Original Article

Qualitative risk analysis on the likelihood of Foot and Mouth Disease (FMD) reintroduction in the Philippines through the importation of dairy cattle from FMD-free zones with vaccination in Brazil

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Abstract

The potential of Girolando cattle from Brazil has generated much interest in the Philippines and the possibility of their importation to contribute to the latter's dairy industry development has been raised. The most crucial issue that needs to be addressed is the probable introduction of exotic livestock diseases or pathogens of different strains like Foot-and-Mouth Disease virus (FMDv) which might destroy the Philippines' livestock industry. This study involved only the work required to conduct a preliminary qualitative risk analysis (RA) on the likelihood of FMDv being reintroduced into the Philippines through the importation of Girolando cattle from FMD-free zones with vaccination in Brazil. Data was obtained from published scientific articles, OIE website and USDA RA report on FMD. The steps of RA: hazard identification, risk assessment (release, exposure, consequence and risk estimation), risk management and risk communication were used. With a low probability of occurrence and a high total assessed consequences in animal health, the overall estimated risk is quite high. Risk management options and risk communication guidelines were formulated. A more comprehensive RA to capture expert opinions and first-hand information from involved veterinary authorities including an in-depth study on the possible risk factors at the source-farms is recommended.

Keywords: Brazil, Girolando cattle, Import risk analysis, Philippines

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Introduction

In 2018, the Philippines' Department of Agriculture (DA) through its former Secretary (term: mid-2016 to mid-2019) made a strong pronouncement that the government will import Girolando cattle from Brazil. This is in line with the DA's target to increase the local dairy animal and milk production from 1.2% of the national requirement to 10% in a few years' time (Bustamante, 2018). Initially, the DA will be importing 5,000 head of Girolando cattle that will be housed in the 3,600-hectare Ubay Stock Farm in Ubay, Bohol, Philippines (Bustamante, 2018). Girolando cattle are a mix of Holstein and Gyr, a breed developed that could thrive in the harsh heat of Brazil. Although the present Secretary (term: mid-2019 to mid-2022) of DA made no direct pronouncements on the importation of Girolando cattle from Brazil, the possibility of pursuing the plan in the near future cannot be ruled out. It is not certain which part of Brazil the cattle will be sourced from.

Nevertheless, there are some issues that need to be addressed before pursuing the importation plans. These include the probable introduction of exotic livestock diseases/pathogens or pathogens of different or more virulent strains like Foot and Mouth Disease virus (FMDv) which might jeopardize the Philippines's livestock industry and the economy as a whole. FMD is the most contagious transboundary animal disease (TAD) affecting cloven hoofed animals (FAO, 2007). Brazil has 27 states of which five (5) and 19 municipalities in two (2) other states have been declared by OIE as FMD-free zones where vaccination is not practiced (OIE, 2021). The rest of the states in Brazil have been declared as FMD-free zones with vaccination (OIE, 2021). On the other hand, the entire Philippine archipelago has been declared as FMD-free without vaccination since May 2015 (Casa, 2015).To ensure that the importation of the said animals will not be detrimental to the livestock industry of the Philippines, a preliminary risk analysis study on the importation of Girolando cattle from Brazil was conducted. An import risk analysis is crucial to prevent destruction of the local animal industry already compromised by emerging diseases, notably African Swine Fever (ASF). This study involved only the work required to conduct a preliminary qualitative risk analysis on the likelihood of FMDv being reintroduced into the Philippines through the importation of live Girolando cattle from FMD-free zones with vaccination in Brazil. The framework developed from this study could be made a reference for future import risk analysis endeavors.

Materials and Methods

Study Design and Data Collection: This study mainly followed the risk analysis manual developed by AusVet Animal Health Services of the Australian Government with contributing authors from the World Organization for Animal Health (OIE) and the Food and Agriculture Organization (FAO) of the United Nations (UN) (Perkins *et al*., 2009). For the risk assessment part of the study, the guidelines provided by Dufour *et al*. (2011), was used. Data was obtained from published scientific articles, OIE website, United States Department of Agriculture (USDA) risk analysis reports on FMD and other grey literature.

Risk Analysis: The following steps of risk analysis were followed: hazard identification, risk assessment (release assessment, exposure assessment, consequence assessment and risk estimation), risk management and risk communication.

Hazard Identification: Hazard identification as defined by OIE is the process of identifying the pathogenic agent which can potentially produce adverse consequences associated with the importation of a commodity (Perkins *et al*., 2009). The hazard of concern in this study is FMD because of its highly contagious nature and potential to cause severe economic loss. This analysis considered the risk of introducing FMDv into the Philippines through importation of live Girolando cattle from FMD-free zones with vaccination in Brazil. A review of published and unpublished literature was conducted. The animal health status of Brazil and the Philippines was also evaluated based on the database of OIE particularly the World Animal Health Information System (WAHIS) and FMD Portal.

To conduct hazard identification, the following information pertaining to FMD was extensively described: etiological agent, epidemiology and the FMD status of the Philippines and Brazil.

Risk Assessment: Risk assessment is one of the components of risk analysis that qualifies a specific level of risk, through the following inter-related steps (Dufour *et al*., 2011):

- Release assessment: estimation of the likelihood of a hazard being introduced in a particular zone;
- Exposure assessment: estimation of the likelihood of susceptible humans or animals being exposed to the hazard;
- Consequence assessment: describing the results of the release and exposure to the hazard for humans and animals (health and/or economic consequences);
- Risk estimation: Combining the results of the preceding three steps.

Release Assessment: This release/entry assessment estimates the likelihood that an imported live cattle from an FMD-free zone with vaccination in Brazil are being infected with FMD virus. Information was gathered from USDA through its Animal and Plant Health Inspection Service (APHIS) – Veterinary Services (VS) and other published scientific articles. The risk of transmitting FMD via vaccinated animals was assessed. The FMD carrier state was also discussed since an asymptomatic FMDv carrier state is recognized in cattle, sheep and goats (Garland and de Clercq, 2011). The possible pathways of movement of FMDv from its origin in Brazil into the Philippines was also laid out. The risk criteria described by Dufour *et al*. (2011) was used to assign the probability score in the release assessment.

Exposure Assessment: Conditions favorable for the exposure and spread of FMDv in the importing

country were elucidated. A scenario tree or the biological pathways necessary for the exposure of animals in the locality was also demonstrated. The risk criteria described by Dufour *et al*. (2011) was used to assign the probability score in exposure assessment.

Probability of Occurrence: The probability of occurrence depends on both the probability of release and the probability of exposure (Dufour *et al*., 2011). A results table with figures that represent the different levels of the ordinal scale associated with the qualitative words as generated by Dufour *et al*. (2011) was used in qualifying the probability of occurrence (Supplementary Table 1).

Consequence Assessment: Only health (animal and human) and the resulting economic consequences were addressed. Explanations from published articles were provided highlighting the consequences of FMD incursion in a given country. The adverse economic effects brought about by production losses and cost of control were underscored. Moreover, a diagram showing the pathways leading to consequences was provided. Following the system shown in Supplementary Tables 2 and 3, scores were given on the health and economic consequences on a particular holding, the spread of the disease to other herds and to the national and international economic consequences of the disease. For public health consequences, scores were given on the effect of the disease at the individual level, community level and the overall health and economic consequences.

Risk Estimation: This section summarized the findings of risk assessment on release or entry of the hazard, its exposure and establishment as well as the consequence in the affected area, following the method used by Dufour *et al.* (2011). As defined by the OIE Terrestrial Animal Health Code, risk (R) is a combination of the probability (p) of an adverse event occurring and the consequences (c) of such an occurrence, giving the equation R = p x c (OIE, 2007). The final step therefore was to combine the qualitative estimated probability of occurrence and the qualitative estimated consequences (Dufour *et al*., 2011) as provided in Supplementary Table 4. Uncertainties were taken into account in the final risk estimation through the use of intervals.

Risk Management:
Risk Evaluation: If the estimated risk is not negligible, the potential hazard is classified as an actual hazard and requires risk management measures.

Options Available: A set of risk management options were laid out for implementation in Brazil based on OIE Terrestrial Animal Health Code (OIE, 2017) and other published articles. This is to ensure that the cattle are not carrying the virus (i.e. not incubating the disease, not viremic, not carrier) when exported into the Philippines. Another set of options to be implemented in the Philippines were also provided to prevent the exposure of susceptible local animals from the possibly FMDv-infected imported cattle.

Risk Communication: The following risk communication guidelines were formulated: communication matrix for stakeholders, factors to be considered for communication to stakeholders, and management measures and key messages specific to risk of contact between FMD-infected and FMD-susceptible animals.

Results and Discussion

Hazard Identification:
Etiological Agent: Foot and Mouth Disease virus (FMDv) of the genus Aphthovirus of the family Picornaviridae with seven immunologically distinct serotypes: A, O, C, SAT1, SAT2, SAT3, and Asia 1 containing more than 60 strains (OIE, 2013; CFSPH, 2015). Serotype O is the most common serotype worldwide (OIE, 2013; CFSPH, 2015). SAT viruses occur mainly in Africa (with periodic incursions into the Middle East) and Asia 1 is currently found only in Asia (CFSPH, 2015).

Epidemiology of FMD: FMD is endemic in parts of Asia, Africa, the Middle East and South America with sporadic outbreaks in free areas (CFSPH, 2015). It produces low mortality rate in adult animals, but often high mortality in young due to myocarditis (CFSPH, 2015). All cloven-hoofed animals are susceptible, including cattle, pigs, sheep, goats, and buffalo with high morbidity in naïve populations (OIE, 2013). Sources of FMDv are incubating and clinically affected animals particularly from breath, saliva, feces, urine, milk and semen; contaminated meat and by-products with a pH of above 6.0 could also contain the virus (CFSPH, 2015). Cattle are particularly susceptible to aerosolized virus and are the maintenance hosts in most areas (OIE, 2013; CFSPH, 2015). A carrier state may occur when FMDv persists for more than 28 days in the oropharynx of recovered, vaccinated or exposed animals (OIE, 2013). In cattle, the carrier state which varies from a rate of 15-50% usually persists within 6 months and although in a small proportion it may last for up to 3.5 years (OIE, 2013; CFSPH, 2015).

Transmission is through direct contact between infected and susceptible animals or direct contact of susceptible animals with contaminated inanimate objects such as hands, footwear, clothing, vehicles, etc. (OIE, 2013). Other modes of transmission are inhalation of infectious aerosols and airborne, especially in temperate zones (up to 60 km overland and 300 km by sea) (CFSPH, 2015). Humans can also harbor FMDv in their respiratory tract for 24–48 hours (OIE, 2013; CFSPH, 2015) and act as mechanical vectors by carrying the virus on clothing (Meyer and Knudsen, 2001). The incubation period for FMD can vary with the species of animal which is reported to be between 2 to 14 days in cattle and up to 21 days in water buffaloes (CFSPH, 2015). Clinical signs include acute febrile illness with vesicles or blisters localized on the feet, in and around the mouth, and on the mammary glands (CFSPH, 2015). Possible complications include temporary or permanent decrease in milk production, hoof malformations, chronic lameness, mastitis and weight loss (CFSPH, 2015). There is no specific treatment for FMD, other than supportive care (OIE,

2013). Inactivated and live attenuated vaccines are available with the former providing 6 months of immunity after two initial vaccinations given one-month apart (OIE, 2013; CFSPH, 2015). However, in a risk analysis report, the USDA (2013) through the National Center for Import and Export (NCIE) of APHIS-VS recognized that the likelihood of FMDv circulating in vaccinated populations cannot be totally excluded. It is important to note that FMD vaccines are not commercially available in the Philippines. Once introduced, the virus can spread rapidly, particularly if livestock densities are high or if detection is delayed resulting in direct and indirect economic losses (including due to local and international trade restrictions) equivalent to several billion US dollars (CFSPH, 2015). On the other hand, FMD is not considered a public health problem, as infections seem to be very rare and their consequences are mild such as influenza-like symptoms that are only self-limiting (OIE, 2013; CFSPH, 2015).

Philippines' FMD Status: During the 83rd General Session of the OIE on 24 to 29 May 2015 in Paris, France, the Philippines officially received recognition as a country free from FMD without vaccination (Casa, 2015). Previous declarations were done on per zone basis, namely Zone 1 and 3 in Luzon Island (2010), Visayas Group of Islands (2002) and Mindanao Island (2001) (Casa, 2015).

Brazil's FMD Status: As per information from WAHIS, the last occurrence of FMD in Brazil was in 21 April 2004 (OIE, 2018). Accordingly, the country has a general and targeted surveillance program on FMD as reported in WAHIS. Based on Resolution No. 13 drafted during the World Assembly of Delegates of the OIE on 27 May 2021, out of the 27 states of Brazil, only five (5) states and 19 municipalities in two (2) other states were declared by OIE as FMD free zone where vaccination is not practiced (OIE, 2021). The other states where declared as FMD free zones where vaccination is practiced. According to Rweyemamu *et al.* (2008) and Grubman and Baxt (2004), South America which includes Brazil has 3 serotypes of FMDv, these are types A, O and C. There are 14 brands of vaccines against FMDv registered in Brazil, all inactivated produced by nine (9) veterinary pharmaceutical companies (OIE, 2018).

Conclusion in Hazard Identification: FMD can spread quickly and causes significant economic losses in the affected country owing to production losses and trade restrictions, locally and internationally. Although Brazil has not had FMD occurrence since 2004 according to its report to OIE, only a few states do not practice vaccination. As explained by USDA (2013), the likelihood of FMDv circulating in vaccinated animals cannot be ruled out. As a result, FMD is classified as a potential hazard that could be introduced in the Philippines through the importation of cattle from FMD-free areas in Brazil where vaccination is practiced. It is very important to note that the Philippines had been declared by OIE as country free from FMD without vaccination since May 2015 and therefore the disease is classified as an exotic disease.

Risk assessment:

Release assessment: In 2013 the USDA through the NCIE of APHIS-VS filed a report on the risk analysis conducted for risk of FMD from the importation of fresh (chilled or frozen), maturated, deboned beef from a region in Brazil into the United States. The report includes an in-depth assessment of the 11 factors used by APHIS to evaluate the animal health status of Brazil (USDA, 2013). The 11 factors were:

1. The authority, organization, and infrastructure of the veterinary services of Brazil;
2. Disease status (i.e., is FMDv known to exist in Brazil?);
3. The status of adjacent regions/countries with respect to FMDv;
4. The extent of an active FMD disease control program, if any, if FMDv is known to exist in Brazil;
5. The vaccination status of Brazil;
6. The degree to which Brazil is separated from adjacent countries/regions of higher risk through physical or other barriers;
7. The extent to which movement of animals and animal products is controlled from countries/regions of higher risk, and the level of biosecurity regarding such movements;
8. Livestock demographics and marketing practices in Brazil;
9. The type and extent of disease surveillance in Brazil;
10. Diagnostic laboratory capacity; and
11. Policies and infrastructure for animal disease control in Brazil

In its release assessment report, USDA (2013) concluded that the surveillance, prevention, and control measures implemented by Brazil are sufficient to minimize the risk of introducing FMD into the United States for the purpose of beef imports, provided that additional mitigation measures are implemented. The report also added that based on evaluation of the 11 factors, observations from the site visits, and information provided by Brazil, USDA (2013) considers that Brazil possesses the detection capabilities, reporting systems, and emergency response systems that are necessary for combating FMD in the export region.

However, the USDA (2013) identified risk factors that might be associated with the importation of FMDv into the United States, these are:

1. USDA cannot totally exclude the likelihood that FMDv may be circulating in vaccinated populations. In that regard, recent experimental studies in vaccinated susceptible animals have not been able to demonstrate effective transmission in unvaccinated animals. In addition, Brazil conducts serological testing specifically to assess the level of protection afforded by the vaccination program.
2. Vaccination of cattle against FMD introduces risks related to the immunological response within the herd or population of vaccinated cattle. While a large percentage of individual

animals in the herd may fully respond to FMD vaccination, some individual animals in the herd may have a limited response, resulting in partial or no immunity.

3. In addition, there is still some concern that current vaccines may have residual Non Structural Proteins - NSP (depending on the manufacturing process) that could result in the detection of NSP antibodies in vaccinated animals,
4. Border areas along the states of Rio Grande do Sul and Mato Grosso do Sul appear to be highly susceptible to disease ingress and require heightened border security to ensure maintenance of the FMD-free status of these Brazilian States. In that regard, the risk of introduction from Argentina, Bolivia and Paraguay is mitigated by the implementation of the high surveillance area in the international borders, and by following a regional approach to FMD eradication.
5. There is a potential for introducing FMDv through illegal introduction of FMD-infected animals or animal products from affected regions. Brazil has several internal and external border areas with few or no natural barriers. Even where there are barriers or checkpoints, there is a potential that people, cars, and animal products could cross both domestic and international borders illegally.

FMDv in vaccinated cattle: Garland and de Clercq (2011) cited a study that said immune animals may still transmit FMDv mechanically, if they have been in contact with a source of the virus. A proportion of vaccinated animals may respond weakly or fail to respond at all even if herd immunity has been reached (Garland and de Clercq, 2011). Possible reasons for these are immunological deficiency, immaturity of the immune system in young animals, interference due to maternal immunity or incorrect vaccine dosage (Garland and de Clercq, 2011). Sutmoller and Olascoaga (2003) added that there are restrictions to the international movement of animals and their by-products from countries or zones where FMD vaccination is practiced. The restrictions are based on the possibility that vaccinated animals and their products may contain FMDv (Sutmoller and Olascoaga, 2003). Vaccination may hide clinical disease and therefore evidence of infection (Sutmoller and Olascoaga, 2003). However, Garland and de Clercq (2011) noted that no definitive evidence suggested that vaccinated animals or their products were involved in FMD outbreaks.

FMD carrier state: The rates of FMDv carriers in cattle vary from 15–50% (OIE, 2013; CFSPH, 2015) irrespective of their immune status (Garland and de Clercq, 2011). Cattle are important maintenance hosts in most areas (CFSPH, 2015). Other modelling of the effects of vaccination in cattle showed that the prevalence of herds with carriers is likely to be very low, approximately 0.2%, with very few carriers, perhaps only a single animal, in positive herds (Garland and de Clercq, 2011). Theoretical calculations have estimated a transmission rate of 0.1128 infections per carrier per month for contact with susceptible cattle (with 95% confidence limits of 0.000 to 0.3078) and a decrease in the proportion of carriers of 0.115 per month (Garland and de Clercq, 2011). These low theoretical values are supported by the observation that many thousands of vaccinated carriers must have been transported within and between countries without any authenticated reports of FMD transmission attributed to this source (Garland and de Clercq, 2011).

Conclusion in Release Assessment: Although empirical evidence over many years strongly indicates the absence of FMD risk from vaccinated animals, some individual animals in the herd may have a limited immunological response, resulting in partial or no immunity against FMDv that could result in a clinical disease or subclinical infection if exposed to the virus. Furthermore, an asymptomatic FMD virus carrier state is recognized in cattle which may last up to 3.5 years. However, studies revealed that the prevalence of herds with carriers is likely to be very low, approximately 0.2% with very few carriers, perhaps only a single animal. As a result the risk of entry of FMDv through the importation of live cattle from FMD-free zones with vaccination in Brazil to the Philippines is low.

The following are the possible pathways of movement of FMDv from its origin in Brazil into the Philippines.

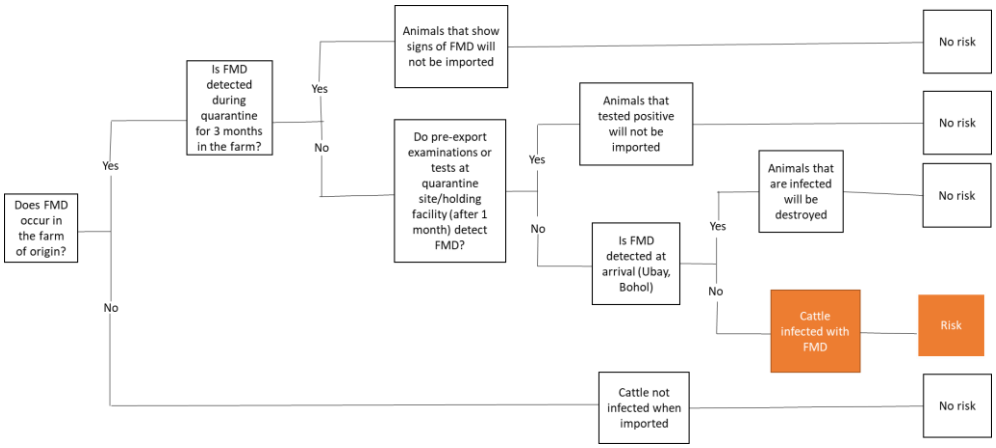

Figure 1 Scenario tree for Foot-and-Mouth Disease Virus (FMDv) introduction into Ubay, Bohol, Philippines (FMD-free without vaccination) through the importation of live dairy cattle from FMD-free zones with vaccination in Brazil.

Exposure assessment: Once FMDv is introduced in the area, it may persist for over a year in infected premises and for 10-12 weeks on clothes and feeds (Admassu *et al*., 2015). Under favorable conditions such as low temperature, high humidity, moderate wind and comfortable topography, the virus in aerosols may spread to long distances. (Admassu *et al*., 2015). Moreover, socioeconomic conditions, mixed animal husbandry practices, unrestricted movement and trade among animals provide a conducive epidemiology niche for the FMDv to flourish, mutate and persist over time and to affect the susceptible animal population (Longjam *et al*., 2011). In the tropics, the most important method of transmission is believed to be direct contact between animals moving during nomadic movement (Admassu *et al*., 2015). It is probable that an outbreak could occur if a viremic cattle are imported into the Philippines which is characterized by animal populations mostly susceptible to FMD and having similar conditions described in the preceding statements. In addition, the incursion of a new serotype would be worse and more difficult to control.

Conclusion in Exposure Assessment: Although the topographical characteristics of the Philippines as an archipelago is an advantage to the containment of FMD preventing its spread to the whole country, there is a high likelihood of FMD becoming re-established in the Philippines if indeed FMD is reintroduced through the importation of these cattle.

Continuing from the release assessment, the biological pathways necessary for exposure of animals in Ubay, Bohol, Philippines are demonstrated in Figure 2.

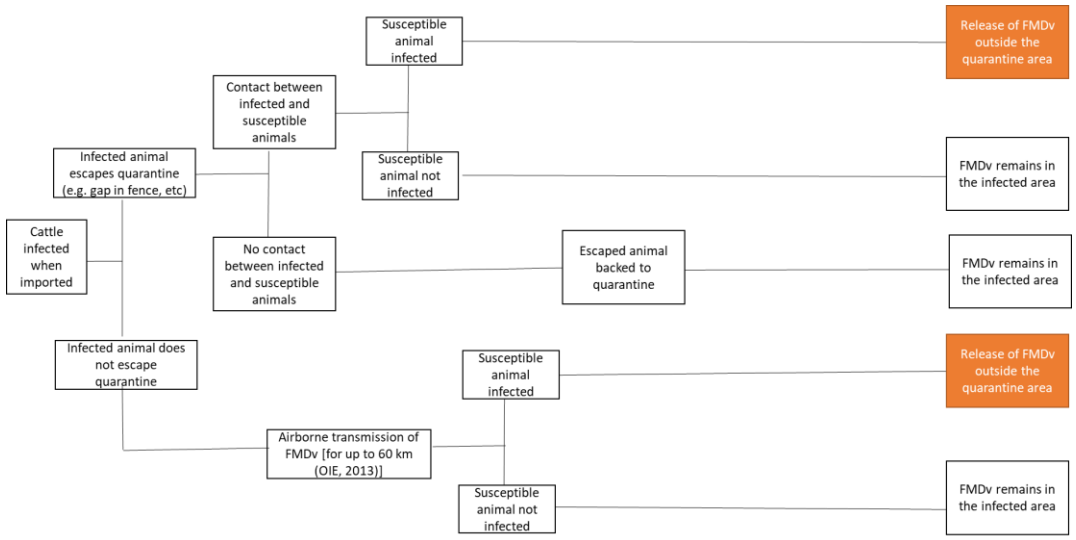

Figure 2 Scenario tree for FMDv exposure and spread in Ubay, Bohol, Philippines (FMD-free without vaccination) through importation of live dairy cattle from FMD-free zones with vaccination in Brazil.

Consequence Assessment: FMD is considered to be one of the most important livestock diseases because aside from being highly contagious, it causes serious production losses (Paton *et al*., 2009; Picardo *et al*., 2011). Highly contagious livestock diseases including FMD affect the certainty of income from livestock enterprises and undermine the potential of the livestock industry, compromise food security, affect livelihoods and increase losses due to disease control costs and mortalities (Vosloo *et al*., 2002; Upton, 2006; Rich and Wanyoike, 2011). Diseases like FMD also necessitates international trade restrictions (Webber *et al*., 2010). A study in Uganda on the economic effects of FMD found that farmers with small and medium herds incurred higher control costs, whereas large herds experienced the highest milk losses (Baluka, 2016). All actors in the industry incur losses during FMD outbreaks but the smallholder farmers are the most affected. (Baluka, 2016). Although FMD typically has short term effects on animal health, chronic FMD reduces milk yield by 80% (Randolph *et al*., 2002).

The cost of control carried out by veterinary services like vaccinations, outbreak control including culling, and surveillance activities will be high. The social and economic impacts of entry and establishment of FMD to any country will be very devastating. One concrete example is the economic cost of the FMD epidemic that affected the United Kingdom in 2001. It was estimated to be approximately £ (Pound Sterling) 3.1 billion in agriculture and £2.7 – £3.2 billion in tourism and related business (Thompson *et al*., 2002). The Philippines is a developing country and greatly depends on agriculture including livestock production for its economy to thrive. Considerable populations of livestock like cattle, buffaloes, sheep, goats, and even pigs are being raised by smallholder farmers. These animals are the main source of their meat and dairy requirements and even as source of draft power in the case of buffaloes. Devastation to the livestock industry caused by FMD outbreaks would severely compromise the livelihood of smallholder farmers and the economy of the Philippines.

Continuing from the release assessment and exposure assessment, the following diagram shows the pathways leading to the consequences:

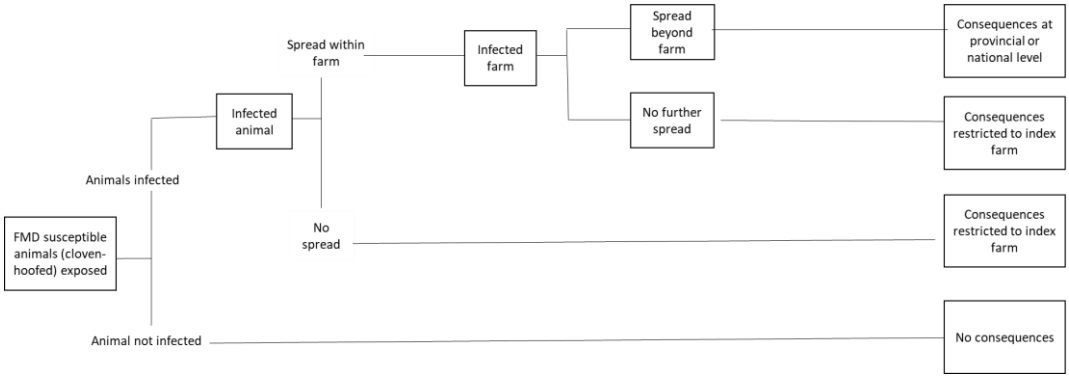

Figure 3 Scenario tree for spread of FMDv in Ubay, Bohol, Philippines (FMD-free without vaccination) through importation of live dairy cattle from FMD-free zone with vaccination in Brazil.

Risk Estimation:

Probability of FMD occurrence: As discussed, the probability of FMDv being reintroduced in the country through the importation of the said commodity is low. On the other hand, the probability of susceptible animals in the country being exposed to FMDv after the disease has gained entry is high. With a low probability of release and a high probability of susceptible animals being exposed, the probability of occurrence is therefore low (Supplementary Table 1).

Consequence score: In so far as animal health is concerned, there is a high consequence expected with FMD establishment and spread in the country. This would mean a significant adverse impact on the economy of the Philippines (Table 1). On the other hand, FMD is not considered to be a public health problem (OIE, 2013).

Table 1 Scores of FMDv consequences on animal and public health (Dufour *et al*., 2011).

Animal Health	**Consequence in the affected farm**	**Probability of spread of disease**	**Consequences at the national and international level**	**Total estimated consequences**
	3	3	3	8
Public Health	**Consequence in the individual human**	**Probability of spread in human populations**	**Overall consequences in public health and economy**	**Total estimated consequences**
	0	0	0	0

Conclusion in Risk Estimation: Using the results table for risk estimation (Supplementary Table 4); with a low probability of occurrence and a high total assessed consequences in animal health, the risk of importation of live Girolando cattle from FMD-free zones with vaccination in Brazil is quite high (QH) (with an interval of "not very high (NVH)" to "high (H)", to recognize uncertainties). Risk management measures are therefore recommended.

Risk Management: To effectively manage the risks of FMDv incursion, sanitary measures must ensure that cattle are not carrying the virus (i.e. not incubating the disease, not viremic, not carrier) when exported into the Philippines. The OIE Terrestrial Animal Health Code (OIE, 2017) provides recommendations for the importation of live domestic ruminants including cattle from FMD-free zones where vaccination is practiced. Article 8.8.11 of the Code states that veterinary authorities should require the presentation of an international veterinary certificate attesting that the animals:

1. Showed no clinical sign of FMD on the day of shipment;
2. Were kept since birth or for at least the past 3 months in an FMD-free zone where vaccination is practiced;
3. Were subjected to a test for FMD with negative results, and;
4. If transiting an infected zone, were not exposed to any source of FMDv during transportation to the place of shipment.

The veterinary authority (VA) of the Philippines must require the VA of Brazil to issue the international veterinary certificate indicating that the live cattle to be imported passed through rigorous examinations for FMD and all the requirements stipulated in article 8.8.11 of the 2017 OIE Terrestrial Animal Health Code had been met. The test that should be used to determine FMDv infection is Non-structural Protein Enzyme-Linked Immunosorbent Assay (NSP ELISA) Antibody. NSP ELISA Antibody is useful in providing evidence of previous or current viral replication in the host, irrespective of vaccination status (Niedbalski and Haas, 2003; Paton *et al*., 2003; OIE, 2017). ELISAs for the detection of antibodies against NSPs are widely used to differentiate vaccinated and infected animals because purified vaccines are free of NSPs and thus elicit antibodies only against structural proteins (Yang *et al*., 2015). The use of the South American 3ABC "PANAFTOSA" ELISA is recommended as it has been the approach that the OIE has recommended to be considered as the reference method to which others should be compared (Paton *et al*., 2003). The test was considered to have been validated in cattle and to have a high diagnostic sensitivity and specificity (Paton *et al*., 2003). This claim was supported by Yang *et al*. (2015) who said that antibodies to the 3ABC NSPs are

reliable indicator of infection, regardless of the FMDv serotype.

As discussed in the release/entry assessment, there are 4 critical points where the cattle to be imported could be or might have been exposed to FMDv, these are: farm of origin or source of cattle, transportation to holding facility, holding facility (quarantine site) in Brazil and transportation to point of destination in the Philippines (Ubay Stock Farm, Ubay, Bohol). Sanitary measures must therefore be implemented in these four (4) critical points to prevent the entry of FMD virus into the Philippines.

Additional specific sanitary measures to be implemented in Brazil were also recommended as follows:

1. Animals should be vaccinated against FMD using inactivated vaccine corresponding to the field strain at least twice, not less than one month and not more than 12 months before the time of export (Garland and de Clerq, 2011);
2. A veterinarian or trained personnel must be assigned in each farm to monitor on a daily basis the cattle to be imported for signs of FMD throughout the 3 month period or until the animals have been transported to the quarantine site. In the event of FMD incidence he/she shall report to the farm management the disease situation. Likewise, the farm management shall report the incidence to the VA of Brazil. In turn, the latter shall report the incidence to the VA of the Philippines, which is also the risk manager. Tests may be required to confirm the clinical diagnosis using NSP ELISA antibody, virus isolation or real-time PCR. A confirmed positive laboratory test result shall automatically cancel the plans for importation of the said animals;
3. Documentary evidence must be presented satisfactorily by each farm (source) to demonstrate that the cattle to be imported were kept since birth for at least the past 3 months in an FMD-free zone where vaccination is practiced. Failure to do so will result in the cancellation of importation of the said animals;
4. All cattle must be tested for FMD NSP ELISA antibody at the farm of origin 3 months after the animals were selected/segregated for import. All animals should yield a negative result. A positive result shall automatically cancel the plans for importation of said animals;
5. In the transport of cattle to the quarantine site and eventually to the Philippines, the transport route shall not pass by in countries/areas or zones that are not FMD-free;
6. All transport vehicles and vessel shall be disinfected prior to loading of cattle using any of the following: sodium hydroxide (2%), sodium carbonate (4%), citric acid (0.2%), acetic acid (2%), sodium hypochlorite (3%), potassium peroxymonosulfate/sodium chloride (1%), and chlorine dioxide (OIE, 2013);
7. All cattle must be tested for FMD NSP ELISA antibody at the quarantine site in Brazil after at least 30 days of quarantine. All animals should yield a negative result. A positive result shall automatically cancel the plans for importation of the said animals;

Specific sanitary measures to be implemented in the Philippines are recommended as follows:

1. All Girolando cattle must be tested for FMD NSP ELISA antibody at the quarantine site in Ubay, Bohol, Philippines after at least 30 days of quarantine. All animals should yield a negative result. All positive animals shall be culled and disposed of following proper culling and disposal procedures;
2. In case any of the Girolando cattle that manifest signs of FMD are proven to be positive to FMDv using OIE recommended laboratory tests for FMDv detection, a 60km-radius ring vaccination must be conducted immediately using inactivated vaccines that match with the FMDv field strain.
3. The national veterinary authority must store inactivated FMD vaccines that matches the FMDv field strain in Brazil. The volume of the said vaccines must be enough to cover all susceptible animals within the 60 km radius proposed ring vaccination zone in Bohol.

Options available should there be exposure in local animals: Vaccination has been found effective in the control of FMD outbreak like in Korea in November 2010 to April 2011 (Park *et al*., 2013). With the FMD strain identified as well as the strain of the vaccine, vaccination has been documented to have high efficacy in the field (Park *et al*., 2013). Should there be exposure of susceptible animals in Ubay, preemptive culling would not be sufficient because it may be impeded by technical and logistical problems, animal density and legal policies. Ring vaccination of susceptible animals in a zone surrounding an infected area is economically optimal strategy for densely populated livestock areas (Kahn *et al*., 2002).

The OIE contingency plan for potential outbreaks include humane destruction of all infected, recovered and FMD-susceptible contact animals; appropriate disposal of carcasses and all animal products; surveillance and tracing of potentially infected or exposed livestock; strict quarantine and controls on movement of livestock, equipment, vehicles, and; thorough disinfection of premises and all infected materials (implements, cars, clothes, etc.) (OIE, n.d.).

Risk Communication: A communication matrix was developed to ascertain the list of stakeholders and their level of importance, the information needed, frequency of information dissemination and the medium of communication (Table 2). The officers responsible for all information requirement were also identified.

Table 2 Communication matrix for stakeholders in the importation of Girolando cattle from Brazil.

	Stakeholder	Importance	Information requirements	Frequency of information required	Communication medium	Responsible officer
1.	National livestock and dairy agencies	High	• Animal health status in Brazil and the Philippines; • FMD Disease recognition including modes of transmission; • Biosecurity measures at quarantine site and all commercial and backyard livestock farms; • Report on Import Risk Analysis; • Emergency response in an event of FMD outbreak • Legal policies needed for the implementation of control measures	Once a week for one month	Meeting	Risk Analysis team and experts on FMD and animal disease control
2.	Regional and provincial livestock and dairy agencies; management team of the proposed dairy farm in Ubay	High	• Biosecurity measures at quarantine site and the proposed dairy farm in Ubay, Bohol; • Report on Import Risk Analysis; • Basic facts on FMD; • Importance of surveillance, monitoring and reporting for the prevention and control of FMD; • Emergency response in an event of FMD outbreak	Monthly for three months	Meeting, Seminars, Video, brochures	Risk Analysis team and authorized national livestock and dairy agencies
3.	Local government units (Provincial, Municipal, Village)	Medium	• Number of susceptible farms surrounding the quarantine site and proposed dairy farm • Importance of surveillance, monitoring and reporting for the prevention and control of FMD; • Emergency response in an event of FMD outbreak	Monthly for three months	Seminars, Video, brochures	Authorized national livestock and dairy agencies
4.	Livestock raisers in Ubay, Bohol	Medium	• Facts on FMD including modes of transmission; • Recognition of FMD; • Reporting of disease incidence; • Biosecurity in backyard farms; • Emergency response in an event of FMD outbreak	Monthly for three months	Seminars, Video, brochures	Authorized regional and provincial livestock and dairy agencies including the Provincial Veterinary Office

Specific factors were considered to be communicated to stakeholders to prevent the entry, exposure, spread and establishment of FMD in the Philippines through the importation of Girolando cattle from Brazil (Table 3). Factors 1 to 3 (risks for entry) are the probable risks that could happen in the exporting country while factors 4 to 7 (risks for exposure, spread and establishment) are the probable risks that could happen in the importing country if indeed FMDv gains entry to the Philippines. As per information from OIE's WAHIS, the last occurrence of FMD in Brazil was on 21 April 2004 (OIE, 2018). Brazil has a general and targeted surveillance program on FMD as reported in WAHIS (OIE, 2018), therefore the risk of FMD outbreaks or incidence not detected since 21 April 2004 is quite unlikely. Therefore the level of risk of FMD present at the source farm in Brazil is low.

Although the level of risk for contact between FMD infected and susceptible animals in Ubay, Bohol is low, the level of uncertainty is moderate. This is because portions of the perimeter fence in USF are not very well secured and animals from outside the farm owned by smallholder farmers can gain access and have contact with the Girolando cattle.

Transmission of FMD through air droplets is highly likely. According to OIE (2013), one of the important modes of FMD transmission is through inhalation of infectious aerosols and airborne up to 60 km overland and 300 km by sea in temperate zones. Although the Philippines is a tropical country, spread of FMD through air up to tens of kilometers is still a high possibility. For this reason, the level of risk of airborne transmission of FMDv in Ubay, Bohol is high, if indeed the virus gains entry in the province.

Table 3 Factors to be considered for communication to stakeholders

Factors Considered	Level of Risk / Statement	Level of Uncertainty	Evidence-based or perceived risk
1. Risk of FMD present at the source farm	Low	Low	Perceived
2. Risk of FMD infection not detected in quarantine at the source farm	Low	Low	Perceived
3. Risk of FMD transmitted during transport within Brazil	Low	Moderate	Perceived
4. Risk of FMD infection not detected at arrival in Ubay, Bohol	Low	Low	Perceived
5. Infected animal misses test in quarantine in Ubay, Bohol	Low	Low	Perceived
6. Risk of contact between FMD infected and susceptible animals in Ubay, Bohol	Low	Moderate	Evidence-based
7. Risk of airborne transmission of FMDv in Ubay, Bohol	High	Low	Evidence-based

The most important risk factor identified in the importation of live dairy cattle from an FMD-free zone with vaccination in Brazil is the possible contact between FMD infected (cattle from Brazil) and susceptible animals (cloven-hoofed animals in Bohol) (Table 3). This is the most important as it is at this point where FMD could spread and be re-established in the Philippines leading to devastating economic losses in the livestock industry.

All stakeholders must be made aware of this risk and should be able to respond effectively in a timely manner should the untoward incident happens. A crucial part of risk analysis therefore is the formulation and dissemination of key messages for each stakeholder (Table 4). The stakeholders involved are the government livestock and dairy agencies across all levels and all livestock raisers in Ubay. Information sources should be the trusted personalities who will deliver key messages on the particular risk. These include veterinarians, agricultural engineers and technical staff from livestock and dairy authorities at all levels. Through these information sources, the importance of conceptual, structural and operational biosecurity measures will be discussed thoroughly with the stakeholders through meetings, seminars, video presentations and printed materials such as brochures. Information on appropriate chemical solutions to be used as disinfectants for farm equipment, facilities and premises will be provided as well. A considerable amount of time should be allotted for the presentations and open forum to allow open communication and achieve mutual understanding between the information sources and the stakeholders. Exchanges of contacts such as email and contact numbers will be encouraged to resolve future complains or address clarifications.

Table 4 Management measures and key messages specific for risk of contact between FMD-infected and susceptible animals for communication to stakeholders

Risk Management Measures	Stakeholders	Key message	Information source	Communication tools	Implementing agencies
1. Perimeter fencing to prevent entry of other animals; Biosecurity measures to restrict or limit entry of visitors, feed suppliers, etc.	Proposed dairy farm in Ubay and all surrounding commercial livestock farms	Types of fence and their advantages/disadvantages; Specifications of fence	Veterinarians and Agricultural Engineers expert on the matter	Meetings	Authorized national livestock agency
2. Footbath at gates between buildings, isolation pens, etc.	Proposed dairy farm in Ubay and all surrounding commercial livestock farms	Appropriate chemical solution: types of chemicals; dosage and frequency; effectiveness	Veterinarians expert on the matter	Seminars	Authorized national livestock agency
3. Proper disposal of dead animals	All livestock farmers in Ubay	Types and sites of disposal: advantages/disadvantages; Handling of dead animals; PPE for cullers	Veterinarians expert on the matter	Seminars, Video, Brochure	Authorized national, regional and provincial livestock agencies
4. Isolation pen	Proposed dairy farm in Ubay and all surrounding commercial livestock farms	Types of isolation pens and their advantages/disadvantages; Specifications of isolation pen	Veterinarians and Agricultural Engineers expert on the matter	Meetings	Authorized national livestock agency
5. Culling (if needed)	Proposed dairy farm in Ubay and all surrounding commercial livestock farms; all livestock farmers in Ubay	Culling procedures compliant to animal welfare laws	Veterinarians expert on the matter	Seminars, Video	Authorized national, regional and provincial livestock agencies

In conclusion and recommendations, the overall estimated risk of FMDv reintroduction in the Philippines through the importation of dairy cattle from FMD-free zones with vaccination in Brazil is "Quite High. The result emerged after taking into consideration all components of qualitative risk assessment, namely release assessment, exposure assessment and consequence assessment. Considering this level of risk, there is a need for strict compliance with the recommendations stipulated in the OIE Terrestrial Animal Health Code and the additional sanitary measures recommended in this study. The government should be more vigilant in imposing proper quarantine procedures and testing at the point of origin in Brazil and at the point of destination in the Philippines. Moreover, there should be continuous surveillance and monitoring, testing in holding areas and imposition of strict biosecurity measures in the farm in Ubay, Bohol where the cattle will be brought in. A more comprehensive risk analysis is also recommended to capture expert opinions and first-hand information from veterinary authorities in the Philippines and Brazil including an in-depth study on the possible risk factors at the source-farms.

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Authors' contribution:

EPT: Conceptualization, Formal Analysis, Investigation, Methodology, Writing (original draft, review and editing)

KOAO: Conceptualization, Formal Analysis, Investigation, Methodology, Writing (review)

Supplementary Table 1 Results table for combinations of probability of probability of exposure (Dufour *et al*., 2011)

		Release Probability									
		0 (N)	**1 (NN)**	**2 (M)**	**3 (EL)**	**4 (VL)**	**5 (L)**	**6 (NVH)**	**7 (QH)**	**8 (H)**	**9 (VH)**
Exposure Probability	**0 (N)**	N	N	N	N	N	N	N	N	N	N
	1 (NN)	N	NN	NN	NN	NN	NN	NN	NN	NN	NN
	2 (M)	N	NN	NN	NN	NN	M	M	M	M	M
	3 (EL)	N	NN	NN	NN	M	M	M	EL	EL	EL
	4 (VL)	N	NN	NN	M	M	EL	EL	EL	VL	VL
	5 (L)	N	NN	M	M	EL	EL	VL	VL	L	L
	6 (NVH)	N	NN	M	M	EL	VL	L	L	NVM	NVM
	7 (QH)	N	NN	M	EL	EL	VL	L	NVM	QH	QH
	8 (H)	N	NN	M	EL	VL	L	NVM	QH	H	H
	9 (VH)	N	NN	M	EL	VL	L	NVM	QH	H	VH

0. N = Null
1. NN = Nearly null
2. M = Minute
3. EL = Extremely low
4. VL = Very low
5. L = Low
6. NVH = Not very high
7. QH = Quite high
8. H = High
9. VH = Very high

Supplementary Table 2 Scores of FMDv consequences in animal and public health (Dufour *et al*., 2011)

Animal Health	**Consequence in the affected farm**	**Probability of spread of disease**	**Consequences at the national and international level**	**Total estimated consequences**
	0 - 3	0 - 3	0 - 3	0 - 9
Public Health	**Consequence in the individual human**	**Probability of spread in human populations**	**Overall consequences in public health and economy**	**Total estimated consequences**
	0 - 3	0 - 3	0 - 3	0 - 9

Supplementary Table 3 Scoring system for consequence assessment (Dufour *et al*., 2011)

Score	Definition
0	No consequences predicted
1	Estimated degree of consequences is low
2	Estimated degree consequences is moderate
3	Estimated degree of consequences is high

Supplementary Table 4 Results table for risk estimation (Dufour *et al.*, 2011)

Consequences	Probability of Occurrence									
	0 (N)	1 (NN)	2 (M)	3 (EL)	4 (VL)	5 (L)	6 (NVH)	7 (QH)	8 (H)	9 (VH)
0 (N)	0	0	0	0	0	0	0	0	0	0
1-3 (NN, M, EL)	0	1	1	1	1	1	1	1	1	1
	0	1	1	1	1	1	1	1	1	2
	0	1	1	1	1	1	1	1	2	3
4-6 (VL, L, NVH)	0	1	1	1	2	2	3	3	4	4
	0	1	1	1	2	2	3	3	4	4
	0	2	3	3	4	4	5	5	6	6
7-9 (QH, H, VH)	0	5	5	5	6	6	6	7	7	7
	0	6	6	6	7	7	7	8	8	8
	0	7	7	7	8	8	8	9	9	9

0. N = Null
1. NN = Nearly null
2. M = Minute
3. EL = Extremely low
4. VL = Very low
5. L = Low
6. NVH = Not very high
7. QH = Quite high
8. H = High
9. VH = Very high

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