Foot & Mouth Disease
Questions & Answers

What is Foot and Mouth Disease (FMD)?

FMD is a highly contagious viral disease of cloven-hooved animals with significant economic impact, in cattle and swine as well as sheep and goats. In wildlife, all species of deer and antelope are susceptible to FMD with some of them such as the African buffalo, acting as carriers of the virus without showing clinical symptoms.
In a susceptible non-vaccinated population, morbidity (the number of animals that will get the disease) could be as high as 100%. The disease is rarely fatal in adult animals but mortality can be high in young animals.

What causes Foot and Mouth Disease?

The virus which causes FMD is an aphthovirus of the family *Picornaviridae*. There are seven immunologically distinct types of FMD viruses, A, O, C, SAT1, SAT2, SAT3, and Asia1. There can be a variety of genotypes within each of these requiring a specific vaccine effective against the circulating viral field strain in the event of an outbreak, to ensure protection.

What are the requirements for reporting FMD to the OIE?

FMD is among the list of diseases that must be notified to the OIE by Member countries and Territories. The following criteria guide Members in determining what events are considered significant and require immediate notification (within 24 hours):

- the first identification in a country or zone of an OIE-listed disease or infection
- the re-occurrence of a listed disease or infection following a report by the Member indicating that the previous outbreak(s) had been resolved
- the first occurrence in a country or zone of a new strain of a pathogen of a disease listed by the OIE.

When an epidemiological event as described above occurs, the relevant Member must send an immediate notification to the OIE. As the control measures are put in place, the affected country must send follow-up reports describing progress and results of the applied control measures. When the incident is over, a final report must be submitted once the disease has been controlled and as long as there are no new reported outbreaks.

Why must Member Countries and Territories of the OIE comply with reporting requirements?

Foot and mouth disease is acknowledged as a disease with severe trade implications for the affected country. The cost of preventing a sanitary crisis of animal origin by early detection of outbreaks and implementation of rapid response mechanisms included in national veterinary surveillance systems are insignificant compared to the social, economic and environmental cost of a disaster resulting from an outbreak of foot and mouth disease.

Early reporting protects and improves a country's reputation and gives it the assurance of a reliable trading partner. Implementation of these measures will subsequently reduce the degree of economic loss and loss of livelihood for a Member Country.

The OIE assists especially developing and transitional countries to identify their ability to comply with international standards to control outbreaks of FMD. This is done by assessing the performance of the veterinary services through application of the PVS tool by selected OIE experts in collaboration with the veterinary authority of a country.

Where is the disease found?

FMD is endemic in several parts of Asia, a large part of Africa and the Middle East. In Latin America, the majority of countries applied zoning and are recognized free of FMD with or without vaccination, and the disease remains endemic in only a few countries or regions within certain countries.

Australia, New Zealand and Indonesia, Central and North America and Western Europe are currently free of FMD. However, FMD can occur sporadically in typically free areas.

Of the OIE Member Countries and Territories, 64 are recognized as free from FMD without vaccination; 2 countries are recognized as free with vaccination. Several other countries are recognized as having zones that are free with or without vaccination. More than 100 countries are still not considered as FMD free.

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What is the public health risk associated with this disease?

FMD is not readily transmissible to humans and is not a public health risk. Only a few benign cases of human infections have been documented, none requiring hospitalisation. These infections resulted from direct contact with infected animals. The infection in humans can be characterised by mild symptoms notably blisters on the hands and in the mouth.

How is FMD transmitted and spread?

FMD virus is found in all excretions and secretions from an infected animal. It can spread easily and rapidly by means of the following:

- introduction of new animals carrying the virus (saliva, milk, semen, etc.) to a herd
- use of contaminated pens, buildings or vehicles to house and transport susceptible animals
- use of contaminated materials such as hay, feed, water, milk or biologics
- wearing contaminated clothing or footwear, or using contaminated equipment
- feeding susceptible animals with animal products, raw or improperly cooked food, infected with the virus
- dissemination of virus by aerosols transported from an infected property via air currents
- accidental release of virus from a laboratory
- use of vaccines containing live virus due to production errors in manufacture.

What are the clinical signs of FMD?

The severity of clinical signs will depend on the strain of virus, the age of the animals and the species and breed affected.
The typical clinical sign is the occurrence of blisters (or vesicles) on the muzzle, tongue, lips, mouth, between the toes, above the hooves, teats and potential pressure points on the skin. Ruptured blisters in the interdigital space can result in extreme lameness and reluctance to move or eat due to vesicles in the mouth. Secondary bacterial infection of open blisters can also occur. Other symptoms often seen are fever, depression, hypersalivation, loss of appetite and weight, and drop in milk production.
The disease is rarely fatal in adult animals however, the disease can leave them weakened and debilitated and result in severe production losses. The health of young calves, lambs, kids, and piglets may be compromised by lack of milk from infected dams. When young animals are infected with the FMD virus, mortality can be high.

What are the control measures taken?

The initial measures in the global strategy for dealing with FMD comprise early detection and warning systems and preventive measures established according to OIE Guidelines for the Surveillance of Foot and Mouth Disease.
The elements included in a response effort to eradicate the disease are:

- surveillance and tracing of potentially infected or exposed livestock
- slaughter of infected animals using humane methods complying with OIE international standards on animal welfare
- appropriate disposal of carcasses and all animal products in compliance with OIE guidelines
- strict quarantine and controls on movement of livestock, equipment, vehicles, and
- thorough disinfection of premises and all infected material (implements, cars, clothes, etc.)
- under certain conditions, complementary use of strategic ring vaccination.

Why do import bans include animal products and foods? Is there a food safety issue?

All products obtained from an infected animal or coming into contact or proximity with them must be considered contaminated.
The ban on products of animal origin and food products derived from animals is justified by the possible presence of the virus in these products and the risk of contamination of susceptible animals, (not people). The OIE has defined standards for the inactivation of virus present in meat, milk for human or animal consumption, hides, wool, hair and bristles. (Foot and Mouth Disease Virus Inactivation Procedures, articles 8.5.32 to 8.5.39, *Terrestrial Animal Health Code 2008*).

What is the degree of risk for a laboratory dealing with FMD virus?

FMD is identified as a Containment Group 4 animal pathogen based on the severe consequences of spread from the laboratory and according to the risk it poses to animal health and the agricultural economy of a country.
OIE standards (*Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2008*, Biosafety and Biosecurity in the Veterinary Microbiology Laboratory and Animal Facilities, Chapter 1.1.2) specify the various risk groups and criteria for defining pathogens. In 2007, the OIE also updated the standards establishing administrative and technical prescriptions for laboratories that handle diagnostic tests of animal infectious diseases.

What level of biocontainment is necessary in labs dealing with FMD virus?

FMD laboratory diagnosis and virus identification must be done in a facility that meets the requirements for dealing with Containment Group 4.
A laboratory should be allowed to possess and handle animal pathogens in Group 4 only if it can satisfy the relevant authority that it can provide and maintain the required containment measures.
The OIE has defined standards to provide guidance on laboratory containment in order to prevent any escape of pathogen from the laboratory into the national animal population. These standards are found in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2008*, Chapter 1.1.2 (Biosafety and Biosecurity in the Veterinary Microbiology Laboratory and Animal Facilities).

Has accidental release of FMD virus occurred in the past?

In Europe more than ten different documented accidental animal infections with FMD virus due to human error were reported; all occurred in the last century. Other than the outbreak in the United Kingdom in 2007 all these accidents occurred before 1991, when vaccination against FMD was stopped in Western Europe. Most of these accidental infections were as a result of poorly inactivated vaccines and only a few were due to escape of virus from the laboratory. Accidents due to human error have occurred at laboratories in Tübingen, Germany, Maisons-Alfort, France, and Pirbright, UK. An escape of FMD virus occurred at Plum Island, NY in the early 1980s as a result of human error during construction work on site. The virus infected animals kept outside the high containment buildings, but still within the confines of the island that houses the laboratory.

What specific biocontainment precautions are necessary in labs dealing with FMD virus?

OIE guidelines for the containment level for Group 4 pathogens are the most stringent required and include the following precautions:

- access to the building through a system of air locks
- maintaining the building under negative air pressure
- filtering incoming air through a single HEPA filter
- filtering outgoing air through double HEPA filters
- conducting all work with infective materials in specialized cabinets
- treating all sewage from the laboratory, laboratory effluent and autoclave drain effluent by appropriate means to destroy all infectious material before entering the public sewerage system
- shower and change of clothing for all staff before leaving the building
- using a one-piece positive-pressure suits to provide additional protection.

Does an FMD vaccine exist and does it work?

Inactivated virus vaccines (where the virus has been subjected to a chemical treatment so it cannot reproduce in vaccinated animals) are highly recommended. Live virus FMD vaccines are not acceptable due to the danger of reversion to virulence and resultant difficulty in differentiating infected from vaccinated animals. The vaccines are formulated for the specific virus strains present in the country and the animal species it is to be used in. Many FMD vaccines are designed to provide cover against several different virus strains likely to be encountered in a given field situation, but no vaccine protects against all the virus strains circulating in the world. The current trend in vaccination strategies is to use highly purified DIVA (Differentiating Infected from Vaccinated Animals) vaccines which allow easy identification of naturally infected animals from vaccinated animals. Vaccination against FMD is used in many countries or zones that are now recognised as free from foot and mouth disease with vaccination.

Does the OIE recommend the vaccination of animals for FMD?

Vaccination remains an option as part of an effective control strategy for FMD and the decision to use vaccination is a national responsibility. Routine vaccination against FMD is used; in many countries or zones recognised as free from foot and mouth disease with vaccination, in countries where the disease is endemic and in countries where there is a risk from circulating virus in neighbouring countries or zones. In disease-free countries using the mechanisms of effective early detection and rapid response, the use of strict movement controls and culling of infected and contact animals when outbreaks occur must be preferred to vaccination.

How safe are FMD vaccines?

In manufacturing FMD vaccines, virulent FMD virus must be used during the process. A key step in the process is the inactivation of the FMD virus. The commercial vaccine must be free from residual live virus. These vaccines must be controlled to ensure the safety of their use. Vaccines must also be field tested to demonstrate safety and efficacy under field conditions and to detect unexpected reactions. These tests are carried out before the vaccine is authorised for general use.

What are the containment requirements for FMD vaccine production?

FMD vaccine production facilities must meet the OIE requirements for Containment Group 4 animal pathogens and must be able to prove to the relevant authority that they can provide and maintain the required containment measures.

The finished FMD vaccine must be shown to be free from residual live virus. The OIE has developed standards for the production of pure, safe, potent and efficacious veterinary vaccines meeting strict guidelines (Principles of Vaccine Production, Chapter 1.1.8, OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2008)*. Regulatory authorities in each country are responsible to develop an appropriate system to ensure the quality of vaccines according to OIE standards, including facility design, control of manufacturing processes, testing of the final product, product tracking and record-keeping.

Why not implement routine vaccination to prevent the occurrence of FMD?

There are several reasons for not considering the use of vaccination as a routine measure for the prevention or control of FMD:

- the cost of vaccine and of administration
- the requirement for administering two injections per year for all susceptible species (cattle, sheep, goats, swine)
- the need to use vaccines adapted to the circulating virus strains or those anticipated
- the cost of a vaccine which protects against all strains of the virus in the world would be prohibitive
- the difficulties with exportation, although, the progress in vaccine design and diagnostic test diminishes this impact
- many countries with the capability of effective early detection and rapid response mechanisms choose to use strict movement controls and culling of infected and contact animals when outbreaks occur to eliminate the disease from the country.

What kind of quality systems are required for laboratories working with FMD virus or facilities producing FMD vaccines?

The laboratories must implement a quality management programme to demonstrate that they meet quality objectives and satisfy the requirements of standard setting bodies. The national competent authorities should subject the facilities to ongoing, in-depth inspections of the entire premises to ensure compliance with required standards. The OIE has developed the "Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases", in: *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases (2002)*. Updated in 2007 this serves as a guide to national authorities in the procedure of accreditation of veterinary laboratories.

How does OIE identify whether laboratories or facilities working with FMD virus are meeting required standards?

Regulatory authorities in each country are responsible to develop an appropriate system to ensure facilities undergo in-depth inspections to ensure compliance with required standards. They must also ensure the quality of vaccines is produced and used according to OIE standards. The OIE does not directly audit laboratories to ensure they meet requirements.

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