



TRUST IN ANIMALS &  
FOOD SAFETY

**A GLOBAL PARADIGM SHIFT IN THE PERCEPTION OF  
“*FMD-Free with Vaccination*” STATUS  
FOR SAFE TRADE OF ANIMAL PRODUCTS**

**A POSITION PAPER  
WITH SOUTH AMERICA AS CASE EXAMPLE**

May 2022

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**Acknowledgements for experts consulted for revision and comments on the document.**

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The TAFS forum was identified and selected to lead this global initiative.

**Keywords:** Foot-and-Mouth Disease, regulations, international trade, sustainability, food security, equivalence, vulnerability, risk, strategic actions, vaccination

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## Executive Summary

In light of the development and use of new vaccine and diagnostics technologies with associated enhanced veterinary services over the last 20 years, the time is ripe for a global paradigm shift in the perception of vaccination against Foot-and-Mouth Disease (FMD) among stakeholders. The majority of countries in South America, for example, have demonstrated that a reliance on vaccination as a primary prevention and mitigation measure against an FMD re-introduction allows for the safe trade of commodities, including export to countries or zones that are “*FMD-free without vaccination*”.

The success of exports from countries or zones that are “*FMD-free with vaccination*” to countries or zones that are “*FMD-free without vaccination*” over the last thirty years provides strong evidence that meat and meat products from vaccinated animals can be traded safely.

The following are examples of successful beef and pork exports in metric tons (MT) from “*FMD-free with vaccination*” countries to “*FMD-free without vaccination*” countries with no evidence of incidents between 2011 and 2020:

- Brazil exported 3.04 million MT to the Russian Federation, 928,000 MT to Chile, 591,000 MT to the European Union, and 61,000 MT to the United States;
- Argentina exported 567,000 MT to the Russian Federation, 392,000 MT to the European Union, and 285,000 MT to Chile;
- Paraguay exported 1.1 million MT to the Russian Federation, 628,000 MT to Chile, and 26,000 MT to the European Union
- Uruguay exported 392,000 MT to the European Union, 313,000 MT to the United States, 121,000 MT to Canada, 76,000 MT to Chile and 73,000 MT to the Russian Federation.

To achieve the paradigm shift in the global perception of the “*FMD-free with vaccination*” status, this position paper has been prepared by a technical working group of experts to form the basis for discussion with stakeholders, including current and potential trading partners with South America.

The objective of this position paper is to achieve a shift in the perception of the “*FMD-free with vaccination*” status as 1) equivalent to the “*FMD-free without vaccination*” status, as 2) sustainable, and as 3) convenient among current and potential trading partners that may import meat, meat products, and germinal materials from areas that are “*FMD-free with vaccination*”. The success that has been demonstrated in South America for safe trade in the presence of FMD vaccination can be used as a model for other countries to achieve and maintain high-quality standards for FMD vaccination, and to maintain sustainable food security by broader market accessibility and by avoiding culling of healthy animals.

Reasons for why a change in global perception is needed, based on the latest evidence, are presented in this position paper in order of importance under public concern, economical, and technical categories.

- **Reasons related to public concern** include
  - Support for global food security through improved access to trade in meat, meat products, and germinal materials from countries and zones that are FMD-free with vaccination and through avoiding stamping out. The use of stamping out could also worsen poor public perception of livestock-based food.

- It is not justifiable for countries to create an avoidable risk through discontinuation of vaccination against FMD and therefore accept that possibly thousands of animals would have to be destroyed without any further use.
- Success in sanitary security achieved through vaccination such as in South America can serve as a model to endemic regions *i.e.*, Asia and Africa and thus advance the global control and prevention of FMD.
- Producers in countries/zones/areas that are “*FMD-free with vaccination*” would be incentivized through increased export opportunities to prevent, control, and eradicate diseases in a sustainable way, respecting animal welfare and the environment.
- FMD is not a zoonotic disease and meat from a vaccinated animal is safe for human consumption .
- **Economic reasons for importing countries** include
  - Vaccination allows for sustainable livestock industries and “vaccine security,” *i.e.*, the maintenance of capacities, resources, and technology to handle FMD emergencies through surge capacity worldwide, including for countries that are “*FMD-free without vaccination.*”
  - International trade regulations should provide feasible options for all FMD-free countries to trade and contribute to the livestock-based food supply chain in the face of FMD vaccination.
  - Vaccination against FMD is an additional protection for other regions that are “*FMD-free without vaccination*” from FMD incursion.
- **Economic reasons for exporting countries** include
  - Vaccination against FMD as a simple insurance policy against the potential impact of the reintroduction of the disease that could potentially affect food security, livestock, agriculture, tourism and public perception.
  - Increased economic opportunities will help the livestock sectors in developing countries to develop and thus boost global economic development and food security.
  - Additional export opportunities support global economic development.
  - In order to guarantee the “*FMD-free without vaccination*” status, sustainable resources allocated by governments for surveillance, emergency preparedness, and surge capacity to meet sudden vaccine and diagnostic demand must be very carefully assessed, especially to make the resources sustainable over time.
- **Technical reasons** include
  - It is very unlikely that FMD virus would be found in the meat or meat products of vaccinated animals due to lack of viremia in accidentally exposed cattle. Animals vaccinated against FMD have been raised with unvaccinated animals (sentinel species) without incidents for more than 30 years in South America
  - FMD has a DIVA system that allows for reliable detection of infection irrespective of vaccination, ensuring the health status of an area, region and/ or country that practices vaccination.

- A rapidly-spreading FMD outbreak in the absence of vaccination and in the absence of the infrastructure to produce vaccine and without the ability to implement rapid vaccination can lead to a situation where too many herds are infected to allow stamping out in which case, disease would become endemic.
- A re-evaluation of the trade regulations based on relevant OIE TAHC and OIE Terrestrial Manual chapters and of the PCP-FMD is needed.
- South American veterinary service capacities have been enhanced through FMD prevention and control, demonstrating the enhanced capacity of the region to coordinate animal health management for FMD and other animal diseases.

A stakeholder meeting is planned to evaluate the reasons in this position paper and to decide on the way forward for the trade of meat, meat products, and germinal materials between countries that are FMD-free. The change in perception should be accompanied with a revision of the World Organisation for Animal Health guidelines and Progressive Control Pathways for FMD (PCP-FMD) to include a required approach to proving FMD freedom with vaccination. Specific conditions as extra assurance for trading partners are presented and subject to further discussion.

With this position paper, a discussion is launched that may lead to a widely accepted change in perception of the “*FMD-free with vaccination*” status as valuable, trustworthy and reliable.

# 1 Objective

The objective of this position is to achieve a global paradigm shift in the perception of the "*FMD-free with vaccination*" status as equivalent to the "*FMD-free without vaccination*" status, as sustainable and as convenient among current and potential trading partners that may import meat, meat products, and germinal materials from countries and zones that are "*FMD-free with vaccination*". The achievement of this objective will allow for:

Maintenance of international market access in the face of FMD re-emergence. The global paradigm shift will minimize the vulnerability of the eventual re-emergence and spread of the disease in both countries that are FMD-free with vaccination and countries that are FMD-free without vaccination.

- Vaccination against FMD allows countries/ zones/ areas that are "*FMD-free with vaccination*" to be better prepared to cope with the potential spread of disease and to recover the status of freedom from disease faster at lower cost. There is a more robust guarantee of the sanitary status from those areas that export products, and supply chains are more reliable. Thus, the sustainability of international markets and value chains can be maintained.
- Vaccination against FMD is an insurance for countries that are "*FMD-free without vaccination*" for appropriately sustaining vaccine supply chain and infrastructure in case of a FMD incursion. Vaccination against FMD guarantees that the FMD vaccine remains available globally. Without the infrastructure for vaccine production and administration in place, a FMD outbreak in countries that are "*FMD-free without vaccination*" could get out of control, and meat exports markets could be lost. Maintenance of FMD vaccine and vaccination infrastructure helps to better deal with FMD incursions globally. Vaccination against FMD in some countries therefore protects the rest of the world.

## 2 Overview

In light of the development and use of new technologies with associated enhanced veterinary services over the last 20 years, a paradigm shift of the “*FMD-free with vaccination*” status among stakeholders, including trading partners, is needed.

The conditions for national FMD-free status were established by the World Organisation for Animal Health (OIE) in 1994 to help countries achieve a disease-free status that builds trust in the safety of animals and animal products among trading partners. Since then, high-quality vaccines and diagnostics that limit the risk of a masked circulation of FMD virus have been developed and used in the field. The majority of FMD-free countries in South America rely on vaccination as a primary prevention and mitigation measure against an FMD re-introduction. With these new technologies and in conjunction with improved veterinary services, 11 out of 12 countries in South America have demonstrated FMD-freedom with safe trade of commodities.

The OIE Terrestrial Animal Health Code (TAHC) considers trade between countries that are FMD-free with and without vaccination to be equivalently safe with regard to the risk of FMD introduction. While the “*FMD-free without vaccination*” status is underpinned by biosecurity, “*FMD-free with vaccination*” is underpinned by not only biosecurity but also by biological disease control through vaccination. Evidence that countries which do not vaccinate are FMD-free is provided by lack of clinical disease. Countries which do vaccinate need to provide additional evidence of FMD-freedom by systematically screening cattle herds for antibodies against the FMD virus non-capsid (so called non-structural) proteins (NCPs) and monitoring species that are not vaccinated for clinical disease. In both cases, this assurance depends on well-funded and staffed professional veterinary services with appropriate authority for monitoring.

Given these developments, with the proven ability of countries such as those in South America to remain “*FMD-free with vaccination*,” it is no longer reasonable for stakeholders to consider two different levels of FMD-freedom. The situation in South America with extensive cattle production systems (such as Argentina, Bolivia, Brazil, Colombia, Paraguay and Uruguay), that have achieved a successful “*FMD-free with vaccination*” status through systematic vaccination programs for the control and prevention of FMD, can be used as a model for other countries in different regions of the world. Vaccination against FMD globally can be considered a long-term, sustainable prevention and control strategy that offers more security than FMD-freedom without vaccination, provided the conditions for sanitary safety are met.

Despite improved guarantees for sanitary security, current and potential trading partners remain reluctant to accept the “*FMD-free with vaccination*” status as equivalent to the “*FMD-free without vaccination*” status for two main reasons:

1. Preconceived notions of the risk of FMD virus introduction and circulation based on information that resulted from outdated vaccine, vaccination coverage and diagnostic technologies.
2. The PCP-FMD, which serves as a tool for FMD management globally, presents “*FMD-free with vaccination*” as a step along the pathway to the final status of “*FMD-free without vaccination*”.

A technical working group of experts has been convened to prepare this position paper that provides the reasons with justifications for why the “*FMD-free with vaccination*” status should be considered to have equivalent safe sanitary value as the “*FMD-free without vaccination*” status. The reasons for and against a paradigm shift are classified into public concern, economic, and technical categories with specifications for exporting and importing countries. A stakeholder meeting is planned to evaluate the reasons in the position paper and to decide on the way forward for the trade of meat, meat products, and germinal materials (*i.e.* embryos, oocytes, semen) between countries that are FMD-free.



### **3 The Problem: Perceptions toward “FMD-free with vaccination” status**

Despite the improved guarantees described and reflected in the OIE TAHC conditions, there are still limitations in trade from countries and zones that are “FMD-free with vaccination”. Trading partners, especially those from countries that are “FMD-free without vaccination”, are still not 100 % convinced that countries that have the “FMD-free with vaccination” status can guarantee sanitary safety to a level that is equivalent to that of countries and zones that have the “FMD-free without vaccination” status.

Trading partners are still reluctant to accept the “FMD-free with vaccination” status as equivalent in sanitary safety to the “FMD-free without vaccination” status because of two main reasons:

- Concerns based on information on outdated vaccines, vaccination coverage, and diagnostics that an introduction or circulation of FMD virus would be masked by vaccination.
- The PCP-FMD presents FMD-free with vaccination as a step along the pathway to the final status of FMD-free without vaccination.

These preconceived notions based on outdated technologies and the paradigm propagated by the PCP-FMD have promoted the hesitations among potential trading partners that are still prominent today. Resulting trade limitations in meat, meat products, and germinal materials from countries that are “FMD-free with vaccination” are hindering global food security and economies.

## 4 Reasons for a paradigm shift

Reasons for a paradigm shift in stakeholder perceptions of the “*FMD-free with vaccination*” status are summarized and classified here under public concern, economic, and technical categories. Reasons are presented in order of importance within each category. Further supporting information for each reason for a paradigm shift can be found in **Annex 1**.

### 4.1 Reasons related to public concern

1. **Global food security can be supported.** Global demands for food can be supported through improved access to trade in meat, meat products, and germinal materials from countries and zones that are “*FMD-free with vaccination*”. The potential for FMD outbreaks (which would shut down trade) in countries that are “*FMD-free with vaccination*” is greatly reduced.
2. **Vaccination is used to avoid stamping out, which is no longer accepted.** Stamping out of high numbers of infected and uninfected animals is at odds with animal welfare, food security, environmental impact, logistical simplicity, economic productivity and last-but-not-least public acceptance and perception. Vaccination is used successfully to control FMD outbreaks and thus avoid stamping out.
3. **Discontinuing vaccination poses an unnecessary risk.** Animals as a food source are precious and should be raised accordingly with the utmost consideration and care for their use. It is ethically not justifiable for countries to create a (perfectly avoidable) risk by discontinuing vaccination and therefore accept that possibly thousands of animals would have to be destroyed without any further use in case of outbreak.
4. **FMD control in endemic countries can be incentivized.** Success in sanitary security achieved in South America can serve as an example to FMD-endemic countries/ regions i.e., Asia and Africa and thus advance the global control and prevention of FMD.
5. **Promotion of animal, public, and environmental health.** Producers in countries that are “*FMD-free with vaccination*” would be incentivized through increased export opportunities to prevent, control, and eradicate diseases in a sustainable way, respecting animal welfare and the environment under the concept of One Health.

### 4.2 No public health risk. FMD vaccines do not affect the food safety of animal products. Meat from a vaccinated animal is as safe for human consumption as meat from a non-vaccinated animal when FMD vaccines are administered with a quality assurance system. Economic reasons

#### 4.2.1 Economic reasons for importing countries

6. **Global reduction in demand for vaccines puts future vaccination campaigns at risk.** Countries that are “*FMD-free without vaccination*” may need to consider FMD vaccination in future. Vaccination allows for “vaccine security,” i.e., the maintenance of capacities, resources, and technological evolution to handle FMD emergencies anywhere worldwide. Vaccination programs will also contribute to sustainable livestock industries. They will encourage technological and scientific development of vaccines and diagnostic tools for vaccination campaigns, as well as antigen and vaccine banks.
7. **Trade continuity in the face of FMD vaccination is needed.** There is a non-zero risk of FMD introduction for FMD-free countries, as acknowledged by the U.S. through use of funds for FMD preparedness. International trade regulations should provide feasible options for all

FMD-free countries to trade and contribute to the livestock-based food supply chain in the face of FMD vaccination.

8. **Vaccination against FMD protects other regions that are “FMD-free without vaccination” from FMD incursion.** As an example, the successful control of FMD in South America through vaccination serves as protection for the rest of the western hemisphere and other countries that are “FMD-free without vaccination” against FMD introduction.

#### 4.2.2 Economic reasons for exporting countries

9. **Vaccination against FMD is a simple insurance policy.** The cost of vaccination avoids serious economic shockwaves of an outbreak on the whole sector i.e., food security, livestock, agriculture, tourism and public perception, which might be very detrimental to overall economies.
10. **Economic support for developing countries.** Increased economic opportunities will help the livestock sectors in developing countries to develop and thus boost global economic development and food security. Strict trade regulations also have a major impact on the development of livestock in poor countries (e.g. in Africa).
11. **Export opportunities** support global economic development. Additionally, it will relieve the economies of weakened governments, leaving the responsibility of the effort for FMD control to the farmers, and will prevent the reduction or shutdown of vaccine production capabilities.
12. **In order to guarantee the “FMD-free without vaccination” status.** Sustainable resources allocated by governments for surveillance, emergency preparedness, and surge capacity to meet sudden vaccine and diagnostic demand must be very carefully assessed, especially to make it sustainable over time.

#### 4.3 Technical reasons

13. **It is very unlikely that FMD virus would be found in the meat or meat products of vaccinated animals due to lack of viremia in accidentally exposed cattle.** Therefore, the risk of virus being introduced into an importing country through meat from a country/zone that is “FMD-free with vaccination” can be considered negligible. **Animals vaccinated against FMD are raised with unvaccinated animals without incidents.** In countries/ zones that are “FMD-free with vaccination,” susceptible animals and vaccinated animals are closely associated, sometimes sharing pasture. These susceptible animals are used as sentinel animals for FMD virus circulation, and there have not been any FMD incidents for more than 30 years in South America.
14. **New technologies have allowed better FMD control.** FMD has a DIVA system that allows for reliable detection of infection irrespective of vaccination, ensuring the health status of an area, region and/ or country that practices vaccination. This technological advancement has neither been considered in the current trade regulations nor among current and potential trading partners with South America.
15. **Discontinuing vaccination could lead to a very large outbreak of FMD that cannot be controlled** given the size and complexity of modern livestock production. A rapidly spreading FMD outbreak in the absence of vaccination and in the absence of the infrastructure to produce vaccine and without the ability to implement rapid vaccination can lead to a situation where too many herds are infected to allow stamping out in which case, disease would become endemic.

16. **A re-evaluation of the trade regulations and the PCP-FMD is needed.** The regulations on the trade of meat from susceptible animals with bone and some giblets from an "*FMD-free country / zone with vaccination*" based on vaccines and diagnostics in Chapter 8.8.21 Free with vaccination of the OIE TAHC (OIE, 2019) and Chapter 3.1.8 of the OIE Terrestrial Manual (OIE, 2018) have not been properly valued and still represent an obstacle to trade. The PCP-FMD does not consider that "*FMD-free with vaccination*" status is equivalent to the "*FMD-free without vaccination*" status.
17. **South American veterinary service capacities have been enhanced through FMD prevention and control.** FMD has been successfully eradicated through vaccination in most of South America, allowing for the strengthening of veterinary services, the improvement of diagnostic methods, and the use of vaccines, demonstrating the enhanced capacity of the region to coordinate animal health management for FMD and other animal diseases.

## 5 Background

### 5.1 History of official recognition of FMD-freedom

Trade of animals and animal products between countries relies on regulations that protect human and animal health and support the sustainable production of food. Safe trade therefore relies heavily on the animal-disease status of exporting countries, especially with regard to FMD. FMD is one of the most economically significant diseases of animals since, although not typically fatal, it results in significant production losses in susceptible domestic species i.e. ruminants and pigs. Countries dedicate significant efforts and resources to prevent and control this disease in order to maintain and develop their animal production capacities and trade markets.

Historically, in FMD-free countries or zones, stamping out through the mass culling of animals has been used to control an introduction of FMD at a devastating economic loss. The 2001 FMD outbreak in the United Kingdom cost the public sector over £3 billion and the private sector more than £5 billion according to a national audit report to the UK parliament. The United States, which eradicated FMD in 1929, determined that a potential widespread outbreak of FMD would cause losses of US \$ 199.8 billion over 10 years on beef, pork and poultry meat production, as well as on production of corn, soybeans and wheat (Hayes et al., 2011). An FMD outbreak in the U.S. would further imply the loss of 1.5 million jobs (Hayes et al., 2011). Therefore, OIE recommends that countries that are FMD-free not consider importation of animals of susceptible species and many of their products from countries that are not FMD-free because the risk of introduction of the disease is not justifiable.

In May 1994, the World Assembly of Delegates of the OIE requested that a procedure be developed for the official recognition by the OIE of the FMD-free status of member countries (OIE, n.d.) to help countries achieve a “freedom from FMD” status that imbues trust among trading partners. The official recognition of FMD status of member countries is of great significance for international trade as it forms the legal basis of the international trade of animals of susceptible species and products from these animals. The attractiveness and trust of commercial trade in the eyes of potential or existing import partners depends on official recognition of its disease status (OIE, n.d.).

There are four official OIE statuses with regard to FMD:

- FMD free where vaccination is not practised
- FMD free where vaccination is practised
- FMD free zone where vaccination is not practised
- FMD free zone where vaccination is practised

For simplicity, reference is made in this position paper to countries or zones as “*FMD-free with vaccination*” and “*FMD-free without vaccination.*” The conditions of all four statuses of FMD-freedom rely on records of disease reporting, declarations of zero FMD-cases to the OIE, documentation of surveillance activities, and documentation of specified biosecurity measures. More information on the definitions and conditions of the statutes can be found in Chapter 8.8. of the OIE Terrestrial Animal Health Code (2019).

International and regional organizations play a vital role in trade through the promotion of effective and sustainable prevention, control and eradication of transboundary animal diseases including FMD. In 2004, the OIE and the Food and Agriculture Organization of the United Nations (FAO) joined forces to establish the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs), which deals in particular with FMD. The prospect of an increase in world demand for food, translated into an increase in commodity prices, provides a strong incentive to the animal production sector to work towards prevention, control and eradication of these diseases

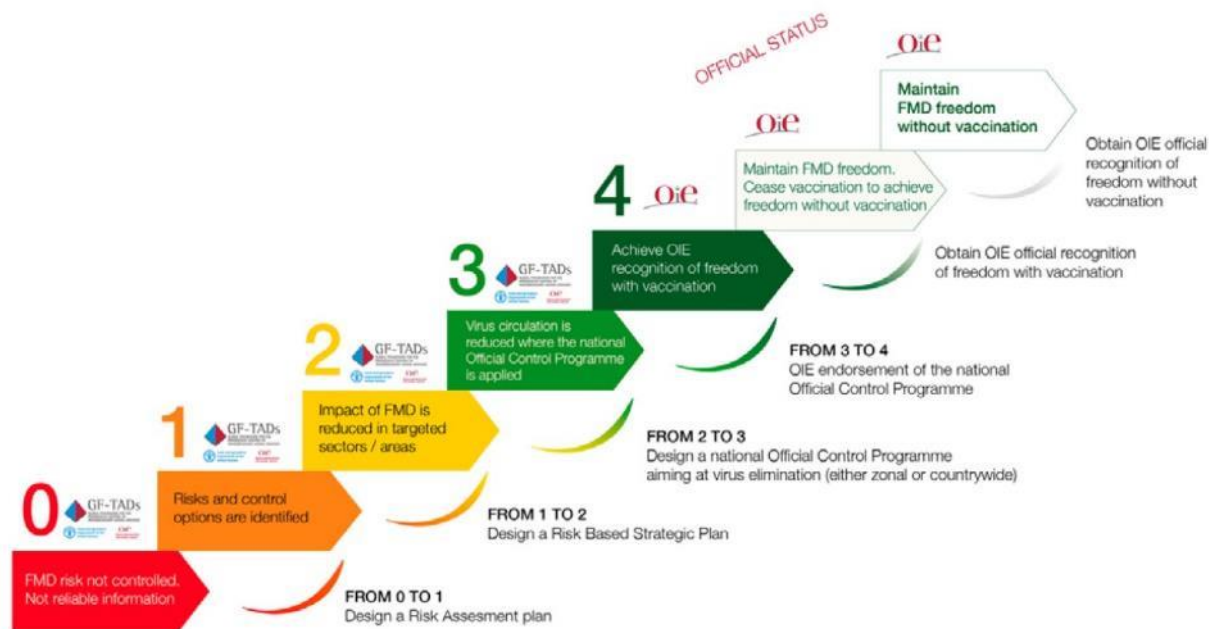
in a sustainable way, respecting animal welfare and the environment under the concept of "One Health".

## 5.2 The Progressive Control Pathway for Foot-and-Mouth Disease

To complement the OIE standards and offer practical guidance to countries globally, the FAO and European Commission for the Control of FMD (EuFMD) developed the Progressive Control Pathway for Foot-and-Mouth Disease (PCP-FMD) in 2008 (Sumption, 2012). The PCP-FMD is a risk and evidence-based framework to guide endemic countries to progressively improve the management of FMD risks and reduce disease impacts and viral circulation (EuFMD & FAO, n.d.). As countries advance through the PCP-FMD, the FMD risks are mitigated to the point where an application to the OIE for official recognition of freedom from FMD (with or without vaccination) may be successful and sustainable. The PCP-FMD is one of the core tools of the Global FMD Control Strategy, along with the OIE Performance of Veterinary Services Pathway (PVS). In 2011, the PCP-FMD was established as a joint FAO-EuFMD-OIE tool with five stages. The fifth and final stage, "maintain zero circulation & incursion: withdraw vaccination," was considered to achieve a final status of "*FMD-free without vaccination*" (Sumption, 2012).

Furthermore, in 2011, the OIE World Assembly of Delegates adopted Resolution No. 19 establishing a new step in the procedure for recognizing the FMD status of a Member, namely the endorsement by the OIE of an official control programme for FMD being in compliance with the provisions of the chapter on FMD in the Terrestrial Animal Health Code (OIE, 2011; 2020). In 2020, five countries in Asia and two countries in Africa were endorsed by the OIE for their official control programs for FMD (OIE, 2020).

A second edition of the PCP-FMD was published in 2018 with several significant changes. New elements were developed to better operationalize the PCP-FMD (Animal Health Works, n.d.). See **Figure 1** of the schematic of the latest version of the PCP-FMD.



**Figure 1.** Progressive Control Pathways for FMD, Second edition (FAO, OIE, GF-TADs & EuFMD, 2018). Countries are encouraged to follow this stepwise approach to FMD-freedom. However, the stepwise format of the PCP-FMD gives the impression that FMD vaccination is a step to the final status of maintaining FMD freedom without vaccination rather than a final step in effective FMD control for safe trade in its own right.

The following main changes were made for the second edition of the PCP-FMD (Animal Health Works, n.d.):

- There is a clear distinction between PCP Stages 0 to 3 which fall under the domain of the GF-TADs and PCP Stage 4 through OIE statuses which fall under the OIE domain of evaluation.
- An acceptance procedure is now possible between FMD regional roadmap meetings through the submission of an application, self-assessment and documentation.
- There is now direct engagement of the Chief of Veterinary Officers (CVOs) into the regional acceptance process through assessment by a Regional Advisory Group composed of three elected CVOs for each regional roadmap meeting.
- Reinforcement of Veterinary Services is emphasized. Throughout the PCP, countries should demonstrate the progressive reinforcement of the capacity of their Veterinary Services, as a driver and guarantee for the efficacy and sustainability of the FMD-specific measures in place.
- A fast-track process made it possible to apply for moving more than one stage at a time, provided that key outcomes of previous stages are fulfilled.

Despite progress made to date and despite international trade incentives, countries that are endemic for FMD are struggling to progress passed Stage 3 of the PCP-FMD.

### 5.3 Improvements in guarantees since 1994

A legal basis for the OIE official FMD-statuses was established in 1994, at which time there were two statuses: FMD-free and endemic. Since then, new technologies and tools for improving veterinary services were made available globally, prompting the distinction between “*FMD-free with vaccination*” and “*FMD-free without vaccination*” statuses. Countries have made varied progress using these new tools over time.

Since this distinction was made, the concern for sanitary safety of importation of meat, meat products, and germinal materials (*i.e.* embryos, oocytes, semen) from countries that are “*FMD-free with vaccination*” has been further addressed through the following improved guarantees:

- Purified and concentrated vaccine have been optimized and are available
- Experience gained through the application of DIVA tests has shown clearly their efficacy to detect infection irrespective of vaccination
- Veterinary service capacity has improved for biosafety and vaccine quality control; and disease detection and control as well.

The latest OIE guidance on FMD vaccines and diagnostic tests can be found in Chapter 3.1.8. Foot and Mouth Disease of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) (2018).

#### 5.3.1 Development of FMD vaccines

##### 5.3.1.1 Background

Great progress has been made since the 1960’s related to vaccine quality and quality control. Current FMD vaccines are produced by infecting established cell lines, such as Baby Hamster Kidney (BHK), with virulent FMD virus, under biosafety conditions. Monolayer cell lines were initially used (Mowat & Chapman, 1962) with subsequent adaptation to grow in suspension (Capstick et al., 1962). Production of suspension cells in large scale fermenters was achieved in 1965 by Telling and Elsworth (Telling and Elsworth, 1965).

Grown virus is chemically inactivated with binary ethyleneimine (BEI) (Bahnemann, 1975), a first order inactivant which was completely effective and reliable at the industrial scale, overcoming the risk of residual live virus of previously used formaldehyde inactivation. Inactivated antigens are further concentrated and purified from cell and medium components and viral non-capsid (structural) proteins (NCPs) by ultrafiltration (Barteling, 2002), polyethylene glycol precipitation (Panina & de Simone, 1973) or more recently by chromatography (Doel, 2003). Thereafter the inactivated viral material can be formulated with adjuvants, either oil (Augé de Melo, 1975) (used for pigs, sheep, goats and cattle) or aluminum hydroxide/saponin (only used for ruminants), into a ready-to-use vaccine, or stored as antigen concentrates over liquid nitrogen for many years.

The development of oil adjuvanted vaccines in the 1980’s, was a key step towards FMD control and eradication in South America. Oil emulsion vaccines are currently preferred because they induce a longer lasting immune response than aqueous vaccines, and they are effective in a larger number of species (Sutmoller, 2003). Vaccines usually include more than one serotype, depending on the epidemiological situation of a country.

In the 1990s, improvements were established related to the quality control of the vaccine, during the production process as well as in the final product, which were accompanied by greater regulatory demands imposed mainly by the increased requirements for biological products destined to livestock of human consumption. In line with the reduction, refinement and replacement (3R)



concept, the veterinary vaccine industry and regulators have been gradually replacing in vivo methods by in vitro approaches (Smitsaart & Bergmann, 2016).

### **5.3.1.2 Use of FMD vaccines in South America**

Undoubtedly, the control and prevention of FMD through vaccination has allowed a large part of South America to supply a growing demand for food to all markets with sanitary security, sustainability and competitive prices, also contributing to the improvement of economies of the countries. South America has contributed greatly to vaccine developments. At present BEI inactivated, oil-based and highly purified vaccines are used, replacing the old aqueous, formaldehyde inactivated and poorly purified formulations. The latter were of questionable quality and limited quality control and not always available in sufficient quantity, resulting in low vaccination coverage. This situation helped to generate the misconceptions regarding vaccination (Bergmann et al., 2005).

Of great value was the harmonization of vaccine strains for use in the region, choosing those of broad antigenic spectrum, high stability and good adaptability to replicate in cell culture at an industrial scale. These strains are: O1 Campos, A24 Cruzeiro and most of the Southern Cone countries comprised also virus C3 Indaial (Allende et al., 2003). The variant A 2001 is also included in vaccine formulations in Argentina (Mattion et al., 2004). The production seeds are characterized and distributed by the official control laboratory at a national level. Also significant was the standardization of methods for safety, purity and assessment of vaccine potency tests by direct challenge or by indirect methods (PANAFTOSA 1994; Maradei, et al., 2008). In fact, substantial efforts have been successfully made in South America to replace challenge potency tests by serological assays. Additionally, in vitro analytical parameters during the vaccine manufacturing process have been defined, which if implemented under strict application of a quality system typically based on good manufacturing practices (GMP), will ensure the effectiveness of the vaccine without the need for in vivo methods (Smitsaart & Bergmann, 2016).

In Argentina, an important improvement for in-process and final quality control was the quantification of FMD virus particles through size-exclusion chromatography (SEC) with UV detection, replacing the traditionally used 140S quantitative sucrose density gradient analysis (Barteling and Meloen, 1974; Bellinzoni et al., 2015).

Strategic schemes of vaccination have also been standardized. The availability of high-quality vaccines, controlled on a batch basis, and in sufficient quantity and applied on a standardized strategic scheme, was essential for the control of outbreaks and for the success of the control and prevention campaigns implemented in South American countries with significant extensively bred cattle herds such as Argentina, Bolivia, Brazil, Colombia, Paraguay and Uruguay. Other countries beyond the American continent have shown success with vaccination programs, such as Chinese Taipei and Republic of Korea, in these cases performing regular vaccination campaigns mainly in Swine. In South America, vaccination policies were put into practice within a strategic eradication plan implemented in 1988. This plan included intense vaccination campaigns of cattle under supervision of the national veterinary service and technical capacity for diagnosis and vaccine control, as well as a good management for the implementation of vaccination programs, with full commitment of the farmers. By applying this strategy, proper herd immunity was achieved, as established by serosurveys (Robiolo et al., 2010; León et al., 2014).

Such achievements contributed towards generating more reliable and visible outcomes of vaccination programs, opening the way towards a new policy known as “vaccination-to-live”.

## 5.3.2 FMD diagnostics

### 5.3.2.1 Overview

Rapid, accurate and transparent diagnosis of FMD virus is imperative, particularly in areas with advanced eradication campaigns or upon emergencies in already FMD-free regions.

Diagnostic challenges need to be considered:

- a) FMD cannot be differentiated clinically from other vesicular diseases, such as swine vesicular disease, vesicular stomatitis and vesicular exanthema. Laboratory diagnosis of any suspected FMD case is therefore a matter of urgency;
- b) The high virus variability resulting in 7 serotypes, which complicates the diagnosis because of the lack of cross-reactivity among the different serotypes and possibly incomplete cross-reactivity between some strains within a serotype.
- c) The ability of the virus to establish subclinical and persistent infection, regardless of vaccination.

Laboratory diagnosis should be performed under appropriate level of bio-containment. Efficacy and transparency of the laboratory procedures should be guaranteed by complying with quality control standards and through their participation in periodic proficiency testings organized by OIE reference laboratories and/or National Reference Laboratories.

In addition to the precise and rapid agent identification and characterization, laboratories need to give additional support to serosurveillance activities. The OIE Terrestrial Manual includes a thorough description of the methods (OIE, 2018).

### 5.3.2.2 Serological tests in support to “vaccination-to-live” policy

Demonstration that the “*FMD-free with vaccination*” status is equivalent to the status of “*FMD free without vaccination*” in terms of sanitary security required thorough investigation and has been met with challenges, mainly because of the myth that vaccination could mask viral circulation.

For this demonstration, and in support of the “vaccination-to-live” policy, the development, the complete validation according to OIE standards, and the application at the field level of diagnostic tests capable of reliably establishing the absence of viral activity, regardless of the vaccination status or the serotype involved, were of great relevance. (Bergmann et al., 1993, 1998; Malirat et al., 1998; Neitzert et al., 1991). This breakthrough was an essential input to support the international recognition of countries/ zones as “*FMD-free with vaccination*”.

The tests, developed in South America, were pioneers of the DIVA technology. They are based on the detection of antibodies to the NCPs of FMD virus indicative of viral replication and are suited to identify past or present infection irrespective of vaccination. They were widely implemented mainly to confirm suspect cases of FMD, to sustain freedom from infection on a population basis and to evaluate prevalence of infection according to their “fit for purpose.” The strategy consisted of a diagnostic algorithm including the use of an indirect enzyme linked immunosorbent assay (I-ELISA) as a screening test, followed by a western blot (EITB) assay to confirm positive ELISA reactors (Bergmann et al., 2000, 2003a; Malirat et al., 1998). This approach allowed for maximal specificity needed to avoid a distortion in the predictive value in low prevalence regions, without compromising the high sensitivity required to detect low titer sera.

Since the first development, other tests became available including several commercial kits (Chung et al., 2002; De Diego et al., 1997; Brocchi et al., 2006). In this context, a proper sampling design needs to contemplate the performance characteristics of the assays for which kit manufacturers and users have available several international standards and serum panels, established in different

OIE reference laboratories, through which performance characteristics can be guaranteed (Campos et al., 2008; Parida et al., 2007).

The extensive and continuous serosurveys using this approach in South America, under conditions of systematic vaccination campaigns, have gathered years of evidence of lack of viral activity. Antibody profiles in FMD-free regions with vaccination are indistinguishable from those without vaccination, sustaining the equivalence between free regions with and without vaccination, in terms of the absence of viral circulation. It was observed that viral circulation tends to die out, even if infected animals are not eliminated after outbreaks (Bergmann et al., 1996; 2003b).

This strategy also enabled assessment of transmission dynamics after outbreaks in longitudinal studies. The analysis of the data taking into account the age distribution indicated a lack of seroconversion in the populations of unvaccinated young cattle, and as already mentioned, in other non-vaccinated susceptible species (sheep, pigs and goats), even when grazed together with vaccinated cattle (Bergmann et al., 1996).

Another achievement attained through the implementation of these methodologies was the demystification of the epidemiological relevance of persistently infected animals, misleadingly called carriers (Bergmann et al., 2005).

Considering that no transmission occurs shortly after outbreaks, and that a minimum of two years without viral activity are needed for the recognition of FMD-free status, it would be highly unlikely to maintain a persistently infected animal in the herd for over two years, the maximum time reported for the duration of the persistent state in cattle. This is reinforced by the finding that, under field conditions, the incidence of persistently infected animals in repeatedly vaccinated herds is substantially reduced compared to non-vaccinated animals (Anderson et al., 1974). Similarly, under experimental conditions it has been demonstrated that high potency vaccines can reduce or even prevent the establishment of the persistent state (Doel, 2003).

It is important to note that serological assays interpreted on a population basis and together with epidemiological indicators can clearly illustrate/ confirm the epidemiological status of a population.

In conclusion, the development and applicability of well controlled, high-quality vaccines in sufficient quantity, allied to serosurveys to confirm viral clearance, opened the way to demonstrate the importance of vaccination to stop the spread of the disease and also to bring to an end the misconception that vaccination masks asymptomatic viral circulation.

To guarantee adequate vaccination coverage to sustain the vaccination status of the population, diagnostic assays to monitor herd immunity have also been developed, validated and implemented based on single dilution ELISA assays that measure antibodies against capsid (structural) proteins (Robiolo et al., 2010; León et al., 2014).

### **5.3.3 Enhanced veterinary services and regional coordination**

#### **5.3.3.1 The OIE Performance of Veterinary Services Pathway**

The OIE has implemented a number of PVS Pathway evaluations globally since its launch 2007 including in countries that vaccinate against FMD. The PVS Pathway serves to sustainably improve national Veterinary Services by providing them with a comprehensive understanding of their strengths and weaknesses, using a globally consistent methodology based on international standards (PVS Pathway, n.d.). It can reveal gaps, inefficiencies and opportunities for innovation from an external perspective (PVS Pathway, n.d.).

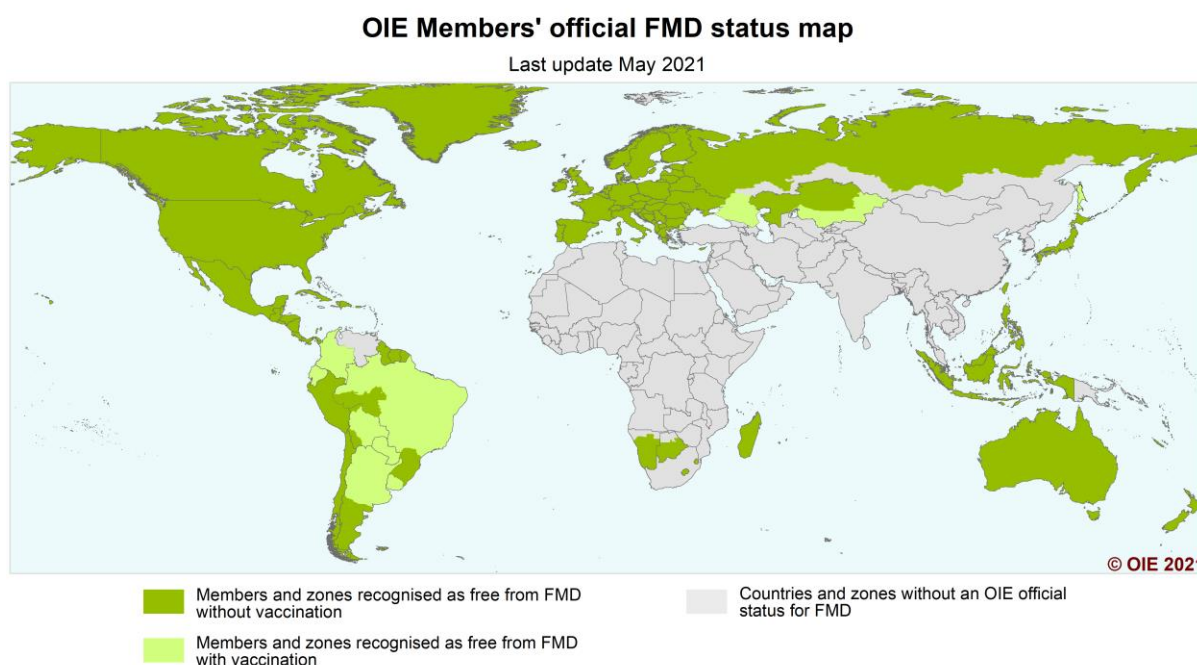
As of 15 April 2021, twenty-six PVS missions have been implemented in the Americas including in Colombia and Venezuela (PVS Pathway, n.d.). Of these, eleven reports are available online. Twenty-

eight missions have been implemented in Asia-Pacific including Chinese Taipei and the Republic of Korea, of which eight reports are available online. Twenty missions have been implemented in Europe, including in Kazakhstan and Turkey, of which three reports are available online.

## 5.4 Current global FMD situation

Today, two-thirds of countries are endemically affected by FMD, mainly in Asia, the Middle East and Africa. Most countries that are endemic for FMD regularly engage with the GF-TADs to follow the PCP-FMD. The PCP-FMD consists of four stages of FMD control followed by achieving OIE recognition of FMD freedom. The global FMD control strategy thus far has been successfully implemented in 72 of 79 affected countries (including in zones) where the majority of countries have advanced to PCP stages 1 and 2 and few countries to stage 3 (GF-TADs, n.d.).

Most of the western hemisphere, Europe, and Oceania have achieved FMD-freedom through meeting the conditions set by the OIE TAHC. The latest list of FMD-free countries and zones can be found in Resolution No. 13 (OIE, 2021a) and are visualized in **Figure 2**.



**Figure 2:** OIE Members' official FMD status map (OIE, 2021b). Two-thirds of countries are endemically affected by FMD. Most of the western hemisphere, Europe, and Oceania have achieved FMD-freedom without vaccination. FMD-freedom with vaccination occurs in most of South America with the exception of Venezuela.

National FMD-free statuses are dynamic and subject to change based on FMD incursions. Although in general, the most developed countries are FMD-free without vaccination as per the OIE conditions, these countries have registered several FMD incursions throughout this century, which have been extremely costly to control. Indonesia has been coping with a re-emergence of FMD since April 2022. Republic of Korea had its "FMD-free without vaccination" status suspended in 2010, which it regained in 2014, but lost again later the same year due to ongoing outbreaks (USDA, 2015; The Dairy Site, 2014). Select FMD-free countries/ zones without vaccination and the year of their most recent FMD incursions are listed here (OIE WAHIS; USDA, 2015):

- Indonesia (2022)
- Bulgaria (2011)
- Cyprus (2007)
- France (2001)

- Ireland (2001)
- Japan (2000 and 2010)
- Republic of Korea (2000 - 2018)
- Philippines (2005)
- United Kingdom (2001 and 2007)
- The Netherlands (2001)
- Chinese Taipei (1997)

Since the first FMD case in Indonesia was confirmed in East Java on April 28, thousands of cattle in Aceh and East Java provinces have reportedly been infected (Xinhua, 2022). In response to the outbreak, Indonesia's Agriculture Ministry has established emergency FMD disease zones and thus lockdowns in the livestock sectors in both Aceh and East Java (Xinhua, 2022). While the cost of this FMD outbreak is still being evaluated, a cost-benefit analysis in 2018 estimated total losses in a year for Indonesia to be US\$ 761.3 million, which includes the loss in cattle production, impacts on trade, declining domestic cattle price and beef sales, and decrease in tourism expenditures (Sumpingtjatur Rasa, 2018). Neighboring countries are also on high alert. A large outbreak of FMD in Australia is estimated to cost as much as AUS\$ 100 billion over 10 years (Sinclair & Felton-Taylor, 2022). This incidence shows the high risk of stopping vaccination in a FMD endemic broader region. It is likely that the cost of the outbreak will offset the additional revenue during the period of FMD free without vaccination status.

There are currently (as of 14 June 2021) eleven countries that are either entirely or have at least one zone that is free from FMD with vaccination distributed between Asia, Europe, and South America. Two of these countries are entirely FMD free with vaccination (Paraguay and Uruguay), and nine countries have FMD-free zones where vaccination is practiced (OIE, 2021a). The eleven countries that are recognized by the OIE as practicing FMD vaccination are summarized in **Table 1** by region:

**Table 1:** List of member countries by region that are FMD-free with vaccination or with an FMD-free zone where vaccination is practiced, according to the provisions of Chapter 8.8. of the OIE TAHC, Edition 2019 as of 14 June 2021 (OIE, 2021a)

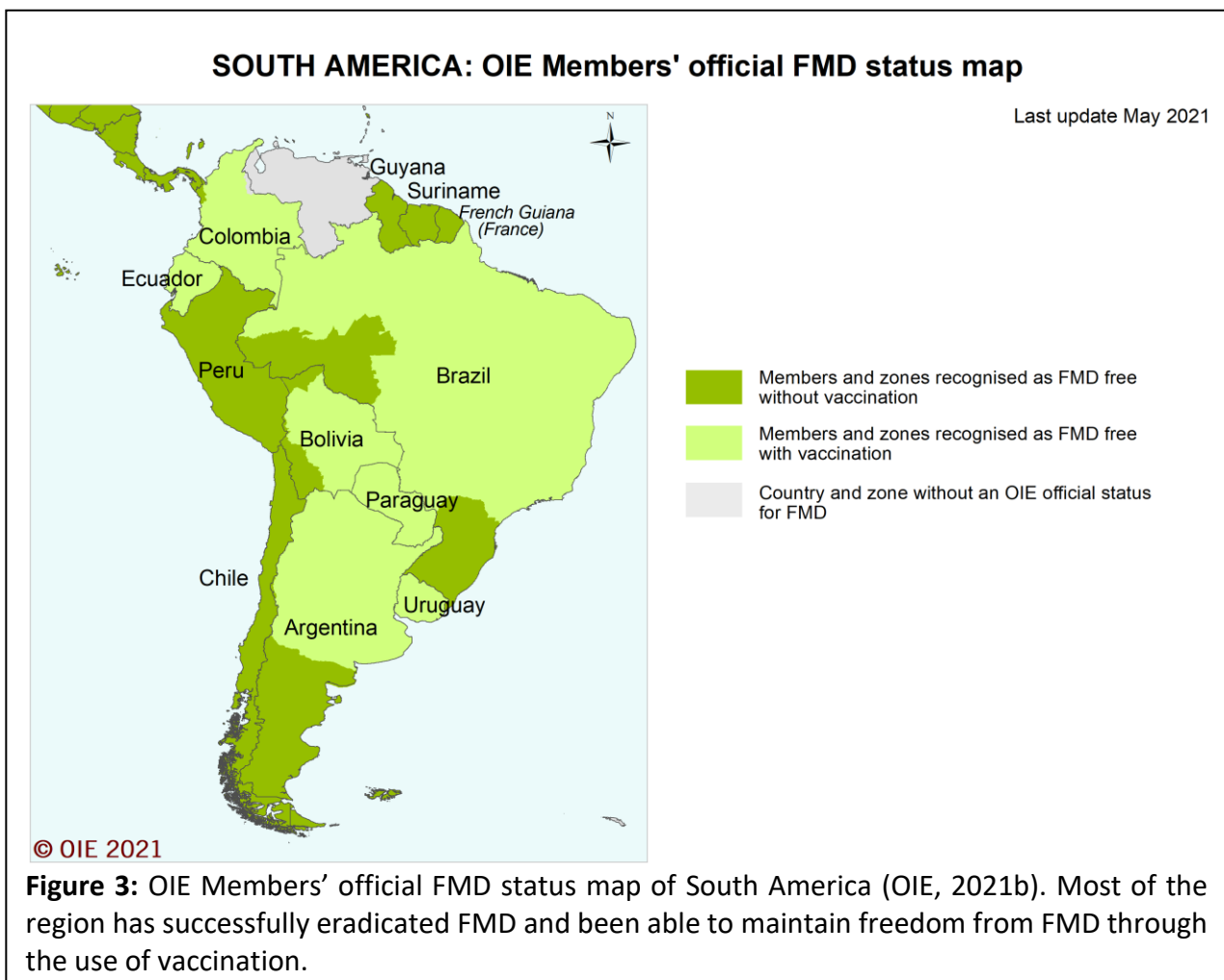
Region	FMD-free countries or zones that practice vaccination
Asia	Chinese Taipei (zone)
	Russian Federation (zone)
Europe	Kazakhstan (zone)
	Russian Federation (zone)
	Turkey (zone)
South America	Argentina (zone)
	Bolivia (zone)
	Brazil (zone)
	Colombia (zone)
	Ecuador (zone)
	Paraguay
	Uruguay

## 5.5 Impact of FMD control in the South American continent

The FMD-free status of countries in South America is visualized in the map in **Figure 3**.

South America has been historically free of introduction of transcontinental viruses for two main reasons:

1. Apart from illegal trade of animals or animal products within the continent (e.g. from Venezuela) illegal trade from other continents is most likely limited, but not absent, due to the limited immigrant population as compared to Europe, UK and Middle East. In these regions, immigrants engage in illegal trade due to price differences and based on preferences in different meat types which are risk pathways for exotic animal disease introduction. We must nevertheless consider the drastic increase in the movement of people and goods between continents as a warning (e.g. Recent transcontinental transmission of African Swine Fever).
2. The large FMD-vaccinated livestock population over years in South America, with good quality vaccines against also O serotype which is globally the most dominant and risky serotype with respect to introduction, has most likely limited the risk of FMD outbreaks from a source beyond the American continent or might even have prevented outbreaks from spreading.



### 5.5.1 Export of meat and meat products from South America

Animal products have been safely traded from countries that vaccinate against FMD for nearly 20 years, setting a successful precedent for expanding the international trade market. Animal products including bone-in meat from beef, swine, and sheep are exported while head including the pharynx is not, as per OIE recommendations. Steps are taken in-country to monitor for silent incursion to help assure trade partners that there is no hidden circulation of FMD virus.

The main MERCOSUR producer countries (Argentina, Brazil, Uruguay and Paraguay), which practice FMD vaccination throughout the country or in zones, export beef, pork and sheep meat to countries all over the world. The enormous productive and economic significance of the livestock sector in the MERCOSUR countries represents a source of income from exports of tremendous economic and social impact, especially in Brazil, Uruguay, Paraguay and Argentina. The region is a strong supplier of red meat (> 24%), which sustainably meets the growing world-demand for proteins of animal origin. In particular, meat exports represent a significant share of Paraguay's and Uruguay's Gross Domestic Products (GDP).

The American region is a major producer and exporter of beef and pork, and the USA is also an important importer. India is a significant producer and exporter as well, but being FMD-endemic limits the trading to low-income countries and regions. China and SEA region are major red meat importers.

For over ten years, most MERCOSUR countries all of which vaccinate against FMD, have been successfully exporting red meat to countries that are “*FMD-free without vaccination.*” Of MERCOSUR countries, Brazil is the largest exporter of beef and pork, with 19,800 metric tons exported globally from 2011 to 2020 (Table 2). Of importing countries that are “*FMD-free without vaccination*”, the Russian Federation imports the most volumes of meat from Brazil (over 15 % of Brazil's meat exports), followed by Chile (4.7 %) and the EU (3.0 %) (Table 2).

**Table 2:** Exports of beef and pork in metric tons (MT) from MERCOSUR countries to select countries that are or have zones that are “*FMD-free without vaccination*” from 2011 to 2020

Exporting Country	Importing Country								
	Russian Federation		Chile		European Union		All other countries, regardless of FMD vaccination		Total exports globally
	MT	%	MT	%	MT	%	MT	%	MT
Brazil	3,039,866	15.4	927,549	4.7	591,055	3.0	15,204,308	76.9	<b>19,762,778</b>
Argentina	567,362	16.7	392,213	11.5	284,560	8.4	2,151,926	63.4	<b>3,396,061</b>
Paraguay	1,089,510	40.5	628,148	23.4	25,981	1.0	946,449	35.2	<b>2,690,088</b>
Uruguay	72,601	2.2	75,562	2.3	391,769	12.0	2,722,098	83.4	<b>3,262,030</b>

Source: COMEXSTAT (Brazil), INDEC (Argentina), Central Bank of Paraguay, and SECEM (Sistema Comercio Exterior del Mercosur).

Tables 4A-D in **Annex 2** identify export volumes in metric tons (MT) of red meat, in particular in relation to beef, from countries that are “*FMD-free with vaccination*” to countries that are “*FMD-free without vaccination*” between 2011 and 2020. Frozen beef has been the biggest meat export commodity from MERCOSUR countries to countries that are “*FMD-free without vaccination*” since 2011. Notably, Brazil exported 1.6 million MT of frozen beef to the Russian Federation and 620,000 MT of fresh or chilled beef to Chile (Table 4A, Annex 2). Paraguay exported 960,000 MT of frozen beef to the Russian Federation and 581,000 MT of fresh or chilled beef to Chile (Table 4C, Annex 2). Most meat exports (70 %) from Paraguay are exported to countries that are “*FMD-free without vaccination*” (Table 4C, Annex 2). The USA and Canada are also major importers of meat from Uruguay (9.6 % and 3.7 % respectively of total exports) (Table 4D, Annex 2).



The loss of the country or zone status with respect to FMD, as the situation occurred in the UK in 2000/01, would result in a serious shortage of the world meat market and in higher prices for meat products. An incursion of FMD into South America would have devastating consequences. The following production, economic, and social impacts can be expected from an FMD outbreak in South America:

- Significant decrease in income due to loss of markets (12 months minimum, as it may take years to restore markets and enable access to markets).
- Decrease in farming, with the consequent loss of direct jobs, drop in the price of cattle, etc.
- Decrease and retrocession of productive indicators, drop in investments, reduction of the whole input chain.
- Increase of costs, sanitary, control, sanitary slaughter, etc.
- Application of stamping out would lead to deterioration in the image of consumers (animal welfare, environment, etc.).

Estimated annual drops in export revenues from Argentina, Brazil, Paraguay and Uruguay, due to possible market closures are described in Table 3. A total closure of markets could result in up to \$15.5 million USD in export losses from the four countries. Furthermore, the recovery process would be slow considering asymmetry in the eradication progress between countries.

Table 3: Estimated annual drops in export revenues from Argentina, Brazil, Paraguay and Uruguay, due to possible market closures as a result of an FMD outbreak

DISMINUCIÓN INGRESOS POR EXPORTACIONES	ESCENARIO 1 Cierre TOTAL	ESCENARIO 2 Cierre Excepto CHINA	ESCENARIO 3 Cierre 30% de mercados	EMPLEO	Pérdida de 20% de puestos de trabajo "exportables"
ARGENTINA	2.791.214	1.109.388	837.364	ARGENTINA	23.520
BRASIL	9.215.297	5.177.785	2.764.589	BRASIL	198.000
PARAGUAY	1.117.724	1.117.724	335.317	PARAGUAY	23.400
URUGUAY	2.465.589	1.016.590	739.677	URUGUAY	11.840
<b>Costos miles de USD</b>	<b>15.589.824</b>	<b>8.421.487</b>	<b>4.676.947</b>	<b>Puestos de trabajo</b>	<b>256.760</b>

### 5.5.2 Cost-benefit analyses for FMD vaccination

The cost-benefit analysis of FMD vaccination under different scenarios may be a worthwhile consideration for countries. These analyses have been carried out all over the world with varying conclusions depending on the country context (Knight-Jones & Rushton, 2013). Certain critical points and parameters need to be considered when conducting such cost-benefit analyses including:

- The critical difference in economic terms between “*FMD-free with vaccination*” and “*FMD-free without vaccination*” statuses: The difference in export values of meat/ meat products between countries.
- Cost elements taken into consideration in the analysis depend on the purpose of the analysis and on the motivations of the stakeholders who request the analysis e.g., farmer, export sector
- Loss of jobs and other social impacts due to an outbreak
- FMD vaccination promote regular veterinary farm visits which help with control and sanitary vigilance of other diseases.

- The real cost to have efficient emergency preparedness including surge capacity for vaccine and diagnostic reagents

It is crucial that a cost-benefit analysis be carried out in each country with a holistic approach. However, with different realities, criteria and interests, the valuation of the different items that are considered may not have the same representativeness in economic terms as in biosecurity.

In all cases, early detection and attention of the contingency are two fundamental aspects to consider and should respond to a critical and deep evaluation of the capabilities and needs under each potential situation. The role of livestock producers is fundamental in early warning, and the confidence in them must be considered in the early-warning system in order to expect appropriate collaboration, since they are the ones who are in daily contact with animals. The participation and protagonism of farmers are fundamental, especially if they have participated in the control of the disease with vaccination. The second element of the chain of events in early-warning is the capacity of the Animal Health Service to rapidly identify the disease, where technical and laboratory capacity are essential in terms of training, resources and speed in action, a situation that must be confirmed by audits and certifications. Veterinary services must consider the different scenarios they could face and what preparedness and resources they need for each of them, and they also need to consider the inevitable consequences of each scenario.

Regarding contingency care, some regulatory procedures are very difficult to apply due to bureaucratic interference, shortage of trained human resources, logistical factors that are very difficult to implement, and especially the absence and/ or lack of availability of financial resources.

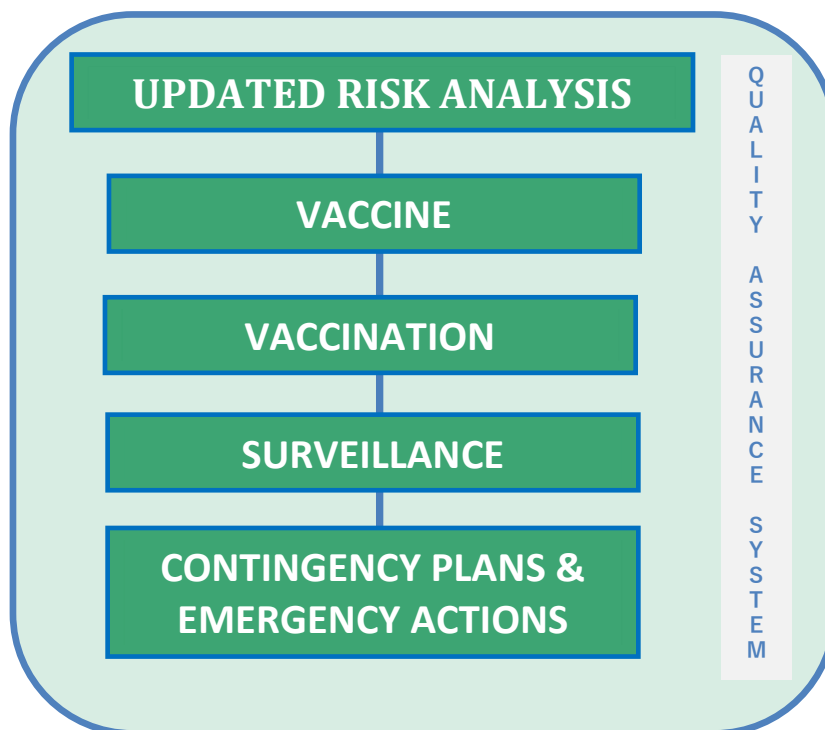
These factors are the main limitations that countries must face in terms of cessation of vaccination against FMD. Since these factors are not adequately valued in existing cost-benefit analyses, it must be considered that any re-emergence of FMD in a territory or area may lead to the worst-case scenario.

## 6 Conclusion & Way Forward

Based on the reasons provided in this position paper, we believe the time is ripe for a change in global perception of the “*FMD-free with vaccination*” status. Safe trade of meat and meat products has been successfully and sufficiently demonstrated from South America. The change in perception should be accompanied with a revision of the OIE guidelines and PCP-FMD to include a required approach to proving FMD freedom with vaccination. Trading partners may be more likely to agree to import commodities from countries that are “*FMD-free with vaccination*” if the OIE recommendations are stricter with the conditions for the recognition of freedom with vaccination. Stricter conditions would imbue more confidence in the “*FMD-free with vaccination*” status in the eyes of trading partners. Each trading partner may add their own requirements or validation to the OIE conditions.

Specific conditions as extra assurance for trading partners are laid down in **Figure 4** and are subject to further discussion. Specific conditions may include for example quality assurance for vaccine licensing and vaccination programs. If countries abide by the quality assurance of the “*FMD-free with vaccination,*” status may be raised and thus trusted by trading partners.

**Figure 4. CONDITIONS “FREE FROM FMD WITH VACCINATION” WITH WHICH COUNTRIES SHOULD COMPLY TO BE EQUIVALENT TO “FREE FROM FMD WITHOUT VACCINATION” COUNTRIES**



The recommendations established by the PCP-FMD programme should be also reviewed in order to support the transit to reach the equivalent FMD-free status with and without vaccination. The change in perception of risk of importing from FMD-free with vaccination areas must be widely accepted. Trading partners who import meat, meat products, and germinal materials only from countries and regions that are “*FMD-free without vaccination*” will often require that those countries do not import products from countries that are FMD-free with vaccination. This interconnected web of trade severely limits policy option decisions by individual countries.

To achieve the objective of this position paper as outlined in Chapter 1, the technical working group proposes the following steps:

1. Identify stakeholders and opinion leaders at international, regional, and national levels;
2. Share the position paper with the stakeholders;
3. Host a stakeholder meeting in Argentina to discuss the position paper including the new certified conditions and the potential of developing a roadmap for improving access to trade markets in the short and medium term by submitting a proposal to the OIE for modifying the OIE TAHC.

A stakeholder meeting is planned because stakeholders are ultimately responsible for administering and managing health policies, because in the event of an emergency, states must be properly prepared to implement contingency actions. That is why the stakeholders must participate and be responsible for the decision that defines in which hands the trust is placed to sustain animal production, health status, guarantee food security and the economic and social well-being of nations affected by health emergencies.

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## Annex 1 – Complete list of reasons with supporting information

Reasons for a paradigm shift in stakeholder perceptions of the “*FMD-free with vaccination*” status are summarized and classified here under public concern, economic, and technical categories with supporting information. Reasons are listed in order of importance within each category.

### Reasons related to public concern

1. **Global food security can be supported.** Global demands for food can be supported through improved access to trade in meat, meat products, and germinal materials from countries and zones that are “*FMD-free with vaccination*”. The potential for FMD outbreaks (which would shut down trade) in countries that are “*FMD-free with vaccination*” is greatly reduced.

In 2019, according to the FAO, 1 in 10 people in the world have been exposed to severe levels of food insecurity. The significant reduction of hunger at a global level is a tremendous challenge for agri-food production responsible of supplying a growing world population in a safe and sustainable way. According to the FAO, to feed a world population of 9.1 billion people projected for 2050, food production would need to increase by 70% relative to food production in the period 2005/2007. By improving access to international trade markets for meat, meat products, and germinal materials from countries or zones that are “*FMD-free with vaccination*”, animal protein can not only safely reach more countries, but also livestock production in these countries can be incentivized, thus making more animal proteins available to the world.

If an outbreak of an FMD virus strain against which the vaccine is effective occurs, it can be rapidly controlled with minimal destruction of livestock and impact on food security. It must additionally be considered that vaccination and re-vaccination in regular vaccination programs elicit broad spectrum protection against many different strains around the world. FMD introduction into South America would affect food security, since up to 30 % of beef and pork exports would be affected. The cost of meat would increase, which may make it unaffordable.

2. **Vaccination is used to avoid stamping out, which is no longer accepted.** Stamping out of high numbers of infected and uninfected animals is at odds with animal welfare, food security, environmental impact, logistical simplicity, economic productivity and last-but-not-least public acceptance and perception. Vaccination is used successfully to control FMD outbreaks and thus avoid stamping out.

Stamping out at current times would have a huge negative impact on the ethical perception of livestock-based food production and consumption, with unpredictable impacts on the sustainability of the livestock industry.

In the last century in North America, and at the beginning of this century in the U.K. and Japan, the control and eradication of FMD was achieved through stamping out methods, also known as culling or depopulation. Stamping out may have been acceptable in the past, but in today’s world, such measures are no longer acceptable. Environmental impacts include not only the impacts due to culling and disposal of animals but also due to the production of animals that are ultimately not utilized. Furthermore, the general population is no longer willing to accept the mass culling of healthy animals. Such measures are generating more and more resistance and are becoming practically unviable in many countries worldwide. There is especially more pressure on promoting animal welfare considering the 2001 FMD outbreak in the U.K. Stakeholders agreed that the magnitude of stamping out required to control the outbreak should never happen again. Vaccines and reagents (kits for diagnosis and monitoring) are acceptable tools to prevent and control FMD and to avoid the enormous impact of stamping out.

- 3. FMD control in endemic countries can be incentivized.** Success in sanitary security achieved in South America can serve as an example to FMD-endemic countries/ regions i.e., Asia and Africa and thus advance the global control and prevention of FMD.

The success achieved in the southern region of the South American continent can very well serve as an example to other countries / regions (Asia and Africa) and thus advance positively in the control and prevention of FMD, ensuring crucial aspects of animal welfare, environmental care, sustainability of livestock production systems, economies of livestock producing countries and world food security. Although this position paper has a focus in South America, the points raised here can be considered in the context in Asia and Africa for countries that are FMD-free with vaccination and for endemic countries that are working toward FMD freedom with vaccination.

A re-evaluation of the PCP-FMD to help countries achieve a sustainable stage of FMD control that allows for safe international trade is needed.

- 4. Promotion of animal, public, and environmental health.** Producers in countries that are "*FMD-free with vaccination*" would be incentivized through increased export opportunities to prevent, control, and eradicate diseases in a sustainable way, respecting animal welfare and the environment under the concept of One Health.

The control of FMD can be used to improve the control of other diseases that relate to humans e.g. zoonotic diseases. The implications for food sustainability, economic impact, and control of other diseases render FMD a One Health issue.

The progressive intensification of animal production systems and the tremendous increase in animal transit and related commodities significantly increase the exposure of animals to diseases. Consequently, animal health is playing a key role in livestock productions and thereby affecting health security, food security, the world economy and the well-being of people.

Emerging and re-emerging diseases, and the importance of their possible consequences for public health and the economies of countries and their citizens, have provoked a strong reaction from animal health organizations, particularly in the implementation of appropriate policies on how to address prevention, control and eradication of animal diseases and zoonoses. Lessons from the latest global FMD epidemics in the United Kingdom (2001 and 2007), Japan (2000 and 2010), South Korea (Republic of Korea) (2000, 2010, 2014, 2015 and 2017) and South America (2001), and the BSE (mad cow) epidemics still remain fresh in our memory and have been updated with the SARS-CoV-2 pandemic and the rapid spread of African Swine Fever (ASF) as a pandemic affecting all continents continents. Such facts represent a clear indication of the colossal current and future challenge for public and animal health, the economy and society as a whole.

By improving access to trade from countries that are FMD free with vaccination, livestock producers in South America would be incentivized to comply with international animal health, animal welfare, sustainability and environmental standards, thereby promoting global health.

- 5. Discontinuing vaccination poses an unnecessary risk".** Animals as a food source are precious and should be raised accordingly with the utmost consideration and care for their use. It is ethically not justifiable for countries to create a (perfectly avoidable) risk by discontinuing vaccination and therefore accept that possibly thousands of animals would have to be destroyed without any further use in case of outbreak.

It is ethically unacceptable to for countries to create a serious risk in the production chain that accepts the destruction of tons of animal protein only for the sake of possible economic reasons if there is the alternative of protection by vaccination.

A parallel can be drawn between the discontinuation of FMD vaccination and the discontinuation of vaccination in humans due to "anti-vaccine" groups which has led to the re-emergence of diseases in humans that were practically eradicated, such as polio and measles. The COVID-19 pandemic has led to public vaccination reappraisal, and the same could be said regarding FMD in animals. The concept that non vaccination for FMD free countries as a maximum status in terms of sanitary warranty, need to be reviewed entirely, An analysis of the different aspects that impact decisions, would be particularly necessary, if stopping vaccinating is a forceful way of showing that a country or region is free of the disease, and that allows detecting much faster if there is a re infection, it is an error because it does not contemplate the social, geographical, economic, political characteristics of different regions, and much worse don't consider the tremendous impact if disease come back and couldn't be properly controlled.

6. **No public health risk.** Trade restrictions are too strict to justify the negative impact on food security and economies considering that FMD is not a zoonotic disease. FMD vaccines do not influence the public-health safety of animal products. Meat from a vaccinated animal is as safe for human consumption as meat from a non-vaccinated animal when FMD vaccines are administered with a quality assurance system.

FMD does not affect public health, but inappropriate policies in their control and action to confront outbreak emergencies will generate impacts on food security, environment, and the economies of livestock countries. The magnitude of these impacts may be irreversible given the evolution that public opinion is having today on the types of food consumed, the impacts on the well-being of animals, and animal and environmental aspects in the way of producing them.

For this reason, OIE standards aim to foster safe trade, protect animal health and ensure fair practices by avoiding unnecessary trade barriers. The paradigm shift of the FMD-free status would in fact enhance the standards of safe food exports, and thus in fact facilitate safe trade (OIE, 2021c).

## Economic reasons

### Economic reasons for importing countries

7. **Global reduction in demand for vaccines puts future vaccination campaigns at risk.** Countries that are "*FMD-free without vaccination*" may need to consider FMD vaccination in future. Vaccination allows for "vaccine security," i.e., the maintenance of capacities, resources, and technological evolution to handle FMD emergencies anywhere worldwide. Vaccination programs will also contribute to sustainable livestock industries. They will encourage technological and scientific development of vaccines and diagnostic tools for vaccination campaigns, as well as antigen and vaccine banks.

Vaccination against FMD guarantees good quality vaccine availability in case of emergencies in countries that are "*FMD-free without vaccination*." Furthermore, vaccination programs will contribute to sustainable livestock industries. They will encourage technological and scientific development on vaccines and diagnostic tools for vaccination campaigns and surveillance, plus antigen and vaccine banks; a concept of "vaccine security" what wasn't comprehensively considered yet in any known risk analysis.

Vaccines and reagents for diagnosis and monitoring are the key tools to prevent and control FMD. To use them properly, the countries concerned must have the resources to have these elements and know how, where and when to use them. Ensuring the availability of these resources is key and must be considered with great care. If vaccination is discontinued, priorities for manufacturers and

the industry in general can change, and it is very possible that these resources can become assigned to other matters, effectively defunding control plans.

Reduction of vaccination in South America will lead to downsizing of the FMD vaccine manufacturing capacity, as seen currently in Brazil. Reduction of the use of FMD vaccines in a situation of “*FMD-free without vaccination*” will inevitably lead to a situation where FMD vaccine manufacturers will downsize or stop vaccine manufacturing for simple sustainability - economic reasons. Since FMD manufacturers are private organizations, if vaccine manufacture is not profitable, they will close. Investments will be delayed or canceled and the whole existing supply chain for vaccine manufacturing will gradually disappear and cannot be rebuilt in a timely manner in case of a serious FMD outbreak. There is also the risk of loss of DIVA capability. Recovered animals have to live out their natural life span before a DIVA system can be applied, setting back FMD-freedom over years. This will result in serious vaccine capacity issues posing the whole population of FMD free without vaccination at serious risks.

There is a risk of FMD introduction into any country through multiple pathways. The virus is likely to spread rapidly in a livestock dense region that does not vaccinate. This will lead to a very expensive multi-year control program including vaccination. Once control with vaccination is achieved, returning livestock production to previous levels will depend on re-establishing exports as quickly as possible while still vaccinating. Therefore, international risk perception and trade regulations should recognize the reality that importation of products from countries that are *FMD-free with vaccination* is safe. Today, the U.S. does not have the capacity to manufacture enough vaccine to control an FMD outbreak in the country. There would not be the necessary surge capacity to address a large outbreak.

Countries that are *FMD-free with vaccination* can be a reliable source of vaccine and technologies for countries that may face an FMD outbreak. Vaccination against FMD guarantees good quality vaccine availability in case of emergencies in countries that are “*FMD free without vaccination.*” As a good example, Argentina has been and still is a main vaccine and antigen supplier to the North American Foot and Mouth Disease Vaccine Bank (NAFMDVB) since 2006; Animal Vaccines and countermeasures Veterinary Vaccine Bank (NAVCVVB) USDA, since 2020, Chinese Taipei since 1997, South Korea (Republic of Korea) since 2016, Viet Nam since 2018. South Korea (Republic of Korea) received enough FMD vaccine from South America in 2016 to control an outbreak.

By improving access to trade markets, countries that are free from FMD without vaccination have the opportunity to benefit from the same advantages as countries that are FMD-free with vaccination. Vaccination can be considered an acceptable tool that allows for the continuation of trade.

Furthermore, vaccination programs will contribute to sustainable livestock industries. It will encourage technological and scientific development on vaccines and diagnostic tools, for vaccination campaigns, plus antigen and vaccine banks. Vaccination is warranted to avoid stamping out, and the huge impact of stamping out on the business continuity of livestock industry, due public/ consumer concern and changes on the ideals about food sources.

- 8. Trade continuity in the face of FMD vaccination is needed.** There is a non-zero risk of FMD introduction for FMD-free countries, as acknowledged by the U.S. through use of funds for FMD preparedness. International trade regulations should provide feasible options for all FMD-free countries to trade and contribute to the livestock-based food supply chain in the face of FMD vaccination.

An evaluation of the national economic impact of a potential widespread outbreak of FMD in the U.S. determined that it would cause losses of USD \$ 199.8 billion over 10 years for beef, pork and

poultry meat production, as well as on production of corn, soybeans and wheat (Hayes et al., 2011). Such an outbreak would imply the loss of 1.5 million jobs (Hayes et al., 2011). As a consequence of the analysis of the impact of an outbreak of FMD in the U.S., contingency policies have been modified to stockpile FMD vaccine. Through a “farm bill” promulgated in 2018, a millionaire fund has been set up for the establishment, maintenance, operation and eventual use of an antigen bank of FMD, in addition to the training, training and operation of a professional body specially assigned to attend to this contingency. FMD vaccine stockpiling in the U.S. marks a fundamental change in the health policies of the U.S. The zero-risk criterion is abandoned and replaced by accepting an estimated probability margin of an eventual introduction of the infection.

If the U.S. is willing to consider vaccination against FMD as a safety guarantee to allow for the continuation of the export of meat, meat products, and germinal materials, then FMD-free countries may also consider importation of meat, meat products, and germinal materials from countries that already vaccinate against FMD. In the short term, the supply chain into the country can be ensured. In the long term, prospectively, should an outbreak occur, vaccination is an option for continuing exportation as before.

9. **Vaccination against FMD protects other regions that are “FMD-free without vaccination” from FMD incursion.** As an example, the successful control of FMD in South America through vaccination serves as protection for the rest of the western hemisphere and other countries that are “FMD-free without vaccination” against FMD introduction.

Before discontinuing vaccination, the risks of reintroduction need to be completely mitigated, and the surge capacity to face re-emergence need to be comprehensive assessed.

#### **Economic reasons for exporting countries**

10. **Vaccination against FMD is a simple insurance policy.** The cost of vaccination avoids serious economic shockwaves of an outbreak on the whole sector i.e., food security, livestock, agriculture, tourism and public perception, which might be very detrimental to overall economies.

Such a continuous but acceptable costs is an economically and politically a preferred situation over a tremendous unforeseen cost in case of an outbreak. In case of an outbreak individual farmers might take a serious hit and costs of the outbreak might be carried a lot by some of the weakest individuals and not divided over the sector as a whole. This is one of the key facts to be considered when speak about farmers trust and commitment on disease alert and vigilance.

11. **Economic support for developing countries.** Increased economic opportunities will help the livestock sectors in developing countries to develop and thus boost global economic development and food security. Strict trade regulations also have a major impact on the development of livestock in poor countries (e.g. in Africa).

Restrictions on trade of meat and meat products from vaccinated animals have a direct impact on finances of developing countries and thereby hamper global development. Countries therefore need to mitigate their vulnerability to FMD reemergence prior to discontinuing vaccination.

12. **Export opportunities** support global economic development Additionally, it will relieve the economies of weakened governments, leaving the responsibility of the effort for FMD control to the farmers, and will prevent the reduction or shutdown of vaccine production capabilities. Even though veterinary services in South America have been strengthened over the years, the COVID-19 pandemic has affected the capabilities at all levels, and of course affected the performance and efficiency of the Veterinary Services. Because of the resulting potential increase

in risk of re-emergence of FMD, vaccination against FMD is now more important than ever to mitigate the risk of an outbreak.

The economic consequences of the COVID-19 crisis have not yet been measured. It is expected that the global economy and well-being will continue to be challenged, making emerging economies even more vulnerable. The crisis caused by the COVID-19 pandemic has accentuated the economic instability of the region and has increased health vulnerability and the risks of reintroduction of diseases such as FMD because of defunding of public services. It is urgent to review proposals such as those of the PHEFA 2021 - 2025 PLAN and the concepts of the GF-TADs to this new global reality. The existing sanitary status that ensures the sustainability of productive systems should be consolidated without generating irreversible damage in important livestock production areas that have made significant progress through vaccination.

By improving access to international trade markets for meat, meat products, and germinal materials from countries that are FMD-free with vaccination, livestock production in these countries can be incentivized, thus providing an economic boost to the industry and the region. The risk to move forward to “FMD-free without vaccination” status should therefore be reconsidered with regard to the increased economic vulnerability as a result of COVID-19.

13. **In order to guarantee the “FMD-free without vaccination” status.** Sustainable resources allocated by governments for surveillance, emergency preparedness, and surge capacity to meet sudden vaccine and diagnostic demand must be very carefully assessed, especially to make the resources sustainable over time.

The historical economic instability in countries that historically were fighting FMD demonstrate that this is very difficult to achieve. Importing meat from FMD free with vaccination will mean a safer option due the robustness obtained through vaccination.

## Technical reasons

14. **It is very unlikely that FMD virus would be found in the meat or meat products of vaccinated animals due to lack of viremia in accidentally exposed cattle.** Therefore, the risk of virus being introduced into an importing country through meat from a country/zone that is “FMD-free with vaccination” can be considered negligible.

It was demonstrated in 1966 and confirmed by recent experiments that FMD vaccination protects against viremia (National Academy of Sciences, National Research Council, 1966). Without viremia, there can be no virus in the muscle or other internal tissues. Experimental data from challenge vaccine control (PGP) confirm this concept (McVicar & Suttmoller, 1976; Stenfeldt et al., 2015). Furthermore, it has been shown that virus does not anyway survive in mature meat due to the decrease in pH. Therefore, meat and meat products exported from vaccinated animals in a country or zone that is “FMD-free with vaccination” is very unlikely to contain virus.

15. The probability that meat from infected and viremic animals would be harvested for export, and/or that virus-contaminated product would come into contact with meat to be exported is highly unlikely even in an FMD-endemic country, and therefore even more unlikely in a country or zone that vaccinates against FMD (Penn State, 2016). The USDA FSIS conducted an audit of relevant slaughterhouses in Brazil to ensure the safety of raw beef exports from Brazil to the USA (USDA FSIS, 2015). The auditors confirmed that the appropriate APHIS requirements for the control of FMD were being met at all five establishments. The pH of

each half-carcass was routinely measured after passing the maturation chamber, and this activity was verified and recorded by government inspectors throughout the production day. **Animals vaccinated against FMD are raised with unvaccinated animals without incidents.** In countries/ zones that are “*FMD-free with vaccination*,” susceptible animals and vaccinated animals are closely associated, sometimes sharing pasture. These susceptible animals are used as sentinel animals for FMD virus circulation, and there have not been any FMD incidents in nearly 20 years.

Considering that no transmission occurs shortly after outbreaks, and that a minimum of two years without viral activity are needed for the recognition of FMD-free status, it would be highly unlikely to maintain a persistently infected animal in the herd for over two years, the maximum time reported for the duration of the persistent state in cattle. This is reinforced by the finding that, under field conditions, the incidence of persistently infected animals in repeatedly vaccinated herds is substantially reduced compared to non-vaccinated animals (Anderson et al., 1974). Similarly, under experimental conditions it has been demonstrated that high potency vaccines can reduce or even prevent the establishment of the persistent state (Doel, 2003).

It is important to note that serological assays interpreted on a population basis and together with epidemiological indicators can clearly illustrate/ confirm the epidemiological status of a population. As with any serologic test, analysis on an individual basis would be ideal, since it would require sampling almost all animals with a perfect test (particularly in low prevalence situations). This methodological limitation is also valid for regions that are “*FMD-free without vaccination*.”

In conclusion, the development and applicability of well controlled, high-quality vaccines in sufficient quantity, allied to serosurveys to confirm viral clearance, opened the way to demonstrate the importance of vaccination to stop the spread of the disease and also to bring to an end the misconception that vaccination masks asymptomatic viral circulation.

In South America, sheep farming in extensive production systems is carried out in many cases in family farming and mixed production systems with cattle breeding, although they may pasture in different slots of the farm (SENASA, 2016). Cattle vaccinated against FMD are usually not associated with unvaccinated cattle, but sheep and pigs that are not vaccinated can be associated with vaccinated cattle. Sheep (unvaccinated) that graze with cattle (vaccinated) are used as sentinels. In all the counties of the region there are two vaccination periods/year, according to production conditions of the country/region: one general vaccination for all cattle regardless their age/category and a 2nd vaccination (3-6 months later) for all cattle younger than 24 months old. Steps are taken in-country to monitor for silent incursion to help assure trade partners that there is no hidden circulation of FMD virus.

16. **New technologies have allowed better FMD control.** FMD has a DIVA system that allows for reliable detection of infection irrespective of vaccination, ensuring the health status of an area, region and/ or country that practices vaccination. This technological advancement has neither been considered in the current trade regulations nor among current and potential trading partners with South America.
17. **Discontinuing vaccination could lead to a very large outbreak of FMD that cannot be controlled** given the size and complexity of modern livestock production. A rapidly spreading FMD outbreak in the absence of vaccination and in the absence of the infrastructure to produce vaccine and without the ability to implement rapid vaccination can lead to a situation where too many herds are infected to allow stamping out in which case, disease would become endemic.

In this case herds will need to be allowed to recover from disease. Surviving animals will have reduced efficiency of production. Recovered animals will have antibody to non-structural proteins and there may be too many to slaughter them all without impacting the potential to rebuild the livestock industry. This would be a very long-term setback for the livestock industry and food security.

18. **A re-evaluation of the trade regulations and the PCP-FMD is needed.** The regulations on the trade of meat from susceptible animals with bone and some giblets from an "*FMD-free country / zone with vaccination*" based on vaccines and diagnostics in Chapter 8.8.21 Free with vaccination of the OIE TAHC (OIE, 2019) and Chapter 3.1.8 of the OIE Terrestrial Manual (OIE, 2018) have not been properly valued and still represent an obstacle to trade. The PCP-FMD does not consider that "*FMD-free with vaccination*" status is equivalent to the "*FMD-free without vaccination*" status.

Chapter 8.8.21 Free with vaccination of the OIE TAHC (OIE, 2019) and Chapter 3.1.8 of the OIE Terrestrial Manual (OIE, 2018) with regard to vaccines and diagnostics need to be re-evaluated. The regulations in these chapters on the trade of meat from susceptible animals with bone and some giblets have recently been modified, penalizing only the head, pharynx and adjacent lymph nodes in the event of trading meat from a country / zone that is "*FMD-free with vaccination.*" However, these conditions have not been properly valued and still represent an obstacle to trade.

19. **South American veterinary service capacities have been enhanced through FMD prevention and control.** FMD has been successfully eradicated through vaccination in most of South America, allowing for the strengthening of veterinary services, the improvement of diagnostic methods, and the use of vaccines, demonstrating the enhanced capacity of the region to coordinate animal health management for FMD and other animal diseases.

FMD vaccination contributes to the involvement of farmers for surveillance and prevention of FMD as many other livestock diseases. Vaccine manufacturing in South America is a strategic reserve of production capacity of high-quality vaccine to control FMD in different continents. Contributing also to the strengthening of veterinary services.

PAHO has been instrumental in the control of FMD in South America. In the 1980's, a control and eradication plan coordinated regionally by PANAFTOSA was implemented. The strengths of the veterinary services, the improvement of diagnostic methods, and the development and use of a high-potency and purified oil adjuvanted vaccines, were decisive in the success of this plan. The PHEFA was established in 1988 with a series of three action plans whose goal is to achieve the absence of FMD in the Americas (with and without vaccination) (PANAFTOSA, 2018). The most recent PHEFA action plan spans 2021 to 2025 with eradication of FMD planned for 2025 (PAHO, WHO & PANAFTOSA, 2020).

Undoubtedly, this achievement as a result of the control and prevention of Foot-and-Mouth Disease through vaccination has allowed a large part of South America to supply in a sustained way a growing demand for food, to all markets, with sanitary security, sustainability and competitive prices, also contributing to improve the economies of the countries. The ultimate sanitary indicator in countries that are FMD-free with vaccination is that they have had no FMD outbreaks since 2018 in Colombia (WRLFMD, n.d.).

As a supplement to the OIE Terrestrial Animal Health Code, the technical working group has developed conditions with which countries should comply so that the "*FMD-free with vaccination*" status is equivalent to the "*FMD-free without vaccination*" status.



## Annex 2 – Export of meat and meat products from South America

For over ten years, most MERCOSUR countries all of which vaccinate against FMD have been successfully exporting red meat to countries that are “FMD-free without vaccination.” In 2020 alone,

- Brazil exported 96,856 MT of beef to the EU, 90,420 MT to Chile, and 28,021 MT to the USA (ABIEC, ABPA, Statista, COMEXSTAT).
- Argentina exported 41,749 MT of beef to the EU; 32,595 MT to Chile; and, 20,539 MT to the USA. (INDEC)
- Paraguay exported 103,831 MT of beef to Chile (CBP)
- Uruguay exported 76,469 MT of beef to the USA and 39,869 MT to the EU (INAC)

Tables 3A-D identify export volumes in metric tons (MT) of red meat, in particular in relation to beef, from countries that are “FMD-free with vaccination” to countries that are “FMD-free without vaccination” between 2011 and 2020. Frozen beef has been the biggest meat export commodity from MERCOSUR countries to countries that are “FMD-free without vaccination” since 2011. Notably, Brazil exported 1.6 million MT of frozen beef to the Russian Federation and 619,000 tons of fresh or chilled beef to Chile (Table 4A). Paraguay exported 960,000 MT of frozen beef to the Russian Federation and 583,000 MT of fresh or chilled beef to Chile (Table 4C). Most meat exports (70 %) from Paraguay are exported to countries that are “FMD-free without vaccination” (Table 4C). The USA and Canada are also major importers of meat from Uruguay (9.6 % and 3.7 % respectively of total exports) (Table 4D).

**Table 4A: BRAZIL MEAT EXPORTS TO SELECTED MARKETS WITH FMD-FREE WITHOUT VACCINATION STATUS 2011-2020**

Exports of Beef and Pork from BRAZIL to Selected Markets with "Foot and Mouth Disease (FMD) Free Without Vaccination" Status						
2011-2020 (MT)						
HS Codes	0201 Beef (fresh or chilled)	0202 Beef (frozen)	02062 Edible offals of bovine animals	0203 Pork (fresh, chilled, frozen)	02064 Pork offals (frozen)	Total meat exports
<b>TOTAL to the World</b>	<b>1.422.336</b>	<b>10.738.602</b>	<b>1.324.696</b>	<b>5.593.595</b>	<b>683.549</b>	<b>19.762.778</b>
<b>RUSSIAN FEDERATION (*)</b>	19.941	1.632.988	31.538	1.337.950	17.449	<b>3.039.866</b>
<b>CHILE</b>	619.802	111.663	-	196.085	-	<b>927.549</b>
<b>EUROPEAN UNION (27)</b>	214.801	371.173	2.515	2.351	216	<b>591.055</b>
<b>PHILIPPINES</b>	-	178.586	-	22.710	15.650	<b>216.945</b>
<b>PERU</b>	2.862	6.923	41.072	-	-	<b>50.858</b>
<b>UNITED STATES</b>	-	34.884	1.221	25.153	-	<b>61.258</b>
<b>UNITED KINGDOM</b>	12.990	22.641	-	-	-	<b>35.631</b>
<b>INDONESIA</b>	-	7.612	-	-	-	<b>7.612</b>
<b>SWITZERLAND</b>	2.985	2.985	-	139	-	<b>6.109</b>

Note (\*): most of the Russian population lives in zones that are free of FMD without vaccination.

Source: COMEXSTAT

**Table 4B: ARGENTINA MEAT EXPORTS TO SELECTED MARKETS WITH FMD-FREE WITHOUT VACCINATION STATUS 2011-2020**

Exports of Beef from ARGENTINA to Selected Markets with "Foot and Mouth Disease (FMD) Free Without Vaccination" Status				
2011-2020 (MT)				
HS Codes	0201	0202	02062	Total meat exports
	Beef (fresh or chilled)	Beef (frozen)	Edible offals of bovine animals	
<b>TOTAL to the World</b>	<b>713.379</b>	<b>1.856.408</b>	<b>826.274</b>	<b>3.396.061</b>
RUSSIAN FEDERATION (*)	1.892	148.574	416.896	567.362
EUROPEAN UNION (27)	365.216	26.476	520	392.213
CHILE	281.002	3.558	-	284.560
PERU	1.365	1.202	40.260	42.827
UNITED STATES	3.445	19.851	253	23.549
SWITZERLAND	4.563	36	-	4.599
UNITED KINGDOM	3.301	771	-	4.072
PHILIPPINES	-	2.320	10	2.330

Note (\*): most of the Russian population lives in zones that are free of FMD without vaccination.

Source: INDEC

**Table 4C: PARAGUAY MEAT EXPORTS TO SELECTED MARKETS WITH FMD-FREE WITHOUT VACCINATION STATUS 2011-2020**

Exports of Beef from PARAGUAY to Selected Markets with "Foot and Mouth Disease (FMD) Free Without Vaccination" Status				
2011-2020 (MT)				
HS Codes	0201	0202	02062	Total meat exports
	Beef (fresh or chilled)	Beef (frozen)	Edible offals of bovine animals	
<b>TOTAL to the World</b>	<b>826.892</b>	<b>1.601.388</b>	<b>261.808</b>	<b>2.690.088</b>
RUSSIAN FEDERATION (*)	1.499	960.019	127.992	1.089.510
CHILE	581.845	46.302	-	628.148
TAIWAN	192	62.839	-	63.031
EUROPEAN UNION (27)	16.081	9.900	-	25.981
PERU	103	2.586	10.125	12.814
SWITZERLAND	6.407	347	-	6.754
UNITED KINGDOM	2.171	409	-	2.580

Note (\*): most of the Russian population lives in zones that are free of FMD without vaccination.

Source: Central Bank of Paraguay

**Table 4D: URUGUAY MEAT EXPORTS TO SELECTED MARKETS WITH FMD-FREE WITHOUT VACCINATION STATUS 2011-2020**

Exports of Beef from URUGUAY to Selected Markets with "Foot and Mouth Disease (FMD) Free Without Vaccination" Status				
2011-2020 (MT)				
HS Codes	0201	0202	02062	Total meat exports
	Beef (fresh or chilled)	Beef (frozen)	Edible offals of bovine animals	
<b>TOTAL to the World</b>	<b>389.277</b>	<b>2.376.430</b>	<b>496.322</b>	<b>3.262.030</b>
EUROPEAN UNION (27)	217.923	173.543	302	<b>391.769</b>
UNITED STATES	21.103	292.266	92	<b>313.461</b>
CANADA	412	120.397	-	<b>120.810</b>
CHILE	62.025	13.537	-	<b>75.562</b>
RUSSIAN FEDERATION (*)	2.747	235	69.619	<b>72.601</b>
JAPAN	3.819	1.352	-	<b>5.170</b>
MEXICO	1.178	429	-	<b>1.607</b>

Note (\*): most of the Russian population lives in zones that are free of FMD without vaccination.

Source: Sistema Comercio Exterior del Mercosur SECEM