

## TECHNICAL NOTE

### HEMISPHERIC PROGRAM FOR THE ERADICATION OF FOOT-AND-MOUTH DISEASE - PHEFA BEYOND 2020

unedited English translation of the document submitted in Spanish at the 46th Ordinary Meeting of the  
South American Commission for the Fight Against Foot-and-Mouth Disease (COSALFA)

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#### INTRODUCTION

The Action Plan 2011-2020 of the Hemispheric Program for the Eradication of Foot-and-Mouth Disease (PHEFA) is approaching the end; therefore, it is appropriate to examine the progress achieved, the pending work, and the challenges looming in the horizon, looking beyond 2020.

The 42nd Meeting of COSALFA, Quito, Ecuador, April 2015, recognized that the Action Plan 2011-2020 had progressed beyond what was initially expected. This was proven by the absence of new disease notifications in most regions of South America and the sustained progress in OIE official recognitions of the disease status in countries without recognition. Therefore, COSALFA requested that a Technical Guide for the last stage of the PHEFA be developed to guide disease-free countries with vaccination to transition toward the free without vaccination status.

The evidence of the progress of the PHEFA is the OIE recognition of disease-free with or without vaccination of the whole territory of the Region, except for Colombia – temporarily suspended – and Venezuela. The latter remains without recognition and currently shows remarkable weaknesses in its capacity to implement the national FMD control program.

The reoccurrence of outbreaks in the inner Colombian FMD-free territory and its borders with Venezuela during 2017 and 2018 illustrates the persistence of the FMD risk in the north of the Andean subregion and it has raised questions of its implications for the rest of the region.

South America is the only region of the world that includes countries and areas recognized FMD free with vaccination by the OIE, along with areas of Kazakhstan, Taiwan and Turkey. Furthermore, it has been maintaining systematic and regular vaccinations, for an indefinite period of time, on the same animal species that are the reservoir of the infection.

This Technical Note provides an update of the FMD risk in the region and address its potential effects, which are critical for defining the health strategies to deal with the pending challenges, maintain the achievements made and complete the process of FMD eradication, withholding vaccination in the American Continent.

## **ADVANCES OF FMD ELIMINATION DURING THE PHEFA ACTION PLAN 2011-2020**

At the early stages of the PHEFA Action Plan 2011-2020 the region made significant progress in the eradication process, particularly in the Southern Cone subregion, while the Andean subregion was falling behind, with a persistent occurrence of FMD outbreaks in some of its countries. Despite the progress achieved, the sporadic occurrence of FMD outbreaks in free zones with vaccination that affected countries of the Southern Cone up to 2012 that led to the consecutive suspension of their health status, was raising doubts on the real epidemiological situation of the region and on the credibility of the respective national authorities. Although it was initially argued that the disease persisted in border areas of Southern Cone countries, it was later established that the clinical form of the disease observed in these areas was a consequence of persistent endemic infection in niches located within countries. Significant changes were made in the vaccination programs in order to eliminate the transmission of the infection and, since January 2012, the Southern Cone subregion has not reported new cases of FMD and has kept its free status, with or without vaccination, unchanged.

On the other hand, the Andean subregion presented a sustained progress in the eradication process, achieving the recognition of FMD-free status, with or without vaccination, except for the territory of Venezuela. However, in 2017, Colombia notified the occurrence of an FMD outbreak in a department bordering Venezuela. The reoccurrence of the disease in Colombia led to the suspension of its status and the country is currently devoted to regaining its official free status with a health strategy aimed at mitigating the risks of a new introduction of FMD virus.

In the Amazon subregion, Surinam received recognition as FMD-free without vaccination and the Amazon territory of Brazil achieved the disease-free status with vaccination, in 2018.

The occurrence of outbreaks in the north of the Andean region should not be considered an unexpected epidemiological event. Since 2004, an FMD virus type O lineage 6, has been sporadically isolated in outbreaks occurring in several Venezuelan states and Colombian departments. Phylogenetic studies of the virus O have determined that the lineage 6 isolated in the north of the Andean region is a specific FMD genotype associated with the bovine production systems prevalent in the affected zones and represents a risk of transboundary transmission.

Different lineages of the FMD virus circulate in the cattle populations of the subregions of South America (Amazon, Andean and Southern Cone subregions), without historical evidence of their presence in other subregions of the South America. Therefore, the evidence provided by phylogenetic studies conducted on endemic virus strains in the region supports the subregional approach promoted by PHEFA and the health strategies at subregional level that have enabled a sustained progress in FMD eradication, based on the high degree of epidemiological independence of the subregions.

The risk assessment on the persistence of virus C conducted in 2016 concluded that enough evidence had been gathered to prove that the infection caused by the FMD virus type C would have been extinguished from the historically affected territories of South America. Consequently, COSALFA 45 approved the elimination of the type C virus from the vaccines of the four countries of the region still using it, a decision that was also aligned with a recommendation of the OIE. This recommendation has been implemented by Bolivia, Brazil y Paraguay, but not by Argentina yet.

## GLOBAL FMD RISK

In order to establish strategies for managing the FMD risk beyond 2020, it is necessary not only to evaluate the risk of occurrence of outbreaks caused by those viral strains that have been endemic in South America, but also to consider the risks due to strains circulating in other regions of the world.

The PHEFA has supported the significant progress made in the past 30 years by South America and is the regional framework of the FAO/OIE Global FMD Control Strategy of 2012. Global distribution of FMD viruses is not random but occurs in patterns. Thus, viruses tend to circulate in ecological pools that share common FMD virus genotypes, circulating and evolving within their respective geographical areas, which are associated with the predominant livestock systems and livestock trade patterns.

Seven pools of the FMD virus are recognized globally<sup>1</sup>. The pool 7 corresponds to the region of South America and represents the genotype within the FMD virus O, A and C characteristic of this region. This approach allows to define health strategies to manage the FMD risk from a regional viewpoint and with vaccines that should be developed for the specific regions.

The risk assessment of introduction of FMD virus in FMD-free countries of the Americas should consider that the FMD virus O circulating in the north of the Andean region includes a specific genotype which has been restricted to states of Venezuela and neighboring departments of Colombia. This FMD virus O has been associated with the bovine production systems predominant in those areas and has not been isolated outside those territories.

On the other hand, a risk assessment of the introduction of FMD virus in the Americas from pools 1 to 6, circulating in the rest of the world, should consider the historical evidence that the introduction of these viruses has never been recorded in the Americas. Most likely, this is due to the geographical remoteness, the exporting vocation of livestock products of the region, as well as the early prevention measures implemented by the FMD national programs to mitigate those risks, which have been reinforced after the countries achieved the disease-free status.

As a result, a qualitative risk assessment of the introduction of FMD virus in disease-free countries of the region - with the exception of Colombia - would be of very low probability for lineage 6 of virus O and extracontinental viruses of pools 1 to 6; however, it must not be ruled out.

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<sup>1</sup> For further information on this subject, please refer to Dr. Edvigés Pituco presentation: "Situación Actual de la Fiebre Aftosa en el Mundo" [Current situation of the Foot-and-Mouth Disease in the World], Pre-COSALFA seminar, Cartagena, Colombia, April 2019. [<http://www.panaftosa.org/cosalfa46/>]

## **ANNUAL COST OF FMD PROGRAMS IN SOUTH AMERICAN COUNTRIES WITH FMD-FREE WITH VACCINATION STATUS**

FMD causes direct and indirect costs to countries' economies. Direct costs are those related to the losses caused by the morbidity and mortality observed during disease outbreaks. Indirect costs are those due to the health measures for disease prevention, surveillance and control. Since the disease affects production animals, indirect costs also include those derived from trade restrictions to livestock products of FMD-free with vaccination zones, which reduce incomes from and the value of livestock products.

Once a territory achieves the FMD-free status, direct losses disappear, and the cost of the disease is limited to the indirect costs, which result from health measures for disease control (i.e. vaccination), surveillance and prevention, and costs associated with trade restrictions.

Countries with FMD-free with vaccination status, except for Colombia and Venezuela, spend a total of U\$S 1,067,231.35 million a year (figures from 2017<sup>2</sup>), from which U\$S 644,957.04 million are funded by the public sector and U\$S 422,274.31 million by the private sector. From these costs, around US\$ 281,056.00 million are due to the cost of the vaccine and the remuneration of vaccinators. These costs do not include those associated with corralling and handling animals for vaccination, or the loss caused by lesions caused by repeated vaccine injections. In addition to these costs, there is the impact of trade restrictions to livestock products imposed by international markets to countries with FMD-free with vaccination status, or additional health measures imposed to traded products. Therefore, indirect costs are even higher than those informed by the countries. As from 2012, the FMD-free countries of the Southern Cone of South America have not had new outbreaks, consequently, current FMD costs are entirely due to indirect costs.

## **TO VACCINATE OR NOT TO VACCINATE. IS THIS THE DILEMMA OF SOUTH AMERICA?**

Systematic vaccination programs implemented as control strategy indefinitely are not technically justified once the absence of transmission of the infection is verified with an acceptable certainty. Moreover, if a potential virus introduction is the reason for maintaining vaccination, this strategy should be implemented after a risk analysis indicating the need of systematic vaccination as a mitigation measure, while providing guidance on the strains against which to vaccinate. In this regard, the current vaccination programs maintained in most of the territories of the region as a prevention strategy is, at the very least, inadequate, because vaccines are serotype-specific and do not protect against the other FMD virus circulating around the world. Maintaining these vaccination programs also entails, as discussed above, additional costs for farmers, together with trade restrictions that reduce the competitiveness of livestock products and threaten the profitability of the livestock industry.

Therefore, after a long period without new clinical cases and with evidence of the absence of transmission of infection and of high vaccination and immunity coverage, verified by the information provided by passive and active surveillance, national health authority should change their FMD elimination strategy from the systematic FMD vaccination to the prevention at borders and timely detection and early response.

Furthermore, the current prevention policies adopted by FMD-free countries with or without vaccination, provide an adequate high protection (which has been evidenced by the PSV assessments conducted by the OIE), not allowing legal imports of animals and livestock products without a previous risk analysis.

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<sup>2</sup> Foot and Mouth Disease Pan American Center PAHO/WHO (2018): Informe de Situación de los Programas de Erradicación de la Fiebre Aftosa en Sudamérica y Panamá, año 2017 [Report on the Situation of the Programs for the Eradication of Foot-and-Mouth Disease in South America and Panama, 2017]. 239 pages. Rio de Janeiro. Brazil.

One of the likely entry points of the FMD virus is the introduction of contaminated products in the luggage of international passengers or international postal parcels. If these contaminated products manage to avoid border controls, the FMD virus, at an adequate infective dose, could affect swine fed with leftovers of these contaminated products. Therefore, a potential FMD introduction could have a swine herd or other susceptible species as the primary focus, leading to several disease outbreaks. For such scenario, systematic vaccination of cattle is not an effective or timely prevention measure to prevent FMD occurrence in a disease-free country.

Therefore, to assume that the dilemma of the countries that are currently FMD-free with vaccination in South America is “to vaccinate or not to vaccinate” is wrong since the vaccine used in the region do not provide universal protection against all FMD virus serotypes circulating around the world, nor would it prevent the occurrence of an outbreak of the disease. In this regard, it is appropriate to establish a regional antigen/vaccine bank, as the proposed BANVACO, which, based on a risk analysis, maintains an adequate stock of different antigens and vaccines to be used in case of potential FMD health emergencies.

The North and Central America FMD-free without vaccination regions apply preventive policies like those of the disease-free countries of South America and are a clear evidence of the efficacy of these measures to prevent virus incursions from the FMD affected regions of the world.

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## THE CHALLENGES FOR THE PHEFA - BEYOND 2020

The current epidemiological situation is very favorable when comparing with the situation at the beginning of the PHEFA Action Plan 2011-2020. Important lessons have been learnt during the period, which enabled to make better informed and more assertive decisions based on the epidemiological situation achieved.

The international recognition by the OIE of an FMD-free country or region implies that the disease has been eliminated from that territory and that an official veterinary service is in place to ensure compliance with the prevention and surveillance measures of the International Animal Health Code, whether vaccination is used or not. FMD vaccination should not be permanently maintained in a disease-free country or area, unless there is the uncertainty on the work carried out or a compelling external risk.

The challenges of the PHEFA, beyond 2020, include the following:

1. To recover and maintain the official free status of Colombia, based on strengthening the prevention, immunization and strategic zoning system.
2. To address the situation of transboundary risk affecting the north of the Andean region in which the Venezuelan control program – which was validated by the OIE for a few years during the last decade – could be reestablished so that the country could consistently advance toward elimination. The elimination of FMD in Venezuela does not pose technical complexities more significant than those faced by other countries of the region. Nevertheless, it requires a clear and consistent political will from the top, technical rigor for its execution, support of livestock sector and the availability of resources to provide sustainability over time in order to achieve its purpose. A project appealing for international collaboration and solidarity could be an initiative to provide a new drive for a final effort for disease eradication in Venezuela.
3. The robust progress observed in the Southern Cone and Amazon subregions, together with the information provided by the surveillance activities, should allow – with a confident degree of certainty – the decision to move to the FMD-free without vaccination status. Suspending the vaccination will be the best proof of the elimination of the FMD infection in the population and it will avoid costly serological studies to demonstrate disease free status. The transition towards a new status imposes challenges to prevention, surveillance and to the response system in case of a potential FMD incursion. However, countries have made and adopted significant decisions and implemented actions in this regard.
4. Emergency preparedness and contingency plans should be reinforced, with better integration between the animal health response system and the inter-institutional country emergency preparedness and response structure. These should include a dedicated plan of work during times of peace, alignment of the contingency plans with the OIE Code, and formal advanced training programs for technical staff to manage emergencies.
5. The implementation of the Regional Antigen and Vaccine Bank – BANVACO – is an unavoidable step in order to acquire the emergency vaccination tool in case of a potential virus incursion, as well as to acquire the widest range of FMD antigens strains to address FMD contingencies.

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