

CHAPTER 11

VACCINATION

INTRODUCTION

Routine prophylactic vaccination against FMD is prohibited within the EU. However, under certain exceptional circumstances, emergency vaccination may be used. This chapter describes the situations in which vaccination may be used, the criteria to be taken into account when deciding to use vaccination, the details to be included in a vaccination plan and the restrictions that will apply to the movement of animals when emergency vaccination has been used.

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1. PROHIBITION ON ROUTINE PROPHYLACTIC VACCINATION

- 1.1 Under Article 13.1 of Council Directive 85/511/EEC, and Article 49 of the draft Commission proposal to amend the Directive [Document COM (2002) 736 – March 2003] the use of vaccine against FMD is prohibited.
- 1.2 The use of FMD vaccine has been prohibited in the EU since 1992, and has never been permitted in Ireland.

2. EMERGENCY VACCINATION

- 2.1 By way of derogation from this prohibition, emergency vaccination is permitted under Article 13.3 of Council Directive 85/511/EEC under certain circumstances.
- 2.2 If a Member State wishes to avail of this derogation it must present a detailed vaccination plan to the Commission and the Member States at the Standing Committee of the Food Chain and Animal Health (SCoFCAH).
- 2.3 Article 50.3 of the draft proposal to amend the Directive states that the decision to vaccinate must be adopted by SCoFCAH procedure, at the request of the Member State directly affected by an FMD outbreak, or a Member State at risk from another Member State which is affected.
- 2.4 Article 50.6 provides for emergency vaccination in an infected Member State to be proposed by the Commission, where certain conditions apply, and in consultation with the Member State.
- 2.5 Article 50.4 allows a Member State to introduce emergency vaccination without SCoFCAH approval after written communication of its Vaccination Plan to the Commission. This would then be reviewed at the next SCoFCAH meeting.

3. DECISION TO VACCINATE

- 3.1 Article 50 of the draft Commission proposal to amend the Directive [Document COM (2002) 736 final] would allow the possibility of emergency vaccination to be considered in Ireland if one of the following criteria were met:
 - outbreaks of FMD have been confirmed in Ireland and threaten to become widespread
 - other Member States are at risk due to the geographical situation or the prevailing meteorological conditions from FMD outbreaks in Ireland
 - other Member States are at risk due to epidemiological links between holdings on their territories and holdings keeping animals of susceptible species in Ireland (when FMD outbreaks have been confirmed in Ireland)
 - Ireland is at risk due to the geographical situation or the prevailing meteorological conditions from an FMD outbreak in a neighbouring country.

- 3.2 The decision to vaccinate will depend on:
- the criteria listed in **Annex 1**
 - access to suitable vaccine in sufficient quantities (see **Section 4**)
- 3.3 The NDCC, in consultation with the National Expert Epidemiology Group, will assess these factors and make their recommendations to the Minister.

4. VACCINE SUITABILITY AND AVAILABILITY

- 4.1 Prior to a decision to vaccinate being taken, an appropriate vaccine must be available, in sufficient doses, which can be delivered to the infected area within a short time period.

4.2 Characterisation of the virus

- a) Upon confirmation of FMD in Ireland (by the isolation of virus from samples submitted to IAH Pirbright), the Irish authorities will request that the IAH characterise the virus in terms of strain, serotype, topotype, nucleotide sequencing and antigen relationship with other viruses. This will be carried out for epidemiological purposes and to determine the relationship between the field strain and the vaccine strains available in the EU and International vaccine banks.
- b) The characterisation is carried out using:
- nucleotide sequencing for genetic relationship
 - serological methods e.g. the Antigen Capture ELISA (ACE) for serotype
 - monoclonal antibody for epitope typing.

4.3 Determination of suitable vaccine strains

The “r” value (the ratio of the titres of the field strain virus to the homologous vaccine strain virus) indicates the level of protection that the vaccine strain is likely to give against the field strain of virus. The “r” value will be determined by cross neutralisation between the field strain and available vaccine strains. An “r” value of between 0.5 and 1.0 is likely to give a good measure of protection against the field strain.

4.4 Vaccines currently available in the International and European Vaccine Banks

A number of vaccine strains are available in the International Vaccine Bank at Pirbright (UK) and the European Vaccine Banks at Lyons (France), Brescia (Italy) and Meriel (UK).

4.5 Access to the International Vaccine Bank

Ireland is a member of the International Vaccine Bank and therefore has access to the FMD vaccine stored there. It is intended to increase Ireland’s drawing rights from the International Vaccine Bank to **500,000 doses** of six PD⁵⁰ vaccine in the short term (PD = Protective dose).

4.6 Access to the European Vaccine Bank

The second source of vaccine is the European Vaccine Bank. Ireland's drawing rights from this bank are the same as for each of the other Member States. Access to the vaccine would be decided at the SCoFCAH.

4.7 Access to commercial sources of vaccine within Europe

- a) If an adequate or suitable supply is not available from either of the vaccine banks, recourse would have to be made to an authorised FMD vaccine manufacturer. There are currently three of these in Europe. In these circumstances, Ireland would seek the supply of vaccine which has already been manufactured and available for sale.
- b) The European Manufacturers with facilities or facilities available and approved for the production of FMD vaccine under Directive 85/511/EEC are:
 - Bayer AG Animal Health AH-OP-Biologicals/RD,
Agriculture Center, Monheim Building, 6210 Alfred Noble Straße 50, D51368
Leverkusen, Germany
Fax +49 2173-384871
 - Intervet International
P.O.Box 31, 5830 AA Boxmeer, The Netherlands
Tel + 31 485 585228, Fax + 31 485 587491
 - Merial Animal Health Ltd
Ash Road, Pirbright, Woking, GU24 ONF, Surrey, United Kingdom
Tel +44 (1483) 238111, Fax +44 (1483) 238102
- c) If a commercial vaccine is also unavailable, Ireland could seek a special production of a vaccine derived from the field strain. The delay in such production would be four to **five weeks**. The ability of the isolate to grow to high titre would be a consideration in vaccine production.

4.8 Authorisation

- a) To obtain vaccine from the International Vaccine Bank agreement would have to be obtained from the Bank's Commissioners (i.e. the representatives from each member country - UK, Australia, New Zealand, Ireland, Malta, Finland, Sweden). The CVO requests authorisation from the Commissioners to release the appropriate vaccine strain.
- b) In accordance with Directive 2001/82/EC, recourse to an unauthorised vaccine is only permitted if there is no authorised vaccine available for the condition concerned. Products from outside the EU may only be considered if they are manufactured in accordance with Good Manufacturing Practice (GMP).
- c) Established vaccine strains which are prepared in advance, are required in quality terms to be free from extraneous agents, meet the criteria of inactivation and identity as laid down in the general guidelines and monographs and in accordance with Annex 2 of Council Decision 91/666/EC.

4.9 Approval

- a) Procedures to ensure the formulation, production, bottling and distribution of FMD vaccine produced from the antigen shall be designated in accordance with a decision of the SCoFCAH.
- b) Should Ireland wish to seek approval from the European Commission for the use of FMD vaccine, a vaccination plan will be drawn up (meeting the criteria set out in **Section 5** below), for presentation to the SCoFCAH. A proposal by way of a draft Commission Decision will be presented by the Commission to the Committee for voting. If the proposal is rejected by the Committee, it will be referred to the Council of Ministers.

4.10 Formulation

- a) The Community will make arrangements for formulation, production, bottling and distribution of vaccines from antigens stored in the European Vaccine Banks.
- b) Annex 2 of Council Decision 91/666/EC states that vaccines shall be formulated in accordance with the prescription of the producer.
- c) Vaccines for pigs will be formulated as oil emulsions. Vaccines for cattle may be formulated using aluminium hydroxide, saponin or oil-adjuvant (paragraph 5b of Annex 2 of Council Decision 91/666/EC).

4.11 Transportation

Paragraph 9 of Annex 2 of Council Decision 91/666/EC requires formulated vaccines to be kept under cool temperature conditions as specified in the European Pharmacopoeia. Care should be taken to maintain the correct temperature during distribution until the vaccine is administered.

4.12 Usage

Vaccine will be transported to the Central Veterinary Research Laboratory, which is the designated place for storage pending further transportation to the point of use. Arrangements for distribution and delivery of the vaccine are set out in the **Irish FMD Emergency Vaccination Plan** (currently in draft).

5. VACCINATION PLAN

- 5.1 Article 14.3 of the draft Commission proposal to amend Council Directive 85/511/EEC [Document COM (2002) 736 final] requires the Competent Authority to make arrangements for emergency vaccination in an area **at least the size of the Surveillance Zone**, immediately the first outbreak of disease is confirmed.
- 5.2 A vaccination plan will be drawn up which will take into account the particular circumstances of the outbreak. In accordance with the criteria in Article 51 of the draft proposal, the plan will include the following details:
- extent of the geographical region in which vaccination is to be carried out
 - species and age of animals to be vaccinated
 - duration of vaccination programme
 - movement controls to be introduced on vaccinated and unvaccinated animals
 - identification and registration of the vaccinated animals.
- 5.3 The logistics for the implementation of a vaccination campaign are detailed in the **Irish FMD Emergency Vaccination Plan** (currently in draft).

6. SUPPRESSIVE AND PROTECTIVE VACCINATION

6.1 Suppressive vaccination (vaccination followed by slaughter)

- a) Article 2 of the draft proposal to amend 85/511/EEC [Document COM (2002) 736 – March 2003] defines suppressive vaccination as:

‘Emergency vaccination which is carried out exclusively in conjunction with a stamping out policy, in a holding or area, where there is an urgent need to reduce the amount of virus circulating and to reduce the risk of it spreading beyond the perimeters of the holding or area, and where the animals are intended to be destroyed following vaccination.’

- b) Under Article 53 of the draft proposal, where suppressive vaccination is used:
- it may only be used within the Protection Zone
 - it may only be used on clearly identified holdings on which the measures which apply to an FMD infected holding are applied (see Chapter 14, **Controls following confirmation of disease**)
 - slaughter may be delayed if necessary for logistical reasons to comply with EU requirements on welfare at slaughter and disposal of carcasses by rendering
 - control measures to be applied by the Competent Authority are at least those required in Protection and Surveillance Zones, and are notified to the Commission.

6.2 Protective vaccination (vaccination to live)

a) Article two of the draft proposal defines protective vaccination as:

‘Emergency vaccination carried out on holdings in a designated area in order to protect receptive animals within this area against airborne spread or spread through fomites of FMD virus and where the animals are to be kept alive following vaccination’.

b) Under Article 52 of the draft proposal, where protective vaccination is used:

- the vaccination zone must be regionalised
- the vaccination zone must be surrounded by a surveillance area (as per OIE rules) of at least 10 km radius from the perimeter of the vaccination zone in which:
 - vaccination is prohibited
 - intensified surveillance is carried out
 - movement controls on susceptible species are in place
 - and which remains in place until OIE FMD-free status is recovered
- vaccination must be carried out swiftly and in conformity with the principle rules on hygiene and biosecurity, to avoid further spread of FMD virus
- the measures which apply to Protection and Surveillance Zones continue to apply to those holdings falling within the relevant Zones
- when the Protection and Surveillance Zones have been lifted, the measures applying to vaccination zones continue to apply (see **Annex 2** below).

c) Under Article 64 of the draft proposal, no vaccinated animal may be traded to another Member State.

7. MEASURES TO BE TAKEN WITHIN AND AROUND A VACCINATION ZONE

7.1 Articles 54-58 of the draft Commission proposal to amend Council Directive 85/511/EEC [Document COM (2002) 736 – March 2003] lays down the measures to be taken within and around a vaccination zone during the following phases:

- **Phase 1:** From the start of the vaccination campaign until 30 days after the campaign has been completed
- **Phase 2:** From 30 days after the completion of vaccination until the clinical/serological survey has been carried out and classification of herds/flocks has been completed
- **Phase 3:** From classification of herds/flocks until OIE FMD-free status has been recovered.

7.2 The measures to be taken are summarised in the diagrams in **Annex 2** below.

8. RECOVERY OF FMD INFECTION FREE STATUS WITH OR WITHOUT VACCINATION

The recovery of FMD infection free status of a region or Member State following vaccination is established by SCoFCAH procedure, taking account of the following criteria:

8.1 Article 60 of the draft proposal allows for recovery of FMD infection free status **without vaccination** when the following criteria have been met:

- the measures applicable in the Protection and Surveillance Zones have been completed and
- the relevant OIE rules have been complied with and/or
- at least three months have elapsed since the last outbreak and clinical/serological surveillance has been carried out in accordance with the Zone Clearance protocol in Annex 1 of Chapter 17, **Creation of control zones, census and surveillance**

8.2 Article 61 of the draft proposal allows for recovery of FMD infection free status **with emergency vaccination** when the following criteria have been met:

- the measures applicable in the Protection and Surveillance zones have been completed and
- the vaccination campaign, sero-surveillance and classification of herds/flocks have been completed and
- either the relevant OIE rules have been complied with
- or at least three months have elapsed since the slaughter of the last vaccinated animal, and serological surveillance has been carried out in accordance with OIE guidelines
- or at least six months have elapsed since the last outbreak of FMD or the completion of the vaccination campaign (whichever is later), and serological surveillance for non-structural protein (NSP) antibodies has been carried out in accordance with OIE guidelines, demonstrating absence of infection in vaccinated animals.

ANNEX 1

CRITERIA FOR THE DECISION TO APPLY PROTECTIVE VACCINATION

(as per Annex X of draft Commission proposal to amend 85/511/EEC)

[Document COM (2002) 736 – March 2003]

1. CRITERIA IN ACCORDANCE WITH THE REPORT OF THE SCIENTIFIC COMMITTEE ON ANIMAL HEALTH 1999

CRITERIA	DECISION	
	FOR VACCINATION	AGAINST VACCINATION
Population density of susceptible animals*	High	Low
Clinically affected species	Pigs	Ruminants
Movement of potentially infected animals or products out of the protection zone (taking into account the presence/absence of susceptible wildlife in the area)	Evidence	No evidence
Predicted airborne spread of virus from infected holdings	High	Low/Absent
Suitable vaccine (with high potency for all species, appropriate strains, sufficient doses)	Available	Not available
Origin of outbreaks	Unknown	Known
Incidence slope of outbreaks	Rising rapidly	Shallow or slow rise
Distribution of outbreaks	Widespread	Restricted
Public reaction to total stamping out policy	Strong	Weak
Acceptance of regionalisation after vaccination	Yes	No

* see definition of **Densely Populated Livestock Areas** on page 3 of this Annex

2. ADDITIONAL CRITERIA FOR THE DECISION TO APPLY EMERGENCY VACCINATION

CRITERIA	DECISION	
	FOR VACCINATION	AGAINST VACCINATION
Acceptance of regionalisation by third countries	Known	Unknown
Economic assessment of competing control strategies	If it is foreseeable that a control strategy without emergency vaccination would lead to significantly higher economic losses in the agricultural and non agricultural sectors	If it is foreseeable that a control strategy with emergency vaccination would lead to significantly higher economic losses in the agricultural and non agricultural sectors
It is foreseeable that the 24/48 hours rule cannot be implemented effectively for two consecutive days ⁽¹⁾	Yes	No
Significant social and psychological impact of total stamping out policy	Yes	No
Existence of large holdings of intensive livestock production	Yes	No

- 1) 24/48 hours rule means:
- a) infected herds on confirmed infected holdings cannot be stamped out within 24 hours after the confirmation of the disease, and
 - b) the pre-emptive killing of animals likely to be infected or contaminated cannot be safely carried out within less than 48 hours.

3. CRITERIA FOR THE DEFINITION OF DENSELY POPULATED LIVESTOCK AREAS (DPLAS)

When deciding about the measures to be taken in application of the Directive, and in particular the measures provided for in Article 52 (2) (i.e. vaccination zones), Member States shall in addition to a thorough epidemiological assessment, consider the provisional definitions of DPLAs (for the relevant species of susceptible animals predominantly kept in the area in question and use the definition which is the more stringent.

The provisional definition may be modified in the light of new scientific evidence in accordance with the SCoFCAH procedure

3.1. Porcine animals:

In the case of pigs, a DPLA is a geographical area with a radius of 10 km around a holding containing susceptible animals suspected of or infected with foot-and-mouth disease, where there is a pig density higher than 800 pigs per km². The holding in question must be situated either in a sub-region as defined in Article 2 (s) (*i.e. in Ireland's case this is a county as defined in Commission Decision 200/807/EC for notification of disease outbreaks on the ADNS*) where there is a density of pigs higher than 300 pigs per km² or at a distance of less than 20 km from such a sub-region.

3.2. Animals of susceptible species:

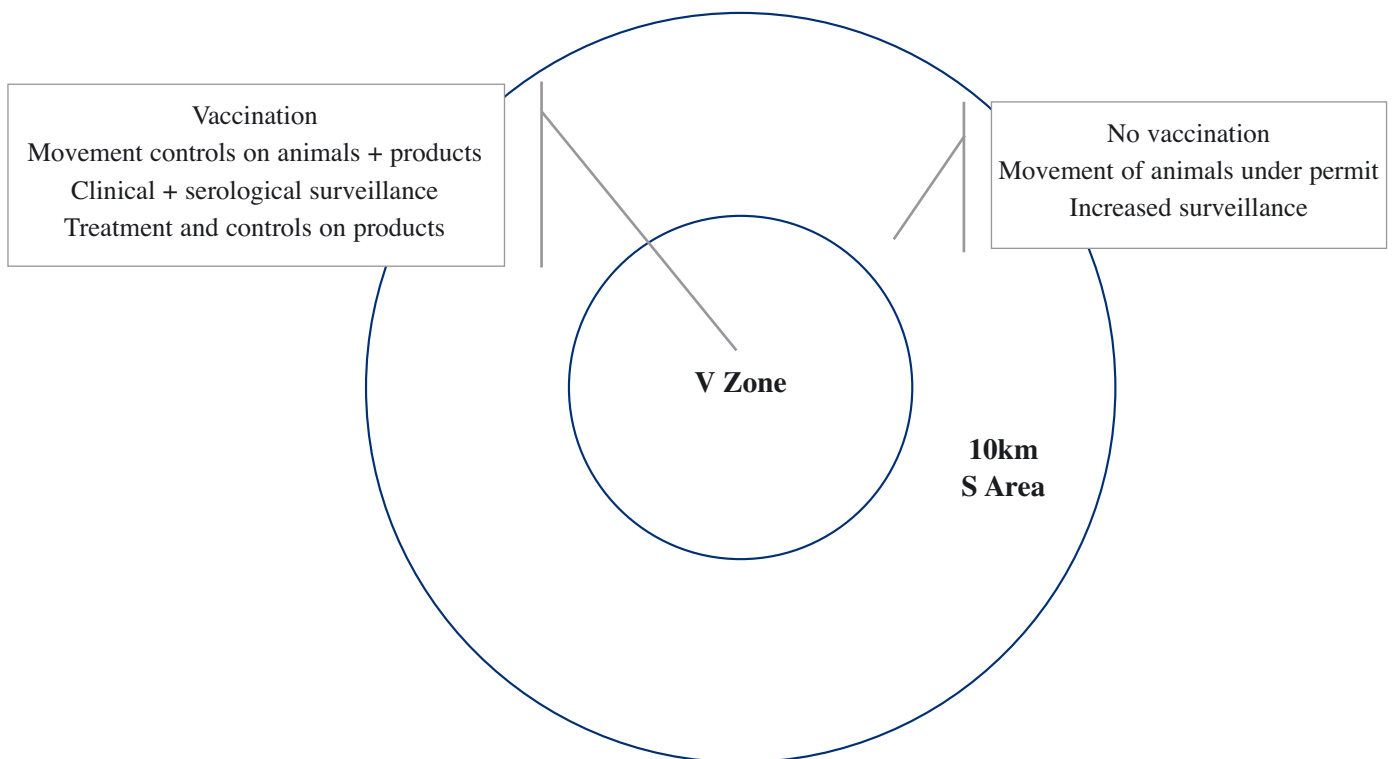
In the case of animals of susceptible species, a DPLA is a geographical area, an area complying with the conditions for porcine animals, or an area with a radius of 10 km around a holding containing susceptible animals suspected of or infected with foot-and-mouth disease, where there is a density of animals of susceptible species higher than 1000 head per km². The holding in question must be situated either in a sub-region as defined in Article 2 (s) (*i.e. in Ireland's case this is a county as defined in Commission Decision 200/807/EC for notification of disease outbreaks on the ADNS*) where there is a density of animals of susceptible species higher than 450 head per km² or at a distance of less than 20 km from such a sub-region.

ANNEX 2

CONTROL MEASURES APPLYING TO FMD VACCINATION

(Articles 52-58 and 61 of draft Commission proposal to amend 85/511/EEC [Document COM (2002) 736 – March 2003])

Article 52



Article 61

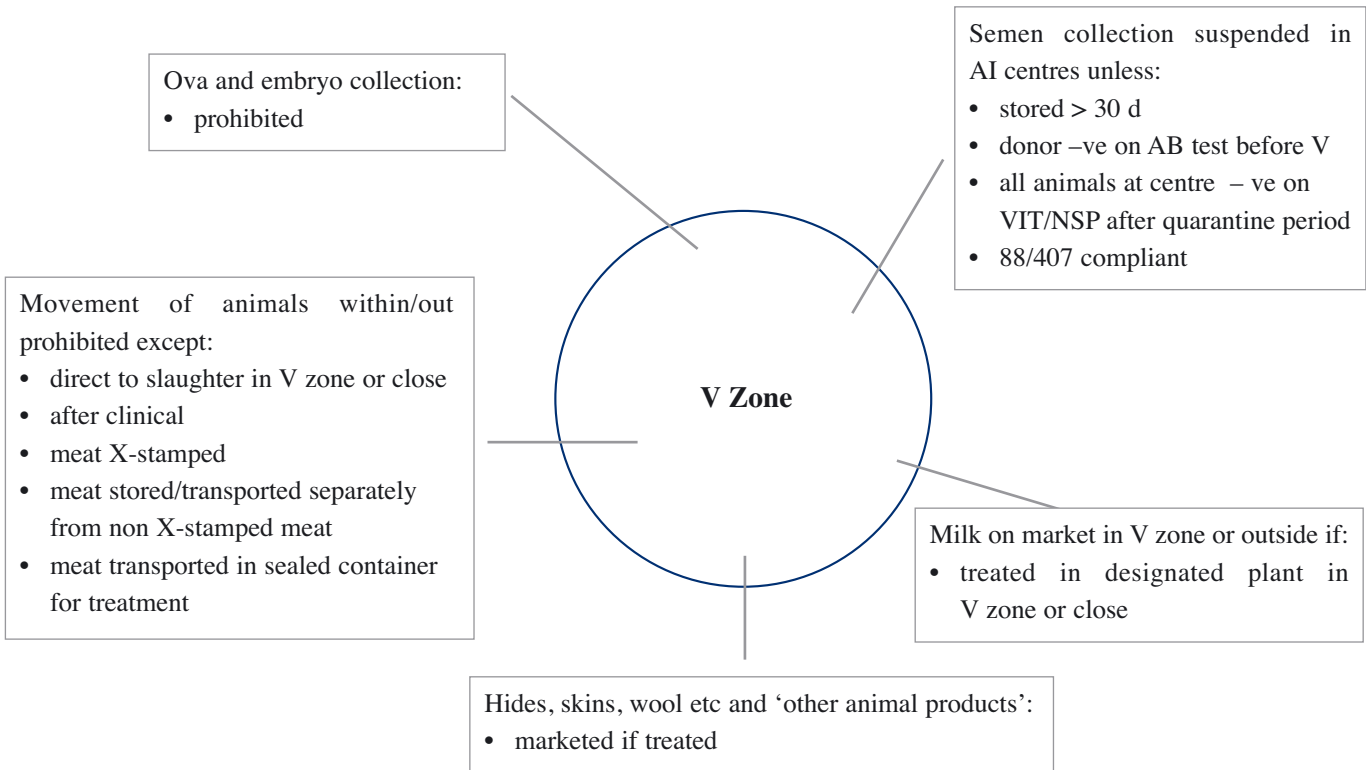
Zones remain in place until:

- the measures applying to Protection and Surveillance Zones have been completed and
- OIE FMD-free status has been recovered or
- at least three months have passed after slaughter of the last vaccinated animal and the sero-survey (as per OIE) has been completed or
- at least six months have passed after the last outbreak or vaccination has been completed and the sero-survey for NSPs (as per OIE) has been completed

EU FMD-free status will then be decided at the SCoFCAH

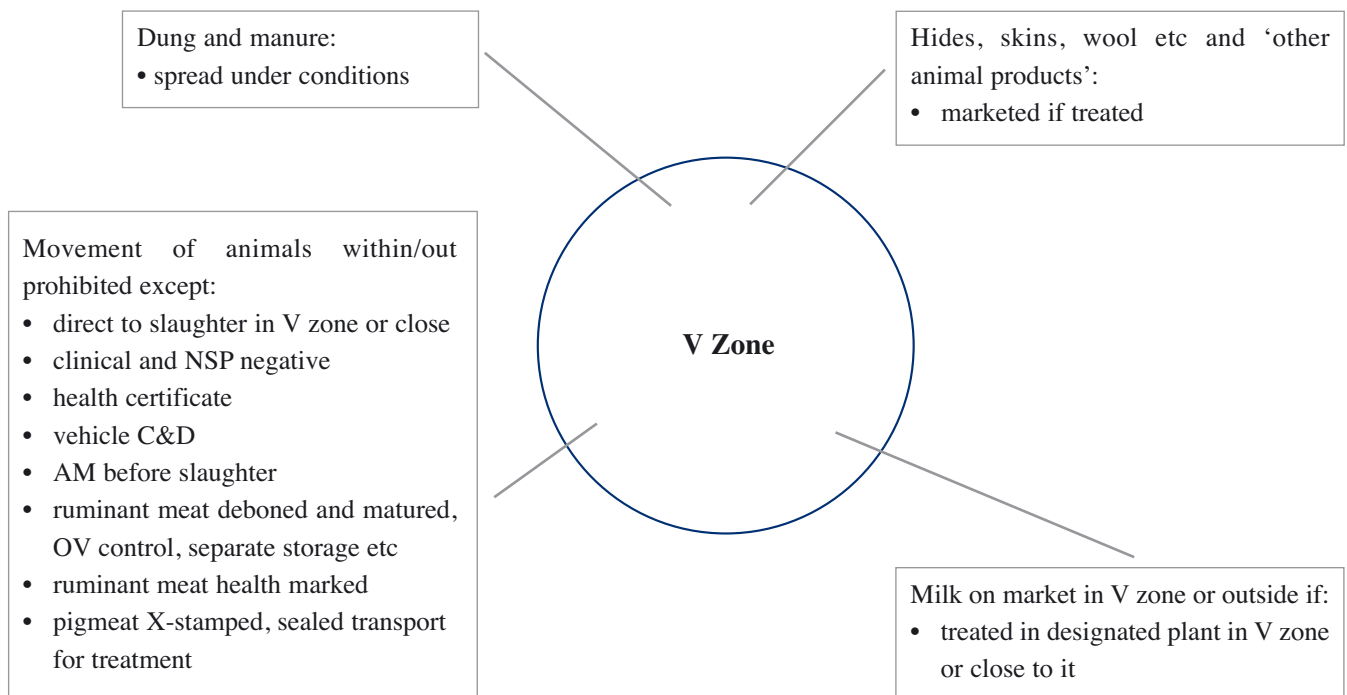
ARTICLE 54

PHASE 1 (DURING VACCINATION CAMPAIGN + 30 DAYS)



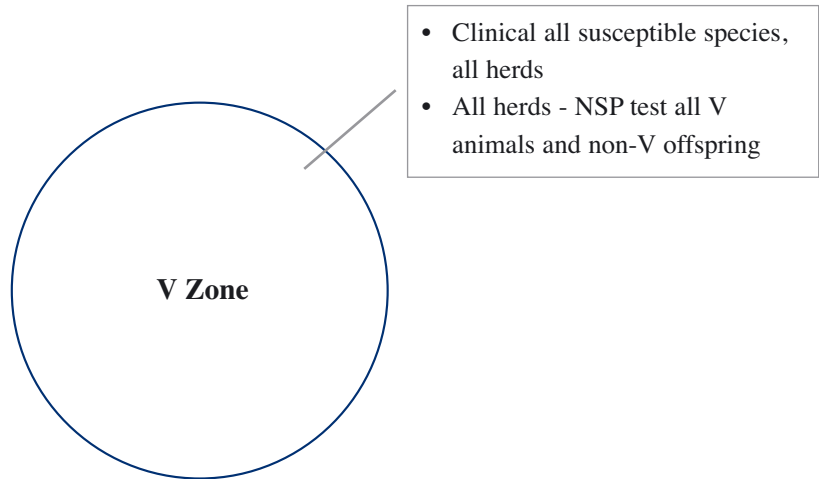
ARTICLE 55

PHASE 2 FROM 30 DAYS AFTER VACCINATION UNTIL SURVEY AND CLASSIFICATION COMPLETED



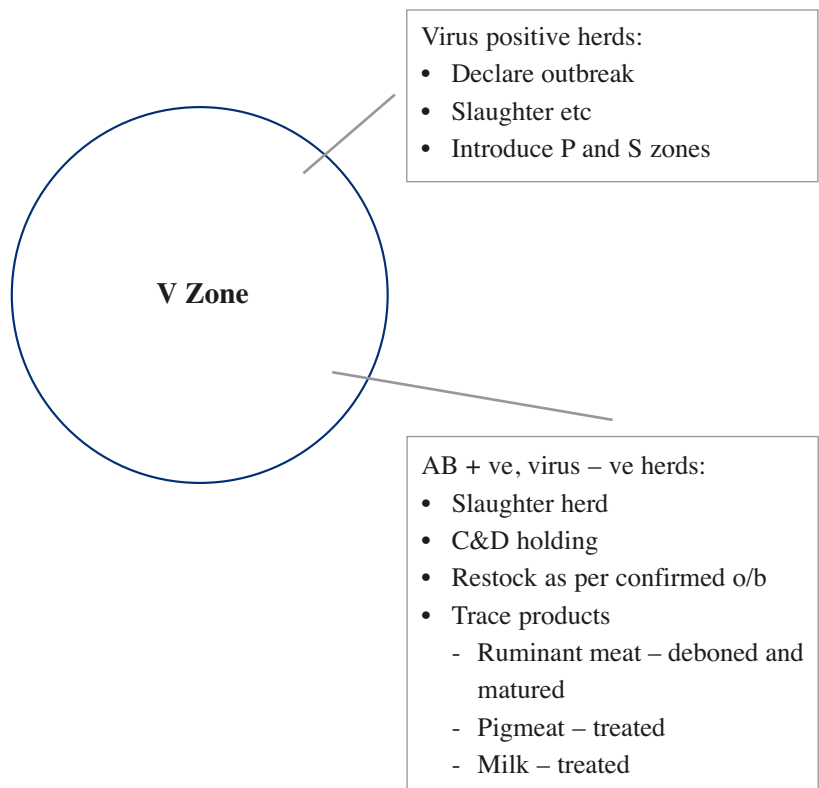
ARTICLE 56

PHASE 2A (FROM 30 DAYS AFTER VACCINATION TO COMPLETION OF SURVEY)



ARTICLE 57

PHASE 2B (CLASSIFICATION)



ARTICLE 58

PHASE 3 (FROM COMPLETION OF CLASSIFICATION UNTIL OIE FMD-FREE STATUS RECOVERED)

