



Hemispheric Program for the Eradication of Foot-and-Mouth Disease **PHEFA**

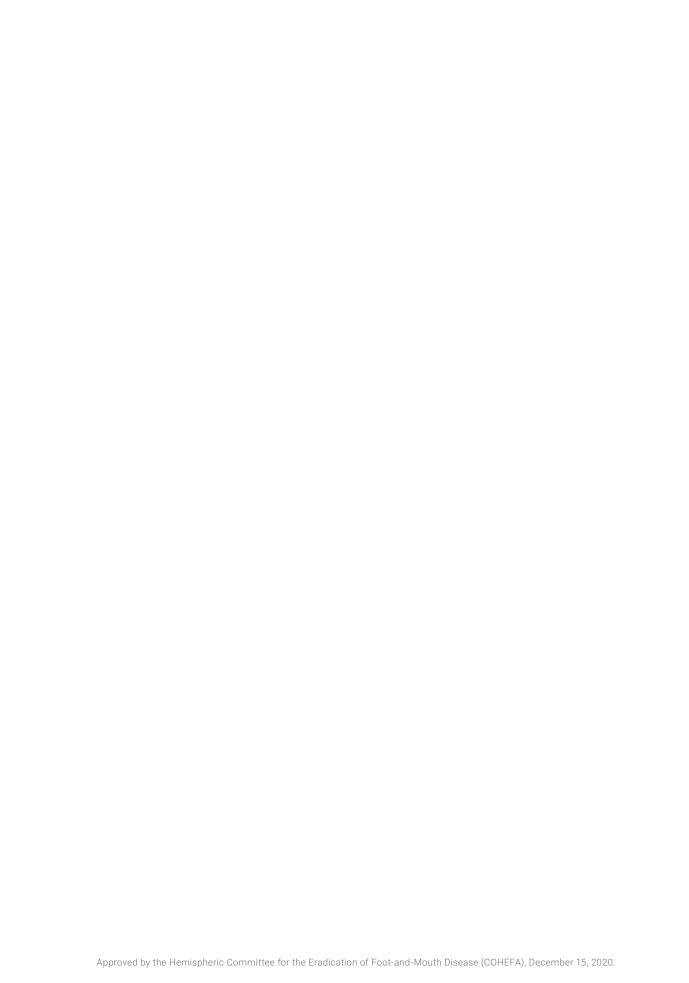
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ACTION PLAN PHEFA 20212025









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Glossary

APHIS/USDA United States Department of Agriculture's Animal and Plant Inspection Service

CAN Andean Community

COHEFA Hemispheric Committee for the Eradication of Foot-and-Mouth Disease

COSALFA South American Commission for the Fight Against Foot-and-Mouth Disease

COTASA CAN Technical Committee on Agricultural Health

CVP Permanent Veterinary Committee of the Southern Cone

FAO Food and Agriculture Organization of the United Nations

IICA Inter-American Institute for Cooperation on Agriculture

OIE World Organization for Animal Health

OIRSA International Regional Organism for Plant and Animal Health

OVS Official Veterinary Service

PAHO Pan American Health Organization

PANAFTOSA Pan American Foot-and-Mouth Disease Center

PHEFA Hemispheric Program for the Eradication of Foot-and-Mouth Disease

WHO World Health Organization

Presentation

The Pan American Foot and Mouth Disease Center of the Pan American Health Organization/World Health Organization (PANAFTOSA-PAHO/WHO) is privileged and honored to present the Action Plan 2021-2025 of the Hemispheric Program for the Eradication of Foot-and-Mouth Disease (PHEFA).

This plan represents a promising turning point for the American continent since it establishes the current context of the advances brought about by the PHEFA since its first Action Plan 1988-2009, which posed the regional challenge of eradicating the disease by 2009. Later, the second Action Plan 2011-2020 achieved that over 95% of the territory and the population of herds and animals reached the status of free of foot and mouth disease with or without vaccination. Now, with the guidelines and strategies of the new Action Plan, the whole continent is expected to be free from foot-and-mouth disease by 2025.

This document describes the specific objectives and goals of the PHEFA Action Plan for a 5-year period (2021-2025). It was elaborated by PANAFTOSA-PAHO/WHO with the collaboration of a group of professionals from the veterinary services of the countries connected with the programs for the eradication and prevention of foot-and-mouth disease of the continent. The PHEFA Action Plan 2021-2025 was approved during the 3rd Extraordinary Meeting of the Hemispheric Committee for the Eradication of Foot and Mouth Disease (COHEFA) on December 15, 2020.

With this instrument, PAHO, through PANAFTOSA, will continue accompanying its Member States in the eradication of foot-and-mouth disease, and ensuring animal health in the Americas, an essential condition for human and environmental health.

Ottorino Cosivi

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Acknowledgements

The Pan American Center for Foot-and-Mouth Disease of the Pan American Health Organization (PANAFTOSA/PAHO) would like to thank all those who participated in the elaboration of this document: technical and editorial coordinators of this publication, Alejandro Rivera, Manuel Sanchez Vazquez, Rodrigo Garcia, Guilherme H.F. Marques, Júlio César Augusto Pompei, Edviges Maristela Pituco and Monica Martini; collaborators and technical reviewers of the countries – Argentina, Facundo Linares (in memorian), Mariano Ramos and Horacio Angélico; Bolivia, Jorge Berrios; Chile, Marta Celeste Rojas Figueroa; Brazil, Geraldo Marcos de Moraes, Ana Carla Martins Vidor, Paula Amorim Schiavo and Diego Viali; Colombia, Alfonso José Araujo Baute; Ecuador, Lidia Alexandra Burbano Enriquez; Paraguay, Victor Darío Maldonado; Peru, Ubaldo Flores; Uruguay, Edgardo Vitale; and Venezuela, Wilmer Alcázar.







Executive summary

At the end of the Action Plan 2011-2020, the South American territory officially recognized free from Foot-and-Mouth Disease has increased from 67.6% in 2010 to 94.7% by the end of 2019. The herds free from foot-and-mouth disease, which at the beginning of the current action plan accounted for 63.7% increased to reach 97.4% and bovine and buffaline free populations raised from 84.4% to 95.4%. Nearly 5% of the territory, of the herds and the cattle population of South America have no animal health status recognition by the end of 2020, including the whole territory of Venezuela. On the other hand, North America, Central America and the Caribbean remained without foot-and-mouth disease outbreaks during the 2011-2020 period as a result of a foot-and-mouth disease prevention policy with high levels of protection.

During this period, a clear advance toward eradication was observed in the territories that were lagging behind in their control programs in 2010 and a preservation of the animal health status is observed in the disease-free countries of the Southern Cone which, at that time, had sporadic occurrence of outbreaks in vaccinated populations.

Nevertheless, with the exception of Colombia, the disease-free countries with vaccination did not advance as expected to the free status without vaccination, according to what the Action Plan 2011-2020 had envisaged. At the end of the decade, only two disease-free countries established a roadmap with defined actions and deadlines to advance in the transition to the free status without vaccination in spite of the increasing evidence, provided by the surveillance actions, that the infection would have been eliminated from their animal populations.

By the end of 2020, the foot-and-mouth disease risk is limited to the north of the Andean sub region. The current animal health situation of Venezuela derives from the fact that control actions have not achieved enough efficacy to change the patterns of infection trans-

mission, resulting in the threat of sporadic viral incursions in Colombia, as confirmed by the outbreaks of 2017 and 2018 in the country. The only cluster of type "0" genotypes active in South America corresponds to lineage 6 according to the classification defined by Malirat *et al* (2011) which have been isolated exclusively in the north of the Andean subregion and suggests that the *pool* 7 of South America shows, at the end of the decade, a limited geographic distribution restricted to the territory of one country.

On the other hand, it should be noted that from a historical perspective, the health policies in the countries of the Americas, those free from foot-and-mouth disease either with or without vaccination, have been effective to prevent the introduction of the foot-and-mouth disease virus from other continents, which is confirmed by the absence of extra-regional viral incursions as of the second half of the XX century. This is probably favored by the development of the livestock industry in the region and the vocation to export animal proteins, a current characteristic of a large part of the continent, which reduces significantly the demands of commercial exchange of animals and livestock products coming from other regions of the world.

After more than 8 years with no new occurrences of foot-and-mouth disease in the disease-free countries with vaccination of South American (except for Colombia), which shows that the sporadic occurrence pattern observed between 2002 and 2012, and most probably the subclinical transmission of the virus have been disrupted, follow-up is necessary to show the virus elimination in vaccinated populations by suspending vaccination campaigns. Maintaining these campaigns indefinitely is not consistent with the term eradication or elimination of an infection, as defined by OIE and WHO, respectively.

The general purpose of the Action Plan 2021-2025 is to complete foot-and-mouth disease eradication in South America and strengthen the prevention and response capacity of veterinary services in the countries of the continent.

This general purpose will be achieved through actions aimed at three specific objectives:

- 1. Eradicate the foot-and-mouth disease virus acting in the Venezuelan territory and mitigate the risk in the north of the Andean subregion.
- 2. Continue with the transition to the official disease-free status without vaccination in the disease-free countries that maintain vaccination.
- 3. Maintain the animal health status of the territories free from foot-and-mouth disease without vaccination.

The specific objective 1 addresses the need to reestablish a revised immunization program in Venezuela as the main focus to stop viral transmission and a substantial improvement of surveillance to achieve the foot-and-mouth disease-free status with vaccination by 2025. Besides, risk mitigation actions should be reinforced in the Colombian departments free from foot-and-mouth disease bordering Venezuela to prevent new viral incursions in the Colombian animal population. In this sense, a segmentation of the disease-free zone with vaccination is advisable as well as a review of the vaccination schedule incorporating risk in its definition.

The specific objective 2 assumes that, except for Colombia, all the other disease-free countries with vaccination can start or complete the transition toward the disease-free status

without vaccination. The changes in the vaccination schedules, the prolonged absence of new cases and the evidence gathered by surveillance studies, account for the high probability of elimination of endemic niches that maintained the viral transmission between 2002 and 2011 and, therefore, it is time to make the decision of discontinuing systematic vaccination of animals and establish a strategy of prevention, timely detection and early response. With that end, it is advisable to:

- a. Reinforce the management to prevent foot-and-mouth disease;
- b. Mitigate the risk of foot-and-mouth virus release in diagnostic, vaccine and biological products-manufacturing laboratories;
- c. Prevent the exposure of swine to food leftovers and organic residues contaminated with the foot-and-mouth disease virus;
- d. Strengthen surveillance for early detection of foot-and-mouth disease infection;
- e. Build capacities for early response to foot-and-mouth disease emergencies

The specific objective 3 encompasses the preservation of the disease-free status without vaccination, which has been maintained during the Action Plan 2011-2020 without any incidence of foot-and-mouth disease. This shows that the disease-free countries without vaccination of the Americas maintain a health policy characterized by a high level of protection to ensure the maintenance of the animal health status, which is supported by a historic absence of extra-regional viral incursions. The priorities in these countries are not significantly different from those established by all the disease-free countries where vaccination is not practiced, which is based on prevention, timely detection and early response.

In order to attain the goals defined in the Action Plan 2021-2025, strategic guidelines are provided to the national programs to help in the review and update of the components and actions contributing to comply with the proposed objectives.

These guidelines are aimed at the surveillance components, emergency preparedness, mitigation of biological risks in laboratories handling viruses, reorientation of resources of foot-and-mouth disease programs in disease-free countries with vaccination and foot-and-mouth disease diagnosis by national reference laboratories.

The chapter PHEFA's Management, included also in the Action Plan 2011-2020, validates the current subregional approach for the management and coordination of the PHEFA, and provides information on monitoring and evaluation tools, coordination and strengthening of international cooperation and funding of the program.

Chapters 9 and 10 have been added to the action plan in order to help disease-free countries with vaccination in the transition to disease-free status without vaccination. Chapter 9 recognizes that the decision has encountered difficulties or resistance in different sectors or stakeholders of the region which do not always rely on an evidence-based risk analysis, science or a reasoned analysis of the costs of continuing with an animal health control strategy in a disease-free area and the benefits and opportunities that advancing toward a new status represents.

For this reason, this chapter introduces a methodological approach, based on economic rationality, to support the decision to advance toward the disease-free status without vaccination. The chapter explores the advantages and disadvantages of adopting a decision using two widely-used methodologies in the economic evaluation of projects: the Cost-Benefit Analysis (CBA) and the Cost-Effectiveness Analysis (CEA). They enable to estimate and compare the economic advantages and disadvantages of a transition to foot-and-mouth disease-free status without vaccination.

Eight (8) costs or disadvantages and nine (9) benefits or advantages are identified in a transition to disease-free status without vaccination. Nevertheless, it should be noted that in the case of South American countries, which still maintain massive vaccination programs, they already have the from foot-and-mouth disease-free status with vaccination, therefore, some of the identified costs have already been internalized because this is a requisite to obtain OIE certification. The change of strategy will probably entail no increased costs or just marginal costs in most cases.

On the other hand, the benefits identified by the change of strategy are clear not only at the producer level – with an immediate effect – but also at state level – represented by its Veterinary Service -, the livestock industry and the society in general.

It is likely that, once animal health risks are mitigated, the cost-benefit analysis will be highly favorable in order to provide follow up in a transition to disease-free country or zone without vaccination, since it implies removing not only one of the most relevant costs of a foot-and-mouth disease control program – such as massive and systematic vaccination of animals - but also a substantial barrier to release all the potential of food production the countries of South America can offer to their people and the world, as well as disseminating the reliability message regarding the foot-and-mouth disease eradication process in the region.

The last chapter, 10, looks beyond the PHEFA and presents future challenges faced by the veterinary services in South America. In this sense, it addresses the evolution of these organizations, the delegation of competences, the training of the professionals involved in inspection and animal health activities, the view of international organizations regarding delegation of competences, and the interaction of veterinary services with the IV Industrial Revolution.



Advances in foot-and-mouth disease eradication in the Americas between 2011 and 2020

Foot-and-mouth disease is described as an acute vesicular disease of cloven-hoofed animals, including domestic ruminants and swine (Alexander et al, 2003). It is one of the most contagious animal diseases and the virus replicates and spreads very fast in an infected animal and among susceptible animals exposed to the infection (Grubman & Baxt, 2004). There are seven different serotypes of the foot-and-mouth disease virus and the disease is most common in Asia and Africa with a global distribution that shows zones of high density of domestic animals and agricultural poverty (Knight-Jones, McLaws, & Rushton, 2017). New viral strains appear regularly and originate new successive waves of infection that sometimes reach disease-free regions. Large-scale immunization with inactivated vaccines is used to control the disease, in spite of the short duration and serotype specificity of induced immunity (Dias-San Segundo et al, 2017).

In 2012, OIE member countries approved a global strategy for the control of foot-and-mouth disease, carried out by the OIE and the FAO. This strategy recognizes the Hemispheric Program for the Eradication of Foot-and-Mouth Disease (PHEFA) as the genuine program of the region of the Americas for the control and eradication of the disease in the continent, and the COHEFA and the COSALFA as their entities for governance in order to avoid duplicated works both in regional organizations and at platforms coordinating regional control programs.

At the end of the PHEFA Action Plan 1988-2009, on one hand, a remarkable accomplishment of goals and commitments was recorded, in particular that 85% of around 350 million cattle in South America have reached the official foot-and-mouth disease-free status, with or without vaccination. This significant progress facilitated the improvement of relevant

bio-productive indicators in the countries of the region by eliminating the impact of the disease on productive animals and systems and made possible to establish the animal health basis for maintaining a growing and sustained export process of livestock products. On the other hand it was clear that the goal of eradicating the disease had not been achieved and some countries continued having endemic occurrences of the disease and zones and territories without foot-and-mouth disease animal health status (PANAFTOSA-OPS/OMS, 2011).

By the end of the 2011-2020 Action Plan, the territory of South America officially recognized as free from foot-and-mouth disease has expanded from 67.6% in 2010 to 94.7% by the end of 2019. The herds free from foot-and-mouth disease, which at the start of the current action plan represented 63.7 %, increased to reach 97.4 % and the bovine and buffaline population free from the disease increased from 84.4% to 95.4%. Nearly 5% of the territory and the herds and the cattle population of South America continue without animal health status recognition at the end of the 2011-2020 Action Plan, including the entire territory of Venezuela, and a department of Colombia bordering Venezuela. On the other hand, North America, Central America and the Caribbean have remained without foot-and-mouth disease outbreaks during the whole 2011-2020 period as a result of a foot-and-mouth disease prevention policy with a high level of protection.

In the global context, the progress showed by the PHEFA at the end of its second action plan is remarkable, with more than 95% of its territory, herd population and animals reaching the foot-and-mouth disease-free status with or without vaccination. During this period, a clear progress in eradication was observed in the territories that were lagging behind in their control programs by the end of 2010 and the maintenance of the animal health status is verified in the disease-free countries of the Southern Cone which, in that time, had sporadic occurrence of outbreaks in vaccinated populations.

The risk of foot-and-mouth disease has been limited to the north of the Andean subregion. The current animal health situation of Venezuela derives from the fact that the control actions have not attained the efficacy nor the population coverage to modify the transmission patterns of the infection. An amendment to the control programs at national and local level should lead to the interruption of the endemic patterns of transmission and achieve the disease-free status with vaccination in the medium term. Therefore, the territory of the Bolivarian Republic of Venezuela is regarded as the last border for the eradication of foot-and-mouth disease in the American continent.

Nevertheless, with the exception of Colombia, the disease-free countries with vaccination did not advance as expected to the free status without vaccination, according to what the Action Plan 2011-2020 had envisaged. In spite of the fact that a technical guideline was elaborated in order to guide the free countries with vaccination in the transition to the free status without vaccination, and the increasing evidence reported by the surveillance actions both to detect viral transmission and to identify the immune status of the animals, which confirm that the infection would have been eliminated from the animal population, at the end of the decade only two disease-free countries established a roadmap with defined actions and deadlines to advance in the transition to the free status without vaccination.



Risk assessment of foot-and-mouth disease

3.1. Introduction

This chapter addresses, in qualitative terms, the current risk of foot-and-mouth disease based on the recent evolution of the occurrence of the disease in South America and the risk associated with the eventual introduction of the infection from extra-regional infection sources such as the virus genotype *pools* circulating in the world, according to the classification used in the global monthly reports of the European Commission for Foot-and-Mouth Disease (EuFMD) and the Food and Agriculture Organization of the United Nations (FAO)¹.

3.2. Regional and hemispheric risk of foot-and-mouth disease

At the end of 2019, the risk of foot-and-mouth disease in the Americas was localized in the north of the Andean subregion of South America, where outbreaks of foot-and-mouth disease were detected in Colombia in 2017 and 2018, associated to the illegal introductions of animals coming from Venezuela, a country in which, although no new cases have been reported since 2013, the existence of viral transmission in their cattle population has never been excluded.

Phylogenetic studies of the viral strains isolated in Colombian outbreaks revealed that the isolates belonged to the lineage 6 of the serotype "O" described by Malirat et al (2011),

Monthly Foot-and-mouth disease reports prepared by the EuFMD can be reviewed at: http://www.fao.org/eufmd/resources/reports/gmr/en/

which have been isolated sporadically in states of Venezuela and bordering departments of Colombia since 2004. A similar geographic distribution has been described for the type A viruses isolated in episodes of foot-and-mouth disease both in Venezuela and in bordering zones of Colombia since 2004. Summing up, O and A virus genotypes, isolated from outbreaks in Colombia and Venezuela since 2004, have had a limited geographic distribution in these two countries, associated with the predominant cattle production system observed both in the Venezuelan and the Colombian plains, and conforms a specific ecosystem of foot-and-mouth disease presentation in this subregion. Phylogenetic analyses of viral isolates confirm this restricted geographic circulation, with no historical presence of these genotypes outside these territories, possibly due to the long natural barrier separating Venezuelan cattle populations from the neighboring countries at the south of its frontier.

The risk of foot-and-mouth disease viral transmission from the geographic neighboring area of Venezuela is estimated as moderate² for Colombia since they share a cattle production ecosystem common to both countries. The risk of introduction is estimated as very low³ for Guyana, a disease-free country without vaccination where cases of foot-and-mouth disease have never been observed associated with the introduction of the infection from Venezuela. A similar estimate can be made for Trinidad and Tobago, a free from foot-and-mouth disease without vaccination island, separated by 11 km from the north eastern cost of Venezuela, and for Brazil, a country that shares geographic limits with two Venezuelan states mainly characterized for being ecosystems belonging to the Amazon rainforest with little animal population and separated from the cattle-raising areas of Venezuela by the Orinoco basin.

On the other hand, the rest of the South American territory, currently free from foot-and-mouth disease with or without vaccination, has not registered new cases of foot-and-mouth disease since December 2011, thus completing, by the end of 2019, more than 8 years with no detection of viral serotypes O. This period increases to 15 years in reference to the last detection of the type C virus and more than 18 years in reference to the type A virus.

Hence, in 2017, both the OIE and the COSALFA approved the removal of serotype C from the vaccines in use, a decision supported by the evidence gathered from surveillance actions for the detection of viral transmission and by an assessment concluding that the risk of persistence of this serotype in the cattle population was negligible. Since then, three out of the four countries in the Americas that included serotype C of the foot-and-mouth disease virus in their vaccines have removed it from the vaccines in use.

A similar conclusion can be made regarding the risk of virus A persistence in cattle populations of the countries using vaccines with these viral strains, except for Venezuela and Colombia. The longevity of the last case, which dates back to the epidemics observed in the Southern Cone in 2001, the evidence presented by serological surveillance studies, and the results of post-vaccination monitoring, allow to estimate that the probability of persistence in endemic niches with circulation of serotype A is negligible.

² Moderate: The probability of occurrence of the event is (has been) sporadic.

³ Very low: The event is highly unlikely, but it cannot be excluded.

Special attention should be given to the risk assessment of type "O" virus genotypes that have been grouped into 10 lineages by Malirat *et al* (2011) in the elaboration of the phylogenetic tree of the viral strains isolated in South America.

Particularly, virus genotypes of serotype 0 grouped into lineage 10, which showed a pattern of sporadic occurrences between 2002 and 2011 in four countries of the Southern Cone, have registered no new occurrences in the region since January 2012, showing a disruption of such pattern of occurrence and suggesting the elimination of the endemic niches that explained its sporadic reoccurrence. The disruption in the occurrence pattern would derive from the changes in vaccination schedules adopted in that time and which strengthened the immunity protection of young animals.

Besides, virus genotypes of lineage 9 circulating in Bolivia until 2007, and lineages 1 and 4 circulating in Ecuador until 2011, evidenced prolonged and stable periods free from disease verified by consecutive serological studies that have not detected transmission patterns in the sampled animals. This leads to the conclusion that intensive and prolonged vaccination programs have eliminated potential endemic niches of these genotypes also in these countries.

Consequently, the only cluster of type "O" genotypes active in South America is that of lineage 6 according to Malirat *et al* classification (2011), which have been isolated exclusively in the north of the Andean subregion and suggests that *pool* 7 of South America shows, at the end of the decade, a limited geographic distribution restricted to the territory of one country.

Central America and North America have not presented cases of foot-and-mouth disease, thus preserving its common status of free regions without vaccination and showing that the prevention measures in force have been effective to mitigate the risk of foot-and-mouth disease introduction.

3.3. Risk of foot-and-mouth disease introduction from exotic viral *pools*

Except for *pool* 7, this section will review the risk of foot-and-mouth disease virus introduction represented by the six *pools* of foot-and-mouth disease virus genotypes globally described.

The *pools* represent geographic areas in which independent, continuous and evolving circulation of foot-and-mouth disease virus genotypes is observed. In spite of the opportunities of spreading to other geographic areas or regions, the foot-and-mouth disease viruses in endemic areas tend to replicate in the same parts of the world, seemingly reflecting a degree of ecological isolation or adaptation. Within the *pools*, cycles of emergence and spread often occur affecting several countries⁴.

Pool 1 encompasses the territories of countries of Southeast Asia, Central Asia and East Asia. Pool 2 is distributed and localized in territories and countries of the south of the

⁴ FAO/eufmd, 2019. Global Monthly Report. Foot-and-Mouth Disease Situation. October 2019. Rome. FAO.

Asian continent. *Pool* 3 comprises territories of countries of Western Eurasia, Middle East and the north of the African continent.

Pool 4 comprises countries of Eastern Africa, *pool* 5 countries and territories of Central and West Africa, and *pool* 6 countries of the south of the African Continent. In each of these *pools*, continuous circulation is observed of different combinations of foot-and-mouth disease virus serotypes, which characterize them, except for serotype C, that has not been detected since 2004.

The physical separation between the American continent and the territories affected by the six described *pools*, determines that possible routes of introduction of the foot-and-mouth disease virus in the Americas could be, on the one side, legal imports of risk animals and animal products that could be introduced by international trade or, on the other, the illegal introduction of risk products contaminated with the foot-and-mouth disease virus in luggage or in air or sea transport vehicles. Therefore, virus release is going to be directly associated with the number and frequency of these imports of risk animals and products as well as with the flow of international vehicles and travelers coming from the affected territories.

The countries of the Americas have long ago adopted animal health policies to mitigate the risk of virus release from imports of risk animals or livestock products. These animal health policies are in line with the recommendations of the OIE Code and show an adequate high level of protection⁵, therefore, the risk of virus release through this route of entry is considered negligible.

Likewise, the countries have taken animal health control measures at the level of the points of entry of international travelers to detect illegal entries of risk livestock products, as well as inspection procedures of vessels and aircrafts for the safe disposal of organic waste. As a result of these measures of animal health management, the risk of virus releases due to the illegal entry of risk products contaminated with the foot-and-mouth disease virus is considered very low.

From a historical perspective, it should be highlighted that the animal health policies of the Americas, free from foot-and-mouth disease either with or without vaccination, have been effective to prevent the introduction of the foot-and-mouth disease virus from other continents, as confirmed by the absence of extra-regional viral incursions since the second half of the XX century, which is probably favored by the development of the livestock industry in the region and the vocation to export animal proteins, a current characteristic of most of the continent, thus significantly reducing the demands of commercial exchange of animals and livestock products coming from other regions of the world.

Adequate level of protection: It is the right of the countries to protect the life and health of people and animals and to preserve plants according to the terms of the Agreement on the Application of Sanitary and Phytosanitary Measures. Uruguay Round.



Concept of eradication of communicable diseases in animal health and foot-and-mouth disease

While in Public Health the concept of eradication refers to the reduction to zero of the worldwide incidence of an infection caused by a specific agent, and therefore, not requiring new intervention measures (Dowdle, 1998), the OIE Terrestrial Animal Health Code establishes that the eradication of a disease in animals is the elimination of a pathogen from a country or zone.

This last definition is similar to that established by Public Health for the elimination of an infection, which defines the reduction to zero of the incidence of an infection caused by a specific agent in a defined geographic area as a result of control actions and where continued measures are required to prevent the entry and reestablishment of transmission (Dowdle, 1998).

In this sense, the OIE definition of eradication and the WHO definition of <u>elimination</u> of an infection have in common that the elimination of the causative agent in a particular geographic territory allows to suspend the animal health measures that led to the elimination of the infection in the populations and to replace them by measures to prevent reintroduction and reestablishment of transmission.

4.1. Is foot-and-mouth disease eradicable in the Americas?

The selection of a communicable disease to be eradicated or eliminated from a population should rely on rigorous criteria which determine whether a pathogen is potentially eradicable. In the field of animal health, these criteria include, among others that the causative organism does not have wild reservoirs, and that the infection should be easily detectable in

susceptible animals, which implies that there is enough information on the life cycle and the dynamics of transmission. Animal health intervention measures should be practical, effective and efficient and high-performance diagnostic tools should be available.

Although foot-and-mouth disease is defined as one of the most contagious diseases of animals, with a large potential to cause significant losses in livestock production based on cloven-hoofed animals because it is caused by seven virus serotypes with no cross-immunity between them, it is also true that the disease presentation pattern in livestock farms is determined by the characteristics of the hosts affected and their environment.

Observational and experimental evidence, supported by scientists and epidemiologists of the region with experience in foot-and-mouth disease, lead to consider that the model of foot-and-mouth disease transmission in South America has been characterized by an acute infection with a short incubation, clinical and viral shedding period, and fast recovery accompanied by a good but medium-term immunity. The condition of carrier is not relevant for transmission and permanence of the infection. No wild reservoirs have been described in the process of transmission, nor environmental variables such as the direction of winds, have explained the pattern of spread.

Infection transmission among herds was mainly associated with the dynamics of cattle movement, verified because the animal health measures applied for disease control, particularly systematic vaccination of cattle only with high-quality vaccines, has stopped transmission and enabled eradication of the disease in the entire population. This evidence allows to conclude that foot-and-mouth disease can be eradicated from the American continent, as endorsed by the progress observed, in particular, in the 2011-2020 decade.

This description characterizing foot-and-mouth disease in South America and its control cannot be extrapolated to other regions of the world, where animal husbandry systems and the species acting as reservoirs, including wild animals, determine more complex models of transmission, preventing the possibility of eradication.

The risk of infection transmission in the Americas is currently located in the north of the Andean region, particularly in the Venezuelan territory, where the animal population has not reached the foot-and-mouth disease-free status.

After more than 8 years with no new occurrences of foot-and-mouth disease in the other South American disease-free countries with vaccination, which shows that the sporadic occurrence pattern observed between 2002 and 2012 – and most probably viral transmission in subclinical conditions – have been disrupted- the time has come to verify virus elimination in vaccinated populations by suspending vaccination campaigns. Maintaining these campaigns indefinitely is not consistent with the term eradication or elimination of an infection, as defined by OIE and WHO, respectively.

Chapter 9 provides methodological guidelines so that the decision has, also, an economic rationality in terms of evaluating the advantages and disadvantages of progressing toward the disease-free status without vaccination.



General purpose of the PHEFA Action Plan 2021-2025

To complete the eradication of foot-and-mouth disease in South America and to strengthen prevention and response capacity of veterinary services of the countries of the continent.

5.1. Specific objectives

- 1. To eradicate the foot-and-mouth disease virus active in the territory of Venezuela and mitigate the risk for the north of the Andean subregion.
- 2. To make the transition to the official disease-free status without vaccination in disease-free countries that continue with vaccination.
- 3. To maintain the animal health status of the territories free from foot-and-mouth disease without vaccination.

5.2. Principles and values

The PHEFA and its action plans promote the following principles and values:

- a. Adoption of decisions supported by science and empiric evidence.
- b. Observing international agreements and guidelines.
- c. Transparent animal health management and respect for the commitments of joint actions within the framework of the PHEFA.



Strategies and goals of the PHEFA Action Plan 2021-2025

In order to establish the strategies and goals of the Action Plan 2021-2025, three types of territories are differentiated in the Americas according to the foot-and-mouth disease official animal health status, recognized by the OIE.

6.1. North of the Andean Sub-region

It consists of a zone conformed by the entire territory of the Bolivarian Republic of Venezuela and the bordering departments of Colombia due to the risk of foot-and-mouth disease spread due to geographic proximity.

The animal health strategy for the North of the Andean subregion differentiates two (2) zones of action:

6.1.1. Territory of the Bolivarian Republic of Venezuela

The strategy in this territory aims at interrupting viral transmission in cattle population. With that purpose, increasing the immunity of the whole cattle population is considered a priority, which should include – in addition to the six-month vaccination cycles – a booster cycle aimed at cattle under 24 months of age and applied 45 days after the first cycle. Executing this strategy for a period of two years would make possible to stop viral transmission. In order to verify the efficiency of this strategy we propose to conduct studies to estimate the immune protection at population and farm level.

In order to ensure vaccination of cattle population, it is advisable to establish a private association such as a Foundation, composed of all the livestock farmer organizations of the country and the slaughterhouse association, to assume the responsibility of the vaccination cycles in Venezuela, while the role of conducting and monitoring the process is reserved to the official animal health authority.

Up to 2015, the country had enough supply of vaccines both for the "social cycle of vaccination" under the responsibility of the state, and for the "private vaccination cycle" under the responsibility of producers and their associations. Serological studies estimating the prevalence of protective antibodies have shown a similar population immunity level with both modalities of vaccination. Therefore, it would be expected that if there is enough supply of vaccines for the program, the level of animal immunization will be recovered.

In general, the supply of vaccines in Venezuela comes from two sources. Imports of vaccines ready for use, and frozen antigens with which a veterinary vaccines laboratory produces vaccines for commercialization. The access to vaccines has been an objective difficulty for producers and for the social program conducted by the National Institute of Integral Agricultural Health (*Instituto Nacional de Salud Agrícola Integral*, INSAI) until 2016.

Once the vaccination program is implemented with the booster cycle, it is necessary to continue reinforcing surveillance actions, which will enable to verify the absence of both disease and viral transmission. With that purpose, both passive and active surveillance actions should be implemented together with an improvement in diagnostic capacities so as to verify the absence of disease and viral transmission as well as to estimate the level of immune protection of the population. Next, it will be possible to verify if the requirements are complied with to apply for the recognition of disease-free status with vaccination. It is estimated that Venezuela could achieve that animal health status within a period of 4 to 5 years, assuming that the modified vaccination schedule is introduced on year one.

This strategy may be complemented by a zoning strategy, taking advantage of the natural geographic limits of the country in which, with the support of neighboring countries, coordinated actions will be carried out which lead to the OIE animal health recognition of these territories as free from foot-and-mouth disease.

6.1.2. Departments of Colombia neighboring Venezuela

After the 2017 and 2018 outbreaks in Colombia were controlled, in 2020 Colombia recovered its disease-free animal health status with vaccination and has postulated the recognition of disease-free with vaccination for part of the territory of the North Santander department, the only territory that acted as a protection zone.

Since 2004, foot-and-mouth disease outbreaks have been the result of viral incursions from Venezuela, mainly affecting bordering departments. Particularly, the outbreaks of 2004, 2008, 2017 and 2018 have occurred in departments bordering Venezuela. The North Santander department has recorded a total of 4 viral incursions in 2004, 2008 and 2017. Besides, the Arauca department recorded an incursion in 2017 as well as La Guajira and El César departments, in 2018. In addition, animals infected with the foot-and-mouth disease virus have been detected twice in consignments of seized smuggled animals.

The aforesaid supports the assumption of moderate risk of introducing the foot-and-mouth disease virus by geographic proximity in Colombia. As of 2020, Colombia has defined a new rezonification of its free zone with vaccination, dividing it into four geographic zones, two of them bordering Venezuela. In fact, the free zone has been divided into a Zone I North Border, involving the departments of La Guajira, César and some municipalities of the North Santander department; a Zone II, East Border, involving the Arauca and Vichada departments and the municipality of Cubará in the Boyacá department; a Zone III, called of Commerce, which involves the departments linked to exports of live-stock products; and a Zone IV that involves the rest of the country, except for the free zone without vaccination. The Santander department will be added to this rezonification of the free zone with vaccination. This zonification is aimed at reducing the social and economic impact of potential viral incursions due to geographic proximity given the historical risk of disease introduction observed. Therefore, the detection of an outbreak will only affect the free zone involved, preserving the animal health status of the rest of the country, as long as the infection is not spread.

Together with the zonification strategy, it is necessary to reinforce the measures that mitigate the risk of introduction and eventual viral transmission in order to reduce the local impact imposed by the emergence of a foot-and-mouth disease outbreak.

In order to mitigate the risk of viral transmission, it is advisable to strengthen the current vaccination schedule, characterized by two annual general vaccination cycles, adding a cycle targeted at young animals (younger than 18 or 24 months) so as to ensure a high immunity level in the population of these departments. Although this level of protection may not prevent the infection of some exposed animals, it will indeed prevent transmission to other animals, accomplishing the main objective of a free zone with vaccination. An annual measurement of the protection level of the different age categories should accompany this vaccination strategy in order to avoid susceptibility time gaps in the population or in areas with sub-optimal levels of protection. Annual studies should be added to these measurements to detect viral transmission.

The rezonification strategy recognizes the different level of territorial risk faced by the country. Based on that, the vaccination schedule may be modified so that in low-risk free zones (in which animal movement is now controlled) vaccination is reduced to release resources and strengthen the immune protection in zones with a higher risk such as bordering departments.

This vaccination strategy may be complemented with a reinforcement of police actions preventing smuggling of animals to mitigate the risk of introduction of infected animals. This strategy should be maintained for the whole period until the Venezuelan territory achieves the OIE animal health recognition.

6.2. Territories free from foot-and-mouth disease with vaccination

The territories free from foot-and-mouth disease with vaccination encompass zones of Argentina, Bolivia, Brazil, Ecuador, and the entire territory of Paraguay and Uruguay. The last case of foot-and-mouth disease in these territories was diagnosed on January 2, 2012.

Since then, a period of at least 8 years of uninterrupted absence of disease was observed, supported by no detected evidence of viral transmission in cattle populations and infection in other susceptible species. By country, this period increases to 9 years in Ecuador, 12 years in Bolivia, 13 years in Argentina and Brazil, and 18 years in Uruguay.

The animal health strategy proposed for these territories is to make a transition to the disease-free status without vaccination as an evidence of the total eradication of footand-mouth disease virus infection and to strengthen prevention measures, prompt detection and early response.

As described in the chapter addressing risk assessment, the 2011-2020 period shows that the foot-and-mouth disease sporadic outbreak pattern observed in the previous decade has disappeared, particularly in the Southern Cone, which responds to the strengthening of the surveillance activities and changes in the vaccination schedule aimed at stopping viral transmission. In view of the knowledge about the epidemiology of the foot-and-mouth disease virus infection, the hypothesis considering the permanence of foot-and-mouth disease virus in residual endemic niches in vaccinated cattle populations without a clinical expression for such a long period of time is unsustainable. Besides, this hypothesis is not consistent with the main definition of disease-free status with vaccination. It should not be overlooked that, together with cattle, there are significant populations of animals susceptible to foot-and-mouth disease that are not vaccinated.

An analysis of the annual and cumulative information on different components of the foot-and-mouth disease surveillance system, particularly active surveillance, shows high confidence in the likelihood that cattle population is free from infection based on the chronological series of negative results to diagnostic tests and clinical examinations of animals.

This evidence supports the decision that it is now appropriate to halt systematic vaccination of cattle in order to prioritize the measures aimed at disease prevention. Maintaining a cattle vaccination program not supported by a risk assessment is not only highly expensive for farmers but even counterproductive as a health strategy, because it might raise arguments that the country is not certain about the actual animal health status of the animal population.

In the transition process, in addition to discontinuing vaccination, veterinary services should review/complement or implement the following components:

6.2.1. Strengthening the management of foot-and-mouth disease prevention

Disease-free countries with vaccination have aligned their animal health management at entry points of risk products according to the recommendations provided by the OIE Code. Therefore, at the level of airports, ports and border crossings an adequate level of high protection is maintained for the import of risk products, together with selective inspection to mitigate the risk of irregular introduction of contaminated livestock products in the luggage of international passengers. Notwithstanding the foregoing, a periodic review and evaluation of the animal health management is advisable to prevent virus shedding and the exposure of the susceptible animal population through approaches based on risk analysis and multi-criteria analysis, among others.

6.2.2. Mitigating the risk of escape of the foot-and-mouth disease virus from diagnostic laboratories and vaccine and biological products producers

The likelihood of virus escape from laboratories handling the foot-and-mouth disease virus may be considered very low; nevertheless, it occurred in countries that have eradicated foot-and-mouth disease. Due to the magnitude of the vaccine manufacturing industry that characterizes the South American region, it is likely that some laboratories aim to continue producing vaccines for extra-regional markets. In the countries making a transition to the status without vaccination, animal population will progressively become susceptible and, therefore, a gap in biosecurity or bioprotection at laboratory level could have detrimental consequences for animal populations and the concerned zone.

It is widely accepted that the risk of escape of infectious agents from laboratories depend on the biosecurity and bioprotection management and it should derive from a specific risk assessment defining the appropriate policies and procedures for an effective mitigation. The COSALFA has established a Biosafety and Biological Risk Commission, has been constituted for the countries regarding biosafety management. For further details, refer to chapter 7.3.

In laboratories and facilities that are no longer manipulating foot-and-mouth disease viruses, a specific strategy for risk management should be implemented to reduce the stocks of viral strains, limiting their use and establishing a control over the stocks of materials containing foot-and-mouth disease virus. In this sense, an option would be to extend the risk management approved by the COSALFA for the type C foot-and-mouth disease virus to the other types of viruses kept in the laboratories of the region that will discontinue viral strains handling.

6.2.3. Preventing feeding swine with food waste and organic waste

Although the control of luggage of international passengers at the entry points of a free territory is a measure that mitigates effectively the risk of entering products contaminated with the foot-and-mouth disease virus, and all the countries have implemented it, it cannot be ruled out that such control may be circumvented and contaminated products may reach swine populations when fed with food waste or animal products.

Since this entry pathway is not only applicable to the spread of foot and mouth disease but also to other viral diseases such as the Classical Swine Fever and the African Swine Fever, it is possible that the countries have established standards or specific instructions to strengthen and mitigate this risk of exposure and spread. These measures may consist in preventing feeding swine with food waste or thermally treating it when used to feed swine. It is necessary to ensure that these provisions are complied with, particularly in zones with non-industrial, peri-urban swine populations that are near to final waste disposal areas, where swine is more exposed to these feeding practices.

6.2.4 Surveillance for early detection of foot-and-mouth disease virus infection

Foot-and-mouth disease surveillance in a disease-free country/zone without vaccination lies in early detection of suspected clinical signs in animals. To that end, the surveillance system should be continuous and universal, that is, it should cover the entire population. These two requirements can only be complied with by owners who, due to care and feeding demands, are continually observing the animals. On the other hand, universality is attained since all herds, regardless of their size, have a holder/keeper or owner. Therefore, the holder/keeper or owner of the animals is the right person to observe abnormalities in animals and report them to the health authorities for verification.

In this way, the responsibility of the holder/keeper or owner of the animal's changes from being responsible of vaccination to being responsible of the surveillance for early detection. Also, private veterinaries and other professionals that assist livestock owners play an important role. For further details, refer to the chapter Strategic Guidelines for National Plans in section 7.1.

A timely surveillance relies not only on the animals' owners knowledge and capacity to recognize suspicious clinical signs of disease but also on the need that official veterinary services have or develop electronic tools to facilitate the notification of suspected diseases to animal's owners, as well as to assist in the evaluation of the time and the response capacity of received reports.

Several countries of the Americas have already identified the need to improve the number and the quality of the attention given to reports of suspected vesicular disease (passive surveillance) and, to that end, they have developed apps for mobile phones and free calling for registering and tracking notifications.

6.2.5. Early response in foot-and-mouth disease emergencies

While detection of suspected disease is under the responsibility of animals' owners, both prevention of new viral incursions and the foot-and-mouth disease emergency response are the main responsibilities of veterinary services since they are the state organization with the authority for adopting all animal health measures for prevention and containment.

To this effect, the work does not start when the outbreak of an exotic disease is confirmed in the territory but long before that. The actions a veterinary service should conduct to have a timely and effective response capacity in a foot-and-mouth disease emergency are listed below.

- a. Create a Management Unit for Animal Health Emergency Preparedness;
- b. Develop a Training Program for Emergency Response;
- c. Incorporate the foot-and-mouth disease outbreak modeling for the analysis of emergency scenarios;
- d. Adhere to a Regional Antigen and Vaccine Bank.

Further details of each component are addressed in chapter 7 about Strategic Guidelines for National Plans, section 7.2, p.35.

6.3. Countries and zones free from foot-and-mouth disease without vaccination

The territory free from foot-and-mouth disease without vaccination includes all the countries of North and Central America and the Caribbean, and, in South America, Chile, Guyana, Peru and Suriname, the territory of the French Guyana, the region to the south of the Colorado River in Argentina, the north of the Chocó department in Colombia, the High-Plains, part of the region of the Valleys and the Pando department in Bolivia, the Galapagos Islands in Ecuador and the state of Santa Catarina in Brazil. It comprises a total cattle population of 176 million, from which North America accounts for 79%, Central America and South America 8.3% each, and the Caribbean 4.3%.

No new cases of foot-and-mouth disease were recorded in North America since 1954, in the Caribbean since 1957 and the disease was never recorded in Central America. The free countries and zones without vaccination of South America recorded the last case in 1956 in the French Guyana, in 1961 in Guyana, in 1987 in Chile, in 1993 in the south of Argentina and the state of Santa Catarina, in 2003 in the Bolivian Altiplano, and in 2004 in Peru.

While the outbreaks occurring before the sixties had been mainly originated by imports of infected animals, later occurrences, all in South America, were a result of the spread of the transboundary infection due to the irregular movement of animals from zones of active infection. Endemic viral strains of the continent were isolated in all these outbreaks. A common characteristic that is common to the entire continent is that serotypes SAT or Asia of the foot-and-mouth disease virus have never been isolated.

This historical pattern of occurrence shows that the free zones and countries without vaccination have a very low profile of exposure for the introduction of the infection, particularly for extra-regional serotypes. In South America, the progress observed in the 2011-2020 decade has mitigated significantly the risk of transboundary spread of infection caused by endemic serotypes acting in that region.

The goal for the territories free from foot-and-mouth disease without vaccination is to maintain the animal health status and eradicate the disease in case of an eventual viral incursion during the period. With that end, the strategy does not differ from that set by all the countries free from foot-and-mouth disease without vaccination, which is based on prevention to maintain the status and the timely detection and early response to eradicate potential incursions of the foot-and-mouth disease virus.

6.3.1. Prevention

Free territories without vaccination have been historically efficient in preventing viral incursions due to the exchange of risk goods. This was due to the alignment of national protocols for risk mitigation with the recommendations of the OIE Code and the high level of protection defined for the trade of livestock goods. It is necessary to maintain this animal

health policy, verifying its application at the entry points of livestock goods, updating it according to the changes made to the protocols of the OIE Code for risk mitigation.

The evidence that several viral incursions have been caused by illegal or irregular introduction of contaminated livestock products, in the luggage of international passengers or postal exchange, suggests to keep a high level of prevention through warning communications and statements from international passengers, inspection of luggage and courier packages, by means of scanning or detection dogs, carried out at entry points (ports, airports) particularly in those coming from infected territories.

6.3.2. Early detection

The surveillance for the early detection of a foot-and-mouth disease virus incursion in a free territory without vaccination should be continuous and universal. Therefore, animal producers/holders or caretakers are the best to observe/detect clinical signs in animals that suggest the emergence of disease. The Veterinary Service may complement this type of surveillance but cannot replace it. In fact, the disease-free countries without vaccination rely mainly on the reporting of suspected cases made by people working in direct contact with animals.

6.3.3. Early Response

The capacity to respond early in case of outbreak occurrence is developed as the stage of preparedness to face health emergencies. Indeed, updated contingency plans incorporating all the tools and approaches allowed by international standards are needed to face a foot-and-mouth disease emergency, particularly, teams acquainted with these contingency plans and continually trained in their procedures, defined sources of resources for the implementation of an Operations Center, compensation policies for producers due to losses that animal health measures may cause, and the access to an antigen bank for the formulation of emergency vaccines.

Although it is known that these actions exist in all disease-free countries without vaccination, it has been demonstrated that it is necessary to strengthen a coordinated systematic program that ensures continuous preparedness and evaluation for a high-standard emergency response. Only a few countries show a national emergency preparedness program addressing not only foot-and-mouth disease but also other potential diseases harmful for the livestock industry. It is advisable that the countries allocate resources for emergency preparedness and develop an international project enabling to promote cooperation among the countries to increase the standard of response in case of animal health emergencies due to animal diseases.



Strategic guidelines for national programs

7.1. Foot-and-mouth disease surveillance

Foot-and-mouth disease surveillance in disease-free areas is aimed at the early detection of viral incursions and verification of the disease-free status.

In disease-free countries and zones without vaccination, total susceptibility of susceptible animals is evidence of the infection-free status, so, the main purpose of surveillance is focused on early detection. The surveillance system should then comply with the requirements of being universal –that is, reach all facilities with susceptible animals – as well as continuous –that is, it should aim at a frequent observation of animals to ensure early detection. A possible spread of an outbreak is prevented in this way to reduce its potential impact in the trade of livestock goods.

In this sense, passive surveillance, that may be conducted by animal owners/holders, becomes very valuable because it gathers the two abovementioned requirements since, unlike free animal populations submitted to vaccination programs, infection will be accompanied by clear clinical signs, particularly in cattle and swine populations, and the frequency of cases will be abnormal.

Surveillance carried out by producers is cheaper because it is integrated to the daily work with animals; more sensitive, because unvaccinated animals show clearer clinical signs of the disease, particularly cattle and swine; and simpler, because it does not require massive application of complex diagnostic systems as in the case of the surveillance of vaccinated animals.

In order that this type of passive surveillance can be carried out with a high level of confidence for timely detection, it should be supported by three elements: 1) a risk communication policy by the veterinary service that promotes an attitude of commitment and alertness of the livestock community against foot-and-mouth disease; 2) to assure the animals' owner that compensation mechanisms exist to guarantee a compensation when a potential occurrence of the disease is confirmed; and 3) be acquainted with the clinical presentation of the disease.

To that end, the Veterinary Service, with the support and coordination of the private sector, should foster a program observing elements 1) and 3) and establish a procedure to compensate potential losses and damages to farmers in case of occurrence of a foot-and-mouth disease outbreak. A timely surveillance depends not only on the knowledge and the capacity to recognize the suspected clinical signs of vesicular disease in animals by their owners, but also on the fact that the veterinary services have or develop electronic tools to facilitate the reporting of suspected cases and help to evaluate the promptness and response capacity of the veterinary service when notifications are received.

In order to ensure priority attention with a rapid and precise diagnosis of each suspected case, it is advisable that veterinary services have duly trained teams strategically located in the national territory, with the technical competences to diagnose a foot-and-mouth disease case in as little time as possible, and have a good information system to support notification.

Passive surveillance may be supported by the Veterinary Service with active surveillance targeted at places or zones at high risk of exposure, such as sites with concentration of animals, aimed at making up for potential deficiencies of the surveillance based on farmers' observations.

7.2. Foot-and-mouth disease emergency preparedness

Reducing the impact of a potential incursion of foot-and-mouth disease in a disease-free territory is directly related to the capacity of the Veterinary Service to provide an early and effective response to mitigate the risk of spread, prevent the establishment of the infection, and reduce the effects in food chains and the trade of livestock goods.

Historically, the response capacity to an emergency has been linked to viral incursions of endemic strains where the affected populations had a degree of protection mitigating the risk of spread. Nevertheless, in a susceptible population, the response capacity will be more linked to the degree of preparedness, organization and resource mobilization than to the acting viral strain. To this effect, it is advisable that emergency preparedness for foot-and-mouth disease be reinforced with the following components:

7.2.1. Establishment of the emergency preparedness management unit

An early and effective response to an emergency cannot be improvised at the time of confirmation, it should be prepared in advance based on a contingency plan and practiced by the responsible veterinary teams.

With a few exceptions, the veterinary services of the region do not count with a permanent entity whose main task is the preparedness for animal health emergencies. For that

reason, it is necessary that the veterinary services include a management unit to implement a work plan aimed at preparing the institution for animal health emergencies in their structures at central level. In this way, response plans are improved, the coordination with different entities involved in an emergency is refined, investments are made to prepare the specialized staff for managing emergencies, and the new technical teams of the organization are trained. This will enable to provide continuity to animal health emergency preparedness, making an effective use of the existing technical capacities, thus ensuring fast mobilization of resources to prevent the spread of a viral incursion.

It is important that the response system for animal emergencies be linked to and coordinated with the national emergency response system of the central government to establish the necessary synergies to provide reaction agility and speed.

The OIE Terrestrial Code has defined six strategies for disease-free countries without vaccination and three for disease-free countries with vaccination with which the occurrence of a foot-and-mouth disease outbreak can be faced in a free territory, depending on whether stamping out of animals and emergency vaccination are used or not, and which the destination of vaccinated animals is. This provides a wide range of animal health strategies to face outbreaks but, on the other hand, they have an impact on the necessary time to recover the status. In this sense, stamping out of animals is critical for the necessary time to recover the status and this is a decision that has to be accompanied by compensation funds. Thus, a country or zone may select the strategy(ies) consistent with the expected impact of a foot-and-mouth disease outbreak and the cost it is willing to accept.

It is advisable to review and update the strategies defined in national contingency plans so that they are supported by the necessary resources for their implementation; therefore, decisions may be made with governmental and community support and may be executed as soon as possible.

Animal health emergency preparedness should not only be focused on foot-and-mouth disease but on all highly contagious diseases and whose introduction will seriously harm the livestock sector and livestock communities. Hence, establishing a unit to manage emergency preparedness is further substantiated, because its scope is larger and makes the best use of the synergies created in the organization regarding response preparedness for other highly impacting animal diseases.

7.2.2. Training Program for Emergency Response

Preparing the teams involved in emergency response is a complex process due to the different competences, skills and practices that have to be developed for their application in different functions, tasks and coordination required by the control of an animal health emergency.

Indeed, to face an animal health emergency caused by the foot-and-mouth disease, an alert stage is observed which, if the case is confirmed, triggers an emergency stage that continues until the last case is eliminated, to give way to a recovery stage. Each stage encompasses several tasks and activities that should be accomplished in a coordinated and synchronized way to achieve the main objective of each one. Each of these tasks and activ-

ities should be performed by staff with specific capacities and skills so that they can be carried out promptly, skillfully and responsibly.

This training process can only be addressed within the context of a medium- and long-term program which, with the adequate funding, establishes an annual cycle of emergency preparedness that starts with Planning, followed by Organization, Training, Equipment, Exercises, Evaluation and corrective actions (WHO, 2017).

For emergency preparedness, several types of scalable exercises are described which enable the progressive training of different technical teams in the tasks and activities required for emergency control. Some of them are discussion-based exercises such as workshops and tabletop exercises, and operation-based exercises such as procedural, functional and field exercises.

Therefore, it is advisable that animal health emergency training be oriented by a medium- and long-term work plan where the objectives and instruments for a continuous and progressive preparedness and training of the Veterinary Service technical teams converge and be endowed with enough resources.

7.2.3. Modeling of foot-and-mouth disease outbreaks

Foot-and-mouth disease has probably been the animal disease to which the scientific world has devoted more time and investment to find models mimicking viral incursions in free environments without vaccination, which have been subject to compared validation studies.

Although the historical experience of previous foot-and-mouth disease outbreaks is relevant for emergency preparedness, it is usually incomplete, limited, and out-of-date, and possibly insufficient to examine the whole range of possible scenarios in which a foot-and-mouth disease outbreak could emerge, and the extent of its magnitude, so as to enable evaluating potential control strategies. Here, simulation models emerge as the adequate tool so that, based on the characteristic of livestock farms, distribution, and the relationship between them, among others, potential spread patterns and different intervention strategies can be tested under reality-like conditions.

Simulation models are currently widely used to support the decisions of veterinary authorities in the development of foot-and-mouth disease contingency plans. Knowing the spread patterns and estimating the magnitude of an outbreak is essential information for a country to be better prepared to respond to an outbreak, as well as to define the response strategy and estimate the deployment of resources required for containment, in the shortest period of time.

The Royal Society Commission on Animal Diseases concluded in 2002 that quantitative models are an essential tool to develop strategies for outbreak preparedness and to predict and evaluate the effectiveness of control policies. A prerequisite is to have a central database with information of premises with animals, their localization and animal movements together with the characteristics of the diseases and the arrangements for the entry of data concerning control measures in a safe and timely manner (The Royal Society, 2002).

The advances in computerization achieved by veterinary services members of the COSALFA enable to have databases of premises, animal populations, geo-referenced localization and records of animal movements that would allow, with the support of a robust tool and the adequate expertise, to use modeling of foot-and-mouth disease outbreaks to improve their contingency plans and emergency preparedness.

The models mimicking epidemics usually have a limited predictive value. Nevertheless, and opposite to the models mimicking epidemics affecting public health, which are difficult to evaluate due to the mobility of modern societies, animal disease models may be more reliable because livestock is handled in a relatively structured way. Localizations of animals are known, the management processes at premises can be simulated and evaluated, and good estimates of contact data can be done to estimate the transmission patterns (Kostova-Vassilevska, 2004).

Recently, the European Commission for Foot-and-Mouth Disease funded a project to develop a modeling tool for epidemics (EuFMDis⁶) that enables to simulate foot-and-mouth disease outbreaks occurring both within and among member countries. This tool is robust and flexible enough to support planning, training and response of European countries in the emergence of a foot-and-mouth disease outbreak (De la Puente, 2019).

The incorporation of tools to simulate foot-and-mouth disease outbreaks, thus supporting emergency preparedness to foot-and-mouth disease in the region, could be the basis for a regional technical cooperation project and most countries would benefit with the methodology.

7.2.4. Regional antigen and vaccine bank

Emergency preparedness for foot-and-mouth disease emergencies is not complete if an established provision of antigens/vaccines for emergencies is not available and having reached the animal health disease-free status without vaccination is not necessary to establish it. While in the past foot-and-mouth disease incursions have been transboundary and caused by viral serotypes covered by the vaccines in use, currently, with the exception of the risk situation in the north of the Andean Sub-region, the risk of viral incursions can potentially be caused by any viral serotype circulating in the affected regions and, if the contingency plan considers emergency vaccination, the relationship with a regional antigen and vaccine bank is a technical and political must.

It is estimated that, in general, higher effectiveness is achieved when the decision is made early. Nevertheless, this decision may completely loose efficacy when the provision of the emergency vaccine is not timely or enough.

⁶ EuFMDis: European Union Foot-and-Mouth Disease Spread Model.

A pending discussion in the region refers to the control of a foot-and-mouth disease incursion caused by a serotype exotic to the region of the Americas, which is intended to be controlled with emergency vaccination. The risk of establishment of an exotic viral type will depend on the efficacy of the animal health measure and the decision adopted with the affected population.

In the Americas, the only regional Bank of Antigens and Vaccines against foot-and-mouth disease is the North American Foot and Mouth Disease Vaccine Bank, established in 1982 by Canada, Mexico and the USA. Since 2010, this bank is part of the International Vaccine Strategic Reserves Network formed by Australia, New Zealand and the United Kingdom. Among the national initiatives in the region, the Antigen and Vaccine Bank in Argentina, established in 1999, can be mentioned.

Since 2012, by the mandate of the COHEFA, the functioning conditions, operative and funding characteristics started to be defined for the Regional Vaccine Bank (BANVACO) of the countries of the COSALFA which, by consensus of the member countries, should be managed by PAHO.

The objective of the BANVACO is to ensure the effective availability of antigens and vaccines for the containment of foot-and-mouth disease outbreaks in populations free from infection in the Americas and has been conceived as an autonomous and independent legal entity where its members have decided to join efforts around the intended objective using the governance bodies defined therein. The Constitution of the BANVACO will be created when at least three of the 13 COSALFA member countries adhere to the Articles of Agreement. The member countries are holders of the antigen stocks that will be maintained in at least two vaccine-manufacturing laboratories of the region.

With the current perspective in which all contingency plans consider emergency vaccination as one of the priority strategies against a viral incursion, the adherence to this regional initiative is absolutely advisable.

7.3. Mitigation of biological risks in laboratories handling foot-and-mouth disease viruses

There are four countries in the Americas that have foot-and-mouth disease vaccine-manufacturing laboratories while six countries have laboratories that maintain foot-and-mouth disease viruses for diagnostic and research purposes. In three of them, there are reference laboratories for the diagnosis of foot-and-mouth disease. On the other hand, the installed capacities in the vaccine-manufacturing laboratories and the worldwide demands of foot-and-mouth disease vaccine anticipate that some laboratories could continue producing vaccines for extra-regional markets.

The risk of escape from laboratories handling the foot-and-mouth disease virus does not rely on a particular serotype but on the biosafety of facilities and the laboratory management regarding biological risk mitigation.

The COSALFA promoted and approved the establishment of a COSALFA Commission for the Management of Biological Risk and Biosafety which was constituted in August 2018, formed by specialists of the region and having the mandate of: 1) provide technical cooperation; 2) promote the management of biological risks at country level; and 3) evaluate the biosafety conditions of laboratories producing antigens/vaccines/reagents, as well as laboratories for diagnosis, vaccine quality control, and research.

With that end, the Commission approved the document of Minimal Requirements for the Management of Biological Risk and Biosafety and an evaluation mechanism of biosafety conditions in laboratories handling foot-and-mouth disease viruses. In this way, the laboratories located in disease-free zones or countries with vaccination which wish to continue handling foot-and-mouth disease viruses once the transition is started, should be inspected and comply with the recommendations of the Commission to ensure the mitigation of biological risks inherent to the activity.

7.4. Reorientation of the resources of foot-and-mouth disease programs in disease-free countries with vaccination

In several forums, representatives of the public and the private sectors have discussed the changes occurring in veterinary services as a result of the transition from free with vaccination to free without vaccination. This situation concerns the countries of South America, excluding the north of the Andean subregion.

Although there is consensus that the decision of a transition is unavoidable since it eliminates costs and enlarges markets, improving the competition of the livestock products of the region, it introduces significant changes in the organizations involved in the program, particularly in private or public-private organizations in charge of vaccination cycles, as well as in the veterinary service in charge of population control actions and inspection of animal health measures. In some cases, it also has an effect on the funding of the veterinary service.

It is recognized that the management carried out during the control and eradication stages has created and organizational and specialized human resources infrastructure that the countries should not waste or eliminate, although it is accepted that it is necessary to adjust it to the new setting. On the other hand, the opening to more demanding markets implies new requirements in the field of food safety and animal welfare that should be considered.

In this sense, it is advisable that the countries:

- Make changes to the rules that linked animal health measures and controls that
 were created to control foot-and-mouth disease. In particular, those that associated
 the registration and update of premises and animal populations with the control of
 foot-and-mouth disease. To update the prevention and surveillance standards for a
 disease-free status without vaccination.
- Make the best use of organizations devoted to foot-and-mouth disease vaccination cycles to establish or support other programs for disease control, not only in vaccination programs but also in other activities established by official services such as surveillance, inspection and certification actions, under the regulatory frameworks of each country.
- Renegotiate the sources of funding of the Veterinary Service when they were associated to the control stages of the foot-and-mouth disease program and link them with other animal health programs or initiatives to support post-eradication stages.
- Institute in the organization an entity in charge of emergency preparedness which will not only address specific preparedness for foot-and-mouth disease but also for

other diseases with a high-impact on the livestock industry. In this field, the private sector may develop plans for the continuity of the productive chain to be activated in emergency situations, aimed at reducing their impact on the food supply chains and the livestock systems vertically integrated, thus avoiding a destabilization of agriculture and economy.

7.5. Recommendations for the diagnosis of foot-and-mouth disease by national laboratories: integration, agility and precision in diagnosis

National and international foot-and-mouth disease reference laboratories included in the network of the Americas have played a key role in the improvement of the hemispheric program, particularly with the perspective of expanding areas free from foot-and-mouth disease without vaccination, since they contribute to epidemiological surveillance actions, investigation of suspected cases and emergency interventions.

In order to better address the new reality, laboratories should have the adequate capacity to respond to emergencies in the diagnosis of foot-and-mouth disease and to meet the analysis demands, following the criteria and requirements established for the accreditation of these methods compliant with ISO/IEC 17025:2017 Standard.

The reference laboratory of PANAFTOSA-PAHO/WHO has supported national diagnostic laboratories, particularly in strengthening the diagnostic capacities for professionals specialized in foot-and-mouth disease and differential diagnosis, providing quality biological supplies and assisting in the harmonization of procedures and support of the antigen bank. It has also contributed to improve the study and research capacity which, in turn, has helped to better understand the strains of the foot-and-mouth disease virus that threaten the region.

It is appropriate that the cooperation actions to harmonize diagnostic methodologies used in the region and the promotion of strategic partnerships to define research lines are carried out with the collaboration of other reference laboratories and collaborating centers.

The main challenge for National Reference Laboratories, in case of infection by the foot-and-mouth disease virus in disease-free countries without vaccination, is the time until obtaining the result of the whole-genome sequencing and submitting the chronological and geographic evidence in a timely manner in order to track the origin of the virus and the spread route. The strengthening of this area is essential to reduce the current time to the get the results from weeks to a maximum of 48 hours, training the teams in the use of the sequencing technology, contributing to the implementation of specific actions to progress in the eradication of the disease in the continent. It is desirable to sequence a large number of virus isolates, which will provide different types of analyses in the future, as the evolution of the virus and the identification of strains with pandemic potential.

National laboratories should participate regularly in inter-laboratory comparison programs for the diagnosis and control tests for foot-and-mouth disease vaccines, in order to evaluate capacities, both in endemic and non-endemic settings, prioritizing virus typification tests such as RT-qPCR (real time PCR) and viral sequencing, as well the detection of antibod-

ies to capsid and non-capsid proteins in order to control the quality of results and evaluate the performance of specific assays.

In addition to reference diagnostic activities, it is necessary to improve the infrastructure for the development and validation of new methods, production of adequate and sufficient standards and reference material such as kits and sera, to supply the demand and for the efficient operation of diagnostic laboratories in the countries. The diagnostic network should be fit to evaluate the performance and the quality of the reagents obtained from different suppliers in order to diversify the use of the adequate reagents, thus mitigating the risk of disruptions in the supply chain, in case of a higher demand due to potential disease outbreaks.

As indicated in item 7.2.4, it is necessary to maintain regional strategic antigen reserves for the elaboration of vaccines for emergencies and establish the parameters for the implementation of antigen banks compliant with the epidemiological requirements of the different regions. This bank should contain intra (historical) and extra continental antigens. Reference laboratories should study potential vaccine candidate strains according to stability and range of immunological coverage aspects and keep adequate vaccine quality control systems and efficient storage mechanisms. These strains and their strain collections should be handled in biosafety level 4 laboratories according to OIE parameters under official control.

Regarding logistic aspects for the safe transportation of infectious samples in the region, it is important to adopt measures to strengthen the logistic support and streamline the safe transportation of samples to the national or international reference laboratory, favoring a rapid and timely diagnosis.

It is important to highlight that the reference laboratories of the countries are generally located in a geographic area to receive samples from any part of the country; however, according to the characteristics of each country with ample and heterogeneous spaces and geographic conditions that hamper movement, associated to a varied logistic support and long distances between regions, defy the OVSs and increasingly demand better activity planning. The OVSs should have contracts with companies transporting biological material, apart from ensuring alternatives for official logistic support, helping to resolve any deficiency, for the immediate and safe transportation of infectious samples to national reference laboratory.

Long-distance land transport of this type of material should be avoided unless there is no other option and as long as it is conducted under the same safety conditions and duly authorized.

Taking into account the increasing susceptibility of cattle due to the suspension of vaccination and the strong spread power of the foot-and-mouth disease virus, the OVSs should count with trained staff to comply with the technical and legal requirements set in the legislation for the transportation of biological material, the necessary documents for shipping, the logistics to be used for transit, the biosecurity conducts in normal circumstances and in case of accidents with biological material. It is worth pointing out that a good diagnosis begins with good collection and transportation of samples. For that end, OVS professionals in the region should receive training in terms of logistics for the safe collection, handling, storage and transportation of infectious samples in the region.

Specifically, regarding biosafety, only laboratories compliant with international biosafety standards should handle the infectious foot-and-mouth disease virus, and they should be

subject to ongoing and adequate inspection. Besides, a registry of foot-and-mouth disease virus serotypes should be elaborated by the laboratories of the region and the necessary mechanisms should be created to verify and ensure that biosafety level 4 conditions are maintained, according to OIE parameters. Also, it is important to identify and mitigate possible risks near the laboratories where animals susceptible to foot-and-mouth disease may be present, in order to avoid their exposure to the agent in case of viral escape from the facilities. In these areas, active surveillance by the OVS and the maximum coordination with the responsible technicians of the laboratories will be essential, as well as educational actions to encourage community participation.

In the transition phase from foot-and-mouth disease-free status with vaccination to without vaccination, reference laboratories should maintain and reinforce some actions, namely:

- Orient the countries in projects for adapting their infrastructure, aimed at handling the foot-and-mouth disease virus in public and private institutions.
- Coordinate, together with official services, regular evaluations and orientation visits
 to each official and private laboratory handling the foot and mouth disease virus
 with any purpose, with the support of the Committee for Biological Risk Management
 and Biosafety of COSALFA countries.
- Promote an ongoing training plan for human resources aimed at improving the diagnostic quality, including training for sample collection.
- Provide technical cooperation for the countries to establish harmonized biosafety standards in the region and to create and maintain national biosafety expert commissions for the foot-and-mouth disease virus.
- Strengthen the biosecurity conditions and mitigate the potential risk of escape and spread of the foot-and-mouth disease virus, involving the diagnosis and production laboratories against foot-and-mouth disease.
- Promote the integration and exchange of information among the laboratories in order to strengthen disease surveillance and control actions in regions with viral transmission/infection and support the transition in countries/zones of the region to the foot-and-mouth disease-free status without vaccination.
- In BL4 laboratories, strategic diagnostic activities are recommended, acting together with the Ministries of Health and Agriculture in order to promote, in an integrated fashion, joint actions for strengthening structures, optimization of resources and sustainability.



Phefa's management

8.1. Sub-regional management and coordination plans

Since the PHEFA Action Plan 1988-2009, it has been recognized that, in South America, and from the perspective of cattle exploitation, which is the main reservoir of the foot-and-mouth disease virus, subregions could be recognized grouping territories that shared ecological and production characteristics, and that it was necessary to consider them in the strategic definitions of the national control and eradication plans, creating a supra-national coordination and management level. The Central American, Caribbean and North American regions added to these regions.

Therefore, the PHEFA subregions were conformed as follows:

- **Southern Cone**: encompasses territories of Argentina, the non-Altiplano region of Bolivia, the South, Center-East and Center-West of Brazil, Chile, Paraguay, and Uruguay.
- **Andean Region**: encompasses territories of the Bolivian Altiplano, non-Amazon territories of Colombia, Ecuador, Peru, and Venezuela.
- Amazon and Brazilian non-Amazon Regions: encompasses territories of the North and Northeast of Brazil, Guyana, Suriname, and Amazon territories of Colombia, Ecuador, Peru, and Venezuela.
- **Central America**: encompasses Belize, Guatemala, Honduras, El Salvador, Nicaragua, Costa Rica and Panama.

Caribbean Region: encompasses territories of 25 sovereign countries and 19 dependent territories.

The subregional approach has been helpful for the consistency and certainty of the advancement of national programs. Moreover, the standpoint of defining a subregional approach, which recognized early that it was the geographic area of the foot-and-mouth disease reservoir species in the subcontinent what determines the presentation and distribution patterns of foot-and-mouth disease outbreaks was, besides, verified by phylogenetic studies of the types O and A viral strains isolated from historic foot-and-mouth disease outbreaks that proved that geographic circulation of these virus types was limited to each subregion, without records of occurrences in other subregions.

Thus, the Southern Cone and Andean subregion presented endemic-like circulation of virus types belonging to specific lineages, without exchange between subregions, while de Amazon subregion was characterized by sporadic occurrence.

On the other hand, in subregions with endemic occurrences, organizations and forums were established which have been essential to coordinate national control and eradication programs, including subregional initiatives to support national animal health management.

By the end of the second PHEFA action plan, all the subregions show a similar animal health condition – foot-and-mouth disease free with or without vaccination – except for Venezuela, where the risk of foot-and-mouth disease persists. For that reason, the suspension of cattle vaccination programs is currently promoted in all disease-free countries that are still using vaccines, except for Colombia, in order to verify the elimination of the endemic viral strains in the Americas.

In this sense, in the Amazon subregion, the territories of the Peruvian Amazonia, Guyana and Suriname are free from foot-and-mouth disease without vaccination, to which the states of Rondônia and Acre, and parts of the states of Amazonas and Mato Grosso in Brazil, will be added, while the same occurs in the Andean subregion, in the Bolivian Altiplano and the coastal and Sierra regions of Peru. In the Southern Cone subregion, on the other hand, to the territories of Chile and the Argentine Patagonia, the Pando Department has been added and, in the near future, Beni and Tarija in Bolivia and, to the state of Santa Catarina in Brazil, in 2021, the states of Paraná and Rio Grande do Sul will be incorporated.

For the period of this Action Plan 2021-2025, it is thought that the Southern Cone and Andean subregions with inter-institutional coordination instances such as the Permanent Veterinary Committee of the Southern Cone and the Andean Community in the Andean subregion, prevention, detection and response capacities against foot-and-mouth disease for animal health emergencies should be strengthened. In fact, although disease-free countries comply with the protocols established by the OIE Terrestrial Animal Health Code, their prevention capacities to detect and exclude risk products introduced either by international passengers or international cargo vehicles should be strengthened. Also, emergency response should be strengthened with regular training programs for specialized technical teams and updating of contingency plans so as to count with the capacities for a rapid and effective response in case of potential viral incursions. It is advisable that subregional organizations promote actively the adherence to antigen banks, so this tool is

really available in case of animal health emergencies. A similar approach is advised for the subregions of Central America, North America and the Caribbean by means of subregional organizations for animal health.

8.2. Monitoring and evaluation

The PHEFA 2021-2025 Action Plan will be carried out through two mechanisms. The progress in the transition of disease-free countries with vaccination will be monitored in loco and through annual reports on the situation of the foot-and-mouth disease programs elaborated by the countries for the COSALFA, which will be discussed and approved in the annual meeting and then published by PANAFTOSA-PAHO/WHO. The actions to be carried out in Venezuela will be monitored more closely through specific reports elaborated by PANAFTOSA-PAHO/WHO within the framework of the technical cooperation agreement established with the INSAI.

COHEFA and COSALFA, in their relevant fields of action and with their respective mechanisms, will be responsible of supervising and providing support to the management of the PHEFA 2021-2025 Action Plan.

8.3. Coordination and strengthening of international cooperation

Technical cooperation organisms - either subregional, regional or international – and PAHO participate and contribute to the achievement of the eradication goal proposed by the PHEFA. This participation is materialized through coordinated actions so that their respective technical cooperation programs may be aligned with the objectives of the PHEFA action plans.

In this sense, the PHEFA 2021-2025 Action Plan will maintain and strengthen the articulation with international organizations to optimize the use of resources and interagency coordination for the benefit of the countries. Table 1 shows the international institutions and organizations associated with the foot-and-mouth disease technical cooperation within the framework of the PHEFA.

TABLE 1

Role of international organizations and institutions associated with the foot-and-mouth disease technical cooperation within the framework of the PHEFA

Organization/ Institution	Role in foot-and-mouth disease technical cooperation within the framework of the PHEFA
PAHO/PANAFTOSA	Coordinates PHEFA's management; develops technical cooperation activities pertaining to epidemiological information and surveillance systems, references in laboratory diagnoses, prevention programs, FMD elimination and control; and acts as ex officio secretariat for the COSALFA and the COHEFA.

CONTINUED ON NEXT PAGE ──►

Organization/ Institution	Role in foot-and-mouth disease technical cooperation within the framework of the PHEFA	
OIE	Leads the PVS process for the strengthening of the OVSs. Reviews and updates the Terrestrial Animal Health Code; recognition of foot-and-mouth disease official animal health status. Together with FAO, coordinates the global strategy for the control of foot-and-mouth disease and the GF-TAD initiative. Provides accreditation to foot-and-mouth disease reference laboratories in the region (PANAFTOSA/PAHO-WHO and SENASA, Argentina).	
FAO	Together with OIE, coordinates the global strategy for Foot-and-mouth Disease Control and the GF-TAD initiative.	
IICA	Promotes and supports the development of capacities for the modernization of agricultural health and food safety.	
OIRSA	Support to the member countries for the prevention, control and eradiation of animal diseases of public health, economic and social importance, in order to contribute to food security and facilitate national and international trade.	
CVP	Coordinates actions between the CVP member countries to increase the capacity to prevent, control and avoid impacts and animal health risks affecting the production and commercialization of animals, animal products and byproducts.	
CAN/COTASA	Coordinates the Andean Subregional Program for the Eradication of Foot-and-Mouth Disease.	
APHIS/USDA	Alliance with PANAFTOSA for the elimination of foot-and-mouth disease and to contribute to the bilateral cooperation of the countries of the region.	

8.4. PHEFA Funding

PHEFA action plans consider different funding sources, such as:

- Direct contributions from public and private sectors of each country for funding the actions of each national eradication and prevention program;
- Bilateral technical and financial cooperation agreements, or multilateral agreements between a group of countries and a financial institution;
- Contributions from financial institutions through refundable and non-refundable credits to support the strengthening of specific programs; and
- PHEFA Trust Fund created by PAHO/WHO to support PANAFTOSA-PAHO/WHO technical cooperation, with the provision of resources from public and/or private sectors.



The impact of the transition to disease-free status without vaccination from the economic perspective

9.1. Introduction

The risk assessment in foot-and-mouth disease-free countries or zones using vaccines in South America, excluding Colombia, enables to conclude that there is enough evidence to sustain that the probability of viral transmission in cattle has been mitigated by systematic vaccination programs, that the risk of reintroduction of the foot-and-mouth disease virus through imported livestock goods is being mitigated by the preventive measures at the level of ports, airports and border crossings, which are also aligned with the OIE Terrestrial Code recommendations, and that the transboundary risk derived from the illegal entry of animals is being mitigated because South American countries – except for Venezuela which has transit restrictions due to geographic reason – share the foot-and-mouth disease-free status, either with vaccination or without vaccination.

Nevertheless, the decision of a transition to a disease-free status without vaccination has encountered difficulties or resistance in different sectors or stakeholders of the region which do not always rely on risk assessments based on evidence, science or a reasoned

The elaboration of this chapter was based on the PANAFTOSA/PAHO document "Programa Hemisférico de Erradicação da Febre Aftosa PHEFA - Análise econômica de ônus e bônus da nova estratégia" which was prepared by Professor Dr. Jorge Madeira Nogueira of the University of Brasilia (UNB), Brazil.

analysis on the costs of continuing with an animal health control strategy in a disease-free zone and the benefits and opportunities that progressing to a new status represent.

The foot-and-mouth disease-free status with vaccination is not equivalent to a complete eradication of the disease and maintaining it represents a significant percentage of the costs of the program, both for governments and farmers, together with a limitation in the export economies for livestock product placement and to disease-free countries without vaccination.

For these reasons, this chapter has been included in the 2021-2025 Action Plan, with the purpose of introducing a methodological approach based on economic rationality to support the decision to move to a disease-free status without vaccination. The chapter reviews the advantages and disadvantages of adopting a decision by means of two methodologies widely used in the economic evaluation of projects.

9.2. Economic analysis of the disadvantages and advantages of a transition to foot-and-mouth disease-free status without vaccination

PHEFA 2021-2025 Action Plan is a unique opportunity to obtain relevant financial and economic profit for producers, societies and economies of the continent. The increased profitability of farmers, new opportunities of employment and income with positive effects on the economic grow rate are some of the potential positive results from the complete eradication of the foot-and-mouth disease in the Americas and the strengthening of prevention and response capacity of veterinary services in the countries of the continent.

Epidemiological and veterinary specialized knowledge must be translated into a language capable of committing the support of public and/or private decision makers for the initiatives proposed in the 2021-2025 Action Plan. We should not forget that non-specialists tend to perceive firstly the costs, uncertainties and risks of a decision, only to observe the potential bonus, gains and benefits of that decision in a later step.

Shifting from the "disease-free country with vaccination" to the "disease-free country without vaccination" status requires a careful analysis of epidemiological aspects and those related to the capacity of the current prevention and surveillance system, as well as the involved economic and market-related aspects. Both animal health statuses have their own direct or indirect costs and benefits distributed in different ways among the sectors, both in the governmental and private sector and the affected production chains.

In democratic regimens, it is reasonable that the society expects that the decision-making authorities consider the potential direct and indirect impacts before legislating. There are several technical instruments to explain and evaluate those impacts. We propose the application of the Cost-Benefit Analysis (CBA) or the Cost-Effectiveness Analysis (CEA). With them, it is possible to estimate and compare the economic advantages and disadvantages of the transition to the foot-and-mouth disease-free status without vaccination.

The CBA has been increasingly applied in Latin America for the ex ante evaluation of programs, plans and public policies (PPP). In the case of the CEA, it can be applied in

different types of PPPs, however, the applications in the (human) health and environment areas predominate.

It is advisable that each country of the region chooses which of the instruments will use to make an efficient decision (in such case, the choice should fall on the CBA) or a cost-effective decision (in such case, the choice should fall on the CEA).

A basic criterion to decide between CBA or CEA is the availability of resources (time, staff, statistical information, budget) to prepare the evaluation. The former is more demanding in terms of resources than the CEA. Whatever the option, it should be clear that the study is being carried out by a multidisciplinary technical team (veterinaries, economists, public administrators) linked to the national executive organism that will make the decision of implementing the new national strategy.

9.3. Cost-Benefit Analysis (CBA) to evaluate the adoption of a strategy of disease-free country without vaccination

The choice of a national team to carry out the Cost-Benefit Analysis (CBA) requires that all parties (consumers, rural producers, governmental technicians, among others) have the objective of evaluating the efficiency in the application of limited national resources to meet the objectives of the new strategy. Besides, a CBA also suggests equity issues: distribution of costs (who bears them) and benefits (who receives them). The involved players should understand this distribution so as to prevent (or minimize) unfairness and suspicions, which only weakens the essential political support for the new strategy to control the footand-mouth disease.

In order to properly execute the CBA with the aim of identifying potential advantages (benefits) and disadvantages (costs) of the strategy considered, it is essential that the actions to be applied as proposed by the 2021-2025 Action Plan be exhaustively defined. "Withdrawal of the foot-and-mouth disease vaccine" is the generic definition of what will be evaluated from a financial and/or economic perspective against the alternative of "maintaining the current situation of systematic vaccinations". Therefore, the comparison "WITH" and "WITH-OUT" is established as an alternative for change, an essential comparison for a rigorous CBA.

Once the situation "WITH" the strategy (the change to foot-and-mouth disease-free without the use of vaccines) is properly defined, the following essential step for the application of the CBA is a careful definition of the characteristics of the line of action of the country at baseline, that is, the situation "WITHOUT" the new strategy (continue foot-and-mouth disease-free with the use of vaccines) for the CBA. What is the relevance of defining the situation WITHOUT for the new strategy? It is highly relevant. In the development of a CBA, financial and economic costs of the new strategy (foot-and-mouth disease-free without vaccination) will be the increase in financial and economic costs compared to the reference situation WITHOUT the new strategy. In the words of an economist: they will be incremental (or marginal or borderline) costs. Likewise, the profits/financial and economic benefits of the new strategy (WITH withdrawal of vaccines) will be the increments in profits/economic and financial benefits compared to the reference situation WITHOUT the new strategy. Again, in the words of an economist: they will be incremental (or marginal or borderline) benefits.

It is necessary to remember that a positive result (benefits) for a social segment (producers, for example) may represent a negative result (losses) for another social segment (vaccine manufacturers and suppliers, for instance). The identification of all potential impacts, their incidence and intensity should be carried out as comprehensively as possible. Identifying all the impacts does not mean that all of them will be measured in money terms. Among all the impacts identified, it is essential to identify those (positive and negative) of financial and economic relevance. This means choosing and concentrating the efforts in those affecting, directly or indirectly, the wellbeing of the citizens concerned as a result of the strategy change.

After calculating the - financial or economic - costs and benefits, the economic-financial evaluation of a new strategy is carried out comparing the monetary values of the costs/expenditures and the benefits/profits. The flow of costs and benefits occurs over time, that is, over the years. The operation of considering all the values at the same time requires several technical options: a) defining the number of years for which the values of costs and benefits will be estimated; as a general rule, these are estimated over average periods of 20 (twenty) years; b) the discount rate (interest); and c) criteria or parameters of choice or merit.

In simple terms: in the cost and benefit analysis of a strategy to fight an animal disease, the evaluation is therefore performed after identifying all the benefits and financial and economic costs, calculating the current values of each of them and using at least one of the three decision criteria. The final result of the CBA will reveal whether the adoption of the new strategy will be an efficient decision or not.

9.4. Cost-Effectiveness Analysis (CEA) for the adoption of a strategy of free country without vaccination

The Cost-Effectiveness Analysis (CEA) is, in turn, an economic evaluation tool that enables to compare alternatives based on the achievement of the same objective, indicating the lowest-cost alternative, that is, it enables to choose the profitable alternative. It has already been mentioned that the CBA is considered demanding in terms of the time required to gather essential data and prepare the calculations to convert the results into monetary values. This requirement is reduced in the case of the CEA, since it takes into account the costs and the effects of the selection of alternatives, which enables to choose those providing the best results for a particular resource expenditure or those minimizing the use of resources for any particular result.

In order to use a CEA, certain criteria should be observed: a) only programs with a similar or identical objective can be compared; b) the choice of the effectiveness measure should be common to the alternatives under study, and c) the data on costs and effectiveness measures may be converted into cost-effectiveness rates that represent an effectiveness indicator obtained for an estimated cost. Therefore, in a CEA, the concept of benefit is replaced by the concept of effectiveness. When it is used, the intention is to compare an absolute quantitative category, that is, the involved cost, with another qualitative category represented by an indicator (attribute) common to the alternatives presented

for the study. In this way, a CEA evaluates whether the objectives can be met in an effective and profitable way.

In the specific case of a CEA to evaluate a change in the strategy for the foot-and-mouth disease, it should be based on the following alternatives: 1) keep vaccination or 2) withdraw vaccination. With that end, a comparison is made between the alternatives in order to achieve the objective at the lowest cost, assuming the same benefits for both. When calculating costs, the three cost categories should be considered: a) explicit and implicit costs; b) direct and indirect costs; and c) costs of the private and the public sectors. On the other hand, the effectiveness measures to choose when a CEA is used should be carefully defined to facilitate valid comparisons among the alternatives proposed. The closer the chosen measure is to a variable affecting directly social wellbeing, the more consistent the CEA will be.

9.5. Potential costs and benefits due to the adoption of a strategy without vaccination

As there are no benefits without costs (or, in economic terms, there is no such thing as a free lunch), it is necessary to explain the potential costs or negative impacts of the new strategy.

Table 2 presents the potential costs that the strategy without vaccination may imply.

The cost table identifies those costs to be considered by a country that aims to achieve the disease-free status without vaccination once the infection has been eliminated from animal populations. Nevertheless, it should be highlighted that in the case of the South American countries that still maintain massive vaccination programs, they have the **foot-and-mouth disease-free status with vaccination**. In fact, this status, temporary on the way to eradication, is granted by the OIE once the country or zone has not only achieved epidemiological disease control objectives but also has a veterinary service with the capacities, facilities and resources to prevent and detect new introductions of the disease and to rapidly respond to potential animal health emergencies.

That is, the costs mentioned in 1, 2 and 3 in table 2, for instance, are costs that have already been internalized because they are a requirement for obtaining the disease-free status with vaccination. The change of strategy will probably not represent higher costs, or they will be marginal. These costs could indeed be relevant in those countries making a transition through progressive zoning of their free territory to the disease-free status without vaccination, where infrastructures should be created within the country to control domestic borders and separate vaccinated from not vaccinated populations.

Potential cost of the new strategy without vaccination

Costs of the New Strategy			
Costs	Description		
COST 1. Cost increase due to investments in physical, material and human resources infrastructure for prevention.	It includes the costs to improve the infrastructure of ports, airports, border crossings for quarantine controls and inspection of international products and passengers.		
COST 2. Cost increase due to training of public and private staff.	Corresponds to the costs associated with the training of staff for a rapid emergency response.		
COST 3. Cost of the creation and maintenance of Private Funds for the foot-and-mouth disease.	It refers to the creation of funds that allow compensating producers for the animal health measures adopted in case of foot-and-mouth disease emergencies.		
COST 4. Potential cost for maintaining the Registry of livestock farms.	It refers to the cost of maintaining a livestock registry when it is associated to the activities of the foot-and-mouth disease program, such as vaccination.		
COST 5. Cost of forbidding the entry of vaccinated animals to the free zone or country.	Includes the cost of interrupting the entry of vaccinated animals to the free zone for breeding and reproduction purposes.		
COST 6. Financial effect in the (industrial, wholesale and retail) sectors linked to the provision of foot-and-mouth disease vaccines, as a consequence of the withdrawal of the vaccine.	Corresponds to the impact of discontinuing the use of vaccines in the industrial sector that produces and distributes vaccines. Also includes organizations devoted to vaccination.		
COST 7. Risk of reoccurrence of new outbreaks.	Cost associated to a foot-and-mouth disease outbreak occurring in the evaluation period, regardless of the probability of occurrence. It is advisable to evaluate the control of a low-level (most probable) and a high-level (less probable) outbreak with different control strategies.		
COST 8. Cost for increasing the herd size (cattle, goats, swine and sheep) to meet an increased demand due to exports.	Includes the costs that farmers may incur to substantially increase the herd size due to a significant demand of livestock products.		

Cost 4 is relevant only for those countries that have linked the maintenance of the cattle registry to the foot-and-mouth disease vaccination program. It should not be disregarded that the countries have mechanisms to maintain ovine, caprine and swine registry which are not linked to foot-and-mouth disease vaccination.

Cost 5 is important in the countries making a progressive transition by zones. Except for Brazil, that has a vaccine withdrawal plan advancing by blocks of states, the other disease-free countries with vaccination of South America are ready to do it all at once. On the other hand, the frequency of exchange of live animals between disease-free countries with vaccination is not high. Therefore, the cost is also considered to be marginal.

Cost 6 is important for vaccine manufacturers, the distribution chain and the organizations responsible for vaccination campaigns because immediate direct losses are seen in their income. Nevertheless, both the industry and the distribution chain and the organizations for vaccination have alternatives for the control and animal health management of other animal communicable diseases. Vaccine manufacturing industry may produce other vaccines and, if it wants to continue in the foot-and-mouth disease vaccination business, it has the technology and scale to produce vaccines to satisfy the demand in foot-and-mouth disease endemic regions of the world.

Cost 7 has the peculiarity of being pertinent to both strategies. With and without vaccination. In fact, in a disease-free country with vaccination, new foot-and-mouth disease outbreaks may (and in fact they do) appear in not vaccinated animal species, or due to a viral type not covered by the vaccines. It may also happen in populations not properly immunized. Consequently, this cost should be evaluated comparing different control strategies (according to OIE and the animal health status, there are 9 strategies), rather than considering that the strategy with vaccination means permanent absence of new foot-and-mouth disease outbreaks.

On the other hand, table 3 below depicts the potential benefits that may be achieved with the strategy without vaccination.

Benefits 1 y 2 are received directly and immediately by producers once the vaccination campaigns are discontinued. That is, they are received by all the producers whose cattle is vaccinated.

Benefits 3 and 4, on the other hand, are for the official Veterinary Service when releasing physical, financial and human resources due to the discontinuation of vaccination campaigns that could be devoted to other animal health activities, improving the performance of the service in the control of other diseases.

Benefits 5 and 6 will be seen in the short-term in already exporting economies, either by expanding the supply of livestock products in current markets and by exploring more demanding new markets and by reducing the costs due to animal health protocols for export. In non-exporting economies – although with exporting potential -, there will be a variable period for the conquest of new markets, negotiation and adaptation for these benefits to emerge in a significant way.

Benefits 7, 8 and 9 represent those benefits with an effect at national level that benefit the society due to increased production, dynamism, technological modernization and productive optimization of the livestock business and the livestock industry.

Benefits of the new strategy without vaccination

Benefits of the New Strategy			
Benefit	Description		
BF1 . Costs avoided by the livestock producer derived from discontinuing vaccination campaigns against foot-and-mouth disease.	The benefit derives from halting vaccination of animals after the discontinuation of massive vaccination campaigns. They include costs avoided due to fines, inspections of the whole vaccine storage and distribution chain and vaccination services.		
BF2 . Reduced losses derived from lesions and drops in milk production associated to the vaccination procedure.	It includes the costs avoided by lesions such as contusions, abscesses, hematomas and abrasions associated to injections and the temporary drops in milk production due to the vaccination process.		
BF3 . Improvement in the structure of the Official Service.	It includes the benefit of having the official veterinary service facilities and equipment available for the control of other animal diseases.		
BF4 . improvement in the efficacy and efficiency of professionals and technicians of the OVSs.	It refers to the benefit of having human resources conformed by highly prepared technical teams for the control of other diseases.		
BF5 . Increased supply of products and opening of new (national and international) markets that pay best to farmers and the cold-storage industry.	It includes increased benefits derived from removing the main restriction to trade animal products with disease-free countries without vaccination.		
BF6 . Costs avoided due to the risk management measures associated to export of livestock products of bovine, swine, ovine and caprine origin.	Corresponds to the benefit due to the reduction of the costs producers must pay to comply with animal health protocols to export animal products such as compartments, stay times, inspections at shipping, dedicated slaughter, inspections to cold-storage facilities, deboning and maturing of meat.		
BF7 . Positive effects on the regional and national GDP as a consequence of the increased number and marginal values of livestock exports.	Exporting economies increase the benefit on national GDP due to an increase in the number, value and diversity of exports.		
BF8 . Incentive to changes in the livestock production cycles at regional and national levels.	In exporting economies, expanded exports will foster the increase, improvement and productivity of herds, reducing production costs.		
BF9 . Possibility of attracting investments for the expansion of the export industry.	In the exporting economies, the expansion of exports will create incentives for investing in the livestock industry, either increasing the capacities of the cold-storage plants or installing new plants.		

Summing up, the benefits identified due to the change of strategy are expressed not only at the level of the producer but also at the level of the state, represented by its Veterinary Service, in the livestock industry and the society in general.

9.6. Conclusions

The CBA or a CEA allow to decide the new strategy with rational foundations, and its advocates can present it as a unique opportunity to obtain significant financial and economic profits for producers, societies and economies of the continent.

The new strategy should not be perceived as an actual national alternative for all social segments directly (or even indirectly) affected by it but as a viable need for the reorientation of the actions executed by the OVSs that have a high (personal and financial) cost, as the activities inherent to systematic vaccination against foot-and-mouth disease.

A CBA or a CEA should be understood as a technical instrument as well as an instrument for political negotiation. As a technical instrument for decision making by the professionals that will participate in the definition and implementation of the new foot-and-mouth disease control strategy and should be involved since the initial stages of its elaboration. They need to understand the procedures, identify sensitive points of the strategy identified by the CBA or CEA, reevaluate and recalculate each cost and each benefit explained herein as long as this is considered necessary, and use the results of the CBA or CEA as an instrument for implementation and management.

As an instrument of political negotiation, it should be used to raise the awareness of leaders and producers. Developing consensus and commitment of leaders that represent the production chain that, directly or indirectly, will be favored by the new foot-and-mouth disease-free status without vaccination should be an essential component in the implementation of the new strategy.

Once animal health risks are mitigated, it is expected that the cost-benefit analysis will be widely favorable to initiate a transition to a disease-free country or zone without vaccination, since it implies removing not only one of the most relevant costs of a foot-and-mouth disease program such as massive and systematic vaccination of animals in a control program, but also a barrier to release all the potential of food production the countries of South America can offer to their people and the world.

Future challenges of veterinary services of South America

As it was possible to observe, animal health progress regarding foot-and-mouth disease in the countries of the American continent is remarkable. Robust (public and private) investment for foot-and-mouth disease eradication has allowed the consolidation of an infrastructure and a technical framework with enough capillarity to comply with all the requirements related to foot-and-mouth disease and other demands.

The activities and the knowledge gained should be more complete and integrated to solve health problems and hazards for animals and humans, particularly in the case of foodborne diseases. A quality assurance approach based on management systems used in production, slaughter and distribution of food animals is essential.

This approach will allow interventions that enable to reduce risks in an integrated, effective and economic way. Likewise, animal health programs for the management of non-food-borne risks should be designed to reduce risks for humans, taking into account animal welfare and environmental issues.

A sustainable and efficient Veterinary service should be flexible and adaptable to the new global trends and challenges.

The Official Veterinary System model began to be structured in Europe at the end of the XVIII and the beginning of the XIX century (FSIS, 2000) focused on actions of food security. In that time, European countries such as Germany, England, France, Austria, Portugal and Prussia started to organize their State Veterinary Services since the main objective of the public health policies recently adopted was to control the etiological agents responsible of zoonotic diseases transmitted through the consumption of products processed at slaughterhouses, thus requiring the work of veterinaries (FSIS, 2000; Gil JI, 2000).

The First World War increased the demand of animal proteins, which fostered the participation of South American countries as exporters in the international market, encouraging the establishment of big Anglo-American slaughter and cold storage facilities in the countries and the necessary organization of a veterinary inspection system.

Nevertheless, in the last two decades, several countries have started processes to restructure and realign the actions of their Food Control Services to migrate from the "Traditional Inspection Service" to "Risk-based Inspection Models" looking to prevent the occurrence of public health hazards, that is, prioritize the application of actions at the stages of the production chain with the highest hazards for society.

In spite of the global demand for the provision of proteins, it was necessary to guarantee the health of herds and the eradication of diseases, particularly the FOOT-AND-MOUTH DISEASE as well as, more recently, animal welfare, which continues restricting the trade of fresh and bone-in products. For this reason, several decades after the implementation of the Veterinary Inspection System focused on public health, the Animal Health System was created in the countries.

In the Americas, particularly in South America, this animal health system was leveraged and structured based on foot-and-mouth disease eradication, which forces us to rethink the future based on a foot-and-mouth disease-free without vaccination scenario, with viral elimination in the entire American continent.

It is important to emphasize that, so far, this animal health system has worked historically and almost exclusively to meet the demand of a commercial service of meat products and live animals (at national and international level), namely, an almost exclusively economic perspective.

As a general rule, in all the 13 COSALFA member countries the actions to fight zoonotic diseases in farm animals are emergent, except for brucellosis, tuberculosis and avian influenza, and almost nil to face zoonotic diseases occurring in any other niche other than farm animals, such as wild animals, companion and synanthropic animals, which end up in a complete and absolute epidemiological silence in these chains.

10.1. Evolution of veterinary services and delegation of competences to the private veterinary practice

The establishment and evolution of the Official Veterinary Service (OVS) have always been based on the demand of the private livestock chain and the demands of the society. The challenges to be faced have been changing significantly with regards to the industrial setting.

In the last 50 (fifty) years, significant changes have occurred in the meat production chain, such as:

a. the unquestionable improvement in the execution of animal health controls applied to the handling of animals for slaughter, reducing the occurrence of diseases, mainly zoonotic diseases. The most remarkable occurred in the integrated chain of swine and poultry;

- b. the emergence of innovations applied to the diet and genetic improvement of meat animals, which allowed to shorten the production cycle;
- c. the improvement in scientific knowledge, which allowed the governments to adopt risk management practices within the public health policy;
- d. the increase in the level of training of rural producers in improvement practices, which allows to achieve animal health and zootechnical advances, among others (FSIS, 2000; Alban et al, 2008).

Jointly with the undeniable improvements produced in the animal health field, food habits have also changed worldwide, increasing the number of people who eat or consume ready-to-eat meat products (Elmi, 2004; FAO, 2008).

Besides, most animals started to be slaughtered in big automatized facilities specialized in the slaughter of younger, healthier and uniform animals, with few zoonotic diseases which represent a food threat for humans (FSIS, 2000).

These factors have changed the historic profile of the risks posed by food consumption for public health and, together with the increasing limitations to (financial and human) resources faced by governments, Veterinary Services have been forced to transform and reinvent themselves.

For this reason, OIE designates veterinary services as governmental or non-governmental organizations that apply measures to protect the health and welfare of animals and the other standards and recommendations of the Terrestrial and the Aquatic Animal Health Codes in the territory of a country. Veterinary Services work under the control and supervision of the veterinary authority, which is the national authority that responds to and represents the country.

Regarding human resources, two issues have become extremely relevant:

1. Training of veterinaries and other professionals involved in inspection and animal health activities

The outbreaks of foodborne diseases are currently most related with failures in the process of slaughter and industrialization, hygiene at industrial level or in the way or preserving and preparing end products.

Pathogens that present serious risks for human health do not show visible signs for detection by a veterinary inspector. Some examples are *Salmonella Thiphymurium*, *Campylobacter jejuni*, *Toxoplasma gondii*, *Escherichia coli 0157: H7*, *Listeria monocytogenes*, *Yersinia enterocolpica*, *Norovirus enterocolpica*, among others (Alban et al, 2008; EFSA, 2011; EFSA, 2012; EFSA, 2013).

This scenario promoted the need that veterinary doctors incorporate wider knowledge that would allow them to take more preventive actions in order to safeguard the health of the human population instead of focusing only on the disposal of carcasses and parts of animals with macroscopic lesions. With that end, it was essential that these professionals deepened their studies in other areas of veterinary knowledge such as microbiology, epidemiology, toxicology, infectious diseases, animal health defense, tech-

nology and food processing implementation of self-assessment tools GMP, SSOP, HACCP, among others. (FSIS, 2000).

It is necessary to achieve a close integration between official veterinary services working in public health and animal health, due to the complementary nature of their activities.

2. Increase in the number of professionals involved in these activities in order to meet the increased demand due to industrial expansion

Regarding the training and maintenance of professional teams consistent with the new challenges to ensure public health, Official Veterinary Services from different countries of the world had to create mechanisms different from the traditional one which would allow to increase the number of professionals whenever necessary, without placing an excessive burden on the State budget with personnel expenses. After all, the "burden" of the state machinery is a concern for all the countries, regardless of their economic power, particularly when the dynamism of the agricultural sector, with the frequent opening and closure of markets, demands a differentiated policy to maintain a permanent qualified staff.

In view of this clear reality, the natural pathway for the OVSs was to establish guidelines that validated the delegation of competence to independent organisms and professionals for the execution of some official controls, thus enabling the performance of private veterinaries in the area of inspection and health, without restricting the direct link of hiring and payment by the State, or in any other way to avoid conflicts of interest.

10.2. Perspective of international organisms regarding delegation of official competences

The functions and responsibilities of National Veterinary Services are continuously expanding as a consequence of several global trends, including: increased demand of animal proteins, (re)emergence of zoonotic pathogens and risks for public health, such as antimicrobial resistance.

Forced by the scarce resources and capacities in the public or private area of Veterinary Services, Public-Private Partnerships (PPPs) offer concrete and timely support to face this complex setting and meet social demands.

PPPs can, for example, contribute significantly to the implementation of global programs in which Veterinary Services play a key role, such as those addressing prevention and control of animal diseases (pest of small ruminants, foot-and-mouth disease, avian flu or rabies), in order to combat antimicrobial resistance or enforce veterinary legislation.

The success of these PPPs depends on the following common criteria:

- a. recognition that collective efforts are more effective than independent efforts of the public or private sector;
- b. willingness of the public sector to create a favorable environment and of the private sector to contribute with its resources and capacities; and

c. identification of shared objectives for the public and private sectors with a clear delegation of responsibilities. It is clear that the success and the sustainability of the PPPs depend on the achievement of these shared objectives, in addition to complying with the needs of each party.

In this context, the member countries may benefit from the OIE PVS pathway. This program, among others, helps to create a favorable environment to promote impressive collaborations between the public and the private sectors and achieve mutual objectives. Especially, the PVS process helps Veterinary Services to operate under the principles of good government and improve the compliance with OIE standards.

Veterinary Services have an unprecedented responsibility to ensure a safer and healthier global community and play a key role to achieve, by 2030, several Sustainable Development Goals (SDG) of the United Nations.

Although The *Codex Alimentarius* Commission and the World Organization for Animal Health – OIE – may present different approaches in some points, they converge when recognizing the need to "capillarize" these services through the possibility of delegating competences to private or professional entities, establishing basic principles that should be observed by Official Veterinary Services – OVSs – to orient the performance of these entities or professionals.

This delegation of competence, internationally recommended and advocated, should be based on preset and unnegotiable principles, such as:

- **a. Impartiality:** private entities or professionals cannot have conflicts of interests that may, directly or indirectly, affect the impartiality of their professional behavior regarding the exercise of their delegated official control functions;
- **b. Power of action established by the legislation:** private entities or professionals should have enough and legally delimited power to carry out their delegated official control tasks;
- **c.** Act in coordination with the competent authority: private entities or professionals should act under efficient and effective coordination by competent authorities, including notification of their actions with the set frequency;
- **d. Qualification:** private entities or professionals should have the technical knowledge, the expertise, the team and the infrastructure necessary to carry out their delegated official control tasks.

Therefore, the OVSs that opt for delegating part of their activities, including those related to veterinary inspection and health (inspection and health), in order to comply with national needs and international mandates, establish procedures and rules to monitor the activities carried out by private entities or qualified professionals, as listed below:

1. competent authorities should organize and carry out audits and inspections to evaluate the execution of the activities delegated to qualified entities or private professionals, avoiding overlapping of tasks;

- 2. competent authorities should immediately remove total or partial delegation of the concession granted to private entities or qualified veterinarians if:
 - a. there is evidence that the qualified entities or private veterinarians do not perform the delegated tasks adequately;
 - b. it is observed that the qualified entities or private veterinarians do not take the adequate and timely measures to correct the identified flaws; or
 - c. there is proof that private entities or veterinarians are not independent or impartial regarding the delegated organism or physical person committed.

10.3. Veterinary services and the fourth industrial revolution

Industry 4.0 is the trend towards automatization and data exchange in manufacturing technologies and, hence, their services. Industry 4.0 is not only a question of technology or digital tools and methodologies. It represents a revolution that will force changes within companies that plan to continue operating in the region and will also affect the survival capacities of companies in emerging countries.

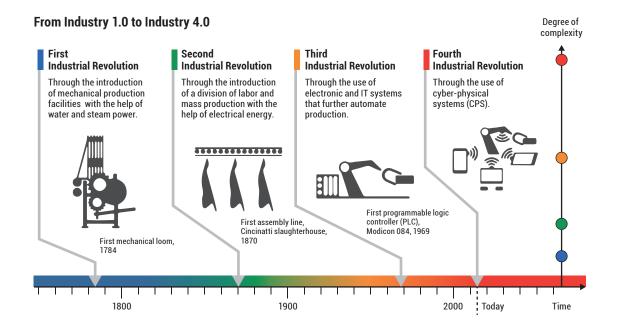
As mentioned above, the challenges of the OVSs will be to face the significant change in the industrial sector and, therefore, they should be in line with the Fourth Industrial Revolution, or Industry 4.0, organizing themselves around the concept of the so-called Intelligent Factories, where machines and systems are interconnected and have the objective of looking for the adaptability and efficiency of production systems.

The succeeding industrial revolutions have also been reflected in agricultural environments.

Agriculture 1.0 integrated the mechanization and steam machines with solutions that are currently representative milestones such as the steam tractor. Electricity brought Agriculture 2.0 by integrating industrialized solutions to everyday work, which enabled to increase production capacities. In the last part of the XX century, robotics and automatization entered the agricultural world (Agriculture 3.0), so, it is currently common to find big machines in the country performing the full cycle of work in tasks such as seeding.

FIGURE 1

The Four Industrial Revolutions



References

- Alban L, Vilstrup C, Steenberg B, Jensen HE, Aalbak B, Thune-Stephensen F, Jensen S. Assesment of risk for humans associated with Supply Chain Meat Inspection The Danish Way. Denmark. Ministry Food, Agriculture and Fisheries; 2008.
- Alexandersen S, Zhang Z, Donaldson AI, Garland AJ. The pathogenesis and diagnosis of foot-and-mouth disease. J Comp Pathol. 2003 Jul;129(1):1-36. doi: 10.1016/s0021-9975(03)00041-0.
- Brasil. Ministério da Agricultura, Pecuária e Abastecimento (MAPA). Secretaria de Defesa Agropecuária. Defesa agropecuária: histórico, ações e perspectivas. Brasília: MAPA, 2018. 298 p. Disponível em: https://www.gov.br/agricultura/pt-br/centrais-deconteudo/revistas/livro-defesa-agropecuaria.pdf
- Centro Panamericano de Fiebre Aftosa (PANAFTOSA-OPS/OMS). Programa Hemisférico de Erradicación de la Fiebre Aftosa: Plan de acción 2011-2020. Rio de Janeiro: PANAFTOSA OPS/OMS. 2011. Disponible en: https://iris.paho.org/handle/10665.2/49641
- Centro Panamericano de Fiebre Aftosa (PANAFTOSA-OPS/OMS). 3a Reunión Extraordinaria del COHEFA. Evento Virtual. 15 de diciembre de 2020. [Youtube]
- De la Puente M. Tools for better emergency preparedness and contingency plans: GET Prepared and EuFMDiS. 46 Pre-COSALFA Seminar. 2019, Cartagena, Colombia. European Commission for de control of FMD [PowerPoint Presentation].
- Diaz-San Segundo F, Medina GN, Stenfeldt C, Arzt J, de Los Santos T. Foot-and-mouth disease vaccines. Vet Microbiol. 2017 Jul; 206:102-112. doi: 10.1016/j. vetmic.2016.12.018.
- Dowdle WR. The principles of disease elimination and eradication. Bull World Health Organ. 1998;76 Suppl 2(Suppl 2):22-5.
- EFSA Panel on Biological Hazards (BIOHAZ). Scientific Opinion on the public health hazards to be covered by inspection of meat (swine). EFSA J. 2011; 9;(10):2251. doi: 10.2903/j.efsa.2011.2351.
- EFSA Panel on Biological Hazards (BIOHAZ). Scientific Opinion on the public health hazards to be covered by inspection of meat (poultry). EFSA J. 2012;10(6):2741. doi: 10.2903/j.efsa.2012.2741.

- EFSA Panel on Biological Hazards (BIOHAZ). Scientific Opinion on the public health hazards to be covered by inspection of meat from sheep and goats. EFSA J. 2013 Jun 27;11(6):3265. doi: 10.2903/j.efsa.2013.3265.
- Elmi M. Food safety: current situation, unaddressed issues and the emerging priorities. East Mediterr Health J. 2004 Nov;10(6):794-800.
- Food and Agriculture Organization of the United Nations (FAO). An introduction to the basic concepts of food security. Rome, Italy: FAO; 2008. Available from: http://www.fao.org/3/a-al936e.pdf
- Food Safety and Inspection Service (FSIS). The Future of FSIS Veterinarians Public Health Professionals for de 21st Century. Washington, D.C: United States Department of Agriculture (USDA); 2000.
- Gil JI. Manual de inspecção sanitária de carnes. 2 ed. Lisboa: Fundação Calouste Gulbenkian. 2000. v. 1, p. 485.
- Grubman MJ, Baxt B. Foot-and-mouth disease. Clin Microbiol Rev. 2004 Apr;17(2):465-93. doi: 10.1128/cmr.17.2.465-493.2004.
- Knight-Jones TJ, Rushton J. The economic impacts of foot and mouth disease what are they, how big are they and where do they occur? Prev Vet Med. 2013 Nov 1;112(3-4):161-73. doi: 10.1016/j.prevetmed.2013.07.013.
- Knight-Jones TJD, McLaws M, Rushton J. Foot-and-Mouth Disease Impact on Smallholders What Do We Know, What Don't We Know and How Can We Find Out More?

 Transbound Emerg Dis. 2017 Aug;64(4):1079-1094. doi: 10.1111/tbed.12507.
- Kostova-Vassilevska, T. On The Use Of Models To Assess Foot-And-Mouth Disease Transmission And Control. United States: N. p., 2004. doi:10.2172/15014467.
- McLaws M, Ribble C. Description of recent foot and mouth disease outbreaks in nonendemic areas: exploring the relationship between early detection and epidemic size. Can Vet J. 2007 Oct;48(10):1051-62. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1978293/pdf/cvj48pg1051.pdf

- Malirat V, Bergmann IE, Campos R de M, Salgado G, Sánchez C, Conde F, Quiroga JL, Ortiz S. Phylogenetic analysis of Foot-and-Mouth Disease Virus type O circulating in the Andean region of South America during 2002-2008. Vet Microbiol. 2011 Aug 26;152(1-2):74-87. doi: 10.1016/j.vetmic.2011.04.021.
- Malirat V, Bergmann IE, Campos R de M, Neitzert E, Villamil M, Quiroga Civera JL, Conde F, Jijón GS. Tracing 2007-20088 Emergency Episodes of Foot-and-Mouth Disease Virus in South America: Phylogenetic Analysis. The Global Control of FMD Tools, Ideas and Ideals. Erice, Italy: 2008 Oct. Appendix 58. Available from: http://www.fao.org/ag/againfo/commissions/docs/research_group/erice/APPENDIX_58.pdf
- The Royal Society. Infectious diseases in livestock. London: The Royal Society. 2002. ppxiv, 160.
- World Health Organization (WHO). Future trends in veterinary public health: report of a WHO study group. Geneva: WHO; 2002. 85 p. (WHO technical report series; 907). Available from: https://apps.who.int/iris/handle/10665/42460
- World Health Organization (WHO). WHO simulation exercise manual: a practical guide and tool for planning, conducting and evaluating simulation exercises for outbreaks and public health emergency preparedness and response. Geneva: WHO; 2017. 69 p. (WHO/WHE/CPI/2017.10). Available from: https://apps.who.int/iris/handle/10665/254741



Annex





PANAFTOSA

Pan American Center for Foot-and-Mouth Disease and Veterinary Public Health

RESOLUTION I

ACTION PLAN 2021-2025 OF THE HEMISPHERIC PROGRAM FOR THE ERADICATION OF FOOT-AND-MOUTH DISEASE (PHEFA)

The 3rd Extraordinary Meeting of COHEFA,

Considering:

- That the Resolution IV of the 46th Meeting of the South American Commission for the Fight Against
 of Foot-and-Mouth Disease (COSALFA) requests PANAFTOSA to make a proposal of an Action Plan
 of the Hemispheric Program for the Eradication of Foot-and- Mouth Disease (PHEFA), to define a
 new political and strategic framework to support the efforts for the eradication of Foot-and-Mouth
 Disease (FMD) in the American Continent;
- That the proposal was prepared by PANAFTOSA with the contribution of a group of experts from the countries, which has been previously shared and discussed with the Heads of Veterinary Service and representatives of the private sector;
- That the Action Plan 2021-2025 of the new PHEFA was presented, submissited to consideration, discussed, analyzed and improved in this extraordinary session of the COHEFA.

It is resolved:

- 1. Approve the proposed Action Plan 2021-2025 of PHEFA.
- 2. Request the Director of the Pan American Health Organization/World Health Organization (PAHO/WHO), as ex officio Secretary of COHEFA, to promote the knowledge and the adhesion to the Action Plan 2021-2025 of the PHEFA, to the highest political and technical level of the countries and of the representative organizations of the livestock production chain; of regional and subregional multilateral organizations and international funding agencies.
- Request PAHO/WHO to continue its efforts to provide cooperation and technical support to the countries of the region, through PANAFTOSA, in order the Action Plan 2021-2025 of the PHEFA can be carried out.

(Approved in plenary session on Dec 15, 2020)





Español:

EN FE DE LO CUAL, el Presidente de la Reunión, Dr. Geraldo Marcos de Moraes, Director del Departamento de Salud Animal (DSA) del Ministerio de Agricultura, Ganadería e Abastecimiento (MAPA); el Director del Centro Panamericano de Fiebre Aftosa – PANAFTOSA-OPS/OMS, Dr. Ottorino Cosivi y los representantes del más alto nivel del sector público y privado de las seis subregiones que integran el Comité: Amazónica, Andina, Caribe, Cono Sur, Mesoamérica y Norteamérica, firman la lista de presencia en la 3ª Reunión Extraordinaria del COHEFA, realizada em formato virtual, en el día 15 de diciembre del 2020.

Português:

EM FE DO QUAL, o Presidente da Reunião, Dr. Geraldo Marcos de Moraes, Diretor do Departamento de Saúde Animal (DSA) do Ministério da Agricultura, Pecuária e Abastecimento (MAPA); o Diretor do Centro Pan-Americano de Febre Aftosa – PANAFTOSA-OPAS/OMS, Dr. Ottorino Cosivi e os representantes do mais alto nível do setor público e privado das seis sub-regiões que integram o Comitê: Amazônica, Andina, Caribe, Cone Sul, Centro América e Norte América, assinam a lista de presença na 3ª. Reunião Extraordinária do COHEFA, realizada em formato virtual, no dia 15 de dezembro de 2020.

English:

IN WITNESS WHERE OF, the Chairman of the Meeting, Dr. Geraldo Marcos de Moraes, Director of the Department of Animal Health (*DSA*, *per its Portuguese acronym*) of the Ministry of Agriculture, Livestock and Food Supply (*MAPA*, *per its Portuguese acronym*); and the Director of the Pan-American Foot-and-Mouth Disease Center - PANAFTOSA-PAHO/WHO, Dr. Ottorino Cosivi and the public and the private sector high-level representatives, from the six sub regions that compose the Committee: Amazon, Andean, Caribbean, Southern Cone, Central American, and North American, have signed the present list of participants at the 3rd COHEFA Extraordinary Meeting, through the virtual platform, on 15 December 2020.

Por la Subregión Amazónica

Geraldo Marcos de Moraes

Geraldo Marcos de Moraes

Diretor, Departamento de Saúde Animal (DSA) Ministério da Agricultura, Pecuária e Abastecimento (MAPA) e Presidente da 3ª. Reunião Extraordinária do COHEFA Brasil K

Lilian Azevedo Figueiredo
Coordenadora de Produção Animal, Confederação
da Agricultura e Pecuária do Brasil (CNA)
Brasil

Por la Subregión Andina

Deyanira Barrero León

DocuSigned by:

Gerente General, Instituto Colombiano Agropecuario (ICA) Colombia Armando (Lacín Armando Chacín Presidente, Federación Nacional de Ganaderos de Venezuela (FEDENAGA) Venezuela

1

Por la Subregión del Caribe

Rafael Bienvenido Murez Mieses

Rafael Bienveที่ที่ดีอี่ที่ใช้ก็ซั่ว Mieses Director, Departamento de Sanidad Animal Ministerio de Agricultura República Dominicana

Patricia McPherson Leue
Co-Founder & Chief Operating Officer, Phoray
Cattle Ranch & Stables
Guyana

Por la Subregión del Cono Sur

José Carlos Martín Camperchioli

José Carlos Martin Camperchioli Presidente, Servicio Nacional de Calidad y Salud Animal (SENACSA) Paraguay Juan Carlos Abularach Suárez
Presidente, Confederación de Ganaderos
de Bolivia (CONGABOL)
Bolivia

Por la Subregión del Mesoamérica

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