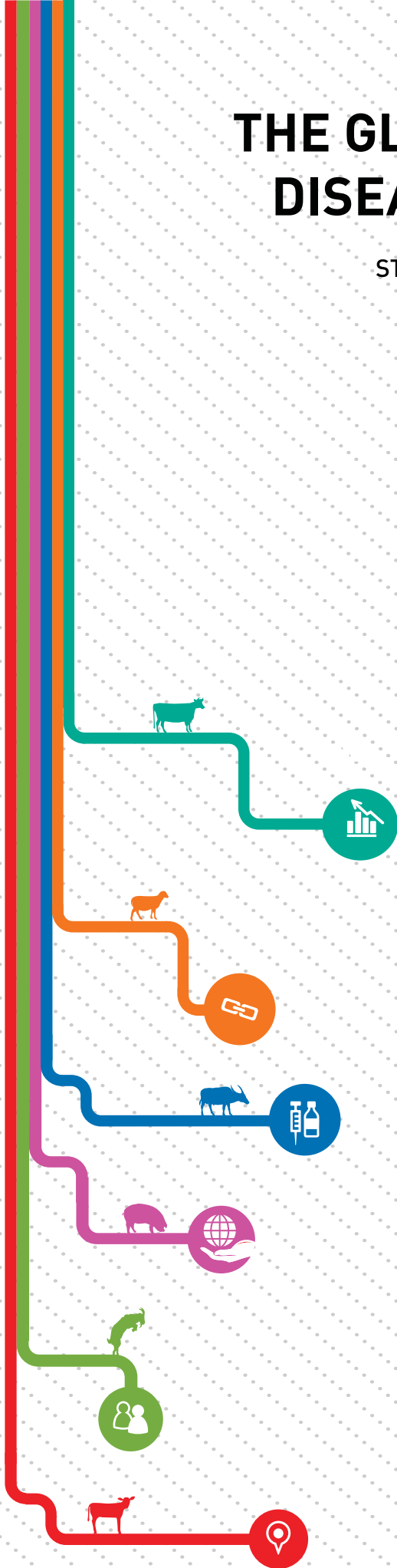


THE GLOBAL FOOT AND MOUTH DISEASE CONTROL STRATEGY

STRENGTHENING ANIMAL HEALTH SYSTEMS THROUGH
IMPROVED CONTROL OF MAJOR DISEASES

2012



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**Strengthening animal health systems
through
improved control of major diseases**

June 2012

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Foreword

Foot and mouth disease (FMD) is notorious for its ability to severely affect and indeed disrupt regional and international trade in animals and animal products. It is also notorious for the enormous financial damage it can cause in FMD-free countries hit by an outbreak and for the heated debates that then occur on control methods and ethics. However, the burden of FMD on developing countries, involving the loss of animals and biological diversity and the lowering of production efficiency, is generally much less well known or is underestimated. In FMD-endemic countries, usually developing countries, the disease threatens food security and the livelihoods of smallholders and prevents animal husbandry sectors from developing their economic potential.

FMD is still widespread throughout the world, particularly in Asia, Africa and the Middle East. By the end of 2011, more than 100 countries were not FMD-free. FMD-infected countries remain a permanent threat to free countries. The risks of introduction of FMD can be reduced, but not fully excluded, and the cost is high. The global increase in travel, trade and transport will inevitably exacerbate the situation. Reducing FMD at source, in other words in FMD endemic countries, is therefore a shared interest and should be considered a Global Public Good.

Following the recommendations of the first international FMD conference held in Asuncion in 2009, a Global FMD control strategy has been prepared under the FAO/OIE Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) in collaboration with experts from reference centres, regional and international organisations, professionals in charge of designing and implementing control strategies against major diseases, policy-makers from various regions of the World and representatives of development partners and private industry.

The Global FMD Control Strategy has been further developed in consultation with experts, national and regional authorities, policy-makers, development partners and private industry. The lessons learned in a number of regions in advanced stages of FMD control have been analysed and incorporated.

The Global FMD Control Strategy described in this document is not presented as a 'stand alone activity', aimed solely at FMD control, but rather as a carrier mechanism to simultaneously progress in other fields, with the strengthening of veterinary systems as the linchpin. To progress with FMD control, strengthening the Veterinary Services (VS) in a sustainable manner will be necessary, and this in turn will create better possibilities to control other priority animal diseases and pursue sensible and cost-effective combinations of activities.

Today, many developing countries are not investing in FMD control, either because they cannot afford it or because they fail to see the cost-effectiveness. Likewise, the level of international investments is relatively low. Improved FMD control on a global scale can only be anticipated if a concerted effort is made by the international community and relevant regional organisations, involving both developing and developed countries, and with sustained support of the development partners. The joint FAO/OIE Global FMD Control Strategy offers a framework and the necessary tools to implement a well-structured global FMD control effort.

We wish to thank the members of the GF-TADs FMD Working Group and all those who have provided assistance and support: the experts and professionals from individual countries, regional and international organisations, NGOs and private industry, OIE and FAO Reference Laboratories/Centres, the OIE Scientific Commission for Animal Diseases, various bodies in charge of implementing regional programmes and, last but not least, the members of the GF-TADs Management and Regional and Global Steering Committees.

Bernard Vallat
Director General
of the OIE

Juan Lubroth
Chief of the Animal Health Service and CVO
of the FAO

Executive summary

Introduction

Diseases are among the most significant limiting factors for livestock production. Their impact can vary from reduced productivity and restricted market access to the elimination of entire flocks or herds, with the resultant loss of biodiversity and valuable genetic resources.

Foot and mouth disease (FMD) is an eminent transboundary animal disease (TAD), severely affecting the production of livestock and disrupting regional and international trade in animals and animal products. In developing countries the adverse effects of FMD are often underestimated. The disease undermines food security and economic development, both at the level of village smallholders and the more organised production chains supplying urban and export markets. In some regions, in particular is southern Africa, the impact of FMD control measures on wildlife conservation has become an important consideration.

The global FMD distribution pattern largely reflects the development stage of countries and regions. Some areas of the world have managed to become or to stay free of FMD for decades, including Central and North America and Australia-Oceania. Others have managed to control the disease or make considerable progress, for instance Europe and South America. However, in 2012, around 100 countries do not have an FMD-free status. The disease still occurs in large parts of Africa, the Middle East and Asia and the countries that are free of FMD today remain under constant threat of an incursion. It is anticipated that FMD and other TAD threats will increase as a result of the increased travel, trade and transport occurring on a global scale.

As recommended by the first OIE/FAO Global Conference on FMD, held in Asunción, Paraguay, in June 2009 (19), FAO and the OIE embarked on the development of a Global FMD Control Strategy. The joint FAO/OIE Working Group presented a first outline of the Strategy during the 79th General Session of the World Assembly of Delegates of the OIE in May 2011 (3) and it was further developed in consultation with experts, national and regional authorities, policy-makers, development partners and private industry. The lessons learned in regions where FMD control is at an advanced stage or where the disease has been successfully controlled were fully taken into account. The Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) provided the governance structure to prepare the Strategy.

The overall objective of the Global FMD Control Strategy is to contribute to poverty alleviation and improving the livelihoods in developing countries and to protect and further the global and regional trade in animals and animal products. The specific objective is to improve FMD control in regions where the disease is still endemic, thereby protecting the advanced animal disease control status in other regions of the world. The Global FMD Control Strategy therefore not only aims to reduce the burden of FMD on animal production in developing countries, but also in FMD-free countries. History has shown that if incursions do occur, the cost of outbreak control may be enormous; furthermore, the FMD control methods used are increasingly criticised. Reducing FMD at source in FMD-endemic countries is therefore a shared interest and should be considered a Global Public Good.

The Global FMD Control Strategy

The Global FMD Control Strategy is not seen as a 'stand-alone activity', aimed solely at FMD control, but as a carrier mechanism to simultaneously progress in other fields, with the strengthening of veterinary systems as the linchpin. To progress with FMD control, strengthening the Veterinary

Services (VS) in a sustainable manner will be imperative, and this in turn will create better possibilities to control other priority diseases and pursue sensible and cost-effective combinations of activities.

The Strategy includes three Components:

- (i) Improving global FMD control,
- (ii) Strengthening Veterinary Services and
- (iii) Improving the prevention and control of other major diseases of livestock.

Component 1. The FMD Progressive Control Pathway (PCP-FMD) is the major tool of Component 1. It offers a structured 5-stage approach to FMD control, from the beginning up to the point where a country can submit a dossier to the OIE for official recognition of freedom from FMD. Detailed descriptions of the PCP stages, activities and outcomes are available. In Stage 1 the focus is on understanding FMD epidemiology and risk assessment; in Stage 2 the focus is on implementing a chosen control strategy which may be targeted to part of the country, a sector or subsector and will usually involve vaccination; in Stage 3, prompt response mechanisms become important as the control efforts are extended to a zone or to the entire country and involve all FMD-susceptible domestic species; in Stage 4 the activities are continued with a strong focus on prevention; in Stage 5 the situation will have improved to the level where a country may apply for OIE recognition as being FMD-free with vaccination. New trade-related options, such as compartmentalisation and commodity-based approaches, become feasible as of Stage 3. The case of wildlife, particularly in Southern Africa, has to be addressed in Stages 4 and 5.

The FMD-PCP will be helpful in both policy development and activity planning. The tool can be used for self-assessment; a possibility for external assessment will be created using the GF-TADs umbrella. In addition, once at Stage 3, a national FMD control programme may be submitted to OIE for endorsement, thereby adding to international credibility. PCP Stage 4 will lead to an application to the OIE for official recognition of country (or zone) free with vaccination and PCP Stage 5 free without vaccination.

The Strategy strongly recommends and supports a regional approach to exchange information and experiences, coordinate efforts and develop regional Roadmaps showing the country's ambitions and allowing regular progress assessment.

The Strategy underlines the importance of Reference Centres operating in a global network, while supporting a network of national diagnostic veterinary laboratories in each region. A similar structure is foreseen for epidemiology centres with global and regional network dimensions and national epidemiology units.

The need to ascertain the availability of sufficient quantities of FMD vaccine fulfilling the OIE criteria is emphasised and the designation of regional vaccine quality control centres is foreseen. The establishment of regional vaccine banks will be supported.

Although the Strategy attempts to achieve progress with the tools and technologies available today, the importance of research is recognised and supported, in particular regarding new and improved vaccines and diagnostic tools, epidemiology and socio-economics.

Other elements to support TAD control will become increasingly important when progressing through the FMD-PCP Stages, including communication, biosecurity awareness and application, identification and registration of animals and farms/epidemiological units, markets and transporters, development of public-private partnerships and effective emergency response mechanisms.

At the national level, capacity building and training will be essential components to implement the Strategy. In addition, the Strategy foresees the provision of finance, materials and vaccines for countries in the early Stages of the PCP. At the regional level, the focus will be on training, creation, maintenance and coordination of networks and providing international expertise in the fields of laboratory diagnosis, epidemiology, disease control and vaccine quality control. At the global level, the

focus will be on general oversight, disease intelligence and trends, virus characterisation, coordination, progress assessment, strategy development and advocacy.

The ambition formulated for the Global FMD Control Strategy is that:

- Within a 15-year period, countries that are currently in PCP Stages 0 and 1 will have progressed at least two stages along the PCP. Achieving this means that at the end of this period all countries will have reached at least PCP Stage 2.
- Countries in PCP Stages 2 or 3 should also move up two stages, but the final objective will depend on a country's decision based on cost-effectiveness studies.
- Countries or zones that already have an OIE-recognised FMD-free status maintain this status or further improve it (i.e. go from FMD-free with vaccination to FMD-free without vaccination).

Component 2. The OIE Performance of the Veterinary Services (PVS) Pathway will be the major tool of Component 2 to structure and plan the activities and assess progress. Relevant articles of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* and *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* will guide and highlight the requirements for countries to have their national FMD control plan endorsed by the OIE or to apply for FMD-free status recognition.

Countries progressing along the PCP Pathway will have to develop in parallel their VS to be able to fulfil the criteria. A correspondence table has been worked out between the PCP Stages and the compliance level required for each of the PVS Critical competencies (CCs) relevant to FMD control. All countries reaching PCP Stage 3 must at least have reached compliancy level 3 (i.e. general agreement with OIE standards) for the 33 FMD-relevant CCs that have been identified.

The Strategy recognises that the approach and the activities proposed under Component 2 (creating an 'enabling environment') are not FMD-specific and therefore are expected to have spill-over effects on the control of all major TADs. At the national level, Component 2-related activities will address various categories of support, such as surveillance systems, laboratories, biosecurity, movement control, identification of farms and animals, wildlife surveillance, legislation and transparency, socio-economic expertise, emergency preparedness, public-private partnerships, monitoring and evaluation, and communication.

Capacity building will be an important activity at national level. At the regional and international levels, the activities will address coordination, support to disease-specific laboratories and epidemiology networks, joint capacity building workshops, strengthening of regional animal health expertise and participation in regional conferences on animal health.

Component 3. The tools to be used for implementing Components 1 and 2 also contribute to Component 3. Achieving progress in FMD control (i.e. reaching a higher FMD-PCP Stage) implies having created an appropriate enabling environment for disease control (i.e. having improved the capacities and capabilities of the VS). This implies that the VS are also better equipped and better prepared to deal with the control of other priority animal diseases.

Reference Centres and regional and international networks already exist for many diseases, but some disease-specific joint OIE/FAO international and regional networks may still be needed. The same applies to networks of epidemiology centres, but the experience and expertise built up in the field of FMD epidemiology at the national level will also benefit other areas. Vaccines against infectious diseases other than FMD exist, but the issue of availability and quality control is a major concern in many countries.

At the international level, the information system of FAO and the OIE (and WHO for zoonotic disease outbreaks in humans), the Global Early Warning System (GLEWS), and the OIE official reporting system WAHIS/WAHID provide support for the control of a range of high-impact animal diseases, including zoonoses.

Sensible and cost-effective combinations of FMD control activities with other TAD control or production-related activities will be implemented, such as vaccinations against other major diseases, epidemiological investigations, diagnostic activities and treatments. Related activities will also be considered at the regional and international levels, and in this respect the Strategy foresees an important role for the Regional GF-TADs Steering Committees. Workshops will help to prepare disease-specific regional strategies and specific epidemiological and socio-economic studies will be undertaken. Disease specific laboratory and epidemiology networks will be supported as will the Crisis Management Centre - Animal Health located at FAO Rome.

In view of the above, the objectives of Component 3 cannot be formulated more specifically at present.

Governance

Overall policy guidance will be provided by the GF-TADs Global Steering Committee (GSC), supported by the FMD WG Secretariat provided and hosted by FAO. The GF-TADs FMD WG will update the Global Strategy in accordance with experience gained and contribute to its implementation. At regional level, the Regional GF-TADs Steering Committees (RSCs) will act as regional platforms with the support of their technical expertise groups (Regional Support Units: RSU), without however duplicating the work of the regional organisations and platforms already coordinating FMD control programmes (e.g. PAHO and COSALFA in South America, SEACFMD in South East and East Asia, EuFMD in Europe and AU-IBAR, with the support of relevant Regional Economic Communities [RECs], in Africa), which will of course continue their activities.

Action plan

Part B of this document presents the Action Plan for the three Components. The 15-year period of the Strategy has been divided into three periods of 5 years, with a description of the relevant progress expected for each period so as to facilitate regular assessment.

Budget

The cost of the activities foreseen under the Global FMD Control Strategy has been comprehensively calculated with the support of experts from the World Bank.

The cost of the Global Strategy for the initial five years of the programme would be US \$ 820 million, of which US \$ 762 million (93%), US \$ 47 million (6%) and US \$ 11 million (1%) are attributable to the country, regional and global levels respectively. The vaccination cost of US \$ 694 million is by far the largest component of the cost.

This cost estimate exercise can be used as a basis for gap analysis and needs to be refined as new information becomes available and more policy issues are addressed.

It should be mentioned here that no global cost estimates and specific budget provisions have been made for support to Components 2 and 3, since they are highly dependent on national socio-economic and policy environments, the disease priorities and choices made by the Governments. The results of a preliminary study of PVS Gap Analyses showed that major variations also exist depending on the level of compliance with OIE standards already attained (i.e. more investments are needed in countries that have reached a high level of compliance) and the density of the livestock population (i.e. lower cost per Veterinary Livestock Unit for countries with a high density).

An FMD portfolio analysis showed that the investments in FMD control worldwide are high, but such investments are made mainly by countries that see clear trade incentives. Developing countries are investing much less in FMD control, presumably either because they cannot afford it or because they fail to see a positive cost-benefit ratio. International investments are relatively limited.

The present level of international investments makes it unlikely that significant progress with FMD control can be anticipated in the near future. To correct this situation, additional investments are needed to support national programmes, in particular in countries in FMD virus pool regions 3, 4 and 5. To obtain the full benefit of FMD control efforts and to protect the progress achieved, support for regional and global coordination is likewise necessary. Better FMD control on a global scale can only be expected if a concerted effort is made, coordinated by the relevant international organisations, and with strong support from all relevant regional organisations, involving both developing and developed countries, and with the sustained support of the development partners.

The joint FAO/OIE Global FMD Control Strategy aims to offer a framework and the tools to initiate and implement a well-structured approach to global FMD control.

A set of annexes provides details on socio-economics, FMD control tools, regional experiences, vaccines, research, activities, costing of the strategy and portfolio analysis. All the annexes are contained in the document 'The Global FMD Control Strategy – Strengthening animal health systems through improved control of major diseases', which is available on the OIE and FAO websites.

List of acronyms

ASEAN: Association of South-East Asian Nations
ASF: African swine fever
AU-IBAR: African Union – Inter-African Bureau for Animal Resources
BT: Bluetongue
BVD: Bovine virus diarrhoea
CCPP: Contagious caprine pleuropneumonia
CMC-AH: Crisis Management Centre – Animal Health
CBPP: Contagious bovine pleuropneumonia
FAO: Food and Agriculture Organization of the United Nations
CCs: Critical competencies (OIE PVS)
CSF: Classical swine fever
COSALFA: South America FMD Control Commission
CVP: Permanent Veterinary Committee of the Southern Cone
EC: European Commission
EC–DG SANCO: European Commission – Directorate General for Health and Consumers
ELISA: Enzyme-linked immunosorbent assay
ECTAD: Emergency Center for Transboundary Animal Diseases (FAO)
EMPRES: Emergency Prevention System (FAO)
EMPRESi: EMPRES Global Animal Disease Information System (FAO)
EuFMD: European Commission for the Control of Foot-and-Mouth Disease
EU: European Union
FAO: Food and Agriculture Organization of the United Nations
FMD: Foot and mouth disease
FMDV: FMD virus
GFRA: Global Foot and Mouth Disease Research Alliance
GF-TADs: Global Framework for the Progressive Control of Transboundary Animal Diseases (FAO/OIE)
GF-TADs FMD WG: GF-TADs FMD Working Group
GLEWS: Global Early Warning System (FAO/OIE/WHO)
HS: Haemorrhagic septicaemia
HSZ: High surveillance zones
IBR: Infectious bovine rhinotracheitis
LFD: Lateral flow devices
LPB ELISA: Liquid phase blocking ELISA
NSP-ELISA: Non-structural protein ELISA
OFFLU: OIE/FAO Network of expertise on animal influenza
OIE: World Organisation for Animal Health
PACE: Pan African Control of Epizootics (AU-IBAR)
PAHO: Pan American Health Organization

PAMA: Mercosur Free from Foot-and-Mouth Disease Action Program
PANAFTOSA: Pan-American FMD Center (PAHO)
PANVAC: Pan African Veterinary Vaccine Centre of the African Union
PARC: Pan African Rinderpest Campaign (AU-IBAR)
PCP-FMD: Progressive Control Pathway for FMD
PCR: Polymerase chain reaction
PHEFA: Hemispheric Programme for the Eradication of FMD
PPP: Public–Private Partnership
PPR: Peste des petits ruminants
PVS Pathway: Performance of Veterinary Services Pathway (OIE)
RAHCs: Regional Animal Health Centres
RECs: Regional Economic Communities
RLLs: Regional Leading Laboratories
RCs: Reference Centres
RP: Rinderpest
RSOs: Regional Specialised Organizations
RSUs: Regional Support Units (of the GF-TADs)
SADC: Southern African Development Community
SAT: South African Territories types of FMD virus
SCAD: OIE Scientific Commission for Animal Diseases (OIE)
SEACFMD: Sub-Commission for Foot and Mouth Disease Control in China and South-East Asia
SEAFMD Campaign: South East Asia Foot and Mouth Disease Campaign
SPCE-ELISA: Solid phase competition ELISA
TAD: Transboundary animal disease
TAHC: OIE Terrestrial Animal Health Code (OIE)
TFCA: Transfrontier Conservation Area
VPH: Veterinary public health
VS: Veterinary Services
WAHID: World Animal Health Information Database (OIE)
WAHIS: World Animal Health Information System (OIE)
WRL: World Reference Laboratory
WHO: World Health Organization

THE GLOBAL FOOT AND MOUTH DISEASE CONTROL STRATEGY

Strengthening animal health systems through improved control of major diseases

Part A. The Global Strategy

1. Context of the strategy

In many countries livestock production contributes significantly to socio-economic development, valorisation of natural resources and sustainable food security for smallholders. It plays an important role, therefore, in global poverty alleviation – a priority for governments and development partners. Livestock provide meat, milk, manure for crops, draught power for transport and ploughing and are in general a source of financial revenue. In addition, livestock contribute to other important but less tangible components, such as capital reserves and social status. Worldwide, an estimated 700 million poor people rely on livestock for their livelihood (13).

Diseases are among the most significant limiting factors for livestock production and their impact can vary from reduced productivity and restricted market access to the elimination of entire flocks or herds with resultant loss of biodiversity and valuable genetic material. Zoonotic diseases directly impact on human health, especially for farming communities (22, 24).

Combating diseases of livestock in developing countries can contribute significantly to poverty alleviation by generating employment, providing funds for education and training, improving opportunities for trade in livestock and animal products and supplying raw materials to industry. The outcomes and severity of infectious diseases are the result of complex relationships between the infectious agent, animal husbandry systems, human behaviour and the environment, and disease management can only be effective if these elements are simultaneously taken into consideration in a holistic approach. The 'One Health' strategy offers the necessary conceptual framework, in terms of a multidisciplinary and multisectoral approach, and it is appropriate to address zoonoses as well as livestock diseases such as foot and mouth disease (FMD) that can have severe impacts on people's livelihood.

Implementation of the Global FMD Control Strategy is seen as an opportunity to initiate actions that will have beneficial consequences far beyond the control of FMD. It also provides an opportunity to improve the quality of the Veterinary Services (VS) and strengthen their capability and capacity to combat other major diseases of livestock, in particular the high impact transboundary animal diseases (TADs).

2. Rationale of the Global Strategy

The reasons why the FMD Global Control Strategy is being proposed are explained for each of the three Components which are interrelated pillars for the control of FMD and other major infectious diseases.

2.1. Global FMD control

FMD is one of the most contagious infectious diseases in animals and, due to its severe impact on trade in animals and animal products, is the most important TAD in the international context. The clinical signs of FMD, the lesions and the main epidemiological features of the disease are described in the literature (text books, technical and scientific articles) (1, 2, 10, 12), in various specialised websites and portals (7, 15) and in proceedings of recent FMD international conferences (4, 5, 19).

Some areas of the world, such as Central and North America and Australia-Oceania, have succeeded in protecting their FMD-free status for decades. In others, most notably Europe, South America and some countries of South-East Asia, FMD prevalence has decreased markedly. However, FMD remains endemic in many countries of Africa, the Middle East and Asia. Furthermore, the risk of FMD for countries free from the disease has increased due to the increased global movement and trade of livestock and animal products. This is illustrated by the recent (2010-2011) FMD epidemics in Japan, Republic of Korea and Democratic People's Republic of Korea. FMD has since been eliminated from most of those countries, but the cost in some cases has been enormous. In addition to the economic damage, FMD outbreaks and the way they have been controlled in developed countries, with massive culling, have been a source of great concern, not just in the farming community, but in society at large. The questions raised include animal welfare, ethical issues and possible threats to domestic animal biodiversity. The global FMD situation is well documented, particularly through the OIE information system (WAHID/WAHID) (14), with ongoing collection and official publication of data concerning any outbreaks reported by the OIE Members. As of May 2012, of the OIE's 178 Member Countries, 102 do not have FMD-free status, 66 are recognised as officially free (65 without vaccination and one with vaccination) and ten have officially free zones (6 without vaccination and 4 having zones with or without vaccination). Out of the 102 countries without FMD-free status, 6 had an official status that is currently suspended.'

In countries where FMD is endemic the disease is often underreported, even though farmers may suffer serious economic losses through undiagnosed neonatal mortality, reduced milk yields, lowered fertility, loss of draught power at critical times and reduced or prohibited access to markets (see Part A Annex 1 and Supporting document 1). Many developing countries are poorly equipped to deal effectively with livestock diseases such as FMD, which consequently continues to negatively affect food security and economic development, both for smallholder farmers and more organised value chains serving urban or export markets. In southern Africa the situation is very complex due to the endemic maintenance of FMD serotype SAT infection in African buffaloes. Furthermore, some FMD control methods in this region can adversely affect wildlife conservation and tourism, which is an economically important and growing sector.

Where the disease is efficiently controlled, the benefits are likely to be shared across the entire society of the country: from consumers who will benefit from greater stability and availability of livestock products, to livestock owners who will have fewer losses and greater market opportunities, and the people working and running businesses in the livestock sector who will have a more reliable source of products. For countries that share borders and trading systems

there will be mutual benefits that will also be available for future generations. Conversely, a country that fails to control FMD may negatively impact on its neighbours and trading partners. This is why control of FMD is considered to be a public good, a concept which has acquired a global dimension over the last few years (global public goods are those which: ‘tend towards universality in the sense that they benefit all countries, population groups and generations’ (11).

Following the recommendations of the first international conference on FMD control, organised by the OIE and FAO and held in Asuncion, Paraguay, in 2009 (19), the two Organisations have embarked, under the umbrella of the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs), on a Global Strategy and Global Action Plan for FMD control. A first outline was presented during the 79th General Session of the World Assembly of Delegates of the OIE in May 2011 (3). The strategy was further developed, taking into account the experience gained in several regions and the views expressed by representatives of countries and regional organisations as well as expert opinions, including those of experts from OIE and FAO reference laboratories/centres.

The Global Strategy proposes a step-wise approach to improve the FMD control capacity of a country in a sustainable manner, the Progressive Control Pathway (PCP) (8), which is also expected to have a positive effect on the performance of the VS and, in turn, improve animal health status in general. The Strategy focuses on regions of the world where the disease is endemic. The challenge for the Global Strategy is how current knowledge of FMD can best be used to control the disease in regions populated by the majority of the world’s livestock and where the economic circumstances are often difficult. A successful outcome will be of great benefit not only to countries where FMD is still present, the majority of which are developing countries, but also to countries that are currently FMD-free.

The national and regional levels will be the priority for intervention and where most activities will be carried out. The global level will focus on international coordination and the monitoring of overall progress. The programme will be long-term: an overall period of 15 years has been set, with 5-year phases and clear milestones and regular evaluations to assess progress.

2.2. Strengthening Veterinary Services

The subtitle of the Global FMD Control Strategy is ‘Strengthening animal health systems through improved control of major diseases’. Although ‘animal health systems’ refers to the entire complex of stakeholders involved in improving and safeguarding animal health, including animal health professionals (veterinarians other professionals and para-professionals) and livestock producers and traders, the main focus within the context of this Strategy is on the VS, which associate public and private sector veterinarians and other animal health professionals¹. Support for the development of private-public partnerships (PPPs) is part of the Global Strategy and is an indirect way of promoting the role of other stakeholders, and especially livestock producers, in the animal health system.

¹ As defined in the OIE *Terrestrial Code* glossary: Veterinary Services means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Terrestrial Code* and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.

The VS are the core component of a system that protects animal health and safeguards animal production. This, in turn, protects the livelihoods of those involved in agriculture and global food security and creates opportunities for economic development.

To function effectively, VS require appropriate infrastructure, a clear organisation and chain of command, trained and effective personnel and a sufficient budget to carry out their disease management activities. Unfortunately, in many developing countries these elements are of insufficient quality and the operating budgets are inadequate.

Harmonisation of control policies with neighbouring countries is often advisable and under some circumstances imperative, for instance in regions where there is cross-border nomadic animal movement.

The actions taken to control FMD correlate with effective VS and will have wider benefits. If a country can successfully control FMD it implies the establishment of more effective VS that will be better able to combat other major diseases of livestock and especially TADs. The OIE PVS Pathway (18a) will be used as a tool to evaluate the quality of the VS (PVS Tool) (18b) in terms of compliance with OIE standards, to monitor their improvement (PVS follow-up missions) and to identify and assess the level of investments a country must mobilise in order to eliminate its gaps in terms of OIE standards (PVS Gap Analysis). The PVS Gap Analysis takes into account the country's priorities, including the prevention and control of TADs.

2.3. Prevention and control of other major diseases of livestock

The cost-effectiveness of the Global FMD Control Strategy will be increased through appropriate linkages with other monitoring, surveillance and disease control activities or with production-related activities. In addition, the activities undertaken to achieve progress in the field of FMD control will result in valuable information and capabilities useful for the control of other TADs.

Diseases that may be considered for control alongside FMD include:

- In cattle: haemorrhagic septicaemia (HS); brucellosis; contagious bovine pleuropneumonia (CBPP); anthrax and in some regions possibly blackleg and rabies.
- In small ruminants: peste des petits ruminants; sheep and goat pox and brucellosis.
- In pigs: classical swine fever and African swine fever.

The above list is not exhaustive – other diseases may be added according to the needs and priorities of individual countries and regions. For example, in parts of Africa FMD vaccination could be applied alongside vaccination against CBPP, anthrax, blackleg or East Coast fever and in Asia it could be combined with vaccination against HS, anthrax and blackleg.

The GF-TADs Regional Steering Committees are the appropriate fora to further investigate useful combinations of activities to fit the priorities of the regions they serve and to fine tune the activities.

TADs other than FMD also have the potential to cause enormous economic damage and, as some are zoonotic, they can have considerable public health importance. In developed countries most TADs have been eliminated and their importance then relates to the cost of prevention. However, as in the case of FMD, it is in the interests of countries free from TADs to decrease the risk of reintroduction of the infection and hence they benefit from better control of TADs at source, which will also be more cost-effective.

3. Objectives and expected results of the Global Strategy

The overall objective of the Global Strategy is to improve animal production, food security and economic opportunities, particularly in developing countries, and thereby alleviate poverty, increase income generation and improve the livelihoods of small farmers and general human wellbeing. The objective of the Global Strategy is also to maintain the production and export capacities and the status of the countries free from FMD.

The specific objective of the Global Strategy is to decrease the impact of FMD in the world by reducing the number of outbreaks and to improve animal health globally by reducing the impact of other major infectious diseases.

Three types of results (corresponding to the three components) are expected:

- Component 1: FMD is controlled in most countries and eradicated in some countries not free today, while protecting the free status of others;
- Component 2: VS and their infrastructure are improved;
- Component 3: Prevention and control of other major diseases of livestock are improved as a result of the FMD control strategy.

4. FMD Control (Component 1)

4.1. Tools to be used for implementing the Global FMD Control Strategy

The Global FMD Control Strategy proposes to use various tools and procedures to combat FMD. Some of them, in particular the PVS Pathway, are designed to strengthen VS and they will be presented in the section on Component 2 of the Strategy. However, they can also be mentioned here since they have an impact on the implementation of FMD control programmes. Others are aimed more specifically at improving the FMD control, e.g. the FMD Progressive Control Pathway (PCP-FMD), FMD-specific surveillance, diagnostic laboratories, vaccines and vaccination coverage, and performance monitoring. Many other tools will bring general benefits to the control of other diseases as well as FMD. These include field surveillance and general diagnostic capabilities, epidemiological and economic analyses, animal identification systems, biosecurity and the development of PPPs.

These tools are presented in Annex 2 of this Part B.

Some tools are highlighted here since they are of particular importance for FMD prevention and control.

The FMD Progressive Control Pathway (PCP-FMD) and regional roadmaps

The PCP-FMD (8) (see Annex 2 and supporting document 2) is designed to guide countries in the planning and management of efforts to increase the level of control of FMD from the early stages up to the point where an application to the OIE for official recognition of freedom from FMD (with or without vaccination) may be successful and sustainable. The PCP-FMD comprises five stages. Stage 1 assists in identifying appropriate control options. Stage 2 involves the implementation of

the chosen policy, which may be aimed at protecting part of the animal population. Stage 3 focuses on progressive elimination of virus circulation. If the situation continues to improve (Stage 4), an application may be made to the OIE for FMD-free status with vaccination (Stage 5). The PCP-FMD can also serve for a country's self-evaluation and monitoring, which can then form the basis for an external evaluation.

Countries that already have an official FMD-free status for the whole or part of their territory will have completed many of the activities specified in the PCP. These countries may find the PCP tool useful for confirmatory purposes.

Regional PCP roadmap meetings provide a platform for countries in a region belonging to one of the FMD virus pools to share information and experience and prepare Regional Roadmaps. Such Roadmaps are important to strengthen country engagement, harmonise the efforts based on the FMD-PCP, monitor progress and jointly advocate for support where appropriate.

Stimulating the regional approach is considered essential for the sustainability of the progress achieved and therefore supporting the regular regional roadmap meetings is foreseen under the Global Strategy.

Clustering countries in regional roadmaps is based on the most common circulating types of FMD viruses (virus pools).

OIE standards, recognition of disease status and endorsement of control programmes

To strengthen the FMD progressive control process and to support the Global Strategy, a recent change to the OIE *Terrestrial Code* (17) provides for the OIE to endorse national FMD control programmes submitted by countries that are not FMD-free. Such countries will already be at an advanced level of PCP Stage 3 and the newly endorsed programme will mark the country's entry into the pathway towards freedom from FMD in the domestic animal population.

Diagnostic laboratories, reference laboratories/centres, regional and global networks

Effective and reliable laboratory diagnostics are indispensable at the national level (see Annex 2). Most FMD-free or sporadically affected countries can call on the services of a national reference laboratory. However, in endemic regions, in particular in developing countries, effective national veterinary laboratories are often lacking. The Global Strategy attempts to rectify this situation by assisting countries in need – mainly those in the lower stages of the PCP – with equipment and reagents.

At the international and regional level, OIE and FAO Reference Centres (RCs) have been essential elements in successful disease control campaigns. The availability of a laboratory of this type for each of the seven 'FMD virus pools' is seen as an indispensable requirement for the success of the Global Strategy. Therefore, the existing global network of OIE/FAO RLs/RCs for FMD will play a major role in supporting the Global Strategy. The Global Strategy foresees the establishment of leading laboratories in regions where there is no RL/RC, along with additional expertise to be placed in the laboratories and financial support to carry out a number of specified tasks.

At the global level, an existing RC (the World Reference Laboratory, Institute for Animal Health, Pirbright, UK) will be requested to act as coordinating laboratory.

The laboratory tests to be made available according to the PCP stages at national, regional or international level are listed in Annex 2 of this Part A.

Vaccines and vaccination

To limit the impact of FMD, in particular in endemic countries, adequate supplies of vaccine are required. The vaccines should meet OIE standards of potency and safety (16). In endemic countries FMD vaccination is usually limited to dairy cattle and buffaloes and/or ring vaccination during outbreaks. The Global Strategy will therefore require an increased production of vaccine as well as effective delivery systems. Support will be given to developing countries that cannot afford sufficient quantities of vaccine meeting OIE standards.

Vaccine production and delivery costs could be greatly reduced if future vaccines or production technologies did not require vaccines to be manufactured in biosecure facilities, if vaccines had improved cross-protection and were more thermo-resistant; however, the Global Strategy is based on existing possibilities.

Vaccination strategies will vary considerably depending on local situations and objectives, e.g. mass vaccination or vaccination targeting specific animal sub-populations or zones, high risk situations, ring vaccination around outbreaks and buffer or protection zones around free zones. The delivery systems can involve the private sector.

Issues relating to ensuring that vaccines match the viruses circulating in the region and to vaccine quality control, including the establishment of independent regional quality control centres and post-vaccination monitoring, are explained in Annexes 2 and 6. The RCs play an important role in this and the Global Strategy foresees supporting a limited number of designated vaccine quality control centres.

National, regional and international surveillance; epidemiology skills and networks

FMD control requires effective epidemiological surveillance and early warning systems at all levels, i.e. national, regional and international. Close cooperation between the epidemiologists and the laboratory experts should be ascertained. The Global Strategy will establish and strengthen regional epidemiology networks financially and by making available and placing additional expertise in the regions. The epidemiology networks should be coordinated by a recognised regional epidemiology centre, preferably one of the existing specialised OIE/FAO Reference Centres.

At the international level the availability and exchange of information needs to be ascertained. The FAO/OIE/WHO Global Early Warning System (GLEWS) (9), which includes WHO for zoonotic disease outbreaks in humans, will be supported and the OIE international information system (WAHIS-WAHID) will continue to be the basis for the dissemination of official disease information.

Other tools

Other elements that will need to be progressively improved while FMD is being controlled are briefly mentioned below; more details are given in Annex 2. Many of these elements become increasingly important while moving to higher stages of the PCP.

- Emergency response (ER) teams are invaluable in helping to eliminate an animal disease outbreak before it spreads. ER teams must be included in national contingency plans and simulation exercises should be carried out. At the global level, support will be given to the FAO/OIE Crisis Management Centre –Animal Health (CMC-AH).

- Registration of farms, identification of animals and records of animal movements are indispensable in the higher PCP stages (3 and above) to enable livestock movements to be traced during epidemiological investigations of outbreaks.
- Appropriate biosecurity methods are required in order to avoid FMD virus introduction and spread in farms or areas, at least in advanced PCP stages and at premises where FMD virus is being handled (e.g. in vaccine production facilities and diagnostic and research laboratories).
- Strong PPPs are required in order to implement FMD prevention and control strategies, with clearly defined roles and responsibilities for each partner. Leadership of the animal health system should remain in the hands of the public services with, when appropriate, delegation of public tasks to the private sector. The emergence of producer associations in developing countries is supported by the Global Strategy.

4.2. Building on experience: lessons to be learned from regional FMD control programmes

The Global FMD Control Strategy takes into account and acknowledges previous successful FMD campaigns and on-going regional programmes. It should be pointed out, however, that critical success factors in one region may not apply in another region, due to differences in socio-economic circumstances, resources, type of animal husbandry and the environment. A few examples of successful and on-going programmes are given in Annex 5 of this Part A.

Experience has shown that annual mass vaccination, using independent quality-controlled vaccines that meet the OIE standards, such as those used in Europe before the 1990s, can drastically reduce virus circulation to a point where elimination from the region becomes possible. Experience has also shown that regional approaches, with harmonisation of control measures, policies and legal frameworks and transparency of information, are crucial.

In South America, another region of the world with successful FMD campaigns, vaccination also played an essential role. Coordination through a continental programme, the Hemispheric Programme for the Eradication of FMD (PHEFA) (20), by the Pan-American FMD Center (PANAFTOSA) of the Pan American Health Organization (PAHO) (21) and the South American Commission for the Control of FMD (COSALFA), was a determining success factor, as was the highly developed partnership between the Veterinary Services and the livestock private sector. The work of the PANAFTOSA laboratory for vesicular diseases, recognised by FAO and OIE as a reference laboratory, was a key factor to advance PHEFA.

In South-East Asia, the OIE and the member countries of the Association of South-East Asian Nations (ASEAN) have, since the end of the 1990s, developed a programme for the progressive control of FMD within the region, called South East Asia Foot and Mouth Disease Programme (SEAFMD). A regional roadmap was developed with the objective of achieving FMD freedom with vaccination by 2020 (23). This programme shows the efficacy of a zonal approach, based on epidemiological characteristics and benefiting from strong political involvement.

The Southern African Development Community (SADC) has developed a regional approach with good results. However, the role of Cape buffalo (*Syncerus caffer*), as an important wildlife reservoir for SAT viruses, provides a challenge to disease management. Some of the classical FMD control methods can have a negative impact on the protection of wildlife populations/habitat connectivity, on wildlife sector activities and on development of the smallholder livestock sector. Other options to increase the export market, such as commodity-based trade, or zoning are already available and being used. Compartmentalisation is being explored and could prove an interesting option in the future. This case also shows that research is needed, for example to

develop a new generation of more potent vaccines, and that efforts have to be made on appropriate broad-based land use planning which will allow balancing of the different interests.

All these examples show that international coordination and support is needed and that surveillance, transparency of information and long-term support to the Veterinary Services and control programmes are indispensable.

4.3. Expected results

The Global FMD Control Strategy is foreseen for a period of 15 years, but it is realised that FMD will not have been eradicated by the end of this period. The ambition is, however, to make significant progress in reducing the burden of FMD for countries where the disease is endemic and considerably lower the risk for FMD-free countries, while achieving major improvements in the quality of veterinary systems and in the control of other regionally or globally important diseases of domestic animals.

The Global Strategy focuses on endemic countries, particularly those in PCP-FMD Stages 0 to 2. Control of FMD in these countries is considered a Global Public Good, requiring public investment from national governments and the international community, as well as progressively increasing private sector involvement. At Stage 3 and above, the private sector should become heavily engaged. For countries at Stage 4 the objective will be to retain that status and eventually to progress to Stage 5. For countries that have already attained Stage 5 the objective will be to maintain that status.

The major proposed result of Component 1 of the Global Strategy is that, within a 15-year period, countries that are currently in PCP Stages 0 and 1 and have not usually started to implement FMD control programmes will have progressed at least two stages along the PCP. Achieving this means that at the end of this period all countries will have reached at least PCP Stage 2. Countries in PCP Stages 2 or 3, which are already implementing a FMD control programme, are also expected to progress. Preferably they should move up two stages, but the final objective will depend on a country's decision, based in particular on the outcome of cost-effectiveness studies on whether to embark on an eradication programme aimed at eliminating FMD virus circulation from all domestic animals (Stage 4) or including wildlife (Stage 5 or beyond) in the country or a zone of the country.

4.4. Underlying principles

The Global Strategy will operate according to a series of underlying principles:

- Technical principles
 - Focus on controlling the disease at source; i.e. regions of the world where the disease is endemic and where the prevalence is high, the so-called 'virus pool' regions.
 - Apply the PCP-FMD, which implies a progressive risk-based approach.
 - Fine tune the strategy to national and regional circumstances.
 - In the higher PCP statuses: adopt the lessons learned from the successful campaigns in Europe and South America, particularly with respect to the use of vaccines, organisation of vaccination campaigns and, at later stages, strategic use of culling and compensation.
 - Maintain the status of countries recognised by the OIE as being free from FMD.
 - Where vaccines are used, ensure that they meet OIE quality standards.

- Apply the PVS Pathway to guide countries and ensure an appropriate environment for animal disease control.
- Organisational principles
 - Adoption of a regional approach with co-ordination at the global level, but with most activities carried out at the national level.
 - Do not create new structures but build on existing international and regional organisations and partnerships.
 - Support the establishment and training of personnel for networks of laboratories and epidemiological centres and their coordination at the national, regional and global level.
 - Support capacity building through a combination of strengthening the VS and provision of training in all areas related to improved operation and management of disease control.
 - Co-ordinate FMD control strategies with local rural development programmes.
 - Ensure full engagement of livestock producers and owners in the design, delivery and ownership of biosecurity and disease control and disease reporting.
- Economic principles
 - Take into account the different national and regional situations, in particular the socio-economic and genetic biodiversity importance of wildlife in Southern Africa, which needs more research and multisectoral approaches.
 - Use incentives (e.g. combined vaccines or vaccinations if known to be effective) and combine other field activities to encourage livestock-keeper participation.
 - Apply FMD control strategies with the expectation of broad benefit against other TADs.
 - Perform regular cost-effectiveness analyses of the control programmes, to assess their impact, especially for smallholder farmers.
 - Review control strategies regularly and, if necessary, modify them to ensure optimal performance.
- Financial and political principles
 - Seek international and regional financial support from development partners.
 - Seek political support at national, regional and international level.

4.5. Research needs and expectations

There are several areas where new research results could further support and accelerate progress reached under the Global FMD Control Strategy, for instance in the fields of (i) laboratory and field diagnosis; (ii) vaccines; (iii) epidemiology and (iv) socio-economics.

The Global Strategy does not seek to finance research activities per se, with a few exceptions such as applied research in the field testing of vaccines for efficacy. However, it is recognised that sustainable research funding is important and should be provided by the stakeholder community, both public and private, and including national governments, international organisations and funding agencies. Research alliances, like the Global FMD Research Alliance (GFRA), are considered to be very important for bringing about new developments that may greatly benefit FMD control in the future. More details are given in Annex 7.

4.6. Actions at the national, regional and global level

The activities to be carried out are summarised schematically in the action plan (Part B, Section 1).

4.7. Incentives and advocacy

The Global Strategy will encourage participation of FMD-infected and FMD-free countries as well as private stakeholders through advocacy and by pointing out the incentives. This work will include:

- Preparing and disseminating a high level Advocacy Document to demonstrate to local governments, national stakeholders and the international community the benefits that the Global Strategy will have for livestock production, smallholders, people in need and overall human wellbeing.
- Developing PPP that ensure that livestock owners are involved in surveillance and control initiatives.
- Strengthening the VS and infrastructure, thereby improving a country's capability and capacity to control animal disease and improve livestock production.
- Combining FMD control strategies with those for other TADs, e.g. combining vaccines or vaccination interventions.
- Using the results obtained through engaging in the PCP-FMD and reaching Stage 3 and higher, to improve external trust in the animal health situation and management and to develop better trade opportunities.
- Emphasising the decreasing risk for FMD-free countries with regard to reintroduction of the virus, as a consequence of the implementation of the Global Strategy which will reduce the amount of virus at source.

5. Strengthening Veterinary Services (Component 2)

5.1. Tools to be used for implementing Component 2

The Performance of Veterinary Services Pathway (PVS)

Chapter 3.1 of the OIE *Terrestrial Code* on the quality of the VS provides 'intrinsic' standards based on four fundamental components: (i) human, physical and financial resources; (ii) technical authority and capability to address current and new issues, including prevention and control of biological disasters; (iii) the sustained interaction with the private sector, and (iv) the ability to facilitate market access.

In order to assist its Member Countries in complying with OIE standards, the OIE has developed the OIE PVS Pathway (18) (see Annex 3), which is a multi-phased approach combining evaluation tools (diagnostic, prescription and monitoring phases) and capacity-building programmes ('treatment phase': legislation support missions, twinning programmes).

The tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool: supporting document 3) is used to assess the level of compliance of national VS with OIE standards on quality of the VS and, at a second stage, to assess the progress made over time (PVS Follow-Up). Forty-six Critical competences (CCs) have been elaborated and for each of them five qualitative levels of advancement are described, from Level 1, corresponding to non-compliance, to Level 5, the highest level of advancement attainable. Level 3 is generally considered to

indicate sufficient compliance with OIE standards. The PVS Pathway has proved a very effective tool to guide and evaluate the strengthening of VS capabilities and capacities. It will also be effective in supporting the implementation of the Global Strategy and in combating FMD and other TADs.

Linking the PCP-FMD stages to the OIE PVS levels of Critical Competencies

A country embarking on the PCP-FMD (Component 1) should acquire the appropriate capacity and capability of the VS to conduct activities aimed at the control or elimination of FMD (and other TADs). This is referred to as the 'enabling environment' in the PCP.

Bridging the PCP stages with the CCs of the OIE PVS tool is an important element in the successful implementation of the Global Strategy. It requires the reinforcement of the VS to be tailored to the needs and timeframe of the PCP stages. A total of 33 CCs of the OIE PVS evaluation tool are of particular relevance to the prevention and control of FMD (and other TADs) (hereafter named 'FMD relevant CCs')² & ³. Table I – stemming from Tables 1 and 2 in Annex 3 of this Part A – indicates the level of compliance to be reached for the 33 FMD-relevant CCs for each of the PCP-FMD stages. In most cases, Level 3 is deemed sufficient to ensure a satisfactory level of compliance with OIE standards. However, for 7 CCs Level 4 and in some cases Level 5 is targeted. A basic principle in establishing the 'correspondence' Table was that once a level is reached for a given CC, it cannot regress, regardless of the relevance of the CC in further PCP stages.

² For greater consistency within the successive phases of the PVS Pathway, the list of CCs is presented in the same way as the Gap Analysis, with five pillars which have been developed in a logical order to avoid repetition and duplication: i) Management of Veterinary Services; ii) Animal health; iii) Veterinary public health; iv) Veterinary laboratories; v) Trade. The CCs relating to staffing, physical and financial resources (part of Chapter 1 –'Human, physical and financial resources'- of the PVS Tool) are grouped together under the heading 'Resources'.

³ It should be noted that, despite the selection of these 33 FMD-relevant CCs, when a country decides to undergo an OIE PVS Evaluation or PVS Gap Analysis mission, the exercises are conducted in their integrality, using the 46 CCs. A special focus is however placed on the results of the FMD-relevant CCs for a country engaged in the PCP-FMD.

Table I: Relationship between FMD PCP Stages and OIE PVS Critical competency Levels

OIE PVS Critical competencies and Levels (in red)	FMD PCP Stage			
	1	2	3	4
Professional competencies of veterinarians (CC I.2.A. ⁴)	3	3	3	3
Competencies of veterinary para-professionals (CC I.2.B.)	1	3	3	3
Continuing education (CC I.3.)	3	3	3	3
Internal coordination (chain of command) (CC I.6.A.)	1	2	3	3
External coordination (CC I.6.B.)	3	3	3	3
Management of resources and operations (CC I.11.)	1	2	3	3
Risk analysis (CC II.3)	3	3	3	3
Emerging issues (CC II.11)	1	2	3	3
Communications (CC III.1)	2	3	4	4
Consultation with stakeholders (CC III.2)	3	3	3	3
Official representation (CC III.3)	2	3	3	3
Accreditation / authorisation / delegation (CC III.4)	1	2	¾	¾
Veterinary Statutory Body authority (or equivalent) (CC III.5.A)	1	2	¾	¾
Veterinary Statutory Body capacity (CC III.5.B)	1	2	3	3*
Participation of producers and stakeholders in joint programmes (CC III.6)	2	3	3	3*
Preparation of legislation and regulations (CC IV.1)	3	3	3	3
Implementation of legislation & stakeholder compliance (CC IV.2)	1	3	3	3
Passive epidemiological surveillance (CC II.5.A)	1	3	3	3
Active epidemiological surveillance (CC II.5.B)	3	3	3	¾
Early detection and emergency response (CC II.6)	1	1	3	3
Disease prevention, control and eradication (CC II.7)	1	2	3	3
Ante and post mortem inspection (CC II.8)	1	2	3	3
Veterinary laboratory diagnosis (CC II.1)	2	2/3	2/3	2/3
Laboratory quality assurance (CC II.2)	2	3	3	3
Quarantine and border security (CC II.4)	1	2	3	¾
Animal identification and movement control (CC II.13.A)	1	2	3	3
Transparency (CC IV.6)	2	3	3	3
Zoning (CC IV.7)	1	2	3	3
Veterinarians and other professionals (CC I.1.A)	2	3	3	3
Veterinary para-professionals and other technical staff (CC I.1.B)	2	3	3	3
Physical resources (CC I.7)	2	2	3	3
Operational funding (CC I.8)	1	2/3	4/5	4/5
Emergency funding (CC I.9)	1	1	3	4/5

The correspondence table shows that:

- At the end of the Global Strategy implementation, when it is expected that all countries will have reached at least PCP Stage 2: (i) all CCs will have improved by one level of compliance (except two that are not crucial in the early stages of the PCP-FMD and those already at level 3 and above) and (ii) minimum compliance with OIE standards on quality of the VS will be reached for at least 18 CCs;

⁴ As per the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool), Fifth edition 2010 (18).

- Countries requesting OIE endorsement of their national FMD control programme (end of Stage 3) will all have reached at least Level 3 for all FMD-relevant CCs;
- Countries embarking on the OIE FMD-free status recognition process will all have reached Level 3 or above for all FMD-relevant CCs.

This correspondence table may remain fully relevant when similar PCP approaches are developed for other TADs (i.e. brucellosis or PPR).

5.2. Expected results

The Global FMD Control Strategy will provide support aimed at ensuring that (i) in countries progressing from PCP Stage 0 to Stage 2 the VS develop in parallel and that evidence of this progression is duly documented, and that (ii) in countries progressing to Stage 3 and above there are robust VS in place, which implies that countries in PCP Stage 3 must at least have reached Level 3 for the 33 FMD-relevant CCs.

The proposed results of Component 2 of the programme are therefore that, within a 15-year period:

- all countries that are not compliant with OIE standards (i.e. level below 3) for the 33 FMD-relevant CCs at the beginning of the implementation of the Global FMD Control Strategy have reached a minimum of Level 3 for selected CCs in relevant PCP-FMD stages.
- all countries that are compliant with OIE standards (i.e. Level 3 or above) at least maintain their level of compliance.

5.3. Underlying principles

- The term ‘Veterinary Services’ is used in accordance with the OIE definition, and thus includes their public- and private-sector components. As a result, activities aimed at reinforcing the capacities of private veterinarians (and veterinary para-professionals), such as putting in place Veterinary Statutory Bodies and ensuring a proper field veterinary network, are fully relevant to Component 2.
- The approach and activities proposed under Component 2 (‘enabling environment’) are intended to facilitate the implementation of FMD-specific prevention and control activities (Component 1). However, the activities are not disease-specific and are expected to have spillover effects on the control of other priority diseases (Components 1 and 3).
- The targets on global progress will be achieved through the strategic application of PCP tools in some regions. For a country undergoing PVS Gap Analysis, FMD will be only one of the priorities identified by the country. This means that the levels to be targeted may be more ambitious (above Level 3) than those for the progressive control of FMD, but not less ambitious.

5.4. Actions to strengthen Veterinary Services

Strengthening of the VS is a horizontal (transversal) activity which will be supported by a series of generic or specific activities. They are summarised in the action plan (Part B, Section 1) and in Annex 1 of Part B.

6. Prevention and control of other major diseases of livestock (Component 3)

6.1. Tools to be used for implementing Component 3

Tools and procedures to be used for implementing Components 1 and 2 also contribute to the implementation of Component 3. PCP principles could for instance be utilised for other diseases and the critical competencies of the PVS Pathway relevant for FMD control can also be considered valid for other infectious diseases.

Guidelines and recommendations for specific diseases are published in the disease-specific chapters of the *Terrestrial Code* and *Terrestrial Manual* (16).

OIE and FAO Reference Centres and regional and international networks of OIE and FAO Reference Laboratories/Centres already exist for many diseases, but some disease-specific joint OIE/FAO international and regional networks may still be needed.

National epidemio-surveillance systems, regional and international reference centres specialised in epidemiology and regional and international networks are indispensable for effective surveillance, early detection and early warning, irrespective of the TAD a country is dealing with.

Vaccines against many infectious diseases other than FMD exist, but the issue of availability and quality control is a major concern in many countries. Progress in this regard with regulating FMD vaccines and with quality control will also have wider beneficial effects.

The technical background needed to advance with vaccine quality control and more generally with TAD control is available. The *Terrestrial Manual* provides the minimum quality standards applicable to vaccines and the *Terrestrial Code* and *Terrestrial Manual* provide disease-specific standards, guidelines and recommendations.

At the international level, the FAO/OIE (and WHO for zoonotic disease outbreaks in humans), the Global Early Warning System (GLEWS) and the OIE official reporting system WAHIS/WAHD provide support for the control of a range of high-impact animal diseases, including zoonoses.

More details are provided in Annex 4 of Part A.

6.2. Building on experience: lessons to be learned from regional programmes

The outstanding example of a successful programme to combat an important transboundary disease in developing countries is the rinderpest programme. In Africa it was carried out by AU-IBAR. Unfortunately, the CBPP programmes launched in Eastern Africa were less successful. Although they reduced the number of outbreaks, the effect was not sustainable in the longer term and eradication of the disease was not achieved.

In developed countries a number of regional disease control programmes have been successful, for instance for bluetongue, tuberculosis and brucellosis in cattle, brucellosis, contagious agalactia, contagious caprine pleuropneumonia in small ruminants and classical swine fever in pigs. In addition to these specific programmes, generic programmes to prevent the introduction of TADs into free countries are implemented on a continuous basis, based on measures such as control of movements at national border post level, surveillance and regular updating of emergency control plans, and simulation exercises.

6.3. Expected results

The objectives of Component 3 cannot be quantified at this stage as they will depend on the outcome of discussions with the authorities and relevant stakeholders in countries in the different regions. In this respect, an important role is foreseen for the GF-TADs Regional Steering Committees. The list of priority diseases will need to be discussed and possible combinations of activities with FMD control activities will have to be investigated, including their cost-effectiveness. It is likely that the selected diseases and the control strategies will be region-specific and in some instances country-specific.

6.4. Underlying principles

The underlying principles mentioned for FMD control are also applicable to the control of other TADs, including the necessity of a regional approach, with global coordination if the problem is global. The strategies will be tailored according to the national and regional situations and socio-economic analysis. Important considerations are the losses for small-scale producers and subsistence farmers in developing countries. Political will and investment to finance the required actions are prerequisites for any control programme and socio-economic studies are crucial for effective advocacy when approaching decision-makers and development partners. Transdisciplinary and multi-sectoral holistic approaches will be stimulated and the importance of wildlife biodiversity will be carefully considered.

6.5. Actions that will improve the control of other diseases

The activities to be carried out are summarized schematically in the action plan (Part B, Section 1).

7. Governance at international, regional and national level

The Global FMD Control Strategy has been developed under the umbrella of the FAO/OIE Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) addressing national, regional and global dimensions. Countries and regional alliances will be empowered to effectively manage and control FMD and priority TADs through greater competency, more capacity and improved experience and leadership. The Strategy will provide a platform for major stakeholders – including development partners – to define and shape the coherent implementation of programmes and projects for the improved control and management of FMD and other priority TADs.

7.1. International level

At the international level, the Global GF-TADS Steering Committee, the Management Committee, the GF-TADs FMD Working Group (WG) and the OIE Scientific Commission for Animal Diseases (SCAD) all play a role in accordance with their terms of reference. It is anticipated that policy development and overall guidance will be provided by the Global Steering Committee, with the FMD WG Secretariat being provided and hosted by FAO.

The GF-TADs FMD WG, under the guidance of the GF TADs Global Steering Committee, will continuously update the Global Strategy and contribute to its implementation. Activities will include the facilitation and promotion of regional and international epidemio-surveillance and laboratory networks; harmonisation of regional strategies; development of a communication strategy; coordination of the global and regional meetings; and publication of a yearly progress report.

7.2. Regional level

At the regional level, the Regional GF-TADs Steering Committees (RSCs) will act as regional platforms with the support of their technical expertise groups (Regional Support Units: RSU), FMD regional laboratories and Epidemiology Centres and also with the support of the GF-TADs FMD WG. Regional platforms which coordinate FMD control programmes already exist in some regions (e.g. SEACFMD in South East Asia, AU-IBAR in Africa and PAHO in South America). They will of course continue their activities and the RSCs will have to be careful not to duplicate their work. The activities of the RSCs and RSUs will focus on adding value to the control of FMD and priority TADs through coordinated regional actions and activities.

Regarding FMD, the role of regional platforms is to coordinate and harmonise regional control strategies. Regional platforms organise country and regional PCP assessments and meetings. They will play an active role in facilitating regional surveillance, laboratory network activities, research, and establishment of vaccine banks, communication/public awareness strategy design and training. They will also ensure effective and productive relationships with other programmes in the region.

For FMD and other contagious diseases, the RSU can be directly attached to the GF-TADs Regional Steering Committee or, with the agreement of member countries, development partners, supporting regional animal health programmes/projects, Regional Organisations, FAO or the OIE, it can be located in the relevant Regional Economic Communities (REC) or delegated to the appropriate operator, such as the OIE (e.g. SEACFMD Regional Coordination Unit), FAO (regional units) or OIE/FAO Regional Animal Health Centres. Where appropriate, RSUs are integrated in or work closely with relevant regional organisations – Regional Specialised Organisations (RSOs) or RECs – which deal with regional economic integration including the livestock sector. These RSOs or RECs usually all have a seat on the relevant GF-TADs Regional Steering Committee.

At the regional level, RLs/RLLs (Regional Laboratories/Regional Leading Laboratories) will be designated and mandated under the GF-TADs mechanism to provide diagnostic services and support for each 'virus pool' region.

7.3. National level

Country level disease surveillance, control and management activities are the basis for improving animal health disease status, and every effort will be made to ensure that support is provided for these front line activities. To ensure that gains at country level are reinforced there will be coordination at regional and sub-regional levels in terms of strengthening the VS and ensuring that public-private partnerships are delivering optimum levels of control and management of FMD and priority TADs. As stated previously, coordination and support will be provided by the regional and global GF-TADs and/or existing regional organisations and/or technical coordinating bodies that are coordinating FMD and other disease programmes. Emphasis will be placed on transparency of disease reporting, particularly in border regions that have important trading routes.

Part B. Action Plan, milestones, cost of the strategy and portfolio

1. Main activities to be implemented and relationships between the activities of the three components of the global FMD Control Strategy

The activities of the three components of the global FMD Control Strategy are interrelated. Component 1 on FMD control is taken as an entry point to define, for each stage of the Progressive Control Pathway (PCP), the activities of Component 2 on strengthening Veterinary Services (VS) and Component 3 on improved control of other TADs. These activities are presented in Table 2.

Table 2. Main activities⁵ to achieve the different components of the Global FMD Control Strategy

	Component 1 FMD Control	Component 2 ⁶ Strengthening Veterinary Services	Component 3 ⁷ Prevention and control of other major diseases of livestock
National level			
PCP Stage 1	Activities and training focusing on: <ul style="list-style-type: none"> - Understanding FMD epidemiology: FMD occurrence, virus types and virus transmission pathways; - Risk analyses: defining geographical areas and/or production systems at higher risk; - The socio-economic impact of FMD in different settings; - FMD surveillance in the field; - Improvement of laboratory facilities and capabilities; - Developing and introducing an information system; - Developing and introducing effective communication with 	Activities and training focusing on: <ul style="list-style-type: none"> - Assessing the situation of Veterinary Services (VS), with respect to resources, staffing, funding and chain of command; - Supporting VS to ensure they have the authority and the capability to develop legislation and regulations; - Assessing and revising the legislation as appropriate; - Supporting establishment of a core team of epidemiologists; - Developing formal coordination mechanisms with all stakeholders (including the wildlife sector) 	Activities and training focusing on (by analogy with the conceptual framework of the PCP-FMD): <ul style="list-style-type: none"> - Epidemiology investigations and socio-economic analysis to assess major animal disease situations in the region and identify regional priority TADs to be targeted. Results of Component 2 activities (Institutional and legislative environments, VS capabilities) will be used while developing Component 3 activities.

⁵ Countries maintain activities described in previous stages. Therefore activities of a previous stage are usually not repeated.

⁶ Most of the activities under this heading are not budgeted under Component 1 and therefore dependent on additional funding.

⁷ Most of the activities under this heading are not budgeted under Component 1 and therefore dependent on additional funding.

	<p>stakeholders</p> <ul style="list-style-type: none"> - Preparing an FMD control strategy to enter Stage 2. 	<p>where appropriate);</p> <ul style="list-style-type: none"> - Developing communication capacity (up to PVS CC level 3), communication materials and a team of specialists; - Supporting reporting capacity / WAHIS notification; - Evaluation of veterinary teaching establishments and identification of gaps; - Strengthening basic laboratory diagnostic capacities, preferably with bilateral support from a reference laboratory; 	
PCP Stage 2	<p>Activities and training focusing on:</p> <ul style="list-style-type: none"> - Continuation of the activities listed for Stage 1; - Control of FMD in target areas/zones or farming systems in accordance with the strategy developed in Stage 1; - In targeted areas/sectors, active (i.e. investigating FMD outbreaks) and passive surveillance; - Vaccination based on vaccine matching information, respecting the cold chain and followed by post-vaccination monitoring; - Raising the participation of producers and stakeholders by means of joint programmes, communication and operational funding; - Raising biosecurity awareness. 	<p>Activities and training focusing on:</p> <ul style="list-style-type: none"> - Developing an enabling environment for control of TAD outbreaks, particularly in high-risk areas/zones or farming systems; - Key issues: VS organisation, appropriate legislation, field veterinary network, laboratory diagnostics, follow-up information regarding emerging issues, data management systems and transparency of information; - NB: These key issues will have to be developed to level 3 at this stage (i.e. compliance with OIE standards) - Establishing a zoning approach with a national animal identification system (if this is part of the chosen strategy); - Improving the resources allocated to animal health programmes; - Developing the Veterinary Statutory Body. 	<p>Activities and training focusing on:</p> <ul style="list-style-type: none"> - Understanding the epidemiology of national priority TADs; - Identifying possible combinations of priority TADs control with FMD control; - Ensuring an appropriate supply of vaccines, logistics and quality control; - Communication activities and strengthening extension services, including information on core animal health care, including use of vaccines and drugs.
PCP Stage 3	<p>Activities and training focusing on:</p> <ul style="list-style-type: none"> - Extension of FMD control measures to all FMD- susceptible domestic species; - Prompt response mechanisms (emergency plan, upgraded surveillance, implementation of emergency response measures, including culling); - Intensive blanket or targeted vaccination (depending on 	<p>Activities and training focusing on:</p> <ul style="list-style-type: none"> - Establishment of an appropriate institutional environment, which includes the required legal/regulatory framework and inter-ministerial cooperation and delegation of activities under the supervision of the VS; - Contingency planning and emergency preparedness, 	<ul style="list-style-type: none"> - Same activities as in Stage 2 above - Implementing cost-effective combinations of disease control or production-related activities with FMD-related activities; - Developing strategies for regional priority TADs. <p>NB: Reaching this stage in TAD control and improved</p>

	<p>strategy);</p> <ul style="list-style-type: none"> - Implementing the legal framework to effectively combat FMD and control outbreaks; - Developing public/private partnerships; - Application to OIE for endorsement of the National FMD Control Plan 	<p>including funding of compensation:</p> <ul style="list-style-type: none"> - Strengthening animal identification and movement controls as well as slaughterhouse surveillance; - An effective prompt response mechanism, preferably with rapid response teams; - Effective management of resources and operations. 	<p>effectiveness of VS may support compartmentalisation and commodity-based approaches in individual countries.</p>
PCP Stages 4/5	<p>The activities are basically the same as those listed for the previous PCP stage:</p> <ul style="list-style-type: none"> - Continued focus on FMD control; - Prompt response mechanism; - Strengthening prevention measures; - Where appropriate: surveillance of wildlife. <p>In this Stage a dossier may be prepared and submitted to OIE for country recognition as FMD-free (with or without vaccination).</p>	<p>The activities are basically the same as those listed for the previous PCP stage, with</p> <ul style="list-style-type: none"> - Continuation of the support for strong surveillance in compliance with OIE standards; - Strengthening procedures to control illegal movements of animals. 	<p>Same activities as above.</p>
Regional level for PCP Stages 1 to 4/5			
	<p>Through strengthened Regional GF-TADs Steering Committees and Regional Animal Health Centres:</p> <ul style="list-style-type: none"> - Coordination and harmonisation of National FMD control strategies, risk analysis methods and communication strategies; - Providing (international) expertise if so requested; - Development of sustainable epidemiology networks for regional surveillance; - Development of laboratory networks, coordinated by a regional leading laboratory or a reference laboratory; - Organisation of Regional FMD roadmap meetings; - Establishment of vaccine banks and independent vaccine quality control centres where appropriate. 	<ul style="list-style-type: none"> - Support to relevant regional meetings of regional and international organisations, regional GF-TADs and roadmap meetings; - Support to regional epidemiology and laboratory networks 	<ul style="list-style-type: none"> - Regional workshops and conferences to assess and identify regional priority TADs and prepare disease-specific regional strategies using the PCP concept; - Monitoring the selected disease situations and updating control strategies; - Undertaking epidemiological and socio-economic studies; - Developing regional disease-specific laboratory and epidemiology networks; - Organising regional training sessions where appropriate.
International level for PCP Stages 1 to 4/5			
	<ul style="list-style-type: none"> - Advocacy of the Global FMD Control Strategy; - Through institutionalisation or the joint FAO/OIE FMD Working 	<ul style="list-style-type: none"> - In the higher PCP stages: participation of country representatives in relevant meetings of international organisations, including the 	<ul style="list-style-type: none"> - At the higher PCP stages: support for country participation in disease-specific international

	<p>Group with a specific Secretariat;</p> <ul style="list-style-type: none"> - Harmonisation and coordination of and support for regional FMD control strategies; - Assisting regions and countries with PCP expertise and assessing PCP stage progress of countries (on demand); - Maintaining a list of international FMD experts fully conversant with the PCP-FMD; - Guiding and supporting the International OIE/FAO Network of FMD Reference Laboratories; - Guiding and supporting the network of Epidemiology Collaborating Centres; - Assessment of the progress of the FMD Control Strategy at the global and regional level and publication of an Annual Report; - Maintaining contacts with all stakeholders in global FMD control. 	<p>OIE, the Codex Alimentarius Commission and the WTO SPS Committee (where applicable) and Global GF-TADs;</p> <ul style="list-style-type: none"> - Active contribution to the international standard-setting process. 	<p>conferences;</p> <ul style="list-style-type: none"> - GLEWS, WAHIS and CMC-AH activities to support countries and regions to be better prepared for emergencies; - Support to the International OIE-FAO Networks of Reference Laboratories/Centres and Epidemiology Collaborating Centres; - Development of new disease-specific global strategies and accompanying disease-specific PCP tools, under the umbrella of GF-TADs and in line with new OIE <i>Terrestrial Code</i> articles, where appropriate.
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2. Milestones: 3 phases of 5 years each

For management and evaluation purposes, the Global FMD Control Strategy will be broken down into three 5-year phases. The milestones are the expected results on the dates indicated. Based on the achievements, the programme can be continued (with or without minor changes) or be substantially modified and reoriented.

As explained before, the Global FMD Control Strategy is foreseen for 15 years and the main objective is to achieve better control of FMD worldwide, while at the same time contributing to the control of other globally important diseases of domestic animals.

The Global Strategy will focus on countries where FMD is endemic, i.e. countries at Stages 0 to 2. For countries at Stage 4 the objective will be for them to retain that status and eventually progress to Stage 5; for countries that have already attained Stage 5, the objective will be to maintain that status. Therefore, significant progress will be made in reducing FMD virus circulation in endemic countries and in reducing the risk for FMD-free countries, while achieving major improvements in the quality of VS and the control of other regionally or globally important diseases of domestic animals.

2.1. FMD Control (Component 1)

The proposed results of Component 1 of the Strategy presented in Part A section 4.4. are that 'Within a period of 15 years, countries that are currently in PCP Stages 0 and 1 and usually have not started to implement FMD control programmes, will have progressed at least two stages along the PCP. Achieving this means that at the end of this period all countries will have reached at least PCP Stage 2. Countries in PCP Stages 2 or 3, which are already implementing an FMD control programme, are also expected to progress. Preferably they should move up 2 stages, but

the final objective will depend on a country's decision, based notably on the outcome of cost-effectiveness studies, to embark on an eradication programme aiming at eliminating FMD virus circulation from all domestic animals (Stage 4) or including wildlife (Stage 5 or beyond) in the country or a zone of the country'.

Table 3 gives an overview of the milestones of the Action Plan.

The percentage of countries which will decide to go to Stage 2 and beyond during the first 15 years has been estimated based on analyses of their current situation and of their road maps when available.

Table 3. Chronogram of the Global FMD Control Strategy (Component 1)

PCP Stage at year 0	PCP Stage at the end of year 5					PCP Stage at the end of year 10					PCP Stage at the end of year 15				
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
0	100 ⁸					10	75	15				50	50		
1	10	75	15				60	30	10			10	70	20	
2	–	25	50	25				60	30	10			25	50	25
3	–		50	25	25			10	50	40			10	20	70
4	–			50	50				25	75					100
5	–				100					100					100

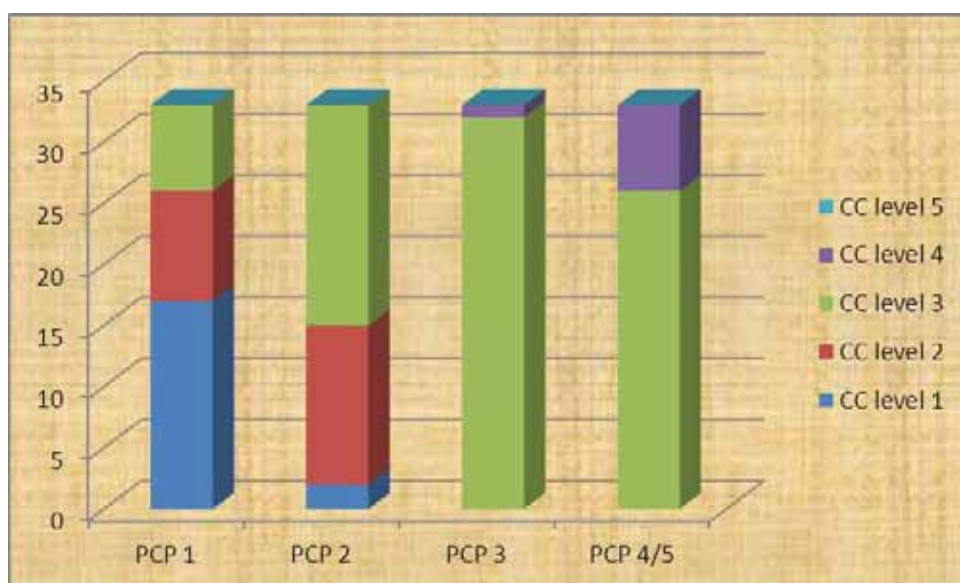
2.2. Strengthening Veterinary Services (Component 2)

The expected results for this component are that within a 15-year period, countries in PCP Stages 0 to 2 having VS that are not compliant with OIE standards (PVS CC Levels below Level 3) for all or some of the 33 relevant CCs will have reached at least Level 3 for all CCs.

For countries that are in PCP Stage 3 and above, and therefore having most CCs compliant with OIE standards (CCs at Level 3 or above), the CC levels will at least be maintained or increased during the 15-year period. The milestones for Component 2 are the same as those for Component 1 (see Table 3. Chronogram of the Global FMD Control Strategy [Component 1])

In Figure 1 the number of CCs and the expected compliance level, as mentioned in the table, is visualized for each PCP stage. The data correspond to those in Table 1 in Part A, section 5.1.

⁸ Percentage of countries in the indicated PCP Stage at year 0 that move to a higher PCP Stage (or remain in the same Stage), estimated for each 5 year period, i.e. the percentages mentioned over the years refer to the original group of countries.



		PCP Stage			
		1	2	3	4 or 5
CC compliance level	1	17	2	0	0
	2	9	13	0	0
	3	7	18	32	26
	4	0	0	1	7
	5	0	0	0	0

Figure 1
Minimum numbers and levels of PVS CCs to be complied with at each PCP Stage

2.3. Prevention and control of other major diseases of livestock (Component 3)

As previously stated, it would be premature to define specific objectives and expected results for this component of the Global Strategy. Priority diseases have been identified in each region by the GF TADs Regional Steering Committees. Activities that may be combined with FMD control activities have been listed, but need further study.

The development of control strategies for other TADs at a national, regional and international level will need further consultations between countries and regional and international organisations.

At this stage, no milestones can therefore be foreseen for this component.

3. Cost of the Global Strategy

3.1. FMD Control (Component 1)

The purpose of this study was to prepare an initial cost estimate of the Global Strategy for Control of FMD at the country, regional and global levels for the first five years of the programme. The full study is presented as supporting document 4.

The cost at the country level has been estimated taking into account the typical FMD-related activities per stage for a total of 87 countries which are at PCP initial Stage 0 to 3. The data of some selected countries have been used and costing assumptions were provided by experts having experience in the region as country-level costing information is not readily available for most countries.

The cost of national FMD programs for 79 initial 0-2 PCP stage countries for 5 years is estimated to be \$68 million (without vaccination cost); three-quarters of these costs are attributable to 'low' and 'lower-middle' income countries. Africa and Eurasia are the regions which incur the largest costs, accounting for 50% and 33% of the total respectively.

The average cost of the activities per country is estimated to be \$ 863,000.

The vaccination cost has been estimated for 45 initial PCP 1-3 countries (not including China and India) assuming that these countries increase progressively the proportion and species of animals vaccinated. The vaccination cost, also for five years, turns out to be \$ 694 million. Per country the costs vary widely depending on the animal population and initial PCP stage.

These country-level costs need to be interpreted with caution as they are subject to two major limitations. First, the estimate should not be viewed as reflecting individual countries' 'budgets'. In particular, low PCP stage countries, which tend to be low-income, may face a larger start-up or fixed cost, due to systemic problems such as weakness of Veterinary Services, infrastructure, and legislative and institutional framework. The second limitation is that the estimate does not account for money that is already being spent on existing programs. Thus, for those countries which already have effective FMD control programs, 'incremental' (or additional) cost which needs to be funded is likely to be lower than the estimate in this study.

At the regional level, the cost has been estimated for the support to the laboratory and epidemiology networks that is proposed by the strategy. A regionally and internationally coordinated approach is regarded as a key to controlling transboundary animal diseases, taking advantage of the positive externalities that each country's disease control actions provide to other countries. The laboratory and epidemiology networks of the strategy are characterised by their 'layered structure', with their main activities clustered amid seven FMD virus pools and in which activities are vertically integrated across national, regional and global levels.

The structure is intended to create economies of scale and is a central cost-saving element of the strategy.

The cost of the global strategy at the regional level for 5 years is estimated to be \$47 million; a large proportion of this money will pay for laboratory and epidemiology activities in the networks; and about half of the regional costs, namely, regional experts' support missions to countries and the regional laboratories' training/support to national laboratories, directly benefit countries.

Finally, the five-year cost of the strategy at the global level, which includes global coordination and harmonization costs, is estimated to be \$11 million.

In total, the cost of the global strategy for the initial five years of the program would be \$820 million, of which \$762 million (93%), \$47 million (6%) and \$11 million (1%) are attributable to the country, regional and global levels respectively. The vaccination cost of \$694 million is by

far the largest component of the cost.

Finally, this exercise should be viewed as an initial step of costing, which may be used as a basis for gap analysis and needs to be refined as new information becomes available and more policy issues are addressed.

3.2. Strengthening the Veterinary Services (Component 2)

To give an indicative cost for strengthening the VS under Component 2 of the Global FMD Control Strategy, relevant PVS Gap Analysis reports available worldwide (21) were studied. They include annual budgets for the first 5 years and an exceptional budget needed to carry out the activities identified to achieve the country's VS objectives, i.e. to improve its compliance with international standards, taking into account national constraints and priorities. All countries had the prevention and control of major TADs as a national priority. Accordingly, animal health and related laboratory activities constituted the biggest part of the overall budget proposed.

Although not all Critical competencies (CCs) are considered crucial for FMD prevention and control (see Table 1. Annex 3. Selection of FMD-relevant PVS CCs), the part of the budget associated with these CCs is considered negligible (max 1% of the overall budget). Therefore no correction was made in the overall budget as calculated in the PVS Gap Analysis.

The PVS Gap Analysis budgets of the countries vary considerably, mainly due to differences with respect to:

- The epidemiological status of the country with regard to major TADs;
- The priorities set by the country (e.g. exports), and its disease control ambitions (e.g. control or eradication);
- The country-specific unit costs used in the different PVS Gap Analysis exercises (for instance the cost of buildings, equipment, and salaries).

To minimise these variations, the VS budgets were considered in the light of macro-economy related indicators, namely:

- annual budget per VLU⁹
- annual budget per agriculture GDP
- annual budget per State budget.

⁹ VLU: veterinary livestock unit. The VLU is used to quantify veterinary activities for a given animal population, calculated by establishing equivalence between species using a coefficient. The number of VLUs in a country is calculated as being equivalent to the number of cattle + 0.1 x the number of small ruminants x 0.1 + 0.5 x the number of horses and dromedaries + 0.3 x the number of donkeys + 0.2 x the number of pigs + 0.01 x the number of poultry. This unit is different from the livestock standard unit (LSU), which determines the equivalence between species according to their production potential.

To try and draw conclusions related to regions, the available PVS Gap Analysis reports were studied:

(i) by region (4 selected) and

(ii) by VS compliancy level of the countries, i.e.

- **Low compliance:** countries with level < 3 for selected FMD-relevant CCs (usually countries at Stages 0 or 1 of the PCP-FMD); and
- **High compliance:** countries with level \geq 3 for selected FMD-relevant CCs (usually countries at PCP-FMD Stage 2 or above).

The budget mentioned below is calculated to support the reinforcement of the VS to enable progress for the countries with low compliance (PCP Stage 0 or 1 to at least PCP Stage 2) and countries with high compliance (PCP Stage 2 to at least PCP Stage 3).

The proposed budget is annual over a 5-year period. An average has been provided as well as the range.

An analysis was also performed to identify possible general trends in countries having a high or low animal production density and in countries having different agricultural GDPs in relation to the national GDP.

The results are shown in Tables 4, 5 and 6.

Table 4: Required annual VS budgets as defined during Gap Analysis and relationship with different parameters for countries with high or low compliance with Critical competencies:

Country	Costs VS / VLU (USD)		% VS budget / GDP		% VS budget / Agri GDP		% VS budget / State budget	
	High compliance	Low compliance	High compliance	Low compliance	High compliance	Low compliance	High compliance	Low compliance
East and South East Asia								
Average	2.28	0.94	0.04	0.09	Na	0.77	1.24	0.48
Range	Na	0.4 – 1.6	Na	0.02 – 0.16	Na	0.48 – 1.06	Na	Na
Africa								
Average	6.28	2.33	0.13	0.10	0.46	0.34	0.9	0.34
Range	2.4 – 13.44	0.66 – 2.88	0.02 – 0.22	0.02 – 0.20	0.06 – 0.86	0.06 – 0.8	0.24 – 1.56	0.16 – 0.6
Latin America								
Average	8.2	2.16	0.15	0.02	1.87	0.98	0.14	0.92
Range	1.28 – 9.52	Na	0.08 – 0.28	Na	0.94 – 2.52	Na	0.04 – 0.24	Na
Central Asia / Middle-East								
Average	21.2	5.15	0.12	0.21	2	1.18	0.68	0.34
Range	Na	1.8 – 8.5	Na	0.08 – 0.34	Na	0.86 – 1.5	Na	0.34

Na: Not available

Table 5. Annual VS budgets according to livestock density

	Costs VS / VLU (USD)		% VS budget / GDP		% VS budget / Agri GDP		% VS budget / State budget	
	High livestock density > 50	Low livestock density < 20	High livestock density > 50	Low livestock density < 20	High livestock density > 50	Low livestock density < 20	High livestock density > 50	Low livestock density < 20
Average	1.73	6.18	0.09	0.15	0.64	0.93	0.70	0.46
Range	0.82 – 2.54	0.66 – 21.2	0.02 – 0.16	0.02 – 0.34	0.33 – 1.06	0.06 – 2.14	0.38 – 1.24	0.04 – 1.56

Table 6. Annual VS budgets according to the importance of agriculture in national GDP

	Costs VS / VLU (USD)		% VS budget / GDP		% VS budget / Agri GDP		% VS budget / State budget	
	Country in which Agri GDP > 25% of national GDP	Country in which Agri GDP <10% of national GDP	Country in which Agri GDP > 25% of national GDP	Country in which Agri GDP <10% of national GDP	Country in which Agri GDP > 25% of national GDP	Country in which Agri GDP <10% of national GDP	Country in which Agri GDP > 25% of national GDP	Country in which Agri GDP <10% of national GDP
Average	2.91	9.33	0.12	0.08	0.36	1.39	0.32	0.46
Range	0.66 – 7.3	0.82 – 21.20	0.02 – 0.22	0.02 – 0.12	0.06 – 0.86	0.86 – 2.52	0.14 – 0.48	0.14 – 0.92

The description of the PVS Gap Analysis budget according to comparable indicators highlights the considerable variability among different regions and, within the same region, among countries having different level of compliance with OIE standards.

This result can be explained by the fact that the improvement in the compliance of a country's VS with international standards does not claim to follow a pre-established list of activities. It is rather country-specific, linked to national parameters (overall organisation of the VS, definition of the veterinary domain in the country, etc.) and the national objectives and priorities.

Some general trends seem to emerge:

- Investment by VLU is much higher for countries with a high compliance with OIE standards than for those with low compliance, reflecting the fact that, in the higher PCP-FMD stages more investments in the VS will become necessary.
- Countries having a high density of livestock (more than 50 VLU/km²) tend to have a lower VS budget per VLU (1.7 USD/VLU) than countries with a low animal density (less than 20 VLU/km²) (6.2 USD/VLU).
- Countries in which Agri GDP accounts for more than 25% of national GDP tend to have a lower VS budget per VLU (2.9 USD/VLU) than countries in which Agri GDP accounts for less than 10% of national GDP (7.0 USD/VLU).
- The share of the VS budget in the overall national budget is, once the results of the PVS Gap Analysis have been fully implemented, still less than 1.6%.

Further detailed studies will be necessary to provide estimated costs for the specific VS-related activities that are needed in a country to move from one PCP-FMD stage to the next.

NB: This exercise was undertaken in order to obtain indicative costs for the strengthening of Veterinary Services (VS) but no 'stand alone' budget provision is made in the Global Strategy.

3.3. Prevention and control of other major diseases of livestock (Component 3)

This component of the Global Strategy cannot be costed at present. The workshops and consultations to be organised at the regional level will better define the priorities and will indicate what specific control programmes will be needed to address some of the major diseases referred to in the Global FMD Control Strategy. Once this has been done, more precise evaluations of the cost of such control programmes can be made and the economies of scale obtained through combinations with the FMD prevention and control activities may then be calculated. It is obvious that such disease control combinations will differ from region to region and therefore cost sharing will also differ from one region to another.

4. Portfolio for the component FMD control (Component 1)

The elaboration of the FAO/OIE Global FMD Control Strategy included a FMD portfolio survey which was conducted by the GF-TADs FMD Working Group. The objectives of the survey were to identify the activities and funds committed worldwide to FMD control related programmes and get an impression of possible gaps. A questionnaire containing twelve questions was sent to 126 persons and organisations, stratified as follows: 99 OIE Delegates of selected countries, mostly from developing and in-transition countries; 10 development partners and 17 regional organizations. The questionnaire aimed to assess ongoing, closed and pipeline projects developed at national, regional and global level from the year 2000 onwards. Responses were obtained from 63 persons and organizations as follows: 45 countries (45%), 8 development partners (80%) and 10 global and regional organizations (59%), Missing data were completed by the authors as far as possible.

The results presented below are based on preliminary and partial data and should therefore be interpreted carefully. Unfortunately some major donors, including global and regional development agencies, did not respond. However, some general trends emerge from an analysis of the responses (see Annex 2 Part B).

From the information received it can be concluded that there are 30 ongoing projects on FMD control receiving outside funding and 12 projects that are in the pipeline. Only a few projects were mentioned that are aimed at the endemic regions of East and Central and West Africa, corresponding to FMD Virus Pools 4 and 5.

Most of the West and Central Asia countries were covered by regional projects until mid-July 2012, but no projects were mentioned that are in the pipeline.

Projects in the same region have often different timescales. The 12 new projects that are being prepared are mainly related to new epidemiological situations (SAT2 in Egypt and neighbouring countries for instance) and to new provisions in the OIE *Terrestrial Code* (chapter 8.5.23) encouraging countries to develop and implement national FMD control programmes endorsed by the OIE.

The majority of FMD projects are carried out at country level (68%) and appear to be 'crisis-driven', as their onset reflected recent FMD outbreaks.

Worldwide about USD 8 billion is spent to control FMD, with marked regional differences. The Americas and Asia together account for 98% of the funds (77% and 21%, respectively), with two countries (Argentina and Brazil) spending the majority of this budget. Of these funds, 94% comes from national budgets, both from public and private sector. Development partners contributed 4% of the funds. In Africa and non European-Union members in Europe, most FMD control activities were supported by external aid. The European Union is the largest development partner, supporting animal health projects in Africa, Asia and Europe. FAO and regional Banks also have a sizeable international FMD portfolio. The information received also showed that there are development partners who are actively supporting animal health projects, but no FMD-related activities whatsoever.

The majority of funds (91%) appear to be used for projects aimed at FMD control, rather than for projects that also aim to better control other TADs. A wide range of FMD control activities are supported; some projects also include a wild life component. In a considerable number of projects (60%) reinforcing VS was included.

The preliminary results of the portfolio show that the investments in FMD control worldwide are high, but such investments appear to be made mainly by the countries that see clear trade incentives. Developing countries are investing much less in FMD control, presumably as they cannot afford it or fail to see a positive cost-benefit balance.

International investments are limited and expected to be insufficient to considerably progress with FMD control in the near future. To correct this situation, additional investments will be necessary, in particular in the countries belonging to FMD virus pool regions 4 and 5 where few FMD projects appear to be ongoing or in the pipeline. The international investment in the West and Central part of Asia (FMD virus pool 3) also appeared to become less. This is surprising view of the geographical and epidemiological situation in this region and the risks this implies for FMD-free regions such as Europe.

Support to national programmes is needed, but regional support should also be increased. External aid can bring seed money and play a catalytic role in national projects and this can also be done through supporting regional and global activities. Up scaling of national and regional activities can notably be obtained through increased capacity building. In this regard regional and international networking activities will allow benefiting from economies of scale. All these programmes would be aligned to the Global Strategy which uses FMD as an entry point for reinforcement of VS and improved prevention and control of other TADs.

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Annexes

The Annexes and supporting documents are available on the OIE and FAO websites

Annexes to Part A

1. Socio-economics of FMD
2. Tools to be used for implementing the FMD Control Strategy component (Component 1)
3. Tools to be used for implementing the Strengthening Veterinary Services component (Component 2)
4. Tools to be used for implementing the Prevention and control of other major diseases of livestock component (Component 3)
5. Building on experience: lessons to be learned from regional FMD control programmes
6. Vaccines
7. Research

Annexes to Part B

1. Activities of the Strengthening Veterinary Services component (Component 2) according to the 5 PCP Stages (Stage 1 to 5)
2. Portfolio

Supporting documents

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Part A

Annex 1: Socio economy of foot and mouth disease

Foot and mouth disease (FMD) is probably the most important animal disease in the world causing impact on trade, both local, national and international, reductions in livestock production and significant costs in prevention and treatment.

The balance of FMD impacts are not the same throughout the world. Much of the global FMD burden of production losses falls on the world's poorest communities, and those which are most dependent upon the health of their livestock. In addition, the presence of FMD in these countries has an impact on the overall herd fertility, modifying the herd structure and affecting the selection of breeds. Overall the direct losses limit livestock productivity creating a food security issue and contributing to malnutrition. In countries with ongoing control programmes, FMD control and management creates significant costs. These control programmes are often difficult to end due to risks of FMD incursion from neighbouring countries. The greater movement of people, livestock and commodities implies that risks of international transmission of FMD are increasing. This risk further compromises these countries in their ability to export livestock and livestock products as the presence, or even threat, of FMD prevents access to lucrative international markets. In FMD free countries outbreaks have re-occurred in some countries and the costs involved in regaining free status have been enormous.

Although other diseases can cause more severe disease in individuals, in order to appreciate the impact of FMD, one must step back and look at the disease at the population level. FMD is widely prevalent, with the disease circulating in an estimated 77% of the global livestock population. In this population it affects a large proportion of animals during an outbreak and affects many species. Collectively these factors lead to a huge burden of disease.

In cattle systems FMD causes a range of production losses. It reduces milk production, with important knock on impacts on the availability of milk for humans and calves. In some areas this has been reported to be as high as 33% reduction in milk output. Cattle in calf can also abort leading to a reduction in calf crops and also an additional impact on milk production. Chronically affected animals with FMD are reported to have an overall reduction of 80% in milk yields. The disease also reduces growth rates, some of these being chronic. There is mortality particularly in young stock, with a range being 2% to 5%. In areas that are dependent on cattle and buffalo for ploughing, the presence of FMD during critical periods of seed bed preparation and sowing can have severe impacts on crop yields and in turn affect food availability. These impacts in combination change the herd structure, requiring more breeding females and fewer animals in production roles, and it limits the farmer's choice on breeds.

Visible production losses are most prominent in pigs in intensive production systems followed by dairy cattle. These two systems are important sources of animal protein in poor countries and their importance continues to grow. Extensive systems of production do not have such pronounced losses, and some species such as sheep and goats show limited clinical symptoms and minor economic losses. Regarding invisible losses, FMD causes problems with fertility, the most obvious are the abortion losses explained above, but there are longer lasting impacts of this loss of both foetus and a reduced probability of conception. These both translate into the need to have a greater proportion of breeding animals in a population implying that for every kilo of meat or milk produced there is an additional fixed cost to cover more breeding stock.

There are also additional costs associated with the presence of FMD. Countries with organised FMD control programmes have specialist units dedicated to the disease with the state Veterinary Services. These groups may be involved in disease investigation, surveillance, diagnostics and control measures such as vaccination, movement control and sometimes culling and compensation. At farm level many vaccination campaigns run on the basis of farmers providing their time to round up animals and also the development of handling facilities. The farmers are also usually expected to pay for the vaccine. When disease does occur

and there is no culling and compensation policy, farmers will spend money on treating animals that are sick and also pay money in the process of their recuperation.

Generally speaking, the socio-economic impacts and methods employed to control FMD in wildlife populations are considered to be underestimated in spite of tourism (including photographic as well as hunting tourism) contributing as much or more as livestock agriculture does to GDP in certain countries such as in Southern Africa. In some regions where there are attempts to limit domestic and wildlife contact expensive fencing has been erected. In addition to the costs of the fence, there are negative environmental aspects on the wildlife and in some cases negative impacts on tourism. In Africa it has been estimated that more is spent controlling FMD than any other veterinary disease.

In countries free of FMD that have naive livestock populations great attention is paid to reducing the possibility of incursions of the virus. These include border and import controls and inspections and sometimes vaccination. There may also be investments to enhance and maintain surveillance and response in order to detect problems early and respond accordingly. If the disease does occur, most countries resort to culling and compensation and movement restrictions, with some also using vaccination. Movement restrictions often disrupt production and marketing systems and if they are widespread can lead to welfare problems and the necessity to cull animals that are not directly affected by FMD.

A consequence of the movement restrictions required to control and manage FMD is a reduction or possible exclusion from markets. Such restrictions can be local, and enforced through local norms, they can also be national where control programmes are in place and with the greatest impacts often reported on the access to international markets. Where livestock trade is affected, animals that come from an FMD area will have lower prices. In countries infected with FMD there will be no live animal trade with FMD free countries. There may also be stringent measures on the trade of livestock products from FMD infected countries such as traceability of animals, increased surveillance for disease and processing of meat. Typically the countries with the best meat prices are FMD free (i.e. European Union [EU], United States [USA] and Japan). If FMD is effectively controlled with vaccination by competent Veterinary Services able to detect outbreaks then deboned, matured and pH-controlled meat, excluding offal, could possibly be exported. The FMD status of a country of destination that a country trades with also affects a country's ability to trade with FMD free countries irrespective of its own status. The lack of access to lucrative markets reduces the incentives for the private sector to develop commercial farming and livestock processing and marketing systems. In turn this limits the generation of employment and tax revenues from the livestock sector.

A rapid assessment of annual production losses caused by FMD were in the region of US\$2.6 billion, and the costs of annual FMD vaccination globally was approximately US\$2.35 billion. These are huge impacts and do not include the significant aspects of how trade is restricted and distorted by FMD presence across the world.

The impact of FMD has led to successful national and regional campaigns for disease eradication most notably in Europe and the Americas. Therefore technologies and control methods exist to control and ultimately remove FMD virus from livestock populations. However, this requires significant management and coordination skills at a national and regional level due to FMD being highly contagious, and therefore, is a disease that generates high levels of externalities. These externalities imply that the control of FMD produces a significant amount of public goods, justifying the need for national and international public investment.

FMD control strategies and tools are typically classed as global public goods since they benefit all countries, or several groups of countries, and all populations and future generations, and these benefits extend beyond national borders and not just the productivity of livestock populations (the fight against poverty and food insecurity, notably in developing countries). Moreover, a single country failing to control the disease can have adverse consequences for neighbouring or even distant countries.

In a review of the peer reviewed and grey literature there have been 30 country and regional cost benefit analysis studies of FMD control and eradication. A large number of these are ex post evaluations after large outbreaks in previously free countries. Countries that are free and have concerns of getting disease have also carried out a number of studies based on simulations of disease, control response and impacts on the economy. Finally there is a set of studies looking at the analysis of the control of FMD in countries having the

disease and looking at investment for control. The major findings from all these evaluations are that control programmes in countries previously free generate positive returns to the economy. In countries free from FMD that suffer an outbreak losses vary between 0.6% to 0.3% of their GDP. In countries with international trade in livestock and livestock products the control of FMD has good economic returns. And finally in countries with limited or no international trade in livestock and livestock products a positive return on FMD control requires targeted programmes.

Part A

Annex 2: Tools to be used for implementing the Component 1 of the Global foot and mouth disease control strategy

The Global foot and mouth disease (FMD) control strategy proposes to use various tools and procedures to combat FMD. Summaries of the tools are provided in the Strategy document under the appropriate headings, i.e. Components 1, 2 or 3.

In this annex the tools are described in some more detail. In case background documents with extensive descriptions are available, they are included as Supporting documents, for instance the document on the Progressive Control Pathway (PCP) for FMD and the Performance of Veterinary Services (PVS) Pathway.

Progressive Control Pathway for FMD (PCP-FMD)

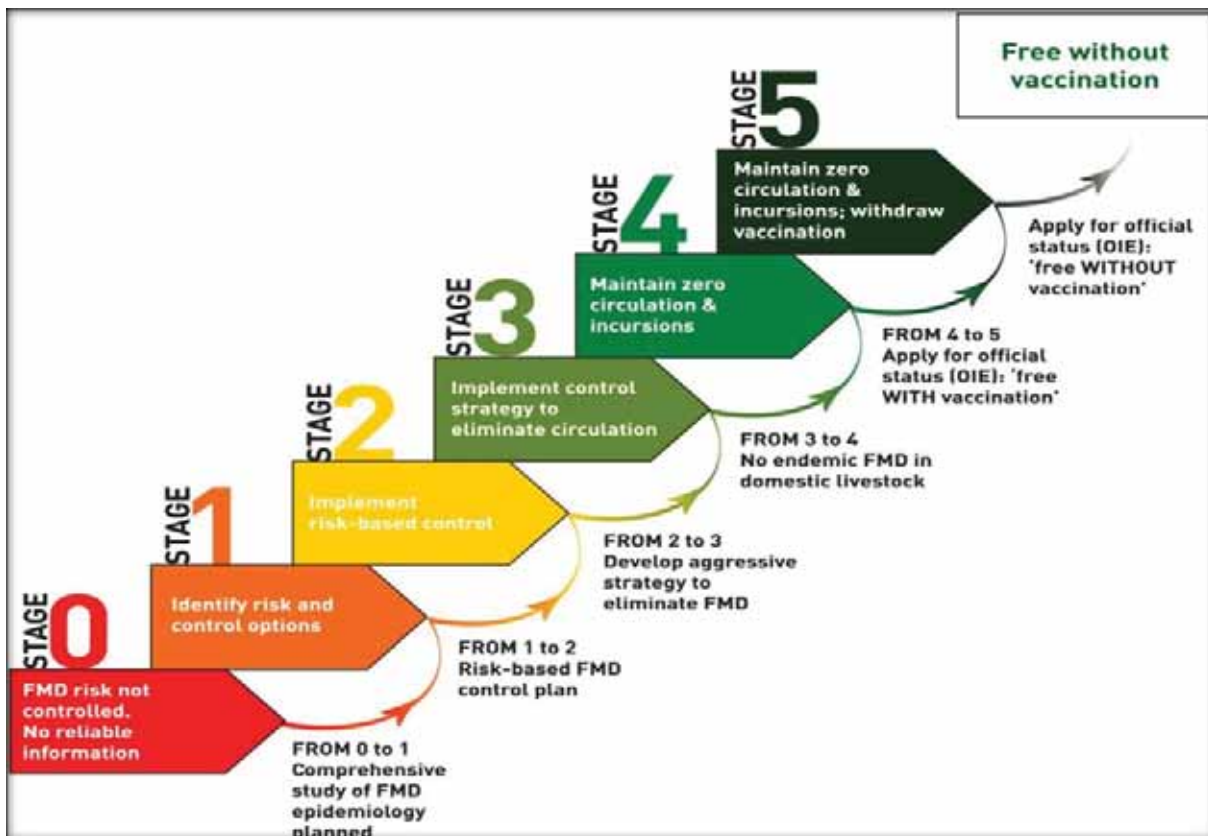
The PCP as a development tool

The PCP-FMD is essentially a development tool. It aims to guide and structure a country's efforts to progress with FMD control by offering a step-wise approach and describing the actions required to proceed through the successive stages. The use of the PCP will assist in developing a country's policy for FMD control, including priority setting and progressively managing the risks.

The tool is intended for countries where the disease is endemic and where a clearer knowledge of the local situation (epidemiological factors, circulating virus strains, etc.) and the preparation and implementation of control programmes to reduce the impact of the disease are needed.

The PCP approach was developed by Food and Agriculture Organization of the United Nations (FAO) and the European Commission for the Control of FMD (EuFMD) and finalised together with the World Organisation for Animal Health (OIE). Numerous experts contributed to the concept and the technical content. In the development stage, the PCP-FMD has been tested in several regions where FMD is still endemic, including West Eurasia and Africa. In 2009, the approach was recommended by the OIE/FAO International Conference on FMD in Asuncion, Paraguay as an important tool to establish, manage and evaluate the impact of FMD at regional level. The current PCP-FMD document published on the websites of FAO, OIE and EuFMD, was finalised during a workshop with experts in Pirbright, United Kingdom (UK), in October 2010.

The PCP-FMD defines five FMD control activity stages that, if implemented, should enable countries to progressively increase the level of FMD control to the point where an application for OIE-endorsement of a national control programme (in an advanced phase of Stage 3) or official freedom from FMD with or without vaccination (end of Stages 4 and 5, respectively) may be successful and the status sustainable.



At the heart of the PCP approach is the notion that routine monitoring of the FMD incidence in populations is essential to the management of the disease. It will generate information that is of immediate use and has local and international value. Monitoring can be undertaken in almost all affected countries with current tools (NSP-ELISA) and in combination with the services of reference laboratories (for virological assessment).

The PCP-FMD describes the level of action against FMD, starting from a basic risk identification and monitoring programme to the level of action and capacity required to prevent virus circulation and set the conditions to enable zonal or national freedom to be attained.

Activities in each PCP Stage are appropriate to the required reduction in virus circulation and mitigation of disease risk to be achieved. The optimisation of resource use for FMD control is achieved through the targeting of measures to the husbandry systems and critical risk points where the impact on disease control and/or virus circulation will be greatest. In general the actions are of increasing intensity and cost.

Although it is not encouraged by the Global Strategy, countries may decide to remain in PCP Stage 2 for some time, for instance based on studies regarding cost-effectiveness of further investments. At the end of Stage 3, countries may proceed with the objective of elimination of the disease and they may submit their National FMD Control Programmes to the OIE for endorsement. An effective implementation of such programmes would bring them up to PCP Stage 4 (i.e. ready, by the end of stage 4, to apply for the status of officially free with vaccination) or Stage 5 (ready to apply by the end of stage 5 for the status of officially free without vaccination).

The successive PCP steps involve a number of criteria which refer to the necessary 'enabling environment' for better prevention and control of diseases such as FMD, e.g. quality of Veterinary Services (VS) and the existence of effective surveillance and at higher stages early outbreak detection and alert systems, as well as immediate response capabilities and appropriate legislation. Therefore, this animal health enabling environment relates to issues which go beyond FMD alone and this will liaise with the PVS approach and bridges with improved control of other major TADs (Components 2 and 3). The relationship between the FMD-PCP and OIE PVS procedures has been worked out in the Strategy to ensure full coherence and continuity.

The PCP as an assessment tool

The FMD-PCP tool is not only useful for guiding and structuring the policy and activities of a country regarding FMD control, but also for self-assessment, i.e. to assess where it stands in terms of FMD control and evaluate the progress achieved. The criteria to be used to monitor progression through the different stages of the PCP are described in detail in the supporting PCP document. They are sufficiently precise for this purpose, but also flexible enough to be adapted to a variety of situations. Based on a self-assessment (for which international expertise can be obtained) a country may declare itself in a certain PCP Stage.

A country may also request the Global FMD Working Group to carry out an evaluation of the FMD-PCP Stage reached. This may result in a 'GF-TADs accepted' PCP Stage, adding to international credibility for a country's progress and to maintaining comparable FMD-PCP standards at the global scale. A provisional procedure for an 'Acceptance procedure' under the GF-TADs umbrella has been laid down in the Supporting document on the FMD-PCP document. This procedure obviously has a different status as compared to the official OIE endorsement procedure of a National FMD Control Programme that can be applied for as of PCP Stage 3 and the official OIE country or zone recognition as FMD-free with or without vaccination (which refers to the disease status) that can be applied for in Stage 5 and represents the highest level attainable.

The provisional 'GF-TADs acceptance procedure' is presently under study and will be revised and refined in the near future. In addition, support tools to assist with PCP self-assessments as well as external evaluations are under development.

Countries that have already acquired an official OIE FMD-free status for all or part of their territory will already be at an advanced stage of FMD control and will not normally need to use the PCP.

Regional approaches and regional roadmaps

Regional approaches to FMD control are imperative as experience in many regions has shown (Part A, Annex 5). This is not surprising in view of the strong transboundary nature of FMD. It is anticipated that in the future the necessity to approach FMD control on a regional if not global scale will increase due to increased trade, transport and travel.

Regional meetings that are held regularly and involve Chief Veterinary Officers as well as FMD laboratory and epidemiology experts, have been found instrumental in developing true regional approaches to FMD control. Such meetings, organised according to the FMD virus pool regions, constitute the appropriate platforms where individual countries embarking on PCP-FMD activities will have the opportunity to share information, share their respective experiences and harmonise control efforts.

The joint exercise of developing Regional Roadmaps, showing where each country is today with FMD control in terms of the FMD-PCP Stage and where it wants to be in for instance 10 year from now, is an important activity to engage the countries, to build commitment and to allow regular assessment of progress. If regional meetings are organised on a yearly basis, significant tendencies or problems may be signaled and actions taken timely. This may include advocacy at the global level for additional support.

During regular regional meetings international organisations will contribute to coordination, they will get an overview which will allow producing a yearly FMD Control Progress Report.

PVS pathway: evaluation of the Veterinary Services

The OIE PVS pathway will be used as a basic tool in Component 2 of the Global FMD Control Strategy. It is used to evaluate the quality of VS, to monitor their improvement and to identify and assess the level of investments necessary to eliminate the gaps as compared to OIE standards. In addition to its function in assessing the situation of a VS, the PVS tool is also used to guide relevant capacity building activities.

As mentioned in the Global FMD Control Strategy document, strengthening VS will have positive effects on a country's capability and capacity to achieve FMD control (Component 1) as well as improved control of other major diseases (Component 3). In the framework of the Global FMD Control Strategy, FMD control is used as an entry point. The underlying notion is that better FMD control will imply the strengthening of VS and this in turn will have broader positive effects.

OIE standards, recognition of disease status and endorsement of control programmes

The standards laid down in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) are the reference cadre for assessing and monitoring the progress reached with the control and eradication of the major animal diseases, in particular the transboundary animal diseases (TADs). The standards usually describe the criteria to be fulfilled for a country to be recognised as free from a disease.

With respect to FMD, the OIE has been involved in the official recognition of FMD-free statuses of countries or zones within countries, for many years. This policy will continue in accordance with the very precise procedures laid down in the *Terrestrial Code*. Country dossiers submitted to OIE are analysed by the Scientific Commission, with the support of its ad hoc Group on the Evaluation of FMD Status. The Commission then submits its recommendations on country status recognition to the World Assembly of Delegates for official endorsement at the annual meeting.

In recent years, the OIE has participated in the finalisation and fine tuning of the PCP which essentially is a development tool for countries wishing to progress with FMD control, but usually still far from the point where they can submit an application to OIE for FMD-free recognition of the country or a zone within the country. The PCP is now a joint FAO/OIE tool.

A major advance in connection with OIE's involvement in the Global Strategy was the adoption of a new article for Chapter 8.5 of the *Terrestrial Code* by the World Assembly of Delegates in May 2011. The new article provides the opportunity for countries that are not FMD-free to have their national FMD control programmes officially endorsed by the OIE. The countries that choose this procedure will already be at an advanced level of FMD control and making substantial investments in FMD control. The level of control will be comparable to PCP Stage 3 and GF-TADs acceptance of Stage 3 is likely. It is also likely that the National FMD Control Programme submitted to the OIE will mark the country's entry into the pathway to disease elimination.

A country's FMD control programme submitted to the OIE should be accompanied by a list of documents demonstrating that the country is in a position to implement the programme successfully. The documents should show that the country meets conditions such as: effectiveness of the VS, knowledge of the FMD situation in the country, a major reduction in the impact of the disease, the existence of suitable legislation, effective surveillance and diagnostic systems, the existence of contingency plans, etc.

The procedure for a National FMD Control Programme to become endorsed by the OIE is the same as described above for recognition of a country or zone as FMD-free. Upon endorsement, the Country's Control Programme will be included in the list of programmes endorsed by the OIE. Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points mentioned above that are essential for its implementation.

More detailed information on the PVS pathway can be found in the OIE website (see ref 18 in the list of References of the main text), in Annex 3 of Part B and in the supporting document N° 3.

Diagnostic laboratories, Reference laboratories/centres. Regional and global networks

Regional FMD campaigns in some parts of the world have had remarkable success, most notably in Europe and South America. Essential elements of those campaigns have been the networks of OIE/FAO Reference Centres (RCs) and regional leading laboratories (RLLs).

A global network of RCs is necessary to exchange information, coordinate, compare and/or harmonise diagnostic procedures, incorporate new scientific developments in a timely manner and maintain peer contacts. One of the laboratories should act as the coordinating laboratory.

The RCs should in turn support national FMD laboratories and coordinate a network, either directly or through a RLL. These RCs and RLLs should through the network attempt to guarantee the quality and harmonisation of diagnostic procedures in their region, provide training, confirm certain findings and carry out follow-up diagnostic work.

In the early stages of the FMD-PCP, FMD diagnosis in the country may be based on lateral flow devices (LFDs) that can be used in the field or an antigen detection ELISA and PCR in the laboratory. It will be necessary, therefore, that national laboratories or the RLL have or develop this diagnostic capability. Further characterisation of the viruses circulating in the region will normally be done at the regional level, including characterisation for vaccine matching purposes. This will need antigenic characterisation which is the remit of RCs or the World Reference Laboratory (WRL).

To carry out initial epidemiological investigations in FMD-endemic countries, NSP- ELISA's can be used if the results are interpreted carefully and taking into account all relevant background information. This type of work can be done in a national laboratory. Further serological tests (solid phase competition ELISA; SPCE-ELISA or Liquid Phase Blocking ELISA) will be required if/when vaccination efficacy and coverage are to be assessed. This work may also be outsourced to a RC.

Most FMD-free or sporadically affected countries can call on the services of a capable National FMD laboratory or a RC in an emergency. Unfortunately some regions of the world lack RCs or RLLs, for instance inter tropical Africa, the Middle East and parts of Asia. These regions are of great epidemiological importance since they encompass six out of the seven FMD eco-systems or 'virus pool' regions. The establishment of at least one RLL or RC in each of the seven virus pool regions is therefore seen as an essential requirement to implement the Global Strategy and provisions to support the RLL/RCs, both in terms of man power (expertise) and finances to carry out the required activities, are made in the required budget.

The current standard of national FMD laboratories is variable due to limited capabilities and inadequate budgets, even to collect field samples and paying the shipping costs to send samples to RCs or the WRL for further examination. The Global Strategy attempts to rectify this situation by providing assistance in various forms to the national laboratories, including materials, equipment, and some financial support. The laboratory activities will be supported by training in disease diagnosis and investigation, including collection, storage and analysis of samples and data.

The already established global network of FMD OIE/FAO RCs fits well within the laboratory structure described above and is expected to play a major role in supporting the implementation of the Global FMD Control Strategy. The activities of the network are coordinated by the WRL of the IAH, Pirbright, UK. The WRL also acts as a focal point for OIE and FAO.

Vaccines and vaccination

In endemic countries FMD vaccine is used rather sparingly, if at all, and for economic reasons its application is usually limited to dairy cattle and buffalo or for the application of ring vaccinations during outbreaks. If the Global Strategy is to have a significant impact worldwide, the production of vaccine will have to be increased and it will have to be made available to countries that are not in a position to afford it themselves. In addition,

the correct delivery and use of vaccines in the field has to be safeguarded. These elements are included in the Global Strategy.

The FMD vaccines that are used should meet the OIE standards of potency and safety. When a vaccine is to be used in campaigns financed or co-financed by public funds, vaccine producers or sales companies may be asked to provide an official Quality Control (QC) certificate. The Global Strategy foresees to support regional vaccine QC centres, such as PANVAC in Africa. It will seek funding to strengthen the expertise and capabilities of countries and laboratories to ensure the potency of vaccines to be procured and the antigenic matching with the virus strains prevailing in the region.

To boost worldwide vaccine production, public-private initiatives may be a way forward. Clearly vaccine producers will need guarantees in terms of return on investment and sustainability of the market.

The Global Strategy intends to focus its activities on endemic regions and especially the 'virus pool' regions. In the framework of the PCP, the monitoring and investigation of FMD outbreaks will be intensified and more isolates will be collected and characterised allowing selecting appropriate vaccines. The PCP also foresees to monitor the components of vaccination campaigns, including vaccine transport and delivery, maintenance of the cold chain, vaccination coverage and post vaccination campaign monitoring (% of immune animals).

Vaccination strategies can be based on massive coverage or be targeted e.g. to specific animal sub-populations or zones (high risk situations, ring vaccinations surrounding outbreaks, buffer or protection zones surrounding free zones...). The targeting of vaccination and the means of delivery will depend of specific conditions and objectives along the PCP pathway. They will be based on the epidemiological analysis of FMD, the assessment of livestock sector and the attitudes of livestock keepers towards vaccination. Delivery systems can involve the private sector through sanitary mandates (delegation of responsibility) given to private veterinarians who will also be able, when appropriate (very extensive and nomadic livestock systems, remote areas, civil unrest...) and under their responsibility, to use technicians and community animal health workers.

The Global Strategy foresees strong links between the epidemiologists and socio-economists working on the Strategy, while drawing lessons from countries that have on-going successful FMD vaccination campaigns.

When countries or zones are considering the possibility of stopping with vaccination against FMD, the use of high quality and purified vaccines will be encouraged. This facilitates the interpretation of positive findings in NSP ELISAs indicative for the presence of virus circulation.

Although the Global Strategy is built on the experience that with the conventional FMD vaccines good results can be achieved, the development of a new generation of vaccines may help to address the issue of vaccine cost and cross-protection. This is a major constraint in the availability and supply. It is expected that novel vaccines will be cheaper to produce and will not be dependent on a cold-chain. Production costs would also be greatly reduced if the novel vaccine did not have to be manufactured within biosecure facilities.

National, regional, international surveillance and epidemiology skills and development of networks

An important goal in the early stages of the PCP-FMD is to design an FMD control programme based on epidemiological evidence generated through monitoring, virological and serological studies. Once a programme is implemented its efficacy and cost-effectiveness should be measured to ensure that the expected results are achieved. To do this, strengthening the national epidemiological capabilities and capacity to design appropriate epidemiological studies (and to promote a more extensive use of the epidemiological methods) will be necessary in many countries where FMD is still endemic.

A central epidemiology unit responsible for collecting, analysing and disseminating the information generated through the implementation of field and laboratory activities is preferred. It is essential that a strong link is established between the national epidemiology unit and the FMD laboratory.

At field level, surveillance methods to be used can be passive or active, comprehensive or targeted. Syndromic surveillance (detection of syndromes instead of specific clinical signs) is currently developing but there is still more to do on the research field before defining appropriate standardised criteria.

Participatory epidemiology, based on village/community animal health workers, can also improve the performance of monitoring, particularly in small farming or nomadic production systems and in remote or unsecure regions.

In analogy with the laboratories, the Global FMD Control Strategy attempts to establish or strengthen a global network of epidemiology centres, as well as regional epidemiology networks. At global level it should include the OIE/FAO Epidemiology Collaborating Centres. At regional level, the members should attempt to guarantee (through the national epidemiology centres) that the procedures in place at national level are harmonised through coordination and training and the countries are encouraged to exchange their information. In the absence of an equivalent of a 'WRL for epidemiology' it is foreseen that one of the Regional Epidemiology Centres with recognised expertise acts as global coordinator. This task could rotate between Centres of equivalent expertise. The main task of the Global Coordinating Centre will be to liaise with the WRL in the UK and provide the necessary support to the collation and analysis of data collected globally and to support the Regional Epidemiology Centres in their efforts to harmonise activities within each virus pool.

The Regional Epidemiology Centres will be responsible for collecting the data generated at national level and produce information with added value for both the national and regional level.

The Global Strategy will strive to increase the epidemiological expertise in each region by supporting the Regional Epidemiology Centres and providing experts. These may be placed in the Regional Animal Health Centres or in the regional leading epidemiology centres. These Centres in turn will work with the laboratory component on sample collection and storage to identify gaps in epidemiological knowledge and application, and will support training in standard methods of disease investigation and risk analysis, analysis of disease outbreak data and the design, implementation and analysis of serological surveys. There will be need for strong links between the epidemiology teams and VS field staff as well as the laboratories involved in diagnosis. The Global Strategy attempts to design and provide a database to be used to store relevant epidemiological data and information produced at national, regional and global level. This will require appropriate agreements for the exchange of information (data property, sharing, transparency, dissemination). This database may be used to undertake risk analysis/risk evaluations to help technical services and decision makers in defining and supporting strategies for FMD prevention and control, supported by cost-effectiveness and cost-benefit analyses.

The two international bodies, OIE and FAO, will be supported to continue carrying out disease intelligence as is currently done by the FAO/OIE Global Early Warning System (GLEWS) which includes also WHO for zoonotic disease outbreaks in humans. The OIE international information system (WAHIS-WAHID) will continue to be the basis of the dissemination of official disease information.

Emergency response

An emergency response refers to a planned series of actions in response to an unplanned event that may have far reaching consequences. This definition clearly indicates that in many countries where FMD is endemic, an emergency response mechanism is not the first priority.

In the early stages of the PCP-FMD the efforts are directed towards gaining an understanding of the epidemiology of FMD and the risk situation in the country, which are the basis for designing and implementing control measures.

Having a comprehensive response in place (which may still not be defined an emergency response) will become an issue when countries have achieved at least PCP Stage 3 which indicates that the level of investment made in the control of FMD is significant and needs to be adequately protected.

A true emergency response is imperative in countries or zones that are nearly free of FMD or already have the official OIE status FMD-free. In such countries the prevention of FMD virus entry should be given high priority. Prevention depends on the maintenance of effective border controls supported by risk assessment and international disease surveillance and transparency.

The implementation of field activities in FMD-endemic countries according to the PCP principles will generate a significant amount of information. The availability of such information at the global level is highly important to support risk analyses and strengthen preventive measures.

As zero risk is impossible to achieve, it is important that FMD-free countries are well prepared to deal with the unfortunate event of a breach, requiring mechanisms and training for early detection, rapid reporting and quick implementation of control and eradication measures. This requires an effective national contingency plan which is regularly tested and updated based on simulation exercises. FMD virus introduction into free countries usually translated into enormous costs to re-acquire the status of officially free (with Japan and the Republic of Korea as the most recent examples).

At the global level, the FAO/OIE Crises Management Centre for Animal Health (CMC-AH) is an available tool which provides emergency assistance during a crisis as well as supporting emergency teams in an affected country.

More details can be found in Nick Honhold, Ian Douglas, William Geering, Arnon Shimshoni, Juan Lubroth, (2011), Good Emergency Management Practice,; the essentials, FAO.

Registration of farms and identification of animals, movement of animals

In some of the developed countries the establishment of identification and registration (I&R) systems, comprising farms (or epidemiological units), animals (weather individual or as a group) and the recording of all movements has become a cornerstones of disease control. It allows rapid and reliable tracing back and tracing forward in case of a disease outbreak.

The implementation of such systems, stimulated by major health crisis such as Bovine Spongiform Encephalitis in order to improve the traceability of meat and meat products, require a significant investment which is not expected for countries at the early stages of the PCP.

The Global Strategy recognises that the development of an I & R system will be expected once a country reaches PCP Stage 3 or higher. The capabilities of countries in this area will be strengthened and the adoption of best practices will be promoted.

More to be found in various documents and websites such as:

- Hoffmann I., Besbes B., Battaglia D. & Wagner H. (2010). – Capacity building in support of animal identification for recording and traceability: FAO's multipurpose and global approach. EU Conference on Identification and traceability along the food chain, Brussels, 14-15 June 2010.
- World Organisation for Animal Health (OIE) (2012). – Terrestrial Animal Health Code. Chapters 4.1 and 4.2. Available at: www.oie.int/en/international-standard-setting/terrestrial-code/.
- International Committee for Animal Recording (ICAR). – Available at: www.icar.org/index.htm.
- World Organisation for Animal Health (OIE) (2009). – First OIE International Conference on Animal Identification and Traceability 'From Farm to Fork', Buenos Aires (Argentina), 23-25 March 2009. Available at: www.oie.int/doc/en_document.php?numrec=3609103.

Biosecurity

'Biosecurity' refers to the prevention of disease causing agents entering or leaving the premises where animals are present (or have been present recently). It involves a number of measures and protocols designed to prevent disease causing agents from entering or leaving a property (e.g. farm, market...) and being spread. Farm to farm movement of infected livestock is the most effective means by which animal diseases such as FMD can be spread and basic biosecurity measures are concerned with minimising the spread through contaminated vehicles, clothing, footwear and equipment.

As a consequence the two key biosecurity measures are:

1. minimising movement of people, animals, animal products, vehicles and equipment from premises where animals are kept;
2. the adoption of best practices (hygiene and protective clothing) whenever there is direct contact with animals.

The level of biosecurity measures adopted should reflect the risk involved. Disease symptoms are not always apparent, especially in the early stages, but this does not mean that no risks exist. On the other hand, disease agents and vectors may still be present even when animals have been removed and hence biosecurity measures should still apply.

A full implementation of biosecurity measures is a complex process that requires a comprehensive understanding of the risks associated with diseases occurrence and spread.

In this regard the promotion of the principles of biosecurity will be an important element of the Global Strategy.

In many developing countries where FMD is endemic livestock keepers may be unaware of risk factors associated with FMD introduction and spread. Therefore the basic principles of biosecurity should be included in extension services. Training courses should be held regularly for field veterinarians, farmers and others involved with livestock as an important component of a national control programme. Guidance in the form of brief hand outs should be available for distribution to farmers in the event of a disease occurrence.

The maintenance of biosecurity is also essential at premises where FMD virus is being handled e.g. in vaccine production facilities and in diagnostic and research laboratories. The level of risk will vary depending on the amounts of virus being handled, e.g. facilities in which susceptible farm animals are infected with the virus will present the greatest hazard.

More to be found in selected websites such as:

- Canadian Food Inspection Agency (CFIA) Biosecurity webpage (the site provides access to CFIA tools developed for producers to help promote biosecurity measures on-farm, to CFIA national biosecurity standards, protocols and strategies and to general biosecurity information. Available at: www.inspection.gc.ca/animals/terrestrial-animals/biosecurity/eng/1299868055616/1320534707863.
- UK Department for Environment, Food and Rural Affairs (DEFRA), (this website provides information on farm biosecurity) and a leaflet on: Biosecurity – Preventing the introduction and the spread of foot and mouth disease. Available at: www.defra.gov.uk/animal-diseases/biosecurity/ and www.defra.gov.uk/publications/files/pb9868b-factsheet2-070807.pdf.
- Farmbiosecurity.com.au. (Farmbiosecurity.com.au is part of the Farm Biosecurity campaign, a joint initiative of Animal Health Australia (AHA) and Plant Health Australia (PHA). This site also provides a collective area where all Farm Biosecurity materials are available for download) Available at: www.farmbiosecurity.com.au/.
- United States National Biosecurity Resource Center for Animal Health Emergencies. Available at: www.Biosecuritycenter.org.

Public-private partnership

Strong links between the public sector and the private sectors have been shown invaluable for countries facing emergency disease situations. An important component is the establishment of adequate platforms to facilitate the development of collaboration between the public sector and private stakeholders which are involved in animal production, including producers, traders and agribusiness.

The VS of a country may also have a public and a private component. Delegation of public health missions to the private sector is possible and often needed and functional collaboration with the private sector is one of the pillars of the OIE standard on good governance.

The Global Strategy will take into account that the institutional arrangements for animal disease prevention and control need to reflect the incentives of the public and private sectors in the different components of livestock production systems. This requires well defined roles and responsibilities and the fact that animal health measures relate to both public and private goods, but also that the leadership for the animal health system should reside with the public services.

In developing countries, producer associations are relatively rare and weak and their emergence has to be supported in order to become full counterparts of the public VS.

Part A

Annex 3: Tools to be used for implementing the Component 2. Strengthening Veterinary Services

The Performance of Veterinary Services (PVS) Pathway (PVS evaluation, PVS gap analysis, veterinary legislation, PVS pathway follow-up)

The OIE standards on the quality of Veterinary Services

Chapter 3.1 of the *Terrestrial Animal Health Code* (TAHC) on the quality of Veterinary Services (VS) provides 'intrinsic' standards with which the VS should first comply, for them to be able to further comply with the other Chapters, like those related to animal diseases – FMD notably (chapter 8.5 of TAHC).

In this Chapter, the fundamental principles of quality of VSs are described and can be classified into four fundamental components:

- i) the human, physical and financial resources to attract and retain professionals with technical and leadership skills and allow them to perform their role in the livestock sector;
- ii) the technical authority and capability to address current and new issues including prevention and control of biological disasters based on scientific principles;
- iii) the sustained interaction with the private sector developing and implementing joint programmes and services; and
- iv) the ability to facilitate market access through compliance with existing standards and the implementation of new disciplines such as the harmonisation of standards, equivalence and zoning.

In order to assist its member countries in complying with the OIE standards, the OIE has developed the OIE PVS Pathway (ref 18 in the main text), which is a multi-phased approach combining:

- evaluation tools (ref 18 and supporting document N°3): 'diagnostic, prescription and monitoring phases' with the PVS Evaluation (see below), the PVS follow up missions and the PVS Gap Analysis. The Gap Analysis determines the activities to be carried out and proposes the tasks and human, physical and financial resources required with an evaluation of a five-year budget for the improvement of the country's Veterinary Services. The analysis is carried out together with the Veterinary Services, in accordance with national priorities and constraints and it defines the expected result (i.e. the level of advancement for critical competencies defined in the OIE PVS tool) at the end of the five-year period for the critical competencies of the OIE PVS tool which are relevant to the national context;
- capacity programmes: 'treatment phase' with country's legislation support missions and twinning programmes for laboratories, veterinary statutory bodies and veterinary education.

The OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)

The OIE has developed a tool for the Evaluation of the Veterinary Services, the OIE PVS tool (9), to assess the level of compliance of national VS with OIE standards on quality of VSs, and at a second stage, to assess the progress made overtime (PVS Follow Up).

To apply the OIE PVS Tool to establish the level of performance of the VS, a total of 46 Critical Competences (CCs) have been elaborated, and for each of them, five qualitative levels of advancement are described: level 1 corresponding to non-compliance and level 5 to the highest level of advancement attainable. Most of the time, level 3 is considered to be in sufficient compliance with OIE standards. A higher level of advancement assumes that the VS are complying with the preceding (non 1) levels (i.e. level 3 assumes compliance with level 2 criteria).

As of May 2012, 109 PVS Evaluations and 58 Gap Analysis have been carried out, as well as 14 Follow-up missions. The PVS Pathway has been found to be a very effective tool for strengthening the capability and capacity of VS in general, but in regard to the Global Strategy, this will strengthen the effectiveness of VS to combat FMD and other TADs.

Linking the PCP-FMD stages to the OIE PVS levels of Critical Competencies

A country embarking into the FMD PCP should ensure to progressively acquire the appropriate structures, organisation, managerial capacities as well as human and financial resources in parallel, to conduct activities aiming at the control – or eradication – of FMD (and other TADs). This is considered as the ‘enabling environment’ of the PCP, which will guaranty the effective management of prevention and control FMD measures put in place and their sustainability in the long run. This implies the progressive institutionalisation of FMD prevention and control.

The capacity and capability of VSs are an essential component of the PCP ‘enabling environment’. Bridging the PCP stages with the Critical Competencies of the OIE PVS tool is therefore key to the successful implementation of the Global Strategy. Unlike Output 1 where a defined number of PCP stages (=2) are to be moved up within 15 years, the Global Strategy proposes that the reinforcement of VSs be tailored to the need and timeframe of the PCP stages. The objectives for Component 2 are therefore deducted from the objectives of Component 1.

Out of the 46 existing Critical Competences (CCs) of the OIE PVS evaluation tool, 33 are of particular relevance to the prevention and control of FMD (and other TADs) in the national territory. The Table 1 in the Section 5.1 of the document – stemming from Tables I and II below in this Annex 3 – indicates the level of compliance to be reached for the 33 FMD-related CCs for each of the PCP-FMD stages. In most cases, Level 3 is deemed enough to ensure a sufficient level of compliance with OIE standards, however, for 7 CCs, Levels 4 or even 5 is targeted. A basic principle when establishing the correspondence table was to state that once a level is reached for a given CC, it cannot regress, regardless of the relevance of the CC in further PCP stages.

This ‘correspondence’ shows that:

- at the end of the Global Strategy implementation when it is expected that 100% countries have at least reached PCP Stage 2:
 - i) one level of compliance will be raised for all CCs – except 2 that are not crucial in the early stages of the FMD-PCPP- and
 - ii) minimum compliance with OIE Standards on quality of VSs will be reached for at least 18 CCs

- countries requesting for an OIE endorsed control program (end of Stage 3) will all have reached at least level 3 for all FMD related CCs;
- countries embarking for the OIE free status recognition process will all have reached level 3 for 32 out of the 33 FMD related CCs.


This proposed ‘progression’ is fully consistent with the OIE standards, since Article 8.5.48 on the endorsement of National FMD Control Programme states the need for documented evidence on the capacity of the Veterinary Services to control FMD; this evidence can be provided by countries following the OIE PVS Pathway. This is even more relevant for official recognition of FMD free status with and without vaccination of the Code (Chapters 1.6 and 8.5).

Overall, it is very important to note that the ‘relation’ PCP-OIE PVS works both ways: a country will be granted with a PCP stage only if the requirements in terms of enabling environment will be met as well (level 3 achieved for all the FMD related CCs for that particular PCP Stage); reversely, the PCP ‘history’/‘continuum’ (pace of progress; possible regression; etc.) of the country will be key if the country wants to have its national FMD control programme endorsed by the OIE at the end of Stage 3 or further embark for PCP Stages 4 and above.

This ‘correspondence’ may remain fully relevant when similar PCP approaches are developed for other TADs, provided that the control measures stand basically alike (although elements to control different diseases can be combined differently. For instance vaccination is not a relevant tool for controlling African Swine Fever).

Table I. Selection of FMD related PVS CCs

Note bene:

- Objective: capacity of VS to prevent and control FMD
- *** Relevance to GS = relevance to the prevention and control of FMD mostly (relevance to other animal diseases targeted the strategy may need to be discussed as VS critical competencies may vary (example: in case of zoonotic TADs, VPH-related CCs may be needed).
-  Indicates the PCP stage when +++ capacity are needed (for the first time); this helps defining the appropriate timing for VS capacity building



Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
General management of VS								
MVS1	I.2.A. Professional competencies of veterinarians	The capability of the VS to efficiently carry out their veterinary and technical functions; measured by the qualifications of their personnel in veterinary and technical positions	Y	 +++	+++	+++	+++	Specific in PCP 1 (epid: risk analysis); general in other PCP stages
MVS2	I.2.B. Competencies of veterinary para-professionals		Y	+	 +++	+++	++	Paravets, less mobilised/involved in epidemio / risk analysis / strategy formulation

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
MVS3	I.3. Continuing education	The capability of the VS to maintain and improve the competence of their personnel in terms of relevant information and understanding; measured in terms of the implementation of a relevant training programme	Y	+++	+++	+++	+++	Specific in PCP 1 (epid: risk analysis); general in other PCP stages
MVS4	I.4. Technical independence	The capability of the VS to carry out their duties with autonomy and free from commercial, financial, hierarchical and political influences that may affect technical decisions in a manner contrary to the provisions of the OIE (and of the WTO SPS Agreement where applicable)	N					This is most important for trading partners, less for a national control programme
MVS5	I.5. Stability of structures and sustainability of policies	The capability of the VS structure and/or leadership to implement and sustain policies over time	N					National activities are well defined through the FMD PCP + regional momentum (Global Strategy); little subject to policy fluctuation
MVS6	I.6.A. Internal coordination (chain of command)	The capability of the VS to coordinate its resources and activities (public and private sectors) with a clear chain of command, from the central level (the Chief Veterinary Officer), to the field level of the VS in order to implement all national activities relevant for OIE <i>Codes</i> (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programs)	Y	0	+	+++	+++	Of most importance in emergency situation, when outbreaks are episodic and in crisis situations (outbreaks). Less needed when situation is enzootic

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
MVS7	I.6.B. External coordination	The capability of the VS to coordinate its resources and activities (public and private sectors) at all levels with other relevant authorities as appropriate, in order to implement all national activities relevant for OIE Codes (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programs). Relevant authorities include other ministries and competent authorities, national agencies and decentralised institutions	Y	+++	++	+++	+++	Usually very important when intersectoral AH-HH collaboration is needed (zoonoses prevention and control). In case of FMD, it is very much needed to understand 'livestock chain profiles' at PCP stage 1, to receive support from hunters (epidemiology in wildlife) or support from police / local authorities / etc. for outbreak management measures
MVS8	I.11. Management of resources and operations	The capability of the VS to document and manage their resources and operations in order to analyse, plan and improve both efficiency and effectiveness	Y	+	++	+++	+++	Needed to manage operations and analyse the efficiency of measures put in place
MVS9	II.3. Risk analysis	The authority and capability of the VS to base its risk management decisions on a scientific assessment of the risks	Y	+++	++	++	++	Crucial in the early stage of the PCP to design a robust risk-based control strategy
MVS10	II.11. Emerging issues	The authority and capability of the VS to identify in advance, and take appropriate action in response to likely emerging issues under their mandate relating to the sanitary status of the country, public health, the environment, or trade in animals and animal products	Y	+	++	+++	+++	In this case, emerging issue may be the apparition of a new strain of FMDV (example SATII in Egypt)
MVS11	II.12. Technical innovation	The capability of the VS to keep up-to-date with the latest scientific advances and to comply with the standards of the OIE (and Codex Alimentarius Commission where applicable)	N					Not needed

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
MVS12	III.1. Communications	The capability of the VS to keep stakeholders informed, in a transparent, effective and timely manner, of VS activities and programmes, and of developments in animal health and food safety	Y	+	+++	+++	+++	Important as early as PCP stage 1 to inform all stakeholders what is at stake and engage them firmly into the PCP. In later stages, it is crucial to inform them on objectives to reach and subsequent control measures to implement
MVS13	III.2. Consultation with stakeholders	The capability of the VS to consult effectively with stakeholders on VS activities and programmes, and on developments in animal health and food safety	Y	+++	+++	+++	+++	Very important to consult stakeholders when (i) control plans are formulated (end of PCP1 and 2) and (ii) when large scale control measures to put in place (stages 2 and 3)
MVS14	III.3. Official representation	The capability of the VS to regularly and actively participate in, coordinate and provide follow up on relevant meetings of regional and international organisations including the OIE (and Codex Alimentarius Commission and WTO SPS Committee where applicable)	Y	++	+++	+++	+++	Notably, most needed for countries to participate in regional FMD roadmap meetings (and also to participate in the Bangkok conference, June 2012, to commit efforts against FMD (and other TADs)
MVS15	III.4. Accreditation / authorisation / delegation	The authority and capability of the public sector of the VS to accredit / authorise / delegate the private sector (e.g. private veterinarians and laboratories), to carry out official tasks on its behalf	Y	0	++	+++	++	Human resources most needed when large scale control measures are put in place. Delegation of public tasks to private vets is proved to be cost effective compared to recruitment of civil servants
MVS16	III.5.A. Veterinary Statutory Body authority	The VSB is an autonomous authority responsible for the regulation of the veterinarians and veterinary para-professionals. Its role is defined in the <i>Terrestrial Code</i>	Y	0	++	+++	++	Closely linked to CCI.2. A/B (competencies of vets and paravets) as the VSB must ensure that minimum standards for vet education are in place and to CCIII.4 to make sure that all vets / paravets are registered / licenced

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
MVS17	III.5.B. Veterinary Statutory Body capacity	The capacity of the VSB to implement its functions and objectives in conformity with OIE standards	Y	0	++	+++	++	
MVS18	III.6. Participation of producers and stakeholders in joint programs	The capability of the VS and stakeholders to formulate and implement joint programmes in regard to animal health and food safety	Y	++	+++	+++	++	As for CC CC III.2, crucial in the formulation and implementation of the control measures
MVS19	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 warranty 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)	Y	+++	++	++	++	The legal and regulatory framework should be prepared in Stage 1 so that it is ready in Stages 2 and 3 when most needed. In stages 2 and beyond, regulation preparation is still needed as control measures evolved with the epidemiological situation, and reg. adjustments may be required overtime
MSV20	IV.2. Implementation of legislation & stakeholder compliance	The authority and capability of the VS to ensure that stakeholders are in compliance with legislation and regulations under the VS mandate	Y	0	+++	+++	++	Crucial in stage 2 and 3 to allow/facilitate the implementation of control measures
MSV21	IV.3. International harmonisation	The authority and capability of the VS to be active in the international harmonisation of regulations and <i>sanitary measures</i> and to ensure that the national legislation and regulations under their mandate take account of relevant international standards, as appropriate	N ???					Not needed as the national prevention and control strategy directly derives from the FAO/OIE Global Strategy for FMD, which is based on the relevant OIE chapters of the TAHC (Chapters 1.6 and 8.5)

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
Animal health								
AH1	II.5.A. Passive epidemiological surveillance	The authority and capability of the VS to determine, verify and report on the sanitary status of the animal populations under their mandate	Y	+	+++	+++	+++	Essential to monitor the circulating strains as well as the efficiency of control measures put in place (Stage 2, 3 and 4)
AH2	II.5.B. Active epidemiological surveillance		Y	+++	+	+++	+++	Essential to understand / assess the situation in PCP stage 1. It is also needed to verify efficiency of measures in place or investigate outbreaks (complementary to passive surveillance activities) once detected
AH3	II.6. Early detection and emergency response	The authority and capability of the VS to detect and respond rapidly to a sanitary emergency (such as a significant disease outbreak or food safety emergency)	Y	0	+	+++	+++	Most needed when the situation is under control, to manage episodic outbreaks
AH4	II.7. Disease prevention, control and eradication	The authority and capability of the VS to actively perform actions to prevent, control or eradicate OIE listed diseases and/or to demonstrate that the country or a zone are free of relevant diseases	Y	+	++	+++	+++	Most needed in Stage 3 when an aggressive control programme is put in place or for countries that wish to embark for an official free status recognition
AH5	II.14. Animal welfare	The authority and capability of the VS to implement the animal welfare standards of the OIE as published in the <i>Terrestrial Code</i>	N					Not needed – except in culling of animals for control purposes (Not a priority here)

Table I (cont.)

Critical competencies	Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments	
			1	2	3	4		
Veterinary Public Health								
VPH1	II.8.A. Ante and post mortem inspection	The authority and capability of the VS to implement and manage the inspection of animals destined for slaughter at abattoirs and associated premises, including for assuring meat hygiene and for the collection of information relevant to livestock diseases and zoonoses. This competency also covers coordination with other authorities where there is shared responsibility for the functions	Y	+	++	+++	+++	FMD is not a food-borne zoonosis. However, slaughter places are crucial for passive surveillance
VPH2	II.8.B. Inspection of collection, processing and distribution	The authority and capability of the VS to implement, manage and coordinate food safety measures on collection, processing and distribution of products of animals, including programmes for the prevention of specific foodborne zoonoses and general food safety programmes. This competency also covers coordination with other authorities where there is shared responsibility for the functions	N					Not relevant to FMD prevention and control activities
VPH3	II.9. Veterinary medicines and biological	The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, i.e. the authorisation, registration, import, production, labelling, distribution, sale and use of these products	N					
VPH4	II.10. Residue testing	The capability of the VS to undertake residue testing programmes for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, metals, etc.	N					

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
Laboratory capacity								
Lab1	II.1. Veterinary laboratory diagnosis	The authority and capability of the VS to identify and record pathogenic agents, including those relevant for public health, that can adversely affect animals and animal products	Y	++	+++	+++	+++	Essential at all stages of the PCP, for disease / infection / virus / strain identification but also monitoring of the efficiency of the vaccination strategy (PCP 2 stage and beyond)
Lab2	II.2. Laboratory quality assurance	The quality of laboratories (that conduct diagnostic testing or analysis for chemical residues, antimicrobial residues, toxins, or tests for, biological efficacy, etc.) as measured by the use of formal QA systems and participation in relevant proficiency testing programmes	Y	++	+++	+++	+++	This CC is relevant only for countries which use national labs to do FMD diagnostic tests, not for countries which outsource them to regional or international reference labs
Trade								
Trade 1	II.4. Quarantine and border security	The authority and capability of the VS to prevent the entry and spread of diseases and other hazards of animals and animal products	Y	0	+	+++	+++	Border post measures are mostly needed when situation in controlled in the country (to avoid new introduction and spread of FMDV)
Trade 2	II.13.A. Animal identification and movement control	The authority and capability of the VS, normally in coordination with stakeholders, to identify animals under their mandate and trace their history, location and distribution for the purpose of animal disease control, food safety, or trade or any other legal requirements under the VS/OIE mandate	Y	0	+	+++	+++	(idem above/movement control)
Trade 3	II.13.B. Identification and traceability of products of animal origin	The authority and capability of the VS, normally in coordination with stakeholders, to identify and trace products of animal origin for the purpose of food safety, animal health or trade	N					Not relevant to FMD prevention and control activities

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
Trade 4	IV.4. International certification	The authority and capability of the VS to certify animals, animal products, services and processes under their mandate, in accordance with the national legislation and regulations, and international standards	N					Not relevant to FMD prevention and control activities (this may be useful to avoid FMD introduction to other trading countries but not to prevent/control FMD in national territory)
Trade 5	IV.5. Equivalence and other types of sanitary agreements	The authority and capability of the VS to negotiate, implement and maintain equivalence and other types of sanitary agreements with trading partners	N					Not relevant to FMD prevention and control activities
Trade 6	IV.6. Transparency	The authority and capability of the VS to notify the OIE of their sanitary status and other relevant matters (and to notify the WTO SPS Committee where applicable), in accordance with established procedures	Y	+	+++	+++	+++	Important in a regional coordinated control effort (to alert neighbours). In 6-monthly reports in PCP stages 2 (when the situation is known) to 3; as immediate notification in stage 4 and above
Trade 7	IV.7. Zoning	The authority and capability of the VS to establish and maintain disease free zones, as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable)	Y	+	++	+++	+++	This CC is relevant only for countries which have decided to put in place a zoning strategy, either for trade purposes or as a mean to start controlling the disease in a specific area, to further expand it. If applied, should be efficient as soon as PCP stage 2, and optimal in Stage 4
Trade 8	IV.8. Compartmentalisation	The authority and capability of the VS to establish and maintain disease free <i>compartments</i> as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable)	N (Not yet)					Never tested for FMD so far

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				Comments
				1	2	3	4	
Resources								
	I.1.A. Veterinarians and other professionals	The appropriate staffing of the VS to allow for veterinary and technical functions to be undertaken efficiently and effectively	Y	++	+++	+++	+++	Need at all stages of the PCP, in stage 1 to assess the situation (active surveillance) and stages 2 and beyond, to implement control measures (mass vaccination in particular)
	I.1.B. Veterinary para-professionals and other technical staff		Y	++	+++	+++	+++	Most need to implement control measures (mass vaccination in particular)
	I.7. Physical resources	The access of the VS to relevant physical resources including buildings, transport telecommunications, cold chain, and other relevant equipment (e.g. computers)	Y	++	++	+++	+++	Most need for vaccination activities (cold chain; vehicles), aggressive in stage 3
	I.8. Operational funding	The ability of the VS to access financial resources adequate for their continued operations, independent of political pressure	Y	++	++	+++	++/+++	In PCP stage 1, operational funding is needed to conduct epidemic and risk analysis studies/surveys in the field. Important funding is needed to implement control measures (stage 3 max); in stage 4, funding depends if countries want to go for a free status with (+++) or without (++) vaccination
	I.9. Emergency funding	The capability of the VS to access extraordinary financial resources in order to respond to emergency situations or emerging issues; measured by the ease of which contingency and compensatory funding (i.e. arrangements for compensation of producers in emergency situations) can be made available when required	Y	0	0	+++	+++	Most needed when the enzootic situation is over (stage 3 and above); indispensable in Stage 4 to maintain 'zero tolerance'

Table I (cont.)

Critical competencies		Definition	Relevance to GS (Y/N)	Relevance to PCP stage				
				1	2	3	4	Comments
	I.10. Capital investment	The capability of the VS to access funding for basic and additional investments (material and non-material) that lead to a sustained improvement in the VS operational infrastructure	N?					Considered as non-needed here

Table II. Rationale / Relevance of targeting level 3 (= minimum compliance)

Nota bene:

The objective of this Table is to check whether Level 3 provides enough VS capacity / capability to implement the GS and reach the expected outcomes. In other words, whether +++ = level 3 for each PVS CC

Critical competence	Level 3 of the CC	Comments
General management of VS		
I.2.A. Professional competencies of veterinarians	The veterinarians' practices, knowledge and attitudes usually allow undertaking all professional/technical activities of the VS (e.g. epidemiological surveillance, early warning, public health, etc.)	Level 3 = OK
I.2.B. Competencies of veterinary para-professionals	The training of veterinary para-professionals is of a uniform standard that allows the development of only basic animal health competencies	Level 3 = OK
I.3. Continuing education	The VS have access to CE that is reviewed annually and updated as necessary, but it is implemented only for some categories of the relevant personnel	Level 3 = OK 'only for some categories of the relevant personnel': this needs to be the personnel involved in FMD control activities
I.6.A. Internal coordination (chain of command)	There are internal coordination mechanisms and a clear and effective chain of command for some activities	Level 3 = OK 'for some activities ' need to be those defined in the GS
I.6.B. External coordination	There are formal external coordination mechanisms with clearly described procedures or agreements for <u>some activities and/or sectors</u>	Level 3 = OK 'for some activities' need to include FMD activities
I.11. Management of resources and operations	The VS have comprehensive records, documentation and management systems and they regularly use records and documented procedures in the management of resources and operations, providing for the control of effectiveness and the conduct of analysis and planning	Level 3 = OK
II.3. Risk analysis	The VS can systematically compile and maintain relevant data and carry out risk assessment. Scientific principles and evidence, including risk assessment, generally provide the basis for risk management decisions	Level 3 = OK
III.1. Communications	The VS maintain an official contact point for communications but it is not always up-to-date in providing information	Up-to-date information is needed for the efficiency of the FMD control measures put in place. → Level 4 more appropriate Level 4: The VS contact point for communications provides <u>up-to-date</u> information, accessible via the Internet and other appropriate channels, on activities and programmes
III.2. Consultation with stakeholders	The VS maintain a formal consultation mechanism with stakeholders	Level 3 = OK

Table II (cont.)

Critical competence	Level 3 of the CC	Comments
III.4. Accreditation / authorisation / delegation	The public sector of the VS develops accreditation / authorisation / delegation programmes for certain tasks, but these are not routinely reviewed	For the efficiency of measures put in place, it is important that the work of the private Vets and/or private organisations that have received delegation is constantly monitored and reviewed. → Level 4 more appropriate Level 4: The public sector of the VS develops and implements accreditation / authorisation / delegation programmes, and these are routinely reviewed
III.5.A. Veterinary Statutory Body authority	The VSB regulates <i>veterinarians</i> in all relevant sectors of the veterinary profession and applies disciplinary measures	Only Veterinarians are regulated, not paravets → Level 4 more appropriate Level 4: The VSB regulates functions and competencies of veterinarians in all relevant sectors and <i>veterinary para-professionals</i> according to needs
III.5.B. Veterinary Statutory Body capacity	The VSB is an independent representative organisation with the functional capacity to implement all of its objectives	Level 3 = OK
III.6. Participation of producers and stakeholders in joint programs	Producers and other stakeholders are trained to participate in programmes and advise of needed improvements, and participate in early detection of diseases	Level 3 = OK Participation of producers in ED is crucial to the success of FMD prevention and control measures
IV.1. Preparation of legislation and regulations	The VS have the authority and the capability to participate in the preparation of national legislation and regulations with adequate internal and external quality <u>in some fields of activity</u> , but lack formal methodology to develop adequate national legislation and regulations regularly in all domains	Level 3 = OK 'in some fields of activities' need to be those related to FMD (and other TADs) prevention and control activities
IV.2. Implementation of legislation & stakeholder compliance	Veterinary legislation is generally implemented. As required, the VS have a power to take legal action / to prosecute in instances of non-compliance in most relevant fields of activity	Level 3 = OK
Animal health		
II.5.A. Passive epidemiological surveillance	The VS conduct passive surveillance in compliance with OIE standards for <u>some relevant diseases</u> at the national level through appropriate networks in the field, whereby samples from suspect cases are collected and sent for laboratory diagnosis with evidence of correct results obtained. The VS have a basic national disease reporting system	Level 3 = OK 'for some relevant diseases', including FMD!
II.5.B. Active epidemiological surveillance	The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases and apply it to all susceptible populations but do not update it regularly	In Stage PCP 4, up to date information/data is needed → Level 4 more appropriate Level 4: The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases, apply it to all susceptible populations, update it regularly and report the results systematically

Table II (cont.)

Critical competence	Level 3 of the CC	Comments
II.6. Early detection and emergency response	The VS have the legal framework and financial support to respond rapidly to sanitary emergencies, <u>but the response is not coordinated through a chain of command</u>	Level 3 is OK if CCI.6.A (level 3) is in place
II.7. Disease prevention, control and eradication	The VS implement prevention, control and eradication programmes for some diseases and/or in some areas with scientific evaluation of their efficacy and efficiency	Level 3 = OK 'for some diseases', including FMD
Laboratory		
II.1. Veterinary laboratory diagnosis	For <u>other zoonoses and diseases present in the country</u> , the VS have access to and use a laboratory to obtain a correct diagnosis	→ Level 2 may be enough in this case Level 2: For major <u>zoonoses and diseases</u> of national economic importance, the VS have access to and use a laboratory to obtain a correct diagnosis
Trade		
II.4. Quarantine and border security	The VS can establish and apply quarantine and border security procedures based on international standards, but the procedures do not systematically address illegal activities relating to the import of animals and animal products	Illegal activities should be addressed in PCP Stage 4 at least. → Level 4 more appropriate? (risk analysis may demonstrate that illegal trade is a factor of risk +++) Level 4: The VS can establish and apply quarantine and border security procedures which systematically address legal pathways and illegal activities
II.13.A. Animal identification and movement control	The VS implement procedures for animal identification and movement control for specific animal sub-populations as required for disease control, in accordance with relevant international standards	Level 3 = OK
IV.6. Transparency	The VS notify in compliance with the procedures established by these organisations	Level 3 = OK (in this case, reporting to the OIE via WAHID)
IV.7. Zoning	The VS have implemented biosecurity measures that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary	Level 3 = OK
Resources		
I.1.A. Staffing: Veterinarians and other professionals	The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at local (field) levels	Level 3 = OK
I.1.B. Staffing: Veterinary para-professionals and other technical staff	The majority of technical positions at local (field) levels are occupied by personnel holding technical qualifications	Level 3 = OK
I.7. Physical resources	The VS have suitable physical resources at national, regional and some local levels and maintenance and replacement of obsolete items occurs only occasionally	Level 3 = OK

Table II (cont.)

Critical competence	Level 3 of the CC	Comments
I.8. Operational funding	Funding for the VS is clearly defined and regular, and is adequate for their base operations, <u>but there is no provision for new or expanded operations</u>	FMD may 'new' and 'expanded' in most of countries/ → Level 4 more appropriate (this clearly depends on available external support from donors) Level 4: Funding for new or expanded operations is on a case-by-case basis, <u>not always based on risk analysis and/or cost benefit analysis.</u> In this case, elements of c/b analysis will be provided in the GS. → To target level 5?
I.9. Emergency funding	Contingency and compensatory funding arrangements with limited resources have been established; additional resources for emergencies may be approved but approval is through a political process	In PCP stage 3 and 4, compensation should be put in place to stimulate early reporting. Substantial funding resources may be needed to do so. → Level 4 more appropriate (this clearly depends on available external support from donors) Level 4: Contingency and compensatory funding arrangements with adequate resources have been established, but in an emergency situation, their <u>operation must be agreed through a non-political process on a case-by-case basis.</u> → To target level 5

Part A

Annex 4: Tools to be used for implementing the Component 3. Prevention and control of other major diseases of livestock

PCP

Implementing the Progressive Control Pathway for FMD (FMD-PCP) will result in the development of skills and capacities in both the public and private sectors that could be adapted and applied in the control of other Transboundary Animal Diseases (TADs) and in finding useful combinations of activities.

PVS Pathway

The PVS Pathway has already been described. It will be used to monitor and guide the achievement of Component 2, but it is also useful as a fundamental tool for implementing the FMD Control Strategy (Component1) and for the control of other TADs (Output 3).

World Organisation for Animal Health (OIE) standards, guidelines and recommendations for other TADs than FMD

OIE standards will contribute significantly to the control and management of TADs in general through the strengthening of the animal health systems and by improving public-private partnerships, and investments in the VS. All relevant OIE standards are published in the disease specific chapters and articles of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* and OIE *Manual of Diagnostic Test and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

Disease-specific diagnostic laboratories, Reference centres, Regional and international networks

In Part A, Annex 2 the essential role foreseen for RCs, RLLs and OIE-Food and Agriculture Organization of the United Nations (FAO) regional and international networks in the implementation of the Global FMD Control Strategy was described. It is anticipated that these networks will link with the World Health Organization (WHO) networks working on zoonotic disease outbreaks in humans in order to strengthen and improve the effectiveness of VS and the control of zoonotic TADs.

Similar laboratory support mechanisms described for the control of FMD are also vital for the prevention and control of other major animal diseases. OIE and FAO reference laboratories/centers already exist for many diseases. Depending on the need, additional disease-specific joint OIE/FAO international laboratory networks will have to be set up as was done for example in the case of influenza: the OIE-FAO network on Animal Influenza (OFFLU: OIE FAO Flu).

The establishment of regional and international OIE-FAO networks is one of the key objectives and expected results to improve the effectiveness of Veterinary Services and to achieve a more effective control of major diseases (Components 2 and 3 of the Global Strategy).

Vaccines and vaccination

Many different vaccines against infectious diseases other than FMD exist. Although they are commercially available in many countries, this is not the case in each country. In addition to the availability issue, quality control is a major concern in many countries.

The OIE *Terrestrial Manual* provides the minimum quality standards applicable to veterinary vaccines. The *Terrestrial Code* presents a number of conditions under which the vaccination programmes have to be implemented. The *Code* also provides guidance on how vaccination is to be considered with regard to trade of animals and animal products.

The issue of availability and quality of the entire vaccination chain (independent quality control centres, transport of the vaccines from producing companies to the field, vaccine banks, cold chain, field operations and delivery systems, monitoring and control of vaccination programmes results) has to be addressed more in depth in the future and such activities will benefit from the experience gained with FMD control under the Global Strategy.

Surveillance and epidemiology: national, regional and international Collaborating Centres and networks

National epidemiology centres and epidemiosurveillance systems, regional and international Collaborating Centres on epidemiology and regional and international networks are indispensable for effective surveillance, early detection and early warning, irrespective of the TAD a country is dealing with. The same methods as described for FMD can be utilised for surveillance: passive or active, disease specific or syndromic, comprehensive or targeted risk-based, classic (veterinary professionals) or participatory (livestock keepers). As in the case of the laboratories, regional networks of epidemiologists are needed, coordinated and supported by a recognised regional centre which can ideally be an OIE/FAO Epidemiology Collaborating Centre. An international network of the Collaborating Centres also has to be available.

Close interactions between laboratory and epidemiology experts are necessary at the national, regional and international levels.

At the international level, the FAO/OIE (and WHO for zoonotic disease outbreaks in humans) Global Early Warning System (GLEWS) has already been mentioned. It plays a role in early warning for FMD but obviously also for other major diseases.

Data bases organised at national, regional and international level will be needed to support risk analysis/risk evaluation studies to help designing policies for animal disease prevention and control.

Part A

Annex 5: Building experience: lessons that can be learned from regional foot and mouth disease control programmes

In developing the Global foot and mouth disease (FMD) control strategy, the impressive progress that has been made with FMD control in some parts of the world has been fully taken into account and attempts have been made to use the experience gained and the lessons learned. At the same time it is realised that the conditions for FMD control in different parts of the world may be quite different and therefore tailor-made solutions may be necessary.

In this Annex short descriptions are given of successful and ongoing FMD campaigns.

In Europe the endemic virus pool was significantly reduced when annual mass vaccination of cattle was introduced on the continent (vaccination was never used in the British Isles). This was during the mid-1950s and resulted in an immediate reduction in the incidence of disease. Within around 20 years the annual incidence had been reduced from several hundred thousand outbreaks per year to a one to two thousand per year. Despite vaccination, there were still some severe epidemics e.g. in 1964-1965 and 1967-1968. Over this period the control measures employed by different countries in the event of outbreaks varied considerably. Some countries used 'stamping out' without vaccination whereas others used total or partial 'stamping out' with vaccination. However, from the mid-1980's, the European Commission (EC) insisted on a harmonisation of the procedures in European Union (EU) member states and this greatly improved the disease situation. In the late 1980s the EC debated with member states whether to introduce a pan-vaccination or non-vaccination policy. The decision was taken in 1990 that vaccination in the EU should cease from 1st January 1991. This decision prompted non-EU countries, in particular those in the former Eastern Bloc, to follow suit until and so by the early 1990s a non-vaccination policy was in operation throughout the European region. Since that time, with the exception of year 2001, when there was a large epidemic in the United Kingdom (UK), Europe has suffered very few outbreaks and has essentially remained FMD-free without vaccination. Among other organisations which have contributed to the eradication of FMD from Europe, the EufMD in particular played a major role, a.o. in the establishment and administration, with European Union financial support, of a Buffer Vaccination Zone in South Eastern Europe to prevent the entry of exotic strains from the Middle East.

The main lessons from the European campaign are clear, namely that effective control of FMD requires a regional or sub-regional approach and the harmonisation of surveillance systems, control measures, policies and legal frameworks. Furthermore, intensive and sustained prophylactic vaccination of cattle, using independent quality controlled vaccines compliant with the World Organisation for Animal Health (OIE) standards, such as in Europe before early 1990s, can reduce drastically the virus circulation and come to the point when eradication becomes possible. The European experience also demonstrates that regional approaches are indispensable with harmonisation of control measures, policies and legal frameworks and transparency of information.

In South-East Asia, the OIE and the member countries of ASEAN have, since the end of the 1990s, developed a programme for the progressive control of FMD within the region, called SEAFMD. Coordination plays an important part and all aspects of the programme are continuously monitored and evaluated. A programme aimed at achieving FMD freedom with vaccination by 2020 has been developed and adopted (SEAFMD 2020 Road Map) and it receives support from the OIE, Food and Agriculture Organization of the United Nations (FAO), ASEAN and all its member countries as well as numerous donors (Australia, Japan, Asian Development Bank, the European Union and some other European countries).

Positive results have been obtained, such as OIE recognition of countries, or zones within countries, as being FMD free, either with or without vaccination (Indonesia, Brunei, Philippines, and Malaysia). The programme includes the establishment of buffer zones between infected zones and of priority control zones such as those of Myanmar, the Lower Mekong, the Red River Delta and the Upper Mekong. In 2010 the Sub-Commission was joined by Brunei, China (People's Republic of) and Singapore, which brought all member countries of the ASEAN into the SEAFMD. This chronological, sequential approach, based on epidemiological characteristics and benefiting from strong political involvement on the part of ASEAN member countries and sound governance, is a good example of what can be achieved collectively at a regional level for the benefit of each partner country. Numerous reports and publications exist on the implementation of the SEAFMD programme, many of which are available on the dedicated website.

A regional approach to the control of FMD has also been adopted by the Southern African Development Community (SADC) after the drastic increase of FMD outbreaks at the beginning of the 21st century, more specifically in the north of Botswana (the first outbreak in 2002 after 20 years of disease freedom), Namibia's Caprivi Strip, the south of Angola and Zambia and the west of Zimbabwe and Mozambique. The SADC Secretariat pledged funding from the International Community, and received support from South Africa, FAO and the EC in form of projects to harmonise the approach to disease control. In 2011, and with the help of FAO and OIE, 8 SADC Member States without formal OIE recognised FMD status agreed to enter the PCP pathway and committed themselves to FMD control (stage 3 or higher) by 2020.

However, in this region (and in some other parts of Africa) the situation is complicated by the maintenance of the SAT viruses in buffalo (*Syncerus caffer*), as an important natural wildlife reservoir. Furthermore the creation of Transfrontier Conservation Areas (TFCAs), linking already existing national parks and conservation areas, is an important development for the future of the region. It results in very large areas for wildlife conservation with great significance in many respects, also economically. Eco- and ethno-tourism are in certain regions possibly more important and sustainable forms of land use than livestock based agriculture. Unfortunately the classical FMD control procedures can impact negatively on the protection of wildlife populations / habitat connectivity, on wildlife sector activities and on small holder's livestock sector development.

The Global FMD Control Strategy allows for regional fine tuning and regional decisions. It is expected that together with a sensible use and timely acceptance of new technological possibilities and insights this will allow balancing the different interests, more effort being focused on broad-based land-use planning, on the development of regionally appropriate vaccines and on the sensitive alignment or re-alignment of physical barriers (fences).

In North Africa, Morocco, Algeria and Tunisia have submitted their official national control programmes for FMD to the OIE and they were, in May 2012 during the OIE General Session, the first countries to benefit from the new Code article regarding the OIE official endorsement of the control plans.

In West Eurasia, a long term (2020) Roadmap has been developed for 14 countries regularly affected by epizootics within virus pool 3. This regional programme involves Central Asia and Trans Caucasus countries, Iran and Turkey and is implemented by FAO, EuFMD and the European Union, with funding from sources such as Italy, the European Union, the World Bank and the Asian Development Bank. The PCP-FMD has been utilised to develop and monitor progress. The initial results are encouraging, but as many countries are at the start of the PCP, efforts will be required over a long term. One zone (Thrace) has achieved freedom with vaccination in 2010, but new outbreaks in 2011 brought it to be suspended.

Historically, the other outstandingly successful FMD campaign has been that in South America. Among the first steps towards the control of FMD in that region were the establishment of the Pan-American FMD Center (PANAFTOSA) in 1951. PANAFTOSA was established with the aim of promoting, organising, and coordinating programmes for the prevention and control of the disease, providing specialised technical cooperation, serving as a reference centre, and training human resources for the countries of the Americas. The formal development of national FMD control programmes, with the financial support of the Inter-American Development Bank during the second half of the 1960s and 1970s, helped initiate organised action in South America. In the 1980's the World Bank became involved strengthening the financial assistance for programmes, especially in Argentina and Brazil.

In 1972, the South America FMD Control Commission (COSALFA) was established with the objectives of regional coordination, promotion, and evaluation of FMD prevention, control and eradication programmes: harmonisation of sanitary standards, and the promotion, evaluation and auditing of bilateral and multilateral agreements for the control of FMD. The Pan American Health Organisation (PAHO) was charged with promoting and coordinating the Commission and PANAFTOSA as the ex-officio Secretariat.

In 1987 PAHO was requested to prepare a Hemispheric Programme for the Eradication of FMD (PHEFA), including mechanism for its eradication. In 1988, a Continental Plan of Action was approved. It is based on three levels of action: a regional hemispheric plan; sub-regional projects; and the national health programmes particularly directed at the control and eradication of FMD.

As a result of these various actions considerable progress has been made in the control of FMD in South America. At the end of the 1990s, Argentina, Chile, Guyana and Uruguay were officially recognised by the OIE as FMD-free without vaccination. However, FMD reappeared in several Southern Cone countries in 2001 and so generalised vaccination was resumed, coupled with actions such as animal movement controls within and between countries, surveillance and an immediate response to outbreaks, the harmonisation and coordination of programmes and the strengthening of Veterinary Services and cooperation between the public and private sector. The results were very positive and, from 2010, only Venezuela, and Ecuador were still reporting outbreaks. In 2012, Paraguay reported new outbreaks which are currently being combated.

A new programme, PAMA has been signed by the regional body Mercosur and its member countries and associated countries: Argentina, Bolivia, Brazil, Paraguay and Uruguay. PAMA is implemented by the Mercosur Committee, which incorporates the representatives of the Permanent Veterinary Committee of the Southern Cone (CVP). PAMA covers 10 domains including surveillance and risk evaluation at bi- and tri-national borders.

A specific agreement between the OIE and the Mercosur CVP, signed in March 2007, provided for the setting up and monitoring of activities in border zones, known as 'high surveillance zones' (not to be confused with the existing officially recognised FMD free zones) extending approximately 15 km each side of the borders encompassing Argentina, Bolivia, Brazil and Paraguay (depending on the particularities of each zone).

Surveillance operations have been considerably strengthened in these high surveillance zones: active search for evidence of virus circulation, complete identification of animals and farms, strict control on animal movements, harmonisation of vaccination schedules for the various susceptible species and quality of the vaccines used, etc. The OIE appointed experts to carry out initial identification mission in 2006 followed by follow-up missions in the four countries concerned, in 2007 and 2009. In February 2011, in view of the progress made with carrying out activities and the satisfactory results achieved (no outbreaks in the high surveillance zones since the start of the operation), the Scientific Commission reinstated the status of 'FMD free with vaccination' for the high surveillance zones of the four participant countries.

Since 2010 a Regional integrated project for FMD eradication in the Andean Region and Venezuela is being carried out by FAO as regional initiative aiming at improving levels of regional coordination of FMD programmes as well as institutional capacity of national Veterinary Services, strengthening the assessment and risk management for FMD control and eradication and improving awareness levels and animal health communication and advocacy, so as to contribute to the progressive control of FMD reducing the impact on food security of vulnerable families and small farmers.

These various programmes, PHEFA, PAMA, Control of High Surveillance Zones by OIE, and the FAO Regional project for Andean countries show that, despite of recent new outbreak occurrences in one of the free countries, a regional approach, supported by a political and financial commitment on the part of governments and the private sector, can achieve excellent results, using a whole range of already available tools, methods and strategies.

Part A

Annex 6: Vaccines

Overview of vaccine production capacity

It was recommended in the Chapter on foot and mouth disease (FMD) Vaccines that any scaling-up of vaccine to meet the demands of the Global FMD Control Strategy should be left to the private sector. This is because public sector FMD vaccine plants have a poor record of producing potent, safe vaccine. The recommendation can be defended on the grounds that historically a significant number of outbreaks have been attributed to breaches of security at state operated facilities. Furthermore, a major source of outbreaks associated with state operated facilities is believed to have been residual live virus in vaccines which have not been fully inactivated (7). In addition, very few state or para-state vaccine plants comply with internationally accepted norms for quality assurance and so the quality and safety of the vaccines they produce is often suspect.

Therefore, if the production of vaccine is to be scaled-up to meet the requirements of the Global project it is recommended that this is done by the private sector, and, as stated previously, manufacturers will need to be persuaded that it will be in their commercial interests to do this (Note: to be expanded following discussions with representatives from industry).

The countries in some regions, generally those that are FMD-free without vaccination, have collaborated to establish regional vaccines banks. Other countries have made independent arrangements with vaccine producers. Access to vaccine from a bank gives a country the security that in the event of an emergency it should be able to obtain potent and safe vaccine without delay. Historically, vaccine derived from antigen banks e.g. European Union (EU) Vaccine Bank, has been used in non-member countries during emergencies.

Types of foot and mouth disease vaccines

The FMD vaccines may be classified as either 'standard' or 'higher' potency vaccines. Standard potency vaccines are formulated to contain sufficient antigen to ensure that they meet the minimum potency level required. Higher potency vaccines are formulated with an increased amount of antigen such that the potency is in excess of the minimum requirements to provide particular features such as a more rapid onset of immunity and a wider spectrum of immunity against relevant field viruses. Higher potency vaccines are thus well suited for emergency use (15, 16). FMD vaccines can be monovalent or polyvalent in relation to the serotype of antigen.

Currently, a number of commercially manufactured (i.e. standard) vaccines are available of differing strain composition, antigenic content, adjuvant formulation and cost. All are produced using inactivated antigens. Vaccine is available as fully formulated and tested product or, more usually in emergency situations, it can be freshly formulated from concentrated, inactivated antigen(s) stored at low temperature in vaccine banks maintained by commercial manufacturers or by national and international authorities (11, 15, 16).

The types of FMD vaccine available from commercial sources have remained virtually unchanged for several decades and there has been less investment in research and development by manufacturers than was formerly the case. This can be due to several reasons such as the uncertainty on the mid to long term national vaccination policies. FMD vaccine is a high-cost product in particular since it must be produced within biosecure facilities which are expensive to establish and maintain, particularly in developing countries and the private companies need their research and development investments to be guaranteed.

Additionally, the increasing cost of the licensing and registering of new biological products impose a new constraint and consequently to the return of R&D investment.

Foot and mouth disease vaccination strategies

Strategies for the control of FMD implemented by various countries tend to reflect the patterns of disease incidence. Thus, countries free from the disease place reliance on a policy of preventing entry of virus through strict control of the importation of livestock and animal products and, in the event of an outbreak, the imposition of movement controls, slaughter of infected and in-contact animals, carcasses disposal and disinfection. This is the so-called 'stamping out' policy and does not involve vaccination. However, some countries, such as in South America continue to vaccinate after being officially declared free: their World Organisation for Animal Health (OIE) status in that case is 'Free with vaccination'. Other countries free without vaccination include in their national contingency plans the holding of or access to vaccine banks or reserves that could be used in an emergency, should stamping out fail to limit the extent of spread or if vaccination seems likely to provide a more effective solution.

The devastating consequences of some recent epidemics of FMD, in particular the United Kingdom and Dutch epidemics of 2001, have shifted political opinion in favour of the implementation of vaccination in future epidemics and accordingly many veterinary services have modified their national contingency plans to accommodate this possibility.

In countries where the disease is sporadic, the usual practice in the event of outbreaks is to carry out emergency vaccination, stringent zoo-sanitary measures and the slaughter of infected stock. In countries where FMD is endemic, but at a low level of incidence, control programmes based on routine vaccination of cattle have had considerable success. For example, in several countries in South America and some parts of Asia well-planned and sustained vaccination programmes carried out in conjunction with the effective application of zoo-sanitary measures have led to a considerable reduction in the incidence of FMD and in some cases its eradication (3, 4). On the other hand, in endemic regions with a high incidence of FMD, the strategic vaccination of valuable animals e.g. high producing dairy animals, may be the only affordable control measure. In the Middle East, for example, the owners of large, intensive, zero-grazed dairy units can afford to pay for intensive vaccination. Globally, however, the highly endemic regions are those inhabited by the world's poorest livestock owners. These regions include, west, central and east Africa and Asia extending from the Middle East to India and China. In these regions the small livestock holders cannot afford to regularly vaccinate their animals and they, in turn, pose a threat to the relatively few more productive herds that are vaccinated. The governments of the countries across that region either cannot afford to pay for FMD vaccine to give to poor livestock owners or see other priorities for spending their scarce resource. Therefore, the challenge for the Global project will be to find a mechanism to make available sufficient quantities of potent, safe, vaccine to provide levels of immunity in the target populations of poor livestock farmers that will have an impact on disease control. This will be key element for the progressive control of the disease

Several critical factors need to be considered in the planning and design of an FMD vaccination programme if it is to achieve optimal results. These have been listed by Garland and De Clercq (17) and include:

- i) coverage should be at least 80%;
- ii) campaigns should be completed in the shortest possible time;
- iii) vaccination should be scheduled to allow for interference from maternal immunity;
- iv) vaccines should be administered in the correct dose and by the correct route;
- v) the efficacy of vaccination should be monitored; and
- vi) the vaccination regimen should comply with the manufacture's instructions and/or the recommendations of the OIE *Terrestrial Manual* (1).

In regard to vaccination coverage, however, a recent recommendation is that the target should be 100% (2).

Vaccine availability including continuous vaccine matching to field strains and quality assurance

Foot and mouth disease vaccines are expensive to manufacture and so their prices are high. Furthermore, the maintenance of their quality up to the time of their administration

requires an established cold-chain system and this too is costly, especially in tropical regions. In temperate regions measures to prevent the freezing of vaccine in winter will be necessary. The cost of increasing vaccination coverage in regions where the disease is endemic is, therefore, a major constraint, especially for developing countries. There are two possible ways by which this issue could be resolved, either by the development of new and cheaper vaccines or by subsidising the cost of existing ones. A major cost in the production of FMD vaccines is the use of virulent virus in production and the high cost of the necessary biosecure containment facilities. The development of vaccines not requiring the use of virulent virus would greatly reduce that cost (see Research Needs, Part A Annex 7). Alternatively, the cost of vaccine and its delivery could be reduced for developing countries by financial support from philanthropic or other donors, perhaps in a similar manner as has happened with the GAVI Alliance, a global health partnership representing stakeholders in immunisation from both the private and public sectors (18).

For FMD vaccine to be effective the strain or strains in the vaccine must antigenically match those circulating in the field. Although there is evidence that highly potent vaccines can induce cross-protection against heterotypic strains (19) the cost of such vaccines mitigates against their routine use in endemic regions. Effective virus matching requires laboratory investigation of virus isolates at the level of a Regional or the World Reference Laboratory and these activities must be on-going and intensive. Paton et al. (20) reviewed the constraints on current vaccine selection processes and proposed some possible solutions. They conclude that while short-term specific initiatives for targeted collection can provide samples on a periodic basis, a long-term solution requires the development of FMD control measures which must be underpinned by the strengthening of local veterinary services and laboratories, and by demand-driven provision of sufficient amounts of high-quality vaccine. A first step in this direction has been the establishment of a network of OIE and the Food and Agriculture Organization of the United Nations (FAO) reference laboratories which has divided the global pool of FMD viruses into seven regional 'virus pools' on the basis of the similarity of their genetic and antigenic characteristics and analysed which vaccine strains, either internationally available or produced locally, may be suitable. This approach should strengthen collaboration between reference laboratories, identify gaps in information, provide better more targeted, regionalised vaccine recommendations (21) and, in the event of no suitable vaccine, market studies should assist the private sector, or possibly international agencies, to decide on producing tailored vaccines.

It is a sine qua non that FMD vaccine production and vaccines should satisfy internationally accepted standards of quality assurance/quality control (QA/QC). The majority of FMD vaccines used around the world are inactivated vaccines for routine prophylactic or emergency use, generally manufactured according to the methods described in the OIE *Terrestrial Manual* (1) and, for Europe, in the European Pharmacopoeia, and for EU Member States in compliance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products as amended by Directive 2004/28/EC. While FMD vaccine manufacturers in Europe and several other countries meet those standards, this unfortunately is unknown or unlikely in the case of other manufacturers. Part of the problem is the lack of national quality assurance organisations with BioSecurity expertise to inspect and accredit the FMD-vaccine production facilities in many countries. Clearly, this deficiency needs to be addressed by strengthening the veterinary and allied services in those countries.

Large volumes of highly concentrated virulent virus are produced during FMD vaccine production and so it is essential that vaccine plants operate in compliance with strict FMD biosecurity rules (22, 23). Similarly, potency tests (the challenge of immunised animals with live virus for controlling the vaccine quality) should only be performed in regularly controlled biosecure facilities as described in the Council Directive 2003/85/EC on community measures for the control of FMD. Again, while the facilities in Europe and several other countries meet those requirements, those in some other countries do not and therefore they need to be upgraded or cease production. Financial support from the EU and FAO and other funding bodies is being provided but more is required.

QA/QC is essential with regard to vaccine safety and efficacy. In addition, purity is essential for confidence in post-vaccination sero-surveillance programmes performed to verify freedom from infection (5). The establishment and maintenance of QA/QC schemes is costly as it requires investment in human resource, training and equipment. While manufacturers in the private sector are generally prepared to commit the necessary financial resources for those purposes those in the public sector are much less inclined to do this. Therefore, programmes to strengthen veterinary services and the laboratories and facilities under their responsibility should include the introduction and maintenance of QA/QC systems.

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Part A

Annex 7: Research

Laboratory diagnosis – current

In countries normally free from foot and mouth disease (FMD) the veterinary service is most likely to require that samples submitted from suspected index cases are investigated within a designated FMD laboratory using tests that have been validated and so the diagnostic research priorities for those countries are the development of tests that can rapidly and accurately identify animals with FMD at the earliest possible stage of infection. In order to reduce the time from sample collection to testing, pen-side tests have been developed which can be used on or near holdings. In countries normally free from FMD the veterinary service may be willing to accept the use of such devices by trained operators for the investigation of secondary cases but not for index ones. However, in countries where FMD is endemic this discrimination is less likely and pen-side tests are likely to be increasingly used, especially because they are cheap and results can be obtained quickly.

Diagnosis – needs

In developed countries the laboratory tests for FMD are generally of a high standard and reliability. There is increasing reliance on recombinant antigens, monoclonal antibodies and nucleic acid-based approaches since they provide good opportunities for standardising the reagents and procedures. Nevertheless, there is still a need to improve the speed, simplicity, safety and reliability of the tests as well as better validation and more precision in understanding the confidence of test systems (20).

The priority diagnostic needs for highly endemic countries are the availability of cheap, simple, robust systems which can be used on or near holdings e.g. LFDs (2, 3). Research is needed to develop and validate LFDs that can serotype FMD virus and that can detect NSPs. The latter would greatly facilitate sero-surveillance in countries or zones to determine whether virus is circulating in vaccinated herds and flocks.

The use of pen-side diagnostic devices should not, however, preclude the collection and submission of samples to a national or regional laboratory for more detailed investigations such as vaccine matching and genome sequencing for epidemiological purposes.

Power failures are not uncommon in developing countries and so diagnostic tests need to be robust and reagents heat-resistant or available in freeze-dried formulations i.e. not dependent on refrigeration. Research is needed, therefore, on the stabilisation of FMD diagnostic reagents.

Vaccines – current

Currently available, standard inactivated antigen vaccines applied intramuscularly or subcutaneously to individual animals, confer serotype and strain specific protection in 1-2 weeks but fail to induce long-term protective immunity. Among the limitations of this vaccine are potential virus escape from the production facility, short shelf-life of the formulated product, short duration of immunity and requirement of dozens of antigens to match viral antigenic diversity.

Different molecular methods have been used to develop novel candidate vaccines, including subunit and DNA vaccines but so far they have proved less potent than whole, inactivated viral capsids. Adeno-virus vectored vaccines delivering interferons or FMD virus capsid proteins, co-expressed with the viral protease

required for their processing, have been shown to provide rapid-onset protection against FMD in pigs and cattle (21) but very large doses are needed for the latter species. Various expression systems have been used to synthesise empty capsids and different approaches used to deliver the products (18). For example, baculovirus-derived virus-like particles are also highly immunogenic (22) and offer the advantages of safe production and freedom from NSPs making them compatible with a DIVA test.

Other strategies being considered are to explore methods to induce stronger T-cell responses and more efficient sequestration of antigen so as to improve the memory response after vaccination and prolong the duration of protection. This might be achieved by stabilisation of recombinant viral capsids which, in addition to giving a longer-lasting immunity might also improve the thermal stability of the vaccine. Further investigations are recommended of mucosally active vaccines to deliver protection in the oropharyngeal region - the usual portal of entry in ruminants, as well as studies of the viral determinants of cross-reactivity in order to develop vaccines that give cross-serotype or pan-serotype protection (18).

Vaccines – needs

Vaccine quality varies greatly in different parts of the world and too much is of poor quality to maintain a durable immunity. Vaccine is often administered too late and animals are traded (as calves) before they are immune, exposing these animals to infection in transit or markets and spreading infection through trading routes to new regions (23). There is a need, therefore, for the increased availability of vaccine that is potent and safe and contains the strain or strains appropriate for the country or region according to the advice of the WRL for FMD and other World Organisation for Animal Health (OIE) and Food and Agriculture Organization of the United Nations (FAO) reference centre for FMD. Vaccines should also conform to accepted standards of quality (20, 24). The following research topics for vaccines and antivirals are based on those identified during a Gap Analysis Workshop conducted by a group of international researchers on FMD in Buenos Aires in August 2010 (4):

- Achieving the stated objectives if likely to take longer than those stated above
- Investigate and overcome the barriers of serotype and strain-specific limitations to generate vaccines that will cross-protect and/or provide wider antigenic coverage
- Improve current vaccines by increasing antigenic yields, improving the stability of viral antigens and developing those that induce a longer-lasting immunity, thereby reduced vaccination frequency
- Investigate new adjuvants and immune modulators to improve the efficacy and safety of current vaccines
- Perform studies to characterise FMD viral capsid structures such as epitope mapping to better understand the immune responses evoked in animals so as to enhance the design of vaccines
- Develop vaccine formulations and delivery systems to target mucosal immune responses
- Investigate the safety and efficacy of novel attenuated vaccine platforms e.g. leaderless FMD virus
- Develop vaccines that prevent viral persistence in vaccinated animals exposed to infection
- Test Ad5-IFN distribution and expression in cattle after aerosol exposure
- Evaluate the ability of GenVec Ad-type 1 IFN platform to confer rapid onset of protection (18h) against several serotypes and strains.

In addition, research is needed into the efficacy of vaccines in non-domestic ruminants (25). Research should be supported to develop and validate vaccines that do not require the growth of virulent FMD virus. Elimination of the need to use biosecure facilities would greatly reduce the cost of vaccine production.

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Part B

Annex 1: Activities under Component 2, strengthening Veterinary Services, according to the PCP Stages

I) Enabling environment activities to get to Stage 1 of the PCP

Critical competencies and level of progression		Activities to enhance the CC level / VS capacity
I.2.A. Veterinary professional competencies of veterinarians	Level 1 → 3	<ul style="list-style-type: none"> Evaluations of the veterinary facilities Identification of the needs and implementation of education programmes to fill the gaps including support to veterinary faculties
I.6.A. Continuing education	Level 1 → 3	<ul style="list-style-type: none"> Undertake studies to identify the needs and to organise trainings for VS focal points
I.6.B. External coordination	Level 1 → 3	<ul style="list-style-type: none"> Description of procedures or agreements in place for some activities and/or sectors Identify gaps Support establishment or strengthening of these mechanisms (concertation mechanisms with wildlife sector, ecologist specialists in the ministries or national agencies in charge of the environment)
II.3. Risk analysis	Level 1 → 3	<ul style="list-style-type: none"> Risk analysis investigations <p>*For memory: many relevant activities are already attached to Output 1 (FMD) or Output 3 (other TADs) activities</p>
III.1. Communication	Level 1 → 2	<ul style="list-style-type: none"> Establish a communication mechanism even if informal Start preparing communication material <p>*Some activities are already mentioned in Outputs 1 or 2: start establishing a core team of specialists – e.g. VS focal point</p>
III.2. Consultation with stakeholders	Level 1 → 3	<ul style="list-style-type: none"> Assessment, establishment or strengthening of the existing consultation mechanisms and analysis of the relevant legislation <p>*For memory: see CC IV.1 and outputs 1 or 3 if its regards to FMD or a specific diseases and output 2/CC III.2 if it is a generic issue</p>
III.3. Official representation	Level 1 → 2	<ul style="list-style-type: none"> Actively participate in some relevant meetings of regional and international organisations including the OIE, Global GF TADs meetings (and Codex Alimentarius Commission and WTO SPS Committee where applicable, making a limited contribution) <p>*For memory: see regional and international activities, for example Output 1 for regional PCP FMD Road Maps, Output 3 for Regional OIE Commission meetings and Regional GF TADs meetings</p>
III.6. Participation of producers and stakeholders in joint programmes	Level 1 → 2	<p>*Assess the concertation mechanisms (see CC III.2) and the communication activities (see III.1). If it relates to a specific disease, see Output 1 or 3</p>

I) Enabling environment activities to get to Stage 1 of the PCP (cont.)

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
IV.1. Preparation of legislation and regulations	Level 1 → 3	<ul style="list-style-type: none"> Assessment of the legislation through PVS Legislation missions and revision of the legislation is appropriate. If it is a legislation issue specific to FMD or other TAD, see Output 1 or 3 *Establishment of a legislation core team (vs. focal point) (see CC I.1.A staffing and I.7/I.8 resources)
II.5.B. Active surveillance	Level 1 → 3	<ul style="list-style-type: none"> Establish and strengthen a core team of epidemiologist (see I.1.A) with physical and operational funding attached to I.7 and I.8. Training and education are attached to I.2.A and I.3.
II.5.A. Passive epidemiological surveillance	Level 0 → 1	<p>There is less focus on passive surveillance during the PCP stage 1 than Stage 2. The activities for passive surveillance are on the establishment, strengthening and maintenance of a field network of veterinary posts, private veterinarians (with a delegation of authority from the Official Public VS, paraveterinarians (under veterinarian umbrella/responsibility). The appropriate activities are attached to the relevant CCs on staffing (I.1.A and B), professional competencies (I.2.A and I.2.B), education (I.3) communication (II.1), external coordination (I.6.B), resources (I.7 and I.8)</p>
II.1. Veterinary laboratory diagnosis	Level 1 → 2	<ul style="list-style-type: none"> Assessment of veterinary capacities and strengthening of basic diagnosis capacities *The support to laboratories can be directly attached to national activities with bilateral support from a reference laboratory (programme of the OIE, FAO, AIEA or other agencies). It is also to be considered within the networking regional activities (see paragraph 3.7.2. or regional activities of the Output 1 (FMD) or 3 (other TADs)
II.2. Laboratory quality assurance	Level 1 → 2	<ul style="list-style-type: none"> Assessment of the needs Support data collection and management *Some of the quality assurance activities can also be attached to the previous CC II.1 or to the Output 1 if it specifically relates to FMD
IV.6. Transparency	Level 1 → 2	Training of VS focal points: see CC I.1.A, I.2.A and I.3: workshops...
I.1.A. Staffing of veterinarians and other professionals	Level 1 → 2	<ul style="list-style-type: none"> Ensure staffing for core teams of professionals in the fields of risk analysis, communication, legislation, active surveillance, transparency *Regarding physical resources and operational funds see CC I.7. and I.8.
I.1.B. Staffing of veterinary paraprofessionals and other technical staff security	Level 1 → 2	<ul style="list-style-type: none"> Ensure staffing for core teams of professionals in the fields of risk analysis, communication, legislation, active surveillance, transparency *Regarding physical resources and operational funds see CC I.7. and I.8.
I.7. Physical resources	Level 1 → 2	*No activities per se but provision of funds to establish and support the activities mentioned before

II) Enabling environment activities to get to Stage 2 of the PCP

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
I.2.B. Competencies of veterinary para-professionals	Level 1 → 3	<ul style="list-style-type: none"> Assess the veterinary para-professional training institutions Support improvement of the capacity of this training institution to meet the country needs Demographic survey, including an assessment of the practice, knowledge and attitude of each category of veterinary para-professionals
I.6.A. Internal coordination (chain of command)	Level 1 → 3	<ul style="list-style-type: none"> Assess the activities carried out under the responsibility of the official veterinary services For each activity (i.e. quarantine, food safety, animal health, etc.), identify the legislative framework and procedures put in place
I.11. Management of resources and operations	Level 2 → 3	<ul style="list-style-type: none"> Census of the resources available for the VS, of stakeholders and animals (update) Determine clear procedures for the analysis Support to increase the range of data captured in the national database for animal and veterinary public health programmes Analyse these data to evaluate the programmes and allocate the needed resources
II.11. Emerging issues	Level 1 → 2	<ul style="list-style-type: none"> Assessment of the census of the human resources available (for memory CC I.11) Establish internet connection at least at central level to follow-up information regarding emerging issue in the region and to be interconnected with the regional epidemiosurveillance networks
III.1. Communication	Level 2 → 3	<ul style="list-style-type: none"> Preparation of communication material <p>*Some activities are already mentioned in Outputs 1 or 2: establishment of a core team of specialists – e.g. VS focal point: see CC I.1.A on staffing and CC I.7/I.8 on resources- and appropriate training and education: see CC I.2.A and I.3.</p>
III.3. Official representation	Level 2 → 3	<ul style="list-style-type: none"> Review the documents to be discussed during the various meetings Organise working groups with representatives of the various departments involved at national Continue the activities the activities mentioned for PCP stage 0 to 1 (CC had to reach the level 2 only) like participation to regional and international. (for memory: when it comes activities related to the FMD Roadmap, see Output 1)
III.4. Accreditation / authorisation / delegation	Level 1 → 2	<ul style="list-style-type: none"> Identify the activities for which accreditation / authorisation / delegation could be needed Endorse the necessary legislation
III.5.A. Veterinary Statutory Body authority	Level 1 → 2	<ul style="list-style-type: none"> Establish a VSB in compliance with international standards (membership representation, autonomy, transparency, etc.) and based on a legislative framework Prepare a code of ethic for the veterinary professions Prepare the procedures for the registration of the professionals
III.5.B. Veterinary Statutory Body capacity	Level 1 → 2	<ul style="list-style-type: none"> Ensure that VSB resources are sufficient to implement its main objectives
III.6. Participation of producers and stakeholders in joint programmes	Level 2 → 3	<ul style="list-style-type: none"> Set up the legislative framework and the procedures to implement joint programmes (For memory: joint programmes implemented for FMD control, see Output 1 and for the control of other TADs, see Output 3)

II) Enabling environment activities to get to Stage 2 of the PCP (cont.)

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
IV.2. Implementation of legislation & stakeholder compliance	Level 1 → 3	<ul style="list-style-type: none"> • Support (needed resources) to carry out inspections • Establish the legal framework giving authority to the inspectors to report non compliance • To follow-up the inspections that highlighted non-compliance with the national legislation, including the initiation of prosecution
II.5.A. Passive epidemiological surveillance	Level 2 → 3	<ul style="list-style-type: none"> • Assessment of the efficiency of the field veterinary network (professionalism, accessibility, reporting) (For memory: organise communication campaign towards stakeholders involved in passive surveillance programmes, see communication III.1.) For memory: passive surveillance programmes implemented for FMD, see Output 1 and for other TADs, see Output 3
II.7. Disease prevention, control and eradication	Level 1 → 2	<ul style="list-style-type: none"> • Establish the legislative framework defining the diseases to be targeted for control programmes • Ensure the appropriate supply in vaccines (quality and quantity), including the cold chain (For memory: support vaccination campaigns implemented for FMD, see Output 1 and for other TADs, see Output 3)
II.8. Ante and post mortem inspections	Level 1 → 2	<ul style="list-style-type: none"> • Assess the conformity of export slaughterhouse facilities with international standards (mostly physical resources) and of the inspection (mostly human resources) (For memory: to ensure that export slaughterhouses meet the necessary conditions to prevent FMD spread, see Output 1 and other TADs spread, see Output 3)
II.1. Veterinary laboratory diagnosis	Level 2 → 2/3	(For memory : see Output 1 [FMD] and 3 [other TADs])
II.2. Quality assurance	Level 2 → 3	• Same activities than for PCP 0 → 1 but here all laboratories in a country will benefit from these activities
II.4. Quarantine and border security	Level 1 → 2	<ul style="list-style-type: none"> • Describe the Border and Inspection Post (BIP) network (activity, resources, etc.) • Establish a data bank to keep records of the consignment inspected in each BIP • Establish the legislative framework defining what has to be checked on each category of product when entering the national territory
II.13.A. Animal identification and movement control	Level 1 → 2	<ul style="list-style-type: none"> • Design a national identification system based on the objectives of the Veterinary Authority • Start to identify some animals
IV.6. Transparency	Level 2 → 3	<ul style="list-style-type: none"> • To notify to the OIE all animal health events (For memory: to have an efficient field veterinary network ensuring an appropriate flow of information from the field to the central level, see II.5.A)
IV.7. Zoning	Level 1 → 2	<ul style="list-style-type: none"> • Design the legislative framework suitable for zoning (For memory: animal identification [see II.13A], laboratory [see II.1], FMD zones [see Output 1], other TADs [see Output 3])

I) Enabling environment activities to get to Stage 2 of the PCP (cont.)

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
I.1.A. Veterinarians and other professionals	Level 2 → 3	<ul style="list-style-type: none"> To ensure that job descriptions for these positions corresponds to the degree of the person in charge of implementing the corresponding activities (For memory: list all professionals involved in the implementation of activities of the veterinary domain, see I.11.)
I.1.B. Veterinary para-professionals and other technical staff	Level 2 → 3	
I.8. Operational funding	Level 1 → 2/3	<ul style="list-style-type: none"> Analyse the financial resources of the VS in order to evaluate its adequacy with the activities foreseen (For memory: operational funding for FMD activities, see Output 1 and for TADs activities, see Output 3)

III) Enabling environment activities to get to Stage 3 of the PCP

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
I.6.A. Internal coordination (chain of command)	Level 2 → 3	<ul style="list-style-type: none"> Describe clearly the chain of command Carry out simulation exercises to test the chain of command
II.11. Emerging issues	Level 2 → 3	(For memory: conduct a risk analysis on the possible emergence of a new FMD strain in the country, see output 1; develop national contingency plans for new FMD strains, see output 1; develop formal collaboration with other ministries / agencies on emerging issues, see CC I.6.B; ensure that the labs have the capacity to conduct non-routine diagnostic tests, see CC II.1 for level 4, accommodate provisions in the legal/regulatory framework for the management of emerging issues, see CC IV.1; take the appropriate measures to prevent and control the emerging issues, see CC II.6 and CC. II.7)
III.1. Communication	Level 3 → 4	<ul style="list-style-type: none"> Full set of appropriate communication material <p>*Some activities are already mentioned in Outputs 1 or 2: core team of specialists provides up-to-date information, accessible via Internet and other appropriate channels, on activities and programmes</p>
III.4. Accreditation / authorisation / delegation	Level 2 → 3/4	<ul style="list-style-type: none"> Put in place a delegation procedure Develop a list of task and activities to delegate to the private sector for the FMD prevention and control programme, with the relevant budget Accredit the appropriate number of licensed/registered private vets (list available) to conduct the FMD prevention and control specific and well-defined activities Put in place some control mechanism (cross-testing, serological control, etc.) to verify the quality of the delegated activities
III.5.A. Veterinary Statutory Body authority	Level 2 → 3/4	<ul style="list-style-type: none"> Register private vets Apply disciplinary measures when appropriate Participate in the definition of Vet and paravet competencies (initial and continuing education)
III.5.B. Veterinary Statutory Body capacity	Level 2 → 3	<ul style="list-style-type: none"> Carry out core missions independently
II.6. Early detection and emergency response	Level 1 → 3	<ul style="list-style-type: none"> List the diseases that are subject to ED and ER To put in place the procedures for Early Warning (non-specific to FMD) <p>(For memory: put in place the appropriate field veterinary network for ED and ER, see CC III.4 and CC.I.6.A; develop a preparedness and contingency plan for FMD, see output 1; train vets for the implementation of ER, see CC I.3; organise simulation exercises on FMD outbreak management, see output 1; put in place an emergency fund for the control of FMD outbreaks, see output 1; have access to correct and timely diagnostics, see CC II.1; develop formal collaboration with other ministries / agencies for emergency responses [army, police, etc.], see CC I.6.B)</p>
II.7. Disease prevention, control and eradication	Level 2 → 3	(For memory: put in place monitoring measures to verify the efficacy and efficiency of the FMD control programmes, including post vaccination monitoring, see output 1)
II.8. Ante and post mortem inspections	Level 2 → 4	(For memory: Legislative framework, procedures, and procedures put in place for export and national slaughter places when level 1 → 2, see PCP stage 2; idem activities as level 1 → 2 but in local slaughter places)

III) Enabling environment activities to get to Stage 3 of the PCP (cont.)

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
II.4. Quarantine and border security	Level 2 → 3	<ul style="list-style-type: none"> Elaborate documented quarantine inspection procedures Control animals at borders <p>For memory: develop a specific procedures for FMD, see output 1</p>
II.13.A. Animal identification and movement control	Level 2 → 3	<ul style="list-style-type: none"> Consult with stakeholders on animal identification and movement control Put in place legal framework for animal identification and movement control Develop procedures to check identification and movement control Develop and maintain a national database for animal identification Put in place physical check points (internal) to check identification and movement control
I.7. Physical resources	Level 2 → 3	<ul style="list-style-type: none"> Properly manage physical resources (telecom, fridges, premises, vehicles, etc.) at all levels <p>(For memory: assess the physical needs for implementing an aggressive FMD control programme, see output 1; as a result of the evaluation, to buy the necessary physical resources for implementing an aggressive FMD control programme, see output 1)</p>
I.8. Operational funding	Level 2/3 → 4/5	<ul style="list-style-type: none"> Programme the appropriate 5-year budget to conduct baseline operations Establish procedures for raising funds and financial governance Get (from ministry of finance) an annual budget compatible with the VS work programme <p>(For memory: carry out a cost-benefit analysis on the cost of the FMD control programme, an 'expanded operation', see output 1; discuss the financial participation of stakeholders in the implementation of control measures, see CC III.6.)</p>
I.9. Emergency funding	Level 1 → 3	<ul style="list-style-type: none"> Put in place the legal and regulatory framework for contingency and compensatory funding arrangements <p>(For memory: develop a specific compensatory regulation for FMD, at Stage 3 and above [when outbreaks become episodic], see output 1)</p>

IV) Enabling environment activities to get to Stage 4 of the PCP

Critical Competencies and level of progression		Activities to enhance the CC level / VS capacity
II.5.B. Active epidemiological surveillance	Level 3 → 3/4	<p>(For memory: implement FMD active surveillance in compliance with OIE standards, see output 1)</p>
II.4. Quarantine and border security	Level 3 → 3/4	<ul style="list-style-type: none"> Develop procedures to control illegal movements of animals
IV.7. Zoning	Level 2 → 3	<p>(For memory: put in place zoning for FMD, according to OIE definition, see output 1)</p>
I.9. Emergency funding	Level 2/3 → 4/5	<p>(For memory: consult with stakeholders on compensation schemes, see CC III.2.)</p>

Part B

Annex 2: Foot and mouth disease Global Portfolio Review (results)

Introduction – Methodology

As part of the preparatory work to support the elaboration of the Food and Agriculture Organization of the United Nations (FAO) / World Organisation for Animal Health (OIE) Global Strategy for the control of foot and mouth disease (FMD) (hereafter named FMD Strategy), the GF-TADs FMD Working Group carried out a survey to collate and analyse the FMD Portfolio of activities worldwide, with the following objectives:

- identify the funds already committed and / or disbursed in the prevention and control of FMD worldwide, with a view to fine-tuning the overall budget of the Action Plan (Part B) and identifying the financial gaps;
- identify possible gaps and overlaps in FMD prevention and control activities, as a transparent and rationale basis for improving coordination at regional and global level.

The survey was based on a questionnaire composed of 12 questions. The questionnaire is provided in Annex. It was sent out through the OIE Delegates to a selection of developing and in transition countries (99) facing a wide range of situations with regards to FMD and in particular in which FMD is known to be present (either enzootic or epidemiological events). Japan was also included to have a concrete example in developed countries. The same questionnaire was also sent to a list of development partners (10) and regional organisations (17) active in the field of animal health, to try and cross-check the information provided by the countries and make the portfolio review as comprehensive as possible.

One hundred twenty-one questionnaires were received back from a total of 63 respondents, namely 45 countries (45%), 8 development partners (80%) and 10 global and regional organisations (59%). The authors took the liberty to complete and add data, whenever aware of them

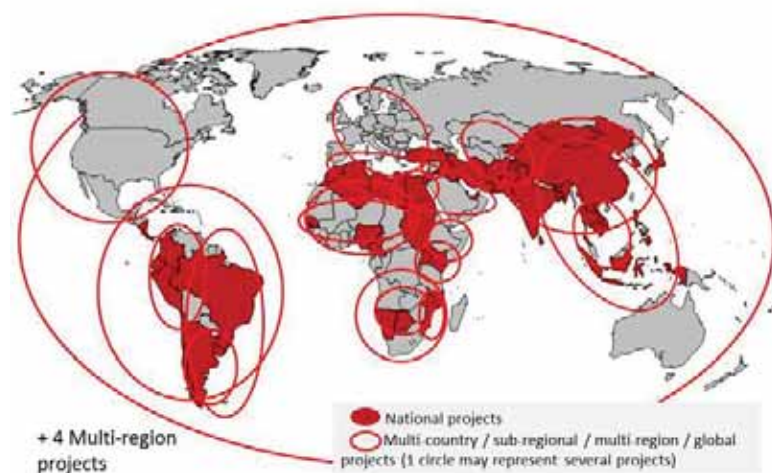
The results presented below are based on preliminary and partial data and should therefore be interpreted carefully. Only general trends can be concluded.

Results

All programmes/projects received through the questionnaires were mapped (Fig. 1) independently of their statuses¹ and whenever possible (six respondents indicated that they had no FMD activities in their portfolio).

All regions and sub-regions were and/or are covered by national, multi-country and/or (sub)regional projects. Regional Virus Pools areas are notably all covered by (sub)regional projects. In South America, Southern Africa and South East Asia, many projects overlap geographically, but have different timelines or range of activities.

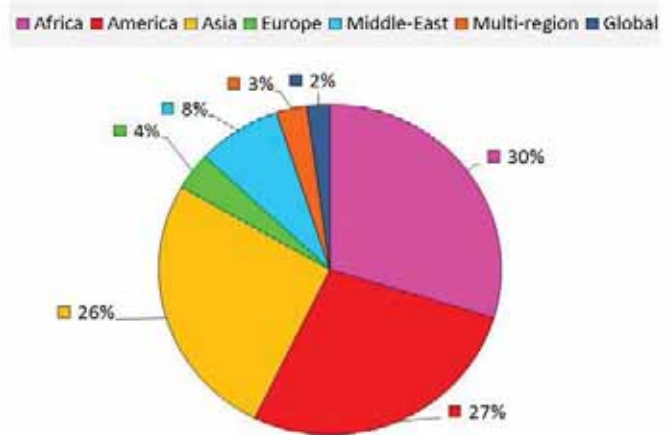
Fig. 1 – Map of FMD projects (all status)



¹ Statuses = closed ; on-going ; pipeline

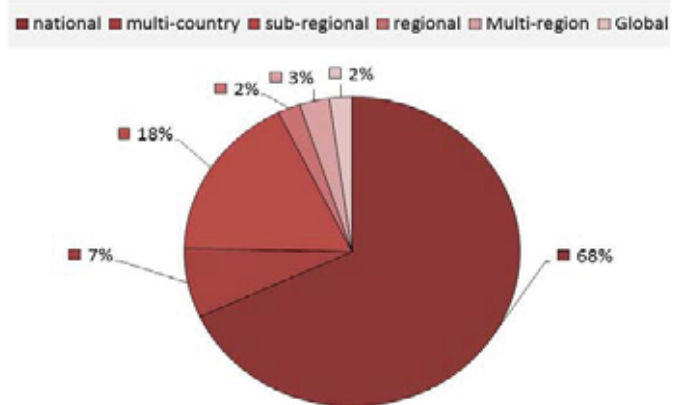
A majority of the inventoried programmes/projects were² are implemented in Africa (30%), then America² (27%) and in Asia (26%) (Fig. 2). Europe and the Middle-East have approx. 2/3 less projects, despite the endemic FMD situation in part of these regions (regional Virus Pool 3).

Fig. 2 – % of FMD projects per region



Most programmes / projects are operated at national level (68%); only 7%, 20%, and 3% have respectively a multi-country, (sub)regional and multi-region coverage (Fig. 3). This indicates that FMD is primarily tackled at country level, while it is known that for transboundary diseases the most efficient level of intervention is sub-regional or in the case of FMD, lined up with the regional FMD Virus Pool areas. Three projects have a global dimension, mainly related to diagnostic and somehow all link to laboratory activities with:

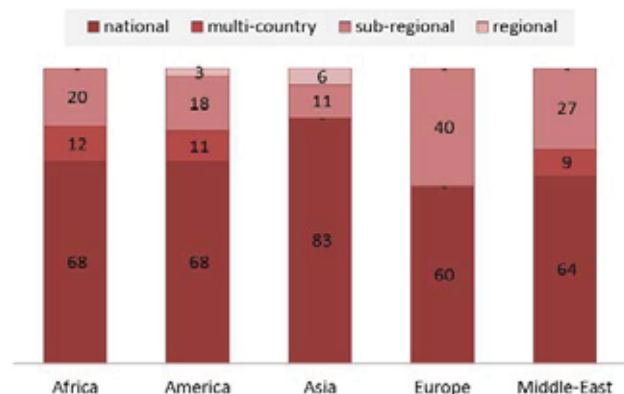
Fig. 3 – % of FMD projects per geographic coverage



i) the work of the FMD World Reference Laboratory in Pirbright (for surveillance, vaccination monitoring, research, etc.) and

ii) the FMD Vaccines Strategic Reserve Network. The FMD Strategy will be the first initiative ever carried out for FMD prevention and control at global level.

Fig. 4 – % of FMD projects per region and per geographic coverage



Europe (40%) and the Middle-East (36%) have the greatest percentage of programmes/projects carried out at supra- national level (Fig. 4). In Asia, 83% of the portfolio is carried out at country level.

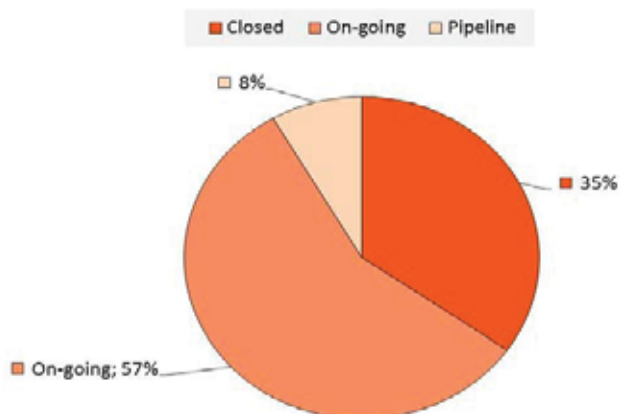
Networking activities (laboratories; epidemiology) are mainly carried out through sub-regional projects.

² In the context of this survey, America is all American countries but United States (USA) and Canada and Europe is all countries except European Union (EU) Member States (EU MSs) – unless otherwise specified.

Out of the inventoried projects, 57% are on-going, 35% are closed and 8% are in the pipeline (Fig. 5). Closed projects concern mainly Africa and Asia, as several FMD activities were conducted together with Rinderpest and HPAI activities, which are now terminated.

Nota bene: only projects closed after 2000 were accounted for in the survey.

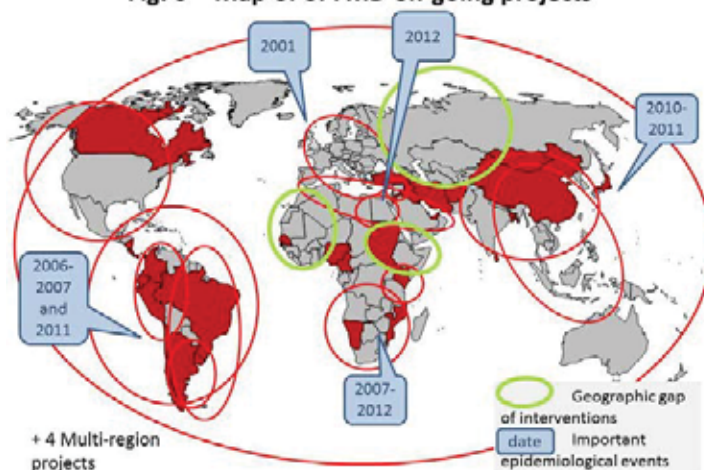
Fig. 5 – % of FMD projects per operational status



Looking more specifically at the portfolio of on-going projects (57%), the mapping of the projects (Fig. 6) indicates that they are mainly located in areas where disease outbreaks occurred over the past five years.

Three regional FMD virus pools are currently not appropriately addressed by regional programmes, namely this concerns Virus Pool 3 (Central Asia and Middle-East), Virus Pool 4 (Eastern Africa) and Virus Pool 5 (Western and Central Africa).

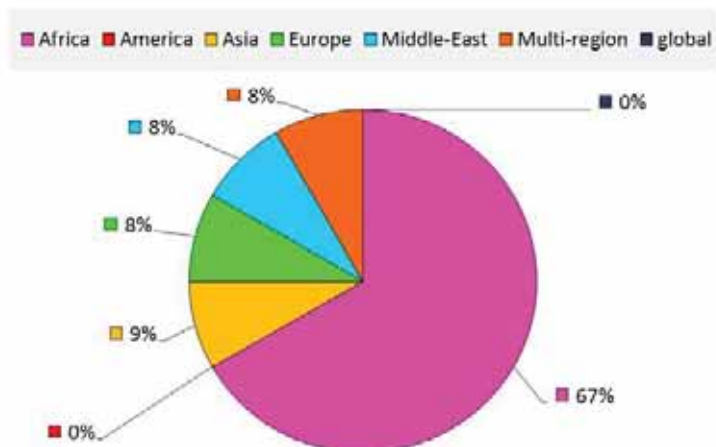
Fig. 6 – Map of of FMD on-going projects



When we come to the forthcoming FMD portfolio (pipeline) (Fig. 7), 12 projects are currently under development, with a majority of them planned in Africa (67%). This is in particular due to:

- i) the new FMD programmes in Egypt and neighbouring countries, with regards to the emergence of the SAT2 strain in the sub-region; and
- ii) the three recently OIE endorsed national FMD Control Programmes in Algeria, Morocco and Tunisia. With this new provision in the OIE *Terrestrial Animal Health Code* introduced in 2011 (Chapter 8.5), the FMD portfolio is expected to grow quite significantly in the coming years.

Fig. 7 – % of FMD projects in the pipeline per region



The timeframe of new projects (Fig. 8) shows that they usually follow the pattern of FMD epizootics in the regions, confirming that this is an 'in-reaction-to' portfolio: peaks of projects occur in 2001-2002, 2006-2007 and 2010, when respectively Europe, America and Asia faced important FMD epizootics.

Remark: 'Before 2000' cumulates all projects started before 2000 (it was not possible to scatter them along the chronological axis for reasons of space); therefore, one should not interpret a drastic drop in the number of projects in 2000.

For the projects considered, a total of USD 7,8 billion were spent worldwide for FMD prevention and control. Such funding for the control of a single disease clearly demonstrates the important involvement of the private sector, as State budgets only of developing and in transition countries can in general not afford such levels of expenses.

Most funds were spent in America (75%) and Asia (21%) (Fig. 9). If Japan is 'withdrawn' (developed country), America's share raises up to 93% of the total funds disbursed for FMD. America's investment (USD 5,8 billion) may be the price to pay for a region free from FMD (many projects still on-going started in the 90's and supported American countries' objective of free status). The funds spent in the three other regions (Europe, Africa and the Middle-East) amount for less than 3% of the overall funds spent, while still representing important amounts (respectively USD million 92, 102 and 54).

The 83% of overall FMD funds are spent at national level (Fig. 10), and more than 80% of them were spent in three countries only, namely Brazil (45%), Japan (20%) and Argentina (20%). In Japan, as reported in the questionnaires, the short (20/04 – 05/07) FMD epizootic in 2010 with less than 300 outbreaks cost USD 69 million, for emergency control measures (emergency vaccination and culling of 300,000 animals) and recovering an OIE official free status without vaccination (in addition to economic losses approx. USD 3,4 billion). This amount is in addition to the current 'routine' budget already devoted to the prevention and control of TADs by the government of Japan (USD 135 million in 2011), which probably also contributed to FMD control.

Fig. 8 – Number of new FMD projects per year

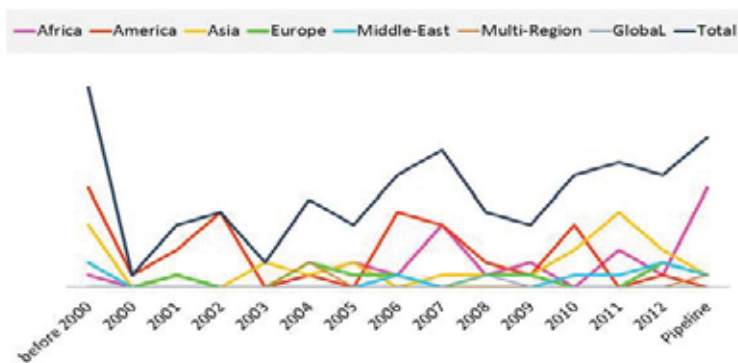


Fig. 9 – % of FMD funds (USD) per region

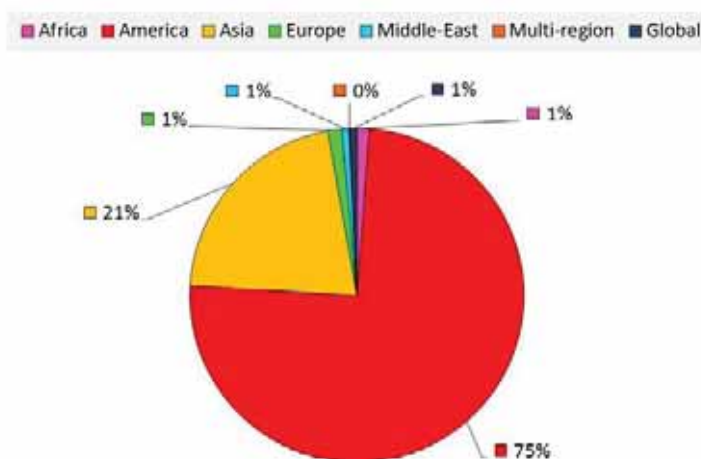
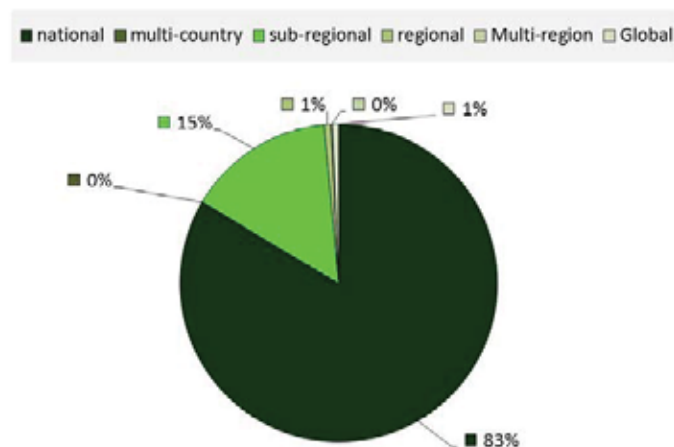
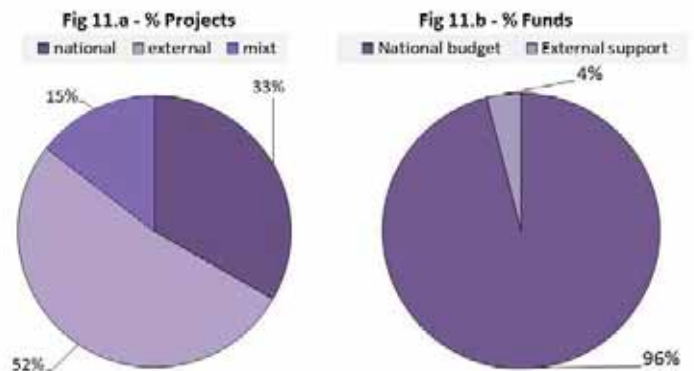


Fig. 10 – % of FMD funds (USD) per geographic coverage



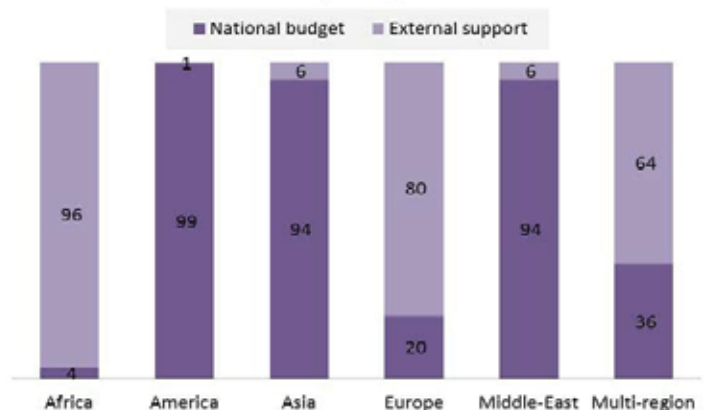
With regards to the sources of funds (Fig. 11a and 11.b), 33% of programmes/projects is financed through national budget (= self-financing) and 52% through external aid (41%). The 15% of projects are financed through co-funding. However, when it comes to the amount of funds spent, external aid (= donor support) amounts for USD 326 Million and represents only 4% of the total amount of funds spent for the prevention and control of FMD worldwide. This is less than what was spent (development partners) for Rinderpest or HPAI, indicating that FMD is not a priority for developing countries. For HPAI and Rinderpest, a global control and eradication programme were however implemented.

Fig. 11 – % of FMD projects and funds (USD) per source of funds



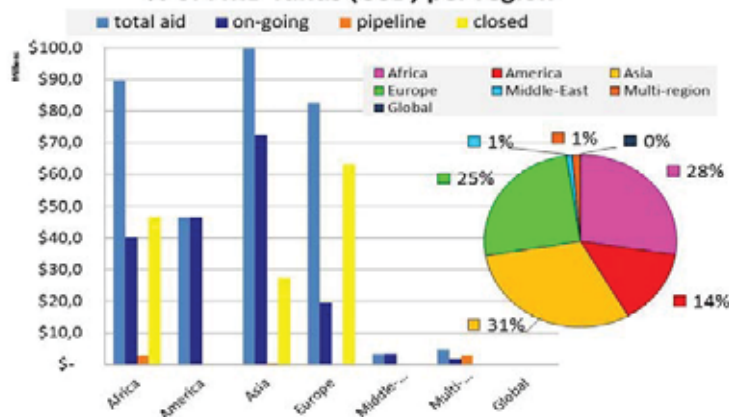
There are some strong regional disparities: in America, Asia and the Middle-East, the countries are financing their own programmes/projects by more than 90%, while in the other two regions, FMD activities are very much conditioned to external aid (Africa 96%; Europe – non EU MS – 80%) (Fig. 12). This is somehow coherent with the countries priorities: in America, FMD is a national priority (trade aspects) with a strong involvement of the private sector, while in Africa, several diseases are more socially and economically important than FMD; control efforts are therefore mainly supported by development partners in an international solidarity/food security objective but also to safeguard their own free status by controlling the disease at source.

Fig. 12 – % of FMD funds (USD) per source of funds and per region



The donor portfolio (external aid) represents 72 projects (all statuses) and amounts for approx. USD 330 Million. A total of 41 projects were closed since 2000, so the current portfolio is only of 31 projects.

Fig. 13 – Donor portfolio (external aid) : % of FMD funds (USD) per region



The majority of funds is spent in Asia (31%), in Africa (28%) and then in Europe (25%) (Fig. 13). America and the Middle-East attract very few funds, confirming that America and the Middle-East are self-financing more than 90% of the FMD national activities (Fig. 12).

EU has a sizeable portfolio in Africa, Asia and Europe (Fig. 14). and is by far the largest contributor in FMD (63% of total aid), followed by FAO (14%). The FAO is not a donor *per se* and mainly contributes through development partners funds – for FMD, funds come mainly from Italy and Spain –; from its own budget (Technical Cooperation Programme), FAO contributes up to 1% of the total FMD external funds. Regional banks and stakeholders contribute significantly to FMD efforts, notably in Africa: the African Development Bank finances 38% of the FMD donor portfolio in Africa. AU-IBAR indicated that they no longer finance any FMD activities in the region.

Similarly, some of the development partners consulted (France, Germany) responded that they currently do not finance/implement any FMD activities in developing/in transition countries.

Project support ('stand-alone + component') remains the preferred financial channel (91%) to carry out FMD activities in all regions (Fig. 15). America is the region where budget support is the most used, even if it remains limited (16%). In most cases, FMD stand-alone projects (mono-disease projects) are developed. However, in Asia (50%) and Europe (40%) as well as for multi-region projects (50%), a more transversal approach integrating FMD as a component of a wider Animal Health programme/project is adopted. This is consistent with Component 3 of the Global FMD Strategy, combining as often as possible FMD to other TADs prevention and control measures.

The projects have in majority (77%) a medium to long term development objective, aiming in most cases (43%), at the control of the disease in endemic zones (Fig. 16), corresponding to countries in stages 1, 2 and 3 of the FMD PCP. Emergency support is also provided in Asia (29%) and Africa (28%) and to a lesser extend in the other regions except the Middle-East. In America, maintaining an OIE official free status logically represents the objective of 70% of the projects carried out.

Fig. 14 – Top 3/4 FMD donors per region

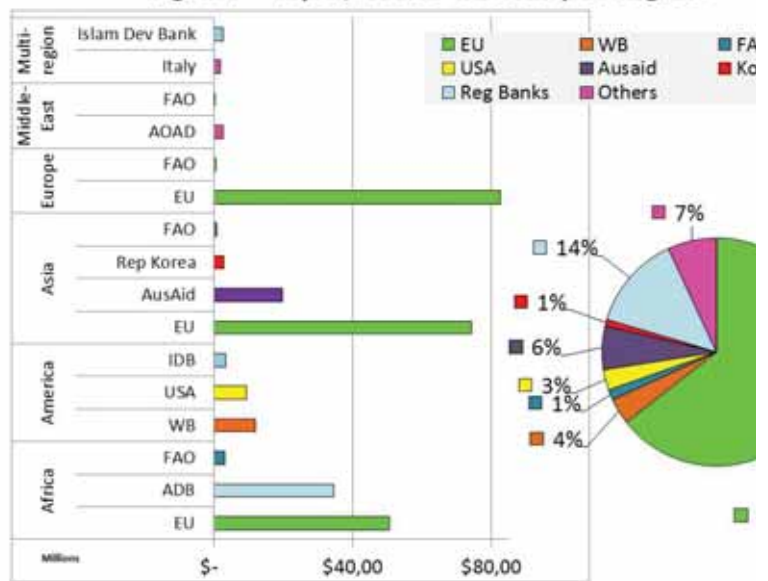


Fig. 15 – % of FMD projects per financial channel per region

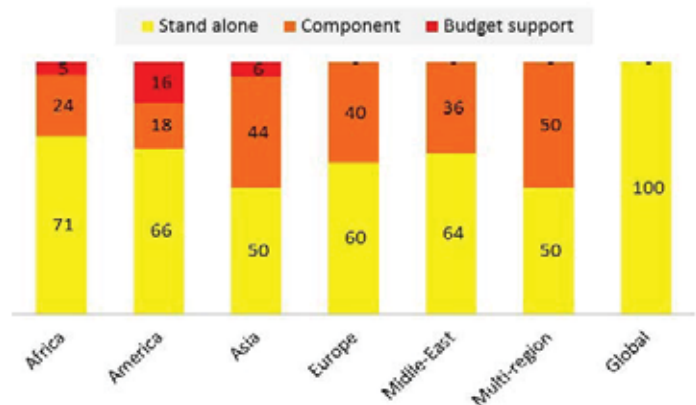
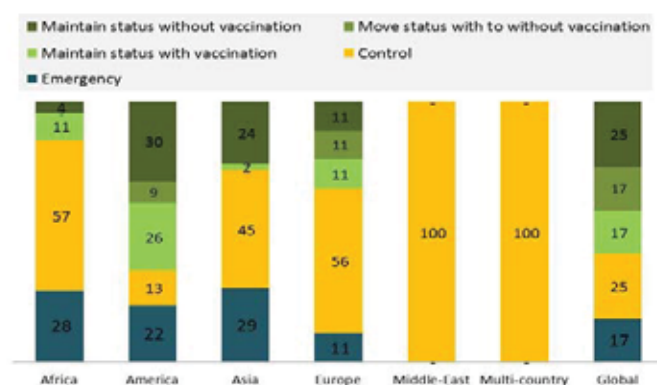


Fig. 16 – % of FMD projects per objectives per region



In terms of FMD activities conducted, activities such as rapid response activities, prevention, early detection, VS, laboratory and epidemiology are present in more than 60% of the FMD projects (Fig. 17). It is interesting to note that epidemiology is implemented in 60% of the projects, probably reinforced by activities in wildlife even if limited (basically only possible activities in wildlife).

Reversely, compensation activities receive very little to no interest at all (14%), as well as research (30%) and coordination (36%). The latter is difficult to understand in the context of a highly contagious transboundary animal disease.

All regions give priority to the reinforcement of VS, except in America (Fig. 18). This is in line with the approach proposed by the Global FMD Strategy (Component 2) where the reinforcement of VS is seen as a condition to the efficiency and sustainability of FMD measures put in place ('enabling environment'). In America - where the situation is no longer endemic – and Europe, priority is given to rapid response activities including emergency vaccination. Communication activities are of utmost importance in Europe (in 80% of projects), while rather neglected in other regions.

Remark: there may be a bias for Fig. 17 and 18 in the fact that activities are not fully discriminant.

Domestic animals/livestock are the main target of the programmes/projects by far (Fig. 19). No project address wildlife alone, but in the Middle-East and Africa, respectively 33% and 48% of the projects jointly address livestock and wildlife species (surveillance/epidemiology activities). This is all the more important in Africa when we consider the important role played by the African Buffalo in the maintenance and spread of FMD.

Fig. 17 – % of FMD activities per category

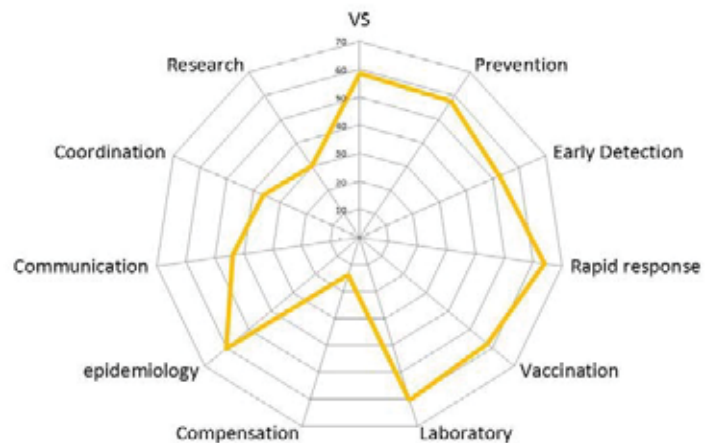


Fig. 18 – % of FMD activities per category per region

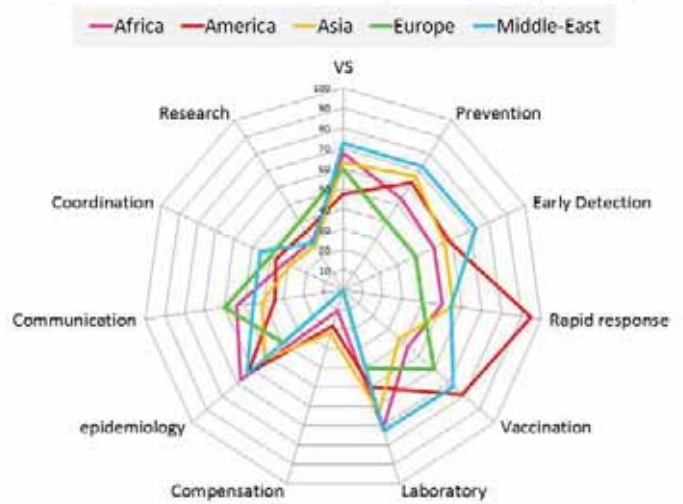
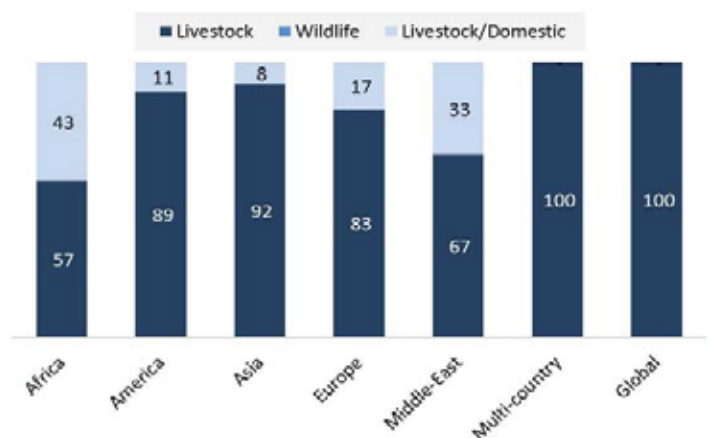


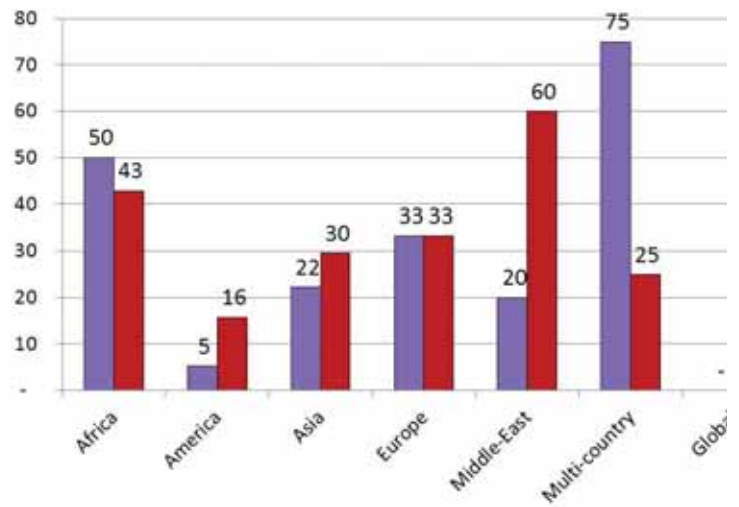
Fig. 19 – % of FMD projects per targeted species



As for the tools used in the programmes/projects (Fig. 20), less than 50% of the programmes/projects make use the FAO-OIE FMD PCP Approach – only 5% in America – and of the OIE PVS tool, except in the Middle-East (60% of the countries make reference to the OIE PVS) – while the reinforcement of the VS is a key activity in most of FMD project (Fig. 18 and 19). The main reason for this is that the portfolio review started in 2000 while the tools were respectively made available in 2007 and 2009 only. Questionnaires show that the most recent projects have started to integrate them more systematically.

Many other important 'tools' for the prevention and control of FMD were listed by the respondents, among others: vaccines and antigens banks, progressive zoning approach, value-chain analysis, Animal Disease Spread Model (NAADSM).

Fig. 20 – % of FMD projects making use of the FAO-OIE PCP-FMD and OIE PVS tools



Supporting document N°1

The impact of foot and mouth disease

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With contributions from Alex Donaldson, Peter de Leeuw,
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Summary

The global impact of foot and mouth disease (FMD) is colossal due to the huge numbers of animals affected. This impact can be separated into two components: the **direct losses** due to a reduction in production and changes in herd structure; and **indirect losses** that relate to the significant costs of FMD control and management and poor access to markets and limited use of improved production technologies. The paper estimates that **annual impact of FMD** in terms of production losses and vaccination alone are in the region of **US\$5 billion**.

The balance of FMD impacts are not the same throughout the world, and the study identifies three broad regions:

1. Much of the global FMD burden of production losses falls on the world's poorest communities, and those which are most dependent upon the health of their livestock. In addition, the presence of FMD in these countries has an impact on the overall herd fertility, modifying the herd structure and affecting the selection of breeds. Overall the direct losses **limit livestock productivity** creating a **food security** issue and contributing to **malnutrition**.
2. In countries with ongoing control programmes, FMD **control** and management creates significant **costs**. These control programmes are often difficult to end due to risks of FMD incursion from neighbouring countries. The greater movement of people, livestock and commodities implies that risks of international transmission of FMD are increasing. This risk further compromises these countries in their ability to export livestock and livestock products as the presence, or even threat, of FMD prevents **access to lucrative international markets**.
3. In FMD free countries outbreaks occur regularly and the costs involved in regaining free status have been enormous.

The impact of FMD has led to successful national and regional campaigns for disease eradication most notably in Europe and the Americas. Therefore technologies and control methods exist to control and ultimately remove FMD virus from livestock populations. However, this requires significant management and coordination skills at a national and regional level due to FMD being highly contagious, and therefore, is a disease that generates high levels of **externalities**. These externalities imply that the control of FMD produces a significant amount of **public goods**, justifying the need for national and international public investment.

Equipping poor countries with the tools necessary to control FMD will involve the development of state veterinary services that in turn will deliver wider benefits to a nation including the control of other livestock diseases. Only through a sustained global effort can the risk of FMD and the heavy burden that it inflicts be controlled for rich and poor countries alike.

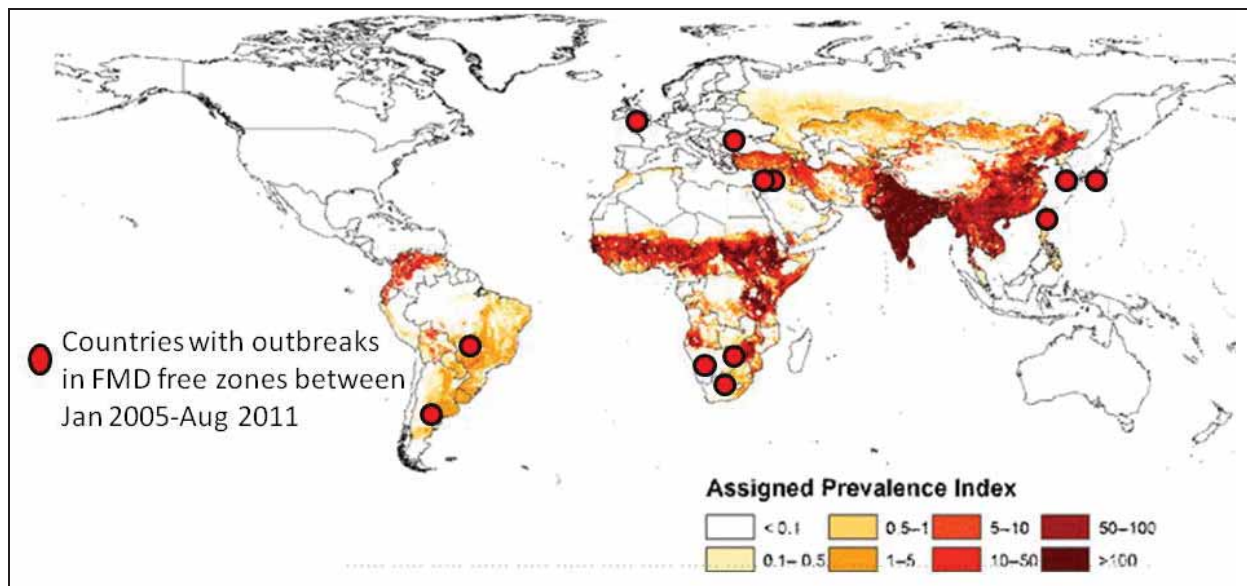
The impact of foot and mouth disease

Introduction

Foot and mouth disease (FMD) is endemic in almost all developing countries. The seven different FMD serotypes circulate within regional viral pools with periodic incursions into virus free developed countries (see Fig. 1). FMD causes high morbidity and low mortality although high mortality of young stock does occur. Clinical signs are generally more severe in temperate breeds associated with intensive farming particularly in immunologically naive populations. The disease affects all the major non-avian livestock species, with cattle being the most susceptible and pigs the best amplifier of virus. Infection in wildlife can further complicate control efforts. It takes only 3 to 5 days (Charleston 2011) before a newly infected animal can spread the infection to other animals, with each case being able to infect many other animals. It is the most infectious human or animal disease agent known, infected cows have been estimated to be able to infect over 70 other cattle in a susceptible herd (Woolhouse 1996); these properties allow the disease to spread with great speed.

When this ease of biological transmission combined with widespread and long distance movements of animals, FMD can move quickly and spread effectively. By the time the first case of the UK 2001 epidemic was detected, it is estimated that over 57 farms around the country were already infected (Gibbens and Wilesmith, 2002). The importance of trade, both legal and illegal, in the spread of the disease implies that any FMD control strategy must have policies and actions to limit risks of FMD spread from an outbreak and the introduction from neighbouring countries and trading partners. These movement controls for FMD management have an economic impact of limiting trade that be local, national and international in its reach. The most extreme and costly impacts are the lack of access to lucrative international markets for countries where FMD is not controlled.

Fig. 1: Global burden of FMD in cattle, burden of FMD in sheep and goats had a similar distribution
Measured as a prevalence score based on estimates of incidence, population distribution and other risk factors. (Reproduced from Sumption et al. 2008)



The paper reviews the economic impact of FMD and its control in different regions of the world using a framework that details the different aspects of the impact from production losses, costs of control, poor technology development through to trade. It presents a short description of the framework used to look at FMD impact followed by sections on what data and information are available FMD economic impacts. A section is included to describe the effect on poverty and food security of this major livestock disease.

The framework

The impact of disease is not equal across all countries and livestock populations due to differences in the genetics of the livestock; the management of the livestock; and the prevailing prices for the livestock systems inputs and outputs (see Rushton, 2009, pages 193-197). A framework has been suggested (Rushton *et al.*, 1999; Rushton, 2009; Rushton *et al.*; forthcoming) to assess disease impact that allows flexibility in terms of approaching this issue, identifying the following elements:

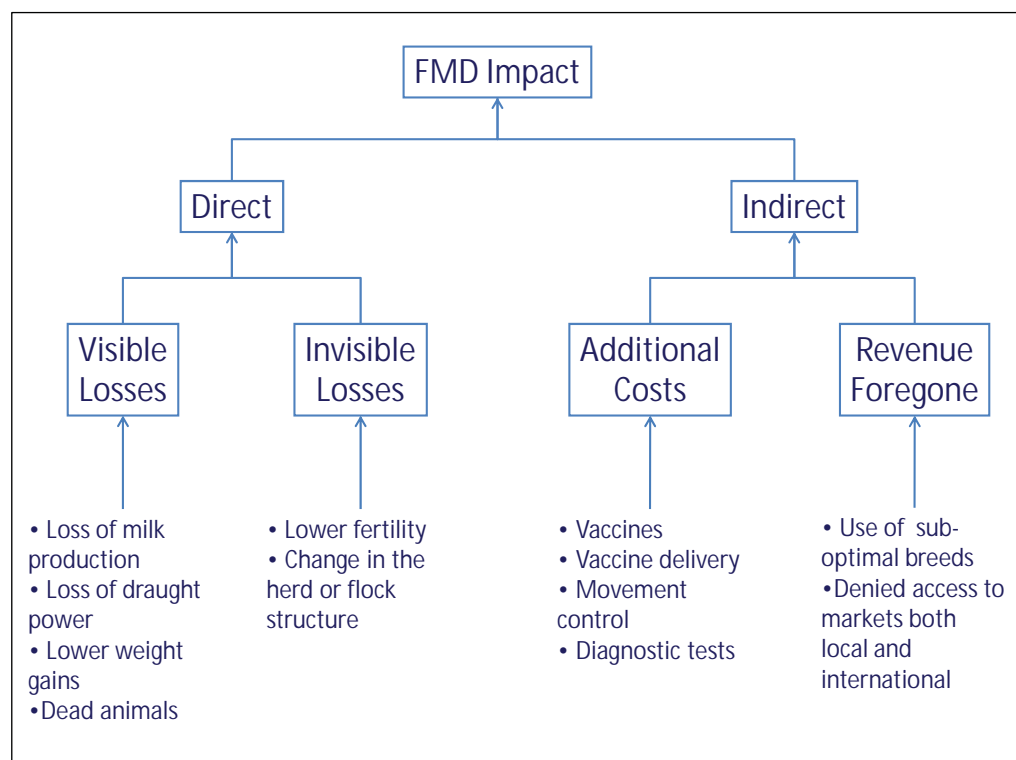
1. direct losses
 - a) visible impacts such as death of animals or reduced performance
 - b) invisible impacts where fertility is affected leading to the need to have a herd structure that contains extra breeding animals
2. indirect losses
 - a) costs of controlling and managing disease
 - b) revenue foregone where the presence of disease limits:
 - i) the use of technologies, particularly improved breeds and more intensive production systems; and
 - ii) market opportunities, both a local, national and international level.

Impact of disease is an important estimation to guide where to apply resources to animal health, which needs to be strengthened through examining the marginal costs and benefits of applying disease control measures. For example if money is spent on disease control, which will increase the indirect losses of the disease, the intention is to reduce the direct losses due to losses in animal and herd productivity. A control campaign is, therefore, useful if the avoidable losses in production are greater than the costs of control. The underlying economic theory on animal disease and their control has been well explained by McNerney (1988; 1992; 1996)

for small additions to disease control. An important extension on these theories is detailed by Tisdell (2009) who looked at the need for fixed cost investments in veterinary education, research and infrastructure.

Applying the framework the following impacts of FMD are shown in Figure 2.

Fig. 2: The impacts of foot mouth disease



The impact of foot and mouth disease

It is possible to apply the disease impact framework to different countries and make global estimates for FMD. The importance of this estimate is the nature of the impact that FMD causes. This is a disease that is highly contagious, affects many species and is not easily contained within one farm or one population. The presence of FMD creates problems to all livestock owners who are connected to a population infected either geographically or through input or output market chains (the livestock value chain). Therefore, FMD creates what economics calls **externalities**, which in this case are negative to all those connected to the problem. Similarly, where a livestock owner protects their animals from FMD they will generate a positive externality as they will be protecting the animals of livestock owner who are connected to the protected population. Where externalities are created there is a need for public investment as not all the costs, in the case of disease presence, or all the benefits, in the case of disease control, can be captured by the livestock owner implementing the actions. A strong role for government for FMD is creating an institutional environment where population level control costs reflect sufficiently the benefits that a livestock owner can capture in terms of benefits. In most cases this requires a combination of:

- investments in veterinary education, research and general infrastructure to develop the animal health system – what economists would call fixed costs
- specific programmes that cover the costs of FMD control and management – what economists would call variable costs

In many countries there is already a fixed cost investment in animal health systems, and adding a FMD control programme is relatively easy. However, countries that have low level investments in fixed animal health costs will not necessarily benefit with a FMD programme alone, there needs to be a combined effort to improve both the fixed and variable costs to get a potential control programme running. The importance of this observation is that the fixed cost element of the FMD programme will generate capacity and skills that will benefit other disease campaigns and therefore not all costs for this fixed cost element should be assigned to FMD.

Economic impact of FMD

Although other diseases can cause more severe disease in individuals, in order to appreciate the impact of FMD, one must step back and look at the disease at the population level. FMD is widely prevalent, with the disease circulating in an estimated 77% of the global livestock population. In this population it affects a large proportion of animals during an outbreak and affects many species. Collectively these factors lead to a huge burden of disease.

Direct impacts

Visible losses

Production losses due directly to FMD include:

- reduced milk production, affecting both the humans and calves that depend on it. This can account for 33% of losses in endemic settings
- reduced livestock growth
- mortality in young stock, typically reported to be between 2%-5%
- loss of traction power where draught animals are used. If this occurs during harvest the effects can be particularly severe (James and Ellis, 1976; Perry *et al.*, 1999)
- abortion: the cost of a single abortion is high as the farmer will have to pay to keep the cow without it producing anything for another year or more, or cull the animal

The impact of foot and mouth disease

- although FMD typically has a short-term effect on an animal's health, chronic FMD typically reduces milk yields by 80% (Bayissa *et al.* 2011, Barasa *et al.* 2008; Bulman & Terrazas, 1976).

Visible production losses are most prominent in pigs in intensive production systems followed by dairy cattle. These two systems are important sources of animal protein in poor countries and their importance continues to grow (Delgado *et al.*, 1999). Extensive systems of production do not have such pronounced losses, and some species such as sheep and goats show limited clinical symptoms and minor economic losses.

Invisible losses

FMD causes problems with fertility, the most obvious are the abortion losses explained above, but there are longer lasting impacts of this loss of both foetus and a reduced probability of conception. These both translate into the need to have a greater proportion of breeding animals in a population implying that for every kilo of meat or milk produced there is an additional fixed cost to cover more breeding stock. These impacts are well detailed in Rushton (2009) for the extensive cattle systems in Bolivia.

Indirect impacts

Additional costs

Control costs

The cost of control measures carried out by the state veterinary services, such as vaccination, outbreak control and sometimes culling and compensation are borne by the tax payer.

- an estimated 2.6 billion doses of FMD vaccine are administered annually (Table I) (Hamond, 2011), with vaccine drug and delivery costs at between \$0.4 to \$3 per dose including delivery costs depending on the setting (Sutmoller, 2003; Barasa *et al.*, 2008; Forman *et al.*, 2009).

Table I: Estimated global FMD vaccine use (Hamond, 2011)

Region	Million doses/year	Comments
China	1.6 billion doses	5 government producers
South America	500	Brazil: 350 million doses
Asia (excluding China)	200	India: 150 million doses
Middle East	20	
European region	15	Mainly Turkey
Africa	15	

- some national FMD vaccination programmes vaccinate all bovines three times a year and all sheep and goats once a year, this limits resources available to combat other diseases
- in endemic settings significant amounts are spent on privately funded vaccination and control
- in some areas wildlife are kept out of FMD free zones with extensive fencing at great financial cost not to mention the impact this restriction has on wildlife.

In Africa it has been estimated that more is spent controlling FMD than any other veterinary disease (Le Gall and Leboucq, 2004).

Even if a country is FMD free there are ongoing costs due to:

- efforts to reduce the chance of disease re-introduction, including border and import controls and inspections and sometimes vaccination

The impact of foot and mouth disease

- efforts to maintain the capability for early detection and control of FMD, including surveillance, ensuring sufficient organisational capacity in the veterinary services which are tested by outbreak simulation exercises (ref, outbreak exercises) and permanent restrictions on the livestock sector (such as post-movement standstills)
- dealing with outbreaks, which may involve culling, movement restrictions and vaccination. Outbreaks in animals lacking prior immunity to FMD are particularly dramatic:
 - i) control measures can affect other industries, for example the UK 2001 outbreak restricted public access to the countryside costing in the region of US\$4 to 5 billion in lost tourism revenue (Thompson *et al.* 2002)
 - ii) the impact of culling based control measures can have other non-financial impacts, suicides increased amongst farmers of culled farms during the UK 2001 outbreak, in South Korea there was concern that burial of large numbers of culled animals would pollute water supplies. Culling healthy animals is a politically sensitive issue and is seen as unnecessary and inhumane by much of the wider public
 - iii) movement restrictions disrupt production and may even lead to welfare problems that lead to further culling.

The 2001 UK FMD outbreak highlights how severe and widespread the consequences of an outbreak in an FMD free country can be. Following outbreaks in the Far East and subsequent outbreaks closer to Europe the disease appeared in the UK unexpectedly, in an area not thought to be linked to international trade. Widespread culling was used to contain the disease and ultimately 6.1 million animals were slaughtered. A high proportion of the animals slaughtered were on farms that did not have virus but were perceived to be under threat or the movement control measures had placed the animals under a welfare threat (Table I).

Table I: The cases and animals slaughtered during the 2001 FMD epidemic in the UK (DEFRA, 2002)

Type of premises	Cattle	Sheep	Pigs	Goats, deer and other	Total
Infected	303,242	952,440	20,200	1,277	1,277,159
DC* Contiguous	195,130	983,313	52,913	1,551	1,232,907
DC* Non Contiguous	81,113	1,296,490	69,083	978	1,447,664
Slaughter on suspicion	14,346	110,803	2,543	299	127,991
Welfare Disposal	169,033	1,586,983	286,912	5,429	2,048,357
Total	762,864	4,930,029	431,651	9,534	6,134,078
Percentage	12.44%	80.37%	7.04%	0.16%	100.00%

* Dangerous Contact

Asia has suffered major FMD epidemics in countries that were previously free. In Taiwan an outbreak of FMD mainly in the pig population decimated the sector and was estimated to have reduced the total GDP of the country by 0.28% (Hsu *et al.* 2005). Japan has had FMD outbreaks in 2000 and 2010, and the Republic of Korea experienced an outbreak in 2010 and 2011 with the destruction of 3.37 million pigs, cows, goats and deer with an early estimate of costs being in the region of US\$ 2 billion.

In addition to the costs of vaccination and culling there are also costs incurred with the need for controlling movement and performing diagnostics for the confirmation of disease presence, or absence. There are no specific data on these additional items.

Revenue foregone

Market access

- Livestock trade is limited; those affected by FMD receive lower prices for their stock, those wishing to purchase animals from FMD free herds face a restricted supply
- countries infected with FMD cannot trade live animals with FMD free countries. Typically the countries with the best meat prices are FMD free (i.e. EU, USA and Japan) (James & Rushton 2002)
- the trade of livestock products is also restricted, if regular outbreaks occur only processed, tinned products can be exported to free countries; if FMD is effectively controlled with vaccination by a competent veterinary services able to detect outbreaks then deboned meat can be exported (James and Rushton, 2002)
- trade of fruit and vegetables can also be affected by FMD status (James and Rushton, 2002)
- the FMD status of nations that a country trades with also affects a country's ability to trade with FMD free countries irrespective of its own status (James and Rushton, 2002)
- lack of access to lucrative markets restricts the development of commercial farming, consequently employment and tax revenue from this area is limited by FMD status
- investment in the livestock sector is limited if there is a perceived risk that FMD may occur
- livestock and livestock products cannot be imported from FMD infected countries, this limits supply, although this is good for domestic producers it limits choice and leads to increased market prices for consumers.

Impacts at the national level ultimately impact on the individual farmer and vice-versa. Similarly impacts on the livestock producer have ripple effects along the entire market chain, impacting on other players, such as markets, abattoirs, dairies to mention a few (Le Gall and Leboucq, 2004).

Disruption of the rural economy

The overall cost to the UK economy was estimated to be US\$9billion (Thompson *et al.*, 2002), furthermore it spread to the Netherlands (costing over \$1billion) and Ireland and France (costing further hundreds of millions of dollars in losses). In the UK the ongoing outbreak became a focus point for the upcoming national elections, in the aftermath the government department dealing with agriculture (MAFF) ceased to exist and was entirely re-organised and rebranded (Defra); ten years on the outbreak still causes bitterness and anger.

Rich and poor countries alike go to great lengths to combat the disease in order to obtain the rewards associated with FMD free status. Although slaughtering animals to combat a non-fatal disease may initially seem illogical, the size of these indirect benefits may justify the use of control measures that have a greater negative impact than the direct costs of the disease (Perry 2007).

Use of sub-optimal technologies

High productivity breeds are typically more susceptible to FMD. The risk of FMD therefore restricts:

- a) the use of these breeds and
- b) prevents the development of more intensive production systems based on these breeds.

Calculating the economic impact of FMD

A country study Bolivia 1999

During the late 90s one of the authors was involved in project in Bolivia to establish a surveillance system that focussed on FMD. His role was to make assessments of the livestock sector, the impact of diseases and where appropriate the cost benefit analysis of strategies. An estimate was made on the impact of FMD in 1999 in the country. The results are presented in Tables II to IV and Figures 3 to 5.

The most important losses are found in the Departments of Santa Cruz and the Beni where a majority of the cattle are found and also where disease at that time was poorly controlled (see Table II).

Table II: Estimate of the direct economic losses, visible and invisible, caused by foot and mouth disease in Bolivia in 1999

Zone	Cattle population 1998*	Number of animals in the zones where there are disease reports	Estimation of the affected animals in 1998	Estimation of the economic losses (US\$)	Human population
Santa Cruz	1,703,901	1,375,113	137,511	783,815	1,703,901
Beni	2,100,000	2,100,000	315,000	1,480,500	346,180
Other Departments	1,643,393	179,711	17,971	102,435	5,899,852
Total	5,447,294	3,654,825	470,482	2,366,750	7,949,933

In addition the departments of Santa Cruz and the Beni had a majority of the costs of control as these regions were vaccinating more animals per year (see Table III).

Table III: Estimates of the additional costs of foot and mouth disease control in Bolivia in 1999

Zone	Number of vaccines purchased	Cost of the vaccine and its application (US\$/head)	Total cost (US\$)
Santa Cruz	783,794	0.5	391,897
Beni	945,000	0.7	661,500
Other Departments	493,018	0.7	345,113
Total	2,221,812		1,398,510

FMD in Bolivia was not well controlled at the time of the analysis as can be seen in Table IV where for every dollar spent of disease control a further two dollars were lost in direct losses due to the disease. The overall impact was calculated to be US\$3.7 million in 1999. The impact per head of cattle was US\$069 and per person was US\$0.47.

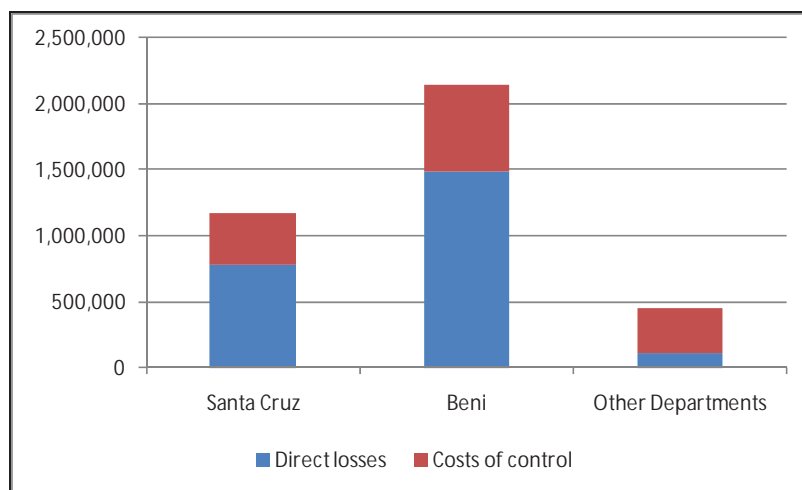
The impact of foot and mouth disease

Table IV: Estimate of the total impact of foot and mouth disease in Bolivia in 1999

Zone	Direct losses	Costs of control	Total	Impact	
				US\$/head of cattle	US\$/ person
Santa Cruz	783,815	391,897	1,175,712	0.69	0.69
Beni	1,480,500	661,500	2,142,000	1.02	6.19
Other Departments	102,435	345,113	447,548	0.27	0.08
Bolivia	2,366,750	1,398,510	3,765,260	0.69	0.47

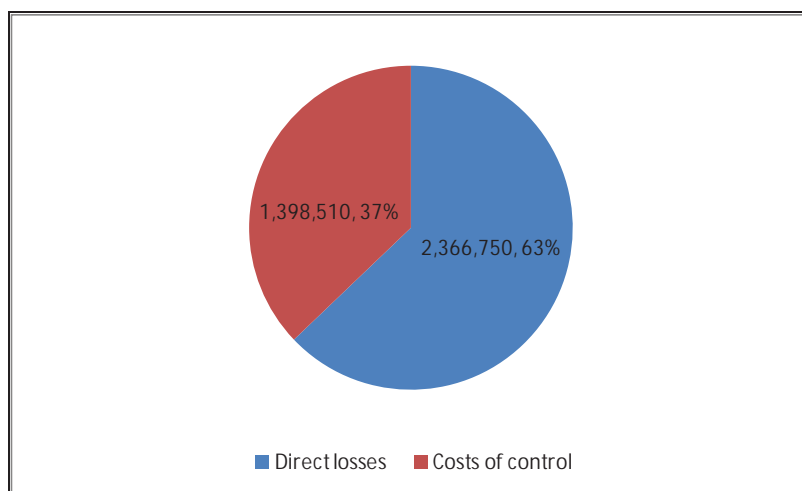
Over half of the FMD impact in Bolivia is in the Beni and a third in the Department of Santa Cruz. A high proportion of this impact in both these departments was due to direct losses (see Fig. 3).

Fig. 3: Estimated impact of foot and mouth disease in Bolivia in 1999 by zone



Approximately two thirds of the impact caused by the disease was estimated to be from direct losses (see Fig. 4).

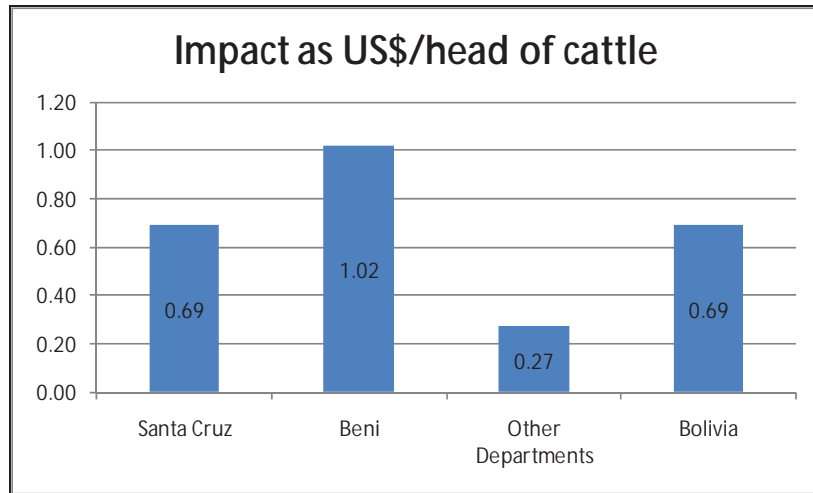
Fig. 4: Total impact of foot and mouth disease in Bolivia in 1999 by type category of impact



The impact of foot and mouth disease

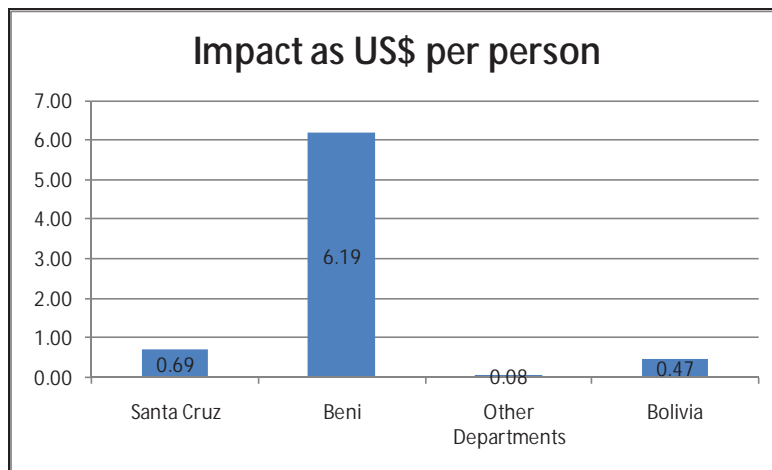
The impact measured as an amount per head of cattle was highest in the Beni followed by Santa Cruz (see Fig. 5).

Fig. 5: Impact of foot and mouth disease as an average per head of cattle and by zone.



The impact as an amount per person was US\$6.19 in the Beni reflecting that there are many cattle per person in this part of Bolivia and that the disease was relatively poorly controlled.

Fig. 6: Impact of foot and mouth disease as an average per person by zone and the overall country



Global distribution and impact

The scale of FMD impact is determined by the losses and costs caused multiplied by the number of FMD susceptible animals in a country (Fig. 2). Perry and Grace (2009) found FMD was the only livestock disease to be consistently prioritised in countries by a range of different sources including those focussed on poverty reduction. By comparing the distribution of FMD (Fig. 1) to the global distribution of people living in poverty that depend on livestock (Fig. 3) it is apparent that those experiencing the highest incidence of FMD are those that are least able to absorb the losses it causes. Many poor livestock keepers limit the impact of a

The impact of foot and mouth disease

single disease by keeping multiple species, this is less effective for FMD as it affects all ruminants and pigs. As well as being strongly associated with poverty, FMD is also correlated with poor governance (Garabed *et al.*, 2008) (Fig. 4); these associations are self-perpetuating as FMD causes losses and limits livestock development at the farm and national level, this in turn limits the resources available to control the disease. Due to the transboundary nature of the disease, this impact is felt at the regional and even global level.

Fig. 7: Density map of foot and mouth disease susceptible species, i.e. cattle, pigs, sheep and goats (FAO, 2005)

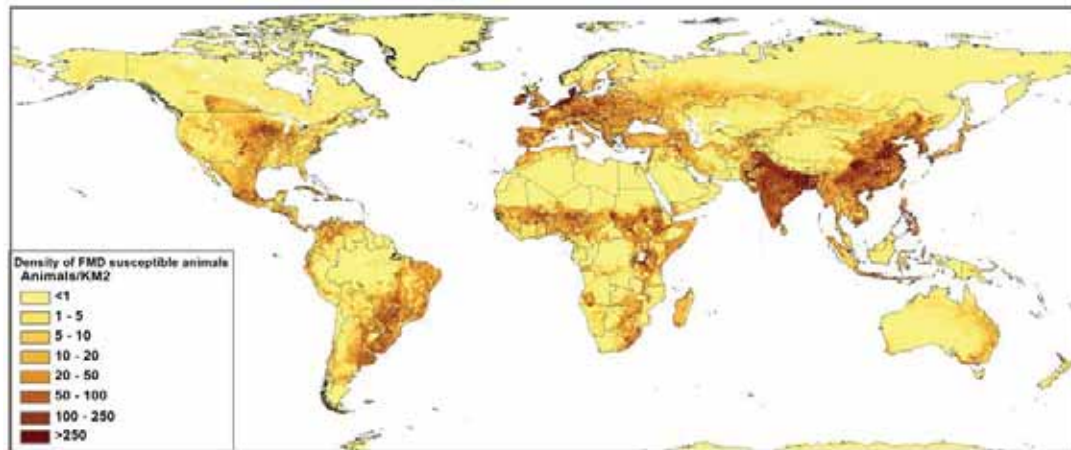
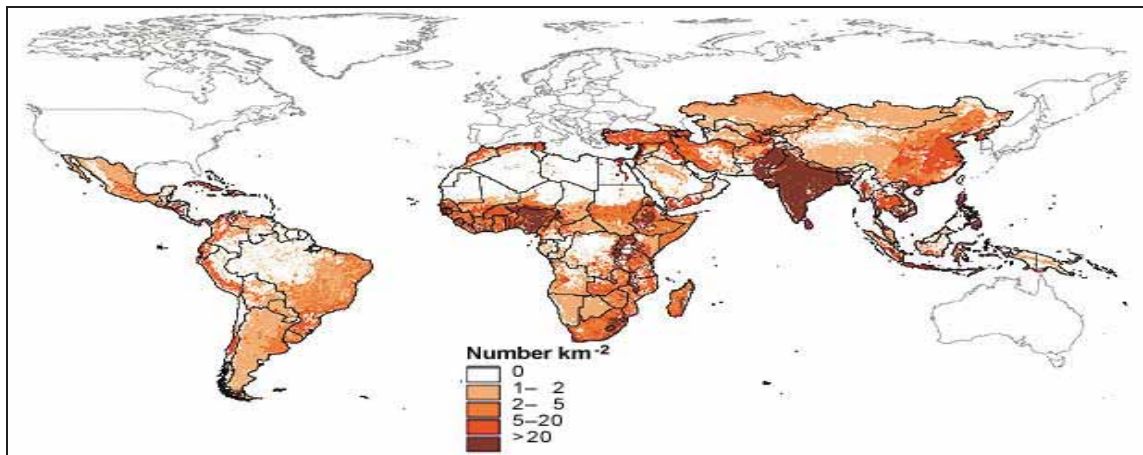
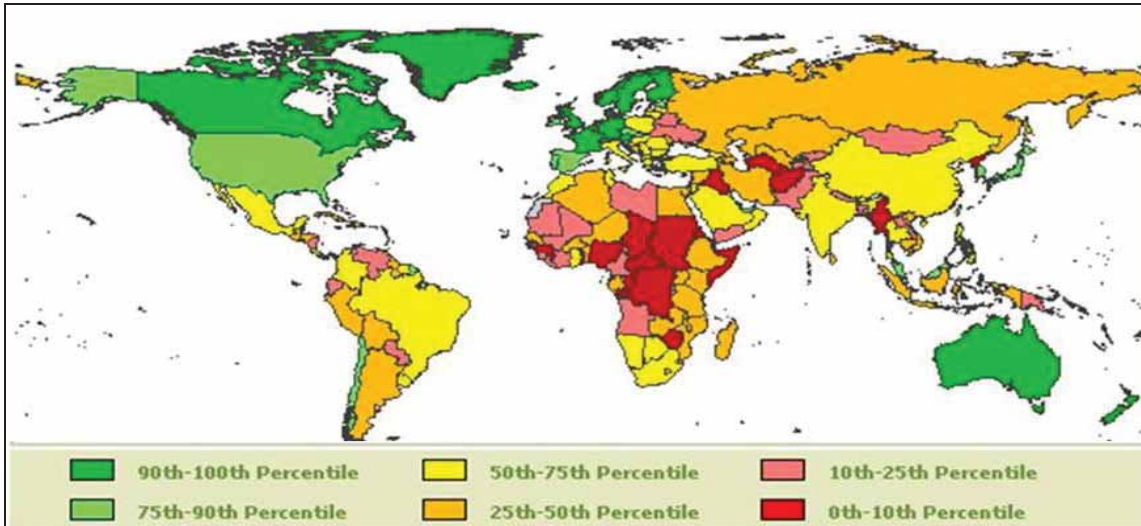


Fig. 8: Density map of the number of people living in poverty that are dependent upon livestock (Anonello, 2000?)



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Fig. 9: Nations categorised by their relative Government effectiveness, the most effective are shaded green (World Bank, 2011)



An individual livestock keeper cannot adequately control FMD by his actions alone, but also depends upon a collective effort from their neighbours and trading partners. The same is true for a country, effective FMD control requires global cooperation (Foreman *et al.*, 2009). Although the benefits of FMD control are experienced by all susceptible livestock owners, the disease affects some production systems more severely than others (Perry *et al.* 2003). Left to individual livestock owners, unequal incentives for FMD control will always lead to pockets where control efforts are very limited. This results in reservoirs of infection that can then re-infect areas where FMD control has been achieved. A recent example of this effect is in Southern Africa, where a break down in FMD control in Zimbabwe has been followed by FMD outbreaks in Botswana and South Africa causing the closure of valuable export markets.

The production and supply of livestock and livestock products involves complex market chains involving many different actors. Trading and moving livestock facilitates the transmission of diseases along these market chains, however, this process is essential for adequate provision of goods and for the income that it generates (Rushton, 2009). Nowhere is this better illustrated than through the export of live animals from Somalia to the Middle East. In 2010 over 4 million livestock were exported via this trade, in addition informal exports could number half as many again (Knight-Jones *et al.*, 2011). The trade is essential, about 55% of the Somali population depend directly upon livestock for a living (Abdirahman SOLICEP press) and there is a huge demand for these animals in the Middle East, particularly during the Islamic festival of Eid when 10 to 15 million sheep and goats are slaughtered in a short space of time. However, FMD frequently disrupts this trade, with the importing authorities rejecting whole ships carrying up to 200,000 animals if FMD is suspected. These animals do not return to Somalia however, but are unloaded elsewhere in the region further spreading disease in the wider region (Knight-Jones *et al.*, 2011) (see Fig. 4, Di Nardo, 2011).

A global estimate

The authors have made an estimate of the impact of FMD globally as of 2011. This focuses on the numbers of animals that have FMD and the associated losses in terms of death and production and the costs of control focussing on an estimation of vaccination and the costs of vaccine production and delivery.

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Numbers of animals affected

Based on FMD incidence estimates (Sumption *et al.*, 2008) and adjustments for under reporting an estimate was made on the number of animals affected by FMD on a year basis with the current control measures in place (see Table V).

Table V: Estimated number of animals infected with foot and mouth disease by species and region

Region	Cattle	Goats	Pigs	Sheep	Buffalo
China	2,805,782	2,469,838	10,965,121	2,346,703	90,993
India	5,912,399	2,162,590	2,313	1,117,811	411,047
Rest of Asia	3,549,507	2,454,426	659,516	1,174,235	174,213
Africa	7,402,839	4,149,367	3,450	3,269,222	219
Europe	108,177	28,825	33	120,708	86
Middle East	434,004	695,858	1	1,643,611	3,603
South America	380,282	11,712	176	37,029	62
Total	20,592,988	11,972,617	11,630,611	9,709,319	680,223

The numbers of animals was converted to livestock units to get an impression of the economic value of livestock affected on a yearly basis. It was estimate that 27 million livestock units are affected by FMD in a year with the current control measures in place. The worse affected regions in terms of absolute numbers are China, Africa and India (see Table VI).

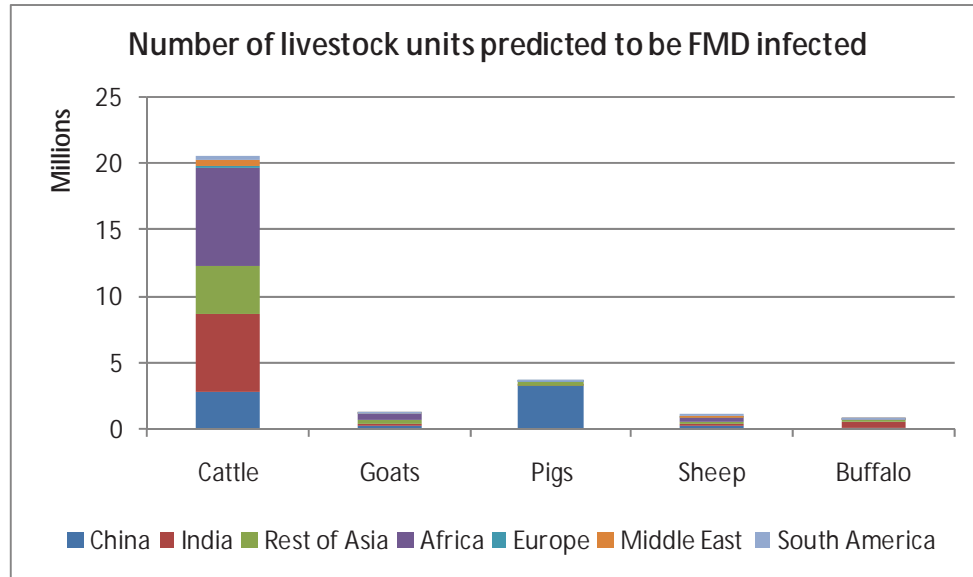
Table VI: Estimated Livestock Units infected with foot and mouth disease by species and region

Region	Cattle	Goats	Pigs	Sheep	Buffalo	Total	%
China	2,805,782	246,984	3,289,536	234,670	90,993	6,667,965	24.8
India	5,912,399	216,259	694	111,781	411,047	6,652,179	24.7
Rest of Asia	3,549,507	245,443	197,855	117,424	174,213	4,284,440	15.9
Africa	7,402,839	414,937	1,035	326,922	219	8,145,952	30.2
Europe	108,177	2,882	10	12,071	86	123,226	0.5
Middle East	434,004	69,586	0	164,361	3,603	671,554	2.5
South America	380,282	1,171	53	3,703	62	385,271	1.4
Total	20,592,988	1,197,262	3,489,183	970,932	680,223	26,930,588	100.0
%	76.5	4.4	13.0	3.6	2.5	100.0	

Three quarters of the livestock units affected by FMD are predicted to be cattle and 13% pigs. The impact on cattle is greatest in Africa, India, rest of Asia and China, whereas the impact of the disease in pigs is estimated to be greatest in China (see Fig. 7).

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Fig. 10: Estimated Livestock Units infected with FMD by species and region



In terms of the proportion of livestock affected we estimate that around 2% of the world’s cattle population has FMD in a year, but there are region differences with no animals affected in North and Central America, Australasia and the Caribbean and that China and India are the worst affected areas (see Table VII).

Table VII: Estimated proportion of the populations affected by FMD by region and species.

Region	Cattle	Goats	Pigs	Sheep	Buffalo
China	3.39	1.72	2.46	1.72	0.39
India	3.39	1.72	0.02	1.72	0.39
Rest of Asia	2.65	1.43	0.76	1.04	0.36
Africa	2.73	1.41	0.01	1.13	0.01
Europe	0.08	0.12	0.00	0.07	0.02
Middle East	3.15	1.47	0.00	1.55	0.39
South America	0.11	0.06	0.00	0.05	0.01
Global	1.78	1.45	1.42	1.02	0.37

Control costs – vaccination

Our estimates on vaccination have been based on the production of vaccine rather than an estimate of what vaccines need to be delivered to achieve vaccine strategies across the world. For example vaccine strategies are known for:

- South America – vaccination of cattle twice a year for animals under two years of age and once a year for animals greater than two years of age
- India – vaccination of cattle twice a year
- China – vaccination of cattle, sheep and goats twice a year with pigs vaccinated once a year.

Most other regions have no official policy on vaccination against FMD. Table 8 presents an estimation of the vaccinations across the world.

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Table VIII: Estimated foot and mouth disease vaccinations by country (based on Hamond, 2011) and the population targeted (based on author's consultations)

Region	Vaccinations		Species	Population targeted	
	Number	%		Population	% population
China	1,600,000,000	68.1	Cattle, shoats, pigs and buffalo	832,581,205	192.2
India	150,000,000	6.4	Cattle and buffalo	279,637,000	53.6
Rest of Asia	50,000,000	2.1	Cattle, pigs and buffalo	282,928,840	17.7
Africa	15,000,000	0.6	Cattle	271,502,418	5.5
Europe	15,000,000	0.6	Cattle	140,021,135	10.7
Middle East	20,000,000	0.9	Cattle and shoats	166,810,147	12.0
South America	500,000,000	21.3	Cattle	342,339,150	146.1
Total	2,350,000,000	100.0		2,035,788,464	115.4

The table indicates that estimated vaccination coverage for China and South America is close to achieving their strategy. However, India falls well short of vaccinating the population targeted twice each year.

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In summary FMD affects 27 million livestock units each year which is approximately 0.64% of the total livestock units globally. In attempt to minimise the economic losses of this disease 2.35 billion vaccines are produced and applied (see Table IX).

Table IX: Livestock units at risk and affected by foot and mouth disease and the number of vaccinations applied by region

Region	Livestock Units			Estimated vaccinations
	At risk	Affected		
		Number	%	
China	832,581,298	6,668,118	0.80	1,600,000,000
India	484,128,039	6,652,238	1.37	150,000,000
Rest of Asia	553,802,584	4,284,496	0.77	50,000,000
Africa	886,172,080	8,146,056	0.92	15,000,000
Australasia	69,850,904	0	0.00	0
Caribbean	10,580,360	0	0.00	0
Europe	517,722,541	123,228	0.02	15,000,000
Middle East	167,952,502	671,579	0.40	20,000,000
North America	172,838,710	0	0.00	0
South America	496,711,006	385,273	0.08	500,000,000
Total	4,192,340,024	26,930,988	0.64	2,350,000,000

The overall economic impact was calculated based on the costs of a vaccine and its application being US\$1 and that for any livestock unit affected by FMD it would cause a loss in production equivalent to US\$100. The latter estimate takes into account the death of an animal, loss in weight gain, milk production and draught power and is felt to be a conservative estimation. The total annual impact of FMD is calculated to be US\$5 billion (see Table X).

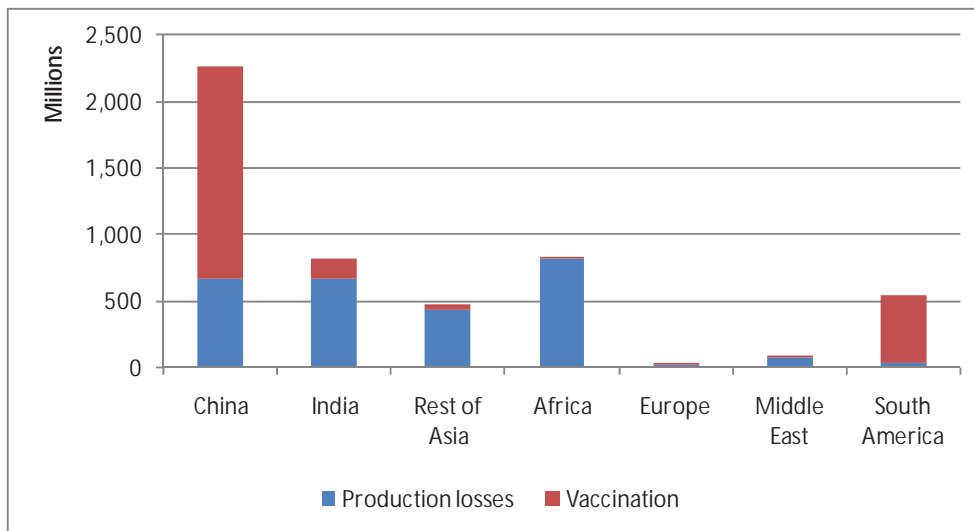
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Table X: Estimated annual impact of foot and mouth disease by region

Region	Impact		US\$	Total % LSU Value
	Direct impact Production losses	Indirect impact Vaccination		
China	666,811,784	1,600,000,000	2,266,811,784	0.54
India	665,223,780	150,000,000	815,223,780	0.34
Rest of Asia	428,449,598	50,000,000	478,449,598	0.17
Africa	814,605,600	15,000,000	829,605,600	0.19
Australasia	0	0	0	0.00
Caribbean	0	0	0	0.00
Europe	12,322,822	15,000,000	27,322,822	0.01
Middle East	67,157,897	20,000,000	87,157,897	0.10
North America	0	0	0	0.00
South America	38,527,315	500,000,000	538,527,315	0.22
Total	2,693,098,798	2,350,000,000	5,043,098,798	0.24

The majority of FMD impact occurs in China, India and Africa. Impact in South America is largely due to the costs of vaccination applications, a control measure to limit the production and trade losses this region would suffer if FMD was prevalent (see Fig. 8).

Fig. 11: Foot and mouth disease impact by region and by the type of cost



The impact estimated does not include the losses due to trade restrictions which are large at both local and international levels, but are difficult to estimate with any accuracy and tend to be very variable. It also does not take into account that the development of the livestock sector tends to be restricted by the present of FMD in terms of production system technology and breed advancement and investment slaughter, processing and marketing systems. Finally, there was no estimate in these calculations in terms of the costs of diagnostics and surveillance required to prevent and control FMD. Therefore US\$5 billion is likely to be a very conservative estimate of global FMD annual impacts.

Foot and mouth disease impact on the poor

Due to the importance of livestock to the world's poor, livestock disease control can cause significant poverty reduction. Pastoralist and agro-pastoralist communities are highly dependent upon livestock for milk, meat and as assets of economic and social value. A questionnaire based survey of African veterinary services found FMD to have the greatest impact on poverty of all the ruminant bacterial and viral diseases (Gall and Leboucq 2004). Livestock keepers living in poverty are particularly vulnerable to FMD. They live in countries which lack the veterinary services to control the disease and depend upon the use of common grazing and water facilities and markets where risk of infection is greatest. Furthermore, quality FMD vaccines are expensive, must be given repeatedly and must be kept refrigerated; this is not feasible for many livestock keepers.

Productivity losses are particularly hard hitting to those that depend upon their stock for traction, particularly where outbreaks in cattle occur during the planting season (Perry *et al.* 2003; Perry *et al.* 1999; Ellis and James 1976). The importance of reduced milk production is clear in commercial dairy operations, however, for many pastoralists milk provides a vital source of nutrition, particularly in children, accounting for over 50% of gross energy intake. By reducing the supply of milk FMD impacts on food security, particularly when outbreaks occur during the times of year when other food sources are limited and dependency upon milk is at its greatest (Barasa *et al.* 2008). Abortions due to FMD further limit milk supply by delaying the next lactation. A benefit-cost analysis found effective vaccination based control of FMD in agro-pastoralist communities of South Sudan could yield \$11.5 for every dollar invested.

Control is possible

Successful FMD control has not been restricted to wealthy countries. FMD freedom with vaccination has been achieved in large parts of South America and Southern Africa and elsewhere, e.g. recently the Philippines and Turkish Thrace (OIE 2011).

By and large control is achieved through widespread vaccination and outbreak control, incorporating movement restrictions with or without culling. Having an effective state veterinary service is Key to coordinating such a zonal or national control programme. The veterinary services must be competent in several different areas, specifically, disease surveillance, outbreak control with the necessary authority and support required to enforce some level of movement restrictions, additionally they must be able to supply and deliver quality vaccines to huge numbers of animals. Support and collaboration with livestock owners is required, in some cases vaccine is even provided to the livestock owners who then vaccinate the animals themselves.

The case of Uruguay emphasises the benefits of FMD disease control, particularly if it allows export markets to open up. Upon gaining free status without vaccination in 1996 the value of exports increased by over 50%, providing an added \$120 million of revenue to the country through exports to America and the Pacific rim (Otte *et al.* 2007). Saving of \$8 to 9million per year were initially made via avoided vaccination costs, however, vaccination was re-introduced due to the threat of infection from neighbouring countries (Sutmoller 2003).

Unlike Uruguay, many countries are not in a position to benefit from export markets even if FMD was eradicated. In any case, lack of both veterinary infrastructure and an organised livestock sector are major barriers for FMD eradication in many countries. However, there are still very strong incentives to control the disease, they include:

1. improved food security through improved livestock productivity
2. stabilised trade; FMD disrupts trade even between non-FMD free countries and regions

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3. focussed efforts to control FMD would incorporate improving state veterinary services. A veterinary service that could control FMD would be competent to control many other livestock diseases such as. Peste des Petits Ruminants, Contagious Bovine PleuroPneumonia and Brucellosis that are often controlled by the same measures, such as movement restrictions, vaccination and outbreak control
4. countries that can export struggle to control FMD adequately without similar control in neighbouring countries. These neighbouring countries may have fewer incentives for control even though the region at large benefits. FMD control can be both an externality, with benefits not captured by the market, and a regional or global public good, as the reduction in risk of FMD is also experienced by countries other than ones controlling the disease; external funding and cooperation is therefore required.

A key issue will be to what extent will vaccination alone control FMD in very poor countries unable to implement other aspects of control? Global Rinderpest eradication was achieved under such conditions, showing that vaccine delivery is possible even in remote areas. But rinderpest was a very different disease with a heat stable vaccine where a single dose gave lifelong immunity. Any global FMD control strategy would have to address the following:

1. can refrigerated FMD vaccines be delivered two to three times a year to large numbers of animals (FMD vaccine immunity is short lived)?
2. to what extent does vaccination reduce losses in productivity and how does this increase in productivity compare to vaccination costs?
3. which species should be included for cost-effective vaccination, just cattle or sheep and pigs as well?

Regardless, with adequate veterinary services the available methods for controlling FMD have repeatedly proven effective even in extensive mixed species production systems.

Cost benefit analyses studies of foot and mouth disease control and eradication

The literature was searched for all the cost benefit analysis studies that have been carried out around the world. There has been no study carried out for a global strategy for FMD control and eradication, but just over 30 country and region studies have been published in the peer reviewed and grey literature. A large number of these are ex post evaluations after large outbreaks in previously free countries. Countries that are free and have concerns of getting disease have also carried out a number of studies based on simulations of disease, control response and impacts on the economy. Finally there are set of studies looking at the analysis of the control of FMD in countries have the disease and are looking at investment for control. The major findings from all these evaluations are:

- control programmes in countries previously free generate positive returns to the economy
- countries free from FMD that suffer an outbreak lose between 0.6% to 0.3% of their GDP
- in countries with international trade in livestock and livestock products the control of FMD has good economic returns
- in countries with limited or no international trade in livestock and livestock products a positive return on FMD control requires targeted programmes

There has been very limited work carried out on the economic analysis of farm-level control of FMD, an important consideration in the success of disease control. Ellis and James (1976) and Bulman and Terrazas (1976) both indicate high impact of FMD and positive returns to its control for dairy systems in India and

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Bolivia, respectively. Rushton *et al.* (2002) indicate that FMD in the UK would have high impact in dairy and pig systems, but limited or no impact on sheep and beef systems. For Bolivia a study indicated that there was no positive return to farm-level control of FMD with preventive vaccination (Rushton, 2008).

Table XI: Cost benefit analyses studies of foot and mouth disease control and eradication programmes

Country/region	Export potential	Returns to control	Type of analysis	Author
Australia	Large	A six month outbreak would reduce GDP by 0.6%	Simulation	Garner <i>et al.</i> (2002)
Australia	Large	Overall losses to the national economy of \$2-3billion or \$8-13billion can be expected depending on outbreak length. Emergency ring vaccination may be appropriate	Simulation	Productivity commission, (2002)
Bhutan	Nil	Negative if the control is unfocused. Positive if the control is focused on endemic areas	Data analysis	Pasang (1995)
Bolivia	Small	Negative, but the analysis was based on a prolonged programme and also on reliable data	Data analysis	FAO (1995)
Bolivia	Small	Positive, but with an short intensive vaccination campaign in the endemic areas	Data analysis	PANAFTOSA (1997)
Bolivia	Small	Positive, but control of FMD is not economic for extensive systems, hence, greater public funding is required	Data analysis	Rushton (2008)
Botswana	Large	Positive with exports, negative without exports	Data analysis	Oarabile (1994)
Canada	Large	Even a small outbreak could cost \$2billion over 5 years	Simulation	Krystynak & Charlebois (1987)
France	Large	Rapidly regaining export market access is key, this is best achieved by stamping out	Simulation	Mahul & Durand, (2000)
Great Britain	At the time of the analysis small	Positive for both a stamping out policy and for vaccination	Data analysis	Power and Harris (1973)
India	Small	Positive due to the large returns in the milk sector	Data analysis	Ellis and James (1976)
Netherlands	Large	Culling is preferable in areas of low livestock density, vaccination is preferable areas of high density. Market acceptance of products from FMD vaccinated animals reduces the impact of an outbreak	Simulation	Backer <i>et al.</i> (2009)
Netherlands	Large	The 2001 FMD outbreak cost the nation €1billion	Data analysis	Huirne <i>et al.</i> (2002)
New Zealand	Large	An outbreak could cost \$NZ10billion, with eradication by slaughter being preferable to vaccinate to live	Simulation	Belton (2004)
Philippines	Unknown	Positive, particularly benefiting the commercial pig sector	Data analysis	Randolph <i>et al.</i> (2002)
Sudan	Nil	Positive with increased food security	Data analysis	Barasa <i>et al.</i> (2008)
Southern Cone	Large	Positive for both culling and vaccination strategies, does not deal with social impacts and feasibility of implementation	Data analysis and simulation	Rich & Winter-Nelson, 2007)
Taiwan	Large in terms of exports of pig products to Japan	Returns according to the information on eradication are large with costs of eradicating 1997 outbreak estimated to be US\$ 378.9 million, but with potential export losses of approximately US\$ 1.2 billion	Data analysis	Yang <i>et al.</i> (1999)
Taiwan	Large	Losses due to the 1997 FMD outbreak were experienced in many sectors, causing a 0.28% loss to GDP	Data analysis	Harel <i>et al.</i> (2005)

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Country/region	Export potential	Returns to control	Type of analysis	Author
Thailand	Possible	Positive with or without export of livestock products	Data analysis	Perry <i>et al.</i> (1999)
Turkey	Unknown	Culling certain highly susceptible cattle could be viable	Data analysis	Senturk & Yalcin, (2008)
United Kingdom	Large	Whether vaccination or culling only depended on other factors, such as outbreak size	Simulation	Risk solutions, (2005)
United Kingdom	Large	Vaccination may not be the most effective way of controlling an outbreak, however, speed of regaining export market access is not the only consideration	Data analysis	Rushton <i>et al.</i> (2002)
United Kingdom	Large	GDP fell by less than 0.2% due to the 2001 FMD outbreak	Data analysis	Thompson <i>et al.</i> (2002)
USA	Large	Vaccination based eradication provides the best return if the vaccine is effective	Simulation	Bates <i>et al.</i> (2003)
USA, California	Large	Delayed detection of incursions causes massive losses	Simulation	Carpenter <i>et al.</i> (2011)
USA	Large	A large FMD outbreak could lead to \$14billion loss in farm income, with loss of exports and fall in demand due to consumer fears the major factors	Simulation	Paarlberg <i>et al.</i> (2002)
Uruguay	Strong	Strong positive returns based on the access to important export markets	Data analysis	Leslie, <i>et al.</i> (1997)
Zimbabwe and Southern Africa	At the time of analysis strong	Positive benefit, particularly for commercial farms, less so for the poor	Data analysis	Perry <i>et al.</i> (2003) Randolph, <i>et al.</i> (2005)

Conclusion

Wealthy countries that have eradicated FMD (see Fig. 1) face ongoing costs from periodic outbreaks and the costs of being prepared to rapidly detect and deal with these outbreaks via means of movement controls, culling and/or vaccination. Many countries reduce the impact of the disease with extensive ongoing or intermittent vaccination programmes, the global scale and costs associated with these programmes is vast with an estimated 2.6 billion doses administered annually (Hamond, 2011).

The impact of FMD in endemic countries has received less attention than the impact of outbreaks in free countries, despite the huge numbers of animals affected by the disease and the importance of livestock to the economies of endemic countries. Direct losses due to death and disease are easy to appreciate, however, in endemic countries the burden of FMD often manifests as widespread and ongoing losses that limit development opportunities for developing the livestock sector.

Overall the production losses and the application of FMD vaccines around the world are causing an annual impact of US\$5 billion, with additional costs on restrictions on trade and adoption of improved technologies across the livestock sector. FMD affects livestock all around the world particularly those in poor countries. In many places little is done to control FMD largely due to a lack of resources and a failure to recognise the benefits that control brings. FMD prevents agricultural development and reduces food security, in many countries it leads to massive losses due to control costs and in some cases by limiting export market access.

These estimates are considered to be of a very conservative nature as the Government of India (2002, 2006) state that Foot and Mouth Disease (FMD), the direct loss due to milk and meat is estimated at Rs. 20,000

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crores per annum. Indirect losses due to reduced work capacity abortions, subsequent infertility and sterility (that account for the reduced milk production subsequently) have not been quantified (ICARs Task Force Report, 2005). For these losses in India alone, not considering any control costs, sum to US\$4.8 billion.

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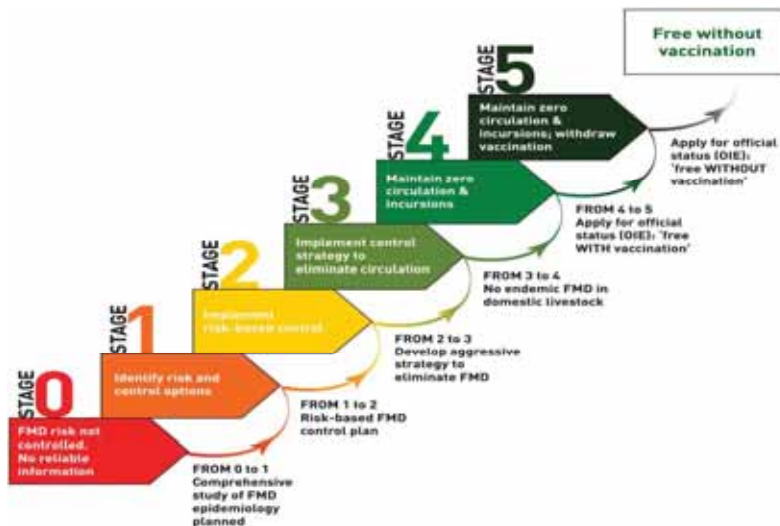
Supporting document N°2

The progressive control pathway for FMD control
(PCP-FMD)

Principles, stage descriptions and standards

The Progressive Control Pathway for FMD control (PCP-FMD)

*Principles, Stage Descriptions and Standards**



* Accompanying explanatory documents will address specific items such as laboratory support and PVS pathway.

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I. PCP-FMD Principles and Application

The Progressive Control Pathway for Foot and Mouth Disease (**PCP-FMD**) has been developed by FAO to assist and facilitate countries where FMD is still endemic to progressively reduce the impact of FMD and the load of FMD virus. The PCP-FMD has been adopted by FAO as a working tool in the design of FMD country (and some regional) control programs, and following appropriate consultation it has become a joint FAO/OIE tool. The PCP-FMD is expected to form the backbone of the **Global FAO/OIE Strategy for the Control of FMD** that is under development. Countries usually free of FMD that detect an incursion of the disease would normally not enter the Pathway, but rather would act to eradicate the disease and re-apply directly to the OIE for re-instatement of an officially recognized FMD-free status as soon as possible. The possibility that OIE could “endorse” a country’s national FMD control program at the higher Stages of the PCP is under consideration and a positive decision by the OIE specialist commissions and the OIE World Assembly of OIE delegates is foreseen.

The PCP-FMD is a set of FMD control activity stages (*Figure 1*) that, if implemented, should enable countries to progressively increase the level of FMD control to the point where an application for OIE-endorsement of a national control programme vaccination (in an advanced phase of **Stage 3**) or official freedom from FMD with or without vaccination (end of Stages 4 and 5, respectively) may be successful and the status sustainable.

A. PCP Principles

The PCP approach is based on the following principles:

- active monitoring for FMDV circulation and understanding the epidemiology of FMD are the foundation of a control program, and therefore activities to meet these requirements are common in all stages. The improved information generated is of benefit nationally and regionally. The monitoring of outcomes (indicators of control effectiveness), within a national FMD management system, is included at the higher stages;
- activities in each PCP stage are appropriate to the required reduction in virus circulation and mitigation of disease risk to be achieved;
- activities and their impacts are measurable in each Stage, comparable between countries, and generate information and potential benefits to national as well as international stakeholders;
- the optimization of resource use for FMD control is achieved through the targeting of measures to the husbandry systems and critical risk points where the impact on disease control and/or virus circulation will be greatest.

B. Expected progression and monitoring achievements along the PCP and beyond

The PCP is not intended to be prescriptive; rather it is outcome-oriented and acknowledges that the most effective approach to achieve the key outcomes might be different in different countries and regions. It is also recognised that priorities will vary across countries, and therefore there is flexibility built into the PCP. Within the lower stages, countries may choose to focus control measures on certain livestock sector(s), and throughout the PCP each country can decide how quickly and how far it progresses. Eventual progression to **Stage 2** is the logical goal of countries that embark on **Stage 1**.

However, countries may decide not to progress further than **Stage 2** or 3, both of which provide sustainable management of FMD to a certain level. Moving to **Stage 4** would almost certainly

indicate the intention to attain officially recognised FMD 'free with vaccination' status or directly strive for the status of FMD- 'free without vaccination' for all or part of the territory. In **Stage 5**, countries may decide to keep vaccinating and not progress to 'free without vaccination' status.

C. Assessment of progress

An evidence-based, transparent assessment procedure that is carried out according to quality standards that are uniform across the world should be applied on a yearly basis to determine each country's status within the PCP. The countries being assessed must be able to provide clear evidence of the activities performed and progress achieved towards the key outcomes of the PCP.

Although the assessment and resultant Stage assignment would be done on an individual country basis, countries within a region would preferably be assessed concurrently, ideally at a yearly regional meeting. The opportunity for countries to cross-examine progress at regional level should be fostered as it is an essential platform which will encourage greater transparency and accountability for progress, and where common regional problems may be addressed. Such regional interaction and transparency should also encourage the transition to greater use of FMD monitoring to inform disease management as well as improve the identification of preventive actions (such as harmonised vaccine selection/standards or vaccination protocols). The assessment procedure is an opportunity not only to assess and recognize progress, but also to identify areas for improvement and needs for assistance.

The formal assessment procedure will utilize the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) in which FAO and OIE cooperate. The key body in the assessment process will be the Global FMD Working Group (FMD-WG) that reports to the Global GF-TADs Steering Committee and the GF-TADs Management Committee. The FMD-WG

will be assisted by the joint (FAO/OIE) Secretariat based in Rome, which will be charged with the daily work.

For continuation along the pathway Stages 1 to 4, countries should provide information on the implementation of the PCP-FMD, in principle on a yearly basis. The FMD-WG will provide a template questionnaire to all countries participating in the PCP-FMD to enable the countries to deliver the information requested in a standardized way.

The PCP-FMD technical assessments will be carried out by experts who may belong to the FMD-WG or Secretariat, or be appointed by and operate under the responsibility of the FMD-WG. Country visits of experts will be undertaken if this is requested by the country or considered necessary to verify the country information provided. The FMD-WG may also field experts to assist during relevant regional PCP-FMD meetings to ensure global coherence and equivalence of PCP stages. The FMD experts will be selected from a list of experts agreed by FAO and OIE.

The reports and recommendations of the experts will be presented to the FMD-WG. The FMD-WG will be responsible for the communication with the individual countries regarding PCP-FMD issues. The FMD-WG will report on the progress of the implementation of the Global FMD Control Strategy on the national, regional and global level to the GF-TADs Global Steering Committee and Management Committee on a yearly basis. This report should contain individual country PCP classification proposals. The decision of the GF-TADs Steering Committee (maintaining the stage, downgrading or upgrading) will be communicated to the country concerned. The country will then have a GF-TADs-supported PCP Stage assignment.

The FMD-WG will maintain close links with the Regional GF-TADs Steering Committees. It is recognized that the Regional GF-TADs Steering Committees should be closely involved in the PCP process since they play an important role in supporting the Global FMD Control Strategy through advocacy and by solving constraints. A briefing on the progress of the FMD-PCP in their region should be part of the agenda of each GF-TADs Regional Steering Committee meeting.

Once a country has entered the GF-TADs-supported PCP-**Stage 3** and has decided it wants to continue along the pathway to **Stage 4** and beyond, implying the intention to eradicate FMD

virus from the domestic animal population, it may ask for OIE-endorsement of its national FMD eradication programme. The procedure for endorsement may be obtained from OIE.

Progression from **Stage 4** to 5, and from **Stage 5** to Pathway completion, would be through the existing official OIE recognition processes of freedom from FMD with or without vaccination, respectively.

Within the country, different areas might attain different levels of FMD control. This is reflected in the PCP through the principle of 'zoning', in which different PCP Stages might be assigned to distinct geographic areas (called zones) within a country. Because the early PCP Stages focus on a general understanding of FMD risk and control within particular livestock sectors, the concept of zones of higher FMD control level within a country usually only applies to PCP Stages 3 and higher. In some exceptional situations, zoning might be applied in **Stage 2**, for example if targeted control is only applied to dairy cattle within one area of the country. In order to consider a geographic area as a 'zone' within the PCP, the country must provide convincing, evidence-based rationale for the decision. The zoning structure should take into account the structure of the livestock industry including animal movement patterns at a national and regional / international level and fulfil the corresponding OIE Terrestrial Animal Health Code regulations.

Since progression from **Stage 3** to **Stage 4** requires evidence that FMD virus is not circulating endemically in the domestic animal population of a country or zone, countries may well use **Stage 4** designation as a means to enable safer trade. It should be noted, however, that **Stage 3** and the beginning of **Stage 4** are not associated with any official OIE recognition of disease-free status. However, since the PCP assessment process is carried out transparently and to high standards and once the national eradication programme is endorsed by OIE, countries may benefit in preparing trade agreements.

D. PCP and alignment with current regional FMD Control initiatives

In some regions, there are already existing bodies and programs established to promote and harmonize regional FMD control efforts. The main examples are the EuFMD Commission, involved with the European neighbourhood and the West Eurasia Roadmap, the 2020 Roadmap for Foot and Mouth Disease Control in South-East Asia and China (SEACFMD) and the Plan Hemisférico de Erradicación de la Fiebre Aftosa (PHEFA) for South America. The PCP is intended to assist those regions without such current programmes, but could also be used in relation to the current regional programs by the GF -TADs Steering Committees to report on the regional progress. The concepts and assessment indicators may also have their application within these existing programmes, for example to progress towards the development of control zones as used in some regions and improved understanding of critical control points as well as risks.

II. PCP and stakeholders

It is fully recognized that true progress in FMD control is not feasible without the support of the owners of the animals and the other stakeholders in all steps from production to marketing. Therefore strong and continuous efforts will have to be made to get and maintain such support. Particularly for the higher stages of the PCP-FMD pathway, evidence that the national FMD Control Plan is backed by stakeholders will be necessary for a proper assessment of what has been achieved and the potential sustainability thereof.

III. PCP and use of information

The gathering of data in the framework of the FMD-PCP is subject to the privacy rules of FAO and OIE.

Countries taking part in the PCP accept that the data they provide will be used by FAO and OIE and their experts for an assessment to classify the country in one of the PCP-FMD Stages. The result of this process is in the public domain and will be published on the website of the FMD-WG. The underlying data, however, will not be freely available unless agreed to by the country concerned.

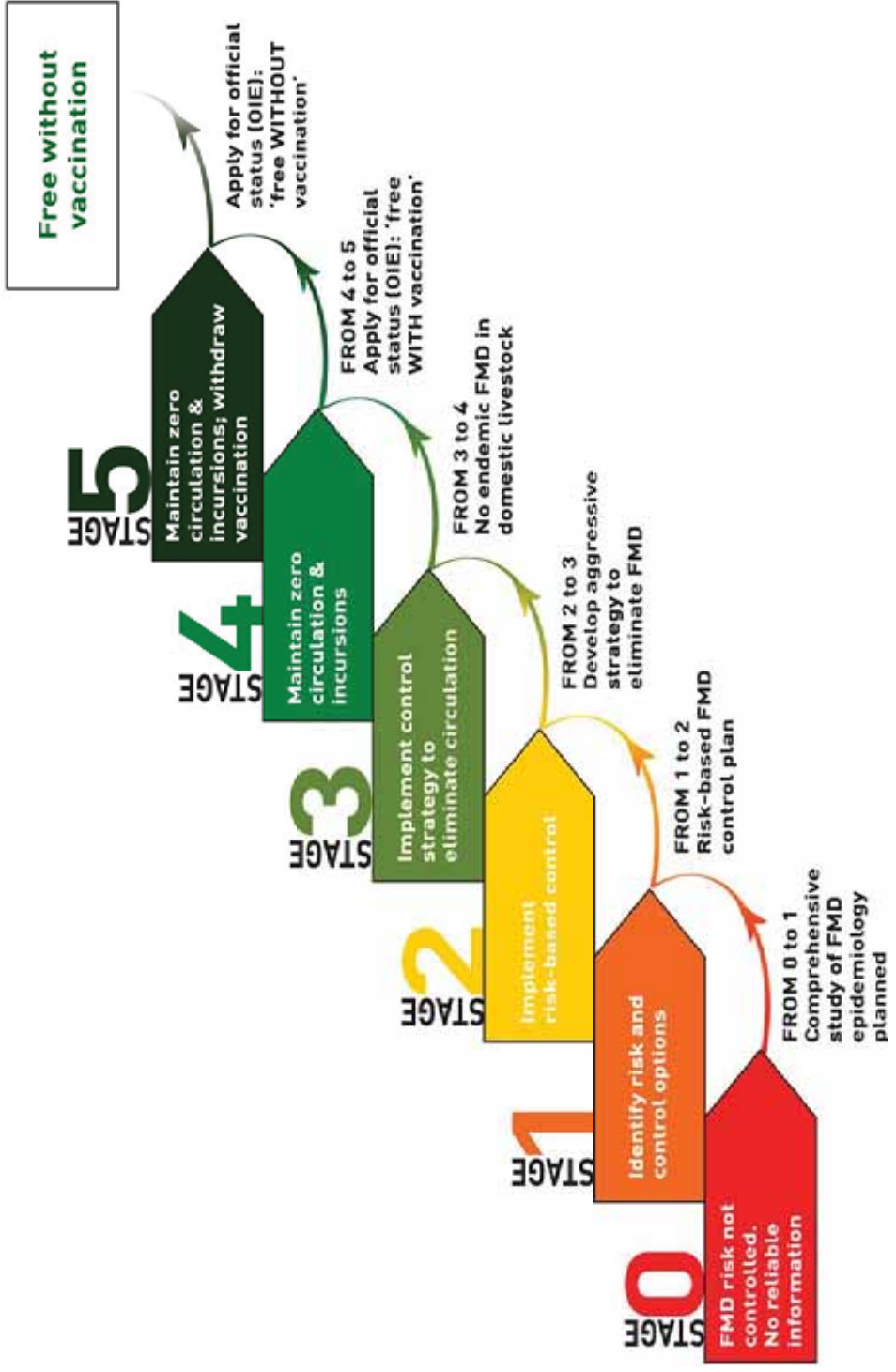


Figure 1: Stage progression in the Progressive Control Pathway

(1) Once in this stage, a country may apply for OIE-endorsement of its national FMD programme, provided its strategy objective has moved from control to eradication (see page 4)

IV. PCP Stage Description and Minimum Standards¹

The PCP stages are summarized in Fig. 1 and described below. The ‘Stage Focus’ represents the usual overall objective or aim of the stage, and the numbered points outline the ‘key outcomes’ necessary to achieve that aim. Countries are able to decide for themselves how far, and how fast, it is appropriate for them to progress along the PCP. The Stage Focus therefore does not necessarily assume that a country will progress to the next stage.

In order to be placed in a Stage, the country must have achieved all of the key outcomes from the previous Stage, *plus* have met the minimum requirement for inclusion in the current Stage as specified below. Completion of a Stage depends on the attainment of a specific ‘indicator’ outcome that the country is ready to move to the next Stage. The indicator for each Stage is described in Fig. 1.

The PCP approach is not intended to be prescriptive and particularly in the lower Stages it is usually possible to realise the key outcomes through different activities or combinations of activities. Therefore, ‘typical activities’ are listed below each key outcome, along with a description of ‘quality indicators’ that are intended both to better define the key outcome, and also to facilitate the transparent assessment of achievement of each outcome. It is essential to address all of the key outcomes to fully complete the Stage and progress to the subsequent Stage.

¹ *Explanatory Notes about the re-defined PCP stages: A Consultative Group meeting was held at the WRL FMD from 4-6 October 2010, in which the definitions and criteria for the PCP stages were reviewed. As a result of this meeting, it became clear that Stage 4, previously called “Freedom from FMD with vaccination’ would more appropriately be described as “Working towards recognition as free with vaccination’’, with the official recognition of ‘Freedom with Vaccination’ marking the division between stages 4 and 5. During Stage 5, the country maintains the official ‘Freedom with vaccination’ status, and may decide to go further and prohibit vaccination and apply for “Freedom without vaccination’’. The awarding of this status also marks the end of the PCP, and ‘automatic graduation’ from Stage 5.*

Stage 1:

- **STAGE FOCUS: “To gain an understanding of the epidemiology of FMD in the country and develop a risk-based approach to reduce the impact of FMD ”**
- **Minimum requirement for inclusion in Stage 1:** There is a comprehensive plan in place to gain insight into the epidemiology and socio-economic impacts of FMD in the country, and results are available from activities working towards Key Outcomes 1 & 2 below.
- **Key Outcomes:**
 1. All husbandry systems, the livestock marketing network and associated socio-economic drivers are well described and understood for FMD-susceptible species (value-chain analysis).
 - *Quality indicators:* This should include an overview of all systems involving FMD susceptible species from input suppliers, through producers of animals, to the marketing system, processors and consumers. Importation of relevant animals and animal products as well as movements of animals associated with transhumance or nomadism should also be described. As these are dynamic processes, the information available should be regularly reviewed and updated.
 - *Typical activities:* Participatory rural appraisal, stakeholder consultation workshops, analysis of existing data.
 2. The distribution of FMD in the country is well described and understood and a ‘working hypothesis’ of how FMD virus circulates in the country has been developed.
 - *Quality indicators:* It is important that all regions of the country and all husbandry systems involving FMD-susceptible species are considered at this stage. Because the FMD situation can change rapidly, the information made available should be current (i.e. collected within the previous 12 months). The information should provide indications of the spatial and temporal distribution of

FMD and normally should include, in addition to monitoring based on clinical signs, a serological survey designed² to identify differences in risk between animal populations or production systems and which can act as baseline for future monitoring.

- *Typical activities:* Passive and/or active FMD monitoring system, serological survey to assess prevalence of FMD in different husbandry systems, participatory epidemiology studies, risk assessment including description of risk pathways to identify important risk hotspots for FMD transmission, where appropriate including wildlife.
3. Socio-economic impacts of FMD on different stakeholders have been estimated.
- *Quality indicators:* A complete economic impact assessment is not expected at this stage, but the different types of losses should be described and the impact of at least direct losses in key husbandry systems due to FMD should be estimated.
 - *Typical activities:* Analysis of secondary data, key informant interviews, primary data collection and analysis.
4. The most common circulating strains of FMDV have been identified.
- *Quality indicators:* Samples should be representative of different production sectors and geographic regions. Because the FMD situation is constantly evolving, samples should be collected and analysed regularly over time.
 - *Typical activities:* Sampling and laboratory testing for FMDV, ship samples regularly to an International reference Laboratory for virus characterization.

² In accordance with the PCP Stage Monitoring and Surveillance Guidelines [GCF - Ref: ...]

5. There has been progress towards developing an enabling environment for control activities.
 - *Quality indicators:* This is important if the country plans to progress to **Stage 2** of the PCP. In **Stage 1**, FMD should be a notifiable disease and reporting of suspect cases should not be discouraged.
 - *Typical activities:* Training as needed to support field and laboratory activities, develop information system to support field activities, outbreak reporting and decision making, assess effectiveness of legal framework to allow the Veterinary Services carry out FMD control activities.
6. The country demonstrates transparency and commitment to participating in regional FMD control.
 - *Typical activities:* Outbreaks notified to OIE, participate and share results of PCP activities at regional level, e.g. Regional Roadmap meeting.
7. Important risk hotspots for FMD transmission are identified.
 - *Quality indicators:* The analysis should use information in relation to key outcomes 1 and 2 above. The hotspots should be prioritised and gaps in knowledge that are required to effectively mitigate the risk of FMD entry/spread identified.
 - *Typical activities:* Analysis of data about the epidemiology of FMD and husbandry systems and, when data allow, conduct a preliminary risk assessment to identify critical points for FMD entry and spread.

➤ **AND TO PROGRESS TO STAGE 2**

8. A strategic FMD control plan that has the aim of reducing the impact of FMD in at least one zone or husbandry sector is developed.
- *Quality indicators:* The plan should be endorsed by the government veterinary authorities and clearly based on the risks identified through other **Stage 1** PCP activities.
 - *Typical activities:* 'Risk hotspots', defined as points in the production system and marketing network where there is a high risk of FMD entry and/or spread, should be identified. Control measures to mitigate the risk at these points are selected on the basis of both their feasibility and expected impact. Risk assessment techniques, particularly the description of risk pathways, will be useful to accomplish this.
 - This is required for the country to progress to **Stage 2**.

Stage 2:

- **STAGE FOCUS:** "To implement risk based control measures such that the impact of FMD is reduced in one or more livestock sectors and/or in one or more zones "
- **Minimum requirement for inclusion in Stage 2:** Completion of previous Stage, and results are available from activities working towards Key Outcomes 1 & 2 below
- **Key Outcomes:**
 1. Ongoing monitoring of circulating strains and risk in different husbandry systems.
 - *Quality indicators:* The country should maintain activities described in **Stage 1**, with data and analysis updated as required to keep the information current. Additionally, critical gaps in understanding should be identified and filled, with particular emphasis on acquiring knowledge that could assist in more effective implementation

of control measures. Thus, the understanding of both the epidemiology of FMD in the country and feasible mitigation options are progressively enhanced.

- *Typical activities:* As for **Stage 1**, plus targeted research studies implemented to address gaps in knowledge (e.g. targeted serological surveys, active surveillance, participatory epidemiology studies, risk assessments etc); awareness and communication.
2. *Risk-based control measures* **are** implemented for the sector or zone targeted, based on the FMD strategic control plan developed in **Stage 1**.
- *Quality indicators:* Control efforts should be targeted at critical risk control points, and will most likely include *both* vaccination and enhanced biosecurity measures.
 - *Typical activities:* The development of vaccination delivery mechanisms and cold chain, introducing measures at markets to reduce transmission of FMD, enhancing awareness of FMD transmission mechanisms and behaviours that can interrupt transmission, improving border controls, movement controls, implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved, and marketed through the country or region).
3. It is clearly established that the impact of FMD is being reduced by the control measures in at least some livestock sectors and /or zones.
- *Quality indicators:* It is important to demonstrate both that control measures are being appropriately implemented, and also that they are achieving the desired impact.
 - *Typical activities:* Serological surveys to assess vaccination coverage of the target population(s), laboratory evidence that the vaccine used is appropriate for circulating strains of virus, analysis of surveillance data to assess the change in FMD prevalence over time in the target population(s), assessment of control measures

(cost effectiveness, degree of implementation, impact), outbreak investigation of selected outbreaks (including some outbreaks that have occurred despite control measures), documented inspections showing compliance with biosecurity and hygiene requirements.

4. *There is further* development of an enabling environment for control activities.
 - *Quality indicators:* The legal framework should ensure that control and surveillance activities can be carried out, there should be evidence that the country is committed to developing an effective and sustainable control program.
 - *Typical activities:* As for **Stage 1 plus** assess legal framework and operational capacity of veterinary services and revise as needed to allow activities such as vaccination and outbreak investigation (e.g. rights to enter premises, examine animals, collect samples and question owner), diversification of vaccine delivery mechanisms such as development of Public Private Partnership (PPP), further development of the information system to include geo-referenced data for *analysis and mapping, introduction* and enforcement of necessary regulations to mitigate risk of disease transmission associated with movement and marketing of animals (e.g. regulations on markets and transporters).

AND TO PROGRESS TO STAGE 3

5. A revised, more aggressive control strategy that has the aim of eliminating FMD from at least a zone of the country has been developed
 - *Quality indicators:* This plan should be endorsed by the government veterinary authorities. The plan should contain provision for rapid detection of and response to outbreaks in order to limit the spread of infection.

- *Typical activities:* Development of contingency and emergency preparedness plans. Compared to the control strategy implemented during **Stage 2**, this strategy is more aggressive. The plan should address the requirement that disease should be rapidly detected whenever and wherever it occurs and every outbreak should trigger a response to limit the onward spread of FMDV. The focus moves from control in a key livestock sector or zone, to elimination of FMD in all susceptible livestock in the country or zone.
- This is required for the country/zone to progress to **Stage 3**.

Stage 3:

- **STAGE FOCUS:** “Progressive reduction in outbreak incidence followed by elimination of FMDV circulation in domestic animals in at least one zone of the country”. **Minimum requirement for inclusion in Stage 3:** Completion of previous Stage, and results are available from activities working towards Key Outcomes 1 & 2 below.
- **Key Outcomes:**
 1. Ongoing monitoring of circulating strains and risk in different husbandry systems.
 - *Quality indicators:* Enhanced understanding of risk is applied to progressively eliminate the impact of FMD in domestic animals through the effective use of available control options.
 - *Typical activities:* The country should maintain activities described in Stages 1 and 2, and analyse the resulting data to ensure that control measures are feasible and effective. Further, control measures should be changed or refined if they are not as effective as expected.

2. The disease control plan developed at the end of **Stage 2** is implemented, resulting in rapid detection of, and response to, all FMD outbreaks in at least one zone in the country.
 - *Quality indicators:* Compared to the control strategy implemented during **Stage 2**, this strategy is more aggressive and the focus moves from a key livestock sector or sectors to include all susceptible livestock in the country or zone. In this Stage countries may request formal OIE endorsement of their national FMD control programme.
 - *Typical activities:* As for **Stage 2** control activities, plus enhanced focus on disease reporting and response – e.g. public awareness campaigns, provision of reporting incentives, free phone lines etc. Every outbreak should trigger a response to limit the onward spread of FMDV (culling of infected livestock, tracings, movement restrictions, tactical [e.g. ring or other barrier] vaccination). Full epidemiological investigations into all outbreaks should be carried out, generating full reports that specifically address the source and spread (spatial, temporal) of infection and develop conclusions as to the most likely mechanisms of disease transmission responsible.
3. The incidence of clinical FMD is progressively eliminated in domestic animals in at least a zone in the country.
 - *Quality indicators:* Credible epidemiological evidence that FMD virus is progressively being eliminated in domestic animals and that control measures are effectively reducing the risk of the incursion and/or spread of FMD from wildlife or a foreign country.
 - *Typical activities:* Analysis of data from surveillance system (active and/or passive) including serological surveys.
4. There is further development of an enabling environment for control activities

- *Typical activities:* As for Stages 1 & 2 *plus* legal framework is in place to restrict the movements of animals to prevent the spread of an outbreak. Reporting of suspect FMD cases is encouraged and accepted by all stakeholders. Legal framework covering compulsory culling of livestock is in place as well as arrangements for compensation and/or insurance when this culling is a necessary part of outbreak response.

NB: As explained on page 4, once a country has entered the GF-TADs–supported PCP-**Stage 3** and has decided it wants to continue along the pathway to **Stage 4** and beyond, implicating the intention to eradicate FMD virus from the domestic animal population, it may ask for OIE-endorsement of its national FMD eradication programme. The procedure for endorsement may be obtained from OIE. In this Stage the results of a recent PVS analysis will probably be necessary to support the country application for endorsement of its FMD eradication programme.

AND TO PROGRESS TO STAGE 4

5. There is a body of evidence that FMD virus is not circulating endemically in domestic animals within the country or zone.
 - *Quality indicators:* There is evidence of high-quality FMD surveillance activities over all regions and husbandry systems – surveillance activity must be demonstrably capable of detecting FMD outbreaks should they occur (e.g. consistent with OIE Terrestrial Animal Health Code on surveillance standards). Incidence of FMD is reduced to zero except for occasional incursions from other countries or wildlife. All outbreaks can be traced to incursion from the outside or wildlife and are quickly resolved. Monitoring of vaccination programmes and of population immunity is successfully implemented.

- Typical activities: Analysis of virological data, analysis of outbreak investigation data including identification of outbreak source, and analysis of serological survey data
- This is required to progress to **Stage 4**.

Stage 4:

- **STAGE FOCUS:** “To maintain ‘zero tolerance’ of FMD within the country/zone and eventually achieve OIE recognition of ‘FMD free with vaccination’.
- **Minimum requirement for inclusion in Stage 4:** Completion of previous Stage, and results are available from activities working towards Key Outcomes 1 & 2 below.
- **Key Outcomes:**
 1. Continued surveillance for FMD and monitoring of risk in different husbandry systems.
 - *Quality indicators:* Enhanced understanding of risk is applied to reduce the impact of FMD through the effective use of available control options.
 - *Typical activities:* The country should maintain activities described in previous Stages.
 2. A plan is developed to fulfil the requirements for OIE recognition of “FMD-free with vaccination” status.
 - *Quality indicators:* The plan reflects the requirements specified in the OIE Terrestrial Animal Health Code.
 3. The risk of FMD entering the country or zone is mitigated.
 - *Quality indicators:* Increased attention to border security is evident.
 - *Typical activities:* Border controls are strengthened, risk mitigating measures to prevent FMD transmission between susceptible wildlife and domestic livestock are improved.
 4. FMD incidence is very low and limited to occasional incursions from outside (which must eventually cease if successful application for recognition of “free with vaccination” is to be achieved).

- *Quality indicators:* Credible epidemiological evidence that FMD incidence is very low and that there is no endemic circulation in domestic livestock.
- *Typical activities:* Active and passive surveillance, serological survey, thorough outbreak investigations.

5. The environment enables the full implementation of control measures.

AND TO PROGRESS TO STAGE 5

6. The OIE requirements for recognition of “free with vaccination” are fulfilled and a dossier is submitted to OIE for recognition of this status.

- *Typical activities:* Effective surveillance activity to prove zero disease incidence over the required period as specified in the OIE Code
- This is required to progress to **Stage 5**.

Stage 5:

- **STAGE FOCUS:** “To maintain ‘zero incidence’ of FMD within the country/zone and eventually achieve OIE recognition of ‘FMD free without vaccination””.
- **Minimum requirement for inclusion in Stage 5:** Completion of previous stage and OIE recognition of “FMD-free with vaccination” status
- **Key Outcomes:**
 1. Zero incidence of FMD outbreaks is maintained in domestic livestock.
 - *Quality indicators:* Credible evidence required that FMD is not circulating and that if an outbreak occurred it would be detected (i.e. vet services competence, surveillance programme working well, reporting of suspect cases is encouraged).

- *Typical activities:* Active and passive surveillance, serological surveys, all suspect reports are immediately and thoroughly investigated.

AND TO EXIT STAGE 5 AND COMPLETE THE PATHWAY:

2. The OIE requirements for recognition of “free without vaccination” are fulfilled and a dossier is submitted to OIE for recognition of this status.
 - *Typical activities:* Effective surveillance activity to prove zero disease incidence over the required period as specified in the OIE Code.
 - This is required to complete **Stage 5** and the Progressive Control Pathway.

Supporting document N°3

OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)

Fifth edition, 2010

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of Veterinary Services
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INTRODUCTION

In this era of globalisation, the development and growth of many countries, as well as the prevention and control of major biological disasters, depend on the performance of their policies and economies on agriculture, animal health and food and this, in turn, directly relates to the quality of their Veterinary Services (VS). Important roles for VS include veterinary public health – including food-borne diseases – and regional and international market access for animals and animal products. To meet current and future opportunities and challenges, VS should be independent and objective in their activities and decisions should be based on sound science and immune from political pressure. Use of the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE PVS Tool) is a key element in the OIE PVS Pathway. Following this pathway allows countries to support VS in establishing their current level of performance, identifying gaps and weaknesses in their ability to comply with OIE international standards, and forming a shared vision with stakeholders¹ (including the private sector), with the goal of establishing priorities and securing the investments needed to carry out strategic initiatives.

The production of and trade in aquatic animals and their products is of increasing importance and the aquaculture sector is growing fast in response to the strong and growing global demand for high quality protein. In some countries the VS are the competent authority for aquatic animal health but other agencies of government hold this responsibility. Regardless of whether veterinarians are involved in the Aquatic Animal Health Services (AAHS), the general principles for quality apply. Appropriate legislation and good governance are required for meeting OIE requirements, including for animal disease detection, reporting and control.

In planning and undertaking an evaluation of performance of AAHS (as part of a PVS evaluation of VS, or as an independent exercise), the OIE *PVS Tool for AAHS* should be used.

In the international trade of animals and animal products, the OIE promotes animal health and public health (as it relates to the prevention and control of zoonoses including food-borne diseases of animal origin) by issuing harmonised sanitary standards for international trade and disease control, by working to improve the resources and legal framework of VS / AAHS and by helping Members comply with OIE standards, guidelines and recommendations, consistent with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO)².

The traditional mission of VS was to protect domestic agriculture and most resources were directed towards the prevention and control of diseases that threatened primary production. The services began at the country's borders and were focused on the national domestic context. The prevention and control of major aquatic animal diseases is similarly the basis of AAHS in many countries. The credibility of these services, as viewed by domestic stakeholders and other countries, largely depended on the effectiveness of these domestic programmes, and the response of VS and AAHS to animal disease emergencies.

¹ A person, institution or organisation with a significant interest (technical, legal, financial, etc.) in the activities of the VS.

² All references in this document to WTO SPS obligations apply only to WTO Members.

In light of the growing technical requirements, consumer expectations and opportunities for international trade, the VS / AAHS should adopt an appropriate mandate and vision and provide services that respond to the needs and expectations of stakeholders. This will entail stronger alliances and closer cooperation with stakeholders, trading partners and other countries, national governmental counterparts and relevant intergovernmental organisations (in particular the OIE, the Codex Alimentarius Commission and the WTO SPS Committee).

Under the WTO SPS Agreement each WTO Member has the right to impose SPS measures to protect plant, animal and human life or health but measures should be based on science and risk analysis and implemented transparently. For animal health and zoonoses, the OIE is recognised as the reference organisation for measures relating to international trade in animals and animal products. The implementation of OIE standards, including on quality and evaluation of VS / AAHS, is the best way to facilitate safe and fair international trade.

Effective VS / AAHS have four fundamental components:

- 1) the **human, physical and financial resources** to attract resources and retain professionals with technical and leadership skills;
- 2) the **technical authority and capability** to address current and new issues including prevention and control of biological disasters based on scientific principles;
- 3) the sustained **interaction with stakeholders** in order to stay on course and carry out relevant joint programmes and services; and
- 4) the ability to **access markets** through compliance with existing standards and the implementation of new disciplines such as the harmonisation of standards, equivalence and zoning.

The structure of the OIE *PVS Tool* recognises these four fundamental components.

Fifth edition of the OIE *PVS Tool*

In recognition of the growing expectations of trading partners and consumers, some critical competencies were modified and new critical competencies introduced in the 5th edition of the OIE *PVS Tool*. These modifications primarily involve the competencies dealing with management and resourcing of veterinary services, veterinary legislation, food safety and animal welfare.

Applying the OIE *PVS Tool*

To establish the current level of performance, critical competencies (CC) with five possible levels of advancement are identified for each of the four fundamental components. A higher level of advancement assumes that the services are complying with the preceding (non 1) levels (e.g. level 3 assumes compliance with level 2 criteria). For each CC PVS assessors use a list of suggested indicators that the OIE has developed on the basis of extensive experience with the conduct of evaluations within the PVS framework.

In addition, the OIE has provided a *Manual for Assessors* as well as Guidelines for countries requesting or considering a PVS Evaluation.

Chapters 3.1. and 3.2. of the *Terrestrial Animal Health Code (Terrestrial Code)* provide the legal base for the OIE quality requirements for VS and for the PVS evaluation and follow-up activities.

Chapter 3.1. of the *Aquatic Animal Health Code (Aquatic Code)* provides a legal base for the OIE quality requirements for AAHS where these are not covered by the VS.

Relevant definitions from the Glossary of the *Terrestrial Code* may be found in the Glossary of Terms. The most important *Code* references are quoted under each critical competency.

Using the results

More than a diagnostic instrument, the OIE *PVS Tool* promotes a culture of raising awareness and continual improvement, which can be used either passively or actively depending on the level of interest, priorities and commitment of the VS / AAHS and its stakeholders. In the passive mode, the OIE *PVS Tool* helps to raise awareness and improve the understanding of all sectors including other administrations regarding the fundamental components and critical competencies these services must have in order to function effectively.

The active mode is where the maximum outcomes are realised but this mode requires a sustained commitment on the part of both the public and private sectors, that is, all relevant stakeholders. In this mode, performance is assessed, differences are explored and priorities are established. This mode is where strategic actions will be outlined, investments evaluated and agreed to, and commitments made and implemented. Continuity of this process requires a true partnership between the public and the private sectors. Leadership on the part of the public sector is a fundamental and critical determinant of success.

The benefits and outcomes of using the OIE *PVS Tool* include:

- an indication of overall performance for each of the four components and a relative performance rating within each of the critical competencies;
- a basis for comparing the performance of the VS / AAHS with that of other relevant government services in the region or globally, in order to explore areas for cooperation or negotiation³;
- a basis for a process of verifying compliance with the OIE standards and assessments of VS / AAHS by independent agents accredited by and under the guidelines and auspices of the OIE;
- where gaps in the legislative framework are identified in the course of a PVS Evaluation and, possibly, through the conduct of an OIE Legislation Mission, obtaining an indication of the specific actions needed to update the veterinary legislation in compliance with OIE recommendations;
- through the conduct of OIE PVS Gap Analysis missions, helping countries to identify their priorities, to quantify their needs and to present justifications when applying for national and/or international financial support (loans and/or grants) from national governments or international donors;
- providing a basis for establishing a routine monitoring and follow up mechanism on the overall level of performance of the VS / AAHS over time, through PVS follow-up, using the OIE *PVS Tool* to monitor progress;
- helping to determine the benefits and costs of investing in VS / AAHS and, through the conduct of specific follow up activities, identifying the actions and securing the investments that are needed to help improve compliance with OIE standards for Good Governance.

³ OIE standards provide a framework for importing countries to conduct audits of exporting countries and in particular to check the compliance of exporting countries with OIE standards on quality and evaluation of VS / AAHS.

GLOSSARY OF TERMS

(Terms defined in the Terrestrial Animal Health Code that are used in this publication are reprinted here for reference.)

Border post

means any airport, or any port, railway station or road check-point open to *international trade of commodities*, where import veterinary inspections can be performed.

Compartment

means an animal *subpopulation* contained in one or more *establishments* under a common biosecurity management system with a distinct health status with respect to a specific *disease* or specific *diseases* for which required *surveillance*, control and biosecurity measures have been applied for the purposes of *international trade*.

Competent Authority

means the *Veterinary Authority* or other Governmental Authority of a Member, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* and the *OIE Aquatic Animal Health Code* in the whole territory.

Emerging disease

means a new *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or public health.

Equivalence of sanitary measures

means the state wherein the *sanitary measure(s)* proposed by the *exporting country* as an alternative to those of the *importing country*, achieve(s) the same level of protection.

International veterinary certificate

means a certificate, issued in conformity with the provisions of Chapter 5.2., describing the animal health and/or public health requirements which are fulfilled by the exported *commodities*.

Laboratory

means a properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results. The *Veterinary Authority* approves and monitors such laboratories with regard to the diagnostic tests required for *international trade*.

Notifiable disease

means a *disease* listed by the *Veterinary Authority*, and that, as soon as detected or suspected, must be brought to the attention of this *Authority*, in accordance with national regulations.

Official control programme

means a programme which is approved, and managed or supervised by the *Veterinary Authority* of a country for the purpose of controlling a vector, pathogen or *disease* by specific measures applied throughout that country, or within a *zone* or *compartment* of that country.

Official Veterinarian

means a veterinarian authorised by the *Veterinary Authority* of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of *commodities* and, when appropriate, to certify in conformity with the provisions of Chapters 5.1. and 5.2. of the *Terrestrial Code*.

Official veterinary control

means the operations whereby the *Veterinary Services*, knowing the location of the *animals* and after taking appropriate actions to identify their owner or responsible keeper, are able to apply appropriate animal health measures, as required. This does not exclude other responsibilities of the *Veterinary Services* e.g. food safety.

Risk analysis

means the process composed of *hazard identification*, *risk assessment*, *risk management* and *risk communication*.

Sanitary measure

means a measure, such as those described in various Chapters of the *Terrestrial Code*, destined to protect animal or human health or life within the territory of the OIE Member from *risks* arising from the entry, establishment and/or spread of a *hazard*.

Surveillance

means the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information to those who need to know so that action can be taken.

Terrestrial Code

means the OIE *Terrestrial Animal Health Code*.

Veterinarian

means a person registered or licensed by the relevant *veterinary statutory body* of a country to practice veterinary medicine/science in that country.

Veterinary Authority

means the Governmental Authority of an OIE Member, comprising *veterinarians*, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in *the Terrestrial Code* in the whole territory.

Veterinary para-professional

means a person who, for the purposes of the *Terrestrial Code*, is authorised by the *veterinary statutory body* to carry out certain designated tasks (dependent upon the category of *veterinary para-professional*) in a territory, and delegated to them under the responsibility and direction of a *veterinarian*. The tasks for each category of *veterinary para-professional* should be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.

Veterinary Services

means the governmental and non-governmental organisations that implement animal health and *welfare* measures and other standards and recommendations in the *Terrestrial* and *Aquatic Codes* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, *veterinary paraprofessionals* or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions.

Veterinary statutory body

means an autonomous authority regulating *veterinarians* and *veterinary para-professionals*.

CHAPTER I - HUMAN, PHYSICAL AND FINANCIAL RESOURCES

Institutional and financial sustainability as evidenced by the level of professional/technical physical and financial resources available.

Critical competencies:

Section I-1	Professional and technical staffing of the Veterinary Services
Section I-2	Competencies of veterinarians and veterinary para-professionals
Section I-3	Continuing education
Section I-4	Technical independence
Section I-5	Stability of structures and sustainability of policies
Section I-6	Coordination capability of the Veterinary Services
Section I-7	Physical resources
Section I-8	Operational funding
Section I-9	Emergency funding
Section I-10	Capital investment
Section I-11	Management of resources and operations

Terrestrial Code References:

Points 1-7, 9 and 14 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity / Veterinary legislation / General organisation / Procedures and standards / Human and financial resources.

Article 3.2.2. on Scope.

Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Point 2 of Article 3.2.4. on Evaluation criteria for quality system: "Where the Veterinary Services undergoing evaluation... than on the resource and infrastructural components of the services".

Article 3.2.5. on Evaluation criteria for human resources.

Points 1-3 of Article 3.2.6. on Evaluation criteria for material resources: Financial / Administrative / Technical.

Points 3 and Sub-point d) of Point 4 of Article 3.2.10. on Performance assessment and audit programmes: Compliance / In-Service training and development programme for staff.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-5 and 9 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Financial management information / Administration details / Laboratory services / Performance assessment and audit programmes.

I-1 Professional and technical staffing of the Veterinary Services	Levels of advancement
The appropriate staffing of the VS to allow for veterinary and technical functions to be undertaken efficiently and effectively.	1. The majority of veterinary and other professional positions are not occupied by appropriately qualified personnel.
A. Veterinary and other professionals (university qualification)	2. The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at central and state / provincial levels.
	3. The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at local (field) levels.
	4. There is a systematic approach to defining job descriptions and formal appointment procedures for <i>veterinarians</i> and other professionals.
	5. There are effective management procedures for performance assessment of <i>veterinarians</i> and other professionals.

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 7 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

B. Veterinary para-professionals and other technical personnel	Levels of advancement
	1. The majority of technical positions are not occupied by personnel holding technical qualifications.
	2. The majority of technical positions at central and state / provincial levels are occupied by personnel holding technical qualifications.
	3. The majority of technical positions at local (field) levels are occupied by personnel holding technical qualifications.
	4. The majority of technical positions are effectively supervised on a regular basis.
5. There are effective management procedures for formal appointment and performance assessment of <i>veterinary para-professionals</i> .	

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 7 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

I-2 Competencies of veterinarians and veterinary para-professionals	Levels of advancement
The capability of the VS to efficiently carry out their veterinary and technical functions; measured by the qualifications of their personnel in veterinary and technical positions ⁴ .	1. The veterinarians' practices, knowledge and attitudes are of a variable standard that usually allow for elementary clinical and administrative activities of the VS.
A. Professional competencies of veterinarians	2. The veterinarians' practices, knowledge and attitudes are of a uniform standard that usually allow for accurate and appropriate clinical and administrative activities of the VS.
	3. The veterinarians' practices, knowledge and attitudes usually allow undertaking all professional/technical activities of the VS (e.g. epidemiological surveillance, early warning, public health, etc.).
	4. The veterinarians' practices, knowledge and attitudes usually allow undertaking specialized activities as may be needed by the VS.
	5. The veterinarians' practices, knowledge and attitudes are subject to regular updating, or international harmonisation, or evaluation.

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 7 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

⁴ Not all professional positions require an academic degree. Nonetheless, the proportion of academic degrees serves as an indicator of professional excellence within the VS.

B. Competencies of veterinary para-professionals	Levels of advancement
	1. The majority of <i>veterinary para-professionals</i> have no formal entry-level training.
	2. The training of <i>veterinary para-professionals</i> is of a very variable standard and allows the development of only limited animal health competencies.
	3. The training of <i>veterinary para-professionals</i> is of a uniform standard that allows the development of only basic animal health competencies.
	4. The training of <i>veterinary para-professionals</i> is of a uniform standard that allows the development of some specialist animal health competencies (e.g. meat inspection).
	5. The training of <i>veterinary para-professionals</i> is of a uniform standard and is subject to regular evaluation and/or updating.

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 7 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

I-3 Continuing education (CE)⁵	Levels of advancement
The capability of the VS to maintain and improve the competence of their personnel in terms of relevant information and understanding; measured in terms of the implementation of a relevant training programme.	1. The VS have no access to continuing veterinary, professional or technical CE.
	2. The VS have access to CE (internal and/or external programmes) on an irregular basis but it does not take into account needs, or new information or understanding.
	3. The VS have access to CE that is reviewed annually and updated as necessary, but it is implemented only for some categories of the relevant personnel.
	4. The VS have access to CE that is reviewed annually and updated as necessary, and it is implemented for all categories of the relevant personnel.
	5. The VS have up-to-date CE that is implemented for all relevant personnel and is submitted to periodic evaluation of effectiveness.

Terrestrial Code reference(s):

Points 1, 7 and 14 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Sub-point d) of Point 4 of Article 3.2.10. on Veterinary Services administration: In-service training and development programme for staff.

Point 9 of Article 3.2.14. on Performance assessment and audit programmes.

⁵ Continuing education includes Continuous Professional Development (CPD) for veterinary, professional and technical personnel.

I-4 Technical independence	Levels of advancement
<p>The capability of the VS to carry out their duties with autonomy and free from commercial, financial, hierarchical and political influences that may affect technical decisions in a manner contrary to the provisions of the OIE (and of the WTO SPS Agreement where applicable).</p>	1. The technical decisions made by the VS are generally not based on scientific considerations.
	2. The technical decisions take into account the scientific evidence, but are routinely modified to conform to non-scientific considerations.
	3. The technical decisions are based on scientific evidence but are subject to review and possible modification based on non-scientific considerations.
	4. The technical decisions are based only on scientific evidence and are not changed to meet non-scientific considerations.
	5. The technical decisions are made and implemented in full accordance with the country's OIE obligations (and with the country's WTO SPS Agreement obligations where applicable).

Terrestrial Code reference(s):

Point 2 of Article 3.1.2. on Fundamental principles of quality: Independence.

I-5 Stability of structures and sustainability of policies	Levels of advancement
<p>The capability of the VS structure and/or leadership to implement and sustain policies over time.</p>	<p>1. Substantial changes to the organisational structure and/or leadership of the public sector of the VS frequently occur (e.g. annually) resulting in lack of sustainability of policies.</p>
	<p>2. The organisational structure and/or leadership of the public sector of the VS is substantially changed each time there is a change in the political leadership and this has negative effects on sustainability of policies.</p>
	<p>3. Significant changes to the organisational structure and/or leadership of the public sector of the VS occur rarely, but this stability does not have a positive impact on the sustainability of policies.</p>
	<p>4. Some changes occur in the organisational structure and/or leadership of the public sector of the VS following a change in the political leadership, but these have little or no negative effect on sustainability of policies.</p>
	<p>5. The organisational structure and leadership of the public sector of the VS are generally stable. Modifications are based on an evaluation process, with positive effect on the sustainability of policies.</p>

Terrestrial Code reference(s):

- Point 1 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.
- Point 9 of Article 3.2.14. on Performance assessment and audit programmes.

I-6 Coordination capability of the Veterinary Services	Levels of advancement
<p data-bbox="185 394 654 450">A. Internal coordination (chain of command)</p> <p data-bbox="185 495 654 712">The capability of the VS to coordinate its resources and activities (public and private sectors) with a clear chain of command, from the central level (the Chief Veterinary Officer), to the field level of the VS in order to implement all national activities relevant for OIE <i>Codes</i> (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programs).</p>	1. There is no formal internal coordination and the chain of command is not clear.
	2. There are internal coordination mechanisms for some activities but the chain of command is not clear.
	3. There are internal coordination mechanisms and a clear and effective chain of command for some activities.
	4. There are internal coordination mechanisms and a clear and effective chain of command at the national level for most activities.
	5. There are internal coordination mechanisms and a clear and effective chain of command for all activities and these are periodically reviewed/audited and updated.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Article 3.2.2. on Scope.

Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

B. External coordination	Levels of advancement
<p>The capability of the VS to coordinate its resources and activities (public and private sectors) at all levels with other relevant authorities as appropriate, in order to implement all national activities relevant for OIE Codes (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programs).</p> <p>Relevant authorities include other ministries and competent authorities, national agencies and decentralised institutions.</p>	1. There is no external coordination.
	2. There are informal external coordination mechanisms for some activities, but the procedures are not clear and/or external coordination occurs irregularly.
	3. There are formal external coordination mechanisms with clearly described procedures or agreements for some activities and/or sectors.
	4. There are formal external coordination mechanisms with clearly described procedures or agreements at the national level for most activities, and these are uniformly implemented throughout the country.
	5. There are national external coordination mechanisms for all activities and these are periodically reviewed and updated.

Terrestrial Code reference(s):

- Points 7 and 9 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.
- Article 3.2.2. on Scope.
- Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.
- Point 4 of Article 3.2.10 on Performance assessment and audit programmes.

I-7 Physical resources	Levels of advancement
The access of the VS to relevant physical resources including buildings, transport telecommunications, cold chain, and other relevant equipment (e.g. computers).	1. The VS have no or unsuitable physical resources at almost all levels and maintenance of existing infrastructure is poor or non-existent.
	2. The VS have suitable physical resources at the national (central) level and at some regional levels, and maintenance and replacement of obsolete items occurs only occasionally.
	3. The VS have suitable physical resources at national, regional and some local levels and maintenance and replacement of obsolete items occurs only occasionally.
	4. The VS have suitable physical resources at all levels and these are regularly maintained.
	5. The VS have suitable physical resources at all levels (national, sub-national and local levels) and these are regularly maintained and updated as more advanced and sophisticated items become available.

Terrestrial Code reference(s):

Point 2 of Article 3.2.4. on Evaluation criteria for quality system: "Where the Veterinary Services undergoing evaluation... than on the resource and infrastructural components of the services".

Points 2 and 3 of Article 3.2.6. on Evaluation criteria for material resources: Administrative / Technical.

Point 3 of Article 3.2.10. on Performance assessment and audit programmes: Compliance.

Point 4 of Article 3.2.14. on Administration details.

I-8 Operational funding	Levels of advancement
The ability of the VS to access financial resources adequate for their continued operations, independent of political pressure.	1. Funding for the VS is neither stable nor clearly defined but depends on resources allocated irregularly.
	2. Funding for the VS is clearly defined and regular, but is inadequate for their required base operations (i.e. disease surveillance, early detection and rapid response and veterinary public health).
	3. Funding for the VS is clearly defined and regular, and is adequate for their base operations, but there is no provision for new or expanded operations.
	4. Funding for new or expanded operations is on a case-by-case basis, not always based on <i>risk analysis</i> and/or cost benefit analysis.
	5. Funding for all aspects of VS activities is adequate; all funding is provided under full transparency and allows for full technical independence, based on <i>risk analysis</i> and/or cost benefit analysis.

Terrestrial Code reference(s):

Points 6 and 14 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Human and financial resources.

Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.

Point 3 of Article 3.2.14. on Financial management information.

I-9 Emergency funding	Levels of advancement
<p>The capability of the VS to access extraordinary financial resources in order to respond to emergency situations or emerging issues; measured by the ease of which contingency and compensatory funding (i.e. arrangements for compensation of producers in emergency situations) can be made available when required.</p>	<p>1. No contingency and compensatory funding arrangements exist and there is no provision for emergency financial resources.</p>
	<p>2. Contingency and compensatory funding arrangements with limited resources have been established, but these are inadequate for expected emergency situations (including emerging issues).</p>
	<p>3. Contingency and compensatory funding arrangements with limited resources have been established; additional resources for emergencies may be approved but approval is through a political process.</p>
	<p>4. Contingency and compensatory funding arrangements with adequate resources have been established, but in an emergency situation, their operation must be agreed through a non-political process on a case-by-case basis.</p>
	<p>5. Contingency and compensatory funding arrangements with adequate resources have been established and their rules of operation documented and agreed with stakeholders.</p>

Terrestrial Code reference(s):

Points 6 and 14 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Human and financial resources.

Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.

Point 3 of Article 3.2.14. on Financial management information.

I-10 Capital investment	Levels of advancement
The capability of the VS to access funding for basic and additional investments (material and non material) that lead to a sustained improvement in the VS operational infrastructure.	1. There is no capability to establish, maintain or improve the operational infrastructure of the VS.
	2. The VS occasionally develops proposals and secures funding for the establishment, maintenance or improvement of operational infrastructure but this is normally through extraordinary allocations.
	3. The VS regularly secures funding for maintenance and improvements of operational infrastructure, through allocations from the national budget or from other sources, but there are constraints on the use of these allocations.
	4. The VS routinely secures adequate funding for the necessary maintenance and improvement in operational infrastructure.
	5. The VS systematically secures adequate funding for the necessary improvements in operational infrastructure, including with participation from stakeholders as required.

Terrestrial Code reference(s):

- Point 14 of Article 3.1.2. on Fundamental principles of quality: Human and financial resources.
- Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.
- Point 3 of Article 3.2.14. on Financial management information.

I-11 Management of resources and operations	Levels of advancement
The capability of the VS to document and manage their resources and operations in order to analyze, plan and improve both efficiency and effectiveness.	1. The VS have some records or documented procedures, but these do not provide for adequate management of resources and operations.
	2. The VS routinely use records and/or documented procedures in the management of resources and some operations, but these do not provide for adequate management, analysis, control or planning.
	3. The VS have comprehensive records, documentation and management systems and they regularly use records and documented procedures in the management of resources and operations, providing for the control of effectiveness and the conduct of analysis and planning.
	4. The VS have adequate management skills, including the capacity to analyse and improve efficiency and effectiveness.
	5. The VS have fully effective management systems, which are regularly audited and permit a proactive continuous improvement of efficiency and effectiveness.

Terrestrial Code reference(s):

Points 7, 11 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Documentation / Human and financial resources.

Point 4 of Article 3.2.1. on General considerations.

Point 1 of Article 3.2.2. on Scope.

Article 3.2.6. on Evaluation criteria for material resources.

Article 3.2.10. on Performance assessment and audit programmes.

CHAPTER II - TECHNICAL AUTHORITY AND CAPABILITY

The authority and capability of the VS to develop and apply sanitary measures and science-based procedures supporting those measures.

Critical competencies:

Section II-1	Veterinary laboratory diagnosis
Section II-2	Laboratory quality assurance
Section II-3	Risk analysis
Section II-4	Quarantine and border security
Section II-5	Epidemiological surveillance
Section II-6	Early detection and emergency response
Section II-7	Disease prevention, control and eradication
Section II-8	Food safety
Section II-9	Veterinary medicines and biologicals
Section II-10	Residue testing
Section II-11	Emerging issues
Section II-12	Technical innovation
Section II-13	Identification and traceability
Section II-14	Animal welfare

Terrestrial Code References:

Chapter 2.1. on Import risk analysis.

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General Organisation / Procedures and standards.

Point 1 of Article 3.2.4. on Evaluation criteria for quality systems.

Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.

Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Sub-point f) of Point 4 of Article 3.2.10. on Veterinary Services administration: Formal linkages with sources of independent scientific expertise.

Points 2 and 57 of Article 3.2.14. on National information on human resources / Laboratory services / Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.

Chapter 4.1. on General principles on identification and traceability of live animals.

Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Chapters 6.6. to 6.10. on Antimicrobial resistance.

Chapter 7.1. Introduction to the recommendations for animal welfare.

Chapter 7.2. Transport of animals by sea.

Chapter 7.3. Transport of animals by land.

Chapter 7.4. Transport of animals by air.

Chapter 7.5. Slaughter of animals.

Chapter 7.6. Killing of animals for disease control purposes.

II-1 Veterinary laboratory diagnosis	Levels of advancement
<p>The authority and capability of the VS to identify and record pathogenic agents, including those relevant for public health, that can adversely affect animals and animal products.</p>	<p>1. Disease diagnosis is almost always conducted by clinical means only, with laboratory diagnostic capability being generally unavailable.</p>
	<p>2. For major zoonoses and diseases of national economic importance, the VS have access to and use a laboratory to obtain a correct diagnosis.</p>
	<p>3. For other zoonoses and diseases present in the country, the VS have access to and use a <i>laboratory</i> to obtain a correct diagnosis.</p>
	<p>4. For diseases of zoonotic or economic importance not present in the country, but known to exist in the region and/ or that could enter the country, the VS have access to and use a <i>laboratory</i> to obtain a correct diagnosis.</p>
	<p>5. In the case of new and <i>emerging diseases</i> in the region or world, the VS have access to and use a network of national or international reference laboratories (e.g. an OIE Reference Laboratory) to obtain a correct diagnosis.</p>

Terrestrial Code reference(s):

Point 9 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.

Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.

Point 5 of Article 3.2.14. on Laboratory services.

II-2 Laboratory quality assurance	Levels of advancement
<p>The quality of laboratories (that conduct diagnostic testing or analysis for chemical residues, antimicrobial residues, toxins, or tests for, biological efficacy, etc.) as measured by the use of formal QA systems and participation in relevant proficiency testing programmes.</p>	1. No laboratories used by the public sector VS are using formal QA systems.
	2. Some laboratories used by the public sector VS are using formal QA systems.
	3. All laboratories used by the public sector VS are using formal QA systems.
	4. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA systems.
	5. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA programmes that meet OIE, ISO 17025, or equivalent QA standard guidelines.

Terrestrial Code reference(s):

- Point 9 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.
- Point 1 of Article 3.2.4. on Evaluation criteria for quality systems.
- Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.
- Point 5 of Article 3.2.14. on Laboratory services.

II-3 Risk analysis	Levels of advancement
<p>The authority and capability of the VS to base its risk management decisions on a scientific assessment of the risks.</p>	1. Risk management decisions are not usually supported by scientific risk assessment.
	2. The VS compile and maintain data but do not have the capability to systematically assess risks. Some risk management decisions are based on scientific risk assessment.
	3. The VS can systematically compile and maintain relevant data and carry out risk assessment. Scientific principles and evidence, including risk assessment, generally provide the basis for risk management decisions.
	4. The VS systematically conduct risk assessments in compliance with relevant OIE standards, and base their risk management decisions on the outcomes of these risk assessments.
	5. The VS are consistent in basing sanitary decisions on <i>risk analysis</i> , and in communicating their procedures and outcomes internationally, meeting all their OIE obligations (including WTO SPS Agreement obligations where applicable).

Terrestrial Code reference(s):

Chapter 2.1. on Import risk analysis.

II-4 Quarantine and border security	Levels of advancement
<p>The authority and capability of the VS to prevent the entry and spread of diseases and other hazards of animals and animal products.</p>	<p>1. The VS cannot apply any type of quarantine or border security procedures for animals or animal products with their neighbouring countries or trading partners.</p>
	<p>2. The VS can establish and apply quarantine and border security procedures; however, these are generally based neither on international standards nor on a <i>risk analysis</i>.</p>
	<p>3. The VS can establish and apply quarantine and border security procedures based on international standards, but the procedures do not systematically address illegal activities⁶ relating to the import of animals and animal products.</p>
	<p>4. The VS can establish and apply quarantine and border security procedures which systematically address legal pathways and illegal activities.</p>
	<p>5. The VS work with their neighbouring countries and trading partners to establish, apply and audit quarantine and border security procedures which systematically address all risks identified.</p>

Terrestrial Code reference(s):

Points 6 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Procedures and standards.

Point 2 of Article 3.2.7. on Legislation and functional capabilities: Export/import inspection.

Points 6 and 7 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.

⁶ Illegal activities include attempts to gain entry for animals or animal products other than through legal entry points and/or using certification and/or other procedures not meeting the country's requirements.

II-5 Epidemiological surveillance	Levels of advancement
<p>The authority and capability of the VS to determine, verify and report on the sanitary status of the animal populations under their mandate.</p> <p>A. Passive epidemiological surveillance</p>	1. The VS have no passive surveillance programme.
	2. The VS conduct passive surveillance for some relevant diseases and have the capacity to produce national reports on some diseases.
	3. The VS conduct passive surveillance in compliance with OIE standards for some relevant diseases at the national level through appropriate networks in the field, whereby samples from suspect cases are collected and sent for laboratory diagnosis with evidence of correct results obtained. The VS have a basic national disease reporting system.
	4. The VS conduct passive surveillance and report at the national level in compliance with OIE standards for most relevant diseases. Appropriate field networks are established for the collection of samples and submission for laboratory diagnosis of suspect cases with evidence of correct results obtained. Stakeholders are aware of and comply with their obligation to report the suspicion and occurrence of notifiable diseases to the VS.
	5. The VS regularly report to stakeholders and the international community (where applicable) on the findings of passive surveillance programmes.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-points a) i), ii) and iii) of Point 7 of Article 3.2.14. on Animal health: Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services* / Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services* / Description and relevant data of current official control programmes including:... or eradication programmes for specific diseases.

B. Active epidemiological surveillance	Levels of advancement
	1. The VS have no active surveillance programme.
	2. The VS conduct active surveillance for some relevant diseases (of economic and zoonotic importance) but apply it only in a part of susceptible populations and/or do not update it regularly.
	3. The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases and apply it to all susceptible populations but do not update it regularly.
	4. The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases, apply it to all susceptible populations, update it regularly and report the results systematically.
	5. The VS conduct active surveillance for most or all relevant diseases and apply it to all susceptible populations. The surveillance programmes are evaluated and meet the country's OIE obligations.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-points a) i), ii) and iii) of Point 7 of Article 3.2.14. on Animal health: Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services* / Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services* / Description and relevant data of current official control programmes including:... or eradication programmes for specific diseases.

II-6 Early detection and emergency response	Levels of advancement
The authority and capability of the VS to detect and respond rapidly to a sanitary emergency (such as a significant disease outbreak or food safety emergency).	1. The VS have no field network or established procedure to determine whether a sanitary emergency exists or the authority to declare such an emergency and respond appropriately.
	2. The VS have a field network and an established procedure to determine whether or not a sanitary emergency exists, but lack the necessary legal and financial support to respond appropriately.
	3. The VS have the legal framework and financial support to respond rapidly to sanitary emergencies, but the response is not coordinated through a chain of command.
	4. The VS have an established procedure to make timely decisions on whether or not a sanitary emergency exists. The VS have the legal framework and financial support to respond rapidly to sanitary emergencies through a chain of command. They have national contingency plans for some exotic diseases.
	5. The VS have national contingency plans for all diseases of concern through coordinated actions with all stakeholders through a chain of command.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-point a) of Point 7 of Article 3.2.14. on Animal health and veterinary public health controls: Animal health.

II-7 Disease prevention, control and eradication	Levels of advancement
The authority and capability of the VS to actively perform actions to prevent, control or eradicate OIE listed diseases and/or to demonstrate that the country or a zone are free of relevant diseases.	1. The VS have no authority or capability to prevent, control or eradicate animal diseases.
	2. The VS implement prevention, control and eradication programmes for some diseases and/or in some areas with little or no scientific evaluation of their efficacy and efficiency.
	3. The VS implement prevention, control and eradication programmes for some diseases and/or in some areas with scientific evaluation of their efficacy and efficiency.
	4. The VS implement prevention, control and eradication programmes for all relevant diseases but with scientific evaluation of their efficacy and efficiency of some programmes.
	5. The VS implement prevention, control and eradication programmes for all relevant diseases with scientific evaluation of their efficacy and efficiency consistent with relevant OIE international standards.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-point a) of Point 7 of Article 3.2.14. on Animal health and veterinary public health controls: Animal health.

II-8 Food safety	Levels of advancement
<p>A. Ante- and postmortem inspection at abattoirs and associated premises (e.g. meat boning, cutting establishments and rendering plants)</p> <p>The authority and capability of the VS to implement and manage the inspection of animals destined for slaughter at abattoirs and associated premises, including for assuring meat hygiene and for the collection of information relevant to livestock diseases and zoonoses. This competency also covers coordination with other authorities where there is shared responsibility for the functions.</p>	1. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are generally not undertaken in conformity with international standards.
	2. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards only at export premises.
	3. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards for export premises and for major abattoirs producing meat for distribution throughout the national market.
	4. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards for export premises and for all abattoirs producing meat for distribution in the national and local markets.
	5. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards at all premises (including family and on farm slaughtering) and are subject to periodic audit of effectiveness.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Points 2, 6 and 7 of Article 3.2.14. on National information on human resources / Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

B. Inspection of collection, processing and distribution of products of animal origin	Levels of advancement
<p>The authority and capability of the VS to implement, manage and coordinate food safety measures on collection, processing and distribution of products of animals, including programmes for the prevention of specific food-borne zoonoses and general food safety programmes. This competency also covers coordination with other authorities where there is shared responsibility for the functions.</p>	1. Implementation, management and coordination (as appropriate) are generally not undertaken in conformity with international standards.
	2. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards only for export purposes.
	3. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards only for export purposes and for products that are distributed throughout the national market.
	4. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards for export purposes and for products that are distributed throughout the national and local markets.
	5. Implementation, management and coordination (as appropriate) are undertaken in full conformity with international standards for products at all levels of distribution (including on farm-processing and farm gate sale).

[Note: This critical competency primarily refers to inspection of processed animal products and raw products other than meat (e.g. milk, honey, etc.). It may in some countries be undertaken by an agency other than the VS.]

 Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Points 2, 6 and 7 of Article 3.2.14. on National information on human resources / Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

II-9 Veterinary medicines and biologicals	Levels of advancement
The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, i.e. the authorisation, registration, import, production, labelling, distribution, sale and use of these products.	1. The VS cannot regulate veterinary medicines and veterinary biologicals.
	2. The VS have some capability to exercise administrative control over veterinary medicines and veterinary biologicals.
	3. The VS exercise effective administrative control and implement quality standards for most aspects of the regulation of veterinary medicines and veterinary biologicals.
	4. The VS exercise comprehensive and effective regulatory control of veterinary medicines and veterinary biologicals.
	5. In addition to complete regulatory control, the VS systematically monitor for adverse reactions (pharmacovigilance) and take appropriate corrective steps. The control systems are subjected to periodic audit of effectiveness.

Terrestrial Code reference(s):

Points 6 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Procedures and standards.

Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.

Sub-point a) ii) of Point 6 of Article 3.2.14. on Animal health and veterinary public health: Assessment of ability of Veterinary Services to enforce legislation.

Chapters 6.6. to 6.10. on Antimicrobial resistance.

II-10 Residue testing	Levels of advancement
The capability of the VS to undertake residue testing programmes for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, metals, etc.	1. No residue testing programme for animal products exists in the country.
	2. Some residue testing programme is performed but only for selected animal products for export.
	3. A comprehensive residue testing programme is performed for all animal products for export and some for domestic use.
	4. A comprehensive residue testing programme is performed for all animal products for export and/or internal consumption.
	5. The residue testing programme is subject to routine quality assurance and regular evaluation.

[Note: This critical competency may in some countries be undertaken by an agency or agencies other than the VS.]

Terrestrial Code reference(s):

Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.

Sub-points b) iii) and iv) of Point 7 of Article 3.2.14. on Veterinary public health: Chemical residue testing programmes / Veterinary medicines.

Chapters 6.6. to 6.10. on Antimicrobial resistance.

II-11 Emerging issues	Levels of advancement
<p>The authority and capability of the VS to identify in advance, and take appropriate action in response to likely emerging issues under their mandate relating to the sanitary status of the country, public health, the environment, or trade in animals and animal products.</p>	<p>1. The VS do not have procedures to identify in advance likely emerging issues.</p>
	<p>2. The VS monitor and review developments at national and international levels relating to emerging issues.</p>
	<p>3. The VS assess the risks, costs and/or opportunities of the identified emerging issues, including preparation of appropriate national preparedness plans. The VS have some collaboration with other agencies (e.g. human health, wildlife and environment) and with stakeholders on emerging issues.</p>
	<p>4. The VS implement, in coordination with stakeholders, prevention or control actions due to an adverse emerging issue, or beneficial actions from a positive emerging issue. The VS have well-developed formal collaboration with other agencies (e.g. human health, wildlife and environment) and with stakeholders on emerging issues.</p>
	<p>5. The VS coordinate actions with neighbouring countries and trading partners to respond to emerging issues, including audits of each other's ability to detect and address emerging issues in their early stages.</p>

Terrestrial Code reference(s):

Points 7 and 9 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.
 Point 1 of Article 3.2.7. on Functional capabilities and legislative support: Animal health and veterinary public health.

II-12 Technical innovation⁷	Levels of advancement
The capability of the VS to keep up-to-date with the latest scientific advances and to comply with the standards of the OIE (and Codex Alimentarius Commission where applicable).	1. The VS have only informal access to technical innovations, through personal contacts and external sources.
	2. The VS maintain a database of technical innovations and international standards, through subscriptions to scientific journals and electronic media.
	3. The VS have a specific programme to actively identify relevant technical innovations and international standards.
	4. The VS incorporate technical innovations and international standards into selected policies and procedures, in collaboration with stakeholders.
	5. The VS systematically implement relevant technical innovations and international standards.

Terrestrial Code reference(s):

Points 7 and 9 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Point 3 of Article 3.2.8. on Animal health controls: National animal disease reporting systems.

Sub-point f) of Point 4 of Article 3.2.10. on Veterinary Services administration: Formal linkages with sources of independent scientific expertise.

Points 6 and 7 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.

⁷ Technical innovation includes new disease control methods, new types of vaccines and diagnostic tests, food safety technologies, and connections to electronic networks on disease information and food emergencies.

II-13 Identification and traceability	Levels of advancement
<p data-bbox="183 376 655 427">A. Animal identification and movement control</p> <p data-bbox="183 472 655 645">The authority and capability of the VS, normally in coordination with stakeholders, to identify animals under their mandate and trace their history, location and distribution for the purpose of animal disease control, food safety, or trade or any other legal requirements under the VS/OIE mandate.</p>	1. The VS do not have the authority or the capability to identify animals or control their movements.
	2. The VS can identify some animals and control some movements, using traditional methods and/or actions designed and implemented to deal with a specific problem (e.g. to prevent robbery).
	3. The VS implement procedures for animal identification and movement control for specific animal sub-populations as required for disease control, in accordance with relevant international standards.
	4. The VS implement all relevant animal identification and movement control procedures, in accordance with relevant international standards.
	5. The VS carry out periodic audits of the effectiveness of their identification and movement control systems.

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.

Chapter 4.1. on General principles on identification and traceability of live animals.

Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

B. Identification and traceability of products of animal origin	Levels of advancement
The authority and capability of the VS, normally in coordination with stakeholders, to identify and trace products of animal origin for the purpose of food safety, animal health or trade.	1. The VS do not have the authority or the capability to identify or trace products of animal origin.
	2. The VS can identify and trace some products of animal origin to deal with a specific problem (e.g. products originating from farms affected by a disease outbreak).
	3. The VS have implemented procedures to identify and trace some products of animal origin for food safety, animal health and trade purposes, in accordance with relevant international standards.
	4. The VS have implemented national programmes enabling them the identification and tracing of all products of animal origin, in accordance with relevant international standards.
	5. The VS periodically audit the effectiveness of their identification and traceability procedures.

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.

Chapter 4.1. on General principles on identification and traceability of live animals.

Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

II-14 Animal welfare	Levels of advancement
The authority and capability of the VS to implement the animal welfare standards of the OIE as published in the <i>Terrestrial Code</i> .	1. OIE standards are generally not implemented.
	2. Some of OIE standards are implemented, e.g. primarily for the export sector.
	3. All of OIE standards are implemented but this is primarily for the export sector.
	4. All of OIE standards are implemented, for the export and the domestic sector.
	5. OIE standards are implemented and implementation is periodically subject to independent external evaluation.

[Note: At this time this competency covers only chapters 7.1. to 7.6. inclusive.]

Terrestrial Code reference(s):

- Chapter 7.1. Introduction to the recommendations for animal welfare.
- Chapter 7.2. Transport of animals by sea.
- Chapter 7.3. Transport of animals by land.
- Chapter 7.4. Transport of animals by air.
- Chapter 7.5. Slaughter of animals.
- Chapter 7.6. Killing of animals for disease control purposes.

CHAPTER III - INTERACTION WITH STAKEHOLDERS

The capability of the VS to collaborate with and involve stakeholders in the implementation of programmes and activities.

Critical competencies:

Section III-1	Communications
Section III-2	Consultation with stakeholders
Section III-3	Official representation
Section III-4	Accreditation / authorisation / delegation
Section III-5	Veterinary Statutory Body
Section III-6	Participation of producers and other stakeholders in joint programmes

Terrestrial Code References:

Points 6, 7, 9 and 13 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards / Communication.

Point 9 of Article 3.2.1. on General considerations.

Points 2 and 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Sub-point b) of Point 2 of Article 3.2.6. on Administrative resources: Communications.

Article 3.2.11. on Participation on OIE activities.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 4, 7 and Sub-point g) of Point 9 of Article 3.2.14. on Administration details / Animal health and veterinary public health controls / Sources of independent scientific expertise.

III-1 Communications	Levels of advancement
The capability of the VS to keep stakeholders informed, in a transparent, effective and timely manner, of VS activities and programmes, and of developments in animal health and food safety.	1. The VS have no mechanism in place to inform stakeholders of VS activities and programmes.
	2. The VS have informal communication mechanisms.
	3. The VS maintain an official contact point for communications but it is not always up-to-date in providing information.
	4. The VS contact point for communications provides up-to-date information, accessible via the Internet and other appropriate channels, on activities and programmes.
	5. The VS have a well developed communication plan, and actively and regularly circulate information to stakeholders.

Terrestrial Code reference(s):

- Point 13 of Article 3.1.2. on Fundamental principles of quality: Communication.
- Sub-point b) of Point 2 of Article 3.2.6. on Administrative resources: Communications.
- Point 4 of Article 3.2.14. on Administration details.

III-2 Consultation with stakeholders	Levels of advancement
<p>The capability of the VS to consult effectively with stakeholders on VS activities and programmes, and on developments in animal health and food safety.</p>	1. The VS have no mechanisms for consultation with stakeholders.
	2. The VS maintain informal channels of consultation with stakeholders.
	3. The VS maintain a formal consultation mechanism with stakeholders.
	4. The VS regularly hold workshops and meetings with stakeholders.
	5. The VS actively consult with and solicit feedback from stakeholders regarding proposed and current activities and programmes, developments in animal health and food safety, interventions at the OIE (Codex Alimentarius Commission and WTO SPS Committee where applicable), and ways to improve their activities.

Terrestrial Code reference(s):

Point 13 of Article 3.1.2. on Fundamental principles of quality: Communication.

Point 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Point 4 and Sub-point g) of Point 9 of Article 3.2.14. on Administration details and on Sources of independent scientific expertise.

III-3 Official representation	Levels of advancement
<p>The capability of the VS to regularly and actively participate in, coordinate and provide follow up on relevant meetings of regional and international organisations including the OIE (and Codex Alimentarius Commission and WTO SPS Committee where applicable).</p>	<p>1. The VS do not participate in or follow up on relevant meetings of regional or international organisations.</p>
	<p>2. The VS sporadically participate in relevant meetings and/or make a limited contribution.</p>
	<p>3. The VS actively participate⁸ in the majority of relevant meetings.</p>
	<p>4. The VS consult with stakeholders and take into consideration their opinions in providing papers and making interventions in relevant meetings.</p>
	<p>5. The VS consult with stakeholders to ensure that strategic issues are identified, to provide leadership and to ensure coordination among national delegations as part of their participation in relevant meetings.</p>

Terrestrial Code reference(s):

Article 3.2.11. on Participation on OIE activities.
 Point 4 of Article 3.2.14. on Administration details.

⁸ *Active participation* refers to preparation in advance of, and contributing during the meetings in question, including exploring common solutions and generating proposals and compromises for possible adoption.

III-4 Accreditation / authorisation / delegation	Levels of advancement
<p>The authority and capability of the public sector of the VS to accredit / authorise / delegate the private sector (e.g. private veterinarians and <i>laboratories</i>), to carry out official tasks on its behalf.</p>	<p>1. The public sector of the VS has neither the authority nor the capability to accredit / authorise / delegate the private sector to carry out official tasks.</p>
	<p>2. The public sector of the VS has the authority and capability to accredit / authorise / delegate to the private sector, but there are no current accreditation / authorisation / delegation activities.</p>
	<p>3. The public sector of the VS develops accreditation / authorisation / delegation programmes for certain tasks, but these are not routinely reviewed.</p>
	<p>4. The public sector of the VS develops and implements accreditation / authorisation / delegation programmes, and these are routinely reviewed.</p>
	<p>5. The public sector of the VS carries out audits of its accreditation / authorisation / delegation programmes, in order to maintain the trust of their trading partners and stakeholders.</p>

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Point 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

III-5 Veterinary Statutory Body (VSB)	Levels of advancement
<p>A. VSB authority</p> <p>The <i>VSB</i> is an autonomous authority responsible for the regulation of the <i>veterinarians</i> and <i>veterinary para-professionals</i>. Its role is defined in the <i>Terrestrial Code</i>.</p>	1. There is no legislation establishing a <i>VSB</i> .
	2. The <i>VSB</i> regulates <i>veterinarians</i> only within certain sectors of the veterinary profession and/or does not systematically apply disciplinary measures.
	3. The <i>VSB</i> regulates <i>veterinarians</i> in all relevant sectors of the veterinary profession and applies disciplinary measures.
	4. The <i>VSB</i> regulates functions and competencies of <i>veterinarians</i> in all relevant sectors and <i>veterinary para-professionals</i> according to needs.
	5. The <i>VSB</i> regulates and applies disciplinary measures to <i>veterinarians</i> and <i>veterinary para-professionals</i> in all sectors throughout the country.

Terrestrial Code reference(s):

- Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
- Point 9 of Article 3.2.1. on General considerations.
- Article 3.2.12. on Evaluation of the veterinary statutory body.

B. VSB capacity	Levels of advancement
The capacity of the VSB to implement its functions and objectives in conformity with OIE standards.	1. The VSB has no capacity to implement its functions and objectives.
	2. The VSB has the functional capacity to implement its main objectives.
	3. The VSB is an independent representative organisation with the functional capacity to implement all of its objectives.
	4. The VSB has a transparent process of decision-making and conforms to OIE standards.
	5. The financial and institutional management of the VSB are submitted to external auditing.

Terrestrial Code reference(s):

- Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
- Point 9 of Article 3.2.1. on General considerations.
- Article 3.2.12. on Evaluation of the veterinary statutory body.

III-6 Participation of producers and other stakeholders in joint programmes	Levels of advancement
The capability of the VS and stakeholders to formulate and implement joint programmes in regard to animal health and food safety.	1. Producers and other stakeholders only comply and do not actively participate in programmes.
	2. Producers and other stakeholders are informed of programmes and assist the VS to deliver the programme in the field.
	3. Producers and other stakeholders are trained to participate in programmes and advise of needed improvements, and participate in early detection of diseases.
	4. Representatives of producers and other stakeholders negotiate with the VS on the organisation and delivery of programmes.
	5. Producers and other stakeholders are formally organised to participate in developing programmes in close collaboration with the VS.

Terrestrial Code reference(s):

Points 6 and 13 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Communication.
Points 2 and 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.
Point 7 of Article 3.2.14. on Animal health and veterinary public health controls.

CHAPTER IV - ACCESS TO MARKETS

The authority and capability of the VS to provide support in order to access, expand and retain regional and international markets for animals and animal products.

Critical competencies:

Section IV-1	Preparation of legislation and regulations
Section IV-2	Implementation of legislation and regulations and stakeholder compliance
Section IV-3	International harmonisation
Section IV-4	International certification
Section IV-5	Equivalence and other types of sanitary agreements
Section IV-6	Transparency
Section IV-7	Zoning
Section IV-8	Compartmentalisation

Terrestrial Code References:

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.

Points 1 and 3 of Article 3.2.8. on Animal health controls: Animal health status / National animal disease reporting systems.

Sub-point g) of Point 4 of Article 3.2.10. on Veterinary Services administration: Trade performance history.

Article 3.2.11. on Participation in OIE activities.

Points 6 and 10 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities / Membership of the OIE.

Chapter 4.3. on Zoning and compartmentalisation.

Chapter 4.4. on Application of compartmentalisation.

Chapter 5.1. on General obligations related to certification.

Chapter 5.2. on Certification procedures.

Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.

Chapters 5.10. to 5.12. on Model international veterinary certificates.

IV-1 Preparation of legislation and regulations	Levels of advancement
<p>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 warranty 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).</p>	<p>1. 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.</p>
	<p>2. 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.</p>
	<p>3. 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 formal methodology to develop adequate national legislation and regulations regularly in all domains.</p>
	<p>4. The VS have the authority and the capability to participate in the preparation of national legislation and regulations with a relevant formal methodology to ensure adequate internal and external quality, involving stakeholder participation in most fields of activity.</p>
	<p>5. The VS regularly evaluate and update their legislation and regulations to maintain relevance to evolving national and international contexts.</p>

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.

Point 6 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities.

IV-2 Implementation of legislation and regulations and stakeholder compliance	Levels of advancement
The authority and capability of the VS to ensure that stakeholders are in compliance with legislation and regulations under the VS mandate.	1. The VS have no or very limited programmes or activities to ensure stakeholder compliance with relevant legislation and regulations.
	2. 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.
	3. Veterinary legislation is generally implemented. As required, the VS have a power to take legal action / to prosecute in instances of non-compliance in most relevant fields of activity.
	4. Veterinary legislation is implemented in all domains of veterinary competence and the VS work with stakeholders to minimise instances of non-compliance.
	5. The compliance programme is regularly subjected to audit by the VS or external agencies.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.

Point 6 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities.

IV-3 International harmonisation	Levels of advancement
<p>The authority and capability of the VS to be active in the international harmonisation of regulations and <i>sanitary measures</i> and to ensure that the national legislation and regulations under their mandate take account of relevant international standards, as appropriate.</p>	<p>1. National legislation, regulations and <i>sanitary measures</i> under the mandate of the VS do not take account of international standards.</p>
	<p>2. The VS are aware of gaps, inconsistencies or non-conformities in national legislation, regulations and <i>sanitary measures</i> as compared to international standards, but do not have the capability or authority to rectify the problems.</p>
	<p>3. The VS monitor the establishment of new and revised international standards, and periodically review national legislation, regulations and <i>sanitary measures</i> with the aim of harmonising them, as appropriate, with international standards, but do not actively comment on the draft standards of relevant intergovernmental organisations.</p>
	<p>4. The VS are active in reviewing and commenting on the draft standards of relevant intergovernmental organisations.</p>
	<p>5. The VS actively and regularly participate at the international level in the formulation, negotiation and adoption of international standards⁹, and use the standards to harmonise national legislation, regulations and <i>sanitary measures</i>.</p>

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.

Article 3.2.11. on Participation in OIE activities.

Points 6 and 10 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities / Membership of the OIE.

⁹ A country could be active in international standard setting without actively pursuing national changes. The importance of this element is to promote national change.

IV-4 International certification¹⁰	Levels of advancement
The authority and capability of the VS to certify animals, animal products, services and processes under their mandate, in accordance with the national legislation and regulations, and international standards.	1. The VS have neither the authority nor the capability to certify animals, animal products, services or processes.
	2. The VS have the authority to certify certain animals, animal products, services and processes, but are not always in compliance with the national legislation and regulations and international standards.
	3. The VS develop and carry out certification programmes for certain animals, animal products, services and processes under their mandate in compliance with international standards.
	4. The VS develop and carry out all relevant certification programmes for any animals, animal products, services and processes under their mandate in compliance with international standards.
	5. The VS carry out audits of their certification programmes, in order to maintain national and international confidence in their system.

Terrestrial Code reference(s):

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Point 2 of Article 3.2.7. on Legislation and functional capabilities: Export/import inspection.

Sub-point b) of Point 6 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities: Export/import inspection.

Chapter 5.2. on Certification procedures.

Chapters 5.10. to 5.12. on Model international veterinary certificates.

¹⁰ Certification procedures should be based on relevant OIE and Codex Alimentarius standards.

IV-5 Equivalence and other types of sanitary agreements	Levels of advancement
The authority and capability of the VS to negotiate, implement and maintain equivalence and other types of sanitary agreements with trading partners.	1. The VS have neither the authority nor the capability to negotiate or approve equivalence or other types of sanitary agreements with other countries.
	2. The VS have the authority to negotiate and approve equivalence and other types of sanitary agreements with trading partners, but no such agreements have been implemented.
	3. The VS have implemented equivalence and other types of sanitary agreements with trading partners on selected animals, animal products and processes.
	4. The VS actively pursue the development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners on all matters relevant to animals, animal products and processes under their mandate.
	5. The VS actively work with stakeholders and take account of developments in international standards, in pursuing equivalence and other types of sanitary agreements with trading partners.

Terrestrial Code reference(s):

Points 6 and 7 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation.
 Sub-point g) of Point 4 of Article 3.2.10. on Veterinary Services administration: Trade performance history.
 Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.

IV-6 Transparency	Levels of advancement
The authority and capability of the VS to notify the OIE of their sanitary status and other relevant matters (and to notify the WTO SPS Committee where applicable), in accordance with established procedures.	1. The VS do not notify.
	2. The VS occasionally notify.
	3. The VS notify in compliance with the procedures established by these organisations.
	4. The VS regularly inform stakeholders of changes in their regulations and decisions on the control of relevant diseases and of the country's sanitary status, and of changes in the regulations and sanitary status of other countries.
	5. The VS, in cooperation with their stakeholders, carry out audits of their transparency procedures.

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.

Points 1 and 3 of Article 3.2.8. on Animal health controls: Animal health status / National animal disease reporting systems.

Chapter 5.1. on General obligations related to certification.

IV-7 Zoning	Levels of advancement
<p>The authority and capability of the VS to establish and maintain disease free zones, as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable).</p>	1. The VS cannot establish disease free zones.
	2. As necessary, the VS can identify animal sub-populations with distinct health status suitable for zoning.
	3. The VS have implemented biosecurity measures that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary.
	4. The VS collaborate with their stakeholders to define responsibilities and execute actions that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary.
	5. The VS can demonstrate the scientific basis for any disease free zones and can gain recognition by trading partners that they meet the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
 Chapter 4.3. on Zoning and compartmentalisation.

IV-8 Compartmentalisation	Levels of advancement
<p>The authority and capability of the VS to establish and maintain disease free <i>compartments</i> as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable).</p>	1. The VS cannot establish disease free <i>compartments</i> .
	2. As necessary, the VS can identify animal sub-populations with a distinct health status suitable for compartmentalisation.
	3. The VS have implemented biosecurity measures that enable it to establish and maintain disease free <i>compartments</i> for selected animals and animal products, as necessary.
	4. The VS collaborate with their stakeholders to define responsibilities and execute actions that enable it to establish and maintain disease free <i>compartments</i> for selected animals and animal products, as necessary.
	5. The VS can demonstrate the scientific basis for any disease free <i>compartments</i> and can gain recognition by other countries that they meet the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

Terrestrial Code reference(s):

- Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
- Chapter 4.3. on Zoning and compartmentalisation.
- Chapter 4.4. on Application of compartmentalisation.

Supporting document N°4

THE GLOBAL FOOT AND MOUTH DISEASE CONTROL STRATEGY

Strengthening animal health systems through improved control of major diseases

The initial cost estimate of the global FAO/OIE strategy for the control of foot and mouth disease¹

Emiko Fukase
June 19, 2012

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¹ This paper is a product of a close cooperation between the World Bank (WB) Team and the FAO/OIE Global Framework of Transboundary Animal Diseases (GF-TADs) FMD Working Group. The paper is mainly written by Emiko Fukase (Consultant-Economist to WB/OIE) under direct supervision of Will Martin (WB) and general guidance of François Le Gall (WB). We would like to thank the members of GF-TADs FMD Working Group for discussions and advice. We are especially indebted to Joseph Domenech (OIE) and to Peter DeLeeuw (FAO) for overall guidance and inputs, including during our meetings at OIE Headquarters in Paris on November 21-22, 2011, and at FAO Headquarters in Rome on December 19-21, 2011. We are also deeply grateful to Giancarlo Ferrari (FAO), Samia Metwally (FAO), Nadège Leboucq (OIE) and Bernardo Todeschini (OIE) for generously sharing their data and expertise. We also would like to thank Brian Bedard (WB), Cyril Gay (United States Department of Agriculture (USDA)), Alex Donaldson (FAO/OIE consultant), Stephane Forman (WB), Mimako Kobayashi (WB), Caroline Plante (WB), Jonathan Rushton of Royal Veterinary College, University of London and Juergen Voegele (WB) for very useful inputs, comments and discussions.

Introduction

Foot and Mouth Disease (FMD) is widely believed to be the most economically devastating livestock diseases in the world (USDA 2007). FMD is endemic in many low-income countries including in most parts of Asia, Africa and the Middle East, and a few countries in South America. An FMD outbreak causes devastating impacts on farmers with adverse effects on livestock assets, production income and consumption. FMD is highly contagious and may spread to FMD-free countries through animal movement and international trade, as seen in outbreaks in the United Kingdom (2001), Japan and the Republic of Korea (2010)². The control of FMD is therefore a global public good (Forman, Le Gall, Belton, Evans, François, Murray, Sheesley, Vandersmissen and Yoshimura, 2009).

The Global Strategy for Control of FMD (hereafter the global strategy) is a fifteen year programme that has been developed by the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE) as part of the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs). The Progressive Control Pathway (PCP) for FMD involves FMD endemic countries progressively increasing their levels of FMD control through, for instance, building adequate laboratory and surveillance systems, creating effective veterinary services, and supporting quality-controlled vaccination programmes. In addition, the laboratory and epidemiology network proposed by the strategy is designed to provide an efficient and effective regional coordination and support mechanism, by clustering its main activities amid the seven FMD 'regional virus pools'. While much can be done to control the disease at the national level, an internationally-coordinated strategy takes advantage of the positive externalities that each country's disease control actions provide to other countries.

The objective of this paper is to prepare an initial cost estimate³ for the first five years of the global strategy at the country, regional and global levels. The paper relies heavily on discussions with and data provided by experts consulted between November 2011 and May 2012. At this initial step of evaluation, the paper is subject to two major limitations. First, as complete cost data at the individual country level are not available, the estimate should not be viewed as reflecting individual countries' 'budgets'. Second, as the global strategy builds on on-going FMD control programmes in some cases, a key question would be how 'incremental'⁴ (or 'additional' or 'marginal') investment would bring extra benefits. The incremental approach is taken for the cost estimate at the regional and global levels, so that the estimate does not include the costs of existing programmes such as salaries of existing staff or the costs incurred by laboratories which are already operating. However, in terms of our cost estimate at the country level, as the information to calculate incremental costs is not readily available, the paper reports 'total' costs as a first step.

This exercise should be seen as a preliminary one, allowing re-examination of costs with budget refinements, and providing a base from which reassessments may be made as information about the benefit-cost ratios of particular activities becomes available – perhaps from analyses of the type undertaken by Hagerman, McCarl, Carpenter and O'Brien (2012). The international budget costs required actually to implement the strategy would also depend heavily upon the extent to which resources generated for the strategy were used to supplement national and regional resources. If, for instance, support to countries were conditional on their own or regional commitments of resources, the budget would adjust depending

² These outbreaks cost the UK £5.8-6.3 billion (Thompson, Muriel, Russell, Osborne, Bromley, Rowland, Creigh-Tyte and Brown, 2002); Japan ¥235 billion (The *Japan Times*, August 12, 2010, Foot-and-Mouth Losses may Cost Miyazaki ¥235 billion); and Korea 3 trillion won (\$2.7 billion), (*JoongAng Daily*, March 25, 2011, 'With FMD Over, New Precautions Unveiled by Government').

³ The economic cost of an animal disease is typically assessed in terms of two distinct components in the literature: (i) losses following disease occurrence such as production losses and (ii) expenditures made to control disease or prevent its occurrence. See, for instance, Rushton, Thornton and Otte (1999). The scope of this paper is limited to the second component of the cost, specifically focusing on the cost of the global control strategy.

⁴ In this paper, the term 'incremental' is used to indicate activities which are 'additional' relative to existing ones.

upon the share of the total cost to be met from national and regional, versus international sources, and the willingness or ability of countries and regions to commit their own resources to the strategy.

Following this introduction, Section II presents briefly the background of this study, including the nature of the PCP, the characteristics of countries by PCP stage and the mechanism of the proposed global laboratory and epidemiology network. Section III turns to Tisdell (2006, 2009)'s simple model to illustrate the costs and benefits of animal disease control programmes especially when countries face initial fixed costs in starting a programme. Section IV presents data, methodology and our initial cost estimates of the global strategy at national, regional and global levels. Section V presents conclusions. We also document the spreadsheets used to calculate the costs of the global strategy. The spreadsheets are designed to be flexible so that one can easily change assumptions and data as new information becomes available and alternative approaches are investigated.

Background

The Progressive Control Pathway for Foot and Mouth Disease

The Progressive Control Pathway for Foot and Mouth Disease is a tool developed by FAO and OIE to assist countries where FMD is still endemic to progressively increase the level of FMD control (FAO, 2011). Figure 1 shows that the PCP consists of five stages in addition to stage 0 where no or only marginal FMD activities are undertaken, and for each stage (1 to 5), includes a set of typical FMD control activities.

The PCP takes into account the diversity of participating countries, and allows them flexibility in the speed and extent of their progress. Countries with no reliable information on FMD (Stage 0) would initiate comprehensive studies on epidemiology and socio-economic context. Once risk and control options are identified, countries may target their control measures upon a key livestock sector and/or critical risk points (from Stage 1 to 2). At higher stages, the focus moves from targeted approaches to elimination of FMD virus circulation in at least one zone of the country with more aggressive control strategies (FAO, 2011).

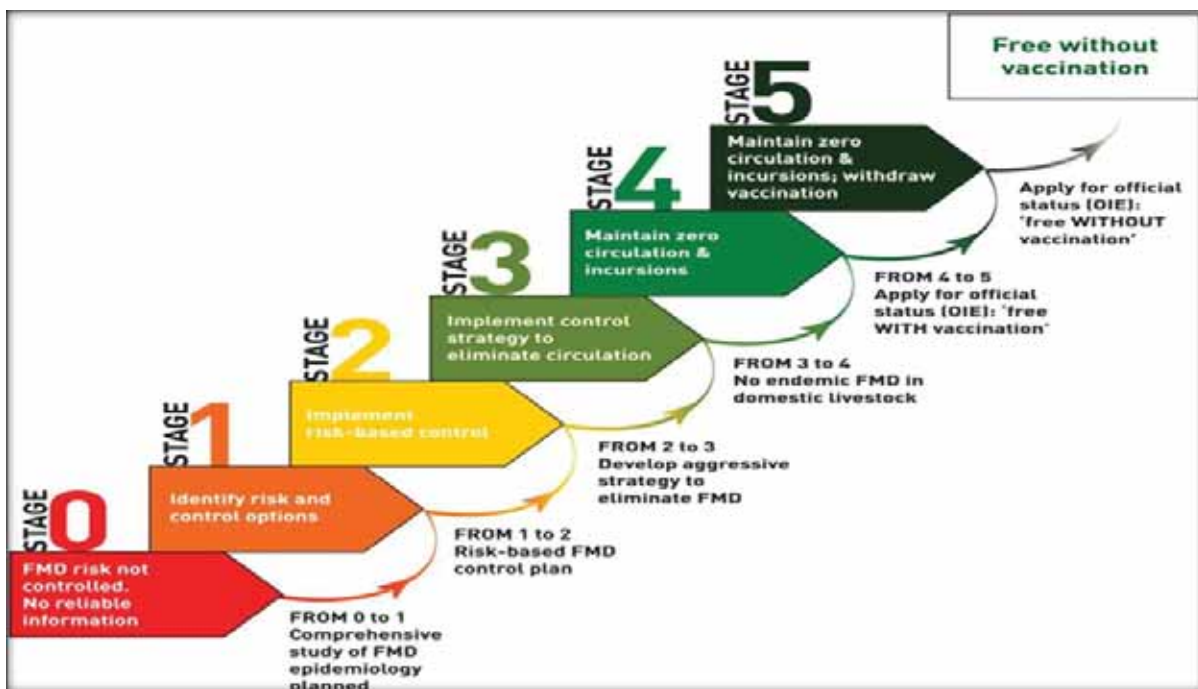


Fig. 1: Stages of the progressive control pathway for foot and mouth disease (Source: FAO, 2011)

While the PCP provides a guide for countries to progress to the point where they attain officially recognised FMD 'free with vaccination' or 'free without vaccination' status at the end of Stages 4 and 5, respectively, countries may decide not to progress beyond Stages 2 or 3, both of which provide sustainable management of FMD at lower levels and provide both domestic benefits and reduced risk of international externalities resulting from disease outbreaks (FAO, 2011).

Characteristics of countries by PCP stage

There is substantial variation in economic structure and income level across different PCP stage countries.⁵ Figure 2.a shows the average proportion of agricultural value added in Gross Domestic Product (GDP) by PCP stage countries. Countries in PCP stage 0 followed by those in PCP stage 1 are the economies whose incomes depend most on agriculture, with their average agricultural value added representing 26.0% and 20.5% of GDP respectively. In contrast, FMD-free⁶ countries are those which rely the least on agriculture, with their income from agriculture averaging 6.2% of GDP.

Figure 2.b shows average Gross National Income (GNI) per capita by PCP stage.⁷ Countries in PCP stage 0 are the poorest with their average GNI measuring \$1,514 (versus \$4,762 in PCP 1 countries) whereas GNI in FMD-Free countries averaged \$23,054 in 2010.⁸

⁵ As of May 2012, out of the OIE's 178 member countries, 66 are recognised as officially FMD free: 65 countries are officially recognised as 'FMD free without vaccination' as described in Article 8.5.2 (country) of the *Terrestrial Code* and one is 'FMD free with vaccination' as described in Article 8.5.3 (country). Ten countries have officially free 'zones': 6 countries have free zones without vaccination under Article 8.5.4 and 4 countries have free zones with vaccination under Article 8.5.5 and free zones without vaccination. Out of the 102 countries without FMD free status, 6 had an official status that is currently suspended. The mapping of countries into PCP stages in this paper is as per discussion with GF-TAD FMD Working Group on December 19, 2011. (See the spreadsheet for the list of countries). Thirty-nine countries are assumed to be in PCP stage 0, 23 in stage 1, 17 in stage 2, 8 in stage 3, and 11 in stage 4 or 5. 65 countries had 'FMD free without vaccination' status as mentioned above. The remaining countries were assumed to be 'Historically free of FMD' countries as described in Article 1.4.6.a of the *Terrestrial Code*. The 'Historically free of FMD' countries have no official recognition by OIE and their status is based on the absence of notification of the disease for 25 years (with or without vaccination) (e-mail communication with the GF-TADs FMD Working Group).

⁶ In this section, the term 'FMD free' refers to 65 countries which are officially recognised as 'FMD free without vaccination' and do not include 'Historically free of FMD' countries explained in Footnote 5.

⁷ GNI figures are reported here since the income group classification by the World Bank used in this paper is based on GNI per capita.

⁸ Some caution needs to be exercised in looking at national poverty levels with average GNI, as a small number of high income countries included in the group may increase the average substantially. If GNI measures are reported in median, the median GNI for PCP 0 and PCP 1 countries measured \$785 and \$1,450 respectively. If we use the proportion of people who live on incomes under \$1.25 in Purchasing Power Parity (PPP) as a measure of poverty, 43.4% and 23.5% of people in PCP 0 and PCP 1 countries on average lived on less than \$1.25 per day (author's calculation based on 'HDR_2011_Statistical_Tables' downloaded from the United Nations Development Program (UNDP) website (Available at: hdr.undp.org/en/reports/global/hdr2011/download/en/)).

Fig. 2.a.:
Agricultural Value Added in GDP
by PCP Stage⁹ (%) (Source: the
World Development Indicator
(WDI), the World Bank)

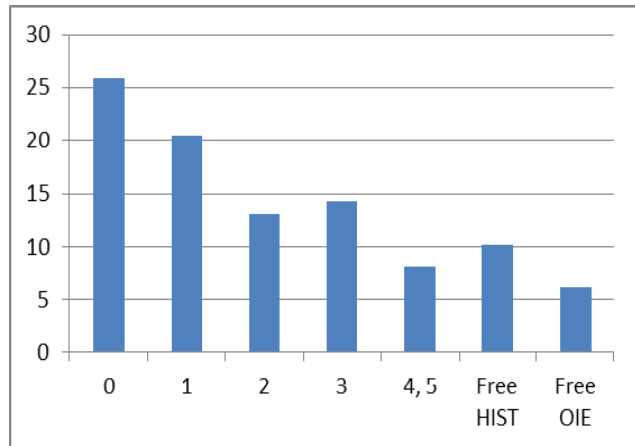


Fig. 2.b.:
Gross National Income per capita
by PCP Stage (\$)
(Source: the WDI, the World Bank)

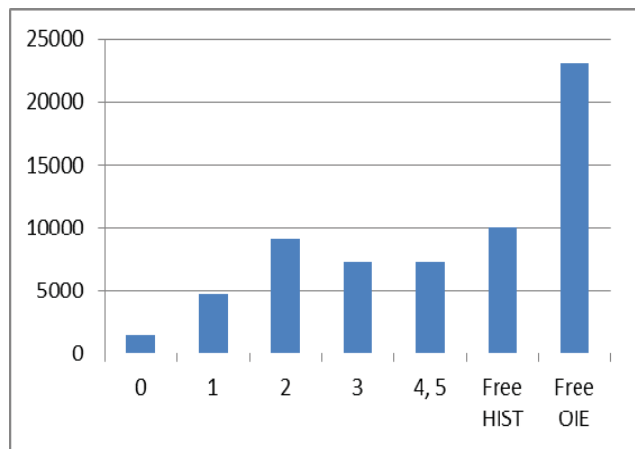
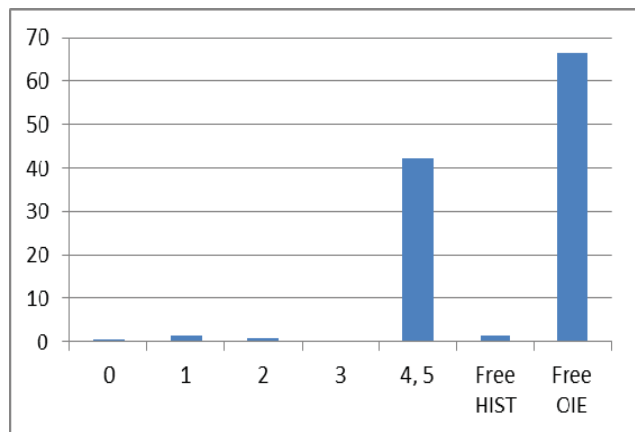


Fig.2.c.:
Exports of FMD Live Animals &
Meat per Capita by PCP Stage (\$)
(Source: the U.N. COMTRADE
System; the WDI, the World Bank)



In 2009, world exports of ‘meat’ and ‘live animals’ susceptible to FMD¹⁰ were \$67.9 billion, and FMD-free and PCP Stage 4, 5 countries accounted for 83.7% and 11.8% of the exports of this category respectively.

⁹ The categories ‘Free HIST’ and ‘Free OIE’ refer to the ‘Historically free of FMD’ and ‘FMD free without vaccination’ categories explained in Footnote 5.

¹⁰ The ‘Live animals’ considered are live bovine animals (HS (Harmonised System) 0102), live swine (HS 0103), and live sheep and goats (HS 0104). ‘Meat’ includes meat of bovine animals, fresh or chilled (HS 0201), meat of bovine animals, frozen (HS 0202), meat of swine (pork), fresh, chilled or frozen (HS 0203), and meat of sheep or goats, fresh, chilled or frozen (HS 0204). (Source: the U.N. COMTRADE System).

Figure 2.c presents exports of live animals and meat susceptible of FMD per capita by PCP stage. In 2009, FMD-free and PCP Stage 4 and 5 countries exported \$66.3 and \$42.4 worth of these products per capita respectively. The countries below PCP stage 4 appear to have much less opportunity to participate in (official) export markets with their average exports in per capita terms measuring around \$1.0 per year. FMD presence may play a role in this low level of export market participation, although structural limitations in the livestock sectors in those countries, such as low investments in processing and marketing infrastructure, may also play a role.

Laboratory and epidemiology network

The laboratory and epidemiology network proposed by the global strategy is characterised by its 'layered structure', at the national, regional and global levels, with its main activities clustered at the regional level (E-mail communication with the GF-TADs FMD Working Group). The latter structure is designed to provide the global strategy with an effective and efficient regional approach addressing the issues of externality, epidemiology, economies of scale and quality assurance.

The transboundary nature of animal diseases implies the existence of an externality (Ramsay, Philip, Riethmuller, 1999) as the participation (or non-participation) of a country in a control programme will lead to a decreased (or an increased) risk of contracting the disease for other countries. In the presence of externality, economic theory suggests lack of coordination between countries can lead to suboptimal outcomes in terms of control effort levels of each country and at the aggregate level. A regional approach through which countries coordinate and harmonise control or eradication programmes has long been recognised as a key strategy in addressing highly contagious and transboundary animal diseases. For FMD control, good contemporary examples of regionally coordinated approaches are already seen in the cases of the European Commission for the Control of Foot-and-Mouth Disease (EuFMD), the Pan American Health Organization (PAHO) and the Sub-Commission for Foot and Mouth Disease Control in China and South-East Asia (SEA-C-FMD) (GF-TADs FMD Working Group, 2011).

The specific viruses responsible for the disease differ by region and the concept of 'regional virus pools' provides an organising principle for coordinating laboratory and epidemiology activities. The vaccines needed in each country depend on the virus pool responsible for infections in that country. Figure 3 shows the seven epidemiological regions or virus pools of FMD.

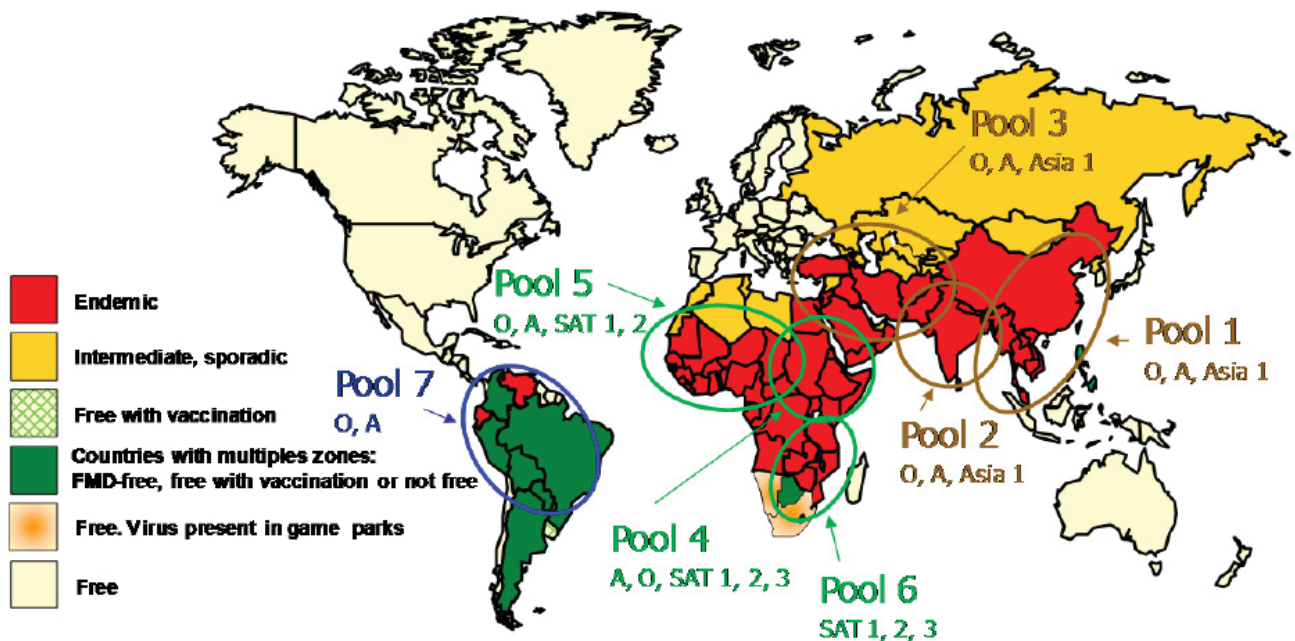


Fig. 3: Seven Regional Virus Pools of FMD (Source: OIE/FAO, 2009)

There are seven serotypes of the FMD virus (FMDV), namely, O, A, C, SAT 1, SAT 2, SAT 3 and Asia 1 and more than sixty subtypes, that infect clovenhoofed animals (OIE, 2009; USDA 2007). As vaccination against one serotype does not confer immunity against another, the vaccines needed differ between Pools and this creates a demand for laboratory and epidemiology services specific to each virus pool. Clustering laboratory and epidemiology activities at the regional level also generates economies of scale through pooling and sharing resources, expertise and technical capabilities.

Building on FAO/OIE's existing reference laboratory network, the global strategy would strengthen regional laboratory networks. While there is a number of OIE/FAO FMD Reference Centres (RCs) worldwide,¹¹ they are lacking in East and West Africa and in West Eurasia. In these regions, the global strategy would support existing leading regional laboratories, perhaps those in Egypt, Ethiopia, Senegal, Mali, Nigeria and Turkey, to become OIE/FAO RCs or equivalent laboratories through training, technical assistance and support in strengthening their laboratory networks.

The global strategy would recruit ten new epidemiologists to be based amid seven virus pools: one person each for Pools 1 (East and South-East Asia), 2 (South Asia), 5 (East Africa), 6 (Central and South Africa), and 7 (South America), three people for Pool 3 (West Eurasia) and two people for pool 4 (West Africa). The global strategy also foresees hiring seven laboratory specialists (one for each pool). These experts play a catalytic role in engaging in key activities at the regional level while providing technical assistance to countries through support missions.

The laboratory network would be integrated vertically at the national, regional and global levels. Ideally, there would be one national laboratory per country; with regional laboratories (RCs when they exist in the region or leading regional laboratories) assisting national laboratories through training, technical assistance, and laboratory testing¹²; and one of the RCs (perhaps the WRLFMD in the UK) serving as a global coordinating laboratory. The establishment of the laboratory network across all levels, with its major activities clustered at the regional level, is a central cost-saving element of the strategy.

The global strategy would also establish and strengthen an epidemiology network with a structure similar to that of the laboratory network: it would consist of national units for epidemiology, regional epidemiology centres (either official OIE/FAO collaborating centres or leading epidemiology regional units when an official OIE/FAO collaborating centres does not exist in the region)¹³; and one of the OIE/FAO collaborating centres for Epidemiology would coordinate and harmonise at the global level (GF-TADs FMD Working Group, 2011).

Another rationale for strengthening regional networks is to create a vehicle through which national FMD control programmes will be reinforced, through the progressive institutionalisation of Veterinary Services (VS) and their strengthening according to OIE standards on quality of VS, as well as through standardisation of safe and good quality vaccines.

Finally, progress of the global strategy would require strong coordination and cooperation mechanisms. One advantage of the GF-TADs performing the coordination role is that the strategy can benefit from the expertise and experience of OIE and FAO, including through insights from their successful campaign to

¹¹ There are eleven OIE/FAO RCs in Argentina, Botswana, Brazil, Canada, China, India, Russia, South Africa, Thailand, the UK and the USA. Some laboratories are not labeled as 'Reference Centres' but participate in the network, for instance, by providing data and hosting or taking part in events (e-mail communication with the GF-TADs FMD Working Group).

¹² Improving the quality of laboratory tests requires sharing and joint evaluation of surveillance information on laboratory diagnoses, serotyping, genetic characterisations and vaccine matching tests and harmonising standards for diagnostic procedures (OIE/FAO, 2009).

¹³ The Regional GF-TADs Support Units and/or the Regional Animal Health Centres may play a role when appropriate.

eradicate rinderpest¹⁴. Another advantage lies in the fact that the strategy can use these organisations' existing worldwide platforms (e.g., as seen in their network of OIE/FAO RCs) as well as their close ties with the regional organisations.

The proposed coordination mechanism of the global strategy is also characterised by a layered structure. At the international level, the GF-TADs' FMD Working Group, under the supervision of the GF-TADs Management Committee and the guidance of the GF-TADs Global Steering Committee, contributes to prepare and monitor the implementation of the global strategy, promotes the laboratory and epidemiology network at the regional and international levels, and contributes to the harmonisation of the various regional and national strategies (GF-TADs FMD Working Group, 2011).

At the regional level, where regional platforms which coordinate FMD control programmes do not already exist, the Working Group provides support to the Regional GF-TADs Steering Committees which in turn coordinate FMD activities at the regional level. At the national level, the Working Group provides technical assistance by providing international experts in the field of FMD activities and through its technical and administrative involvement in the procedures of GF-TADs acceptance of PCP country status. The FMD Working Group could also be involved by stimulating countries to ask for Performance of Veterinary Service (PVS) status if they progress along the PCP pathway.

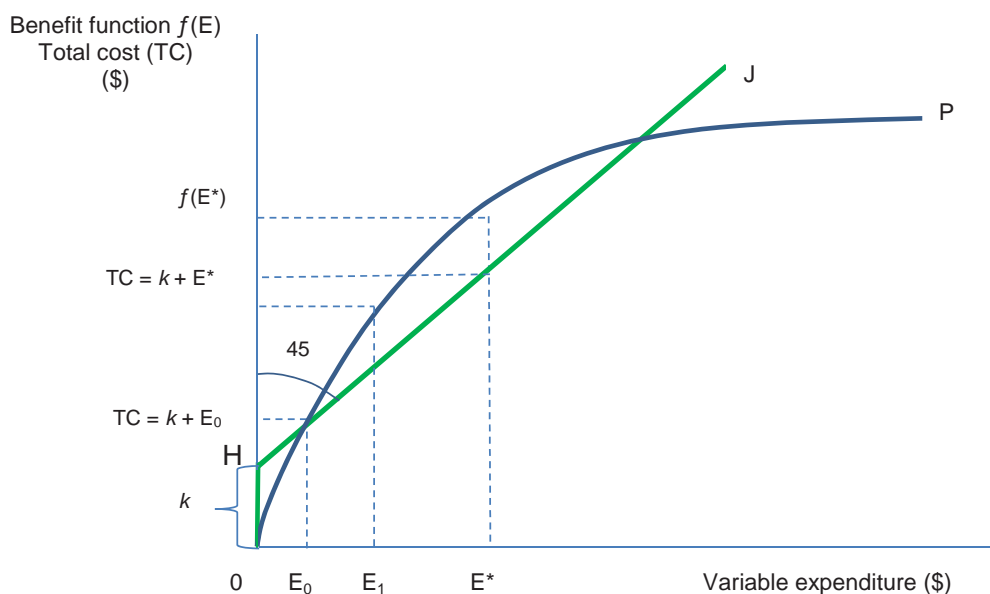


Fig. 4.a.: A Cost Benefit Model for Livestock Disease¹⁵

In the figure, the curve marked OP is the benefit function $f(E)$, which measures the benefits arising from reduction in economic loss from the disease and E represents the level of variable expenditure¹⁶ of control of the disease chosen by policy makers. The benefit function increases at a decreasing rate over the relevant range around the optimal level of activity, ($f' > 0$ and $f'' < 0$) with respect to E . In other words,

¹⁴ The New York Times, June 27, 2011, 'Rinderpest, Scourge of Cattle, Is Vanquished.' (Available at: www.nytimes.com/2011/06/28/health/28rinderpest.html?pagewanted=all).

¹⁵ In this figure, the benefit function $f(E)$ is shown in blue whereas the total cost, which consists of fixed cost (k) and variable cost (E), is drawn in green.

¹⁶ In the model, the investment in disease control is measured by expenditure in order to simplify the analysis. It should be noted that the success or failure of any control programme would also depend on *how* the expenditure will be used. It would be influenced by the quality of the programme and by the transparency and accountability of expenditures in the disbursement and use of the funds (e-mail communication with the Working Group).

assuming that a country starts its control activity in the area where the return is the highest, the benefit from the first unit of investment in disease control would be larger than each subsequent one.

A simple model: economics of controlling livestock diseases¹⁷

This section illustrates a simple model developed by Tisdell (2006, 2009) which analyses the economics of controlling livestock diseases taking into account initial fixed costs. Whereas this paper's focus is on costing of the strategy, this section is intended to put the cost analysis in a broader perspective; and to provide a link between the analysis in this paper and a Cost-Benefit analysis that may be undertaken in the future.

Tisdell (2006, 2009) develops a model which relates the benefit which arises from a control programme and the total cost of the programme for a country. Figure 4.a illustrates the model with the presence of start-up costs for controlling a disease (Tisdell, Figure 2, p.3, 2006).

The total cost (TC) of control programme consists of potential start-up or fixed costs, k ($k > 0$), and variable outlays E .

$$TC = k + E.$$

In the figure, start-up costs are shown as OH and the line HJ (a 45 degree line) represents the total cost of controlling the disease. The figure indicates that at least the level of expenditure of $k + E_0$ is required before total benefits cover costs.

Under this model, the net benefit (NB) from disease control is given by the difference between the total benefit and total cost

$$NB = f(E) - TC.$$

The net benefits of the control programme are maximised when the extra economic benefit from an additional increment to E equals the marginal cost. Choosing units such that the unit cost of variable expenditure is \$1,

$$f'(E^*) = 1$$

where E^* is the optimal level of variable expenditure.

Tisdell's model aids in explaining the costs and benefits of control programmes for countries in different PCP stages. For countries which are in low PCP stages, the existence of a start-up cost k implies that it may take some time before the benefits start to outweigh the costs. For instance, a comprehensive study of FMD epidemiology and its socio-economic impacts needs to be undertaken before developing a risk-based or targeted control measures (FAO, 2011). Research of this kind is part of the fixed costs.

For countries which have already invested in the control programme, for instance, if a country is at E_1 , the economically relevant question is how much 'incremental' investment would be necessary to reap extra benefits. For instance, if the country wishes to attain the nationally optimal level of investment, the additional expenditure needed to attain E^* would be $(E^* - E_1)$. For countries in later PCP stages, how far countries progress along the PCP may largely depend on countries' benefit functions. For instance, for potential exporters of livestock products, the benefits from striving for the FMD-free status are likely to be larger.

One challenge of the global strategy is that a number of countries in PCP stage zero are low income countries and they may face larger start-up costs due to systemic problems such as weakness of veterinary services, infrastructure, and legislative and institutional framework.

¹⁷ This section draws heavily from Tisdell (2006, 2009). We are indebted to Mimako Kobayashi and Will Martin for the extension of Tisdell's model.

Figure 4.b illustrates the case where a start-up cost for a country is prohibitively high to implement the programme.

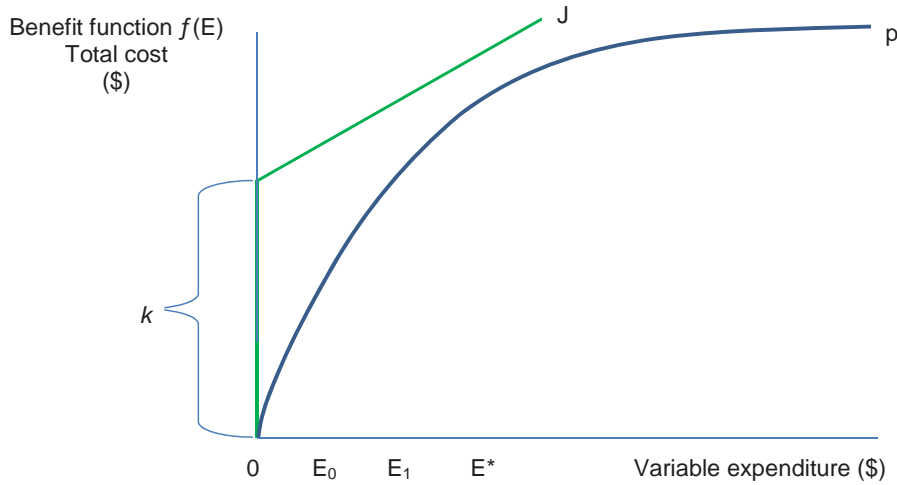


Fig. 4.b.: A cost benefit model for livestock disease control in a country with high start-up cost

Figure 4.b shows a hypothetical case in which the total cost is greater than total benefit at any level of investment ($NB = f(E) - TC < 0$) and that, in such a case, a country has no incentive to commit to the global FMD control programme alone. However, given the negative externalities for other countries created by the presence of the disease in another country, a 'big push' from the international community to cover these fixed costs – and perhaps some variable costs – may potentially be justified.

Figure 4.c introduces the concept of externality, taking into account the implications of increased disease control levels for other countries through, for instance, reductions in the probability of disease outbreaks.

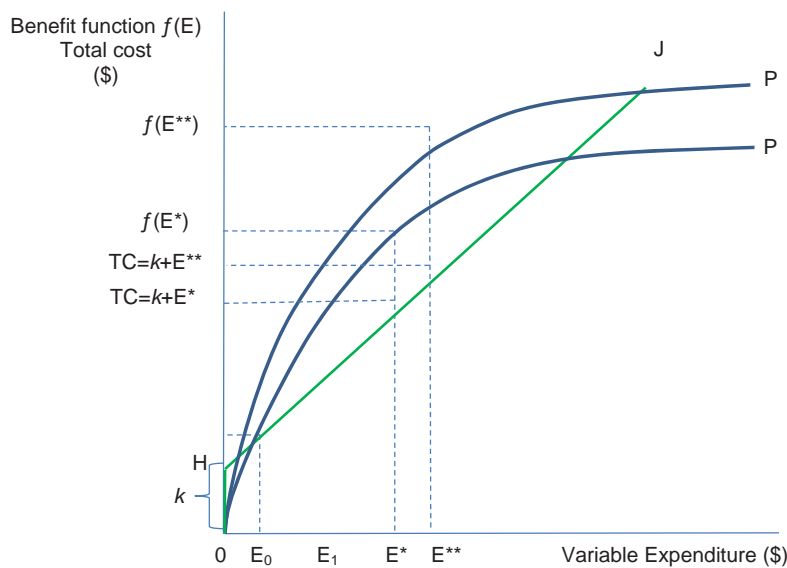


Fig. 4.c.: A cost benefit model for livestock disease with externality

When countries invest collectively in disease control programmes, the national benefit function shifts upward (OP') due to the resulting reduction in the risk of infections from other countries. The higher national benefit function associated with positive externality (OP') suggests there are both greater benefits $f(E^{**})$ and a higher optimal level of control at E^{**} than would be chosen by the individual country.

The current proposal for the PCP reflects professional judgement about the best approach to move forward on control of this disease. Before making final judgements about whether to support this proposal, countries are likely to want detailed estimates of the costs of this approach, and analyses of both the total benefits of

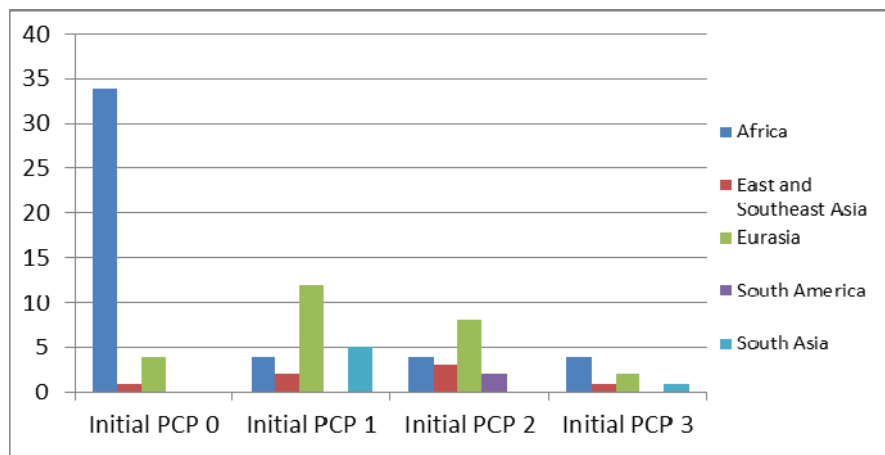
the currently-proposed package and estimates of the costs and benefits of some extensions to, or deletions from, the current proposal. This analysis is an initial step in the direction of providing this information by measuring the costs of the current proposal. If this cost corresponds to a level like E1 in the figures, knowing the magnitude and the composition of this cost might, alone, prove valuable to policy-makers for whom the scale of the cost is an important criterion for deciding whether a move forward is likely to be feasible. Information on the composition of the cost is likely to be important for policy makers interested in scaling up or scaling down the activity in some dimensions, such as by country or by the distance moved along the PCP.

Costing the global FMD strategy

Costs of the strategy at the country level

We included all countries in PCP stages 0, 1, 2 and 3 for potential support (a total of 87 countries). Countries in initial PCP stage 4 and beyond will be part of the regional and global networks even though they would not receive general support.

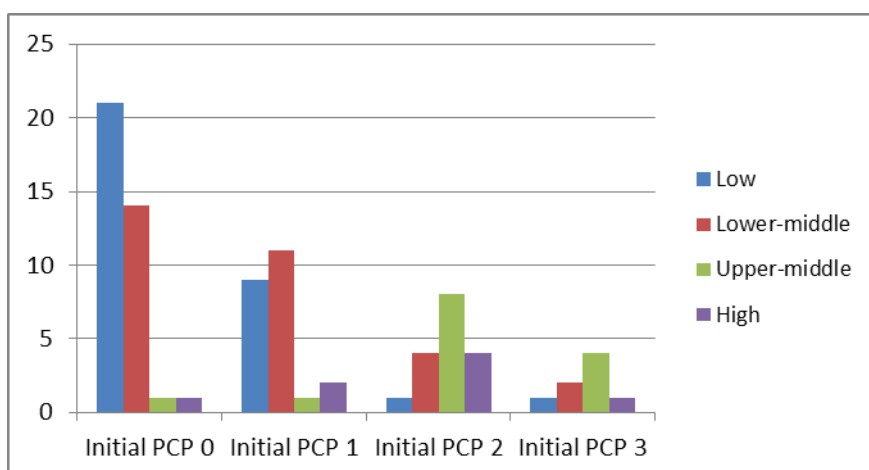
Figure 5.a presents the number of countries which belong to each PCP stage by region.¹⁸ The figure shows that the PCP 0 countries are predominantly in Africa. It is also clear that the majority of Eurasian countries belong to PCP stage 1 or 2; four out of five South Asian countries are mapped in PCP 1 (one in Stage 3); and the only two South American countries included are both in stage 2. While we are not sure that higher income Eurasian countries and SEA-C-FMD countries need support, they are included for the purpose of this initial cost estimate



	Africa	East and Southeast Asia	Eurasia	South America	South Asia	Total
Initial PCP 0	34	1	4	0	0	39
Initial PCP 1	4	2	12	0	5	23
Initial PCP 2	4	3	8	2	0	17
Initial PCP 3	4	1	2	0	1	8
Total	46	7	26	2	6	87*

Fig. 5.a.: Composition of PCP 0-3 countries by PCP stage and by region

¹⁸ 'Central and South Africa', 'North and East Africa', and 'West Africa' are aggregated as 'Africa'. 'Eurasia' includes 'Europe' and 'West Eurasia'. The country classification is as per the document 'FMD_Copie_de_List_of_Countries_PCP_Status_(1)' provided by GF-TADs FMD Working Group in November, 2011. See the spreadsheet for the countries included in each region.



	Low	Lower-middle	Upper-middle	High	Total
Initial PCP 0	21	14	1	1	37
Initial PCP 1	9	11	1	2	23
Initial PCP 2	1	4	8	4	17
Initial PCP 3	1	2	4	1	8
Total	32	31	14	8	85*

Fig. 5.b.: Composition of PCP 0-3 countries by PCP stage and by income group

Notes: *The totals of figure 5.a and figure 5.b differ since two countries which are not classified by the World Bank's income groups are not included in Table 5.b.

Figure 5.b shows the number of countries at each PCP level by income group¹⁹. As shown already in Figure 2.b, there appears to be a high correlation between low PCP level and low income level. In particular, PCP 0 countries are overwhelmingly low and lower-middle income economies and PCP 1 countries show a similar pattern, but to a lesser extent. The countries in PCP stages 2 and 3 include higher proportions of upper-middle and high income countries relative to PCP 0 and 1 countries. The PCP 2 and 3 countries are less likely to be low income countries, with some exceptions.

The total cost of the FMD Global Strategy for each country is calculated by summing up the cost of FMD activities across five years and across activities weighted by the probability of moving on to the next stage. It is assumed that 100% of countries in PCP 0 move to PCP 1 in five years. 75%, 50% and 25% of PCP 1, PCP 2 and PCP 3 countries, respectively, are expected to move on to the next stages at the beginning of the fourth year respectively.

Total Cost (TCs) of the programme for each country at the initial stage s is calculated using the following formula (the country subscript is omitted for simplicity):

$$TC_s = \sum_{j=1}^M [\sum_{y=1}^{Y_s} C_{j,s,y} + \alpha_s \sum_{y=Y_s}^{Y_s+4} C_{j,s+1,y} + (1 - \alpha_s) C_{j,s,Y_s} (5 - Y_s)]$$

where $C_{j,s,y}$ is the cost of the programme j ($j = 1, \dots, M$) in PCP stage s ($s = 0, \dots, 3$) in year y ($y = 1, \dots, Y_s, \dots, 5$) where Y_s is the years required to move to the next stage (for those countries that move). α_s is the probability of moving to the next stage at stage s ²⁰.

¹⁹ The income group is as per July 2011 classification defined by the World Bank. Economies are divided according to 2010 GNI per capita: low income, \$1,005 or less; lower middle income, \$1,006-\$3,975; upper middle income, \$3,976-\$12,275; and high income, \$12,276 or more (Available at: data.worldbank.org/about/country-classifications).

²⁰ For instance, consider calculating the cost of laboratory testing for a small country (Item 5 in Annex 1) whose initial PCP level is one ($j = \text{laboratory testing}$, $s = 1$). 75% of countries move to the next stage ($\alpha_1 = .75$) and it takes three

Cost of the FMD programme without vaccination costs

As the costing information on individual countries is not available at this stage, we employ a strategy of using an 'average' of countries which typically participate in PCP and costing assumptions provided by experts having experience in the regions. Annex 1 presents the data used for this calculation by FMD activity, by PCP stage, and by country size.

Table I presents the results for the 5-year FMD global strategy costs without including vaccination costs for 79 initial PCP 0-2 countries.²¹ Since these costs do not vary with the number of animals treated, they are part of the fixed costs. Once FMD activities start in a country, one national coordinator and an administrative assistant are typically hired as the national focal points (Item Country 1 (C1)).²² Whereas other FMD activities also involve local labor, their labor costs are not adjusted assuming that higher operational costs resulting from a variety of constraints in poorer (thus, lower labor cost) countries may offset their lower labor costs. Support for socio-economic appraisal (Item C2) is costed at a relatively higher amount in the first year of PCP stage 0 to initiate research, and is continued in the later stages. (Annex 1). Communication cost to disseminate information and raise public awareness, a crucial activity to control a disease by increasing outbreak reporting and changing behaviours, is costed in Item C3.

Table I. Initial 5-year cost of FMD activities at the country level (\$1,000)

Category	Sub-category	Est. Cost
C1. Personnel	C1. Salaries for a national coordinator and an administrative assistant	12,047
C2. Socioeconomic assistance	C2. Includes description of animal populations and husbandry systems, value chain analysis, socio-economic studies, and analysis of FMD impacts.	4,621
C3. Communication & public awareness	C3.1. Communication and Public Awareness	5,581
C4. Operation costs	C4.1. Office equipment (computers, printers, etc.)	1,580
	C4.2. Unforeseen (other)	3,950
C5. Laboratory and epidemiology	C5.1. Purchase/Replacement of machine, equipment and warranty	4,768
	C5.2. Annual cost for equipment, quality assurance (QA), and training	11,850
	C5.3. Local Labor for sample collection	1,689
	C5.4. Local Labor for sample laboratory testing	1,057
	C5.5. Cost of laboratory testing	3,532
	C5.6. Sampling material (vacutainers, needles, syringes, cryovials, etc.)	1,975
	C5.7. In-country training for field staff	9,875

years for progressing countries to go to the next stage ($Y_1=3$). The annual costs of laboratory testing for PCP stage 1 and stage 2 countries are \$5,000 and \$10,000 respectively. Thus, the expected total cost for laboratory testing for the next five years is $\$5,000 \times 3 + .75 (10,000 \times 2) + (1-.75) \times \$5,000 \times 2 = \$32,500$.

²¹ We assume that countries who move from PCP 2 to PCP 3 receive general support for the first two years of transition. However, for countries that are already in PCP stage 3, it is assumed that they do not receive general support for their national programme but receive some support for their vaccination programme.

²² Salaries of these personnel are estimated based on U.N. salary scales applying uniform assumptions that the salary of a national coordinator is about 50% of the total net remuneration across steps in levels NO-A and NO-B in the national officer category, while the administrative assistant salary is computed as 50% of average U.N. salaries across steps in level G4 of the general service category (Available at: www.un.org/Depts/OHRM/salaries_allowances/salaries/gs.htm). These assumptions are based on the actual FMD project experience in selected countries in Eurasia.

Table I. (cont.)

Category	Sub-category	Est. Cost
	C5.8. Travel expenses to participate in regional wet laboratory training	1,106
	C5.9. Travel expenses to participate in regional calibration trainings	988
	C5.10. Proficiency panel and shipping costs	988
C6. Database	C6.1. Database including user training and maintenance	2,573
Total		\$68,177

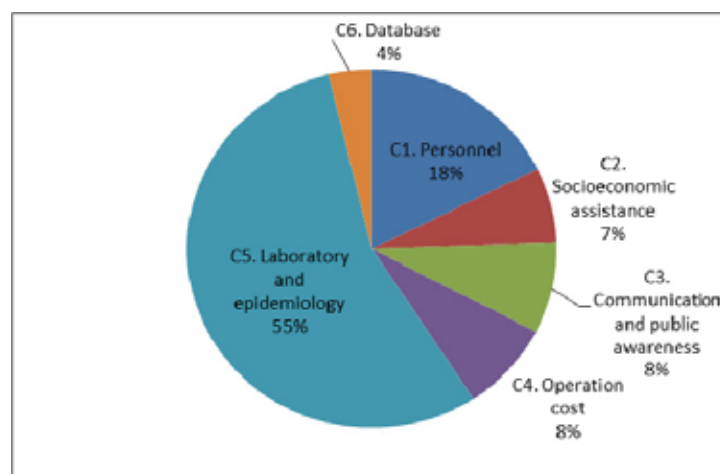


Fig. 6: Composition of FMD costs at the country level

Developing adequate laboratory and surveillance systems at the national level is an essential part of the strategy²³. The costs of doing so include the purchase and replacement of machinery every five years (Item C5.1)²⁴ and annual costs such as maintenance of equipment, quality assurance (QA) and provision of training (Item C5.2). The costs of sample collection (Item C5.3), laboratory testing (Item C5.5) and local labor for testing (Item C5.4) vary depending on PCP stages and country size. The farther a country has advanced in PCP stages and the larger the country's animal population (and consequently the number of tests per year)²⁵, the higher generally are the costs of sample collection and laboratory testing.

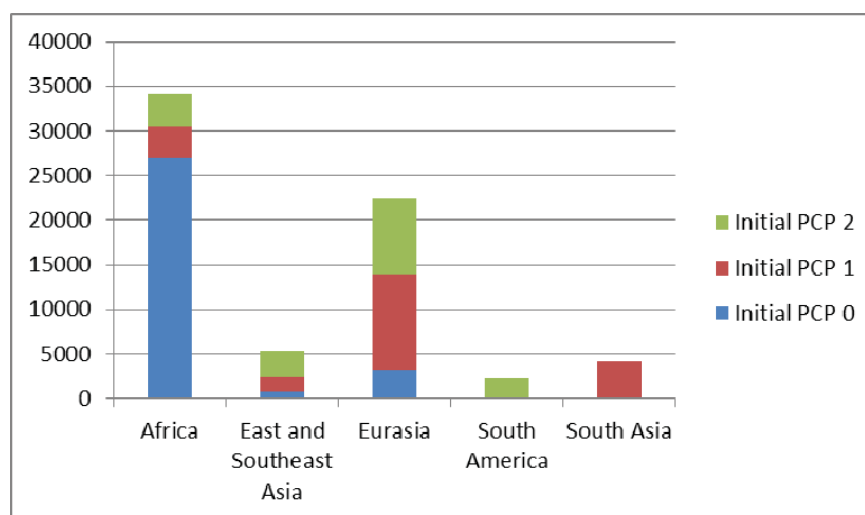
Our cost estimate includes expenses for national laboratories to participate in the regional laboratory network such as travel expenses for technical staff from the national laboratory to attend regional laboratory training (Items C5.8-C5.9) and the cost for proficiency panels and shipping (Item C5.10). The FMD Database that will be put in place will include regional and national modules (Item C6). Overall, the costs of PCP-related activities across PCP 0, 1, and 2 countries over the initial 5 years add up to \$68 million, not including vaccination costs.

Figure 7.a and Figure 7.b demonstrate the total FMD activity costs for initial PCP 0-2 countries by region and by income group respectively.

²³ In endemic areas, some countries lack effective central National Reference Laboratories (NRL)s for FMD and are in this case reliant on the services of an OIE/FAO reference laboratory or a veterinary laboratory in a neighbouring country (GF-TADs FMD Working Group, 2011). Many of them have limited laboratory capabilities and some of them face financial constraints in collecting samples from the field or in paying the airfare for shipping isolates to regional reference laboratories for further investigation.

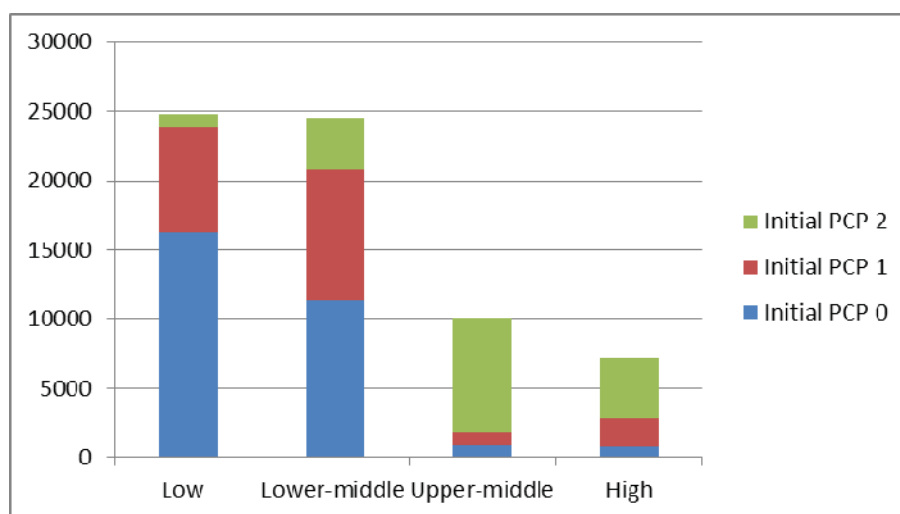
²⁴ An ELISA reader needs to be purchased/replaced every five years and an RT-PCR machine needs to be purchased for countries which move to PCP stage 2.

²⁵ Country sizes are classified into three categories: small if a country's FMD-susceptible animal population is less than 10 million; medium if it is between 10 and 30 million; and large for those with more than 30 million animals.



	Africa	East and SE Asia	Eurasia	South America	South Asia	Total
Initial PCP 0	26,936	800	3,131	0	0	30,867
Initial PCP 1	3,481	1,580	10,860	0	4,070	19,990
Initial PCP 2	3,747	2,984	8,356	2,233	0	17,319
Total	34,163	5,364	22,347	2,233	4,070	68,177*

Fig. 7.a.: Costs of FMD activities by region for initial PCP 0-2 countries (excluding vaccination costs) (\$1,000)



	Low	Lower-middle	Upper-middle	High	Total
Initial PCP 0	16,301	11,408	832	744	29,283
Initial PCP 1	7,494	9,392	961	2,144	19,990
Initial PCP 2	957	3,741	8,282	4,341	17,320
Total	24,751	24,540	10,074	7,228	66,593*

Fig. 7.b.: Costs of FMD activities by income group for initial PCP 0-2 Countries (excluding vaccination costs) (\$1,000)

*The totals of figure 7.a and figure 7.b differ since two countries which are not classified by the World Bank's income groups are not included in Table 7.b

Figure 7.a reveals that Africa followed by Eurasia are the regions which incur the largest costs accounting for \$34 million and \$22 million (50% and 33% of total costs) respectively. The high proportion of these regions in total cost appears to reflect a large number of countries belonging to these groups which are considered for support. In contrast, excluding vaccination costs, the South America region generates only \$2 million (3% of the total cost), as the latter region consists of only two countries. Figure 7.b shows that low and lower-middle income countries account for a large majority of costs with the combined costs of these countries amounting to \$49 million (74% of total cost).

Across all the countries, the average cost of the activities per country for five years (excluding vaccination costs) comes out to \$863,000. The costs of FMD activities for the countries whose initial PCP stages are 0, 1 and 2 are estimated to be \$791,000, \$869,000, and \$1,019,000 respectively. The higher the initial PCP stage, the higher is the cost of activities as there are more activities as countries progress (more machines, more surveillance activities etc.); and higher PCP stage countries tend to be higher-salary countries.

There is little variation in FMD costs across countries in the current data as we worked on the 'averages' of representative countries so that the sum of the costs across countries adds up to a reasonable cost estimate. At a later stage, when we develop individual country budgets, we expect to see much larger variation in national FMD activity costs. On the one hand, some countries may face a huge start-up cost, for instance, if they need to build necessary minimum infrastructure (see Figure 4.b). On the other hand, other countries may need little support if they are already integrated into a good FMD control programme.

Whereas PCP related activities included in this paper contribute to develop national veterinary services, the costing does not include budgets to strengthen the overall capacity of national veterinary services proposed in Component 2 of the global strategy.²⁶ Under the OIE PVS Pathway for the strengthening of Veterinary Services, 117 countries have officially requested an evaluation of performance of their Veterinary Services. On the basis of the high number of countries engaged in this process, there is a clear widespread expression of interest to address good governance of Veterinary Services. In any case, the success of this programme is linked to the overall capacity of national veterinary services in charge of these activities.

Vaccination costs²⁷

Vaccination is an essential tool for reducing the incidence of disease in endemic countries. In this section, we estimate the cost of vaccination using the vaccination schedule in which vaccination coverages per PCP stages/years and per region are indicated (See Annex 2). We assume that countries start vaccinating large ruminants (cattle and buffalo) in the first year of PCP stage 2 with vaccination targeted at critical risk points and in high risk groups, and that they progressively increase the proportion of animals vaccinated as they move along the vaccination schedule. At the beginning of stage 4, the focus moves to include more categories of susceptible livestock, starting to vaccinate both large and small ruminants (except in South America). The progression rates are specified to be the same as those used in calculating the costs for the FMD national activities above, i.e., 100% of countries in initial PCP 0 move to PCP 1 in five years whereas 75%, 50% and 25% of initial PCP 1, PCP 2 and PCP 3 countries respectively progress to the next stage at the start of the fourth year.

The data on population for cattle, buffalo, goat, and sheep are taken from FAOSTAT for the year 2009. Thus, other things equal, the higher a country's PCP stage within the range considered, the higher would be

²⁶ The available data emanating from country PVS evaluations and PVS Gap Analysis reports show that the budget necessary to reinforce national animal health systems over a five year period varies from US\$ 6.14 million to US\$ 199 million for a sample of 26 countries for which the livestock sector contribution to the national agriculture GDP is greater than 15% (15.2% to 86.9%) (OIE country PVS evaluations and PVS Gap Analysis reports).

²⁷ Throughout the paper, the 'Vaccination Costs' are defined to include the cost of vaccines, vaccination costs (vaccine administration) and Post Vaccination Monitoring (PVM).

the total vaccination costs. For the same fraction of the animal population vaccinated, the countries with larger animal populations will have higher vaccination costs. It is also assumed that the cost per dose of high quality, killed vaccine is \$.72 in South America and \$1.00 in other regions²⁸; all treated animals are vaccinated twice a year. The cost of vaccination is \$.70 per dose²⁹; and the cost for PVM is set to be .9% of the sum of the vaccine and vaccination costs (Personal and e-mail communication with the GF-TADs FMD Working Group).

Figure 8.a and Figure 8.b show the costs of vaccination by region and by income group respectively. Two countries with large vaccination costs, namely China and India, are not included in the Figures.³⁰

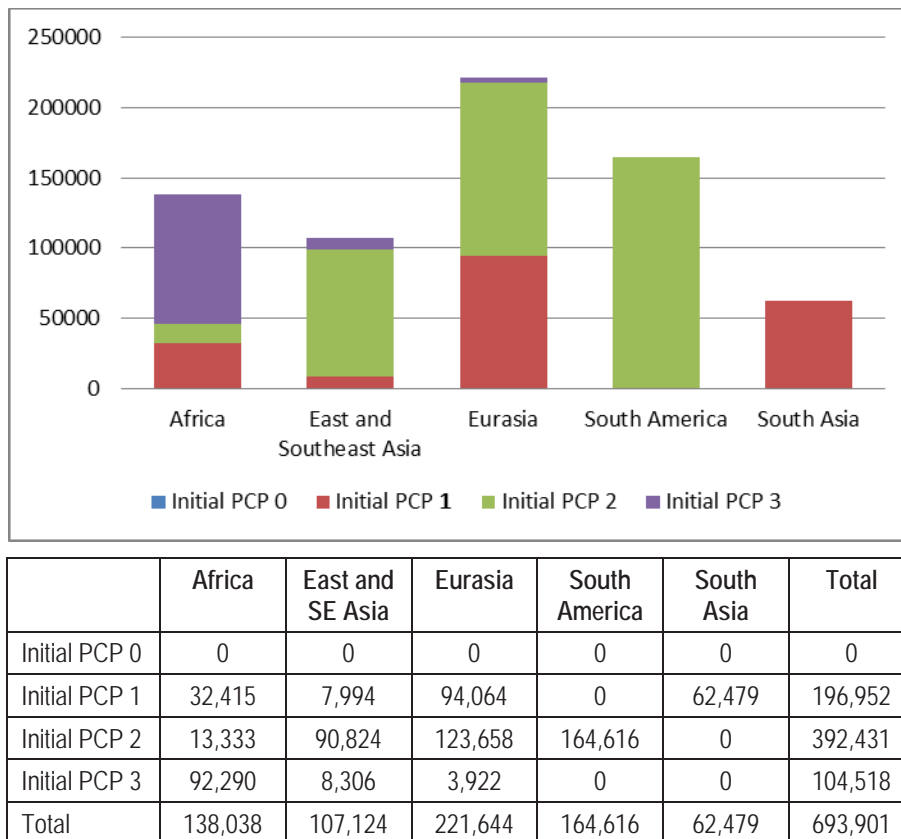
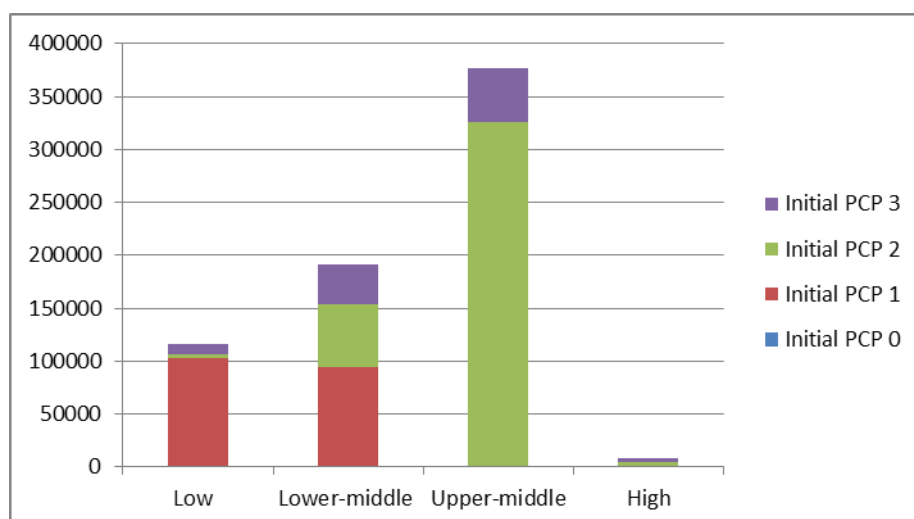


Fig. 8.a.: Costs of vaccination by region (\$1,000)

²⁸ The cost of vaccine in South America is based on the actual vaccine costs weighted by treated animal population for selected countries. For other regions, the assumption is based on the best estimate provided by the GF-TADs FMD Working Group.

²⁹ The non-labor cost of vaccine administration in countries with dispersed production systems is likely to be higher, other things being equal. However, as the latter countries tend to be low income countries, lower labor costs are assumed to offset higher other vaccination costs.

³⁰ China and India are not included in the initial vaccination cost calculation since: the global strategy is unlikely to provide full support to vaccination programmes for countries with huge animal populations; massive vaccination programmes are already taking place in China; and, the vaccination status in India is too complex to apply an uniform criterion (e-mail communication with the Working Group).



	Low	Lower-middle	Upper-middle	High	Total
Initial PCP 0	0	0	0	0	0
Initial PCP 1	102,724	94,055	89	83	196,951
Initial PCP 2	3,617	59,271	325,434	4,109	392,431
Initial PCP 3	10,104	38,632	51,860	3,922	104,518
Total	116,445	191,958	377,383	8,114	693,900

Fig. 8.b.: Costs of vaccination by income group (\$1,000)

Note: China and India are not included in the figures

The overall cost of vaccination is estimated to be \$694 million for initial PCP-stage 1-3 countries for the initial 5 years. Figure 8.a reveals that Eurasia generates the highest cost of vaccination, at \$222 million, followed by the South America region at \$165 million. In particular, it is worth noting that only two South American countries which are in initial PCP stage 2 account for 24% of total vaccination cost, reflecting the large animal population in these countries. The high proportion of vaccination costs for initial PCP 3 countries in Africa reflects mainly the cost for North African countries. Finally, the average vaccination cost per country turns out to be \$15 million with a standard deviation of \$25 million over the 5 initial years. The large dispersion of vaccination costs reflects a large variation in animal population across countries and different vaccination schedules depending on PCP stages.

Two caveats are suggested in interpreting these vaccination cost estimates. First, when countries are already using vaccination, the goal of the global strategy is not to replace but to complement and improve the existing programmes. Thus, for countries which already have good vaccination programmes, the estimated cost for the global strategy would be likely to decrease as more information comes to light. On the other hand, many current national vaccination programmes are believed to be ineffective, especially when cheaper but low quality vaccine is used.³¹ In these cases, a vaccination programme administered under the global strategy, with better technical support from international experts and superior quality vaccine, would more effectively enable countries to make progress in controlling FMD (e-mail communication with the GF-TADs FMD Working Group). Another distinction which needs to be made is whether livestock production is conducted under a commercial (or semi-commercial) system or by traditional smallholder producers. Since commercial producers would have already paid or would pay for FMD vaccination, funding may be sought

³¹ For instance, there have been several occasions when FMD vaccines have even caused outbreaks mainly because the viral antigen in the vaccine has not been fully inactivated and the product has not been properly tested for safety (e-mail communication with the GF-TADs FMD Working Group).

mainly for the vaccination of livestock raised by smallholders. It is also recognised that a good public-private partnership would reduce financial implications to governments and donors³².

Secondly, a limitation of the calculation in this study is that the vaccination cost is estimated based on a set of uniform assumptions rather than actual costs. Vaccination costs vary for a number of reasons, including variations in vaccine price, labor cost, infrastructure and production systems, to name a few. In particular, vaccine prices vary over a wide range, partly because the types of FMDV against which vaccines are supposed to protect differ depending on the epidemiology of the region.³³ Perhaps, the next step would be to evaluate the actual status of vaccination at the individual country level and determine which ‘additional’ steps would be necessary in each country to progress further along the PCP path.

Finally, the vaccination cost of \$ 694 million is by far the largest component of the cost of the strategy accounting for 91% of national costs. The high costs at the country level may lead to the introduction of mechanisms to secure economies of scales at the regional or global levels. For instance, the establishment of regional/global banks for the distribution of antigen/vaccine, based on an international call for tenders, might provide a means to realise savings on vaccination costs. The high proportion of vaccination costs and large variation in the costs across countries suggest that there may be considerable flexibility – and important policy choices to be made – with respect to the extent and regional coverage of the programme if insufficient resources were available for the full programme as currently envisaged.

Cost of the strategy at the regional and global levels³⁴

Regional level

Table II and Figure 9 present the result for the costing of the global strategy at the regional level³⁵

Table II: Initial 5-year costs of the global strategy at the regional level (\$1,000)

Category	Sub-category	Est. Costs
R1. Personnel	R1.1. Regional epidemiologists	7,500
	R1.2. Regional laboratory experts	2,100
	R1.3. Communication specialist	350
R2. Expert support missions	R2.1. Support missions to countries by regional epidemiologists	1,750
	R2.2. Support missions to national laboratories by regional laboratory experts	1,225

³² For instance, in some PCP 0 or 1 countries, whereas private wealthy producers may be ready to pay themselves to protect their own herds, the services and products for they would be ready to pay are not available. In such a situation, the national governments have an important role to play in lowering the start-up costs, for instance, by allowing vaccine imports or by equipping laboratories for basic capabilities (e-mail communication with the Working Group).

³³ The sources of vaccine price variation include the claimed potency of the vaccines, the extent of purification, whether vaccines are monovalent or multivalent, whether the manufacturer is in the private or public sector, where the vaccines are produced and so on (e-mail communication with the FMD Working Group). The price of vaccine can range from \$.5 per dose (or even less) up to around two dollars (e-mail communication with the FMD Working Group). If we assume that the low and high end costs of vaccine are \$0.5 and \$2 per dose, and assuming the other components of vaccination costs are unchanged, the corresponding vaccination costs become \$513 million and \$1.2 billion respectively.

³⁴ In this paper, the costs are mapped at the level where money will be paid, which is not necessarily the level where benefits will be reaped.

³⁵ The spreadsheet presents in greater detail how the costs at the regional and global level are calculated.

Table II (cont.)

Category	Sub-category	Est. Costs
R3. Coordination	R3.1. Regional SC meetings	230
	R3.2. Regional PCP meetings	420
R4. Laboratory	R4.1. Regional laboratory trainings for national laboratories	10,000
	R4.2. Training on calibration for national laboratories	1,280
	R4.3. Regional laboratory proficiency testing	8,000
R5. Epidemiology	R4.1. Regional epidemiology network coordination meetings	860
R6. Quality control	R6.1. Quality control centre for vaccine testing	3,000
R7. Database	R7.1. Set-up/maintenance of database for epidemiology and laboratory	7,500
	R7.2. Personnel for the management and analyses of the database	2,625
Regional total		\$46,840

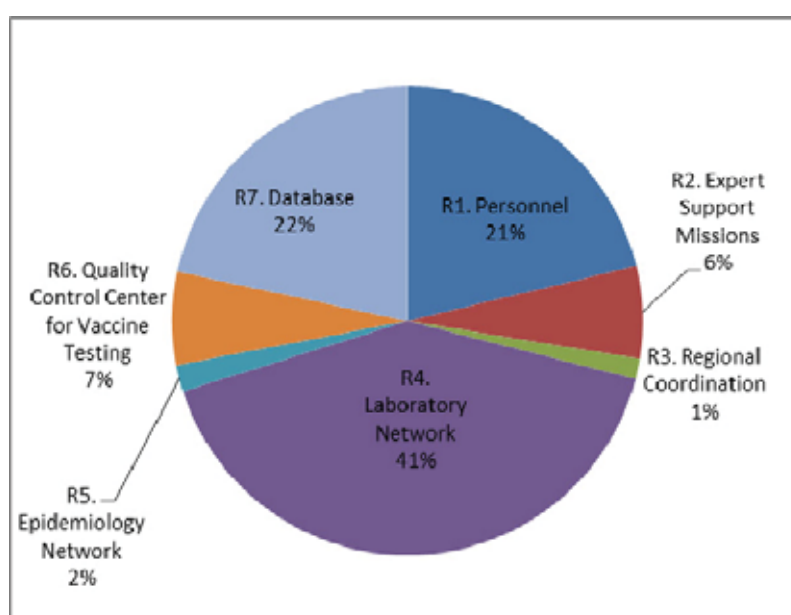


Fig. 9: Composition of FMD costs at the regional level

Item R1 (Regional 1) in Table 2 estimates the cost of recruiting ten epidemiologists and seven laboratory specialists to be based in one of the OIE/FAO regional units (Regional GF-TADs Support Unit or Regional Animal Health Centre) or regional organisations. These experts will also provide technical assistance to countries through support mission travel (Item R2).

Items R4.1 and R4.2 represent the cost of regional laboratories' provision of training (such as costs for trainers, overhead and materials) to staff from national laboratories, while Item R4.3 represents their costs for proficiency testing. The regional activities are reinforced through the regional epidemiology network (Item R5), three Quality Control Centres for vaccine testing (one Centre each in Asia, Africa and Eurasia) (Item R6), and the creation of databases for epidemiology and laboratory (Item R7).

Overall, the cost of the global strategy at the regional level for the initial five years is estimated to be \$47 million. The composition of the regional costs in Figure 9 reveals that a large majority of the funds to support regional activities (71%) will pay for laboratory and epidemiology activities (Items R4 through R7), reflecting the fact that the major activities of the laboratory and epidemiological network will take place at the regional level. Figure 9 also shows that about half of the regional costs, namely, expert support missions to countries (R2) and the regional laboratories' training/support to national laboratories (R4), directly benefit countries.

Global level

Table III and Figure 10 present the result of the costing of the global strategy at the global level.

Table III: Initial 5-year costs of the global strategy at the global level (\$1,000)

Category	Sub-category	Est. Costs
G1. Personnel	G1.1. GF-TAD staff (P5)	1,710
	G1.2. GF-TAD staff (P4)	1,350
	G1.3. Communication specialist	50
G2. Support Missions	G2.1. Support missions, such as Veterinary Service support, to regions and countries	175
	G2.2. Support materials to the SC and PCP meetings	350
G3. Coordination	G3.1. GF-TAD regular meetings	420
	G3.2. Participation in regional SC meetings	115
	G3.3. Participation in regional PCP meetings	324
	G3.4. Participation in workshops and conferences	69
	G3.5. Support to expert group to participate in conferences	69
	G3.6. Support to expert group to participate in Working Group meetings	115
G4. International conferences	G4.1. International conferences	1,000
G5. Laboratory	G5.1. Training for regional laboratories	1,500
	G5.2. Support to proficiency testing	1,500
G6. Epidemiology	G6.1. Global Epidemiology Network Coordinating meetings	243
G7. Database	G7.1. Maintenance of database for epidemiology and laboratory	1,000
	G7.2. Personnel for the management and analysis of the database	750
Global total		\$10,741

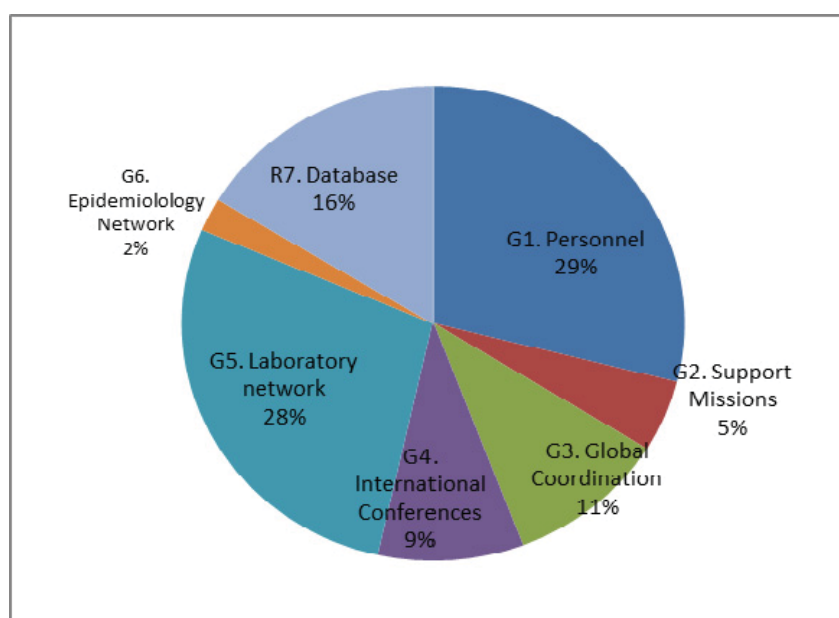


Fig. 10: Composition of FMD costs at the global level

The global strategy involves hiring an additional 1.5 P5 level staff and 1.5 P4 level staff for GF-TADs (Item Global 1 (G1)). Besides these new staff, since the salaries of current GF-TAD staff are already paid, the coordination costs consist mainly of travel expenses. For instance, the Working Group staff will provide support to regions and countries through support missions (e.g., PCP assessment support missions) and provision of materials (Item G2). The Working Group will support the GF-TADs Regional Steering Committee in organising country and regional PCP assessments and in facilitating regional surveillance and laboratory activities (Item G.3).

In the laboratory and epidemiology network, a global coordinating laboratory will play a leading role in providing training to regional RCs and leading laboratories (Item G5.1) and in supporting them in proficiency testing and laboratory analysis (Item G5.2). Similarly, one global epidemiology centre will play a coordinating role for the Regional Epidemiology Centres (Item G6). The cost for management and analyses of the laboratory and epidemiology database at the global level is costed in Item G7. Finally, International Conferences provide a forum for the key stakeholders to share visions and resources (Item G4). Overall, the costs of the global strategy for the initial five years at the global level add up to \$11 million. It is noted that about one-third of the cost, namely the global laboratory's support to regional laboratories (Item G5) and Support Missions (Item G2) directly benefits countries and regions (Figure 10).

Conclusion

This paper provides initial cost estimates for the Global FAO/OIE FMD Control Strategy at the country, regional and global levels for the first five years of the programme. Table 4 and Figure 11 present summary results for the costing of the global strategy by broad FMD activity category and by activity level.

Table IV: Summary results: cost of the global strategy for an initial 5 years at the country, regional and global levels and by broad category (\$1,000)

	Country	Regional	Global	Total
Sub Total A + B	68,180	46,840	10,741	125,761
Laboratory and epidemiology activities*1	40,401	33,265	4,994	78,660
Other FMD costs*2	27,779	13,575	5,747	47,101
Vaccination costs	693,900	0	0	693,900
Total	762,080	46,840	10,741	819,661

Notes: *1 This category includes Laboratory and Epidemiology (C5), Database (C6) at the country level; Laboratory (R4), Epidemiology (R5), Quality Control (R6), Database (R7) at the regional level; and Laboratory (G5), Epidemiology (G6), and Database (G7) at the global level. *2 This category includes Personnel (C1), Socioeconomic Assistance (C2), Communication and Public Awareness (C3) and Operation Costs (C4) at the country level; Personnel (R1), Expert Support Mission (R2), Coordination (R3) at the regional level; and Personnel (G1), Support Missions (G2), Coordination (G3) and International Conferences (G4) at the global level.

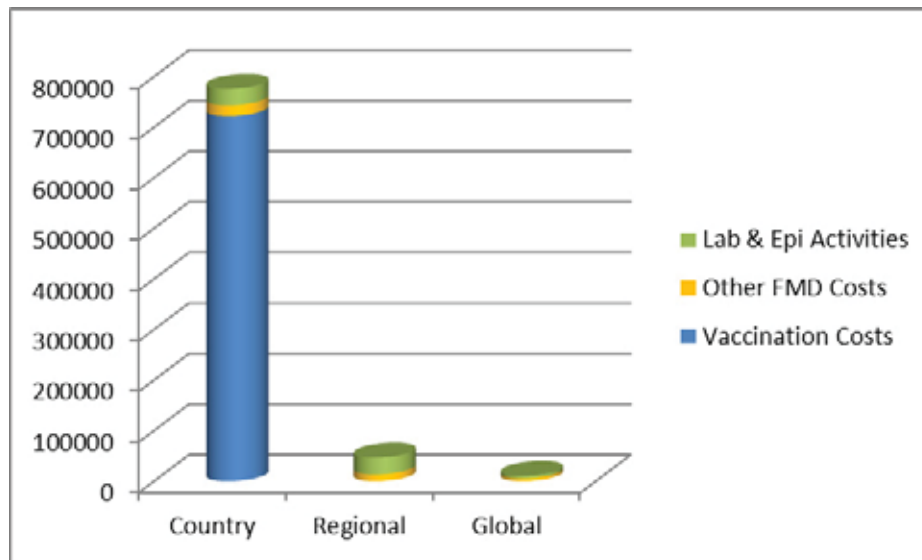


Fig. 11: Cost of the global strategy at the country, regional and global levels (\$1,000)

The results imply that the cost of the global strategy – as initially estimated – for the first five years of the programme would be \$820 million, of which \$762 million (93%), \$47 million (6%) and \$11 million (1%) are attributable to the country, regional and global levels respectively. The cost at the country level is estimated taking account of the typical FMD-related activities per stage for 87 countries which are initially at PCP Stages 0 to 3. The vaccination cost of \$694 million for the 45 initial PCP 1-3 countries is by far the largest component of the cost of the strategy. However, since the estimate does not account for the costs that are already being spent by existing programmes, the ‘incremental’ (or additional) costs which need to be funded are likely to be lower for those countries which already have effective vaccination programmes. The high proportion of vaccination costs and large variation in the costs across countries suggest that there may be considerable flexibility – and important policy choices to be made – with respect to the extent and regional coverage of the programme if insufficient resources were available for the full programme as currently envisaged.

The 5 year cost of national FMD programmes (other than vaccination costs) for 79 countries in the earliest stages of control (initial PCP stages 0-2) is estimated to be \$68 million (without vaccination costs). One limitation in the country cost estimate is that the estimate does not reflect the actual variation in the costs of national programmes since we used the data of selected countries that were assumed to be representative. However, some low PCP stage countries, which tend also to be low-income countries, may face much larger start-up or fixed cost, due to systemic problems such as weakness of veterinary services, infrastructure, and legislative and institutional frameworks. Strengthening national veterinary services is especially important since the success of the control programme is closely linked to the overall capacity of national veterinary services in charge of these activities.

A regionally and internationally coordinated approach is regarded as a key to control transboundary animal diseases taking advantage of the positive externalities that each country’s disease control actions provide to other countries. The cost at the regional level is characterised by a high proportion of the cost going to laboratory and epidemiology activities clustered around the seven FMD ‘regional virus pools’. About half of the cost at the regional level directly benefits countries through training, laboratory support and expert support missions, and approximately one-third of the cost at the global level benefits regions and countries directly in a similar way.

Finally, this exercise should be viewed as an initial step of costing, which may be used as a base for gap analysis and needs to be refined as new information becomes available and policy issues such as the design of support arrangements are addressed.

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Annex 1. Costing the FMD global strategy per stage other than vaccination costs

	1	2	3	4	5	6	7	8	9	10	11	12	13
PCP	5-y Maintenance of lab capacity (machine & replacement & OA)	5-y PCR equip, warranty, OA, training	5-y AbELISA equip, warranty, OA, training	1-y Cost for equip, OA, training	1-y Cost testing - Small country (pop < 10 mil)	1-y Cost testing - Med country (pop 10- 30 mil)	1-y Cost testing - Large country (pop > 30 mil)	Twice in 5-y Regional wet lab training	1-y Regional Calibration training	1-y Proficiency panel/ lab (2 panels+ shipping)	Local Labor for sample laboratory testing 1 yr (1 Lab Expert) (small country)	Local Labor for sample laboratory testing 1 yr (1 Lab Expert) (medium country)	Local Labor for sample laboratory testing 1 yr (1 Lab Expert) (Large country)
From 0 to 1	30000	0	30000	30000	5000	7000	10000	14000	2500	2500	2000	2500	3000
From 1 to 2	100000	70000	30000	30000	10000	15000	20000	14000	2500	2500	3000	3500	4000
From 2 to 3	100000	70000	30000	30000	15000	25000	35000	14000	2500	2500	4000	4500	5000
From 3 to 4	No general support is anticipated for countries going to stage 4 or 5												

	14	15	16	17	18	20	21 ¹	22	23	24	25		
PCP	Local Labor for sample collection 1 yr 1 Field Vet (each 200 samples) (Small country)	Local Labor for sample collection 1 yr 1 Field Vet (each 200 samples) (Medium country)	Local Labor for sample collection 1 yr 1 Field Vet (each 200 samples) (Large country)	1-y Sampling material (vacutainers, needle, syringes, cryovials, etc.)	5-y Socioeconomic assistance (study and description of animal populations, value chain analysis, etc.)	1-y in-country training for field staff	1-y Salaries for National Coordinator and administrative assistant	5-y office equipment (computers, printers, etc.) and operating costs	1-Y Database- user's training and maintenance	5-y unforeseen (others)	1-y communication and public awareness	Proportion of countries expected to move from one stage to the next	Time required (in years) to move to the next stage
from 0 to 1	3500	4000	5000	5000	65000	5000	n.a.	20000	5000	50000	14000	100%	5
from 1 to 2	4500	5000	6000	5000	50000	5000	n.a.	20000	10000	50000	14000	75%	3
from 2 to 3	5500	6000	7000	5000	50000	5000	n.a.	20000	10000	50000	17000	50%	3
from 3 to 4	No general support is anticipated for countries going to stage 4 or 5											25%	3

Source: This estimate is developed based on the 'Costing per Stage_rev1.xlsx' provided by GF-TADs FMD Working Group.

Notes: The table reflects the schedule for countries that move on to the next stage.

* 1 See footnote 22 for the labour cost calculation.

Annex 2. Vaccination schedule

PCP	Color
0	Red
1	Orange
2	Yellow
3	Light Green
4	Dark Green

Region: Asia and Eurasia

PCP stage	Y1	Y2	Y3	Y4	Y5
from 0 to 1	0%	0%	0%	0%	0%
from 1 to 2	0%	0%	0%	20%	25%
from 2 to 3	20%	25%	30%	45%	50%
from 3 to 4	45%	50%	50%	50%*	60%*

Region: Africa

PCP stage	Y1	Y2	Y3	Y4	Y5
from 0 to 1	0%	0%	0%	0%	0%
from 1 to 2	0%	0%	0%	10%	10%
from 2 to 3	10%	15%	15%	30%	30%
from 3 to 4	30%	40%	40%	50%*	50%*

Region: South America

PCP stage	Y1	Y2	Y3	Y4	Y5
from 0 to 1					
from 1 to 2					
from 2 to 3	50%	50%	50%	60%	60%
from 3 to 4	60%	70%	80%	80%	80%

Source: GF-TADs FMD working group discussion on December 20, 2011

Notes: The percentages in the tables indicate the vaccination coverage for countries that move on to the next stage. For countries which remain in the same stages, the vaccination coverage in the fourth and fifth years is assumed to be the same as in the third year.

* indicates that both large (cattle, buffalo) and small (sheep, goat) ruminants are treated. Otherwise, only large ruminants are targeted.

