Ben Chimera, Director of the Department of Animal Health and Livestock Development (DAHLD) and OIE Delegate for Malawi for requesting the OIE to undertake this mission and for the assistance he gave in making the arrangements both before and during the mission.

Special thanks go to Drs Patrick Chikungwa and Poya Njoka, who helped to complete Questionnaire Part II and assembled a dossier of useful legislative and other important documents to guide our understanding of the situation with regard to the Veterinary Services (VS) prior to the mission, and who ensured that the Team was able to meet with a wide range of stakeholders, which enriched discussions during the succession of meetings held during the mission.

In addition, we would like to thank all the other members of staff of the DAHLD, Dr Pat Boland, (Director, National Rural Poultry Centre) and the representatives of other agencies, and ministries and organisations, who freely gave of their time and experience to assist in the successful accomplishment of this mission.

Finally, we would like to thank Mr Cryson Chawinga, the Department's driver, for his careful attention to our safety in looking after our logistical arrangements during the mission.

Executive Summary

Background

Malawi is a small land-locked and densely populated country in central, southern Africa, bordered on the north by Tanzania, to the east by Zambia and to the south and west, by Mozambique. More than 80% of Malawi's population of 16.8 million, (increasing at the rate of 3.1% / annum), are engaged in agriculture.¹ Small-scale mixed crop and livestock farming predominates, with only 15% of livestock owners classified as being commercial². As the human population density increases, so more and more land, which was formerly available as grazing land, is being cultivated to grow subsistence crops, mainly maize, cassava, millet and sorghum. Nevertheless, livestock production probably contributes close to 11% of Gross Domestic Product (GDP).

Livestock development in Malawi is guided by a Livestock Policy which was formulated in 2006, and which is currently under review. Although this Livestock Policy pre-dates the Malawi Agricultural Sector Wide Approach (ASWAp), an investment plan prepared in 2009, and the overall strategy for national development (the Malawi Growth and Development Strategy II (MGDS II) 2011 – 2016), it is still extremely relevant, with the mission statement:

“A sustainable livestock development to improve nutritional well-being of Malawians and improved rural livelihoods while guaranteeing the safety of the general public from consumption and utilisation of livestock products and by-products.”

Amongst the strategic objectives within this Livestock Policy is the promotion of commercial agricultural production, value addition and developing domestic and export markets demonstrating a shift towards investments which will stimulate farmers to increase production beyond the level of subsistence towards a marketable surplus.

In recent years a project known as “The President’s Initiative” which involves the distribution of goats to farming households on the basis of a soft loan that is repaid through “passing-on” the first progeny to another household, thus becoming self-perpetuating, has been extremely successful. The goat population in Malawi has more than doubled in the last ten years. Commercial poultry production is starting to become well established in Malawi with six or seven large producers, which are able to gain access to relatively cheap animal feeds. There is already a surplus of hatching eggs and day-old chicks available to commercial producers, which is being exported to neighbouring countries.

The VS of Malawi have undergone considerable structural adjustments over the past decade, with decentralisation of services through local government and the privatisation of routine clinical VS. The privatisation process has lacked any formal support and is not progressing as well as had been expected. With the shortage of qualified veterinarians and the large number of veterinary para-professionals (VPPs), private VS delivery faces regulatory challenges in terms of supervision of veterinary activities and the use of prescription only medicines by VPPs. Enforcement of veterinary drug supply regulations is weak, with farmers also having ready access to medicines, “over the counter”, from pharmacies.

In spite of these shortcomings, the Team has found that the Department of Animal Health and Livestock Development (DAHLD) has a small cadre of well qualified veterinarians who are directly involved with the drafting and implementation of the legislation covering the veterinary domain in Malawi. At the field level, the Team was impressed with the knowledge

¹ <http://www.worldbank.org/en/country/malawi> -accessed 16/05/16 (hereinafter World Bank Report)

² Livestock Policy (2006) (MoAIWD)

and dedication of the veterinary (para-professional) inspector deployed at the Dedza border inspection post (border with Mozambique). During the mission the Team appreciated the commitment and enthusiasm demonstrated by the veterinarians and VPPs who participated in the review of their legislation.

Summary of Main Findings and Recommendations

Three ministries regulate the veterinary domain in Malawi, namely the Ministry of Agriculture, Irrigation, and Water Development (MoAIWD), the Ministry of Health (MoH), and the Ministry of Industry and Trade (MoIT). The MoAIWD is responsible for the prevention and control of animal diseases, the regulation of the veterinary profession and the inspection of animals for food. The MoH, through the *Public Health Act* (1948) (PHA) and the *Pharmacy, Medicines and Poisons Act* (1988) (PMPA), respectively, has responsibility for regulation of food of animal origin and veterinary drugs. Imports and exports of animals and animal products are the responsibility of the MoAIWD (through the DAHLD) as well as the MoIT (*Control of Goods Act* (1954) and Regulations).

The MoH and the MoAIWD share responsibility for regulating food safety of animal products, the import and export of animal products, the control of food processing premises and the import, manufacture, distribution, sale and use of veterinary medicines. Similar overlap of responsibility with regard to the import and export of animals, animal products and other commodities exists with the MoIT and the MoAIWD. The Malawi Bureau of Standards (MBS) is also undertaking certain inspectorate functions in order to enforce its standards, going beyond the usual remit of a standard-setting body.

In each case there is a need to review and reach agreement on the respective roles of each competent authority in order to avoid duplication of effort and to ensure that all aspects of regulatory control are covered effectively.

It is recommended that the MoH and MoAIWD establish a formal working group for collaboration and communication with regard to the revision of existing and development of new legislation and for sharing information concerning the enforcement of regulatory controls, especially in the areas of food safety of animal products, the regulation of the distribution and use of veterinary medicines and biologicals and the prevention and control of zoonotic diseases. A “One Health” committee may be considered as an appropriate mechanism for creating a long-term relationship between the two ministries whereby issues of mutual interest are resolved through closer collaboration and perhaps sharing of scarce resources.

Although there is a chain of command from DAHLD headquarters to veterinary officers and VPPs deployed in the field it is not clearly articulated in the legislation. It is recommended that in future proposed legislation, a clear chain of command be established from the Minister down to the field. It is recommended that provisions are made to ensure that the post of Chief Veterinary Officer (CVO) is always held by a registered veterinarian and that this person is designated as the executive head of the DAHLD, which may be identified as the competent authority for animal health and welfare and veterinary public health. Powers and functions assigned to the CVO can then be delegated to veterinary officers and VPPs working at lower levels of the state VS, including private animal health practitioners, according to their qualifications or specialised training.

The principal piece of legislation covering animal health is the *Control and Diseases of Animals Act* (CDAA) (1967). This Act is outdated and does not cover some important aspects of disease surveillance and disease prevention and control, the regulation of veterinary diagnostic laboratories, authorisation of official tests and analyses and the quality assurance of test reagents. In view of the extent of the gaps identified during this mission, the Team recommends that the CDAA be replaced with a new draft proposed Animal Health Act. Several options exist as to whether or not to include provisions in this proposed new law

covering animal identification and animal welfare. These areas of regulation could easily be incorporated into the Act and then be supported by separate regulations. Alternatively, each topic may be developed in a separate stand-alone law.

As is mentioned above, the regulation of import and export of animals, animal products and other commodities which might present a risk to human or animal health or life or the environment is shared by MoH, MoAIWD and MoIT, however, there are currently no provisions in any of the legislation which make reference to compliance with any international standards. It is recommended that import and export regulation be revised to include provisions which ensure compliance with OIE (and Codex Alimentarius, in the case of foods of animal origin) standards and especially that sanitary measures to be imposed on imported animals or other commodities are made in accordance with OIE standards or shall be based upon scientific justification derived from an internationally recognised risk analysis procedure.

A *Veterinary and Para-Veterinary Practitioners Act* (VPVPA) was enacted in 2001, but as yet there has been no appointment made to the Board of Veterinary Surgery. Furthermore, no distinction is made in this Act between the prerogatives of qualified veterinary surgeons and VPPs. Exemptions placed in a Schedule to the Act allow any government officer, in the course of his / her duties, or any person engaged in farming who does not seek payment or material advantage, to perform acts of veterinary medicine and surgery. There are no provisions in this Act to confer authority on the Board of Veterinary Surgery to regulate the quality of veterinary education and training. Furthermore, there is no mechanism for approval of attendance at short courses, seminars, workshops or self-learning exercises as Continuing Education (CE) and there are currently no requirements for a minimum CE requirement for annual retention on the veterinary or VPP registers. It is recommended that the VPVPA be reviewed and revised according to the recommendations made under Section 4.1.2 of this report.

Legislation covering the control of veterinary medicines and biologicals is included in the PMPA, administered by the MoH and the *Fertilisers, Farm Feeds and Remedies Act* (FFRA), under the MoAIWD. A revised draft Pharmacy, Medicines and Poisons Bill prepared solely by the MoH is close to being presented to Parliament. It is strongly recommended that this Act be withdrawn from the final stage of approval and reviewed by the DAHLD in order to ensure that provisions to ensure that withdrawal periods are enforced effectively. Both Ministries need to collaborate closely over the enforcement of the regulations with regard to sale and use of veterinary medicines in order to reduce the risk of development of antimicrobial resistance and the presence of drug or other residues entering the human food chain.

An *Animal Identification and Registration Bill* (2004) has been formulated largely for the purpose of controlling stock theft. This Bill has not yet been presented to Parliament for enactment. In view of increasingly rigorous requirements for the traceability of products of animal origin destined for human consumption, this Bill could benefit from review and revision to broaden its scope to include provisions for movement control and traceability of animals and animal products. Alternatively, it may be considered possible to incorporate the main provisions which define the powers and authority of the DAHLD with respect to animal identification and the limitations which affect the constitutional rights of property and privacy in a proposed draft Animal Health Act. Separate subsidiary legislation can then be developed to define the means of introducing and implementing an animal identification, movement control and traceability system. Alternatively, revised Animal Identification, Registration and Traceability Act (& Regulations) to be issued by the Minister under the CDAA could be developed.

With regard to the prevention of animal diseases associated with breeding materials, Section 6 of the CDAA makes provision for the Minister to prohibit the importation of semen, but does not make reference to ova and embryos, or domestic trade. There are no provisions for the regulation of animal breeding establishments and the safety and quality of semen, ova or

embryos which are produced locally. It is recommended that a revised Animal Health Act would have comprehensive provisions to ensure the safety and quality of all types of breeding material, both imported and domestically produced.

The FFRA makes provisions for the licensing of premises where animal by-products are processed as well as for manufacturing animal feeds. Animal by-products are not well defined in any of the existing legislation. Part of the reason for this is that almost all animal by-products, with the exception of hides, skins, hair, wool and feathers, are considered as being edible and are thus classified as “meat”. It is recommended that the FFRA be repealed, the Remedies section being redundant with the *Pharmacy, Medicines and Poisons Act* (PMPA). Proposed new draft legislation needs to be prepared to replace the existing Fertilisers and Farm Feeds sections keeping most of the existing provisions but also making provisions for the DAHLD to specify standards for construction, hygiene and food safety management at processing or manufacturing premises and the safety and quality of processed animal by-products and animal feeds. Restrictions should be made on the use of by-products from locally slaughtered animals by farmers, as animal feeds. Finally, there is a need for provisions to be made for the recall of infected or contaminated animal by-products which could pose a threat to human or animal health or life.

The *Protection of Animals Act* (1968) is the main piece of legislation related to animal welfare. However, this Act is more concerned with the prevention of cruelty to animals rather than the promotion of animal well-being. In this Act the Minister has been authorised to make rules without reference to any technical authority. As yet there have been no regulations which make provisions for the setting of standards to ensure animal well-being during production (handling, management and nutrition), during transportation, at slaughter, in the case of slaughter animals, for humane killing of animals for disease control purposes or in emergency situations and for the conduct of experiments and for working animals or animals used in sport or exhibition. It is recommended that new provisions be made either in a draft proposed “Animal Health, Welfare and Veterinary Public Health Act”, or as a stand-alone Animal Welfare Act. It is recommended that an Animal Welfare Board or Committee be established and this Board/committee be given the responsibility for setting welfare standards which would then be placed in Animal Welfare Regulations. The Regulations should also include standards for the training and CE of inspectors responsible for animal welfare.

As has been mentioned above, there is shared responsibility for the food safety of animal products destined for human consumption. Apart from concerns over clarity of the respective responsibilities of the MoH and MoAIWD, in addition there are a number of other important shortcomings in the current legislation. Firstly, it is recommended that provisions be made in proposed new Regulations for the gradual introduction of risk-based food safety management systems, such as the Hazard Analysis and Critical Control Point (HACCP) system, in all major abattoirs. A similar approach should also be adopted for all smaller slaughter facilities. It is also recommended that the responsibility for the safety and quality of their products be placed on the owners of all food processing facilities, in accordance with the standards set in the legislation. There is also need for collaboration between the DAHLD and the MBS in order to better define their respective roles in setting and enforcing standards of food safety.

A detailed analysis of all of the abovementioned issues is given in Chapter 4 of this Report and a proposed outline strategic plan for the process of review and revision of the veterinary legislation is provided in Chapter 5.

Report

1. Background to the mission

There have been two previous PVS Pathway missions carried out in Malawi, a PVS Evaluation Mission conducted in June 2007 and a PVS Evaluation Follow-up Mission undertaken in January 2014. This Veterinary Legislation Identification Mission (VLIM) was conducted in May 2016 by Dr John Woodford, (Team Leader), Dr Tania Thomson, (Technical Expert [Veterinary]), and Ms. Jessica Vapnek, (Technical Expert [Legislation]), at the request of Dr Ben Chimera, Director, Department of Animal Health and Livestock Development (DAHLD) and OIE Delegate representing the DAHLD of Malawi.

The overall objectives of the VLIM are:

- (i) to evaluate Malawi's veterinary legislation and its compliance with Chapter 3.4 of the OIE Terrestrial Animal Health Code (TAHC),
- (ii) to support the identification of Malawi's national priorities in terms of veterinary legislation, and
- (iii) to identify the available human resources, and
- (iv) to propose a comprehensive plan to modernise Malawi's veterinary legislation.

Malawi ranks as one of the least developed countries in Africa. Eighty-five percent of the population live in rural areas where they are mainly engaged in small scale mixed crop and livestock farming³. In recent years several large commercial poultry enterprises have been established and these now produce a surplus of hatching eggs and day-old chicks which are being exported to neighbouring countries. A project launched some years ago to distribute goats to less well-off farmers has been successful in more than doubling the number of goats held by small-scale famers in Malawi over the past decade. If this trend continues, it is likely that a surplus of goat meat may become available for export in the future. Enormous opportunities exist to satisfy the growing demand for meat in the Middle East and Malawi has a comparative advantage over many of its competitors in the region due to the absence of endemic Rift Valley Fever (RVF) and Peste des Petits Ruminants (PPR).

The vision of the DAHLD is embodied in a Policy Document on Livestock in Malawi dated 2006. It states:

"Malawi becoming a nation that is self-sufficient in safe locally produced livestock and livestock products."

More recently an agriculture sector policy and strategic plan which includes components related to the livestock sub-sector was included in ASWAp in 2009. The ASWAp includes three components directly related to the activities of the DAHLD:

- A Food Security and Risk Management Component that *"calls for malnutrition to be reduced by measures that includes small stock (goat meat and milk), pigs, rabbits, chicken and guinea fowl meat and eggs, and fish"*, and
- A Commercial Agriculture, Agro-Processing and Market Development Component that *"will entail promoting commercial agriculture production involving smallholder farmers, agricultural diversification, agro-processing for import substitution and value addition, developing the domestic and export markets for inputs and outputs"*, and

³ World Bank Report, *supra* note 1

- An Institutional Strengthening and Capacity Building Component that *“will focus on strengthening public institutions, building capacity in public management systems and improving resource allocation for effective implementation of agricultural programs.”*

The intention is to develop more public private partnerships involving producers, buyers, input dealers, service providers and policy makers in the value chain. The inclusion of the promotion of commercial agricultural production, value addition and developing domestic and export markets demonstrates a shift towards investments which will stimulate farmers to increase production beyond the level of subsistence towards a marketable surplus.

In a document entitled Departmental Document - A Contribution Towards Ministry of Agriculture and Food Security Website, dated 2008, the DAHLD has identified the need for a review and revision of the legislation covering the veterinary domain.

This report records an analysis of the existing legislation and some draft legislation covering the veterinary domain in relation to its compliance with OIE standards as defined in Chapter 3.4 of the TAHC. The report identifies gaps and drafting inconsistencies in the existing legislation and provides guidance for the continuing review and revision of the veterinary legislation for Malawi.

2. Methodology

The Veterinary Legislation Identification Mission (VLIM) which is the subject of this Report has been conducted following two previous OIE PVS Pathway missions, A PVS Evaluation Mission conducted in April 2007 and a PVS Evaluation Follow-up Mission conducted in January 2014.

This mission was conducted by Dr John Woodford, (Team Leader and Veterinary Expert), Dr Tania Thomson (Veterinary Expert) and Ms Jessica Vapnek (Legal Expert).

The VLIM was conducted in the English language, the official language of the Government of Malawi. The overall responsible person for the conduct of the mission was Dr Ben Chimera, Director, DAHLD and OIE Delegate representing the government of Malawi. The focal point for assisting with the conduct of this mission was Dr Patrick Chikungwa, Deputy Director, Department of Research and Investigation.

The mission was conducted after the offsite review of some of the more important legal texts covering the veterinary domain, responses to Questionnaire Part II and other documents covering the operations of the DAHLD which were described in a series of reports provided to the Team prior to the mission.

Questionnaire Part I was completed during the mission with the assistance of the veterinary legislation focal point and legislative counsel at the Office of the Attorney General, MoJCA.

The itinerary and selection of stakeholders for consultation during the mission was planned in collaboration with the Deputy Director, Department of Research and Investigation through an exchange of emails prior to the mission. Some amendments to the draft proposed itinerary were made at a meeting held between the Team and the Director DAHLD on the morning of the first day of the mission.

With the exception of MoH food safety authorities, the Team was able to meet with all of the principal actors involved with development and implementation of the key Acts and Regulations covering the veterinary domain, including the Registrar of the Pharmacy Board of the MoH in the area the control of veterinary medicines and biologicals.

There were some inaccuracies noted with regard to some responses to Questionnaire Part II due to misunderstandings in interpretation of the questions and analysis of the existing Acts and Regulations. A thorough review of Questionnaire Part II was undertaken during a succession of meetings held at the meeting room adjacent to the Central Veterinary Laboratory (CVL) to which a wide range of stakeholders were invited, as appropriate to each section of the questionnaire. The discussions held during these meetings proved to be extremely useful and resulted in a much clearer understanding of the quality of the existing legislation covering Malawi's veterinary domain with respect to the OIE standards embodied in Chapter 3.4 of the TAHC.

The offsite review of existing legislation carried out before, during and after the mission combined with the detailed onsite review, completion and correction of the Questionnaires is the basis for the assessment of Malawi's veterinary legislation to determine compliance with the standards defined in Chapter 3.4 of the OIE TAHC.

On the penultimate day of the mission the Team had an opportunity to visit the Dedza border inspection post approximately 100 km from Lilongwe on the border between Malawi and Mozambique. This field trip allowed the Team to have a snapshot of how veterinary legislation is being implemented by a well-trained cadre of VPPs. The border inspector at Dedza border inspection post, a Veterinary Assistant with many years of experience, demonstrated a good understanding of his responsibilities and confirmed that he has been able to enforce regulations effectively in the recent past.

The official correspondence relating to the organisation of this mission is provided in Appendix 1 to this Report.

3. Socio-economic and policy context of the veterinary services

3.1 Economic Factors

The economy of Malawi is predominantly agricultural with about 80% of the population living in rural areas. Agriculture accounts for one-third of GDP and 90% of export revenues. The livestock industry contributes about 8% to the total GDP and about 36% to the value of total agricultural products. However, taking into consideration other important uses of livestock such as food provision, income generation, manure, animal traction and social security, then the livestock sub-sector contributes well over 11% to the GDP.⁴

Nevertheless, Malawi's economy depends on substantial inflows of economic assistance from the International Monetary Fund, the World Bank, the European Union (EU) and individual country / agency donor contributions. In 2006, Malawi was approved for relief under the Heavily Indebted Poor Countries (HIPC) program.

According to the World Bank⁵, *"The government faces many challenges including developing a market economy, improving educational facilities, facing up to environmental problems, dealing with the rapidly growing problem of HIV/AIDS, and satisfying foreign donors that fiscal discipline is being tightened."*

Real gross domestic product (GDP) grew by 5.7% in 2014 but slowed down to 2.8% in 2015 as Malawi suffered from dual challenges of adverse weather conditions and macroeconomic instability. Flooding in southern districts followed by countrywide drought conditions saw a contraction in agricultural production. Maize, the key crop for food security purposes, saw a 30.2% year-on-year drop in production. As a result, an estimated 2.8 million people (17% of the population) are unable to meet their 2015/16 food requirements."

Farming systems in Malawi are characterised by two complementary forms of land tenure, large "estates" where commercial scale production of mainly tobacco and certain food crops takes place and smallholdings with a mixed crop / livestock production system of low productivity, allowing for largely subsistence consumption with some small surpluses available for sale in local markets.

During the 1970s and 1980s, agricultural policy was aligned towards achieving food security under a centrally managed economy; however, during the 1990s, the policy shifted in favour of market liberalization in order to respond to changing circumstances. It was also realized that diversified agricultural production would promote availability of varied food crops and livestock to improve human nutrition and serve as a source of foreign exchange.

Despite such efforts in the sector, poverty has remained widespread and severe. The poor performance of the livestock sector at that time was partly blamed on the lack of emphasis in the formulation and implementation of agricultural strategies and policies targeting livestock as well as the poor performance of the cropping sector. Furthermore, as the demand for cropping land has been increasing in response to human population growth, so more and more land, formerly available for livestock grazing, has come under the plough, pushing livestock production towards more marginal land.

In the light of this historical context, the former Ministry of Agriculture and Food Security (now MoAIWD) reviewed its structure and mandate to better articulate its

⁴ <https://www.cia.gov/library/publications/the-world-factbook/geos/mi.html>

⁵ <http://www.worldbank.org/en/country/malawi/overview>

functions and meet the increasing demand for service delivery and expectations of the public.

The guiding principles which were used to provide direction in terms of areas of intervention in the livestock sub-sector are embodied in the Policy Document on Livestock in Malawi dated 2006. This policy document was prepared in order to articulate specific areas of intervention responding to the policy guidelines provided in the Ministry of Agriculture Strategic Plan prepared in 2002 and the Road Map on Agricultural Development in Malawi prepared in 2005. The priority areas are:

- 1 *“Demand driven livestock services delivery - Delivery of extension services will respond to new demands from farmers - Livestock extension agents shall be sensitized to facilitate the evolution of demand driven system.*
- 2 *Pluralism of service delivery - DAHLD to promote various private actors in the provision of extension service delivery.*
- 3 *Privatisation of some livestock services - The Department shall advocate privatization of non-core functions. The public sector shall limit its functions to core activities of clear “public good”. This policy acknowledges the transfer of responsibility for routine preventive and curative services to the private sector.*
- 4 *Cost recovery and cost sharing – DAHLD to introduce cost recovery for provision of certain services of private good nature.*
- 5 *Participatory approach and community empowerment - Farming communities will have an opportunity to prioritise and have commitment to their activities enhancing ownership, accountability, transparency and sustainability.”*

And the overall objectives for livestock development were stated as:

- *“to articulate the specific strategies and activities that can boost livestock production.*
- *to respond effectively to the challenges of poverty reduction and improving rural livelihoods in Malawi.*
- *to create an enabling environment and promotion of private sector, NGOs and farmer participation with government providing inspection, regulatory roles and backup for export markets.”*

The specific objectives of the policy were:

- *“to liberalise marketing and involvement of non-governmental organizations (NGOs) and farmer groups to facilitate capacity development in the livestock sub-sector.*
- *to specifically tailor the livestock development strategies to contribute to challenges of poverty reduction and improvement of rural livelihoods in Malawi.*
- *to coordinate and network the roles of the various stakeholders in the Livestock sub-sector, and in particular the private sector (commercial producers), NGOs, farmers associations and cooperatives and the public sector.*
- *to prevent and control animal diseases in order to create an enabling environment for the improvement of livestock production.*
- *to protect the public from zoonotic and food-borne diseases.”*

The changes which are now in the process of being introduced respond to the implementation of the ASWAp, which is a five-year investment plan⁶. The total budget over a four year period (2011-2015) for the ASWAp was estimated at US\$ 2,191,678,026, which was to be sourced from both the Government of Malawi and development partners.

In effect, the ASWAp has acted as a strategic development and investment plan providing a framework for the coordination of funding for government and donor-assisted programmes and projects in agriculture. The plan has been elaborated in line with the policies outlined in the Malawi Growth and Development Strategy II (MGDS II) 2011 – 2016, it is consistent with the Comprehensive African Agricultural Development Programme (CAADP) and the Development Assistance Strategy. The CAADP, sitting under the umbrella of the New Partnership for Africa's Development, provides the regional context of achieving sustainable agricultural growth and development through actions implemented at the national level. The Development Assistance Strategy provides an international framework on aid harmonisation.

One of the most successful projects to have been introduced under ASWAp for the livestock sector has been the "Presidential Initiative on Small Stock Production" programme initiated in 2012 by former President of Malawi, Joyce Banda. The small stock production programme is being implemented through a partnership between government and NGOs and is based on the concept of "Pass-on", whereby a householder receives 4-5 young female goats on credit and repays the "loan" through passing on an equivalent number of offspring to other farmers in their locality. The scheme is working well and Malawi's goat population has more than doubled over the past ten years as more small-holders learn of the benefits to be derived from keeping goats as better quality grazing resources become scarcer.

It has been recorded in the PVS Follow-up Report of 2014 that the "Presidential initiative" mentioned above has boosted current funding for DAHLD from about Malawi Kwacha (MK) 56 million in previous years to MK 4 billion in 2014. However, the animal health program has been heavily dependent on "development" funding from an Animal Health Improvement Project and a Southern African Development Community (SADC) Trans-boundary Animal Disease (TAD) project that ended in 2013. This dependency on donor assistance would suggest that the sustainability of financing of DAHLD activities is questionable. Furthermore, the conduct of certain core functions at and below the district level may be compromised by the dual technical / administrative chains of command between the DAHLD and the Ministry of Local Government. It was also recorded in the same PVS report that DAHLD has negotiated for the establishment of a Livestock Trust Order, which will see more of the revenue collected by the DAHLD for services rendered, being retained for use by the department. At present it is evident from the findings of previous OIE missions and our observations during this mission that the DAHLD does not receive sufficient funds to maintain, repair or replace existing infrastructure or equipment nor to perform all of its core functions effectively and in accordance with international standards.

⁶ <ftp://ftp.fao.org/tc/tca/CAADP%20TT/CAADP%20Implementation/CAADP%20Post-Compact/Investment%20Plans/National%20Agricultural%20Investment%20Plans/Malawi%20Post%20Compact%20Investment%20Plan.pdf>

3.2 Social Factors

Malawi is landlocked, bordered by Mozambique to the south and west, Zambia to the east and Tanzania to the north. It had an estimated population of 16.8 million as of 2014, increasing at the rate of 3.1% annually⁷.

The agricultural sector employs about 80 percent of the workforce, generates over 80 percent of foreign exchange earnings and contributes significantly to both national and household food security.

Although Malawi has been able to make important economic and structural reforms and sustain its economic growth rates over the last decade with support from the World Bank and the International Monetary Fund, poverty is still widespread and the economy remains undiversified and vulnerable to external shocks. The livestock sector has seen significant developments in terms of diversification with the expansion of commercial poultry production, the rapid expansion of goat and pig production and the introduction of semi-commercial fresh water fisheries, rabbits and guinea fowl as alternative sources of household protein.

Farming systems in Malawi are characterised by two complementary forms of land tenure, large “estates” where commercial scale production of mainly tobacco and certain food crops takes place and smallholdings with a mixed crop / livestock production system of low productivity, which allows for largely subsistence consumption with some small surpluses available for sale in local markets. However, as the demand for cropping land has been increasing in response to human population growth, so more and more land, formerly available for livestock grazing, has come under cultivation, pushing livestock production towards more marginal land.

3.3 Animal Health and the Veterinary Services

The DAHLD is one of the 6 departments of the MoAIWD. Below these departments there are 8 Agricultural Development Divisions (ADDs). Each ADD replicates the activities of the 6 departments at the national level. Under the 8 ADDs there are 28 District Agricultural Development Offices (DADO). Each ADD covers several districts. The 28 DADOs are divided into 154 Extension Planning Areas (EPAs). The departments are responsible for policy formulation, regulatory functions and general coordination while ADDs are responsible for implementation of core functions through the DADOs. Administratively, ADDs are headed by Program Managers while District Agricultural Division Officers head the District Offices. Animal Health Officers at the district offices are administratively responsible to the Program Managers and technically responsible to Director DAHLD. The split between technical and administrative / financial reporting has been identified in previous PVS reports as being potentially unsatisfactory, since there have been instances where district level officers were unable to perform their core technical functions due to lack of resources being made available by the local authority administration. Such administrative / organisational difficulties may compromise the ability of field personnel to respond appropriately to either animal or human health sanitary emergencies in the future.

Currently there are 17 qualified veterinarians working within the DAHLD. Almost all of these are working in the CVL or at an administrative post located within the central headquarters in Lilongwe. The majority of core functions at the field level are performed by a well-trained cadre of approximately 400 VPPs.

⁷ World Bank Report, *supra* note 1

In a report prepared in 2014, (Template for Country Presentation on the Status and Assessment of Strengths, Weaknesses, Gaps and Needs) the DAHLD has identified four core functions which have been listed as follows:

Regulatory functions:

- *Disease surveillance, control of notifiable diseases and planning for disease emergencies and reporting to international bodies and neighbouring countries.*
- *Regulation, monitoring and support of other partners in the animal health care system.*
- *Accreditation of veterinary personnel.*
- *Creation of an enabling environment for the private sector.*
- *Formulation of livestock development policy.*
- *Livestock movement control.*
- *Provision of quarantine services.*
- *Import/export certification.*
- *Veterinary medicinal products registration and quality control of remedies and vaccines.*
- *Promotion of animal welfare.*
- *Reviewing and updating veterinary legislation.*
- *Compliance monitoring.*

Inspectorate functions:

- *Provision of meat inspection (oversight of food of animal origin safety).*
- *Safe disposal of veterinary medical products and livestock feeds.*
- *Quality control of foods of animal origin and livestock feeds.*
- *Inspection and accreditation of hatcheries, livestock farms, dairy and meat processing plants for certain standards such as tuberculosis and brucellosis free status.*
- *Investigations of feed additives and unregistered growth promoters used in animal production and emergence of resistance to drugs and acaricides.*

Extension and training:

- *Provision of livestock extension in animal husbandry in order to improve production of beef, dairy, poultry, small ruminants and pigs.*
- *Strengthening of farmer livestock groups.*
- *Facilitation of private sector participation in animal husbandry and delivery of veterinary services.*
- *Training of farmers and field staff in animal husbandry and health techniques e.g. artificial insemination, Basic Animal Health Interventions etc.*

Veterinary investigation, diagnostics and research services:

- *Investigation of disease outbreaks in support of field services.*
- *Provision of a routine diagnostic service to monitor the animal health status of the country.*
- *Conducting demand driven research in animal production and health.*

It was reported in the OIE PVS Report in 2007 that the livestock sector had, in recent years, attracted considerable investments through government, international agencies, bilateral aid from individual donor countries and NGOs enabling the importation of 250 dairy cattle and significant numbers of goats and poultry.

The PVS Follow-up Mission was unable to obtain accurate figures on the budget allocation or actual fund disbursements made to the DAHLD but it is recorded that the budget had increased from MK 56 million to MK 4 billion, in 2014. In spite of this increase in financial resources, there appears to have been little investment in infrastructure maintenance and repairs since 2014.

With regard to equipment and mobility, the situation at headquarters is now considerably improved through investments made under the SADC TAD project and the “President’s Initiative” programme.

At a meeting held with the Principal Secretary (PS) on the penultimate day of the mission the Team was informed that the EU has recently signed an agreement with the Government of Malawi with a commitment for 1 million Euros for agricultural development. A (OIE) PVS Gap Analysis would help to identify the resources required by the DAHLD for prioritized areas of intervention for investment in the livestock sub-sector.

Table 1 makes a comparison between the national herd in 2007 compared with that recorded in the 2014 PVS Follow-up Mission Report.

Table 1. A comparison between livestock numbers 2007 - 2014

Livestock Numbers	2007⁸	2014⁹
Cattle	880,000	1,220,734
Sheep	188,000	254,891
Goats	2,720,000	5,180,785
Pigs	929,000	2,711,221
Poultry	32,000,000	61,577,432
Rabbits	N/a	1,306,871
Guinea Fowl	N/a	1,650,382
Ducks	N/a	1,324,075

Of considerable interest are the trends for poultry, goat and pig populations, each of which have more or less doubled in the last seven years. Commercial poultry producers are already in a position to export day-old chicks and hatching eggs. It would seem likely that with the rapid growth in the pig and goat populations there will soon be an exportable surplus of pork and goat meat. Both of these opportunities alone provide a strong justification not only for the revision of the legislation covering the veterinary domain but also considerable investments to be made to develop the capacity of the VS to perform its regulatory functions to the standards required by potential trading partners, especially those of the Middle East for goat meat. Malawi has a comparative advantage over East African competitors due to the absence of RVF and PPR.

The DAHLD has been an active participant in several regional and continental livestock programmes supported by SADC, the Common Market for Eastern and Southern Africa (COMESA) and the African Union (AU). A National Livestock Policy

⁸ National Census of Agriculture and Livestock 2006/07

⁹ Source not identified (OIE PVS Follow-up Mission Report 2014)

Hub has been established under an African Union-Inter-African Bureau for Animal Resources (AU-IBAR) supported initiative within the implementation of the program “Reinforcing veterinary governance in Africa” that engages mainly public sector institutions. It currently has committees on breeding policy, animal health strategy and national livestock policy.

3.4 National legal framework

Malawi is a unitary state; the government consists of 28 administrative districts and a unicameral National Assembly.

The Constitution of the Republic of Malawi was adopted in 1994 and as the supreme law of Malawi, is binding on the state at all levels. Any act of government or any law inconsistent with the provisions of the Constitution is invalid.

The Constitution guarantees the separation of powers. Sections 7 to 9 of the Constitution provide the obligations of three distinct and independent branches of government: the executive, the legislature, and the judiciary.

The Constitution can be amended by a two-thirds majority of the National Assembly but the substance of the Constitution can only be changed following a popular referendum. A number of amendments to the Constitution have been made to date, including the elimination of a second house of Parliament.

Section 12 contains the fundamental principles of the Constitution:

- (a) All legal and political authority of the state derives from the people of Malawi and shall be exercised in accordance with the Constitution solely to serve and protect their interests.
- (b) All persons responsible for the exercise of powers of state do so on trust and shall only exercise such power to the extent of their lawful authority and in accordance with their responsibilities to the people of Malawi.
- (c) The authority to exercise power of state is conditional upon the sustained trust of the people of Malawi and that trust can only be maintained through open, accountable and transparent government and informed democratic choice.

The Constitution contains a Bill of Rights, which guarantees certain fundamental rights to all people of Malawi including the rights to life, liberty, personal freedom, dignity, equality, and privacy, as well as academic freedom and freedom of conscience, expression, information, belief, thought, religion, movement and assembly. These rights include the right to be protected from unreasonable search and seizure and to be unreasonably deprived of personal property. Restrictions on the exercise of these rights must be reasonable, recognized by international human rights standards and necessary in an open and democratic society. Expropriation of property is permitted only when done for a public purpose and only when there has been adequate notification and appropriate compensation, provided that there shall always be a right to appeal to a court of law.

Malawi has a mixed legal system. Its sources of law include constitutional law, statutory law, English law (received English law and other English law), common law, customary law, religious law and customary international law.

The Constitution provides for the continued application of the common law and customary law in force at the time the Constitution was adopted, except insofar as they are inconsistent with the Constitution. It also states that as they evolve, customary law and common law should respect the provisions of the Constitution. In addition, religious law is respected and enforced in certain instances, for example, marriage and inheritance.

With respect to international law, any international agreement that was binding before or at the creation of the 1994 Constitution remains binding; any international agreements made thereafter require an Act of Parliament to take effect as domestic law. The Constitution also provides that in interpreting the Constitution, courts shall *'where applicable, have regard to current norms of public international law and comparable foreign case law'*.

Malawi is a member of SADC, the AU, the UN (United Nations), the Commonwealth, COMESA, the Food and Agriculture Organisation of the UN (FAO) and the ILO (International Labour Organisation) and the World Organisation for Animal Health (OIE).

Executive

The executive consists of the President, Vice-President and Cabinet. The President is the head of state and government. The role of the executive is to propose policies and laws and to implement laws in accordance with the will of the people in line with the provisions of the Constitution. The presidency is limited to two consecutive terms of five years each. The President is responsible for assenting to Parliamentary Bills; calling and chairing Cabinet meetings; making government appointments; and negotiating and entering into international agreements. The President appoints both the Vice President and the Cabinet.

The Cabinet serves an advisory role to the office of the President. Its members include the President, First Vice-President, Second Vice-President and other Ministers appointed by the President. Functions of the Cabinet include initiating bills for submission to the National Assembly, preparing the budget and assisting the President in determining what international agreements are to be concluded.

Judiciary

The judicial power consists of a court system with three levels. The Supreme Court of Appeal, which is the highest court in the country, only has appellate jurisdiction on appeals from the High Court and other courts. It is composed of the Chief Justice and nine other Justices.

The High Court of Malawi, consisting of three divisions (General Division, Commercial Division and High Court Sitting on Constitutional Matters), has unlimited original jurisdiction to make determinations on civil, criminal and constitutional matters brought under any law in the country. Most High Court cases are heard before a single judge, without a jury, but cases on constitutional matters must be heard by three judges.

At the bottom of the judicial hierarchy are the subordinate courts, consisting of the Industrial Relations Court, which adjudicates labour and employment disputes, and Magistrate Courts (of which there are five grades and whose powers vary depending on their grades). According to section 35 of the Courts Act, all Magistrate Courts have territorial jurisdiction throughout Malawi. Hence they can hear any criminal or civil case. In practice, however, they ordinarily defer to the magistrate court in the area where the crime was committed.

Other subordinate courts are traditional courts, recognized under the 1994 Constitution. Their jurisdiction is limited exclusively to civil cases at customary law, defined minor common law cases and statutory civil cases. In April 2011, the National Assembly passed the Local Courts Act, which effectively formalized the traditional court system below the Magistrates Court level.

Officials of the MoJCA include the Attorney-General, the Solicitor-General and the Director of Public Prosecutions, who are all appointed by the President. The Minister of Justice is the political head of the Ministry. The Minister is responsible for the

Malawi legal sector and reports directly to the President and Cabinet, as well as to the people through the National Assembly.

The Attorney-General is the principal legal advisor to the government. In addition to advising the government on all legal matters, the Attorney-General conducts civil litigation for and on behalf of the government. The Solicitor-General supervises and monitors civil litigation, the drafting of legislation, and the negotiation of agreements for and on behalf of the government. The Solicitor General is also responsible for the operations of the MoJCA in the performance of its legal functions.

Legislature

Legislative power belongs to the National Assembly, which consists of 193 members who represent constituencies in the country. Each Member of Parliament is elected by a simple majority of votes for a term of five years. The National Assembly may delegate the power to make subordinate legislation to the executive or the judiciary, provided that such legislation does not substantially and significantly affect the fundamental rights and freedoms recognized by the Constitution.

Where a Bill is presented to the President, he or she must assent or not assent within 21 days. When the President withholds assent, the Bill is returned to the Speaker of the National Assembly and after 21 days the Bill can be debated again. When a Bill is assented to it is published immediately in the Gazette. No Act can come into force until it has been published in the Gazette, but Parliament may prescribe a later effective date in the publication in the Gazette.

According to the Constitution, an Act of Parliament has primacy over other forms of law but is subject to the Constitution. Subsidiary legislation consists of regulations, rules and other statutory instruments including notices and orders.

The Malawi Law Commission (MLC) is a constitutionally mandated body, made up of 11 lawyers, with the power to review the laws of Malawi to ensure that they are in accordance with the Constitution and relevant international laws. Once the law has been reviewed, the MLC issues recommendations contained in a report to Parliament.

Veterinary legislation

Three ministries regulate the veterinary domain in Malawi, namely, the MoAIWD, the MoH and the MoIT. The MoAIWD is responsible for the prevention and control of animal diseases, the regulation of the veterinary profession and the inspection of animals for food. The MoH, through the PHA and the PMPA, respectively, has responsibility for regulation of food of animal origin and veterinary drugs. Imports and exports of animals and animal products are the responsibility of the MoAIWD (through the DAHLD) as well as the MoIT (*Control of Goods Act* (1954) and Regulations).

The DAHLD is responsible for developing and implementing the government's livestock policy. To prepare new or amended legislation, DAHLD staff work with their assigned Legislative Counsel in the Drafting Section of the MoJCA. The Drafting Section is headed by the Chief Legislative Counsel (CLC) who is appointed by the President. The CLC is assisted by the Assistant Chief Legislative Counsel, Legislative Counsel, Assistant Legislative Counsel of various grades, Law Revision Officers and a Bill transcriber.

The OIE Team was heartened to hear that the DAHLD relies on its assigned Legislative Counsel when it wishes to draft or revise legislation. Nonetheless, the team believes that some additional effort to cultivate and involve the relevant Legislative Counsel(s) in committee meetings or discussions will be time well spent with the goal of continuing to sensitize the legal experts to the livestock context and needs of DAHLD.

DAHLD states that it carries out public and stakeholder consultations when preparing legislation. Evidence suggests that this is not particularly widespread or institutionalized across the government: During this mission the Team and the DAHLD became aware of the MoH's new draft proposed Medicines, Pharmacy and Poisons Act, which covers veterinary drugs and which is approaching the final stages of adoption, which was prepared without consultation with MoAIWD.

The Ministry of Home Affairs and Internal Security, through the Police Service, assists with the enforcement of legislation in the veterinary domain.

Malawi legislation is not generally available online although a handful of statutes are at the site www.malawilii.org. In book form, the Consolidated Laws of Malawi is a collection of key statutes updated periodically (most recently through 2010).

In addition to developing closer contacts with the Legislative Counsel, DAHLD is recommended to continue to cultivate contacts on the agricultural committee of the National Assembly so that it is aware of all pending legislation that may affect the veterinary domain.

4. Review of the national veterinary legislation

Table 2. Critical competency levels achieved at PVS Evaluation Follow-up Mission 2014

The levels of achievement of the critical competencies related to the veterinary legislation have not changed during the period that has elapsed between the conduct of the PVS Evaluation conducted in April 2007 and the Follow-up Mission conducted in January 2014. In spite of this finding, there is a small group of senior veterinarians in the DAHLD who are familiar with many of the issues concerning the performance of regulatory functions and the need to review and revise the veterinary legislation.

Critical Competency	PVS Follow-up 2014
IV.1 Preparation of legislation and regulations	2
IV.2 Implementation of legislation and regulations and compliance therewith	2
IV.3 International harmonisation	2
IV.4 International certification	2

The main legal instruments governing the veterinary domain in Malawi are as follows:

1 Acts and Regulations administered by the MoAIWD (DAHLD and, in the case of the FFFRA, other competent authorities):

- 1.1 CDAA (Cap 66.02) (1967) and subsidiary Regulations, Orders, Rules and Notices.
- 1.2 VPVPA (Cap 53.04) (2001)
- 1.3 FFFRA (Cap 67.04) (1970) and Regulations
- 1.4 Meat and Meat Products Act (Cap 67.02) (1975) and Regulations
- 1.5 Milk and Milk Products Act (Cap 67.05) (1971) and Regulations
- 1.6 Slaughter of Cattle Act (Cap 50.04) (1969)
- 1.7 Hides and Skins Trade Act (Cap 50.02) (1955)
- 1.8 Pesticides Act (Cap 35.03) (2000) and Regulations
- 1.7 Protection of Animals Act (Cap 66.01) (1944)

2 Acts and Regulations administered by other competent authorities:

- 2.1 PHA (Cap 34.01) and Regulations administered by MoH
- 2.2 PMPA (Cap 35.01 and Regulations, administered by MoH with veterinary representation on Pharmacy Board
- 2.3 Control of Goods Act (1954) (Cap 18.08) (1968) (administered by the MoIT)
- 2.4 Biosafety Act (Cap 60.03) (2002) and Regulations, administered by the Ministry of Natural Resources, Energy and Environment (MoNREE)
- 2.5 National Parks and Wildlife Act (1992) (administered by MoNREE)

Two additional pieces of legislation which have been drafted but not yet presented to Parliament for approval and promulgation, the draft revised *Milk and Milk Products Act* and the draft *Animal Identification and Registration Bill* (2004), were reviewed and comments are provided in the relevant sections of this Chapter of the report.

A full list of Acts, Regulations and Orders covering the veterinary domain in Malawi is provided in Appendix 7.

The CDAA mainly addresses the prevention and control of animal diseases, import and export of animals and animal products, animal quarantine and movement control. In this Act, “disease” has been defined as a list of important diseases which are common in Malawi, but the list is incomplete, thus many of the provisions of the Act refer only to those listed diseases. The Act is supported by a number of Regulations, Rules and Orders defining the modalities of implementation and the conditions of compliance.

The VPVPA establishes a Veterinary Statutory Body (VSB), the Board of Veterinary Surgery, which has the responsibility for setting minimum qualifications for eligibility for registration of veterinarians and VPPs and the maintenance of a Register; it has detailed provisions to define how the Board functions and provisions for making enquiries and taking disciplinary action in connection with alleged cases of improper conduct on the part of registered persons.

Although the Act was promulgated in 2001, as yet the Board has not been established nor have any regulations been developed or promulgated. In this Act no distinction is made between the respective prerogatives of veterinarians and VPPs with regard to the practice of veterinary medicine and surgery, and an exemption clause within the Schedule of the Act allows any government employee to conduct “operations, treatments, tests, advice and diagnosis” in the course of his/her duties. Such exemptions are unusual and contrary to OIE standards.

The *Meat and Meat Products Act* (1975) and the *Milk and Milk Products Act* (1971) both make provisions for the regulation of the food safety of products of animal origin destined for human consumption. There is some overlap between the authority and powers of the MoAIWD and the MoH in the PHA. Furthermore, there is a need to include certain other provisions, to be detailed below, which will bring both of these Acts in line with OIE and other international standards.

The FFFRA covers the registration of plants at which animal by-products are sterilised prior to being used as ingredients in animal feeds and the registration of “remedies” and fertilisers. Remedies are defined as medicines used for the prevention or treatment of animals which are not prescription-only medicines. The provisions of this Act overlap with those of the PMPA.

A detailed analysis of these Acts and their compliance with OIE standards is given in the following sections of this report.

4.1 General assessment of selected subject areas

General observations on the legislation covering the veterinary domain

The most important overall observations made with regard to internal and external quality of the legislation covering the veterinary domain are as follows:

4.1.1 Inconsistencies in definition of terms and the use of subjective adjectives

There are a number of instances where subjective adjectives or adverbs (underlined below) have been used in the legislation. Examples include: Part 1, section 2 of the Veterinary and Para-Veterinary Practitioners Act – which states “providing of any treatment [...] such as is usually performed, given or provided by veterinary surgeons”; Section 27(c) of the same Act refers to a person who “is in all aspects as to character and otherwise, a fit and proper person to be registered.” And in Section 28 “acting on the advice of the Board, deems sufficient.” In the draft revised *Milk and Milk Products*

Act Section 2: “milk” means exclusively the normal mammary secretion” and “raw milk” means “normal fresh milk milked from cows and other bovines.” In each of the above instances a subjective judgement must be made as to what is “usually”, “fit or proper”, “sufficient” or “normal” or “fresh”. It is recommended that the use of such adjectives and adverbs be avoided and instead a precise requirement be prescribed in the law.

4.1.2 Inconsistencies / overlap or lack of clarity in roles and responsibilities between different competent authorities

There are several instances where there is either overlap or lack of clarity of roles and responsibilities between two distinct competent authorities each of which has been mandated with similar authority, powers and responsibilities.

One such inconsistency is in the PHA where the Minister of Health has been given the authority to enforce border control through the restriction of the importation of “*animals, articles or things*” (Section 38 (1) (b). The same authority has been given to the Minister of Agriculture under Section 6 of the CDAA and to the Minister of Trade in the *Control of Goods Act* (1954), which makes provisions for the control of the import and export, manufacture, distribution and sale of animals, animal products and other commodities.

Once again in the PHA, and this time in relation to food safety of animal products, Section 106 (1) makes provision for the prohibition of the importation, sale or presenting at a market of any “*unwholesome or adulterated “food”*” and provides authority to *any medical officer of health, veterinary officer, health inspector, or any administrative officer or police officer of or above the rank of a sub-inspector*”, to seize and destroy any such food; Such a provision allows officers who do not hold a technical qualification to make technical decisions on food safety.

Under Section 109 of the PHA, the Minister is given the authority to make rules related to the inspection of animals, dairy stock and premises used for manufacture or processing of meat and milk and the taking of samples of meat or milk for bacteriological testing and finally the seizure, destruction and disposal of animal products which have been found to be unfit or unwholesome for human consumption. Similar provisions giving the same responsibilities to the DAHLD, exist in the *Meat and Meat Products Act* (1975), the *Milk and Milk Products Act* (1971) and the subordinate Regulations under these two Acts.

Section 109 of the PHA also gives the Minister the authority to make rules governing the licensing of premises for the retail sale of meat, milk and fish, however no authority has been given for the licensing and registration of premises used for the processing of meat and milk or the transport of meat and milk from such premises to wholesale or retail outlets. In the case of licensing and registration of premises used for processing meat and milk, and the transportation of meat and milk, appropriate provisions are made in the *Meat and Meat Products Act* (1975) and the *Milk and Milk Products Act* (1971), respectively.

Finally, Section 35 of the PMPA provides the Pharmacy Board with the responsibility to license persons who wish to import, manufacture, distribute or sell medicinal products and Section 66 of the same Act, makes provisions for the Minister of Health to make regulations covering all aspects of the regulation of medicinal products. However, Section 2 of the FFFRA defines a “remedy as being: “*any substance which is intended or offered, [] in regard to poultry, domestic animals, livestock or plants, for the prevention, treatment or cure of any disease, infestation or other unhealthy or unfavourable condition, or for the maintenance of health, but does not include any substance prescribed by a veterinarian for a specific patient or group of patients*”. Thus this definition covers veterinary medicines which would be sold to the public

without prescription. Section 3 of the FFFRA prohibits the importation, manufacture, sale or distribution of any remedy unless it has been registered by a Registrar appointed by the Minister (of Agriculture). There is thus overlap of responsibilities between the MoAIWD and MoH.

4.1.3 Gaps in the existing legislation

The most important gaps where no legislation exists or where existing legislation is incomplete or insufficient are as follows:

Competent authority, governance of veterinary services, chain of command:

- the lack of a definition of “Minister” as being the Minister responsible for animal health and veterinary services;
- the lack of identification of the DAHLD as being the competent authority for the regulation of animal health, welfare and veterinary public health;
- the lack of designation of the Director DAHLD as CVO, who shall be a registered veterinary surgeon, as the executive with responsibility for the day-to-day management, implementation and enforcement of the Act and subsidiary legislation pursuant to it;
- lack of authority of the CVO to delegate powers and responsibilities to technically qualified veterinary officers or VPPs depending on technical training and the task to be performed;
- lack of authority of the CVO to contract the services of private registered veterinarians or VPPs to perform certain defined public functions on behalf of the DAHLD.

Veterinarians and VPPs:

- lack of a good definition of “the practice of veterinary medicine and surgery”;
- lack of any distinction between the prerogatives of a registered veterinary surgeon and the different categories of registered VPPs;
- lack of inclusion of provisions for the regulation of Continuing Education (CE) for veterinary surgeons and VPPs, including provisions for mandatory CE requirements to retain registration.

Veterinary diagnostic laboratories:

- the lack of any provisions for the designation, roles, responsibilities, obligations and quality requirements for national or other reference laboratories for the conduct of official tests and analyses;
- the lack of authorisation of public or private veterinary diagnostic laboratories to perform official tests and analyses or to conduct tests for the purpose of quality control;
- the lack of provisions for official accreditation and approval of procedures for conducting official tests or analyses;
- the lack of authorisation of reagents used to perform official tests and analyses;
- the lack of provisions to ensure the quality assurance of manufacturers of reagents used to perform official tests and analyses;
- the lack of provisions to ensure the surveillance of marketing of reagents.

Animal production:

- lack of provisions which define the scope of an animal identification, movement control and traceability system (other than for the prevention of theft);
- lack of definitions and provisions for specifying:
 - animal identification marks and animal identification marking devices;
 - registration of animal identification marks,
 - the regulation of movement of identified animals;
 - restricted access to and management of animal identification information management, including the confidentiality of animal identification information;
- no definition with respect to the respective roles and responsibilities of government and owners of animals which have been identified;
- insufficient provisions covering the authorisation and inspection of animal gatherings / markets;
- insufficient provisions covering the safety and quality of animal breeding materials;
- insufficient provisions for setting standards of compliance related to construction, hygiene control at processing premises and the safety and quality of animal feeds and animal by-products.

Food safety of animal products:

- Lack of clarity as to which competent authority is responsible for regulation of safety of animal products at all stages of the value chain from “farm to fork”.
- No provisions to ensure the adoption of risk-based management procedures at food processing premises handling products of animal origin destined for human consumption;
- Lack of reference to international standards for Maximum Residue Limits (MRLs) (Codex Alimentarius);
- No provisions for the recall of animal products destined for human consumption;

Animal health:

- no prescribed obligation on the part of the DAHLD to investigate suspected cases or outbreaks of notifiable diseases, to determine a diagnosis based upon laboratory confirmation and to maintain accurate records of all suspected or confirmed cases or outbreaks of notifiable disease;
- no provisions to ensure the development of contingency plans for prevention and control of exotic or emerging diseases and the administrative and logistical organisation of such plans;
- no provisions to pay compensation to the owners of animals / animal products which have been subjected to seizure and/or slaughter or destruction in the event of an outbreak of a notifiable animal disease;
- no provisions to define the circumstances under which the competent authority may exercise “exceptional powers” and gain access to “emergency funds”;

Animal welfare:

- lack of a requirement in law for the owner of an animal to ensure the well-being of an animal in his or her care.
- lack of appropriate definitions of “animal”, “animal well-being”, “humane killing”, “humane slaughter”, “journey”, “resting period” and others;
- lack of provisions for DAHLD to collaborate with private sector institutions and NGOs with an interest and competency in animal welfare;
- lack of an appropriately qualified, designated (Animal Welfare) Board or Committee to set, review, revise, as necessary and implement / enforce animal welfare standards;
- lack of provisions to authorize the Minister (on the advice of an Animal Welfare Board / Committee), to make regulations for setting standards of: management, handling and nutrition of animals, the humane slaughter of food animals and the humane destruction of animals for other reasons, the conduct of experiments using animals and the use of animals in sport or for exhibition.

Veterinary medicines and biological substances:

- the definition of what is a “veterinary medicine” or “biological substance” in legislation related to the control of veterinary medicines and biologicals;
- the establishment / labelling of withdrawal periods of veterinary medicines at the time of dispensing;
- lack of provisions to ensure that withdrawal periods are respected by the users of veterinary medicines on food-producing animals;
- lack of specific provisions for setting standards for MRLs in animal products destined for human consumption or other commercial purposes;
- lack of provisions to allow the use of prescription-only veterinary medicines and biologicals by VPPs under the supervision of a registered veterinary surgeon.

Import and export certification:

- lack of any reference to compliance with World Trade Organisation (WTO) or other international standards for international trade of animals, animal products and other commodities which may present a risk to human or animal health or life or the environment;
- lack of provisions requiring sanitary measures, which have been set as requirements for import to be complied with before and at departure of a consignment of animals or animal products and other commodities and certified as such, by the competent authority of an exporting country, to be in accordance with OIE standards or based upon scientific justification derived from the conduct of an internationally approved risk analysis procedure;
- lack of provisions detailing inspection procedures on arrival at a designated border inspection post.

4.2 Detailed assessment of selected subject areas

Where appropriate, sub-sections below are numbered with reference to the corresponding numbered sections in Questionnaire Part II. For clarity, those Questionnaire numbers are preceded by the letter Q.

4.2.1 Competent authorities, chain of command, veterinary governance (Article 3.4.5 TAHC)

The following Acts and Regulations (indented) were consulted to analyse the various competent authorities covering activities within the veterinary domain:

CDAA (1961) (competent authority for animal health and some aspects of veterinary public health – zoonotic disease prevention and control)

Diseases of Animal Rules (1928)

Movement of Livestock Regulations (2003)

Prohibition of Treatment except by Veterinary Officers (1928).

Animals Quarantine Rules (1968)

Control and Diseases of Animals (Prohibition of Importation of Animals) Order (1990)

'Draft' Animal Identification and Registration Bill (2004)

Hide and Skin Trade Act (1955)

Control of Goods Act (1954) (MoIT)

Control of Goods (Import and Export) (Agriculture) Order (1967)

Control of Goods (Import and Export) (Agriculture) Regulations (1967)

Control of Goods (Import and Export) (Commerce) Regulations (1967)

FFFA (1970)

Protection of Animals Act (1968)

PHA (1948) (competent authority for public health and food safety)

Meat and Meat Products Act (1975)

Meat Inspection Regulations (1968)

Slaughter of Cattle Act (1969)

Milk and Milk Products Act (1971)

Draft revised Milk and Milk Products Act (undated)

Q1.1 – 1.5 Competent Authorities

(legal mandate, powers, qualification, authority to apply sanctions, liability, access to premises and property, sample collection, seizure, destruction and disposal, delegation of powers).

Animal health – veterinary governance, chain of command

Although not specifically designated as such in the veterinary legislation, the *de facto* competent authority for the prevention and control of diseases and animal welfare in Malawi is the DAHLD. A definition of “disease” in the Act is inadequate. This is because the list of diseases provided in Section 2 of the CDAA is incomplete, missing some important zoonotic diseases and certain other animal diseases which are not

present in Malawi but which could enter from a neighbouring country or through the international trade of animals or animal products. Although section 4(2) allows the Minister to specify additional diseases to be covered by the provision of this Act, this would be a time consuming and cumbersome process. In future, it is recommended that a list of notifiable animal diseases be placed in a Schedule to the Act, which can be amended and updated as and when necessary. The list of notifiable diseases should be all those diseases listed by the OIE which occur in Malawi and certain other important diseases which occur in neighbouring countries or the region and which may pose a threat through international trade.

Sections 4, 6 and 8 of the CDAA provide the Minister with the authority to make Rules and Regulations. However, in none of the veterinary legislation has the “Minister” been identified as the Minister responsible for animal health and veterinary services. Furthermore, these provisions which allow the Minister to make Rules and Regulations without reference to any technical authority, (Section 8, CDAA), could compromise the technical independence of the Chief Veterinary Officer (CVO) and the DAHLD. It is therefore recommended that as and when this Act is revised, provisions shall be made firstly to identify the Minister as being the Minister responsible for animal health and veterinary services. It is further recommended that provisions be included which oblige the Minister to make Rules and Regulations only on the advice of a “Technical Standing Committee”, which should be established within the DAHLD under the Chairmanship of the CVO.

Similarly, although the CVO is mentioned in the CDAA as having certain powers, he or she has not been identified as being a registered veterinary surgeon nor as the executive head of the DAHLD. With the exception of provisions regarding “infected areas”, (Section 4), no powers have been given to the CVO to delegate any of his powers, authority or responsibilities to veterinary officers, inspectors or other official persons, including VPPs employed by the DAHLD. Instead, separate provisions are made in the Act which provide powers and define the responsibilities of authorised persons and inspectors. Furthermore, no powers have been given to the CVO to delegate certain defined public functions to private registered veterinary surgeons or private registered VPPs.

It is recommended that in proposed draft new legislation covering animal health, welfare and veterinary public health the CVO should be required to be a registered veterinary surgeon and the Director of the DAHLD. Consideration may then be given to identifying the DAHLD as being the competent authority responsible for animal health, welfare and veterinary public health. It is recommended that provisions be made to assign most core regulatory functions to the CVO and then introduce provisions which allow the CVO to delegate certain of his powers and authority to other officers, as appropriate to their level of training, thus creating a direct chain of command from headquarters to the network of officers deployed at regional and district offices, down to the field level. A distinction may be made as to which powers and authority are given to qualified veterinarians and which are given to VPPs with or without specialised training.

With the emergence of veterinarians and VPPs working in the private sector it is also recommended that provisions be included in the draft proposed new legislation to provide the CVO with the authority to engage the services of private registered veterinary surgeons or private VPPs to undertake certain defined public functions on behalf of the DAHLD. Examples of such functions might include the performance of outbreak investigations following a report of the clinical suspicion of a notifiable animal disease, collection and submission of samples to the nearest veterinary diagnostic laboratory, active surveillance activities, such as blood or other types of sample collection, performance of “public good” vaccination services and carrying out extension activities on behalf of government.

Competent authority for food safety of animal products

The MoH is recognised under the PHA as the competent authority to regulate food safety of all foods, including products of animal origin. Section 109 of the PHA provides the Minister of Health with the authority to make rules related to inspection of dairy animals and animals destined to be slaughtered for human consumption, and of dairy premises, stock sheds/ yards, slaughterhouses and milk containers, factories, stores and shops where food is manufactured, prepared or kept. Section 109 of the PHA also empowers the MoH to make Rules related to:

- *the taking and (bacteriological) examination of samples of milk, dairy produce, meat or other articles of food and from animals or articles suspected of being diseased or unfit for human consumption; and*
- *the veterinary inspection of dairy stock, and the prevention of the sale, or the keeping; transmission or exposure for sale of milk from a diseased or infected animal; and*
- *the duties of dairymen in connexion with the occurrence of infectious disease amongst persons residing or employed in or about their premises and the furnishing by them of the names and addresses of their customers, and in connexion with reporting the occurrence, in animals on the premises or any dairy cattle, of diseases which are communicable to man and of any disease of the udder;*
- *the inspection and examination of, and the regulation of the manufacture, preparation, storage, keeping and transmission of any article of food intended for sale or for export from Malawi and the prohibition of the manufacture, preparation, storage, keeping, transmission, sale or export from Malawi of any such article which is, or contains, an ingredient which is diseased or unsound or unfit for human consumption, or which has been exposed to any infection or contamination.”*

In the case of the safety and quality of meat and milk, similar powers are vested in the Minister of Agriculture in the *Meat and Meat Products Act* (1975), the *Meat Inspection Regulations* (1976) and the *Milk and Milk Products Act* (1972).

There is thus some overlap between the respective roles and responsibilities of the two Ministries.

There is a need to review and revise the PHA and the *Meat and Meat Products Act* and the draft revised *Milk and Milk Products Act* in order to harmonise responsibilities between the two Ministries to avoid duplication of effort and yet ensure the safety and quality of animal products destined for human consumption. It is recommended that the DAHLD engages with the MoH in order to define more precisely the roles and responsibilities of the two competent authorities with regard to the regulation of food safety of animal products along the entire value chain from farm to fork. The discussion may be informed by Chapters 6.1 and 6.2 of Volume I of the TAHC, for animal products destined for human consumption and 6.3 for animal by-products which may be used as animal feed. It is recommended that detailed Regulations are then prepared in order to set standards for safety and quality of animal products during production, processing, distribution and retail sale.

Competent authority for the regulation of veterinary medicines and biologicals

Section 35 of the PMPA provides the Pharmacy Board of the MoH with responsibility for licensing the importation, manufacture, distribution, sale and use of all medicines (including raw materials for their manufacture). A veterinary surgeon is appointed to

the Board in order to ensure that the interests of the veterinary profession are taken into consideration when applications for licenses are being considered by the Board. However, Section 3 of the FFFRA also prohibits the importation, manufacture, sale or distribution of any “remedy” unless it has been registered by a Registrar appointed by the Minister (of Agriculture). A remedy has been defined in this Act as being any medicine which does not require a prescription and thus includes all “general sales” veterinary medicines. There is thus overlap of responsibilities between the MoAIWD and MoH.

In practice the Team was informed that there has always been a good working relationship between the MoH and the MoAIWD with regard to making decisions for the importation of veterinary medicines. However, it was discovered during a meeting with the Chairman of the Pharmacy Board during this mission that the PMPA has recently been reviewed and revised and a final version is about to be presented to Parliament, without there having been any discussion between the two Ministries (MoH and MoAIWD). It is recommended that the DAHLD request that they are consulted before the draft Bill is presented to Parliament in order to ensure that provisions, currently missing from the legislation, such as the inclusion of withdrawal periods on dispensing labels and the enforcement of withdrawal periods by end users are included in the final draft Bill.

Competent authority for the regulation of animal welfare

The DAHLD is the *de facto* competent authority for animal welfare. Although there are elements touching on animal welfare in many other pieces of legislation, the *Protection of Animals Act* (1944) is the only law which covers animal welfare in any detail. In this Act the Minister has been authorised to make Rules without reference to any technical authority. The Act focusses more on the prevention of cruelty rather than ensuring the well-being of animals. Since the standards which are now being set (by OIE and other standard-setting bodies) for the well-being of animals during housing, handling and transport and at slaughter or for destruction, are based upon scientific evidence it is important that there is established a corps of animal welfare experts with specialised knowledge of animal welfare standards. It is recommended that in revised Animal Welfare legislation an Animal Welfare Board or committee be established and that this Board or committee be responsible for advising the Minister as to what standards apply when developing the regulations. Since it is unlikely that there will be a separate animal welfare inspectorate in Malawi, the veterinary officers deployed by the DAHLD at the district veterinary office level should be designated as animal welfare inspectors and provided with the necessary training to allow them to enforce the regulations correctly. Consideration may be given to authorising members of NGOs with an interest in animal welfare to act as inspectors in order to support the activities of the DAHLD.

4.2.2 Veterinarians and VPPs (Article 3.4.6 TAHC)

The following pieces of legislation were consulted:

VPVPA (2001)

Section 3 of the Act establishes the Board of Veterinary Surgery as a Veterinary Statutory Body (VSB). As yet no Board members have been appointed and no Regulations have been developed for the implementation of the Act. No veterinarians or veterinary paraprofessionals have been registered, as yet. A number of other shortcomings in terms of OIE-recommended standards are detailed in the sub-sections which follow.

Following a detailed analysis of this Act it is recommended that the Act be reviewed and amended in accordance with the recommendations given below:

Q2.1 Veterinary medicine / science

Q2.1 (a) Definition of the prerogatives of veterinarians and various categories of VPPs

The current definition of the “practice of veterinary surgery” in Part 1 Section 2 of the VPVPA lacks sufficient clarity and may lead to legal uncertainty. Firstly, there is a reference to “the practice of veterinary medicine”, which is not defined and secondly, there are references to performing “any operation” and certain acts which are “usually” performed by a veterinary surgeon, which is vague and may lead to legal uncertainty.

At present there is also no distinction made between the prerogatives of a registered veterinary surgeon and those of a registered VPP. It is recommended that provisions be made in an amendment to this Act to authorise the Board to define different categories of VPP and the different acts of veterinary medicine and surgery which may be performed by each category of VPP. The range of interventions to be chosen will depend on the Day One competencies which have been determined by the Board as being appropriate for each category and by the level of training / qualification awarded to each category. This in turn will define the requirements for registration of each different category of VPP.

It is therefore recommended that “the practice of veterinary medicine and surgery” be clearly defined in an amendment to this Act, avoiding the use of subjective adverbs and including the words “surgical operation”, which in turn needs to be defined. These definitions will have an important bearing on defining precisely what acts of veterinary medicine and surgery can and cannot be undertaken by different categories of registered VPPs. Additionally, such definitions will help to provide clarity in interpretation of provisions made in animal welfare regulations, which are yet to be developed.

Q2.1 (b) & (c) Define minimum initial and continuing education requirements and competencies / prescribe the conditions for recognition of the qualifications for veterinarians and VPPs

Section 27 of the VPVPA establishes the power of the Board to recognize the initial qualifications which would entitle a veterinarian or VPP to apply for registration. For the purpose of Section 24 (Application for Registration), Section 28 then provides the Minister, acting on the advice of the Board, to “deem sufficient” any such qualifications. It is recommended that the Minister should, on the advice of the Board, define precisely, in a Schedule, which can be amended regularly, all of the degrees or other qualifications (especially those of universities of neighbouring countries which are commonly held by Malawian graduates) which are approved for registration of veterinary surgeons and each category of VPP.

There are no provisions in the VPVPA for accreditation of training courses or other educational activities as “Continuing Education” (CE), nor is there any mandatory requirement for registered veterinarians or registered VPPs to improve their professional knowledge and skills through attendance or participation in approved CE events. It is recommended that the Act be amended to make a provision empowering the Board to approve CE courses or other events and that a mandatory minimum requirement for CE, set as a condition of annual retention on the register, is gradually introduced.

Q2.1 (d) The conditions to perform the activities of veterinary medicine / science and,

Q2.1 (e) Exceptional circumstances when persons other than veterinarians can carry out activities normally carried out by veterinarians

Section 25 of the VPVPA prohibits the practice of veterinary surgery by any person unless that person is registered by the Board. However, exemptions to this section, which have been made in a Schedule to the Act permit: *“Operations, treatments, tests, advice, diagnosis and attendance which may be performed, given or provided by unregistered persons -*

(a) Any non-surgical treatment given to an animal by:

(i) its owner;

(ii) a member of the household of which the owner is a member;

(iii) a person in the employment of the owner;

(iv) a person in the employment of a person referred to in sub-paragraph (ii);

(b) anything done, otherwise than for payment or material advantage, by a person engaged or employed in farming to any animal owned for the purpose of agriculture;

(c) anything done in the course of his duties by a person employed by the Government;

(d) The rendering in an emergency of first aid for the purpose of saving life or relieving pain; and

(e) The performance of the following operations [...].

No exemption is made in the case of a sanitary emergency, when the CVO may need to delegate certain powers or authority to unregistered persons to perform certain defined tasks in order to help to control an outbreak of an epidemic animal disease.

The above exemptions would seem too lenient and would allow unqualified persons to perform acts of veterinary medicine and surgery which should only be performed by qualified veterinarians or qualified VPPs. It is recommended to revise the exemptions schedule accordingly and to include an exemption allowing the CVO to authorise unregistered persons to perform certain activities on behalf of the DAHLD in the case of a sanitary emergency when such assistance is required.

The licensing to practice as a private practitioner is covered in Section 36 of the VPVPA, however the wording of that section could be improved. The Board has been authorised to issue a license to any person it considers “has had suitable experience”. This allows for a subjective decision to be made on the part of the Board. For the sake of transparency, it is recommended that the Board should define precisely what conditions it considers appropriate for licensing and publish them in Regulations.

Q2.2 Control of veterinarians and veterinary para-professionals (VPPs)

Q2.2 (a) General system of control in terms of political, administrative and geographic configuration of the country

Neither the VPVPA nor the CDAA describes any general system of control in terms of political, administrative or geographic configuration of the VS. It is recommended that an amendment to the VPVPA introduce a section which outlines the geographical distribution of veterinarians and VPPs and the manner in which they are controlled,

whether through their employment by the state VS or through sanctions applied by the Board following a disciplinary enquiry.

Q2.2 (b) Describes the various categories of VPPs

No distinction is made in the VPVPA between different categories of VPP. It is recommended that an amendment be made to the Act whereby, the Minister, on the advice of the Board, may declare different categories of VPP to be registered according to their educational qualification. The same provision should also empower the Board to define precisely the acts of veterinary medicine and surgery which may be performed by each category of VPP and the requirements of supervision or direction, as the case may be. In view of the opening of a new veterinary faculty in Malawi, there is a need to make a provision in the VPVPA for the temporary registration of students taking a full-time degree course in veterinary medicine in order to allow such students to perform acts of veterinary medicine and surgery during their training, under the direct supervision of a registered veterinary surgeon.

Q2.2 (c) Powers to deal with conduct and competence

Sections 39 to 47 of the VPVPA make provision for the establishment of a “Disciplinary Committee”, which is empowered to investigate any allegations of improper or “disgraceful” conduct. Section 48 of the Act allows the Board to make regulations to define what is meant by “improper or disgraceful conduct”. Disgraceful is a judgement-laden word inappropriate for legislation.

Q2.2 (d) Delegation of powers to a professional organisation

A Board of Veterinary Surgery is established under Section 3 of the VPVPA as the Veterinary Statutory Body (VSB) for Malawi. Although the VPVPA was enacted in 2001, priority has not been given by the Minister to appoint members of the Board, nor for any regulations for its operation. Under Section 4 of the Act, the composition of the Board includes (Section 4(1)(b)), “*three registered veterinary surgeons appointed by the Minister*”. For the sake of transparency, it is advised that the three veterinarians be selected by members of the Malawi Veterinary Association through an election, and then appointed by the Minister. A similar provision already exists, in the case of the two representatives of VPPs, in Section 4 (1) (c).

Q2.2 (e) Rights and responsibilities of the VSB

Section 7 of the Act defines the functions of the Board, but these do not give the Board all of the necessary powers of an autonomous VSB. It is recommended that the Board be authorised to set standards of education and the training required to meet the Day One competencies of veterinarians and VPPs. Furthermore, the Board should have a legally mandated role in the accreditation of veterinary training institutes in Malawi and to harmonise standards with those that are being developed in other countries in the region.

In terms of its role in the regulation of the practice of veterinary medicine and surgery, the Board should be authorised to set standards of practice. These standards can be used as a mechanism to reinforce the control of the use of veterinary medicines and biologicals by VPPs and for the enforcement of animal welfare standards.

Finally, the Board should be empowered to license and inspect premises from which veterinarians or VPPs have been licensed to practice.

Following revision and amendments being made to the existing VPVPA, it is recommended that the DAHLD request the Minister to appoint the members of the Board and to start to develop regulations, especially those that would help to reduce the risk of the misuse of veterinary medicines leading to anti-microbial resistance and

the presence of drug residues in animal products destined for human consumption. It is also recommended that the Board be provided with the necessary funding to allow it to perform its functions effectively.

4.2.3 Laboratories in the veterinary domain (Art 3.4.7)

Q3.1 Facilities

Q3.1 (a) There is almost no reference to veterinary laboratories in the existing legislation.

It is recommended that a new Part be drafted to be included in a revised Animal Health Act. This Part should cover the designation of the Central Veterinary Laboratory (CVL) as the “national reference laboratory”. Any other laboratories which may be expected to perform tests or analyses for the diagnosis or identification of a notifiable disease, for the certification of an imported / exported animal or animal product or for certification of an animal product, animal by-product as being fit for human or animal consumption or other official purposes should also be authorised by the DAHLD. The DAHLD should be given the authority to develop and impose the adoption of laboratory management systems to ensure the quality of the services being offered at any laboratory which has been designated to undertake any official tests or analyses.

Q3.1 (b) There should be provisions which ensure that the CVL and any other laboratory which has been approved to perform “official” tests and analyses can be accredited with whichever national, regional or international accreditation bodies that have been approved by the Government of Malawi.

Q3.1. (c) Another category of laboratory which will need to be authorised are those laboratories which perform self-inspection tests for the purpose of quality control checks. An example would be a laboratory in an abattoir which performs hygiene tests such as the measurement of the concentration of chlorine in water used to rinse carcasses along the processing line.

Q3.1 (d), 3.2 (a)-(c) It is recommended that any private laboratories which provide the public with results of tests and analyses related to animal health or the safety or quality of products of animal origin, animal by-products or animal feeds should also be registered and regularly audited by the DAHLD in accordance with standards prescribed by regulations, in order to ensure that good laboratory practices are being maintained. Similarly, assurance of the quality of imported or locally manufactured laboratory reagents needs to be addressed in the revised subordinate legislation. A system for the surveillance of laboratory reagents used in official tests needs to be established in a revised Animal Health Act and then standards elaborated under regulations.

A comprehensive set of regulations to govern veterinary diagnostic laboratories and the conduct of official tests and analyses must be developed. It is recommended that the DAHLD adopt the standards for notifiable animal disease diagnostics as defined in the OIE texts including the TAHC Volumes I and II, the Terrestrial Manual of Diagnostic Tests and Vaccines and, in the case of food safety of animal products destined for human consumption, the Codex Alimentarius.

Provisions should be made for the biosecurity and biosafety of veterinary diagnostic laboratories in accordance with the guidelines provided in Chapter 1 of the Terrestrial Manual of Diagnostic Tests and Vaccines.

4.2.4 Health provisions relating to animal production (Art 3.4.8)

The following enacted legislation covering animal production was reviewed during the mission:

- CDAA (1968) and *Animals Quarantine Rules* (1968)
- *Meat and Meat Products Act* (1975)
- *Milk and Milk Products Act* (1972)
- FFFRA (1970)
- *Fertilisers, Farm Feeds and Remedies (Farm Feeds) Regulations* (1996)
- *Fertilisers and Farm Feeds (Sterilization of Animal Products) Regulations* (1996)
- *Biosafety Act* (2007)

In addition, the draft 'Animal Identification and Registration Bill' (2004) was analysed at the request of the OIE Delegate. Outcomes of the analysis of these pieces of legislation are presented below.

Q4.1 Animal identification and traceability

Q4.1 (a), (b), (c), (e) & (f) - Animal identification and traceability

The only reference found to animal 'identification' in enacted legislation is in Section 9 of the *Animals Quarantine Rules* (1968) which refers to an inspector having the authority to brand / mark any animals found in an infected area or animals in isolation at quarantine stations. The absence of regulations to control animal identification and traceability in order to decrease stock theft, led to a feasibility survey on the implementation of a national animal identification scheme being carried out in 2004 through funding from FAO. This resulted in the drafting of the *Animal Identification and Registration Bill*, 2004. As of 2016, this Act is still in draft form and has yet to be passed by Parliament. With reference to OIE recommendations regarding identification and traceability, the draft Bill does not clearly identify the desired outcomes and scope of any registration system and it is difficult to ascertain whether or not all animals, or only key strategic populations within Malawi, would be required to be registered. The purpose of the draft Bill is to '*make provision for the identification and registration of animals and to provide for incidental matters*', and reference in section 13 to '*proof of ownership*' and '*acquiring an animal unlawfully*', indicate that this Act has been developed around 'animals being property', rather than for the purpose of 'preventing and controlling animal diseases' or for providing evidence of traceability of animals or animal products. Chapter 4.1.1 of the TAHC indicates that '*Animal identification and animal traceability are tools for addressing animal health (including zoonoses) and food safety issues. These tools may significantly improve the effectiveness of activities such as: the management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock husbandry, zoning/compartimentalisation, surveillance, early response and notification systems, animal movement controls, inspection, certification, fair practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level.*

Q4.1 (d) & (g) - Access to data/confidentiality

Data on marked animals is kept with the Registrar, as well as the marking operator (section 12(4)); however, no mention is made of ensuring the confidentiality of this data.

Offences are specified in section 18, and although specific penalties are not given, fines and periods of imprisonment can be imposed by a magistrate's court (section 18(3)). No funding mechanisms are mentioned in the draft Act.

It is therefore recommended that a thorough review of this draft Act be carried out to ensure it is relevant to help address '*animal health (including zoonoses) and food safety issues*', in addition to stock theft.

Q4.2 Animal markets and other gatherings

The main Act which references animal markets and other gatherings is the CDAA, which allows the Minister to make regulations for the '*cleansing and disinfection of any public market, private auction, or sale yard*' (section 8f). However, this Act does not:

- Specify the need or process for registration, or other official approval;
- List all places where animals may gather, for example, dog or agricultural shows
- Specify any provision for veterinary checks.

To the team's knowledge, subsidiary legislation which details specific measures to prevent disease transmission, using specific procedures and products for cleaning and disinfection, does not exist.

Q4.3 Animal reproduction

Section 6 of the CDAA makes provision for the Minister to prohibit the importation of semen, but does not make reference to ova, embryos or domestic trade. Section 5f of the *Biosafety Act* (2007) approves '*safety aspects of import, export, manufacture, processing and selling of genetically modified organisms and products thereof*', and section 41g of the same act allows regulations to be made for the '*control, or regulation of the sale or supply, export or the importation, of genetically modified organisms or products thereof*'. It is assumed that any genetically modified reproductive material would be covered under these provisions.

Q4.4 Animal feed

The *Milk and Milk Products Act* (1972) allows the Minister to make regulations for '*the inspection, examination, treatment and control of animal feed used in connexion with the production of milk or milk products*' (Section 3(1)(i)), however, it is understood that these regulations do not exist at present. The FFFRA allows the Minister to establish committees to provide advice '*on matters relating to the registration, sell [sic] and use of... farm feeds*'; and '*to keep a record of farm feeds*' (Section 9 (2)). The following regulations which can be made under the Act and which would support the production, and registration, of farm feeds are:

- *composition, efficacy, fineness, purity or other property required in any substance before it is sold or registered as a... farm feed*; (Section 16c)
- *requirements as to the containers in which.... farm feeds shall be packed and the manner in which such containers shall be branded, labelled, marked or sealed*; (Section 16d)
- *the process by which...farm feeds or substances used in the manufacture of.... farm feeds shall be sterilized, and the manner of inspection of sterilizing plants*. (Section 16e)

Section 16(2) allows that '*Different regulations may be made in respect of different classes of fertilizers, farm feeds and remedies, or in respect of different classes or groups of persons*'. The *Fertilizers, Farm Feeds and Remedies (Farm Feeds) Regulations* (1996) specify information on labelling, which '*in the case of added*

vitamins, antibiotics and drugs, [includes] *the content of the active constituent*' (Section 8(1)(c)). The Team did not find any specific standards for farm feeds, although there are a number of provisions made in the regulations and which could be consolidated to produce standards, such as it being an offence to '*register or sell any farm feed which.....is manufactured or intended for consumption by pigs or poultry and which, when prepared according to the instructions of the manufacturer, will contain more than 1 per centum of salt expressed as NaCl*' (section 12). In addition, the Food and Agriculture Division of the Malawi Bureau of Standards is responsible for '*the development of standards covering food technologies, food safety, agricultural produce, livestock and livestock products, poultry and poultry products, etc.*'¹⁰. A quick search of their website did not identify any standards related to farm feeds and there are no relevant Technical Committees in existence¹¹. Part IV of the regulations provides detailed information on how sampling and analysis of farm feeds should be carried out. There is no provision for recall from the market in the current legislation.

In view of the need to revise or possibly even repeal the FFRA, it is recommended that consideration be given to preparing a new Animal Feeds Act and Regulations. The Act should identify the DAHLD as the competent authority for the regulation of the safety and quality of animal feeds. Provisions are needed for authority to regulate the importation, manufacture, distribution, sale (including recall) and, in certain instances, the use of (medicated or feeds with ingredients of animal origin) feeds. Provisions for licensing, and inspection of imported feeds and feed manufacturers, for setting standards for safety and quality and for recall of infected / contaminated animal feeds from the market can be included in Regulations. Part IV of the existing *Fertilizers, Farm Feeds and Remedies (Farm Feeds) Regulations* (1996) is good and should be carried over into the new legislation as a Schedule to the new Regulations.

Q4.5 Animal by-products

Animal by-products are not defined in Malawian legislation. Many by-products, for example, hooves and offal, are eaten and covered by the *Meat and Meat Products Act* (1975) under the definition of meat¹². However, the *Meat and Meat Inspection Regulations* (2003) do provide definitions for viscera¹³, and offal¹⁴, which does not include '*hide, skin, horn or hoof*'. The FFFRA regulates sterilising plants¹⁵ which use animal by-products and need to be '*suitable and sufficiently effective for the purposes for which it is intended and complies with the prescribed requirements*' (Section 9(2)(a)). These plants must be registered under Section 8 of the Act. The second schedule of the *Fertilizers and Farm Feeds (Sterilization of Animal Products) Regulations* (1996) specifies '*Methods of sterilising substances of animal origin and used containers*'. Section 12 gives powers of entry to inspectors to inspect these plants. The *Hides and Skin Trade Act* (1955), is more concerned with the licensing of traders in hides and skins and the premises used for processing or drying hides and skins, rather than the protection of humans or animals from potential health threats associated with handling of hides and skins. Section 7, however, prohibits the export of hides or skins except through a designated port or exit point and under the

¹⁰ <http://www.mbsmw.org/index.php/standards/overview> [Accessed 23rd May 2016]

¹¹ <http://www.mbsmw.org/index.php/standards/technical-committees>

¹² "*meat*" means the carcass, or offal, or any part of the carcass or offal, or any product of the carcass or offal of any livestock and, in the case of poultry, includes the eggs thereof;

¹³ "viscera" means stomachs and intestines

¹⁴ "offals" means any part of the dead animal removed from the carcass in the process of dressing it but does not include hide, skin, horn or hoof;

¹⁵ "sterilizing plant" means a plant used for the sterilizing of bones or other substances derived from an animal carcass

authority of a licence issued by the Director, DAHLD and each consignment being subject to an export certificate issued by an inspector certifying that the hides and skins have been prepared in accordance with conditions prescribed by the Act. For the sake of transparency and in order to ensure that the correct standards are being applied, it is recommended that conditions for licensing of people and premises involved in processing any animal by-products and export certification, shall be prescribed by regulations in the future.

Q4.6 Disinfection

Section 8 of the CDAA allows the Minister to make rules for the '*destruction of buildings and places wherein animals suffering from any disease have been stalled or kept*' (e); '*cleansing and disinfection for any public market*', or other specified gathering (f); disinfection of '*in contact*' animals (g); or disinfection of '*in contact*' persons (h). However, the procedures and products to be used are not specified. Powers of entry are provided to inspectors in Section 12 to ascertain whether cleansing and disinfection has been carried out as directed, but again standard mechanisms for disinfection are not identified.

It is recommended that as and when the CDAA is reviewed and revised, provisions are made to allow the Technical Standing Committee to propose approved disinfectants for the purpose of controlling certain defined pathogens as well as the procedures for disinfection of any vehicle, premises, animal, animal product or commodity which has undergone inspection. Such standards shall then be published by the Minister in the Gazette as an Order.

4.2.5 Animal diseases (Art 3.4.9)

Table 3. The current legislation covering disease surveillance and the prevention and control of animal diseases includes:

Legislative instrument	Year of enactment	Responsible Ministry
CDAA	1961	MoAIWD
Diseases of Animals Rules	1928	
Animals Quarantine Rules	1968	
Control and Diseases of Animals (Prohibition of Importation of Animals) Order	1970	
Prohibition of Treatment except by Veterinary Officers (Rules)	1928	
Movement of Livestock Regulations	2003	

Q5.1 Basis for management of diseases of importance in accordance with Chapters 1.1 & 1.2 of the TAHC

Under Section 2 of the CDAA “disease” has been defined through a list of diseases which were considered to be important in Malawi at the time this Act was enacted in 1967. Many of the provisions of the Act are therefore limited to being relevant to only those diseases listed in Section 2. Unfortunately, this list of diseases is incomplete, especially in relation to zoonotic diseases and certain other animal diseases which are not present in Malawi but which could enter from a neighbouring country across inadequately policed borders or through the international trade of animals or animal products. Although the Minister has been authorised to declare any other disease of animals to be a disease and to declare any other animal as being an animal for the purposes of the Act (Section 4 (2) & (3)), no such declaration has been made. Such a requirement would seem cumbersome. In future, it is recommended that a list of notifiable animal diseases be placed in a Schedule to the Act or in Regulations, which can be amended and updated as and when necessary. The list of notifiable diseases should include those diseases listed by the OIE which are known to occur in Malawi and other important (OIE listed) diseases which occur in neighbouring countries or the region or which may pose a threat through international trade. The Minister should only be empowered to declare or amend such list on the advice of a “Technical Standing Committee”.

Q5.2 Surveillance

The requirement for an owner of an animal to report the suspected occurrence of a “notifiable” animal disease to the “nearest inspector or police officer” is provided in Section 3 (1) (b) of the CDAA. Section 3 (2) requires that: “any police officer so notified shall forthwith notify the nearest inspector, who shall give such directions and take such steps as may be necessary for the purpose of ascertaining the existence and nature of the disease, and on being satisfied that such disease exists he shall forthwith report the disease to the Chief Veterinary Officer.” Whilst this provision places the responsibility for the conduct of an outbreak investigation on an “inspector”, it does not explicitly define what actions should be taken and when such actions should be taken. There is no further reference to disease surveillance in the veterinary legislation as such, with the exception that Section 30 of the *Meat Inspection Regulations* (1976) requires a meat inspector in a Category A slaughterhouse to submit samples for bacteriological examination from any carcass which he suspects not to be fit for human consumption. It is recommended that provisions be made in revised legislation for the immediate reporting of suspected cases or outbreaks of notifiable animal diseases by the owner of an animal and by any veterinarian or VPP. Additional provisions should be made to ensure that all reported cases / outbreaks of suspected notifiable animal diseases are investigated through the collection of epidemiological information and the submission of samples to the nearest reference laboratory. It is also then recommended that provisions be made to ensure the establishment of an animal disease information management system within the DAHLD for recording all suspected and confirmed (by laboratory confirmation) cases of notifiable animal diseases. An analysis of such information can be used to inform risk-based decisions for disease prevention and control schemes and for targeting future active disease surveillance activities. The laboratory confirmation of clinical suspicion of any suspected case or outbreak of a notifiable animal disease should be performed using an “official” test, in accordance with the standards provided in the OIE Terrestrial Manual of Diagnostic Tests and Vaccines. It is recommended that a section making provisions for animal disease reporting and surveillance be included in proposed new draft legislation in accordance with the standards presented in Chapter 1 of the TAHC.

Q5.3 Disease prevention and control

Sections 4 and 5 of the CDAA make provisions for the declaration of an infected area and for all the necessary actions which may be taken in order to prevent the spread of any disease out of such declared area. As has been mentioned previously, these provisions would only apply to the diseases listed under the definition of “disease” in Section 2 of the Act.

Sections 6 and 7 provide the Minister with the power to restrict the import and export of animals and certain animal products, to establish quarantine stations and to direct that any animal or animal product be placed in quarantine during importation under such conditions as he/she determines. As has been mentioned previously, whilst the Minister should have the power to endorse or approve such decisions, it should be the CVO or the (proposed) “Technical Standing Committee” that should make such decisions in order to ensure the technical independence of the DAHLD.

Section 8 of the CDAA (1967) empowers the Minister to make rules for the purpose of implementing the provisions of the Act. Amongst these provisions, rules may be made for: *“the control, isolation, muzzling, inoculation, seizure, detention, removal and slaughter of animals suffering from or suspected to be suffering from any disease or known or suspected to have been in contact with diseased animals otherwise exposed to the infection or contagion of disease or of any dog”*. This provision is comprehensive but does not go so far as to ensure that contingency plans shall be made in order to have the capability to respond to any exotic disease outbreak. It is recommended that provisions be made to ensure that contingency plans are developed for all of the major exotic diseases which may enter Malawi. Such provisions should ensure quick access to emergency funding and include special administrative and logistical procedures for an effective response to be made.

There are currently no provisions covering compensation which may be paid to the owner of an animal which has been the subject of compulsory slaughter, in the event of the outbreak of a notifiable disease. Modalities should be developed for ensuring that compensation is only payable to the owner of such animal(s) when a certificate of death has been issued by a veterinary officer or an authorised officer. The rates for compensation should be based on current market values of animals of the same species and age / developmental stage. Provisions for payment of compensation will help to avoid instances of non-reporting of outbreaks of notifiable diseases.

It is also recommended to include provisions which give the CVO exceptional powers in order to enable him/her to have access to emergency funds and the services of the police in order to respond effectively to any sanitary emergency. Such provisions should allow the CVO to engage the services of unqualified persons to perform certain functions which would normally be performed by a veterinary officer or a VPP.

Section 9 of the CDAA provides a veterinary officer with the authority to kill any animal suspected of being affected by a disease or having been in contact with a diseased animal. In the future it is recommended that any such provision ensure that a humane method of destruction is employed in such instances.

Sections 12, 13, 14 and 16 confer upon inspectors the powers of entry, detention and seizure of animals upon suspicion of a case or outbreak of a notifiable disease or a contravention of the Act. There are currently no provisions which give inspectors access to records or other documents held by the owners of animals or at the premises which are inspected by DAHLD inspectors. It is recommended that inspectors be given the power to examine and take copies of any documentation at

an inspected premises, when such documents may be relevant to the particular circumstances.

4.2.6 Animal welfare (Art 3.4.10)

There are a number of Acts and Regulations in existence which contain, or omit provisions which could have an impact on animal welfare. These are presented in the table below.

Table 4. Acts and Regulations

Piece of legislation	Date of enactment	Ministry responsible for enforcement	Types of animals covered
Protection of Animals Act	1944	MoAIWD	<i>Any domestic¹⁶ and captive¹⁷ animal</i>
CDAA	1968	MoAIWD	<i>Any bull, cow, ox, heifer, calf, sheep, goat, horse, mule, donkey, pig, domestic fowl, and any game animal' (as defined in the 'Game Act'), 'any wild carnivore tamed and kept as a pet, guinea fowl, pigeon, pea fowl, dog, cat and any other creature which the Minister' may order</i>
Animals Quarantine Rules	1968	MoAIWD	As above

Piece of legislation	Date of enactment	Ministry responsible for enforcement	Types of animals covered
Malawi National Parks and Wildlife Act	1992		"animal" - includes any member of the animal kingdom and includes man Note that, provisions of the Act can either protect, or negatively impact on the welfare of the following types of animals: "Dangerous animal" - hyaena, lion, leopard, hippo, elephant, rhinoceros, buffalo, crocodile; "Domestic animal" - any animal which is sufficiently tame to serve some purpose for the use of man....includes animals which were once tamed or are in the process of being tamed; "game species" - designated under section 44; "listed species" - plant or animal species listed under any international, regional or bilateral agreement to which Malawi or the Government is a party, and under section 99; "protected species" - any plant or animal declared under section 43; "specimen" - any wild plant or animal, alive or dead....and any readily recognizable part of derivative of such plant or animal; "Wild animal" - any animal which is <i>ferae naturae</i> (does not include any domestic animal);

¹⁶ any horse, ass, mule, bull, sheep, pig, goat, dog, cat, or fowl, or any other animal.....which is tame, or which has been or is being sufficiently tamed to serve some purpose for the use of man

¹⁷ any animal....including any bird, fish, or reptile, which is in captivity, or confinement, or which is maimed, pinioned, or subjected to any appliance or contrivance for the purpose of binding or preventing its escape from captivity or confinement

Milk and Milk Products Act	1968	MoAIWD	No definition given. Assumed to be any animals producing milk
PMPA	1991	MoH	No definition given
Meat and Meat Products Act	1972	MoAIWD	No definition given, though assumed to refer to all meat producing animals
Biosafety Act	2002	Minister for Environmental Affairs	No definition given
VPVPA	2001	MoAIWD	No definition, but provides for a number of exceptions regarding who can carry out procedures, during which animal welfare may be compromised

Q6.1 General provisions

In general there is:

- Inconsistency in definition of '*animal*' amongst the legislation, and in the case of the *Protection of Animals Act* (1968), no protection for wild animals, whilst protection for animals that have already had their welfare severely compromised by the actions of humans (such as those which have been '*maimed, pinioned, or subjected to any appliance or contrivance for the purpose of binding or preventing its escape from captivity or confinement*') is provided for. The different groups of animals defined under the Parks and Wildlife Act (1992) can result in some species having their welfare respected, whilst others have their welfare compromised by provisions made in this Act.
- An absence of regulations to promote animal welfare, with the *Protection of Animals Act* (1968) concentrating on preventing cruelty
- Lack of cross referencing between Acts, and lack of clarity on the qualifications, experience and criteria used to identify the different inspectors appointed under the different Acts.
- Frequent exemptions, or omissions which would make it difficult to carry out a prosecution under the various acts for a 'welfare / cruelty' issue. For example, the *Protection of Animals Act* (1968) does not provide a definition of 'owner' and provides exemptions for anything carried out by medical and veterinary practitioners (Section 3(3)). The Schedule of the VPVPA allows '*operations, treatments, tests, advice, diagnosis*' to be carried out by a '*person engaged or employed in farming to any animal owned for the purpose of farming*', as long as it is not for '*payment or material advantage*' (b) and '*anything done in the course of his duties by a person employed by the Government*' (c).
- The language in the Acts does not reflect a concern for welfare and tends to treat animals as inanimate objects / property as opposed to sentient beings. For example, the *Protection of Animals Act* (1968) refers to '*disposal of the animal*' (section 5) and section 4 refers to the '*animal being destroyed*'. It would be preferable in an amended Act to refer to 'humane destruction', or the animal being '*destroyed in a humane manner*' or '*destroyed in a manner which minimises pain and suffering*'.
- Reference to a number of different 'facilities' where animals may be detained, such as '*quarantine stations*' (Section 7 of CDAA, '*infirmaries*' (Section 13 of the *Protection of Animals Act* 1968), '*pound or enclosure*' (Section 16(1)) of the CDAA (1968)). The care of these animals is meant to be paid for by 'owners', but this may be difficult if ownership cannot be determined, or it takes time to recover

these debts from the owners. The *Animals Quarantine Rules* (1968) provide a payment schedule for examinations, tests, treatment, stabling and feeding for different species, but these amounts are in tambala and would be insufficient to provide for an animal's welfare needs.

During the one week mission it was not possible to provide a comprehensive analysis of all the legislation related to animal welfare, but key points from the analysis to date are detailed below.

Q6.2 Legal definition of cruelty

Section 3 of the Protection of Animals Act (1968) identifies a number of instances when actions are deemed to be cruel, for example: '*cruelly beat, kick, ill-treat, override, overload.....*' (3a), fighting or baiting (3c), administration of a poisonous or injurious substance (3d), or subject '*any animal to any operation which is performed without due care and humanity*' (3e). Although these offences relate to acts carried out by '*any person*', there are a number of references to the '*owner*', but no definition provided. This may cause difficulties in establishing ownership / responsibility for the welfare of the animal, or in implementing Section 4 which refers to the court ordering the destruction of the animal, if the owner of an animal is convicted of an offence of cruelty. If any prosecutions under this Act are successfully made, the punishment of imprisonment may act as a sufficient deterrent to others, but the fine, in Pounds Sterling (£), may not. There is also a concern regarding section 3 which exempts any act carried out:

- '*by a registered medical practitioner or by a veterinary surgeon which may be lawfully done under the Cruelty to Animals Act, 1876 of the United Kingdom*' (3(3)) (which is now obsolete, but under certain circumstances allows '*performance on any living animal of an experiment calculated to give pain*'¹⁸)
- '*in the course of the destruction, or the preparation for destruction of any animal as food*' (3(3)a)
- For '*coursing or hunting of any captive animal*' (3(3)b).

Although cruelty is not defined in Parks and Wildlife Act (1992), there are a number of instances where causing detrimental effects to an animal's welfare is listed as an offence. (Bold emphasis made to highlight that different types of animals are treated in different ways). For example, section 82 makes it an offence where '*Any person who willfully and without just excuse or cause-*

(a) *molests or provokes any **protected or game animal** in a manner which results or is likely to result in its destruction: or*

(b) *molests or provokes any **wild animal** in a manner which results or is likely to result in the provocation, harassment or destruction of any protected or game animal.*

Section 83 makes it an offence to '*causes unnecessary or undue suffering to any **wild animal**, whether the animal lives in the wild or is being kept in captivity*'.

Provisions for the direct intervention of the competent authority in the case of neglect by animal keepers: There is no specific mention of the competent authority in the Protection of Animals Act (1968). In the case of an owner being convicted of

¹⁸ An Act to amend the Law relating to Cruelty to Animals (15th August 1876) <http://web.archive.org/web/20061214034848/http://homepage.tinet.ie/~pnowlan/Chapter-77.htm> [Accessed on 24th May 2016]

cruelty, the Act does allow the court to '*direct that the animal be destroyed*' (Section 4), or to deprive a convicted owner of the ownership of the animal (Section 5). Section 8 gives powers of entry to magistrates or police officers of, or above the rank of inspector, or allows them to '*authorise any inspector, veterinary officer, or police officer above the rank of constable to enter and search the place*'. Any criteria for the selection, or requirements for CE, of these officers is not specified in legislation.

Q6.2 (a) Transport and handling

Section 14 of the *Protection of Animals Act* (1968) makes provision for the Minister to make Rules for:

- *insuring for animals carried on inland waters a proper supply of food and water and proper ventilation during the passage and on landing*' (14(2)(a))
- *protecting animals from unnecessary suffering during the passage and on landing* (14(2)(a))
- *protecting animals from unnecessary suffering during inland transit* (14(2)(a))

However, these rules have yet to be developed or enacted. Key welfare provisions which would need to be stipulated in these rules are those which allow:

- '*freedom from thermal and physical discomfort*', includes stocking densities, provision of shelter from adverse weather, construction of transport vessels (for example, floors and walls, loading and unloading ramps), and journey times;
- '*freedom from pain, injury and disease*' which can include provision for quarantine facilities, and types and life stages of animals which should, can and should not be transported together;
- '*freedom to express normal behaviour*', which relates to stocking densities / space requirements, appropriate presence of conspecifics,
- '*freedom from fear and distress*', which includes the design of vehicles and manner in which animals are loaded, transported and unloaded.

No mention is made of the transport or handling of wild animals in the *Parks and Wildlife Act* (1992).

Q6.2 (b) Accepted practice in animal production

There is no legislation governing the production of animals using accepted practices. *The Milk and Milk Products Act* (1972) does allow the Minister to make regulations for '*the inspection, examination, treatment and control of animals used in connexion with the production of milk or milk products*' (section 3(1)(i)), but at present these do not exist and it would be unclear who would carry out these inspections, which should include aspects of animal welfare. Section 4(1)(g) of the *Meat and Meat Products Act* (1975) allows the Minister to make regulations requiring the registration and licensing of '*producers (including persons who keep poultry with a view to selling the carcasses or eggs thereof for human consumption)*'. Section 4(1)(h) also allows him to prescribe the qualifications, powers and duties of inspectors, who are concerned with animal production, but again, does not specify that animal welfare concerns should be taken into account during any inspections, nor the qualifications and experience of those carrying out these inspections.

Q6.2. (c) Slaughter for human consumption

The *Meat and Meat Products Act* (1975) allows the Minister to make regulations for '*prescribing the methods to be employed in the slaughter of animals in slaughterhouses and the implements to be used for such purposes*' (section 4(1)(f)). Section 4(1)(p) allows him to make regulations '*controlling and regulating the establishment, design, construction, standards, locality, supervision, equipment, maintenance and management of slaughterhouses....*' which can have implications on an animal's welfare. Section 7 of the *Meat and Meat Products Regulations* (2003) makes reference to '*casualty animals*' and ante-mortem inspection, but only refers to ensuring the health of animals / preventing the spread of disease. The qualifications and training of inspectors related to their ability to promote the welfare of animals are not specified. Although the *Parks and Wildlife Act* (1992) makes reference to the Minister being able to make regulations providing for: '*the control of trade in the carcasses, meat and skins of such animals*' (section 87(1) (a), the Act, or any subsidiary legislation do not specify how this 'slaughter' should be carried out. As the killing of wild animals / animals which are not accustomed to being handled can be an extremely stressful experience for the animals concerned, there is a need to specify the ways in which slaughter or killing for disease control purposes should be carried out in order to ensure both human safety and animal welfare.

Q6.2. (d) Killing for disease control purposes

Section 7(1) of the *Protection of Animals Act* (1968) allows District Commissioners, inspectors, veterinary surgeons, veterinary officers or police officers above the rank of inspector to kill animals found in public places, or roads which are '*so diseased, severely injured, or in such physical condition*', '*in such a manner, as to inflict as little suffering as practicable*'. Section 8a of the CDAA allows the Minister to make regulations for the '*slaughter of animals suffering, or suspected to be suffering from any disease*', and section 9 allows a veterinary officer to cause an animal suspected of, or being infected by a disease to be slaughtered. Section 8 (m) allows the Minister to make rules '*authorising the destruction of any dog or other animals unlawfully introduced in Malawi*'. However, methods for, and qualification of persons, carrying out '*killing for disease control purposes*' are not specified, nor is the word '*killing*' mentioned (only destruction, or slaughter). Another area where reference should be made to humane killing of animals is under the Emergency Response plans in the Fifth Schedule (section 84) of the *Biosafety Regulations* (2002) which refer to '*Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread*' [of genetically modified organisms].

Q6.2. (e) Use of animals in research and education

Section 43 of the PMPA covers 'animal testing', but does not specify any rules or frameworks, for example 3Rs¹⁹ (Replace, Reduce, Refine), Five Freedoms²⁰, or key points mentioned in Chapter 7.8 of the TAHC²¹ which consider, and help to promote the welfare of animals involved in research and education. The Biosafety Act (2002) covers the genetic modification of organisms; importation, development, production, testing, release, use and application of genetically modified organisms; and use of

¹⁹ Animal Ethics Infolink [Accessed on 22nd May 2016] <http://www.animaethics.org.au/three-rs>

²⁰ United Kingdom Government Web Archive, Farm Animal Welfare Council <http://webarchive.nationalarchives.gov.uk/20121007104210/> <http://www.fawc.org.uk/freedoms.htm> [Accessed on 24th May 2016]

²¹ Terrestrial Animal Health Code. Use of animals in research and education. OIE. [Accessed on 22nd May 2016] http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_aw_research_education.htm

gene therapy in animals. It is administered by the Minister responsible for environmental affairs and overseen by a steering committee on which a representative from the MoAIWD sits. This Act gives little mention to animals, focusing more on plants. There is therefore a need for DAHLD to ensure that the MoAIWD representative on the Biosafety Committee is conversant in the main issues relating to the ethical use of animals (including respecting / promoting their welfare) and that the Act is either updated, or subsidiary legislation developed which ensure the ethical use and welfare of animals is considered in licensing (Section 22) of experiments and the importation, development, production, testing, release, use and application of genetically modified organisms. The Act also needs to be reviewed to ensure any exceptions granted by the Minister, for example, for licensing of scientific research or experimental purposes (section 17a), emergency supply of food for human beings (section 17b) or importation (Section 20) still consider the ethical use of animals and respect for their welfare. Variations to licenses (Section 25) only consider the safety, quality or efficacy of genetically modified organisms, not their welfare. Inspectors who are concerned with the implementation of this Act (Section 30 (4)) are required to be '*competent in biotechnology or biosafety*', but do not need to have an understanding of how experiments can impact on animal welfare. Section 41(j)(vii) of the Act refers to '*the disposal of genetically modified organisms or products thereof which have become unusable or otherwise unwanted*', but again does not make reference to how this should be done, or how in the case of animals, this should be carried out humanely. It is also of concern that licenses and permits '*shall not be required for organisms that are used under conditions of contained use in academic and research facilities*' (section 12(2) of the Regulations). Licenses for the use of wild animals in scientific research, or for educational purposes can be issued under section 53 of the Parks and Wildlife Act. However, there is no reference to how licenses will ensure their ethical use, or welfare.

Q6.3 Stray dog population control

Section 8 of the *Control of Animal Diseases Act* (1968) allows the Minister to make regulations for the registration of dogs (m) and their compulsory immunisation against rabies or any other disease (n). Aside from this no other references to stray dog control were found in the legislation reviewed during the mission. As mentioned earlier the *Protection of Animals Act* (1968) makes it an offence to give an animal an 'injurious substance' (such as strychnine), but the same act provides exemptions to anything done by a veterinary surgeon, or medical practitioner.

Q6.4 Abandoned animals

Section 13(1) of the *Protection of Animals Act* (1968) allows the Minister to '*appoint places to be infirmaries for the treatment and care of animals*', Section 13(2) makes provision for animals to be detained in these infirmaries, until they are fit for the work or labour which they normally carry out, which may mean putting them back into the same situation where the original cruelty offence, for example, 'overriding, excessive beating', was carried out. The legislation makes provision for the cost of treatment, feeding and watering at the infirmary to be covered by the owner (Section 13(3)), but as mentioned earlier there is no legal definition of the owner, and there is no guarantee that the owner can afford to pay for the animal's upkeep at the infirmary, or that funds would be available at the time the animal was detained within the infirmary. The legislation does not provide for a 'contingency fund' which can be used to run the 'infirmaries' whilst debts are being recovered, or the identity of the owner being debated. There is provision for the animal to be sold to recover the owner's debts (Section 13(5)), but this provision may be against the welfare interests of the animal.

The *Animal Quarantine Rules* (1968) allow for the detention of stray animals which are suspected to be diseased (section 4). Payment for their care is expected to be paid for by the owner, but again this may be difficult if the identity of the owner cannot be determined, or there is a delay in recovering the necessary funds from the owner.

It is recommended that animal welfare issues be thoroughly reviewed by the DAHLD in partnership with NGOs with a shared interest in the subject. Two options are presented as a potential way forward. Firstly, it may be considered possible to include a Part in a proposed new draft “Animal Health Act” to define animal well-being and to establish an Animal Welfare Board with the responsibility for advising the Minister and proposing draft regulations and empowering the Minister to make animal welfare regulations on the advice of the Board.

4.2.7 Veterinary Medicines and Biologicals (Art 3.4.11)

The regulation of the importation, manufacture, distribution, sale and use of “medicines”, the definition of which would include vaccines, but not other biological products, is made principally under the following two pieces of legislation:

Table 5. Legislative instrument

Legislative instrument	Year	Ministry
PMPA	1988	MoH
FFRA	1970	MoAIWD

Q7.1 – 7.6 Veterinary medicines and biologicals

Section 35 of the PMPA provides the Pharmacy Board of the MoH with responsibility for licensing the importation, manufacture, distribution, sale and use of all medicines (including raw materials for their manufacture).

Section 3 of the FFFRA prohibits the importation, manufacture, sale or distribution of any “remedy” unless it has been registered by a Registrar appointed by the Minister (of Agriculture). A remedy has been defined in this Act as being any medicine used to treat animals but which does not require a prescription and thus includes all “general sales” medicines. There is thus overlap of responsibilities between the MoAIWD and MoH with respect to a large group of veterinary medicinal products.

Although a veterinary surgeon is included as a member of the Pharmacy Board (PMPA Section 4 (1) (e)), in practice it would appear that no formal mechanism of collaboration between the two Ministries exists. The Team was informed that there has always been a good working relationship between the MoH and the MoAIWD with regard to making decisions for the importation of veterinary medicines. However, it was discovered during a meeting with the Chairman of the Pharmacy Board during this mission that the PMPA has recently been reviewed and revised and a final version is about to be presented to Parliament, without there having been any discussion between the two Ministries, MoH and MoAIWD.

Although there are adequate provisions for the licensing of persons who handle medicines, premises where medicines are manufactured or stored or from which they are sold and the importation, manufacture, distribution and sale of medicines, there are gaps in the existing legislation with regard to avoiding the presence of harmful residues in the food chain and ensuring that the use of veterinary medicinal products, including pesticides, does not give rise to human health risks, including the development of anti-microbial resistance.

Section 50. of the PMPA - Medicinal product to be in labelled containers or packages - states (1) *“No person shall, in the course of a business carried on by him, sell or supply or have in his possession for the purpose of selling or supplying any medicinal product in a container or package which is not labelled in accordance with regulations made under section 66”*. Part 16 of the *APPLICATION FOR A PRODUCT LICENCE, VETERINARY MEDICINE CLINICAL STUDIES DATA* (Section 66) – requires data to be provided on the withdrawal periods of veterinary medicines. However, there are no regulations which state that the withdrawal period should be included on a prescription of a veterinary medicine and nor are there any provisions which would ensure that the end user of a prescription only medicine adheres to the withdrawal period, which should be included on the label of the product.

It is recommended that the DAHLD request that they are consulted before the draft revised Pharmacy, Medicines and Poisons Bill is presented to Parliament in order to ensure that provisions, currently missing from the legislation, such as the inclusion of withdrawal periods on dispensing labels and the enforcement of withdrawal periods by end users are included in the final draft Bill.

Firstly, there is a need to include a definition of what is meant by “veterinary medicinal product” and “biological substance” in the revised Bill. Thereafter, it is recommended that the revised Bill include provisions to set MRLs (in accordance with Codex Alimentarius standards) of any residues which may enter the food chain whether through misuse of medicines and chemicals or through contamination.

With regard to the use of prescription only veterinary medicines and biological substances by VPPs, there is a need to make provisions, either in the revised Pharmacy, Medicines and Poisons Bill or in an amendment to the VPVPA (or both), to ensure that such medicines may only be used by VPPs under the supervision of a registered veterinary surgeon.

Finally, there is a need for provisions to ensure that any unusual or adverse reactions to the use of a veterinary medicinal product or a biological substance in an animal is reported to the Pharmacy Board immediately, in order to ensure that such cases are investigated and appropriate action taken.

4.2.8 Human food production chain

Table 6. Key pieces of legislation in the area of food safety are:

Legislative instrument	Year of enactment	Implementing agency
PHA	1948	MoH
Meat and Meat Products Act	1975	MoAIWD
Meat Inspection Regulations	1976	
Milk and Milk Products Act	1971	
Slaughter of Cattle Act	1969	

Q8.1 – 8.3 Human food production chain

The PHA establishes the MoH as being the competent authority with primary responsibility for the safety and quality of “food”, which would include all products of animal origin destined for human consumption.

Section 109 of the PHA provides the Minister of Health with the authority to make rules related to inspection of dairy animals and animals destined to be slaughtered for human consumption, and of dairy premises, stock sheds / yards, milk containers and

slaughterhouses, factories, stores, shops where food is manufactured, prepared or kept.

The Act also empowers the MoH to make Rules related to:

- *the taking and (bacteriological) examination of samples of milk, dairy produce, meat or other articles of food and from animals or articles suspected of being diseased or unfit for human consumption and*
- *the veterinary inspection of dairy stock, and the prevention of the sale, or the keeping; transmission, or exposure for sale of milk from a diseased or infected animal; and*
- *the duties of dairymen in connexion with the occurrence of infectious disease amongst persons residing or employed in or about their premises and the furnishing by them of the names and addresses of their customers, and in connexion with reporting the occurrence, in animals on the premises or any dairy cattle, of diseases which are communicable to man and of any disease of the udder;*
- *the inspection and examination of, and the regulation of the manufacture, preparation, storage, keeping and transmission of any article of food intended for sale or for export from Malawi and the prohibition of the manufacture, preparation, storage, keeping, transmission, sale or export from Malawi of any such article which is, or contains, an ingredient which is diseased or unsound or unfit for human consumption, or which has been exposed to any infection or contamination.”*

Some of these provisions would seem to be encroaching on the normal range of responsibilities of a Veterinary Authority.

In the case of the regulation of the safety and quality of meat and milk, similar powers to those provided to the MoH are vested in the Minister of Agriculture in the *Meat and Meat Products Act* (1975), the *Meat Inspection Regulations* (1976), the *Meat and Meat Products Regulations* (2003) and the *Milk and Milk Products Act* (1971).

The *Meat and Meat Products Act* (1975) allows the Minister to make regulations for ‘*prescribing the methods to be employed in the slaughter of animals in slaughterhouses and the implements to be used for such purposes*’ (section 4(1)(f)). Section 4(1)(p) allows him to make regulations ‘*controlling and regulating the establishment, design, construction, standards, locality, supervision, equipment, maintenance and management of slaughterhouses....*’ which can have implications on an animal’s welfare. Section 7 of the *Meat and Meat Products Regulations* (2003) makes reference to ‘*casualty animals*’ and ante-mortem inspection, but only refers to ensuring the health of animals / preventing the spread of disease. The qualifications and training of inspectors related to their ability to promote the welfare of animals are not specified. The *Meat Inspection Regulations* (1976) are well drafted and include all of the necessary provisions covering ante- and post-mortem inspection of slaughter animals and meat.

There is however an overlap in some of the responsibilities of the two Ministries, especially with regard to ante- and post-mortem inspection of meat, the collection and processing milk and the licensing or authorisation of the owners of premises where either meat or milk are processed.

The *Slaughter of Cattle Act* (1969) has been enacted solely for the purpose of preventing the slaughter of female or immature cattle and is not relevant with regard to food safety of animal products but does have a bearing on animal welfare issues to be met before and at slaughter.

A copy of the revised *Draft Milk and Milk Products (Amendment) Act* (2013) was provided to the Team during the mission and reviewed very briefly during the mission. This Act establishes a Dairy Advisory Committee and, as and when necessary, a National Dairy Industry Development Authority. The main deficiencies noted in this piece of legislation are:

- The Act does not place the primary responsibility for the sale of safe milk on the owner of a premises where milk or milk products are processed.
- The definitions of “milk” and “raw milk” need to be revised to avoid the use of subjective adjectives such as “normal” and “fresh”.
- Although there are references to the Malawi Bureau of Standards, there are no references to the international standard setting bodies such as OIE and Codex Alimentarius;
- There are no provisions which ensure that premises where milk and milk products are processed are managed in accordance with a risk-based food safety management system, such as HACCP.
- Although the power to make regulations which cover the inspection of milk and the taking of samples etc, there are no provisions which allow inspectors to apply sanctions in cases of non-compliance with standards, e.g. seizure, detention and disposal of milk or milk products which are found to be unfit for human consumption.
- There are no provisions which confer the authority of the DAHLD to order the recall of any batch of milk or milk product from the market, by a processor or distributor, in the event that such a batch is found to be unfit for human consumption.

It is recommended that this draft Act is reviewed and amended accordingly, taking into consideration the above mentioned deficiencies.

The first step in the process of drafting revised legislation covering the food safety of animal products will be to engage the MoH and the Ministry of Natural Resources, Energy and Environment (MoNREE) in discussions whereby each step in the process of ensuring food safety of animal products, from the farm to the fork is critically examined and the associated risks are identified for the purpose of developing appropriate control measures. The areas where there may be shared or an overlap of interests might be in the areas of environmental pollution, the hygiene of premises where meat or milk is being processed and the health of persons working at such premises and who are involved in handling meat or milk. At present there is lack of clarity as to which Ministry is responsible for the hygiene of vehicles used to transport meat from an abattoir or other meat processing facility to a wholesale or retail outlet. The MoH currently has responsibility for ensuring the hygiene at all wholesale and retail outlets (Section 109, PHA).

Once an agreement has been reached between the two Ministries, the PHA and the *Meat and Meat Products Act / Milk and Milk Products Act* may be reviewed and amended accordingly.

Regulations should then be developed which clearly define the detailed respective roles of the two Ministries. It is recommended that provisions are made in Regulations to ensure the following standards:

- placing the onus of primary responsibility for the safety and quality of any animal product, which is placed on the market for human consumption, on the owner of the processing facility;

- ensuring that the premises used for processing meat and milk introduce and adopt a risk based food safety management system equivalent to the Hazard Analysis Critical Control Point (HACCP) system; (once operators are licensed on the basis of adhering to defined standards for hygiene and management, in effect this helps to ensure that required conditions have been met prior to any activity taking place).
- in the case of meat which is destined for export, the requirements of potential importing countries will need to be considered. It is recommended that provisions relating to the recording of important animal health events during production and the traceability of animal products back to the production location are included for this purpose.
- setting the MRLs in meat and milk and other animal products destined for human consumption in accordance with Codex Alimentarius standards;
- establishing which Ministry is responsible for sampling and testing meat and milk products for residues;
- establishing provisions for administrative and judicial seizure of animal products deemed to be hazardous or to prescribe any possible treatments or alternative uses for a product which is unfit for human consumption;
- establishing a procedure for the recall by the retailer or distributor of any food of animal origin which is confirmed to be infected or contaminated in such a way as to be unfit for human consumption.

For the purposes of reaching an agreement with the MoH as to the respective roles and responsibilities of the respective competent authorities the DAHLD may cite the following references included in the TAHC Chapter 6.1 - The Role of the Veterinary Services in Food Safety) Section 6.1.3, Section 5, which states:

“Slaughterhouse inspection of live animals (ante-mortem) and their carcasses (post-mortem) plays a key role in both the surveillance network for animal diseases and zoonoses and ensuring the safety and suitability of meat and by-products for their intended uses. Control and/or reduction of biological hazards of animal and public health importance by ante- and post-mortem meat inspection is a core responsibility of the Veterinary Services and they should have primary responsibility for the development of relevant inspection programmes.” [...] and, “wherever practicable, inspection procedures should be risk-based. Management systems should reflect international standards and address the significant hazards to both human and animal health in the livestock being slaughtered. The reader is referred to Chapter 6.1 of the Terrestrial Animal Health Code”.

And, under Section 6.1.3 – Part 6 - Certification of animal products for international trade, it states...

“Another important role of the Veterinary Services is to ensure that health certification for international trade complies with animal health and food safety standards. Certification in relation to animal diseases, including zoonoses, and meat hygiene should be the responsibility of the Veterinary Authority. Certification may be provided by other professions (a sanitary certificate) in connection with food processing and hygiene (e.g. pasteurisation of dairy products) and conformance with product quality standards.”

Chapter 6.2 (TAHC) - Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection - Section 6.2.4 - Veterinary Services and meat inspection programmes – it is stated:

“Veterinary Services are primarily responsible for the development of ante- and post-mortem meat inspection programmes. Wherever practicable, inspection procedures should be risk-based and management systems should reflect international norms and cover the significant hazards to both human and animal health in the livestock being post-mortem meat inspection slaughtered, as determined by the Veterinary Services. In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of Veterinary Services include:

- 1) risk assessment and risk management;*
- 2) establishment of policies and standards;*
- 3) design and management of inspection programmes;*
- 4) assurance and certification of appropriate delivery of inspection and compliance activities;*
- 5) dissemination of information throughout the meat production chain.”*

It is recommended that the legislation be revised to authorise only veterinarians and trained veterinary para-professionals, including meat inspectors, to carry out ante- and post-mortem inspection. The qualifications and knowledge of VPPs undertaking this role will need to be defined; these staff should also receive training to allow them to assess, register and audit slaughter premises.

4.2.9 Import and Export

Table 7. The Import and Export of animals, animal products and biologicals (including vaccines) is regulated under the following pieces of legislation.

Legislative instrument	Year	Responsible Ministry
CDA	1967	MoAIWD
Control of Goods Act	1954	MoIT
Control of Goods (Import & Export) (Agriculture) Regulations	1967	MoIT
Control of Goods (Import & Export) (Agriculture) Order	1967	MoIT
Control of Goods (Import & Export) (Commerce) Regulations	1967	MoIT
FFRA	1970	MoAIWD
Parks and Wildlife Act	1992	

Q9.1 - 9.3 Import and export

Section 6 of the CDA provides the Minister with the authority to prohibit the importation into or the exportation from Malawi, of all animals and “carcasses, hides, skins, horns, hoofs, hair, wool, semen, litter, dung or fodder”. Whilst this provision is fairly comprehensive it is not complete in terms of protecting Malawi from all threats associated with the international trade of animals and animal products. Section 4 (1) (m) of the Meat and Meat Products Act, and Section 3 (1) (a) of the Milk and Milk Products Act both authorise the Minister (MoAIWD) to regulate the import and export of meat and milk, but there are no provisions in the existing legislation to regulate the international trade of bees and honey, for instance.

The *Control of Goods Act* (1954) and subsidiary legislation, also authorises the Minister of Industries and Trade to regulate the import and export of animals. Whilst it is understandable that a trader’s licence is necessary for the purposes of importing and exporting any goods, the authority for the regulation of the import and export of

animals and animal products for the purpose of preventing the entry and establishment of a notifiable animal disease or to protect human or animal health and life and the environment from risks associated with the importation of live animals and animal products should lie with the DAHLD. The DAHLD has the competent personnel to make decisions on the sanitary measures to be met by an exporting country, through the issuance of an import permit and to determine, at the time of entry, whether or not a consignment of an animal or animal product has met the sanitary requirements which would be certified on the international veterinary certificate accompanying such consignment. Part XI of the Parks and Wildlife Act (1992) covers the '*Import, Export and Re-Export of Wildlife Specimens of Protected and Listed Species*', which would include animals, or animal products. Section 99.- (1) allows '*The Minister, after consulting the Minister responsible for Trade and Industry*', to '*make regulations imposing additional restrictions on imports, exports or re-exports of specimens of a protected species or listed species*', which could be assumed to include provisions preventing the spread of diseases.

Neither the *Control of Goods Act* (1954), the CDAA nor the *Meat and Meat Products / Milk and Milk Products Acts* makes any reference to the international standards which are embodied in the Sanitary and Phytosanitary Agreement of the WTO nor of the OIE or Codex Commission. It is recommended that the revised legislation shall include references to the international standards (WTO/OIE/Codex) for import and export of animals and animal products, especially in relation to the determination of sanitary measures, which should be based upon scientific justification, developed through an internationally approved risk analysis procedure.

As yet, no regulations define the procedures for import and export regulatory controls, other than the requirement to apply for authorisation to import/export, from the Minister. For the sake of transparency and to ensure that procedures are implemented fairly, it is recommended that all procedures for regulating the import and export of animals and animal products before and at entry, in the case of import and export inspection and certification requirements for export, are provided in detailed Regulations.

5. Overall conclusions and recommendations

The DAHLD has a small group of senior veterinarians deployed at the headquarters in Lilongwe who are well qualified and have a keen interest in bringing the legislation covering the veterinary domain up to date and into compliance with OIE and other international standards.

Much of the existing legislation covering the veterinary domain is outdated and incomplete. There are a number of overlaps in the responsibilities of the DAHLD with other competent authorities, especially, the Pharmacy Board of the MoH and the food safety department of the MoH.

The VPVPA establishes a VSB but no officers have as yet been appointed. Furthermore, the provisions of the Act do not make any distinction between the prerogatives of a registered veterinary surgeon and those of different categories of VPP. There are currently no provisions to allow the Board to approve training and other events as CE nor the requirements for CE to maintain annual retention on the Register(s). Exemptions provided in a Schedule to the Act allow government employees and any person who is engaged in farming to perform acts of veterinary medicine and surgery. As yet, no Regulations for the implementation of this Act have been promulgated. In view of the large number of VPPs, most of whom work for government, but who practice veterinary medicine during their own time, it is strongly recommended that this Act is reviewed and Regulations for its

implementation are prepared and promulgated in accordance with OIE standards as soon as possible.

In the case of the Pharmacy Board, it became apparent during this mission that a revised Pharmacy, Medicines and Poisons Bill has been developed by the MoH without any consultation with the MoAIWD. It is strongly recommended that this Bill is withdrawn from the legislative approval process in order that the authority to make regulations to control the sale and use of prescription only medicines and pesticides with food animals, in particular, can be included in the proposed Bill.

Among the more important gaps in the existing legislation is the absence of provisions to regulate veterinary diagnostic laboratories. It is recommended that proposed new draft legislation makes all of the provisions required to ensure the quality of veterinary diagnostic laboratory services, especially those related to official tests and analyses to support international certification.

Although the Pharmacy Board (under the MoH) has responsibility for regulating both human and veterinary medicines, and has established a committee with representation from the DAHLD in decisions concerning licensing of veterinary drugs (product licence), during this mission the OIE Team was not convinced that veterinary drugs are being fully regulated and controlled in the country. For example, it is widely acknowledged that members of the public are able to purchase prescription only medicines over the counter from pharmacies and there are no provisions for ensuring compliance with withdrawal periods on the part of end-users.

The FFFRA would benefit from a detailed review, as the remedies sections generally overlap with the PMPA while the sections dealing with fertilizers are apparently not being enforced. A freestanding Animal Feeds Act would rationalize the system for control of animal feeds.

The DAHLD is seriously under-resourced in terms of human and financial resources and for this reason does not have the capability to perform all of its core regulatory functions covering the veterinary domain effectively. Although a Veterinary Faculty has now been established at the Lilongwe University of Agriculture and Natural Resources (LUANAR) and the first batch of veterinary graduates will be available in three years' time, there is a serious shortage of qualified veterinarians who are required to supervise the activities of VPPs in the field. It is recommended that the Ministry reviews the budgetary allocations for the DAHLD in order to allow the replacement of obsolete or non-functional equipment, provide new IT equipment, software and vehicles and to provide an operational budget which would allow them to come closer to meet international standards especially those related to food safety of animal products and the international trade of animals and animal products.

At each step during the process of revising or developing new legislation it is important that the DAHLD starts to undertake a cost : benefit analysis in terms of the human and financial resources required to allow full compliance with the standards being set in the new legislation and the potential gains to be made in terms of improved animal health and welfare status, improved standards of food safety and thus human health benefits, and increased opportunities for the export of poultry and other commodities, in the future. The impact of new legislation should also be measured in terms of compliance through keeping accurate records of any administrative sanctions which are applied or cases successfully brought to court.

General recommendations –

In view of the general observations recorded above and taking into consideration the results of the detailed analysis provided in Section 4.1 of this report, it is recommended that the following steps are taken by the DAHLD to initiate a comprehensive review and reform of the veterinary legislation governing the veterinary domain:

Step 1 The Policy hub, (established under the VET-GOV project), should review and update livestock and veterinary policies bringing them in line with recent developments in animal health initiatives both in Malawi and in the region and the

improved prospects for the export of surplus poultry products and possibly goat meat in the future.

Step 2 Collaborate and coordinate with other Ministries and stakeholders and hold discussions with interested parties to harmonise respective roles and responsibilities of the competent authorities with shared responsibilities for the regulation of veterinary medicines and biologicals, food safety and import / export of animals and animal products and by-products.

Step 3 Consider to repeal all, or part of the following Acts for the following reasons:

a) **CDA**

- Substantial gaps in important areas of veterinary domain (e.g. diagnostic laboratories; disease surveillance; contingency planning and sanitary emergencies) and definitions (e.g. types of animals covered) – (a revised Act could include provisions to give authority to make Regulations covering animal identification and animal welfare)

b) **Protection of Animals Act**

- The current focus of this Act is on cruelty, not well-being. There are some confusing definitions (e.g. species of animals covered); Exemptions would allow veterinarians and medical practitioners to be allowed to practice interventions in contravention of animal welfare standards.

c) **FFRA**

- The remedies part of this Act is redundant due to overlap of responsibilities for registration of medicines with the Pharmacy Board which is the competent authority for registration of all medicinal products.

Step 4 Option 1

- Draft new “**Animal Health and Welfare Act**” (and regulations) incorporating provisions for regulation of:
 - animal health (disease surveillance, disease prevention and control, animal disease emergencies, contingency planning);
 - veterinary diagnostic laboratories;
 - animal identification movement control and traceability;
 - safety and quality of animal feeds (licensing of manufacturers);
 - animal breeding (safety and quality of semen, ova and embryos);
 - licensing and inspection of animal gatherings (including animal markets);
 - animal welfare.
- Draft new Animal Feeds Act (and regulations)

Step 4 Option 2

- Draft new “**Animal Health Act**” (and regulations) incorporating provisions for regulation of:
 - animal health (disease surveillance, disease prevention and control, animal disease emergencies, contingency planning);
 - veterinary diagnostic laboratories;
 - animal identification movement control and traceability;

- safety and quality of animal feeds; (licensing of manufacturers etc.);
- animal breeding (safety and quality of semen, ova and embryos);
- licensing of animal gatherings (including animal markets);
- Draft separate **Animal Welfare Act** (and regulations)
- Draft new Animal Feeds Act (and regulations)

Step 5 **Review and amend:**

- **VPVPA**
 - Make clear distinction between the prerogatives of qualified vets and veterinary paraprofessionals. Review and adjust as appropriate, the exemptions allowing treatment of animals by govt. officers and agricultural workers, Develop provisions for CE.
- **Meat and Meat Products Act**
 - Definitions need improving.
 - Provisions for recall required.
 - Harmonise with other food safety legislation along the value chain.
 - Minister should make Regulations only on advice of Technical Committee.
- **Draft revised Milk and Milk Products Act**
 - Confer responsibility for the sale of safe milk on the owner of a premises where milk or milk products are processed.
 - definitions of “milk” and “raw milk” need to be revised to avoid the use of subjective adjectives such as “normal” and “fresh”.
 - Provide references to compliance with the international standard setting bodies such as OIE and Codex Alimentarius.
 - Make provisions which ensure that premises where milk and milk products are processed are managed in accordance with a risk-based food safety management system, such as HACCP.
 - Make provisions which allow inspectors to apply sanctions in cases of non-compliance with standards, e.g. seizure, detention and disposal of milk or milk products which are found to be unfit for human consumption.
 - Make provisions which confer the authority of the DAHLD to order the recall of any batch of milk or milk product from the market.

Step 6 Participate in making consequential amendments to:

- a) **PHA** – For example: “Define precisely the respective roles and responsibilities of the MoH and the MoAIWD for ensuring the food safety of animal products along the food production chain, from “Farm to Fork”.
- b) **PMPA** – Define precisely the respective roles and responsibilities for the regulation of the importation, manufacture, distribution, sale and use of veterinary medicinal products. Ensure that provisions are made for inspection of retail outlets and for enforcing the restrictions on the sale of prescription only medicines. Ensure that provisions include the requirement for compliance with withdrawal periods stated on the label of medicines used to treat food animals.
- c) **Control of Goods Act** – Provide an explanation of the basis of controls enforced by the MoIT – e.g. Import duty as opposed to food safety.

6. Evaluation of capacity to undertake future work on legislation

The DAHLD has a small group of staff who have a good understanding of the more important shortcomings of their veterinary legislation and would be competent to undertake the review and revision of the legislation as has been proposed in Section 5 of this Report, in partnership with their assigned Legislative Counsel at the MoJCA. In addition, there are a number of stakeholders working for various NGOs in Malawi, who have some experience with legislation and who have expressed an interest in providing assistance when possible.

There is no legal counsel working in the MoAIWD. Legal counsel is however available at the Office of the Attorney General to provide assistance with legal drafting.

The DAHLD has a very limited budget from government sources, however, there is currently an EU- funded veterinary governance project which is being implemented in the SADC region by the AU-IBAR. This project may have the necessary resources and the interest to assist the Government of Malawi to undertake a review and revision of the more important pieces of veterinary legislation.

During a meeting with the Principal Secretary (PS) for the MoAIWD, the PS assured the Team that in view of the current potential for export of live poultry and poultry products and other animal products, as well as the potential gains in improved food safety for domestic consumers, she would give priority to supporting the process of legislative reform to bring Malawi's veterinary legislation in line with international standards.

List of appendices

- Appendix 1 Correspondence between the OIE and the country
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- Appendix 4 List of persons consulted
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Appendix 1 Correspondence between the OIE and the country



Organisation
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de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

The Director General

Our Ref.: 16.066 FC/DS/

29 February 2016

Dr Bernard Chimera
Director of Veterinary Services
Department of Animal Health & Livestock Development
Ministry of Agriculture and Food Security
P.O. Box 2096
Lilongwe
MALAWI

OIE Veterinary Legislation Identification Mission

Dear Delegate,

In regard to the earlier letter from W.G. Lipita, former Director of Animal Health and Livestock Development dated 15 February, 2008 (Ref.:15/10/32) requesting the assistance of the OIE on the review and updating of Malawi's veterinary legislation and in consideration of your more recent, direct participation in the OIE IBAR VETGOV Regional Seminar for SADC Member States on Legislative Drafting for Regional Harmonization of Laws in the Veterinary Domain held in Maseru, Lesotho 6 – 10 July 2015, I am pleased at this time to propose a Veterinary Legislation Identification Mission for Malawi. For this mission, I propose a team of technical experts certified by the OIE, comprising Dr John Woodford as Team Leader with Dr Tania Thomson as Technical Veterinary Expert and Ms. Jessica Vapnek as Technical Legal Expert to undertake this mission. The proposed dates for the mission are 09 – 13 May 2016.

The aim of this mission will be to i) evaluate your veterinary legislation and its compliance with Chapter 3.4 on Veterinary Legislation of the OIE Terrestrial Animal Health Code; ii) support the preparation of your national priorities in terms of veterinary legislation; iii) identify the available human resources; and iv) propose a comprehensive plan to modernise your veterinary legislation.

For further information on the Veterinary Legislation Support Programme (VLSP), I recommend that you consult the OIE website at <http://www.oie.int/en/support-to-oie-members/veterinary-legislation/> which also includes a link to Chapter 3.4.

International travel costs, per diem allowances (to cover hotel and other accommodation costs and meals) and remuneration of the OIE experts that will participate in this mission will be covered by the OIE. However, it is expected that your government will take care of the expenses related to local travels, logistical support to the experts, the cost of the participation of the local team from your services, and any other expenses deemed appropriate to support the mission.

Should this proposal be acceptable, I would ask you to please designate a contact person who will collaborate with Dr Woodford to organise the mission and to provide him, beforehand, with documents he may request to ensure the appropriate preparation of the evaluation and to guarantee the quality of the results.

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Additionally, we will ask you to provide a personalised invitation letter to the experts once the Team Leader has provided their contact information. This is intended to facilitate the visa issuing process and other procedures.

Yours sincerely,



Dr Monique Eloit

- CC:
- Dr J.P. Dop, Deputy Director General, Institutional Affairs and Regional Activities;
 - Dr A. Dehove, Director of Finance;
 - E. Tagliaro, J. Macé, S. Riviere, V. Wong, World Animal Health and Welfare Fund;
 - Dr F. Caya, Head of the Regional Activities Department;
 - Dr M. Gonzalez, Deputy Head of the Regional Activities Department;
 - Dr D. Sherman, Coordinator of the Veterinary Legislation Programme;
 - Dr K. Tounkara, OIE Regional Representative for Africa;
 - Dr M. Letshwenyo, OIE Sub-Regional Representative for Southern Africa;

- 2 -

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MINISTRY OF AGRICULTURE,
DEPARTMENT OF ANIMAL HEALTH &
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P.O. BOX 2096,
LILONGWE,
MALAWI

Ref. No. 15/32/10 OIE
The Director General
World Organisation for Animal Health
12 rue de pronay
75017
Paris, France.

22nd March, 2016

OIE VETERINARY LEGISLATION IDENTIFICATION MISSION-MALAWI

Reference is made to the official communication as per your letter **Ref. No. 16.066 FC/DS/** dated 29th February, 2016 regarding above subject.

On behalf of Malawi Veterinary Services, I am pleased to inform you that your proposal to undertake Veterinary Legislation mission for Malawi between 9th -13th May 2016 is accepted. We therefore commit ourselves to collaborate with you on this mission whose aim will be 1) to evaluate the veterinary legislation and its compliance with chapter 3.4 on the veterinary legislation of the OIE Terrestrial Animal Health Code 2) Support the national priorities in terms of veterinary legislation; 3) identify available human resources and 4) Propose a comprehensive plan to modernize the veterinary legislation.

To this effect, be informed that Dr Patrick Chikungwa, Deputy Director for Animal Health has been designated as a contact person to collaborate with Dr Woodford to organise the mission. The email address for Dr Chikungwa is pchikungwa@yahoo.com and his phone number is + 265 888 371 509.

Please do not hesitate to contact the undersigned for any further clarification that might be required.

Your sincerely
(Signed)

Dr Bernard Chimera

OIE DELEGATE-MALAWI

DIRECTOR OF ANIMAL HEALTH AND LIVESTOCK DEVELOPMENT

Cc: Secretary for Agriculture, Irrigation and Water Development, P.o Box 30134, Lilongwe 3
Dr. M. Letshwenyo OIE Sub Regional Representative for Southern Africa

Dear Dr Chimera,

I have been informed by the Director General of the OIE that you have agreed to a veterinary legislation Identification Mission being carried out in your country.

The mission will take place from 9th to 13th May 2016 and will be conducted by myself, Dr John Woodford as Team Leader, Dr Tania Thompson (Veterinary Legislation Expert) and Ms Jessica Vapnek (Legal Expert).

To help me to prepare the mission, I am copying this letter to Dr Patrick Chikungwa, who I hope can assist me in setting up our mission.

Dr Patrick,

Before we can propose the work programme for this mission we shall require some further information. I am therefore enclosing a two-part questionnaire which you are kindly requested to complete and return to me at your earliest convenience. Part II of the questionnaire is self-explanatory. With regard to Part I, the accompanying advisory notes should answer any queries you have regarding its completion. However, if you or your colleagues responsible for completing it have any questions about the process of completing either Part I or II, you are welcome to contact me by email at: jdwoodford@gmail.com.

Our past experience suggests that the completion of Part I of the questionnaire can be facilitated by enlisting the assistance of legal advisors with knowledge of the veterinary legislation, either within your Ministry, or from the Office of the Attorney General.

In addition to the completed questionnaire, a number of other documents would be useful. These include:

- a copy or an internet link to the constitution of (country) currently in effect;
- a list of the main laws and regulations relating to the organisation of the Veterinary Services;
- a list of the titles of all laws and regulations pertaining to the veterinary domain currently in effect;
- copies of or internet links to the full texts of key laws and regulations applying to the veterinary domain. The OIE defines the veterinary domain as 'all the activities that are directly or indirectly related to animals, their products and by-products, which help to protect, maintain and improve the health and welfare of humans, including by means of the protection of animal health and welfare, and food safety'. A maximum of four full texts is sufficient (e.g. Animal Health Law, Food Safety Law, Veterinary Pharmacy Law, Veterinary Professions Law); and
- a copy of any draft law or regulation currently under development (if there are any).

After I have studied these documents, I shall be able to propose the key elements of the mission.

It would also be useful for you to identify senior staff in other administrations associated with the veterinary domain and let them know that this mission is being planned, as it may be worthwhile for the team to meet with them during the mission or for them to be involved in the preparation of the mission.

Finally, since legislation is a matter for political decisions, it will be important to arrange a meeting with the Minister in charge of the Veterinary Services. This of course will depend on the Minister's schedule, but a meeting at the end of the mission would be best as the team would then have some preliminary recommendations to share with the Minister.

I should be grateful if you would assist us in identifying a suitable hotel which is convenient for collection and drop-off to and from your offices and well located for local restaurants etc. We do not require 5 star accommodation, something in the middle of the range (about \$100-\$150, would probably be suitable). The hotel should have internet access.

Since we will almost certainly require to obtain a Business Visa (Single entry) we will almost certainly each require a letter of invitation from your Ministry of Agriculture addressed to the Consular Department of our respective Malawi Embassies. For my part I am British but live in France, so I will probably need to obtain my visa at the Malawi High Commission in London, since there is no longer an Embassy in Paris. Dr Thompson is British, but lives in Perth Australia. She may have already

become an Australian citizen. I will check with her. I am unsure about Ms Vapnek, but will get back to you as soon as we know more about the process of visa application, and whether it is actually going to be necessary. Perhaps you have experience of the procedures ?

If at all possible could you try and see if it would be possible to have us exempted from requiring a visa as this is in effect an "official mission" ? This would certainly make it a lot easier for all of us. I will get back to you with scanned copies of each of our passports as soon as possible.

Yours sincerely,

Enclosures:

List of experts and their contact details:

Dr John Woodford – jdwoodford@gmail.com

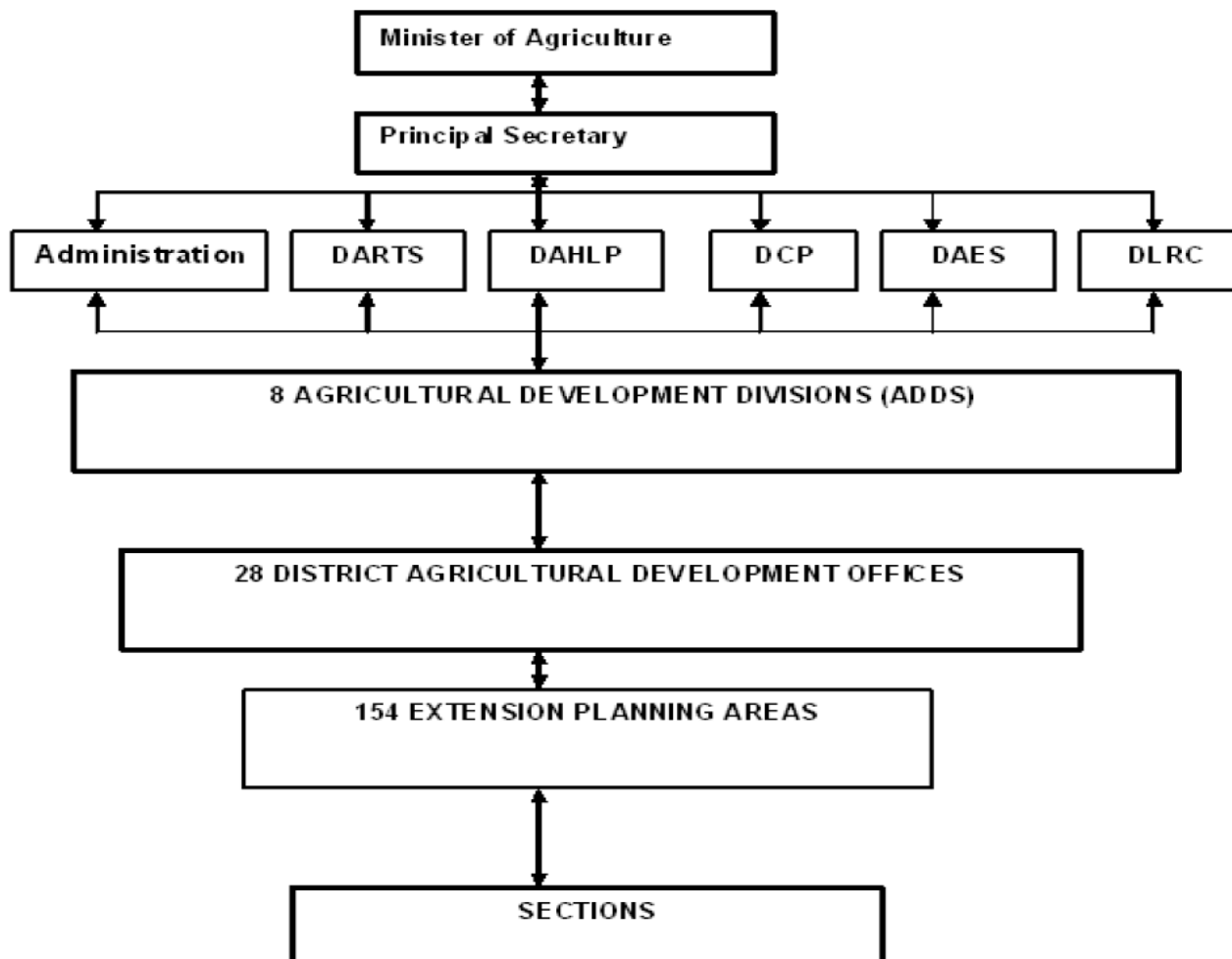
Dr Tania Thompson - vetania@hotmail.com; tania.dennison74@gmail.com

Ms Jessica Vapnek - JVapnek@dpkconsulting.com

Questionnaire parts I and II and advisory notes for part I

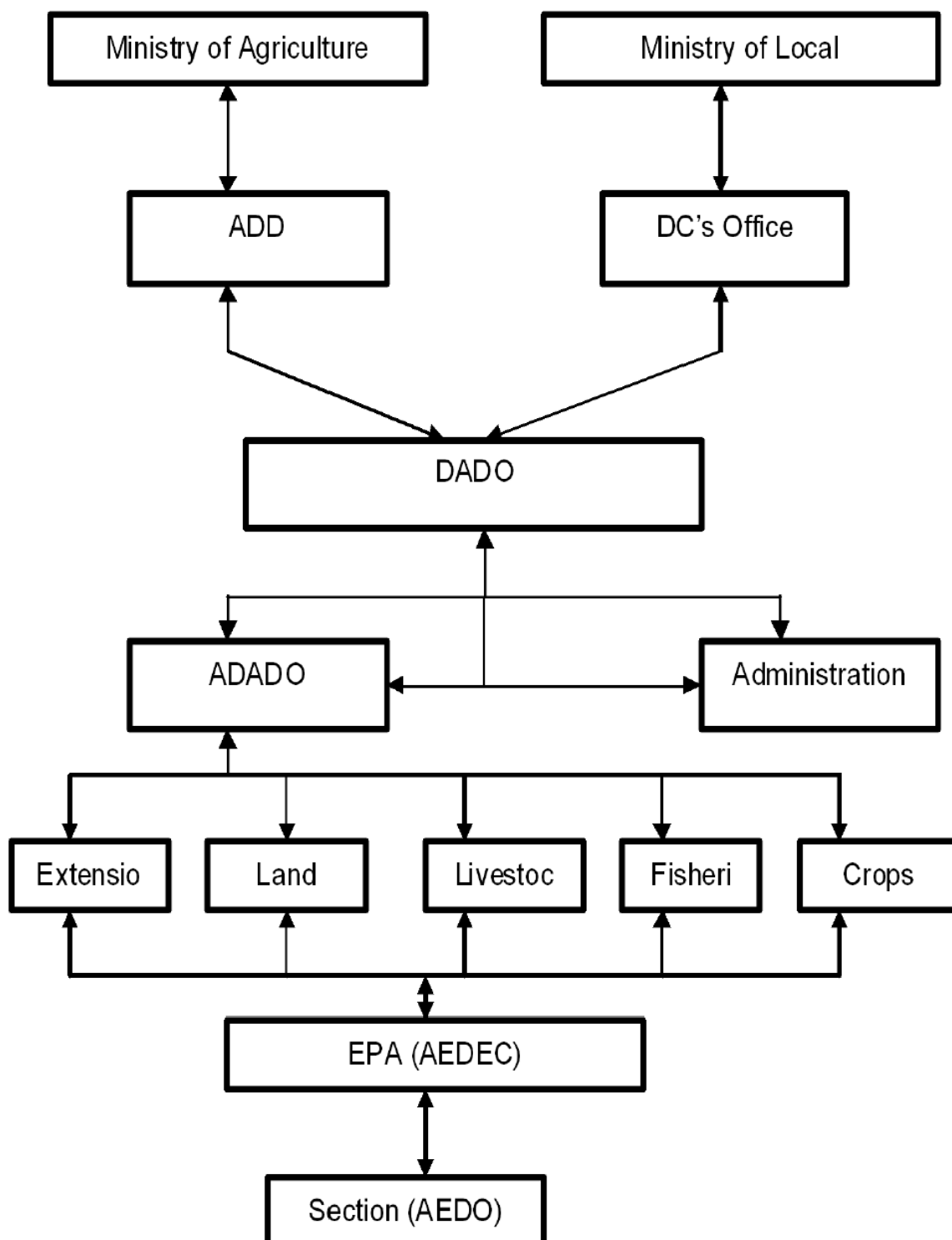
Appendix 2 Organogram of the Veterinary Services

Source: GoM (2003)



Technical and Administrative lines of communication – Agricultural & Livestock Services

Source: GUM (2003)



Appendix 3 Mission Programme

DATE	TIME	ACTIVITY
08/05/16	Afternoon	Arrival of OIE Mission Team transport to Woodlands Lodge, welcome by DAHLD Staff
09/05/16	0900 -10:00	OIE Mission Team meeting with Director and Senior Management team of the Department of Animal Health and Livestock Devt. – Discuss / revise Mission Programme.
	1000 - 1230	Opening meeting presentation OIE – Veterinary Legislation Identification Mission
	1230 - 1430	Lunch Break
	1500 - 1630	Focal group meeting senior veterinary professionals - Questionnaire II responses – Competent Authority / Animal Health, Disease Surveillance / Disease reporting / Animal identification & registration etc. legislation
10/05/16	09:00 - 12:00	Meeting with Representatives of Malawi Veterinary Association /LUANAR– Questionnaire II - Veterinary Professions and para-professions / Delegation of responsibilities to Private Sector legislation / Veterinary medicines
	1200 - 13:30	Lunch Break
	14:00 - 17:00	Meeting to discuss Questionnaire II responses – Animal Health – disease prevention and control, contingency planning etc; Animal Production (Import/Export);
11/05/16	09:00 - 10:00	Visit to Pharmacy Medicines and Poisons Board – (Questionnaire II - Veterinary Medicines Regulation
	10:30 - 11:30	Meeting Questionnaire II – Food Safety of Animal products;
	1200 - 1300	Lunch Break
	1330 - 1700	Meeting – Questionnaire II – Animal Welfare legislation / enforcement / Import / Export legislation
12/05/16	0800 - 0830	Meeting with Principal Secretary, MoAIWD
	0900 -1000	Meeting with Legal Counsel, Office of Attorney General to finalise Questionnaire I - seek advice on procedures for legal drafting assistance)
	1000- 1630	Visit to Dedza Border Post on Border control - implementation of control procedures / compliance
13/05/16	0900 - 1200	Closing Meeting OIE presentation – Preliminary Findings and Recommendations
	1230 - 1330	Lunch Break
	1400 - 1700	Report writing
14/05/16		DEPARTURE OF THE OIE MISSION TEAM

Appendix 4 List of persons consulted

DATE / SESSION	NAME	TITLE	INSTITUTION
09/05/2016 / morning	Dr Bernard A.R. Chimera	Director	DAHLD
	Dr Patrick Chikungwa	Deputy Director for Research & Investigations	DAHLD
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD
	Dr Gilson Njunga	Chief Pathologist	DAHLD
	Dr Julius Chulu	Chief Microbiologist	DAHLD
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
09/05/2016 / afternoon	Dr Bernard A.R. Chimera	Director	DAHLD
	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	DAHLD
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD
	Dr Gilson Njunga	Chief Pathologist	DAHLD
	Dr Julius Chulu	Chief Microbiologist	DAHLD
	Dr Joseph Nkhoma	Animal Health Officer	Lilongwe Agricultural Development Division (LADD)
	Dr Danny Chinombo	Lecturer/MVA Treasurer	LUANAR-NRC
	Dr George Chaka	Ag. Director	CTTBD
	Mr Joseph Munyuma	Principal Animal Health and Livestock Development Officer	DAHLD
	Mr Bernet Lwara	Head of Programs	Small Scale Livestock and Livelihood Program (SSLLP)
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE

10/05/2016 / morning	Dr Bernard A.R. Chimera	Director	DAHLD
	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	DAHLD
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD
	Dr Gilson Njunga	Chief Pathologist	DAHLD
	Dr Julius Chulu	Chief Microbiologist	DAHLD
	Dr Joseph Nkhoma	Animal Health Officer	Lilongwe Agricultural Development Division (LADD)
	Dr Danny Chinombo	Lecturer/MVA Treasurer	LUANAR-NRC
	Mr Joseph Munyuma	Principal Animal Health and Livestock Development Officer	DAHLD t
	Mr Bernet Lwara	Head of Programs	Small Scale Livestock and Livelihood Program (SSLLP)
	Dr Richard Ssuna	Country Director	All Creatures Animal Welfare League
	Dr Pat Boland	Director	National Rural Poultry Centre (NRPC)
	Dr Oliver Bakili	Lecturer	LUANAR
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
10/05/2016 / afternoon	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	Department of Animal Health and Livestock Development
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD
	Dr Joseph Nkhoma	Animal Health Officer	Lilongwe Agricultural Development Division (LADD)
	Dr Danny Chinombo	Lecturer/MVA Treasurer	LUANAR-NRC
	Mr Joseph Munyuma	Principal Animal Health & Livestock Development Officer	DAHLD
	Mr Bernet Lwara	Head of Programs	Small Scale Livestock and Livelihood Program (SSLLP)

	Dr Richard Ssuna	Country Director	All Creatures Animal Welfare League
	Dr Pat Boland	Director	National Rural Poultry Centre (NRPC)
	Mr Anold M. Nthala	District Animal Health & Livestock Development Officer (DAHLDO)	Veterinary Assistants Association of Malawi (VAAM), Dedza District
	Jaco Van Tonder	Central Poultry 200 Limited	Central Poultry 200 Limited
	Mr Thomas Chiputu	Dairy Supervisor	Katete Farm
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
11/05/2016 / morning	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	Department of Animal Health and Livestock Development
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	Department of Animal Health and Livestock Development
	Dr Joseph Nkhoma	Animal Health Officer	Lilongwe Agricultural Development Division (LADD)
	Mr Godfrey Kadeweile	Registrar	Pharmacy, Medicines and Poisons Board (PMPB)
	Mr Edwin Chipala	Registration Officer	Pharmacy, Medicines and Poisons Board (PMPB)
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
11/05/2016	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	Department of Animal Health and Livestock Development
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD
	Mr Kondwani Kawonga	Program Manager	Heifer Malawi
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
11/05/2016 / afternoon	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	DAHLD
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD

	Dr Julius Chulu	Chief Microbiologist	DAHLD
	Dr Pat Boland	Director	National Rural Poultry Centre (NRPC)
	Mr Henry Mtigu	Assistant Veterinary Officer/Meat Inspector	DAHLD-CVL
	Mr Kwamdera Banda	Laboratory Technician-Microbiology	DAHLD-CVL
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
12/05/2016 0800-0900	Mrs Erica Maganga	Principal Secretary for the Ministry of Agriculture, Irrigation and Water Development (MoAIWD)	Ministry of Agriculture, Irrigation and Water Development (MoAIWD)
	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	Department of Animal Health and Livestock Development
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	Department of Animal Health and Livestock Development
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
12/05/2016 0930 - 1000	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	Department of Animal Health and Livestock Development
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	Department of Animal Health and Livestock Development
	Mrs Angela Kaunda	Legislative Counsel	Ministry of Justice and Constitutional Affairs
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
12/05/2016	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	Department of Animal Health and Livestock Development

	Mr Henry Kaonga	Dedza Border Livestock Inspector	Department of Animal Health and Livestock Development
	Mr Andrew Mtukuleni	Station Manager	MRA, Dedza Border Post
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE
13/05/2016 / morning	Dr Patrick Chikungwa	Deputy Director for Research and Investigations	DAHLD
	Dr Poya Njoka	Chief Epidemiologist/MVA Secretary	DAHLD
	Dr Julius Chulu	Chief Microbiologist	DAHLD, Central Veterinary Laboratory
	Dr Danny Chinombo	Lecturer/MVA Treasurer	LUANAR-NRC
	Mr Joseph Munyuma	Principal Animal Health and Livestock Development Officer	Department of Animal Health and Livestock Development
	Lieza Swennen	Program Director	LSPCA
	Dr Gray Matita	Vice Principal	LUANAR-NRC
	Dr Pat Boland	Director	National Rural Poultry Centre (NRPC)
	Dr John Woodford	Team Leader/Veterinary Expert	OIE
	Ms Jessica Vapnek	Legal Expert	OIE
	Dr Tania Thomson	Veterinary Technical Expert	OIE

Appendix 5 Country's responses to the OIE questionnaire Part I

QUESTIONNAIRE: PART I

Q1 – Information on the state's political, administrative and legal organisation

- 1.1. Identify the fundamental legal instrument (e.g. constitution) in force relating to the distribution of powers. Attach the document or provide an electronic link or internet address.**

The Constitution of 1994 is the supreme law of the land.



Malawi Constitution.pdf

- 1.2. Describe the various administrative divisions in the country and their legal responsibilities, from the central state to the local administrative division with respect to the veterinary domain.**

The Constitution provides that there is the central government and then local government authorities which are elected. There are 28 administrative districts. The responsibilities for the veterinary domain are exercised at the national level with representation in some of the districts.

- 1.3. Please indicate if the legal system is mainly based on civil law, common law, religious law or customary law. Describe how the legal system supports the enforcement of the veterinary legislation in your country.**

Malawi has a mixed legal system. Its sources of law include constitutional law, statutory law, English law (received English law and other English law), common law, customary law, religious law, and customary international law. The Constitution provides for the continued application of the common law in force at the time the Constitution was adopted insofar as it is consistent with the Constitution. Similarly, the Constitution provides for the continued application of the customary law in force at the time the Constitution was adopted. The second aspect of the question is unanswerable except simply to say that the system relies on statutes, penalties, and court precedent.

Q2 – Hierarchy of the veterinary legislation

2.1. Veterinary legislation created and adopted by the central state:

(1) Level of legal instrument	(2) Category	(3) Type	(4) Issuing authority	(5) Source of law and procedure for creation
1	Constitution	Legislative	Parliament	Article 5 of the Constitution
2	Act	Legislative	Parliament	Article 48(2) of the Constitution – parliamentary
2b	Regulation	Legislative	Minister	Article 58(1) of the Constitution – originated by Minister
3	Rule	Regulatory	Minister	Originated by Minister
4	Order	Regulatory	Minister	Originated by Minister

2.2. Veterinary legislation created and adopted by decentralised authorities:

(1) Level of legal instrument	(2) Category	(3) Type	(4) Issuing authority	(5) Source of law and procedure for creation
None				

2.3. Veterinary legislation created and adopted by authorities holding delegated powers (if applicable):

(1) Level of legal instrument	(2) Category	(3) Type	(4) Issuing authority	(5) Source of law and procedure for creation
None				

2.4. Veterinary legislation created and adopted by private sector organisations (if applicable):

(1) Level of legal instrument	(2) Category	(3) Type	(4) Issuing authority	(5) Source of law and procedure for creation
None				

Comments.....

Q3 – Publication and management of legal documents

3.1. Is there an official legal database relating to veterinary legislation?

First level legislation?: Yes ☐ No ☒

Second level legislation? Yes ☐ No ☒

Information on the procedures for the implementation of legislation? Yes ☒ No ☐

If the answer is 'Yes' to any of these questions:

Computerised or manual database: Computerised ☐ Manual ☐

Manager(s) of the database:

Method of accessing the database:

For the Veterinary Services:

For the public:

3.2. Is there a system of consolidation?

No ☐ Yes, computerised ☐ Yes, manual ☒

Person(s) in charge: Ministry of Justice

3.3. Is veterinary legislation codified? Yes ☐ No ☒

Title of the Code:

Person in charge:.....

3.4. Does other legislation contain legal tools that are used by the VS? If so, please provide examples.

Civil law:

Penal law:

Penal procedure:

Administrative law:

Environment:

Consumer protection:

Customs and finance:

Other:

3.5. Legal publication

Procedures for legal publication:

Title of the official publication: Consolidated Laws of Malawi

Are the Veterinary Services subscribers? Yes ☐ No ☒

Is there a system of distribution within the civil service? Yes ☐ No ☒

3.6. Are there rules for distributing veterinary legislation other than by legal publication?

Within the Veterinary Services: Yes ☒ No ☐

To other administrations: Yes ☐ No ☒

To organised groups of stakeholders: Yes ☐ No ☒

To the public: Yes ☐ No ☒

If you answered 'Yes' for at least one of the above categories:

Reference document setting out the rules:

Method of dissemination:

Distribution lists:

3.7. Are there rules for disseminating information that is subordinate and relevant to regulatory texts?

Within the Veterinary Services: Yes ☒ No ☐

To other administrations: Yes ☐ No ☒

To organised groups of stakeholders: Yes ☐ No ☒

To the public: Yes ☐ No ☒

If you answered 'Yes' for at least one of the above categories:

Reference document setting out the rules:

Method of dissemination:

Distribution lists:

Rules regarding confidentiality:

Comments:

Q4 – Creation and adoption of legal instruments

4.1. What is the procedure for creating and approving primary veterinary legislation from initial preparation of a draft bill to final enactment in your country? Identify all steps and the administrative divisions involved as well as the range of time from initial preparation to passage.

Standard procedure for a common law country. Technical unit (e.g., DAHLD) prepares a bill, coordinating with the Legislative Counsel assigned to be the liaison with the Ministry of Agriculture. When bill finally prepared, introduced at National Assembly, discussed in committee, approved, enacted, Gazetted.

4.2. What is the procedure for creating and improving the secondary legislation (regulations) in your country? Identify all the steps, the administrative divisions involved as well as the range of time from initial preparation of the draft regulation to final adoption.

Standard procedure for a common law country. Technical unit (e.g., Veterinary Department) prepares the regulation, coordinating with the Attorney General's officer assigned to be the liaison with the Ministry of Agriculture. When regulation finally prepared, introduced at Parliament, discussed in committee, approved, enacted, Gazetted.

4.3. Are there formal rules for legal drafting? Yes ☐ No ☒

If 'Yes', please indicate the reference:

4.4. For the creation or updating of veterinary legislation:

Are the legal instruments always an initiative of the Veterinary Services? Yes ☒ No ☐

Are legal experts involved at the design stage? Yes ☐ No ☒

Do veterinarians/technicians systematically work with legal experts? Yes ☒ No ☐

4.5. Is consultation undertaken during legal drafting?

With the general public?	Yes	☒	No	☐
Is there a formal procedure?	Yes	☐	No	☒
With regulated parties?	Yes	☒	No	☐
Is there a formal procedure?	Yes	☐	No	☒
With professionals?	Yes	☐	No	☒
Is there a formal procedure?	Yes	☐	No	☐
With public administrations?	Yes	☒	No	☐
Is there a formal procedure?	Yes	☐	No	☒

If formal procedures are in place, please briefly describe.....

4.6. Is there a formal evaluation of the applicability and impact of the legal instruments as part of their creation (e.g. regulatory impact assessment)?

For primary legislation?	Never	☐	Sometimes	☐	Always	☒
For secondary legislation?	Never	☐	Sometimes	☒	Always	☐

If formal evaluations occur, please describe the process or give an example... Malawi Law Commission (MLC) is a constitutionally mandated body with the power to review the laws of Malawi to ensure that they are in accordance with the Constitution and relevant international laws. The MLC is made up of 11 lawyers – nine of whom have at least a master's degree. Once the draft law has been reviewed, the MLC issues recommendations contained in a report to the National Assembly, which, where necessary, includes the draft Bill.

4.7. What do these evaluations usually take into account?

If a template exists for these evaluations, please attach a copy or provide an electronic link or address on a website.

4.8. Are performance indicators developed in parallel with the legal instruments to monitor the success of the legal provisions when they are implemented? Yes ☐ No ☒

4.9. Is there usually a defined or expected timetable for implementation? Yes ☐ No ☒

4.10. When primary legislation is drafted, is the relevant secondary legislation drafted at the same time? Yes ☐ No ☒

4.11. What is the status of the pre-existing secondary legislation when new primary legislation is adopted?

Comments:...Depends on what the new Act says: if it says the regulations continue in force, they do. If it says they do not continue, they do not.

Q5 – Definition of veterinary domain and distribution of responsibilities

5.1. Is the 'veterinary domain' defined for official purposes? Yes ☐ No ☒

5.1.1. If you answered 'Yes', please state the definition and give the reference for the legal text:

5.2. For each element of the veterinary domain identified in the following table, please indicate the distribution of responsibilities.

Note: This table, when completed before the mission, will provide valuable guidance to the OIE Mission team on which officials and organisations should participate in the VLSP mission.

Element			Legislation		Control		Texts (8)
Code Chapter 3.4 Article (1)	Primary (2)	Secondary (3)	(4)	Authority responsible for preparation (5)	First level of control (6)	Second level of control (7)	Pertinent texts and comments
3.4.6	Veterinary profession	Private	☒	Department of Animal Health and Livestock Development (DAHLD)	DAHLD		Veterinary and Para- Veterinary Professionals Act Cap 53:04 (2001)
		Public	☒	DAHLD	DAHLD		Veterinary and Para- Veterinary Professionals Act Cap 53:04 (2001)
		Initial education	☐				
		Continuing education	☐				
	Veterinary para- professionals	Private	☒	DAHLD	DAHLD		Veterinary and Para- Veterinary Professionals Act Cap 53:04 (2001)
		Public	☒	DAHLD	DAHLD		Veterinary and Para- Veterinary Professionals Act Cap 53:04 (2001)
		Initial education	☐				
		Continuing education	☐				

Element			Legislation		Control		Texts (8)
Code Chapter 3.4 Article (1)	Primary (2)	Secondary (3)	(4)	Authority responsible for preparation (5)	First level of control (6)	Second level of control (7)	Pertinent texts and comments
3.4.7	Laboratories for Animal Health	Facilities	☐				
		Reagents	☐				
	Laboratories for Food Safety	Facilities	☐				
		Reagents	☐				
3.4.8	Animal production	Identification of animals	☐				
		Animal reproduction	☐				
		Animal feed	☒	DAHLD			Fertilizers, Farm Feeds and Remedies Ac
		Environmental impact	☐				
		Animal markets / other gatherings	☒	Public health inspectors	Public health inspectors		PHA
		Movement of Animals	☒				Movement of Livestock Regulations (2003)
		Animal by- products	☐				
		Disinfection	☐				
3.4.10	Animal welfare	General	☒	DAHLD	DAHLD		Control and Diseases of Animals Act Cap 66:01 (1968)
		Stray/free roaming animals	☒	Police	DAHLD		Control of Dogs Rules Prevention of Rabies Rules
	Protection of species	CITES	☒				Wildlife Act

Element			Legislation		Control		Texts (8)
Code Chapter 3.4 Article (1)	Primary (2)	Secondary (3)	(4)	Authority responsible for preparation (5)	First level of control (6)	Second level of control (7)	Pertinent texts and comments
3.4.9	Animal diseases	Surveillance	☐				
		Disease prevention & control	☒	DAHLD	DAHLD		Control and Diseases of Animals Act Cap 66:01 (1968) Control and Diseases of Animals Rules (various) Animal Quarantine Rules
		Emerging diseases	☒	DAHLD	DAHLD		Control and Diseases of Animals Rules (various)
3.4.12	Human food production chain	Milk production:	☒	DAHLD	Ministry of Health		PHA Milk and Milk Products Act (1986)
		Meat production	☒	DAHLD	Ministry of Health		PHA Meat and Meat Products Act (1975) Meat Inspection Regulations
		Poultry meat	☒				PHA
		Egg production	☐				
		Food of aquatic origin	☒				PHA
		Food processing	☒	Ministry of Health			List food processing rules
		Transport	☐				
		Retail	☒	Municipal authorities			List food retail rules
		Restaurants	☒	Municipal authorities			PHA List food service rules
3.4.11	Veterinary medicines & biologicals	Production	☐				
		Licensing & registration	☒	Pharmacy Board			PMPA
		Retail	☒	Municipal authorities			
		Residue control	☐				

Element			Legislation		Control		Texts (8)
Code Chapter 3.4 Article (1)	Primary (2)	Secondary (3)	(4)	Authority responsible for preparation (5)	First level of control (6)	Second level of control (7)	Pertinent texts and comments
3.4.13	Export certification	Animals	☒	DAHLD	DAHLD		Control of Goods Act (1954) Control of Goods (Import and Export) (Agriculture) Regulations Control of Goods (Import and Export) (Commerce) Regulations Control of Goods (Import and Export) (Agriculture) Order
		Animal products	☒	DAHLD	DAHLD		Meat Inspection Regulations (2003) Control of Goods Act (1954) Control of Goods (Import and Export) (Agriculture) Regulations Control of Goods (Import and Export) (Commerce) Regulations Control of Goods (Import and Export) (Agriculture) Order
3.4.13	Import requirements	Animals	☒	Customs	DAHLD		Control and Diseases of Animals (Prohibition of Importation of Animals) Order (1990)
		Animal products	☒	Customs	DAHLD		Control of Goods Act (1954) Control of Goods (Import and Export) (Agriculture) Regulations

							Control of Goods (Import and Export) (Commerce) Regulations Control of Goods (Import and Export) (Agriculture) Order
		Veterinary medicines and biologicals	☒	Customs	DAHLD		PMPA
		Animal feeds/feed additives	☒	Customs	DAHLD		FFFRA Fertilizers, Farm Feeds and Remedies (Farm Feeds) Regulations (1996)

Comments... The Pharmacy, etc. Act applies to drugs generally, not specifically to veterinary drugs although these would be covered according to the definitions.

Aspects of the Fertilizers etc. Act are no longer enforced.

Appendix 6 Country's responses to the OIE questionnaire Part II

Comparison of Existing Legislation with Chapter 3.4 of the *Terrestrial Code*

1. Competent Authorities (Article 3.4.5)

1.1. Do the Competent Authorities have the legal mandate, capacity and organisation to ensure that all necessary actions are taken quickly and coherently to address animal health, public health and animal welfare emergencies effectively?

Yes: X

No: ☐

Partially:

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02) & Meat & Meat Products Act, Milk and Milk products Act and Regs.

Comments: Although the legal mandate and organisation are there, the system lacks adequate resources to take necessary actions quickly to address livestock emergencies effectively.

1.2. Are the responsibilities and powers of Competent Authorities clearly defined in legislation, so that a clear chain of command is evident, from the central level to those responsible for the implementation of legislation in the field? Where more than one Competent Authority is involved, e.g. in relation to environmental, food safety or other public health matters, is there a reliable system of coordination and cooperation in place?

Yes: ☐

No: ☐

Partially: x

Pertinent legislations: Control and Diseases of Animals Act (Cap 66:02) & Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Despite the fact that the powers are clearly defined with a clear chain of command, there is no reliable system of coordination with other competent authorities. Now that the one health approach is being advocated it seems there is hope for more collaboration in the near future.

1.3. Do the Competent Authorities appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the veterinary legislation? (Note that the principles of independence and impartiality prescribed in Article 3.1.2 of the OIE *Terrestrial Code* are relevant here.)

Yes:

No: ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02) & Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Only technically qualified officials are appointed for instance if the assignment requires a veterinary surgeon then the Competent Authorities appoint a qualified veterinary surgeon to execute the assignment. Many functions which should be performed by a qualified veterinarian are being undertaken by VPPs with minimal supervision

1.4. Necessary Powers of the Competent Authority

Does the veterinary legislation ensure that:

a) Officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force?

Yes: ☐

No: ☐

Partially: x

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02) & Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: It does but it's archaic so sometimes the officials may feel that they are not legally having a strong backing.

b) While executing their legal mandate in good faith, officials are protected against legal action and physical harm?

Yes: ☐

No: ☐

Partially: x

Pertinent legislation: Control and Animal disease Act

Comments: Due to the archaic nature of the legislation officials feel partially covered.

c) The powers and functions of officials are explicitly and completely identified to protect the rights of stakeholders and the general public against an abuse of authority? This includes respecting confidentiality, as appropriate;

Yes:

No: ☐

Partially: ☐ X

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Explicit description required in Regulations

d) Certain essential powers are specifically identified and made available through primary legislation, as exercise of these powers can result in actions that may conflict with individual rights ascribed in fundamental laws. The powers identified, at a minimum, should include:

i) Access to premises and vehicles for carrying out inspections?

Yes: x

No: ☐

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02)

Comments:

ii) Access to records?

Yes: ☐

No: ☐

Partially: x

Pertinent legislation: Control and Diseases of Animals Act (Act 66:02)

Comments: lack of clear regulations – Movement control regulations – Farm feeds and remedies 12 (1) (c)

iii) Taking samples?

Yes:

No: ☐ Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02)

Comments: Only in F,FF and R Act

iv) Retention (setting aside) of animals and goods, pending a decision on final disposition?

Yes: x

No: ☐

Partially: ☐

Pertinent legislation: Control and Animal Diseases Act

Comments: Lack of compensation regulations hinders effective enforcement

v) Seizure of animals, products and food of animal origin?

Yes: x

No: ☐

Partially: ☐

Pertinent legislation: Control and Animal diseases Act

Comments:

vi) Suspension of one or more activities of an inspected establishment?

Yes:

No: ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02)

Comments: Lack of detailed regulations and guidelines for effective enforcement

vii) Temporary, partial or complete closure of inspected establishments?

Yes:

No: ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animal Act (Cap 66:02)

Comments: Meat & Milk processing premises

viii) Suspension or withdrawal of official authorisations or approvals?

Yes:

No: ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02)

Comments: No provisions to modify or withdraw orders / notices

1.5. Delegation of Powers by the Competent Authority

Does the veterinary legislation provide the possibility for Competent Authorities to delegate specific tasks related to official activities to veterinarians or veterinary para-professionals who are not civil servants?

Yes: ☐

No: ☐ X

Partially:

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Non state actors who are involved in animal welfare are allowed to exercise some powers on behalf of the state actors.

Does the veterinary legislation:

a) Define the field of activities, the bodies to which the tasks are delegated and the specific tasks covered by the delegation?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: it is vaguely defined and there are no regulations yet under the provisions of this Act

b) Provide for the control, supervision and, when appropriate, financial remuneration of the delegation?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Supervision and financial remuneration only when the delegation is in form of a consultancy.

c) Define the procedures for making delegation?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: No regulations yet

d) Define the competencies to be held by persons receiving delegation?

Yes: ☐ No ☒ Partially: ☐

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments:

e) Define the conditions of withdrawals of delegations?

Yes: ☐ No ☒ Partially: ☐

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments:

2. Veterinarians and Veterinary Para-professionals (Article 3.4.6)

2.1. Veterinary Medicine / Science

In order to ensure quality in the conduct of veterinary medicine / science, does the veterinary legislation:

a) Define the prerogatives (i.e. rights and responsibilities) of veterinarians and of the various categories of veterinary para-professionals that are recognised in the Member Country?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Whilst the act has defined the prerogatives for the veterinarians and para-veterinarians, other cadres also being trained as support group to the delivery of veterinary services are not included. No clear distinction between the prerogatives of veterinarians and VPPs

b) Define the minimum initial and continuous educational requirements and competencies for veterinarians and veterinary para-professionals?

Yes: ☐ No ☐ Partially: ☐

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: In job descriptions

c) Prescribe the conditions for recognition of the qualifications for veterinarians and veterinary para-professionals?

Yes: ☐ No ☐ Partially: ☐

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: In job descriptions

d) Define the conditions (e.g. licensing) for the exercise / practice of veterinary medicine / science by veterinarians and veterinary para-professionals

Yes: ☒ No ☐ Partially: ☐

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Regulations yet to be developed

e) Identify the exceptional situations, such as epizootics, under which persons other than veterinarians can undertake activities that are normally carried out by veterinarians?

Yes: ☐ No ☒ Partially: ☐

Pertinent legislation: Control and Animal diseases Act &

Comments:

2.2. The Control of Veterinarians and Veterinary Para-professionals

To provide a basis for regulation of veterinarians and veterinary para-professionals in the public interest, does the veterinary legislation:

a) Describe the general system of control in terms of the political, administrative and geographic configuration of the country?

Yes: ☐

No ☐ X

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02) & Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments:

b) Describe the various categories of veterinary para-professionals recognised by the Member Country according to its needs, notably in animal health and food safety, and for each category, prescribe the training, qualifications, tasks and extent of supervision required?

Yes: ☐

No ☐

Partially: X

Pertinent legislation: Control and Diseases of Animals Act (Cap 66:02) & Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Lack of functional Veterinary Board

c) Prescribe the powers to deal with conduct and competence issues, including licensing requirements that apply to veterinarians and veterinary para-professionals?

Yes: ☐

No ☐

Partially: x

Pertinent legislation: Veterinary and para-veterinary practitioners Act (Cap 53:04)

Comments: Functional Veterinary Board required for regulation and enforcement

d) Provide for the possibility of delegation of powers to a professional organisation such as a veterinary statutory body?

Yes: X

No ☐

Partially: ☐

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments:

e) describe the prerogatives (i.e. rights and responsibilities) and the functioning of the mandated professional organisation where powers have been so delegated?

Yes:

No ☐

Partially: ☐ X

Pertinent legislation: Veterinary and Para-veterinary Practitioners Act (Cap 53:04)

Comments: Curricula, institutions, Day On competencies

3. Laboratories in the Veterinary Domain (Article 3.4.7)

3.1. Facilities

Does the veterinary legislation define the role, responsibilities, obligations and quality requirements for?

a) Reference laboratories? (These are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods);

Yes: ☐

No x

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

b) Laboratories designated by the Competent Authority for carrying out the analysis of official samples?

Yes: ☐

No x

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Mostly follow guidelines as provided for in the OIE Manual

c) Laboratories recognised by the Competent Authority to conduct analyses required under the legislation, e.g. for the purposes of quality control?

Yes: ☐

No x

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Mostly follow guidelines/protocols as provided in the OIE manual

d) Does the veterinary legislation define the conditions for the classification, approval, operations and supervision of laboratories at each level?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Mostly follow guidelines/protocols as provided in the OIE manual

3. 2. Reagents

Does the veterinary legislation provide a basis for actions to address:

a) Procedures for authorising reagents that are used to perform official analyses?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: Control And Diseases Of Animals Act (Cap. 66:02)

Comments: Mostly follow guidelines/protocols as provided in the OIE manual

b) Quality assurance by manufacturers of reagents used in official analyses?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: Control And Diseases Of Animals Act (Cap. 66:02)

Comments: Mostly follow guidelines/protocols as provided in the OIE manual

c) Surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: Control And Diseases Of Animals Act (Cap. 66:02)

Comments: Mostly follow guidelines/protocols as provided in the OIE manual

4. Health provisions relating to animal production (Article 3.4.8)

4.1. Identification and traceability

Does the veterinary legislation provide a basis for actions to address all the elements in Article 4.2.3.6, identified as follows?

a) *the desired outcomes and scope of animal identification;*

Yes: ☐

No ☐

Partially: ☒

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Working on another legislation on animal identification and registration system

b) *the obligations of the Veterinary Authority and other parties;*

Yes: ☐

No ☐

Partially: ☒

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

c) *management of animal movement;*

Yes: ☐

No ☐

Partially: ☒

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Working on another legislation on animal identification and registration system

d) *data access/accessibility;*

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

e) *organisational arrangements, including the choice of technologies and methods used for the animal identification system and animal traceability;*

Yes: ☐

No ☐

Partially: ☒

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Working on another legislation on animal identification and registration system

f) *checking, verification, inspection and penalties;*

Yes:

No ☐ ☒

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

g) confidentiality of data;

Yes: ☒ No ☐ Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Working on another legislation on animal identification and registration system

h) where relevant, funding mechanisms;

Yes: ☐ No ☒ Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

i) Where relevant, arrangements to support a pilot project.

Yes: ☐ No ☒ Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Not currently provided for

4.2. Animal markets and other gatherings

Does the veterinary legislation address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

a) Registration or other official approval?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Control And Diseases of Animals Act (Cap. 66:02)

Comments:

b) Measures to prevent disease transmission, including procedures for cleaning and disinfection, and animal welfare measures?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Control And Diseases of Animals Act (Cap. 66:02)

Comments:

c) Provision for veterinary checks?

Yes: ☒ No ☐ Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

4.3. Animal reproduction

Does the veterinary legislation provide a basis for actions to address the health regulation of animal reproduction as appropriate? (Measures may be implemented at the level of animals, genetic material, establishments or operators.)

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: Control And Diseases of Animals Act (Cap. 66:02)

Comments: Not very explicit – import restrictions only cover semen – no provisions to restrict / embryos/ova – safety and quality of any breeding material -domestic production not covered.

4.4. Animal feed

Does the veterinary legislation provide a basis for actions to address the elements listed below:

a) Standards for the production, composition and quality control of animal feed to control biological, chemical and physical hazards to animal and public health?

Yes: ☒ No ☐ Partially: ☐

Pertinent legislation: Control And Diseases of Animals Act (Cap. 66:02) Malawi Bureau of Standards Act provides MBS to license and inspect and implement sanctions – Section 16 F, FF & R Act

Comments: Not very explicit

b) Registration or other procedures for approval of establishments and the provision of health requirements for relevant operations?

Yes: ☒ No ☐ Partially: ☐

Pertinent legislation: Control And Diseases of Animals Act (Cap. 66:02) F, FF & R Act, but duplication in MBS Act

Comments:

c) Recall from the market of any product likely to present a hazard to human health or animal health?

Yes: ☒ No ☐ Partially: ☐

Pertinent legislation Meat and Meat Products Act (Cap 67:02) & Milk and Milk Products Act (Cap 67:05)

Comments: MBSA / PHA Section 109 (1) (b)

4.5. Animal by-products (not intended for human consumption, e.g. meat and bone meal, tallow)

Does the veterinary legislation:

a) Define the animal by-products subject to the legislation?

Yes: ☐No ☐Partially: ☒

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Hides and Skins Act and Milk and Milk Products Act (Cap 50:02)

Comments: Not all animal by-products covered

b) Provide for rules for collection, processing, use and disposal of animal by-products?

Yes:

No ☐Partially: ☐

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Hides and Skins Act (Cap 50:02) & Milk and Milk Products Act (Cap 67:05)

Comments: Integrated industries for production of poultry/ fish / crocodiles not covered

c) Provide for registration or other procedure for approval of establishments and the provision of health requirements for relevant operations?

Yes:

No ☐Partially: ☐

Pertinent legislation: Meat and Meat Products Act (Cap 67:02) & Milk and Milk Products Act (Cap 67:05)

Comments: No such thing a "offal"

d) Provide for rules, if any, to be followed by animal owners in preparation and handling of animal by-products.

Yes:

No ☐Partially: ☐

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Hides and Skins Act (Cap 50:02) & Milk and Milk Products Act (Cap 67:05)

Comments:

4.6. Disinfection

Does the veterinary legislation provide a basis for actions to address the regulation and use of products and methods of disinfection relating to the prevention and control of animal diseases?

Yes:

No ☐Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

5. Animal diseases (Article 3.4.9)

5.1. Does the veterinary legislation provide a basis for the Competent Authority to manage diseases of importance to the country and to list those diseases, guided by the recommendations in Chapters 1.1 and 1.2 of the OIE *Terrestrial Code*?

Yes:

No ☐Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Incomplete list of notifiable diseases – List of diseases needs to be placed in subsidiary legislation – Minister should be obliged to act only on the advice of a technically qualified authority. Decisions should be based on scientifically justified standards.

5.2. Surveillance

Does the veterinary legislation provide a basis for the collection, transmission and utilisation of epidemiological data relevant to diseases listed by the Competent Authority?

Yes:

No ☐Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

5.3. Disease prevention and control

a) Does the veterinary legislation include general animal health measures applicable to all diseases and, if necessary, additional or specific measures such as surveillance, establishment of a regulatory programme or emergency response for particular diseases listed in the country?

Yes: ☒No ☐Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

b) Does the legislation provide a basis for contingency plans, for use in disease responses, including:

i) Administrative and logistic organisation?

Yes: ☐No ☐X

Partially:

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Requires review to provide for contingency fund and/or compensation arrangements – No provisions for making contingency plans

ii) Exceptional powers of the Competent Authority?

Yes:

No ☐XPartially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

iii) Special and temporary measures to address all identified risks to human or animal health?

Yes:

No ☐Partially: ☐X

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Decisions based on scientific justification and risk analysis

c) Does the veterinary legislation provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of killing or slaughtering of animals and seizure or destruction of carcasses, meat, animal feed or other things?

Yes: ☐No ☐

Partially: x

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02) Finance Act ? Treasury Act/Order

Comments: Needs review to provide for contingency funds and compensation aspects

5.4. Emerging diseases

Does the veterinary legislation provide for measures to investigate and respond to emerging diseases?

Yes: ☐No ☐X

Partially:

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: Needs review to address modern risk based approaches – No definition of emerging disease nor provisions to deal with them**6. Animal welfare (Article 3.4.10)**

6.1. General Provisions

The animal welfare requirements are found in Section 7 of the OIE *Terrestrial Code*.

Does the veterinary legislation contain a legal definition of cruelty as an offence, and provisions for direct intervention of the Competent Authority in the case of cruelty or neglect by animal keepers?

Yes:

No ☐Partially: ☐X

Pertinent legislation: Protection of Animals Act Cap. 66:01 and Slaughter of Cattle Act (Cap 50:04) Slaughter of Cattle Act

Comments: The legislations are old and requires revision.

6.2. Specific provisions

Does the veterinary legislation provide a basis for actions to address the animal welfare requirements of the OIE Codes, notably in relation to:

a) Transport (by sea/waterway, by land or by air) and handling?

Yes:

No ☐Partially: ☐X

Pertinent legislation: Protection of Animals Act Cap. 66:01 and Slaughter of Cattle Act (Cap 50:04)

Comments: Though regulations / guidelines require review. Journey times, loading unloading space allocation. Legal basis for guidelines

b) Accepted practice in animal production (e.g. beef cattle production)?

Yes:

No ☐Partially: ☐X

Pertinent legislation: Protection of Animals Act (Cap. 66:01) & Slaughter of Cattle Act (Cap 50:04)

Comments: Not fully comprehensive – eg definition of “humane”

c) Slaughter for human consumption?

Yes:

No ☐Partially: ☐X

Pertinent legislation: Protection of Animals Act (Cap. 66:01) and Slaughter of Cattle Act (Cap 50:04), Meat and Meat Products Act (Cap 67:02) & Milk and Milk Products Act (Cap 67:05)

Comments: Human slaughter techniques

d) Killing for disease control purposes?

Yes: ☐ No ☐ Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02), Protection of Animals Act Cap. 66:01 and Slaughter of Cattle Act (Cap 50:04)

Comments: Humane, equipment needed, firearms / captive bolt. (Regulations)

e) The use of animals in research and education?

Yes: ☐ No ☐ Partially: ☐ X

Pertinent legislation: Protection of Animals Act (Cap. 66:01)

Comments: Lab animals not covered

6.3. Stray dog population control

Does the veterinary legislation provide a basis for actions to effectively control stray dog populations?

Yes: ☐ No ☐ Partially: ☐

Pertinent legislation: Control And Diseases Of Animals Act (Cap. 66:02), Protection of Animals Act Cap. 66:01

Comments: Though not very explicit and require reviews – Definition of “stray” -

6.4. Abandoned animals

Does the veterinary legislation make provision for prohibition of the abandonment of animals, and management of abandoned animals, including transfer of ownership, veterinary interventions and euthanasia?

Yes: ☐ No ☐ Partially: ☐ X

Pertinent legislation: CDAA (Cap. 66:02), Protection of Animals Act Cap. 66:01

Comments: Require reviewing – Welfare issues for abandoned animals which have been captures not comprehensive – Disaster situation not covered by legislation -

7. Veterinary medicines and biologicals (Article 3.4.11)

This question seeks to determine whether the veterinary legislation provides a basis for assuring the quality of veterinary medicines and biologicals and minimising the risk to human, animal and environmental health associated with their use.

7.1. General measures

Does the veterinary legislation provide a basis for actions to address?

a) Definition of veterinary medicines and biologicals, including any specific exclusions?

Yes: ☐ No ☐ Partially: ☒

Pertinent legislation: PMPA Section 35

Comments: Need for specific veterinary medicinal products legislation – need better enforcement

b) Regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

Yes: ☐ X No ☐ Partially: ☐

Pertinent legislation: PMPA Section 35

Comments: Need for specific veterinary medicinal products legislation

7.2. Raw materials for use in veterinary medicines and biologicals

Does the veterinary legislation provide a basis for actions to address?

a) Quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality?

Yes: ☐ X No ☐ Partially: ☒

Pertinent legislation: PMPA Section 35

Comments:

b) Establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate?

Yes: ☐ No ☐ Partially: ☐ X

Pertinent legislation: PMPA Section 35; Pesticides Act does cover MRLs

Comments: Needs to be explicit under regulations (some not available) Issues over compliance with standards - PM&PA provides authority to set withdrawal periods - **PART 16: VETERINARY MEDICINE CLINICAL STUDIES DATA S16 (4) (1).** No mention of MRLs. / reference to Codex

c) Requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks?

Yes: ☐

No ☒

Partially:

Pertinent legislation: Pharmacy, Medicines and Poisons Board Act 1988 Section 35

Comments: Need for specific veterinary medicinal products legislation

7.3. Authorisation of veterinary medicines and biologicals

a) Does the veterinary legislation ensure that only authorised veterinary medicines and biologicals may be placed on the market?

Yes: ☒

No ☐

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments: Poor enforcement – require effective regulations – PPB under review – F, FF&R is redundant

b) Does the veterinary legislation make special provisions for:

i) medicated feed?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments: Not explicit

i) Products prepared by authorised veterinarians or authorised pharmacists?

Yes: ☒

No ☐

Partially:

Pertinent legislation: PMPA Section 35

Comments: Require review

iii) Emergencies and temporary situations?

Yes: ☐

No ☒

Partially:

Pertinent legislation: PMPA Section 35

Comments: Not for emergency importation – (clinical trials and emergencies)

c) Does the veterinary legislation address the conditions associated with the granting, renewal, refusal and withdrawal of authorisations?

Yes: ☒

No ☐

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments:

d) In defining the procedures for seeking and granting authorisations, does the veterinary legislation:

i) Describe the role of the relevant Competent Authorities?

Yes: ☒

No ☐

Partially: ☒

• Pertinent legislation: PMPA Section 35 and VPVPA

Comments: overlap FFFRA

ii) Establish rules providing for transparency in decision making?

Yes: ☒

No ☐

Partially: ☐

Pertinent legislation: PMPA Section 35 and VPVPA

Comments: Needs to be explicit – Under review – Vet sub-committee in pipeline

e) Does the veterinary legislation provide for the possibility of recognition of the equivalence of authorisations made by other countries?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments: Needs review to accommodate mutual recognition – Included in the new draft law –

7.4. Quality of veterinary medicines and biologicals

Does the veterinary legislation address the following elements?

a) The conduct of clinical and non-clinical trials to verify all claims made by the manufacturer?

Yes: ☒

No ☐

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments: There is provision for the establishment of the clinical trials and ethics subcommittee

b) Conditions for the conduct of trials?

Yes: ☒

No ☐

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments: Protocols are provided for

c) Qualifications of experts involved in trials?

Yes: X

No ☐

Partially: ☐

Pertinent legislation: PMPA Section 35

Comments:

d) Surveillance for adverse effects arising from the use of veterinary medicines and biologicals?

Yes: ☐

No ☐ X

Partially:

Pertinent legislation: PMPA Section 35

Comments: Not explicit enough

7.5. Establishments producing, storing and wholesaling veterinary medicines and biologicals

Does the veterinary legislation provide a basis for actions to address?

a) registration or authorisation of all operators manufacturing, importing, storing, processing, wholesaling or otherwise distributing veterinary medicines and biologicals or raw materials for use in making veterinary medicines and biologicals?

Yes: ☐

No ☐

Partially: ☐ X

Pertinent legislation: PMPA Section 35

Comments: Need for specific veterinary medicinal products legislation – VPPs / POMs

b) Definition of the responsibilities of operators?

Yes:

No ☐

Partially: ☐ X

Pertinent legislation: PMPA Section 35

Comments: VPP supervision

c) Good manufacturing practices?

Yes: X

No ☐

Partially: ☐

Pertinent legislation: PMPA 1988 Section 35

Comments:

d) Reporting on adverse effects to the Competent Authority?

Yes: ☐

No ☐ X

Partially: x

Pertinent legislation: PMPA Section 35

Comments: Uncoordinated efforts by various enforcing agents

e) Mechanisms for traceability and recall?

Yes: ☐

No ☐ X

Partially:

Pertinent legislation:

Comments: Requires to be explicit for veterinary products

7.6. Retailing, use and traceability of veterinary medicines and biologicals

Does the veterinary legislation provide a basis for actions to address?

a) Control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use?

Yes: ☐

No ☐

Partially: ☐ X

Pertinent legislation: PMPA Section 35

Comments: Require proper regulations and enforcement arrangements

b) Establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users?

Yes: ☐ X

No ☐

Partially:

Pertinent legislation: PMPA Section 35

Comments:

c) Restriction to authorised professionals and, as appropriate, authorised veterinary para-professionals of commerce in veterinary medicines and biologicals that are subject to prescription?

Yes: ☐

No ☐

Partially: ☐ X

Pertinent legislation: PMPA Section 35

Comments: Inadequate enforcement

d) The supervision by an authorised professional or organisations approved for holding and use of veterinary medicines and biologicals?

Yes: ☐ No ☐ Partially: X

Pertinent legislation: PMPA Section 35 S66(e) (i)

Comments:

e) The regulation of advertising claims and other marketing and promotional activities?

Yes: ☐ X No ☐ Partially: ☐

Pertinent legislation: PMPA S52 , s34

Comments:

f) Reporting on adverse effects to the Competent Authority?

Yes: ☐ No ☐ X Partially:

Pertinent legislation: PMPA

Comments:

8. Human Food Production chain (Article 3.4.12)

The role of the Veterinary Services in food safety is described in Chapter 6.1 of the OIE *Terrestrial Code*.

8.1. General Provisions

Does the veterinary legislation provide a basis for?

a) Controls over all stages of the production, processing and distribution of food of animal origin?

Yes: ☐ No ☐ Partially: x

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04)

Comments: MBS are interested in inspection of abattoirs – sometimes apply sanctions – have checklist of hygiene standards

b) Recording all significant animal and public health events that occur during primary production (i.e. pre-slaughter)?

Yes: ☐ No X Partially: ☐

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04) Disease Control Act

Comments: Movement permit information

c) Giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability, established by the Competent Authority?

Yes: ☐ No ☐ X Partially:

Pertinent legislation: PHA, Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04) Maybe not explicit

Comments: Need for harmonised legislation for the control of quality systems on Food safety

d) Inspection for compliance with food standards that are relevant to health or safety?

Yes: x No ☐ Partially: ☐

Pertinent legislation: Meat and Meat Products Act and Milk and Milk Products Act and Slaughter of Cattle Act (Cap 50:04) and PHA. Legal basis for Guidelines in Regulations

Comments: Need for harmonised legislation for the control of quality systems on Food Safety and Public Health – No provisions for compliance with MRLs

e) Inspection of premises?

Yes: x No ☐ Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02), PHA, Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04)

Comments:

f) Prohibition of the marketing (i.e. sale) of products not fit for human consumption?

Yes: x No ☐ Partially: ☐

Pertinent legislation: PHA, Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04) PHA Section 109

Comments: Check

g) Provisions for recall from the marketplace of all products likely to be hazardous for human or animal health?

Yes: ☐ No ☐X Partially: x

Pertinent legislation: PHA, Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04)

Comments:

8.2. Products of Animal Origin Intended for Human Consumption

Does the veterinary legislation provide a basis for actions to address?

a) Arrangements for inspection and audit?

Yes: x No ☐ Partially: ☐

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05), & Slaughter of Cattle Act (Cap 50:04) POHA -Regulations

Comments:

b) The conduct of inspection and audit?

Yes: x No ☐ Partially: ☐

Pertinent legislation: & Control and Diseases of Animals Act (Cap. 66:02) Meat & meat products. Milk & milk products – (Eggs are meat)

Comments:

c) Food safety standards?

Yes: No ☐ Partially: ☐X

Pertinent legislation: PHA, Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04) S.110 (1) PHA

Comments: Honey not defined as an animal product – honey is included in definition of “food”

d) The application of health identification marks that are visible to the intermediary or final user?

Yes: ☐X No ☐ Partially:

Pertinent legislation: Meat and Meat Products Act (Cap 67:02), Milk and Milk Products Act (Cap 67:05) & Slaughter of Cattle Act (Cap 50:04)

Comments:

Does the Competent Authority have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain and to prescribe uses or treatments that ensure the safety of such products for human or animal health?

Yes: ☐ No ☐ Partially: x

Pertinent legislation: Meat and Meat Products Act and Milk and Milk Products Act and Slaughter of Cattle Act (Cap 50:04)

Comments:

8.3. Operators responsible for premises and establishments pertaining to the food chain

Does the veterinary legislation provide a basis for actions to address, as appropriate?

a) Registration of premises and establishments by the Competent Authority?

Yes: x No ☐ Partially: ☐

Pertinent legislation: M&MPA, M&MPA

Comments:

b) The use of risk-based management procedures?

Yes: No ☐X Partially: ☐

Pertinent legislation:

Comments:

c) Prior authorisation of operations that are likely to constitute a significant risk to human or animal health?

Yes: No ☐X Partially: ☐

Pertinent legislation: ????

Comments:

9. Import and Export procedures and Veterinary certification (Article 3.4.13)

9.1. Does the country belong to the World Trade Organization?

Yes: x No ☐ Partially: ☐

Pertinent legislation:

Comments:

9.2. Does your veterinary legislation make specific reference to the World Trade Organization?

Yes: ☐

No ☒

Partially: ☐

Pertinent legislation: Control and Diseases of Animals Act (Cap 67:2) & Hides and Skins Act (Cap. 50:02),

Comments: no provisions for scientific justification & risk analysis

9.3. Does the veterinary legislation provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Section 5 of the OIE *Terrestrial Code*, including:

a) Certification procedures?

Yes: ☐

No ☐

Partially: ☒

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments: authorisation of export officers

b) Animal health measures applicable before and at departure?

Yes:

No ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02)

Comments:

c) Border posts and quarantine stations?

Yes:

No ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02),

Comments:

d) Animal health measures applicable on arrival?

Yes:

No ☐

Partially: ☐ X

Pertinent legislation: Control and Diseases of Animals Act (Cap. 66:02),

Comments:

e) Classification, importation and laboratory containment of animal pathogens?

Yes: ☐

No ☐ X

Partially:

Pertinent legislation:

Comments: Need provisions to classify organisms based on risk

f) Quarantine measures applicable to non-human primates?

Yes: ☐

No ☐ X

Partially:

Pertinent legislation: Veterinary and para-veterinary practitioners Act (Cap 53:04) and Control and Diseases of Animals Act (Cap. 66:02),

Comments:

Appendix 7 List of acts and subordinate legislation consulted

Legislation	Year of enactment	Ministry responsible for implementation
Control & Diseases of Animals Act	1967	MoAIWD
Control and Diseases of Animals (Prohibition of Importation of Animals) Order	1990	
Diseases of Animals Rules	1928	
Animals Quarantine Rules	1968	
Movement of Livestock Regulations	2003	
Prohibition of Treatment except by Veterinary Officers Rules	1928	
Meat and Meat Products Act	1975	
Meat Inspection Regulations	1976	
Milk and Milk Products Act	1986	
Protection of Animals Act	1968	
Fertilisers, Farm Feeds and Remedies Act	1970	
Fertilisers, Farm Feeds and Remedies Regulations	1973	
Pesticides Act	2000	
Dairy Industries Corporation (Establishment) Order		
Fisheries Conservation and Management Act	1997	
Pig Grading Regulations		
Milk and Milk Products (Dairy Advisory Committee) (Establishment) Order		
Hide and Skin Trade Act	1955	
Veterinary and Para-Veterinary Practitioners Act	2001	
Animal Identification & Registration Bill	2004	
Biosafety Act	2002	MoNREE / Environmental Affairs Department
The Biosafety (Genetically Modified Organisms) Regulations	2007	MoNREE
Control of Goods Act	1954	MoIT
Control of Goods (Import and Export) (Agriculture) Order	1967	
Control of Goods (Import and Export) (Agriculture) Regulations	1967	
Control of Goods (Import and Export) (Commerce) Regulations	1967	
PHA	1948	MoH
PMPA	1988	
National Parks and Wildlife Act	1992	MoNREE

Appendix 8 List of reports consulted during the mission

Policy Document for Livestock in Malawi (2006), DAHLD

PVS Evaluation Report (2007) OIE.

PVS Evaluation Follow-up Report (2014), OIE

Departmental Document - A Contribution towards Ministry of Agriculture and Food Security Web site (2008) DAHLD

Department of Veterinary Services, Malawi – A Template for Country Presentation on the Status and Assessment of Strengths, Weaknesses, Gaps and Needs. (Undated) DAHLD.

Disease Control Programmes, Malawi - Country Presentation on the Status and Assessment of Strengths, Weaknesses, Gaps and Needs. (Undated) DAHLD.

A Synopsis of Legislation Governing Animal Health and Livestock Development in Malawi – (2008), DAHLD.

The Malawi Agriculture Sector Wide Approach (2011 – 2015) – Ministry of Agriculture and Food Security -

<ftp://ftp.fao.org/tc/tca/CAADP%20TT/CAADP%20Implementation/CAADP%20Post-Compact/Investment%20Plans/National%20Agricultural%20Investment%20Plans/>

The Malawi Growth and Development Strategy II (2011 – 2016) Government of Malawi - <http://www.gafspfund.org/sites/gafspfund.org/files/MGDS%20II%20final%20document%20January%202012.pdf>

Appendix 9 PowerPoint presentations used at entry/exit meetings

Opening Meeting presentation - 8th May 2016

03/06/2016



OIE Veterinary Legislation Support Programme (VLSP)
Veterinary Legislation Identification Mission for Malawi
9th – 13th May 2016

Dr John Woodford, (Team Leader / Technical Expert)
 Dr Tanis Thompson, (Technical Expert)
 Ms Jessica Vapnek, (Legislation Expert)



Brief History of the OIE

- Founded in 1924 in Europe in response to rinderpest outbreak.
- Headquarters in Paris.
- Objective was to coordinate activities in neighboring countries to effectively control outbreak.
- OIE evolved into a global, international organization, now with 178 member countries and territories.
- In 2003, The International Office of Epizootics became the World Organisation for Animal Health, but kept its historical acronym, OIE




Overview of this presentation

- Background on the OIE
- Background on the OIE PVS Pathway
- Introduction to the VLSP
- Malawi's experience with the PVS Pathway
- Veterinary legislation and the veterinary domain
- Chapter 3.4. of the OIE Terrestrial Code
- Conclusions



OIE now has a mandate far wider than when it was first created

The OIE was created in 1924

- ▶ To prevent the spread of animal diseases throughout the world

The 4th Strategic Plan 2006-2010 extended the OIE's mandate to

- ▶ "The improvement of animal health worldwide"



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OIE and the World Trade Organization

- The global visibility of the OIE increased in 1995 with the adoption by the World Trade Organization (WTO) of the Agreement on Sanitary and Phytosanitary (SPS) Measures.
- OIE became the WTO's standard setting organization for safe trade in animals and animal products.



WTO functions:

- Facilitate free trade,
- Negotiate trade rules,
- Implement trade agreements,
- Resolve trade disputes,
- Review national trade policies



03/06/2016

The Global Expansion of Trade

- International trade is an engine for economic growth
- Trade in livestock and foods of animal origin is especially important to developing countries with agriculture-based economies
- Control of livestock and zoonotic disease creates new opportunities for trade
- Global cooperation and coordination on standards for health and safety are essential
- Sanitary and Phytosanitary (SPS) Measures of the WTO
 - FAO/WHO Codex Alimentarius for trade in food
 - OIE for trade in livestock and aquatic animals



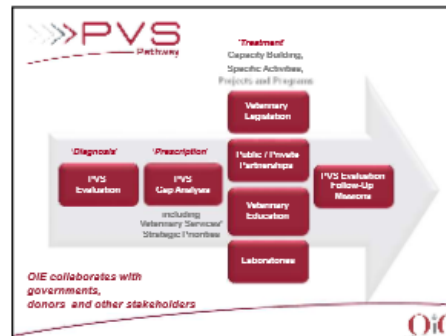
OIE Assistance to Members: The PVS Pathway

- PVS Evaluations (Performance of Veterinary Services) – Terrestrial and Aquatic
- PVS Gap Analysis
- Veterinary Legislative Support Programme (VLSP)
 - Identification Mission
 - Agreement
- Twinning Programmes
 - Laboratories
 - Veterinary Education Establishments
 - Veterinary Statutory Bodies
- Follow up evaluations



Increased trade is not the only benefit of compliance with international standards

- The activities of the OIE to strengthen Members' Veterinary Services and their compliance with international standards can also:
 - Improve the health and productivity of national flocks and herds,
 - Increase the supply of animal protein for domestic consumption,
 - Improve food safety,
 - Reduce the incidence of zoonotic diseases, and
 - Improve the general health and welfare of the nation's people and animals.



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PVS Pathway

OIE PVS Pathway is a continuous process aiming to sustainably improve compliance of Veterinary Services with international standards and their sustainable efficiency

03/06/2016

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Component One of the VLSP: Identification Mission - Logistics

- Initial request, OIE Team selection & designation of local contact
- Pre-mission information gathering
 - Constitution, key veterinary laws and questionnaires
- On-site mission of one week by OIE Team of experts
 - VLSP tools and concepts presented and overview of the current situation is discussed
 - Current legislation and questionnaires are reviewed to determine existing coverage of the veterinary domain
 - Needs are assessed, especially regarding methodology of legal drafting and provisional findings and recommendations presented
- Follow up report and recommendations
- Possible recommendation for an OIE Legislation Agreement



Structure of the VLSP

- The VLSP is a 'treatment' in the PVS Pathway
- Two key VLSP components
 - **Veterinary Legislation Identification Mission**
 - **Veterinary Legislation Agreement**



Component Two of the VLSP: Legislative Agreement

- **Objectives**
 - To establish specific objectives of legislative reform/modernization
 - To sharpen skills in legislative drafting
 - To develop specific new laws and regulations according to the Member's priority needs
- **Logistics**
 - Based on findings of the Identification Mission, Member may request to enter into an agreement
 - 6 month preparatory phase to identify work plan, working group, and benchmarks
 - One year agreement working with OIE expert to implement plan.
 - Role of expert is to provide methodological support, not to draft text.
 - Renewable for an additional year.



Component One of the VLSP: Identification Mission - Objectives

- Raise awareness of the importance of veterinary legislation for modern, effective operation of the veterinary services
- Review principles for developing high quality veterinary legislation
- Review the current status of the Member's legislation relative to the OIE standards for veterinary legislation presented in Chapter 3.4



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PVS Pathway Participation in Malawi



- PVS Evaluation Mission in June 2007
- PVS Follow-up Mission in January 2014
- VLSP Veterinary Legislation Identification Mission May 2016
- Future Activities?

Levels of advancement CC IV-1

IV-1 Preparation of legislation and regulations

The authority and capability of the VS to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to guarantee its quality with respect to principles of legal drafting and legal issues (internal quality) and its accessibility, acceptability, and technical, social and economical applicability (external quality).

This competency includes collaboration with relevant authorities, including other ministries and Government, national agencies and coordinated institutions that share authority or have mutual interest in relevant areas.

Levels of advancement

- The VS have neither the authority nor the capability to participate in the preparation of national legislation and regulations, which result in legislation that is lacking or is outdated or of poor quality in most fields of VS activity.
- The VS have the authority and the capability to participate in the preparation of national legislation and regulations, and can largely ensure that internal quality, but the legislation and regulations are often lacking in external quality.
- The VS have the authority and the capability to participate in the preparation of national legislation and regulations, with adequate internal and external quality in some fields of activity, but lack the formal methodology to develop adequate national legislation and regulations regularly in all domains.
- The VS have the authority and the capability to participate in the preparation of national legislation and regulations, with a robust formal methodology to ensure adequate internal and external quality, involving participation of interested parties in most fields of activity.
- The VS regularly evaluate and update their legislation and regulations to maintain relevance to existing national and international contexts.

Sample PVS Evaluation Results for Malawi in 2014

PVS Critical Competency*	PVS level (out of 5)
III-5 Veterinary statutory body authority	2
II-1 Laboratory disease diagnosis	2
II-9 Control of veterinary products	2
II-5 Passive epidemiological surveillance	2
II-6 Early detection/emergency response	2
I-8 Operational funding	2
IV-1 Preparation of legislation and regulations	2
IV-2 Implementation of legislation and regulations and compliance thereof	2

Levels of Advancement CC IV-2

IV-2 Implementation of legislation and regulations and compliance thereof

The authority and capability of the VS to ensure compliance with legislative and regulations under the VS mandate.

Levels of advancement

- The VS have no or very limited provisions of activities to ensure compliance with relevant legislation and regulations.
- The VS implement a programme or activities comprising inspection and verification of compliance with legislative and regulations and recording instances of non-compliance, but generally cannot or do not take further action in most relevant fields of activity.
- Veterinary legislation is generally implemented. As required, the VS have the power to take legal action to ensure compliance in instances of non-compliance in most relevant fields of activity.
- Veterinary legislation is implemented in all domains of veterinary competence and the VS work to ensure enforcement of non-compliance.
- The compliance programme is regularly updated to suit by the VS or external agencies.

Critical competencies IV-1 & IV-2 related specifically to legislation

IV-1 Preparation of legislation and regulations

The authority and capability of the VS to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to guarantee its quality with respect to principles of legal drafting and legal issues (internal quality) and its accessibility, acceptability, and technical, social and economical applicability (external quality).

IV-2 Implementation of legislation and regulations and compliance thereof

The authority and capability of the VS to ensure compliance with legislation and regulations under the VS mandate.

Critical competency IV-1

IV-1 Preparation of legislation and regulations

The authority and capability of the VS to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to guarantee its quality with respect to principles of legal drafting and legal issues (internal quality) and its accessibility, acceptability, and technical, social and economical applicability (external quality).

Malawi result: 2/5

The VS have the authority and the capability to participate in the preparation of national legislation and regulations and can largely ensure their internal quality, but the legislation and regulations are often lacking in external quality.

03/06/2016

Critical competency IV-2

IV-2 Implementation of legislation and regulations and compliance thereof

The authority and capability of the VS to ensure compliance with legislation and regulations under the VS mandate.

Malawi result: 2/5

The VS implement a programme or activities comprising inspection and verification of compliance with legislation and regulations and recording instances of non-compliance, but generally cannot or do not take further action in most relevant fields of activity.



Quality of Veterinary Legislation

- Good legislation must have **internal quality** and **external quality**
- **Internal quality** relates to the legal aspects of the law. **Good internal quality**
 - Respects the principles of the Constitution,
 - Respects the hierarchy of legislation,
 - Is clearly written for legal certainty,
 - Does not contradict other laws.
- **External quality** relates to the technical aspects of the law
 - All necessary activities are included
 - Proper authorities and powers are identified



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Principles of Veterinary Legislation

- The veterinary legislation must have its basis in **established veterinary policies** and objectives and represent those policies & objectives.
- There cannot be only one veterinary law
- The whole is necessarily very complex
- Practically we need a definition of veterinary legislation for the VLSP
- And so, the definition is:
 - « the set of legal texts necessary for the governance of the veterinary domain »



Objectives of Veterinary Legislation

- To provide a legal basis for effective regulation of the veterinary domain in order to achieve:
 - Food security through the protection of the primary resource (livestock health);
 - Food safety (through involvement from farm to fork);
 - Human health and safety (through control of dangerous animals and zoonoses);
 - Human welfare through assurance of animal welfare and animal health;
 - Safety of international trade in animals and animal products through compliance with the SPS.



Principles of Veterinary Legislation

- Veterinary legislation must be designed holistically, i.e.:
 - ✓ Legal aspects
 - ✓ Technical veterinary aspects
 - ✓ Organisational and administrative aspects
- With the development of a full set of measures including:
 - ✓ Basic laws
 - ✓ Derived regulations
 - ✓ Evaluation measures
 - ✓ Effective administration
 - ✓ Financial provisions!
- Improvement of veterinary legislation is a prerequisite to improving capacity of VS



03/06/2016

Definition of the veterinary domain

"All actions directly or indirectly related to animals, their products and by-products, whenever such actions help to protect, maintain and improve human health, namely the physical, moral and social welfare of humans"



Brief history of Chapter 3.4

- The Veterinary Legislation Support Programme (VLSP) was inaugurated as part of the PVS Pathway in 2008
- In 2009, at Members' request, the OIE developed *Guidelines on Veterinary Legislation*, identifying the essential elements that should be covered by legislation to meet the OIE standards. These were posted on the OIE website.
- In December 2010, the first *OIE Global Conference on Veterinary Legislation* was held in Djerba, Tunisia.



Brief history of Chapter 3.4

- A recommendation of the Djerba Conference was that the OIE propose the adoption & publication of the current *Veterinary Legislation Guidelines as standards in the Terrestrial Code*
- In response to this recommendation, OIE convened an *Ad Hoc Group on Veterinary Legislation* to develop the draft chapter on veterinary legislation.
- The *draft chapter on veterinary legislation* was unanimously adopted by the World Assembly of Delegates at the 80th OIE General Session in May 2012.
- It is now Chapter 3.4 of the OIE Terrestrial Animal Health Code**



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Chapter 3.4 of the OIE Terrestrial Animal Health Code

"The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising veterinary legislation so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain."



03/06/2016

Overview of Chapter 3.4 Veterinary Legislation

General matters

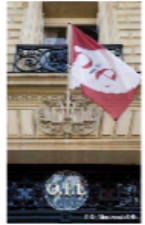
- > Introduction & objectives
- > Definitions
- > General principles
- > The drafting of veterinary legislation

Specific matters

- > Competent authorities
- > Veterinarians & veterinary para-professionals
- > Laboratories in the veterinary domain
- > Health provisions relating to animal production
- > Animal diseases
- > Animal welfare
- > Veterinary medicines & biologicals
- > Human food production chain
- > Import & export procedures & veterinary certification



Thank you for your attention..... questions?



Organisation mondiale
de la santé animale

World Organisation
for Animal Health

Organización Mundial
de Sanidad Animal

12 rue de Ploisy, 75017 Paris, France
www.oie.int oea@oie.int



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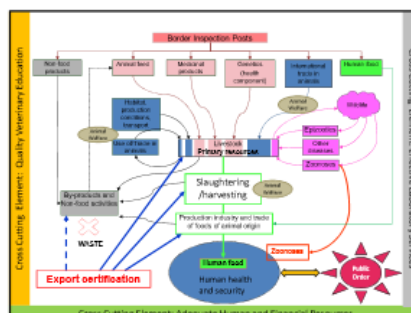
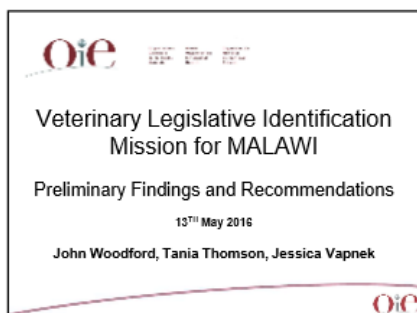
Conclusions

- Veterinary legislation is necessary to provide a **legal basis for the Competent Authority** to properly & effectively regulate the veterinary domain.
- The OIE Veterinary Legislative Support Programme (VLSP) is an integral component of the OIE's PVS Pathway which is dedicated to the robust development of Members' Veterinary Services consistent with international standards.
- The VLSP serves specifically to provide advice and assistance to Members on the formulation or modernisation of high quality veterinary legislation so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.



Closing Meeting Presentation – 13th May 2016

03/06/2016



OIE Legislation Identification Missions

- VLSP Identification Missions usually last one week and take place after the PVS evaluation and Gap Analysis missions.
- Objectives:** to clarify the situation in the country and analyse its needs relative to veterinary legislation.
- Preparatory phase** - involves questionnaires to ascertain information on the fundamental characteristics of the legal system and the technical content of existing laws.
- Step 1** – concepts and tools presented at in-country discussion; overview of current situation.
- Step 2** – Review of legislation and questionnaires to determine coverage of the veterinary domain.
- Step 3** – Assessment of needs, especially regarding methodology.

Strengths of Malawi's VS noted

- There is definite recognition of the importance of legislation as a foundation of good governance;
- There is genuine enthusiasm for continuing to improve the legal framework covering the veterinary domain;
- A core group of well qualified veterinarians with a good understanding of the regulatory issues which require to be resolved;
- A large number of well qualified and highly motivated veterinary para-professionals;
- Senior officials acknowledge existing problems and are actively seeking solutions;
- Some revised Drafts have been prepared (but need some revision);
- Healthy engagement with key stakeholders.

Definition of the veterinary domain

"All actions directly or indirectly related to animals, their products and by-products, whenever such actions help to protect, maintain and improve human health, namely the physical, moral and social welfare of humans"

Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code

Governance, Competent Authority, Chain of command (Art 3.4.5)

- Although the DAHLD is the de facto Competent Authority for the purposes of prevention and control of animal diseases and the safety of products of animal origin destined for human consumption, it has not been explicitly defined as such in the existing legislation.
- Overlap of authority and powers of different Competent Authorities to regulate the same areas of the veterinary domain:
- Meat & meat products, Milk & milk products and Public Health Act (MoH)
- Fertilisers, Farm Feeds & Remedies Act and Pharmacy, Medicines and Poisons Act (MoH)
- Control & Diseases of Animals Act and Goods Act (Import/Export)

03/06/2016

In addition

- In none of the (older) existing legislation has the "Minister" been defined as the Minister responsible for animal health and production.
- The Chief Veterinary Officer is not identified as the executive officer of the DAHLD.
- Currently no provisions to oblige the VS to comply with standards defined in the OIE Codes, The Codex Alimentarius or the SPS Agreement.
- No provisions to allow the CVO to delegate the performance of defined public functions to private veterinarians or private VPPs.

**Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code****• Animal production (Art 3.4.8)**

- No provisions exist in the legislation for:
- defining the scope / outcomes of an animal identification & trace-back system;
- the compulsory identification of individual animals;
- defining the technology to be employed for the identification of animals;
- authorisation of persons to place identification devices on animals;
- provision of information on identity of identified animals by the owner;
- defining animal movements to include births, deaths, sales)
- Prohibition/ licensing of animal gatherings, markets, etc.

**Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code**

- **Veterinarians & veterinary para-professionals (VPPs) Art 3.4.6)**
- No Regulations to support the implementation of the Veterinary & Para-Veterinary Practitioners Act;
- No distinction between the prerogatives of a registered veterinary surgeon and VPPs;
- No provisions for defining Continuing Education and possibility of mandatory CE requirements for retention of registration;
- No legal basis for establishing a Code of Conduct;
- Exemptions to allow unqualified persons to perform acts of veterinary medicine and surgery
- Some Definitions require to be improved, additional definitions may be required.

**Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code****• Animal feeds, animal by-products, animal breeding (Art 3.4.8)**

- No provisions for setting standards for the production, composition & quality control of animal feeds /
- No provisions for recall of contaminated/infected animal feeds to control biological, chemical or chemical hazards to animal / human health;
- No rules governing the handling of animal by-products by animal owners;
- Consideration may be given, in the future to licensing/registration of animal by-product processing establishments;
- Animal breeding – no provisions for regulating safety and quality of ova and embryos;

**Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code****• Veterinary diagnostic laboratories (Art 3.4.7)**

- The CVL not designated as the national reference laboratory
- No provisions exist for:
- classification, approval, operations and supervision of other public or private veterinary diagnostic laboratories;
- designation of laboratories for conduct of analysis of official samples;
- Procedures for authorizing reagents used to perform official analyses;
- ensuring the quality of reagents used in official analyses;
- the surveillance of marketing of diagnostic reagents.

**Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code****• Animal Diseases (Art 3.4.9)**

- list of notifiable animal diseases incomplete and placed in Act – suggest to place comprehensive list in a Schedule;
- No provisions for:
- collection, transmission & utilization of epidemiological information, sample collection for laboratory confirmation of clinical suspicion;
- administrative / logistic organization for dealing with animal disease emergencies;
- compensation following compulsory slaughter in the event of a notifiable disease outbreak;
- special and temporary measures to address all risks to human and animal health;
- Investigation of or response to exotic / emerging diseases; (contingency planning);



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Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code
• Animal Welfare – (Art 3.4.10 / Section 7)

- Lack of provisions to define animal well-being;
- Provisions to regulate transportation of animals incomplete;
- **No provisions for:** management of farm animals or animals used for experimentation (intensification, space allocation etc.);
- prohibition of abandonment of animals and provisions for dealing with stray animals (other than dogs);
- Some existing definitions need to be revised (e.g. "animal");
- Additional definitions required; e.g. "space allocation", "humane slaughter", "humane killing", "surgical operation" "journey", "resting period", "stray animal" etc.
- Exemptions need to be refined. (e.g. "free rein" for vets and medical practitioners);
- Penalties need to be revised.


Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code

- **Import / Export procedures / certification (Art 3.4.13)**
- No reference to WTO / SPS Agreement standards;
- **No provisions for:**
- Declaration of sanitary measures for import of animals & animal products based on Risk analysis and scientific evidence before and at departure;
- Equivalence of measures of exporting country;
- Export certification in accordance with OIE standards;
- Animal health measures on arrival;
- Classification and containment of animal pathogens;


Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code

- **Veterinary medicines & biological products (Art 3.4.11)**
- Duplication of authority to register General sales veterinary medicines between MoH and MoAI&VD
- **No or incomplete provisions for:**
- Equivalence of authorisations made by other countries;
- Establishment of withdrawal periods (exception is Pesticides Act).
- Requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks;
- Medicated feed;
- Surveillance / reporting of adverse effects arising from the use of VMPs / biologicals.


Strategic Plan for legislative reform

1. Review and update livestock and veterinary policy.
2. Consider to repeal all, or part of the following Acts:
 - a) **Control and Diseases of Animals Act**
 - Substantial gaps in important areas of vet domain (e.g. labs; disease surveillance; contingency planning and sanitary emergencies) and definitions (e.g. types of animals covered)
 - b) **Protection of Animals Act**
 - Focus on cruelty, not well-being. Confusing definitions (e.g. types of animals covered). Exemptions (e.g. "free rein" for vets and medical practitioners)
 - c) **Fertilisers, Farm Feeds and Remedies Act**
 - Remedies part is redundant.


Gaps in Legislation for the Veterinary Domain as presented in Chapter 3.4 of the Terrestrial Code
Human food production chain – (Art 3.4.12)

- Overlap in responsibilities of MoA, MoH & MBS;
- No clear delineation of respective responsibilities of each CA;
- **No provisions for:**
- recording of significant animal & public health events occurring during primary production;
- establishing risk based Food safety management systems (e.g. HACCP at premises processing animal products destined for human consumption);
- primary responsibility for safety of animal products on the part of the owner of an abattoir;
- Reference to international food standards e.g. Codex Alimentarius);
- recall from the marketplace of all products likely to be hazardous for human or animal health?


Strategic Plan for legislative reform

- 3 Option 1
- Draft new "Animal Health & Welfare Act" incorporating provisions for regulation of:
- animal health (disease surveillance, disease prevention & control, animal disease emergencies, contingency planning)
 - Veterinary diagnostic laboratories,
 - animal identification movement control and traceability,
 - Safety & quality of animal feeds (licensing of manufacturers);
 - animal breeding (safety and quality of semen, ova & embryos);
 - Licensing and inspection of animal gatherings (including animal markets);
 - Animal welfare



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Strategic Plan for legislative reform

3 Option 2

3.1 Draft new "Animal Health Act" (& Regulations) incorporating provisions for regulation of:

- animal health (disease surveillance, disease prevention & control, animal disease emergencies, contingency planning)
- Veterinary diagnostic laboratories,
- animal identification movement control and traceability,
- Safety & quality of animal feeds; (licensing of manufacturers etc),
- animal breeding (safety and quality of semen, ova & embryos);,
- Licensing of animal gatherings (including animal markets);

3.2 Draft separate Animal Welfare Act



Legislation Agreement with the OIE

- Preconditions: a PVS mission, a legislative identification mission, a formal request from the country concerned and **approval by the OIE Director General**.
- Country commits to a **strategic plan** and designation of a project leader to undertake a 6 month **preparatory phase**.
- The OIE provides methodological support and external references via an accredited expert with possible advice and participation of the OIE Regional Representation.
- If approved after the preparatory phase, a 1 year Agreement is signed which can include 1 or 2 country missions by the expert.
- Between visits, the country takes primary responsibility for the preparation of new legislation with consultation by the expert from a distance.
- The OIE does not draft legislation on behalf of the country concerned or finance its activities.



Strategic Plan for legislative reform

4 Review and amend:

Veterinary and Para-Veterinary Practitioners Act

- No distinction between prerogatives of qualified vets and veterinary paraprofessionals. Large exemption allowing treatment of animals by govt. officers and agricultural workers. No provisions for CE;

Meat and Meat Products Act

- Definitions need improving. Provisions for recall required. Harmonise with other food safety legislation along the value chain. Minister should make Regulations only on advice of Technical Committee.



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Strategic Plan for legislative reform

5 Coordinate with other Ministries to harmonise respective roles and responsibilities of Competent Authorities in the areas of Veterinary Medicines and Biologicals, Food Safety and Import / export of animals and animal products and by-products.

6 Participate in making consequential amendments to:

- a) Public Health Act
- b) Pharmacy, Medicines and Poisons Act
- c) Control of Goods Act



Thank you for your attention

...questions..?



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