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Developing an emergency vaccination plan for foot-and-mouth disease in free countries

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Introduction to the guide

BACKGROUND

The guide has been drafted based on the outcome of two European Commission for the Control of Foot-and-Mouth Disease (EuFMD) workshops on *"Putting vaccination into practice"* held in Grange, Ireland from 13 to 16 March 2017, and in Malaga, Spain from 19 to 22 March 2019. The workshops identified the key elements required for the development of an emergency vaccination implementation plan. Further information has been included to extend the guide to all aspects of an emergency vaccination plan.

PURPOSE

The purpose of the guide is to assist countries free of foot-and-mouth disease (FMD) in the preparation of emergency vaccination plans.

SCOPE

The guide provides recommendations for the structure and content of an emergency vaccination plan, once the decision to vaccinate has been made, and the vaccination strategy has been decided. It does not include any consideration of the decision-making process on if, when and how to proceed with vaccination. The plan should be adapted to the context and requirements of the country.

AUDIENCE

This guide is intended to be used by veterinary contingency planners in countries free from foot-and-mouth disease (FMD) without vaccination. The concepts presented can also be adapted to other animal health threats.

APPLICATION

As emergency vaccination operations have to be implemented quickly in the face of a disease outbreak or imminent threat of disease introduction, an emergency vaccination plan is best drafted in "peace-time". The plan can then be updated, once the strategy and details on the specific vaccine(s) to be used in the disease situation are known.

Contents of an emergency vaccination plan

1. INTRODUCTION

The introduction to the emergency vaccination plan should include the purpose, scope and audience. Document ownership, duration of validity and responsibility for updating the plan should also be clearly specified.

The **purpose** of the plan should be well defined.

> Example:
> *"To comply with legislative requirements for the field deployment of FMD vaccine in an outbreak setting within the territory."*

The **scope** of the plan should be specified.

> Example:
> *"The key elements required to implement emergency vaccination in the field – including standard operating procedures (SOPs), checklists and templates."*

The **audience** for the plan should be specified.

> Example:
> *"Individuals or units within the veterinary services, its agents or functions within the FMD emergency response structure tasked with implementing the plan, including e.g. the planning (epidemiology), logistics and/or operations sections at central and regional/provincial level."*

2. EPIDEMIOLOGICAL SITUATION AND CRITERIA FOR THE DECISION TO VACCINATE

The prevailing epidemiological situation and the criteria used to make the decision to vaccinate should be stated.

3. AIM, OBJECTIVES AND STRATEGY

It is important that there are well-defined overarching **strategic aims, objectives and clear strategies** for the vaccination programme. If these are not clear to the stakeholders, the vaccination campaign may be ineffective.

Aim

The **strategic aim** of the vaccination programme should be a high-level statement of intent that answers the question "*How will emergency vaccination contribute to FMD control?*".

> Example:
> *"The strategic aim of the vaccination programme is to contribute to a reduction and elimination of disease spread."*

Objectives

The **vaccination programme objectives** should answer the question, "How will the strategic aim be achieved?". The vaccination programme objectives should be more specific than the strategic aim, and well defined to allow prioritization of limited resources in the response. Yet, they should be broad enough to accommodate modification to the actual vaccination strategy or strategies to be employed as the situation evolves.

> Example:
> *"The objectives of the emergency vaccination programme are to:*
> *a) contain FMD to current disease clusters or infected areas (including preventing spread to other provinces or regions);*
> *b) prevent the spread of FMD to and within high disease transmission risk areas;*
> *c) protect high economic value properties, industry sectors and regions; and*
> *d) prevent spill-over infection into wildlife populations."*

Strategy

To achieve the objectives, different vaccination strategies may be implemented either alone or in combination. These will consider the epidemiological and geographical characteristics of occurrence of the disease. Four vaccination strategies are defined in Article 4.18.5 of Chapter 4.18 (Vaccination) of the "World Organisation for Animal Health (WOAH) Terrestrial Animal Health Code ":

- Barrier vaccination: This means vaccination in an area along the border of an infected country or zone to prevent the spread of infection into or from a neighboring country or zone.

- Blanket vaccination: This means vaccination of all susceptible animals in an area or an entire country or zone.
- Ring vaccination: This means vaccination of all susceptible animals in a delineated area surrounding the location where an outbreak has occurred.
- Targeted vaccination: This means vaccination of a subpopulation of susceptible animals.

The strategy includes any associated policies in relation to the management of vaccinated animals under the applicable policies and legislation. Vaccinated animals may be allowed to remain in the population and live out their normal commercial lives ("vaccinate-to-live/retain") or be removed by killing and disposal of carcases ("vaccinate-to-kill/remove").

Protective vaccination means emergency vaccination carried out to protect animals of susceptible species from infection or clinical disease. The term "protective vaccination" may be associated with an intent to allow vaccinated animals to live out their commercial lives.

Suppressive vaccination means emergency vaccination where there is a need to reduce the amount of foot-and-mouth disease virus circulating within and out of an infected area to reduce the risk of it spreading. The term "suppressive vaccination" may be associated with an intent to remove vaccinated animals from the population.

For plans developed in peacetime, consideration should be given to different scenarios and potential vaccination strategies. Where protective vaccination is to be carried out, the animals may be permitted to live out their normal productive lives or be slaughtered sooner to facilitate the recovery of trade. For an example, see United States Department of Agriculture: Red Book (2020, Chapter 3.)

For plans developed or updated during a disease outbreak or threat of introduction, the strategy(s) chosen for the specific situation should be clearly defined in the plan and should include sufficient information to communicate the necessary details to relevant stakeholders (including industry sectors, farmers, field response personnel and consumers).

- a description of the geographical area(s) in which vaccination will be carried out;
- a description of the surveillance area(s) around the vaccination zone (if applicable);
- the strategy that will be used in each area (barrier, blanket, ring or targeted);
- whether vaccination will be suppressive or protective;
- whether vaccination is compulsory;
- the approach to be used (from the outside perimeter of the zone-in, inside-out, or both);
- the personnel responsible for administration of the vaccine;
- the target species, age groups, production sectors or holding types to be vaccinated;
- the target coverage (if known);
- how premises will be prioritized;
- the vaccination schedule, timing and duration of the vaccination campaign;
- the special identification and registration requirements for vaccinated animals; and
- the restrictions that apply to movements of vaccinated and non-vaccinated animals of susceptible species, their products and by-products within and from the vaccination zone.

Example:

"The strategy of the emergency vaccination programme is to:

a) commence protective vaccination as soon as possible;

b) carry out ring vaccination following confirmation of infection on a premises;

c) vaccinate all cattle over two weeks of age in proximity to infected premises and dangerous contacts;

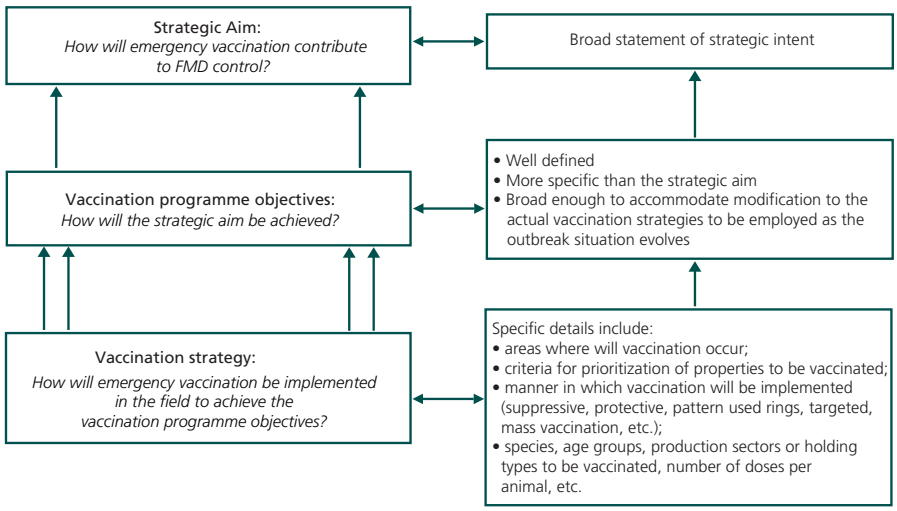
d) prioritize holdings located the shortest distance to any infected premises or dangerous contacts identified within the past ten days;

e) use a single dose of high potency vaccine for each animal; and

f) vaccinate at capacity every day."

FIGURE 1

Aim, objectives and strategy for an emergency vaccination programmeme



Source: Authors' own elaboration.

Figure 1 Summarizes the development of the aim, objectives and strategy for an emergency vaccination campaign.

4. GOVERNANCE

The success of a vaccination campaign depends on good governance. Governance includes the legislation, policies, procedures, templates, checklists, records, training programmes, management, supervision, monitoring and auditing procedures associated with the campaign.

Legislation is required for marketing authorization of the vaccine, vaccine importation and use, powers of entry to farms and to administer the vaccine, authorization of vaccinators,

definition of vaccination zones (areas and measures), and compulsory compliance and subsequent destruction of vaccinated animals if suppressive vaccination is employed. Compensation for adverse reactions from vaccination may also be considered. Policies cover the vaccination strategies, including the personnel to be involved in administration of the vaccine, the prioritization of animals to be vaccinated and the exit strategy. Procedures are required for biosecurity measures for personnel, cleaning and disinfection of vehicles and equipment, disposal of waste, vaccine storage and handling, breaches of the cold chain, vaccination centres, vaccination team briefings and debriefings, vaccine administration, identification of animals, registration of vaccinated herds/flocks and animals, pre- and post-vaccination surveillance, suspicion of disease following pre-vaccination surveillance, needle-stick injuries, reporting of adverse reactions and travel and subsistence reimbursement.[1]

Templates are required for vaccination certificates, vaccine and equipment requisition, vaccine stock and inventory control, travel and subsistence claims, tenders and contracts. Checklists are required for vaccination kits, biosecurity kits and information packs for vaccination teams. A training programme is required for vaccination teams. The roles and responsibilities of various stakeholders in the vaccination campaign should be established.

Additional management and supervision aspects are included in **Sections 5**, **6** and **11** below. All components of the vaccination campaign should be audited to ensure that all procedures are documented and verifiable, and the system is functioning according to the plan. There are several indicators that can be monitored and for which a recording system needs to be in place. These include the:

a) proportion of the targeted population of animals and herds vaccinated within the defined timeframe;
b) number of vaccine doses used compared with the number of animals vaccinated;
c) number of animals vaccinated compared with census figures for the relevant animal population;
d) number of reports of breaches of the cold chain;
e) performance of vaccinator teams in complying with the standard operating procedures;
f) timing and duration of the campaign; and
g) overall cost and cost per individual animal vaccinated.

See FAO and WOAH (2016, Annex 1) for additional indicators.

5. LOGISTICS

Logistics cover the organization and distribution of the vaccine. The aim is to ensure that the selected vaccine will be sourced from the supplier on the day requested (also considering airline shipping delays), in the correct amount and packages, appropriately labelled, stored, distributed, repackaged and delivered in a traceable manner and under the appropriate storage conditions to the holdings where it is needed without delay.

[1] See the following examples of Nationally Agreed SOPs on FMD vaccination from Animal Health Australia (2011):
- ordering of FMD vaccine and distribution to states and territories
- control of FMD vaccine at a designated vaccination centre
- assessing and inspecting a property prior to admin FMD vaccine and
- vaccinating livestock on a property for FMD.

Countries that do not have their own vaccine or antigen banks may source vaccine using public (routine and emergency) procurement procedures. When purchasing through a tender process, it is important to include key information in the call for tender, to enable the manufacturer to provide an appropriate tender dossier. "*Key information to be included in a call for tender*" is set out in **Annex 1** below. For countries intending to request vaccine from an existing antigen bank, a list of key information required for a "*Request for formulation of FMD vaccine from antigen stocks in an antigen bank*" can be found in **Annex 2**.

The vaccine distribution chain will depend on who will be authorized to carry out the vaccination (see **Section 6** below). The distribution chain should include a central storage facility (central vaccination storage centre), where the vaccine is stored prior to distribution to local facilities close to the vaccination zone. A national vaccination manager should be responsible for the central vaccination storage centre, and local vaccination managers responsible for distributing vaccine to the field veterinarians. The managers will be responsible for keeping records on the amounts of vaccine used, the holdings and animals vaccinated, and for collecting any unused vaccine.

Maintenance of the cold chain is a key component of the plan. Either freezing or warming above 8 degrees Celsius is harmful to the FMD virus capsid (virion/virus particle) integrity and promotes capsid disintegration and loss of immunogenicity. It is therefore important to maintain the cold chain up to the point of vaccination, and vaccine vials should be kept in cool boxes even on farm, especially in warm conditions. Daily monitoring of storage temperatures and the use of temperature loggers are recommended.

6. PERSONNEL

To implement an emergency vaccination programme (or any vaccination programme), it is necessary to have appropriate personnel, with the legal authorization, technical knowledge and resources to carry out the vaccination and all associated tasks.

The composition of the field vaccination team size, structure and roles will need to be decided. Vaccinators may be official veterinarians or private veterinarians. Alternatively, veterinary paraprofessionals, contract personnel or farmers may carry out vaccination under official supervision. When considering the use of lay vaccinators, it is important to weigh up the advantage of freeing up veterinary personnel for other critical activities against the risk of improper vaccination and loss of on-farm clinical surveillance opportunities. The decision may depend upon the severity of the crisis, the strain on resources and the availability of competent lay vaccinators.

The teams should include personnel to handle and identify the animals. The number of teams required should be estimated. The number will be based on a target number and size (in livestock numbers) of holdings to be vaccinated per day. The vaccination workstream (i.e. organizational structure of the workforce) will also need to be decided.

In addition to the vaccination teams, consideration should be given to the personnel who will be responsible for other tasks necessary to design and implement a vaccination plan:

1. Source budget for the vaccine, vaccination implementation, vaccination monitoring, database development, movement controls, clinical and serological surveillance, and laboratory testing.

2. Draft or amend legislation to permit vaccination and authorize vaccinators.
3. Issue a marketing authorization for the vaccine.
4. Source and purchase vaccine plus equipment and consumables for vaccination, cold chain, animal identification, biosecurity and laboratory testing.
5. Issue licences for the import and use of vaccine.
6. Identify, select and/or procure vaccination teams.
7. Draft protocols for surveillance and vaccination teams, vaccine storage and handling, stock reconciliation and monitoring and evaluation of vaccination implementation and impact.
8. Draft protocol for investigation of potential vaccine breakdowns.
9. Draft template vaccination record cards and certificates.
10. Draft information packs for farmers and vaccination teams.
11. Carry out pre- and post-vaccination surveillance.
12. Carry out laboratory testing (including vaccine matching and potency tests).
13. Implement movement controls.
14. Develop training material and train vaccination teams.
15. Set up local vaccination centres.
16. List and prioritize farms to be vaccinated.
17. Roster vaccination teams.
18. Brief and debrief vaccination teams.
19. Distribute vaccine and equipment for vaccination, maintenance of the cold chain, animal identification and biosecurity.
20. Develop an electronic database for recording and reporting on vaccinated herds/flocks and animals.
21. Record vaccination in the database.
22. Monitor and reconcile vaccine stocks.
23. Monitor and evaluate vaccination implementation and impact.
24. Reimburse non-government personnel engaged in vaccination.
25. Develop and deliver the communications plan.

7. BIOSECURITY

The implementation of strict biosecurity measures by vaccinators and staff at vaccination centres is essential during vaccination campaigns. This includes the use of appropriate personal protective equipment (PPE) and disinfection equipment, entry/exit procedures to/from farms[2], safe disposal of unused vaccine, and safe disposal or disinfection of vaccination equipment. In addition, vehicles should be cleaned and disinfected.

8. SURVEILLANCE

Surveillance programmes include:

a) pre-vaccination surveillance in the vaccination zone;
b) adverse reactions following vaccination;
c) surveillance in the vaccination surveillance area; and

[2] See EuFMD advice on biosecurity in the Knowledge Bank here.

d) post-vaccination surveillance in the vaccination zone.

Pre-vaccination surveillance involves clinical examination of animals in the vaccination zone, prior to vaccination, to confirm that they are disease free. It is usually carried out by surveillance teams during visits in advance of the arrival of the vaccination team, or by the vaccination teams at the time of vaccination.

Adverse reactions to vaccination should be routinely reported and investigated. Where clinical signs of FMD are reported following vaccination, a full investigation should be carried out. Laboratory testing may be necessary to determine if this is due to the field strain or to the vaccine. See FAO and WOAH (2016, Chapter 4) for further information.

A vaccination surveillance area may be established and remain in place until FMD infection-free status is recovered. Intensified surveillance should be carried out to prove that the disease did not escape from the vaccination zone. Increased surveillance is required, but when there are no specific details, it is taken to mean clinical examination of animals, carried out both during the vaccination campaign and after vaccination has been completed.

Post-vaccination surveillance must be carried out after vaccination has been completed, to evaluate the effectiveness of vaccination. It may be carried out by the vaccination teams or other personnel. Details on post vaccination surveillance are given in Section 11 below.

9. LIVESTOCK IDENTIFICATION AND REGISTRATION

Identification is required to differentiate vaccinated from unvaccinated animals, and for monitoring and certification of vaccination. All vaccinated animals must have a means to identify their vaccinated status, in addition to normal identification requirements. The means of identification should be readily visible or detectable to ensure that movement of vaccinated and non-vaccinated animals can be adequately controlled. Traceability should be ensured by registration of all vaccinated animals and herds/flocks in a central official electronic database. Existing databases may need to be developed to capture vaccinated animals and herds/flocks. It should be possible to track herd/flocks listed for vaccination, those where vaccination is in process, and those where vaccination has been completed. Protocols should be drafted for data capture, data entry, and reporting.

10. MOVEMENT CONTROLS

There is no risk to human health from vaccinated animals and their products. The risk to animal health is very low, but not negligible as vaccination is not always effective. For further reading on this subject see Feng (2017), Paton et al. (2010) and Sutmoller et al. (2003).

A key requirement when implementing vaccination for FMD is the application of movement controls on animals of susceptible species, their products and by-products from and within vaccination zones. These movement controls are additional to those to be applied in the protection and surveillance zones. Controls must be maintained until FMD infection-free status has been recovered.

Depending on legislation in place at the time, certain movements of vaccinated animals may be permitted. Permit conditions may include:

- pre-movement inspection of holdings;
- biosecurity measures;
- designation of holdings, establishments and transport routes;

- separate transport and storage arrangements;
- special ante-mortem inspections;
- supervision;
- use of special identification marks for meat ;
- use of special treatments for products and by-products; and
- licensing and certification.

A major consideration for the emergency vaccination plan is any treatments required under legislation for ruminant and porcine meat from vaccinated animals. Requirements may include heat treatment of meat from ruminants and pigs or deboning, trimming and maturing to specific standards. In order to meet any conditions set out, suitable processing establishments would need to be identified, stamps made and protocols put.

11. VACCINATION EVALUATION AND EXIT STRATEGY

Monitoring and evaluation should be carried out periodically during the campaign to enable the timely application of corrective measures if necessary. Based on the objectives and targets of the vaccination programme, the following outcomes should be assessed:

a) vaccine efficacy;
b) vaccination coverage;
c) population immunity;
d) absence of undisclosed infection in vaccinated animals;
e) reduction of incidence, prevalence or impact of disease; and
f) frequency and severity of side effects.

Once disease is eradicated, the aim is to recover FMD-free status. The pathway to recovery of free status is referred to as the "exit strategy." When vaccination ceases, it will be necessary to amend legislation to prohibit the import and use of vaccine and take appropriate measures to control remaining vaccine stocks.

In order to recover FMD-free status, evaluation is necessary to support proof of freedom and to reassure trading partners. Two types of evidence are required, and both should be well documented:

a) implementation (evidence that vaccination has been done well); and
b) impact (evidence that disease and infection no longer occur).

Monitoring of the implementation of the vaccination programme (evidence that vaccination has been done well)

The information required to monitor the implementation of the vaccination programme include vaccine efficacy, vaccine coverage and population immunity. See FAO and WOAH (2016, Chapter 4) for full details.

a) Vaccine efficacy (potency and match)

Vaccine efficacy is a measure of how well a vaccine protects an animal against disease, virus replication, virus shedding or virus transmission, when tested under controlled conditions where the vaccination and challenge infection are well characterized. The efficacy indicates the intrinsic quality of the vaccine. The efficacy of each batch of FMD vaccine should be guaranteed by the manufacturer. However, independent evaluation can provide additional

assurance of vaccine potency and strain suitability. It can also indicate the level of antibody expected in animals at a known time after vaccination, using a specific schedule and vaccine, and measured using a specific test. Ideally, this evaluation should be carried out prior to wider use of the vaccine. Whilst it is often not possible to complete such a study before a decision on vaccination is needed, the study is still worthwhile to provide reassurance to trade partners, and to help calibrate population immunity surveys.

Note: Vaccine efficacy differs from vaccine effectiveness. The latter is a measure of the protection afforded against a given undesirable outcome, usually disease or infection, derived from a comparison between the incidence of the outcome in vaccinated and unvaccinated animals within the same population. It not only depends upon the initial (intrinsic) quality of the vaccine, as supplied by the manufacturer, but also upon extrinsic factors, such as the impact of vaccine storage and distribution, the vaccine match, the vaccination schedule and, indirectly, vaccine coverage.

b) Vaccine coverage

Vaccine coverage is normally determined as the proportion of animals that are **eligible to be vaccinated** that are actually vaccinated. However, it can also have a different meaning, i.e. the proportion of the **entire susceptible population** that are vaccinated. Therefore, it is important to be clear about which denominator is being used.

The vaccine coverage required to control FMD depends upon the rate of spread of the virus – which is dependent upon the way the animals are kept and moved and other risk factors related to indirect virus spread. A target of 80 percent is often quoted for FMD.

Vaccine coverage is used as an indicator of the performance of the distribution and delivery system. The data should be stratified by species, age, geographical location and type of production system. The information on coverage is used for a variety of purposes: to monitor the performance of vaccination delivery; to guide disease control initiatives and to identify areas of weakness that may require extra resources and attention. Ideally, the vaccine tracking system should allow for individual batches of vaccine to be followed from central to local centres and to vaccinators.

c) Population immunity

Population immunity is differentiated into:

- overall population immunity (OPI), i.e. the proportion (percentage) of animals with immunity in the whole population susceptible to FMD; and
- vaccinated population immunity (VPI), i.e. the proportion of animals with immunity in the part of susceptible population targeted for vaccination.

Population immunity is a function of the vaccine coverage and the proportion of animals that responded to vaccination and includes immunity due to infection or maternally derived antibodies. The OPI is the best indicator of how readily the virus can spread and cause disease. The VPI is an indicator of the response to vaccination, and when combined with data on vaccine coverage, provides an overall measure of the quality of the vaccination programme. It is important to be clear on whether the aim is to sample only vaccinated animals or the entire population.

Population immunity surveys should be stratified by species, geographical location and type of production system. It is easiest to interpret immunity at around 21 to 28 days post vaccination. It may be possible to use a subset of the Non-Structural Proteins (NSP) survey samples collected during the vaccination campaign. In the case of multiple vaccination zones, the survey may be stratified by vaccination zone.

To assess whether the immunity is as expected, serological titres in the population may be compared to those elicited in animals given the same batch of vaccine under controlled conditions as part of the manufacturer's batch release testing procedure. Estimates of actual protection levels may also be made by comparison with serological findings from experimental vaccine/challenge tests and/or by serology that measures antibody levels to the specific outbreak virus.

See below for examples of vaccine coverage and population immunity calculations.

The impact of vaccination on the disease (evidence that disease and infection no longer occur)

Evidence of the impact of vaccination comes from three sources:

a) Epidemiological tracing

Epidemiological tracing requirements including identification of 'dangerous contact holdings' linked to infected holdings, where there are animals suspected of being infected or animals suspected of being contaminated from the same source. It is important that all dangerous contact holdings are followed up.

b) Clinical surveillance

Clinical surveillance should be carried out in the protection, surveillance and vaccination zones. In these guidelines, "protection zone" is the zone around and including the location of an outbreak, where disease control measures are applied in order to prevent the spread

BOX 1

Vaccine coverage and population immunity calculations

If: *Total population = 30 animals*
Eligible population = 24 animals
Vaccinated population = 20 animals
Immune population = 14 animals

Then: ***Vaccine coverage*** *(% of eligible animals actually vaccinated) is 20 out of 24 =* ***83%***
Vaccinated population *is 20 out of 30 =* ***67%***
Vaccinated population immunity *is 14 out of 20 =* ***70%***
Overall population immunity *is 14 out of 30 =* ***47%***

of the disease from that zone. The "surveillance zone" is the zone established around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from the protection zone. The "vaccination zone" is the area in which vaccination is to be carried out and may include parts or all of the protection and surveillance zones.

The timing and requirements for clinical surveillance in the protection, surveillance and vaccination zones may be specified in the relevant animal health legislation applicable to the country in which the outbreak has occurred.

c) Serosurveillance

The timing and requirements for serosurveillance in the protection, surveillance and vaccination zones may also be outlined in legislation or policy documents. Serosurveillance is particularly recommended for unvaccinated susceptible species where clinical surveillance is unreliable (such as sheep and goats) The within-herd and between-herd design prevalence of two to five percent should be based on applicable legislation.

In the **vaccination zone,** a proportion (which may be specified in legislation) of vaccinated animals and their non-vaccinated offspring must be sampled using the NSP serological test. The NSP test specifically measures the immune response to infection and not vaccination (as long as purified vaccines with reduced NSP contamination have been used). This assessment is useful to detect virus circulation in vaccinated animals.

Testing all vaccinated animals and their non-vaccinated offspring is referred to as "census sampling." Census sampling is resource intensive for field services and laboratories, and the availability of test kits needs to be considered. Whilst census sampling maximizes sensitivity, it causes specificity problems. If 100 000 animals are tested with a test of 99.5 percent specificity, around 500 false positive results may be expected. If a herd with 600 animals is tested, three false positive results may be expected. These will need to be classified as herds which are FMD-infected or FMD-free using other means, such as clinical and epidemiological investigations and further laboratory tests.

If there is evidence of continued transmission, this may be the result of inadequate immunity (due to poor vaccine quality or match, vaccination implemented late or insufficient animals correctly vaccinated) or inadequate controls (due to delayed detection and/or response, poor surveillance or inadequate biosecurity measures).

12. COMMUNICATIONS STRATEGY

The success of the emergency vaccination programme will depend on the awareness, acceptance and cooperation of the various stakeholders. The benefits and drawbacks of vaccination should be clearly explained in advance of implementing the vaccination campaign.

The aim, objectives and strategy for the vaccination campaign form the basis of the communication strategy and must be clear to all stakeholders.

A communications plan should identify the behavioural changes required, key stakeholders to target, strategies, tasks, messages, products and channels, timing, and monitoring and evaluation of effectiveness. Information for key stakeholders, e.g. veterinary staff, vaccination teams, private veterinary practitioners, farmers, meat and milk processers, retailers and consumers, should be prepared before commencing vaccination. The roles and responsibilities

of the key stakeholders in the communication plan should be clear. For more information, see *EuFMD Planning Risk Communication on FMD: A Guide* (2021).

Information for vaccination teams should include, e.g. notice of legislative authority to enter premises and vaccinate animals, herd/flock owner's rights, factsheets on FMD vaccination and movement controls, and information on support networks and sources of advice.

Some key messages on FMD emergency vaccination are shown in **Annex 3** below.

Checklist for emergency vaccination operational plan

A checklist containing the key elements required to implement the operational aspects of an emergency vaccination plan is provided in **Annex 4** below. The list is divided into three implementation phases (pre-vaccination, vaccination and post-vaccination operations) for ease of reference. However, there is significant overlap between some key elements and phases, and the allocation of specific elements to phases is less critical than ensuring all items in the plan are addressed.

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Annexes

Annex 1

Key information to be included in a call for tender when purchasing foot-and-mouth disease vaccine[3]

The information contained in this annex is indicative and may be adjusted depending on the legal requirements of each country, and other relevant factors.

a) Information about the vaccine required:

- the virus strain(s) to be included in the vaccine;
- the target species for vaccination;
- the number of doses requested;
- the volume of the vaccine dose and the number of doses per vial;
- the nature of the preferred adjuvant and the formulation of the vaccine; and
- special requirements concerning the label (e.g. size, language and warnings).

b) Information to be provided by the manufacturer

General requirements:

- The vaccine manufacture process and the quality control testing of the final batch and the finished product must be conducted in accordance with World Organisation for Animal Health (WOAH) standards.
- The vaccine must be produced in facilities that comply with appropriate requirements and under licence from the national regulatory authorities.

Specific requirements are as follows:

- vaccine type – specify the vaccine serotype(s) and strain(s);
- species – the FMD vaccine must be approved for use in the target animals;
- quantity – specify number of doses and doses per vial;
- route – specify route of administration;
- adjuvant – specify type of adjuvant (single oil emulsion, double oil emulsion, or aluminium hydroxide and saponin);
- potency – specify vaccine potency in PD_{50}[4] (*at least six PD_{50} is usually preferred*

[3] The information in Annex 1 is an extract from chapter 1 of FAO and WOAH, 2016.

[4] PD_{50} is the 50 percent Protective Dose = dose of vaccine that protects 50percent of the animals challenged. High potency vaccines provide broader protection.

for emergency vaccination), specify the onset (*usually two weeks*) and duration of immunity (*usually six months*);

- stability – the shelf life of the vaccine (finished product or batch) must be stated (*usually a period of at least 12 months*);
- reference sera – indicate if sera for homologous vaccine strains to use as reference standards in serological tests for post-vaccination monitoring can be made available to the tenderer;
- recommended vaccination schedule – a two-dose primary course is normally recommended to achieve six months of protection with a three PD_{50} vaccine, but a single dose at six PD_{50} may be sufficient for emergency vaccination depending on the vaccine match.

The tender dossier should be submitted in the desired language and must provide documentation/proof of all the points listed above, as well as the date and entry point of delivery, the storage recommendations and the expiry date.

Annex 2

Request for formulation of foot-and-mouth disease vaccine from antigen stocks in an antigen bank

The information is indicative and may be adjusted, depending on the legal requirements of the country, contractual terms, the epidemiological situation and so on.

1. What information may accompany a request for vaccine?

The information required is the vaccine serotype(s) and strain(s), species to be vaccinated, number of doses, formulation, vial size, delivery details and urgency of delivery.

a) Strain (s)

- There are seven serotypes and many strains of FMDV that can be genetically split into various topotypes and genetic lineages (genotype) of FMD, and the virus is constantly mutating creating new lineages.
- Vaccine matching can be carried out by a nominated reference laboratory.
- Vaccine matching (r1 values) uses heterologous intra-serotype serological tests such as Virus Neutralization Test (VNT) and liquid-phase blocking ELISA (LPBE) to evaluate the expected heterologous protection against the field isolate.
- r1 values of ≥ 0.3 (on a scale of 0–1) suggest that there is a close antigenic relationship between field isolate and vaccine strain. A potent vaccine containing the vaccine strain is likely to confer protection.
- r1 values below 0.3 suggest that the field isolate is antigenically different to the vaccine strain. Where there is no alternative, the use of this vaccine should follow careful consideration of vaccine potency, the possibility to use additional booster doses and monitoring of vaccinated animals for heterologous responses.
- The reference laboratory may make a recommendation on the most appropriate match to the affected country, after consultation with the supplier.
- It is feasible that more than one strain would be recommended in order to provide adequate protection.

- Data on currently circulating field isolates can be found in the World Reference Laboratory Quarterly Reports.
- A request for vaccine should not be sent to the supplier until the most appropriate match is known.

b) Number of doses and species

- The number of doses should at least equal the number of animals, and take into consideration possible vaccine wastage or loss during the vaccination campaign (which can reach 10 percent of more).
- One cattle dose = two ml (generally), therefore 100 ml = 50 cattle doses. The dose for sheep, goats & pigs may be 1ml to 2 ml.
- Only a single dose may be needed to elicit a protective response, due to the high potency of the vaccine. To ensure the claimed protection for the vaccine, the authorized vaccination schedule should be followed, which generally consists of a primary course of two doses.
- Only high potency vaccine should be requested for emergency use in countries previously free of FMD.
- There may be a minimum number of doses that can be formulated; if the request is for a smaller amount, there will be a need to agree how any surplus doses are dealt with, e.g. where they are stored and who is responsible for them and who bears the costs.
- Any unused vaccine should be kept for the duration of the shelf-life at the recommended storage temperature of +2 to +8 degrees C for most vaccines.

c) Formulation

Vaccines available for emergency use are generally conventionally manufactured inactivated products, although a novel live-vectored vaccine has been licensed in the United States of America (adenovirus-vectored A24 topotype). Inactivated FMD vaccines are fixed formulations containing a defined quantity of one or more BEI[5] inactivated cell-culture-derived preparations of FMD strains manufactured using a seed-lot system and blended with adjuvant/s and excipients for an aqueous or oil based vaccine. The following information refers to conventionally manufactured inactivated vaccines.

The type of formulation and adjuvant will depend on the target species and may be mineral oil or aqueous based. For cattle and other ruminants, either aluminium hydroxide and saponin adjuvanted aqueous vaccines, mineral oil (e.g. liquid paraffin as an oil/water emulsion) or double oil emulsion (water-in-oil-in water) adjuvanted vaccines may be used. For pigs, mineral oil-based vaccines, formulated as a water-in-oil-in water emulsion are generally preferred to ensure adequate protective immune responses. For emergency use, where both ruminants and pigs are vaccinated, the preferred vaccines of choice are oil emulsion adjuvanted vaccines.

[5] BEI: Binary ethyleneimine – commonly used for inactivation of FMD virus during vaccine manufacturing.

Vaccines for emergency use should have high potency (≥ six PD50) and meet WOAH standards for manufacture, pharmaceutical quality, safety and efficacy.
Labels will be in one of the official languages of the country of destination (except in the case of **immediate supply** – when labelling in English may be considered sufficient with agreement of the competent authority).

An **Early Release Certificate** testifies that the recipient country agrees to the manufacturer delivering vaccine before completion of the final quality control tests, according to the "Emergency Use" conditions prescribed by the European Pharmacopeia 9th Edition, Monograph 01/2017:0063. If a country wishes to use the vaccine immediately it is available, an Early Release Certificate should be requested.

d) Container/bottle/vial size

FMD vaccine primary container or bottle/vial tend to be plastic and can range from small bottles (10-20 ml or 5-10 cattle doses) through to relatively large sizes of 250-500 ml (125 to 250 doses). Veterinary authorities should consider the target populations to be vaccinated, the size of the farms, herds or units when placing vaccine orders and discuss the optimal bottle size with the manufacturer as the number of doses supplied in an emergency can be limited by the bottle size due to the fill-run capacity in the bottling facility.

e) Delivery details

- The destination airport(s) should be specified.
- Appropriate contact persons must be specified (name, address and telephone number of the authority or institution to where the vaccine will be delivered).

f) Urgency of delivery

- The request should specify whether the vaccine is required for "immediate supply" or "urgent but not immediate supply."
- "Immediate supply" generally means that vaccine will be delivered to the destination within <7 days of receipt of the notification by the vaccine supplier, but this will vary with the contract conditions between the supplier and the country/ies requesting supply.
- There will be an additional lead-in time for transport from the destination site (e.g airport of country receiving the shipment) to vaccine storage site(s) in the destination country.

Annex 3

Key messages on foot-and-mouth disease vaccination

1. Currently, there is no universal FMD vaccine. There are multiple serotypes and many strains of FMD, and FMD vaccines must closely match the infecting strain. Vaccination with one serotype does not protect the animal against other serotypes and may not protect the animal completely or at all from other strains of the same serotype.

2. FMD vaccines work like other vaccines used to protect animal health – by stimulating an immune system response to produce antibodies against the virus.

3. The objective in vaccinating contact animals and animals on nearby farms is to reduce the amount of virus that exposed animals might transmit, to reduce environmental contamination by the virus, and to help control the outbreak.

4. For trade, the World Organisation for Animal Health (WOAH) has specific guidelines depending on the FMD status of a country. Use of vaccination during an outbreak would affect and could delay the return to FMD-free status.

5. If vaccination is used to help control an outbreak, vaccination would be conducted under the control of the government.

6. It is important that vaccinated animals are properly identifed and that this is documented to regain trade status.

7. If properly handled and administered, emergency vaccines that are currently available are 90–100 percent effective in generating an immune response and are effective in preventing disease or greatly reducing transmission.

8. All vaccines go through a licensing process which assesses the safety of the vaccine and establishes appropriate pre-market withdrawal periods if necessary.

9. When vaccination is used and vaccinated animals are allowed to enter the market, appropriate withdrawal periods will be followed.

10. The vaccine is made with a killed virus and cannot cause infection in humans or animals.

11. We routinely vaccinate animals for many diseases, and the vaccines are not detectable in meat or milk.

12. FMD vaccines are used on a daily basis to protect animals from disease in countries where FMD is endemic, and the specific strain affecting that area is known. Approximately 2.38 billion[6] doses of FMD vaccine are administered annually worldwide (Miller, 2018).

13. Millions of people worldwide safely consume meat and milk from animals vaccinated against FMD.

[6] EuFMD is developing a calculator for the annual worldwide use of FMD vaccines, which may be used to update this figure.

Annex 4

Checklist for developing an foot-and-mouth disease emergency vaccination operational plan

Key element	Implementation phase	Policies, plans, standard operating procedures (SOPs), work instructions, checklists or templates required
Logistics	Pre-vaccination operations	☐ FMD confirmation, genotyping, vaccine matching, doses available, decision on formulation, adjuvant, dosage request ☐ Template for vaccine request submission to vaccine bank, in compliance with any relevant legislation ☐ Template for ordering formulation, and/or purchase of vaccine from national bank/vaccine manufacturer/supplier ☐ Vaccine importation (including air transport waybill), customs clearance and licensing (where relevant), including communication and logistical coordination with vaccine manufacturer/supplier, and relevant contact persons ☐ Specifications for central designated vaccination storage centre/field vaccine distribution point or equivalent ☐ Location, responsibilities and contact details of national vaccination manager/central designated vaccination storage centre(s) or equivalent (identify in advance) ☐ Location, responsibilities and contact details of local vaccination manager/field vaccine distribution point(s) or equivalent (identify in advance) ☐ Responsibility for cold chain maintenance and verification within storage centre facilities (including e.g. contracts, supply arrangements with commercial providers) ☐ Responsibility for supply of vaccination equipment to accompany vaccine (including e.g. contracts, supply arrangements with commercial providers) ☐ Appropriate transport for vaccine, equipment, personnel and funding for maintenance and fuel
	Vaccination operations	☐ Control of FMD vaccine by national vaccination manager/ central designated vaccination storage centre or equivalent ☐ Ordering and control of FMD vaccine by local vaccination manager/field vaccine distribution point or equivalent ☐ Vaccine stock control and information requirements for orders of vaccine received and dispatched, including: • batch number and expiry date • quantity provided or received • source • contact details or recipient responsible for vaccine • dates of transport • vehicle identification • intended use: administer to animals or destruction ☐ Vaccine storage and handling guidelines ☐ Vaccine package insert and user instructions in national language

(Cont.)

Key element	Implementation phase	Policies, plans, standard operating procedures (SOPs), work instructions, checklists or templates required
Logistics	Post-vaccination operations	☐ Responsibility for inventory control and steps for managing vaccine distribution and reconciliation ☐ Quality assurance and auditing (inventory of vaccine used, including following minimum information): • batch numbers (serial number, expiry date) • legal description of vaccination zone and premises location • date of vaccination • identification numbers of vaccinated animals • temperature log data for cold chain • any additional information deemed appropriate ☐ Vaccine inventory template
Personnel	Pre-vaccination operations	☐ Organizational structure (chart) of the vaccination coordination and delivery network ☐ National vaccination manager/central designated vaccination storage centre or equivalent ☐ Regional/local vaccination manager/field vaccine distribution point or equivalent ☐ Responsibility for cold chain management ☐ Responsibility for supply of vaccination equipment ☐ Coordination between various organizational levels and stakeholders (veterinary services, commercial suppliers, etc.)
	Vaccination operations	☐ Identify source of personnel to comprise vaccination teams ☐ Procurement contract template for vaccination personnel ☐ Vaccination team size, structure, functional roles ☐ Training requirements and delivery methods ☐ Vaccinator training content developed ☐ Legislative authority to vaccinate ☐ Workplace health and safety guidelines, e.g. hazard register template, emergency SOP for needle stick injury, etc. ☐ Vaccination team work flow/process (chart)
	Post-vaccination operations	☐ Post-vaccination field visit debriefing checklist ☐ Capturing records upon return from vaccination field visits
Biosecurity	Pre-vaccination operations	N/A
	Vaccination operations	☐ Biosecurity procedure for entry-exit of premises to be vaccinated ☐ Instructions on good vaccination practice ☐ Training requirements and delivery method ☐ Personal protective equipment (PPE) checklist ☐ Cleaning and disinfection checklist
	Post-vaccination operations	☐ Bio secure decontamination, and/or disposal and reconciliation of unused vaccine and disposable equipment

(Cont.)

Key element	Implementation phase	Policies, plans, standard operating procedures (SOPs), work instructions, checklists or templates required
Surveillance	Pre-vaccination operations	☐ Database of herds including herd size, species, category, location, contact details, private veterinarians, regional/ local veterinary authority ☐ Generating lists of priority areas, premises, species to be targeted for vaccination ☐ Surveillance protocols (e.g. active telephonic surveillance, pre-vaccination property visits, etc.) to assess likelihood of FMD infection being present on premises prioritized for vaccination ☐ Nature of pre-vaccination farmer/manager contact ☐ Farmer contact checklist
	Vaccination operations	☐ Pre-vaccination property risk assessment ☐ Clinical surveillance of animals to be vaccinated ☐ Protocol in case of FMD suspicion ☐ Checklist for sampling and inspection ☐ Protocol if FMD infection confirmed ☐ Administering vaccine to livestock ☐ Vaccination kit checklist ☐ Adverse vaccine reaction recording template ☐ Information package for vaccinated premises
	Post-vaccination operations	☐ Refer to post-vaccination monitoring and vaccination programme evaluation plan
Livestock identification and traceability	Pre-vaccination operations	☐ Responsibility for supply of animal identification equipment to accompany vaccine (including, e.g. contracts, arrangements with commercial suppliers)
	Vaccination operations	☐ Permanent identification type for vaccinated animals, per species/production sector/holding type, etc. ☐ Vaccinated animal identification equipment checklist ☐ Vaccinated animal identification recording template
	Post-vaccination operations	☐ Quality assurance and auditing (record the following minimum information, if applicable): • Movement permits (origin and destination) of any vaccinated animals • Date and location of destruction or slaughter • Destination and intended end-use of animal products ☐ Data entry operations manual

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Developing an emergency vaccination plan for foot-and-mouth disease (FMD) in FMD free countries

Corrigendum

[28/11/2022]

The following corrections were made to the PDF of the report after it went to print.

The publication has been amended to remove reference to specific disease control legislation, making it more widely applicable to FMD-free countries.

Page	Location	Text in printed PDF	Text in corrected PDF
31	Annex 3	Annex 3: Movement controls in the vaccination zone as set out in Council Directive 2003/85/EC	Removed
30	Figure 2	Summary of the EU Process following decision to vaccinate	Removed
	Throughout	OIE Office international des épizooties	WOAH World Organization for Animal Health
5	5. Logistics	For tendering processes "Key information to be provided by the tenderer and manufacturer of the vaccine" is set out in Annex 1 below. For EU Member States who wish to request vaccine from the EU Antigen Bank, a list of key information required for a "Request for formulation of FMD vaccine from antigen stocks in the EU antigen bank" can be found in Annex 2 below.	When purchasing through a tender process, it is important to include key information in the call for tender, to enable the manufacturer to provide an appropriate tender dossier. "Key information to be included in a call for tender" is set out in Annex 1 below. For countries intending to request vaccine from an existing Antigen Bank, a list of key information required for a "Request for formulation of FMD vaccine from antigen stocks in an antigen bank" can be found in Annex 2.
6	6.Personnel	The decision may depend upon the severity of the crisis, and the resulting strain on resources and the availability of competent lay vaccinators.	The decision may depend upon the severity of the crisis, the strain on resources and the availability of competent lay vaccinators.
14	11.Vaccination evaluation and exit strategy	Implementation of the vaccination program	Monitoring of the implementation of the vaccination program
22	Annex 1	Key information to be provided by the tendered and manufacturer of the vaccine	Key information to be included in a call for tender when purchasing FMD vaccine
22	Annex 1		Added: The information contained in this annex is indicative, and may be adjusted depending on the legal requirements of each country, and other relevant factors.
22	Annex 1	a) Information to be provided by the tenderer:	a) Information about the vaccine required:

This guide to developing an emergency vaccination plan for foot-and-mouth disease aims to provide support to foot-and-mouth-free countries in the preparation of their emergency vaccination plans. It sets out the recommendations for the structure and content of an emergency vaccination plan once the decision to vaccinate has been made.

The document is intended to be used by veterinary contingency planners in foot-and-mouth disease free countries. This guide will help you define the key elements of the emergency vaccination plan in accordance with legislation and international standards.

An emergency vaccination plan should be adapted to the context and requirements of each country and should be drafted in advance of an emergency. The plan can be further updated in response to lessons identified through exercises or disease incidents or changes in legislation and international standards.

The concepts presented in this guide can also be adapted to other animal health threats.

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