ITEM 2.1 MINIMUM STANDARDS OF BIORISK MANAGEMENT FOR LABORATORIES UNDERTAKING DIAGNOSTIC INVESTIGATIONS OF LOW-RISK SAMPLES DURING AN OUTBREAK OF FMD

[Emergency FMDV labs for serology and for testing inactivated samples]

B. Haas

The following is a supplement to the “minimum containment standards for fmd laboratories”

INTRODUCTION

The following Minimum standards for laboratories undertaking diagnostic investigations during an FMD emergency or during FMD surveillance after an outbreak only apply to

The testing of blood samples from holdings without clinical signs

The testing of samples from holdings with or without clinical signs that have been treated in a way that FMDV infectivity is inactivated by laboratory tests which do not contain or require live FMD virus.

Serology by commercially produced FMD - ELISA kits can be performed in many laboratories, e.g. regional veterinary laboratories, which can process samples with a high throughput. In case of an outbreak, this allows to increase the throughput of diagnostic samples significantly, which will often be a crucial factor for successful disease control.

Blood sampling is often combined with surveillance and staff taking samples may also examine the mouth of possibly infected animals, which may increase the risk of a surface contamination of packing material. This risk, as well as the risk of leakage during transport has to be mitigated by appropriate provisions. The risk of FMD occurring as a result of sero-diagnostic activities within laboratories is associated with escape of virus following receipt of blood samples from viraemic animals. While the likelihood of virus being present in samples originating from holdings without clinical signs during an FMD epidemic generally is moderate to low, it is almost impossible to predict due to the dynamic nature of an epidemic. However, the maximum virus titres in blood of viraemic animals is about 10 000 to 100 000 fold lower then in vesicular material.

Real-time PCR has been introduced in many laboratories, e.g. regional veterinary laboratories, which can process samples with a high throughput. Testing samples that have been treated at the site under suspicion in a way that infectivity is inactivated for FMDV genome in regional laboratories may facilitate a significantly increased sample throughput and a shortened time between sampling and reception of results.

Requirements for testing samples during an FMD outbreak (for any disease or purpose)

Classification of samples and overview on required laboratory

<table>
<thead>
<tr>
<th>Sample FMD Risk Level</th>
<th>Origin of samples</th>
<th>Sample Risk</th>
<th>Laboratory Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Holding with signs indicative of FMD</td>
<td>High risk, material has to be considered to contain infectious virus</td>
<td>“Infectious FMDV Lab”</td>
</tr>
<tr>
<td>B</td>
<td>Holding without clinical signs indicative of FMD</td>
<td>Low risk, to be mitigated by appropriate bio-</td>
<td>“Serology/inactivated sample FMDV Lab”</td>
</tr>
</tbody>
</table>
Holding with or without signs indicative of FMD, samples treated in a way that FMDV infectivity is inactivated

| C | FMD free area | No obvious risk | No specific requirements |

-Packaging of samples classified as FMD sample risk level B

Samples must be put into watertight primary containers (e.g. plastic tubes) and the primary containers must be packed in watertight secondary packaging, which should be a strong crushproof and leak-proof container, with absorbent material that can absorb the entire contents of all the primary containers. The packaging process must include a disinfection of the secondary packaging. The packaging should comply with the European agreement concerning the international carriage of dangerous goods by road (ADR). Samples should be labelled as biological substance, category B (UN3373).

-Treatment of samples to inactive FMDV infectivity

Samples from holdings with signs indicative of FMD must be treated in a way that FMDV infectivity is inactivated before shipment by a procedure authorised by the competent national authority in order to be permitted to be investigated at a laboratory not meeting the minimum containment standard for FMD laboratories.

Minimum Requirements for laboratory biorisk management

Personnel
1. A biorisk officer (BRO) and deputy (DBRO) must be designated, and one or both present on-site at all periods in which samples are being received, and contactable at all periods when diagnostic activities are ongoing.
2. The BRO/DBRO must have sufficient experience and technical training to enable assessment of FMD risk and risk management procedures.
3. There must be a designated restricted area or areas with controls in place to limit human access.
4. Personnel must be authorised to enter the restricted area by the BRO/DBRO.
5. Authorised personnel working in the restricted area must be trained in biorisk management and evidence of the training recorded. Where facilities for the inactivation of waste from the restricted area are located outside of this area, also staff working with such waste must be trained in biorisk management and evidence of the training recorded.
6. Authorised personnel must change clothing before entering the restricted area and take a shower when leaving the restricted area. Authorised personnel must not have any contact to animals of susceptible species, must not enter buildings or enclosed fields where animals of susceptible species are kept, and must not handle items used in the care of susceptible species, for at least 3 days after leaving the restricted area. The agreement of the authorised personnel to these conditions must be recorded and a reminder notice of the training placed in a visible location at the exit point of the restricted area.
7. Entry and exit of personnel to the restricted area should be recorded.
8. Entry and exit points to the restricted area will be kept to the minimum—preferably a single point of entry/exit.
9. A step-over line, or other clearly demarcated boundary shall indicate the exit point.
10. In case the shower facilities are not placed at the border of the restricted area, outer protective garments, including shoes or shoes coverings, shall be removed before exit from the restricted area. All clothing worn in the restricted area must be stored in a secure way, e.g. in designated lockers, until treatment.
11. An incident recording system, SOPs for risk identification and notification procedures and target response time, must be in place to ensure early notification of the authorities responsible for FMD surveillance in the event that
   - Samples have been received which are considered FMD sample risk level A
   - Samples have been received in unsatisfactory state of packaging

Buildings
12. Access doors to the restricted area should display a warning sign that access is restricted to authorised personnel only.

13. Changing facilities and lockers are required to enable staff to deposit unessential items outside the restricted area.

14. Entering of the laboratory premise by farmers or staff working on farms should be avoided. If possible, it should be attempted to separate vehicles bringing samples from vehicles entering the premise for other purposes.

15. Shower facilities must be available onsite, preferably at the border of the restricted area.

16. Sample reception area
   a. The restricted area must contain a specified area for reception of packages.
   b. This area must:
      i. Be easily disinfectable in the event that leakage of samples occurs into packing materials or following opening of the packages;
      ii. Be equipped to enable packages considered to potentially contain samples of FMD sample risk level A to be re-packaged into appropriate transport containers for dispatch to laboratories licensed for handling FMD virus;
      iii. have suitable facilities for waste disposal and have hand-washing facilities at exit points

17. Sample preparation area
   a. The restricted area must contain a specified area for serum separation and/or RNA extraction
   b. This area must have suitable facilities for surface disinfection and waste disposal and have hand-washing facilities at exit points

18. Testing area
   a. The restricted area must contain a specified area for testing
   b. This area must have suitable facilities for surface disinfection and waste disposal and have hand-washing facilities at exit points

19. Sample storage area
   a. The restricted area must contain a specified area for the storage of samples
   b. This area must have suitable facilities for surface disinfection

20. Communications and reporting office space

21. The laboratory must have an adequate provision of office space, computing and communications facilities (e.g. electronic communications, facsimile) to reduce the need to a minimum for staff, papers and physical records to exit the restricted area.

22. Rest rooms

23. The restricted area should have sufficient rest rooms and lavatory facilities in relation to the staff number expected at peak periods of activity, sufficient to reduce the need to a minimum for staff to exit the restricted area.

24. Location of autoclave

25. Facilities for wet heat treatment must be present on the site, preferably with sufficient capacity for throughput at the maximum operating capacity of the laboratory

Waste

26. Liquid waste
   a. Heat or chemical treatment of all waste water is the PREFERRED treatment, in compliance with the prescribed standards specified for FMD laboratories.
   b. Alternatively, or additionally, the laboratory may demonstrate that it has put in place a system for inactivation of virus if present in liquid waste that has contacted risk materials. If treatment of all liquid waste from the restricted area (including waste water from the showers) is not possible, at least the ELISA buffers and washing fluids must be collected and treated.

27. Solid waste
   a. For biological, solid waste, and all solid, disposable materials that have been in contact with specimens, treatment by wet-heat in an autoclave within or at an entrance point to the restricted area is the preferred option.
   b. If such a treatment of all solid waste is not possible, it may be packed into suitable watertight containers and, after spraying of the containers with disinfectant, removed for treatment at a different site.

28. Removal of equipment, materials and clothing from the restricted area
   a. Removal of any material and equipment from the restricted area shall be subject to authorisation by the BRO.
   b. The reason for removal, date, and destination will be recorded.
c. The BRO will ensure that materials and equipment which has been in contact with risk materials (specimens) will not be removed from the restricted area without a validated treatment to inactivate FMDV.

27. Declassification of the restricted area
   a. A decontamination plan must be agreed with the competent authorities, before restrictions can be lifted.
   b. If heat treatment or scanning of all paper from the restricted area is not possible, it should be packed into suitable containers, which should be disinfected and kept under lock for at least two years. If the containers have to be opened before, this has to be done in a restricted area meeting the standards described above.