Requirements of the Terrestrial Code for FMD surveillance

WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

Dr Wilna Vosloo

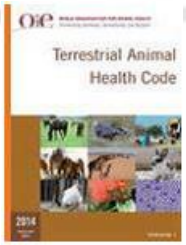
When is surveillance needed?

- Establishment, maintenance or recovery of freedom from FMD at the country, zone or compartment level

- Seeking endorsement of an official control programme for FMD

OIE Standards for FMD surveillance

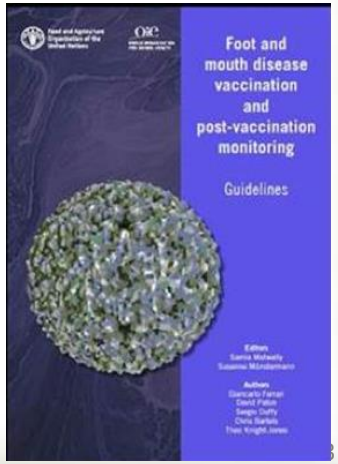
FMD Code Chapter



Article 8.8.40.	General principles of surveillance
Article 8.8.41.	Methods of surveillance
Article 8.8.42.	The use and interpretation of serological tests

Other standards relevant, not only FMD Code Chapter

- Surveillance chapter (1.4.) in Code
- Manual of diagnostic tests and vaccines
- Guide on post vaccination monitoring



Article 8.8.40.
General Principles of Surveillance

1. Early detection
2. Demonstration of freedom
3. OIE endorsed official control programme
4. Surveillance strategies
5. Follow-up of suspected cases and interpretation of results
6. Demonstration of population immunity

Article 8.8.40.
(1) Early Detection

- Responsibility of the Veterinary Authority
- Early warning system to report suspected cases throughout the entire production, marketing and processing chain
- Rapid collection and transport of samples to a laboratory for FMD diagnosis / confirmation

Article 8.8.40.
(2) Demonstration of freedom

- Continuing programme required
- Approach tailored to local circumstances
- Risk-based and proportionate

To substantiate FMD freedom

Where vaccination is not practised	Demonstrate absence of infection
Where vaccination is practised	Demonstrate absence of transmission
For a compartment	Identify the prevalence, distribution and characteristics of FMD outside the compartment

Clarification of terms

- FMD infection
  - FMD virus has been isolated from a sample; or
  - FMD viral antigen or viral RNA has been identified or
  - antibodies to structural or non-structural proteins of FMDV, that are not a consequence of vaccination, have been identified

- FMD transmission (vaccinated population)
  - Change in virological or serological evidence indicative of recent infection, even in the absence of clinical signs

Article 8.8.40.
(3) OIE endorsed official control programme

- Surveillance should demonstrate
  - Effectiveness of any vaccination
  - Ability to rapidly detect all FMD outbreaks

- Need to establish for the whole territory/part of it
  - Free from FMDV infection and transmission
  - Understand the epidemiology of FMD
  - Demonstrate how all the risk factors, including the role of wildlife, are identified and managed

Article 8.8.40.
(4) Surveillance strategies

- Clearly state the aim/purpose of the survey
- Strategy to establish
  - the prevalence of FMDV infection or
  - substantiate freedom from FMDV infection or transmission
    - randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence
    - targeted sampling may be appropriate if an increased likelihood of infection in particular localities or species can be identified
  - Justify the surveillance strategy chosen and the frequency of sampling

Article 8.8.40. (5) Follow-up of suspected cases and interpretation of results

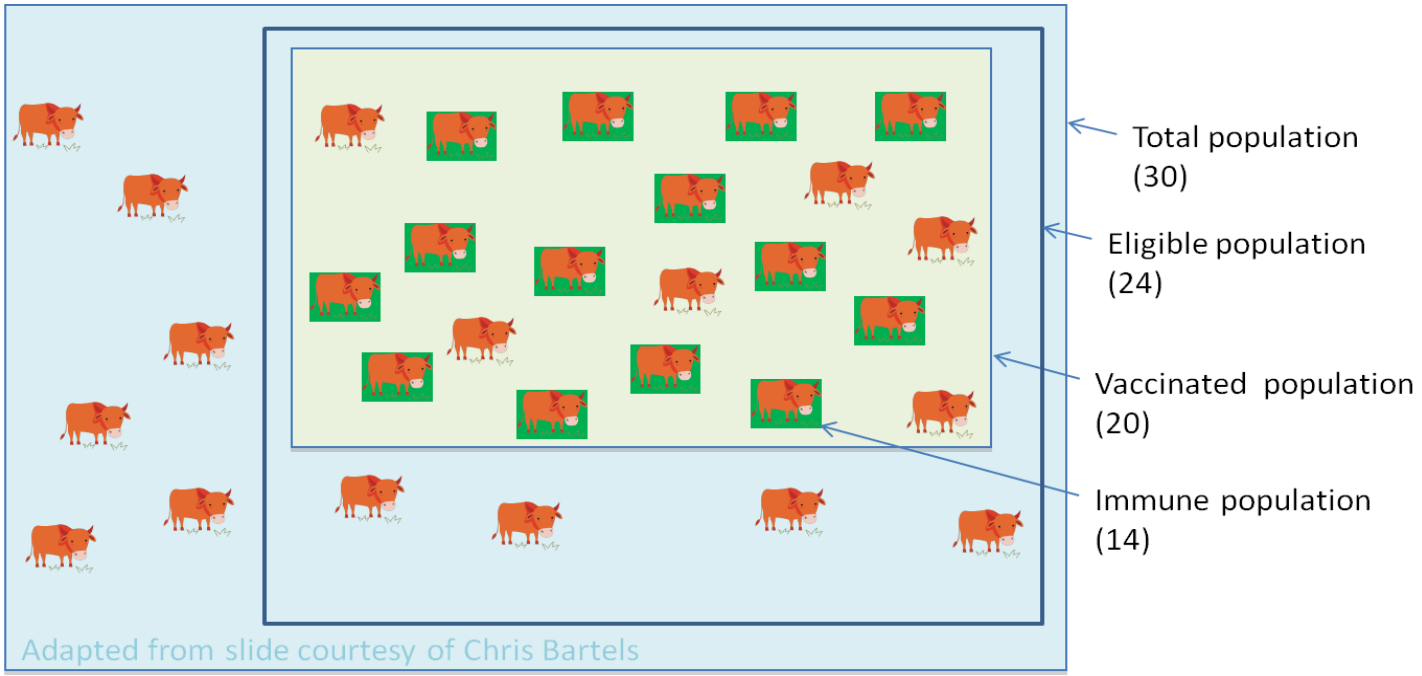
- Suspected cases require immediate follow-up and investigation to confirm or exclude FMD
- Samples should be taken and submitted for diagnostic testing, or ruled out by epidemiological and clinical investigation
- Details of the occurrence, investigations and final results of suspected cases should be documented
  - Diagnostic testing results
  - Control measures

Article 8.8.40. (6) Demonstration of population immunity

- After routine vaccination, evidence is needed
  - Effectiveness of vaccination programme (coverage and population immunity)
- Time for testing depends on the aim
  - 1-2 months post vaccination – vaccination efficiency
  - At the time of next vaccination – duration of immunity
- Multivalent vaccines
  - Test for each serotype
- Cut-off levels for immunity and protection are important

Article 8.8.40. Demonstration of population immunity

Vaccination coverage and population immunity



Vaccine coverage $20/24 = 83\%$ **Population immunity amongst vaccinated** $14/20 = 70\%$

Vaccinated population $20/30 = 67\%$ **Population immunity overall** $14/30 = 47\%$*

* Ignoring impact of immunity from colostrum, past vaccination or infection

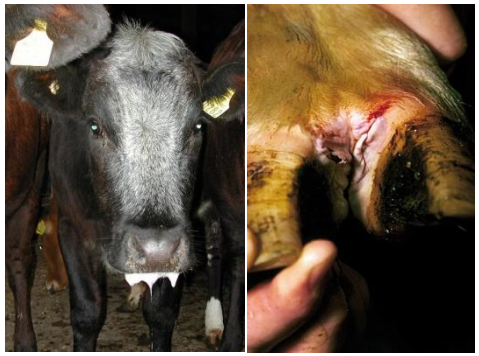
Article 8.8.41.
Methods of surveillance

1. Clinical surveillance
2. Virological surveillance
3. Serological surveillance

Article 8.8.41.
Methods of surveillance (1)

Clinical surveillance

- Across whole livestock chain
- Legal basis of notification
- Awareness and compensation
- Inspect enough animals often enough
- Document investigations
- Corroborate lab/epidemiological findings
- Limitations
  - Lack of opportunity for inspection
  - Livestock species showing mild signs of disease
  - Wildlife difficult to monitor
  - Vaccination masks disease
  - Insufficient time for disease to be disclosed

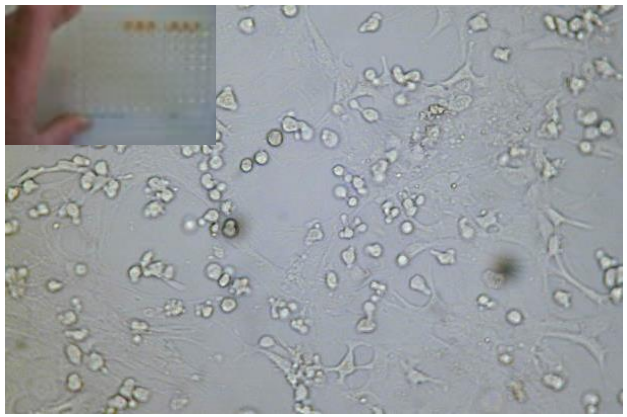


Article 8.8.41.
Methods of surveillance (2)

Virological surveillance

- Confirm clinically suspected cases
- Follow up positive serological results
- Characterise isolates for epidemiological studies and vaccine matching
- Monitor populations at risk for the presence and transmission of the virus

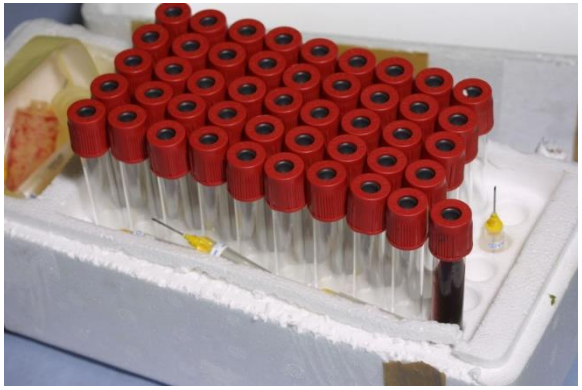
Robotic sample preparation for rRT-PCR



Virus isolation confirmed by Ag ELISA

Article 8.8.41.
Methods of surveillance (3)

Serological surveillance



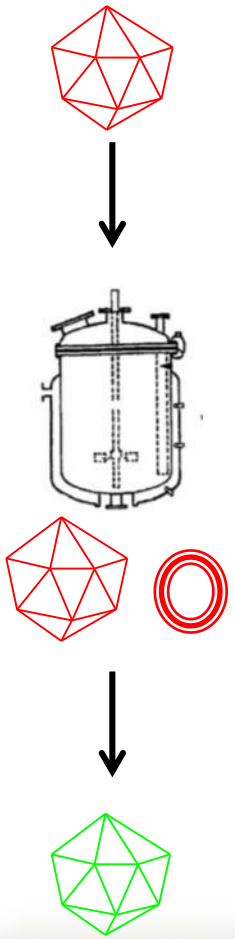
- Estimate prevalence or substantiate freedom from infection / transmission
- Substantiating freedom should be risk-based
  - When clinical surveillance is unreliable
  - Target high risk populations
    - ✓ Close to borders with infected zones or countries
    - ✓ Enterprises that buy in animals from many/distant sources
    - ✓ Enterprises with shared grazing or transhumance
- Monitor population immunity after vaccination

Article 8.8.42.
Use & interpretation of serological tests

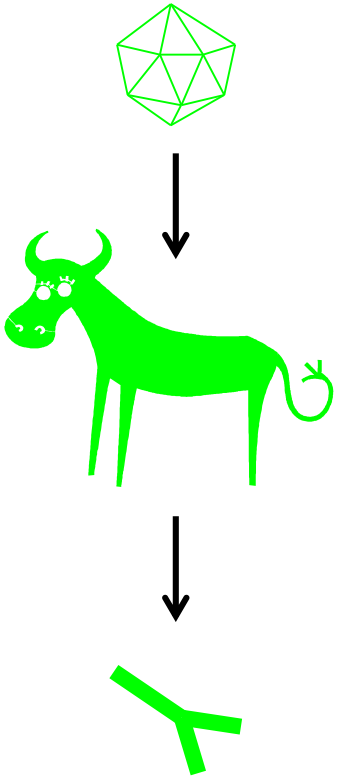
- Tests for antibodies
  - FMDV structural proteins (ELISA and VNT)
  - FMDV non-structural proteins (ELISA and western blot)
- Causes of positive results
  - Infection
  - Vaccination
  - Maternal antibody
  - Non-specific reactivity

NSP / SP Serology

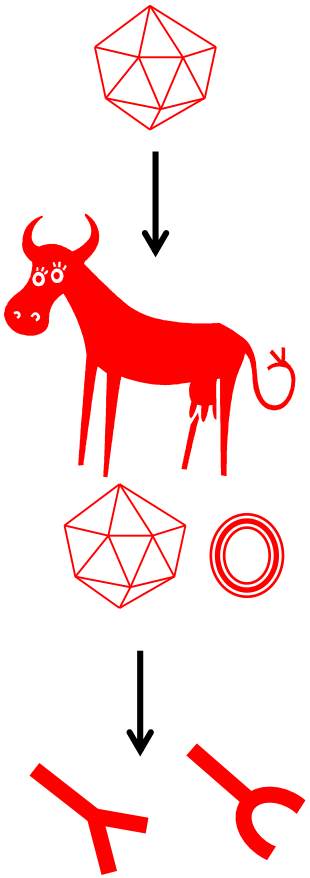
Growth of vaccine virus



Vaccination with purified vaccine



Infection with replicating virus



KEY TO FIGURE

- Live virus
- Inactivated purified virus (structural proteins)
- Viral non-structural proteins
- Antibodies to viral structural proteins
  - Serotype-specific
  - Correlate to protection
- Antibodies to viral non-structural proteins
  - Pan-serotype reactive
  - Used for DIVA testing

Procedure for positive test results

- Suspect false pos should be retested in the lab
- All herds with at least one lab confirmed reactor should be investigated
- Clustering of seropositive results within herds or a region should be investigated
- Investigate the reactor animals, susceptible animals of the same epidemiological unit and animals that have been in contact or linked
- Investigate sentinel animals
- Present results in detail!

Follow up of field and lab findings

- If transmission is demonstrated, an outbreak is declared
- Significance of small numbers of sero-pos is difficult to determine
  - Past infection/carrier state
  - Repeated vaccination
  - Non-specific reactions
- If the number of seropositive animals > than the number of expected false positive results (Sp), further investigations are needed

Evaluating vaccines before and after purchase

- Advice from OIE Reference Laboratories on vaccine selection – dependant on surveillance
- Evidence from vaccine manufacturer – potency and batch release tests
- A pre-purchase study of immunity in a small group of local animals
- A larger study in the field after vaccination
- Monitoring vaccine coverage and population immunity

Establishing PVM serology thresholds

- Need to consider antigenic differences between three components:
  - The vaccine virus
  - The test virus
  - The challenge or field virus

	Sensitivity of tests for antibodies induced by vaccines or field infection	
Tests incorporating different virus strains	Vaccine or field infection A1	Vaccine or field infection A2
FMDV A1	+++	+
FMDV A2	+	+++
FMDV A3 (example)	++	+

Need to consider variability of immune responses and tests

Establishing PVM serology thresholds

- Test for expected response or for protection
  - Expected response: need sera from the vaccine batch produced under controlled conditions
  - Protection: correlate serology with potency test results for homologous protection threshold
- Substitute field virus for vaccine virus in serology test to estimate heterologous protection
- Work closely with the vaccine manufacturer and a reference laboratory

Final remarks

- Documentation is important
  - Survey designs and reasoning
  - Results and follow-up actions
  - Interpretations and conclusions

Thank you for your attention!

Wilna Vosloo
CSIRO-Australian Animal Health Lab
wilna.vosloo@csiro.au

Acknowledge: David Paton

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