VRA 25 - What are the risks of causing a new outbreak of foot and mouth disease (FMD) by authorisation of laboratories to test raw milk samples produced on premises in a PZ or SZ?

1. SUMMARY OF OVERALL RISK

This risk assessment was based on EPIC's generic framework suitable for veterinary risk assessments (VRAs) and the GB Foot and Mouth Disease Code of Practice for hauliers, processors and buyers of milk (subsequently referred to as "the milk industry's code of practice"). This document may require updating as new information becomes available or legislation develops, or if more in-depth assessment is necessary.

The purpose of this document is to qualitatively assess the risk of the specified activity in the face of an FMD outbreak in the UK. The assessment includes proposed actions to mitigate the risks associated with the specified activity, and which could form the basis of licence conditions, should the activity be permitted. The summary of overall risk below assumes that the risk mitigation measures in Section 8 are implemented.

DEFINITIONS OF RISK LEVEL (OIE 2004, DEFRA 2011):

Negligible So rare that it does not merit consideration
Very low Very rare but cannot be excluded
Low Rare but could occur
Medium Occurs regularly
High Occurs very often

Very High: Events occur almost certainly

Overall risk: The risk of allowing the activity described is **VERY LOW.** This assessment is the combined risk offered by the potential risk pathways, detailed in section 5 below.

POTENTIAL OPTIONS FOR MITIGATING RISK (SEE POINT 8).

2. LEGISLATION, DEFINITIONS & ASSUMPTIONS

Statutory disease control requirements are applicable to livestock premises on suspicion and confirmation of FMD. When suspicion of disease cannot be ruled out, and diagnostic samples are taken, a Temporary Control Zone will be put in place (TCZ) surrounding the suspect premises. On confirmation of disease, a national movement ban (NMB) will be enforced by introducing a national Restricted Zone (RZ). A 3 km Protection Zone (PZ) and 10km Surveillance Zone (SZ) will be implemented which place restrictions on movements and activities around infected premises to prevent spread of disease. Later in the outbreak, restrictions may be relaxed either through reducing the size of the RZ or through allowing some resumption of normal activities under licence within the RZ, SZ or PZ. In this VRA, RZ is used to refer to areas which are within the RZ, but do not also fall within the PZ or SZ

General prohibitions on movement of raw milk and associated sampling and testing activities do not apply if authorised by a licence granted by a veterinary inspector or an inspector at the direction of a veterinary inspector: FMD (Scotland) Order 2006 at Schedule 4, paragraphs 25 and 32.

Disinfectants used must be approved for use by the Diseases of Animals (Approved Disinfectants) (Scotland) Order 2008.

3. HAZARD IDENTIFICATION

- (a) **Hazard**: FMD virus (FMDV)
- (b) **Specific risk**: Milk from the PZ/SZ may contain FMDV. Reception and handling of such milk at a laboratory may result in spillage or leakage, allowing dispersal of FMDV within and outside the laboratory. This could lead to further outbreaks.

It is essential that milk from unrestricted dairy farms continues to be sampled and tested, as quality control of milk is intrinsic to milk treatment/processing.

4. POTENTIAL RISK PATHWAYS

Infection Sources:

A1 Milk samples are contaminated externally with FMDV A2 Milk inside the sample containers contains FMDV.

Risks of transmission:

B1 Virus passing to uninfected premises in the vicinity of the laboratory via release of contaminated milk.

B2 Virus passing to uninfected premises from the laboratory via contaminated personnel/fomites/vehicles.

5. EXPOSURE ASSESSMENT

Factors which are likely to affect this probability of exposure are:	Comments and risk estimates if/where appropriate:
Infection source: A1 Milk samples are contamin	ated externally with FMDV
Requires milk sample(s) to have been taken from a premises that is infected but not yet disclosed.	 Milk collection is not permitted from premises where FMD is suspected or confirmed. Virus shedding is most likely around the time of or shortly after the appearance of clinical signs (Charleston et al. 2011). However, infected cattle may excrete FMD virus for several days before the appearance of clinical signs, potentially leading to transmission or contamination prior to disease detection (Alexanderson et al. 2003, Orsel et al. 2009). Thus personnel/equipment involved in taking milk samples at apparently unaffected farms may become contaminated with FMDV. Virus shedding in milk can occur up to four days prior to clinical signs (Burrows 1968). Thus milk from apparently unaffected herds may be contaminated with FMDV. Milk samples are collected in leak-proof containers by the milk tanker driver. While collecting the milk sample, it is possible to transfer milk splashes/other contaminated material onto the outside of

- the sample container, resulting in FMDV on the external surface of the container.
- The milk industry's code of practice requires that the milk dipper is disposedof on the farm, also that the outside of the containers are wiped clean of spilt milk, the wipe disposed-of on the farm and the outside of the container is disinfected. Cleaning and disinfection of the outside of the sample containers will reduce the risk of transmission of FMDV to a negligible level.

Infection source: A2 Milk inside the sample container(s) contains FMDV

 Requires at least one of the milk collections in the round to have been contaminated with FMDV

- Virus shedding in milk can occur up to four days prior to clinical signs (Burrows 1968). Thus milk samples from apparently unaffected herds may be contaminated with FMDV.
- The milk industry's code of practice requires that, once testing is complete, the milk sample is treated to destroy FMDV and the sample containers are disposed of or (for re-usable containers) autoclaved. These measures will reduce the FMDV contamination of samples and containers to a negligible level.

Risk of transmission: B1 Infection passing to uninfected premises in the vicinity of the laboratory via release of infected milk.

 Raw milk containing FMDV could result in further outbreaks if it comes into contact with susceptible livestock.

- Samples should be received and unwrapped in a dedicated reception area where spills/leaks can be immediately cleansed and disinfected. Use of appropriate disinfectant will reduce the risk of releasing FMDV to a negligible level.
- The milk industry code of practice requires that milk entering the laboratory must be treated to destroy FMDV before the milk is released from the laboratory. The same applies to milk residues resulting from tests carried out in the lab. Appropriate treatment of all milk/milk residues will reduce the risk of FMDV to a negligible level.
- Appropriate laboratory records should be kept to demonstrate that all samples are identifiable and that all milk/milk residues have been suitably decontaminated or disposed-of prior to leaving the laboratory.

Risk of transmission: B2 Infection passing to uninfected premises from the laboratory via contaminated personnel/fomites/vehicles.

 Handling of raw milk samples containing FMDV at the lab may result in crosscontamination of laboratory equipment, staff, vehicles

- The milk industry's code of practice requires lab staff to wear clean PPE.
- Susceptible livestock kept at the laboratory are at risk of infection through release of FMDV from contaminated samples. Milk samples from the PZ/SZ should not be sent to laboratories that

have a standing population of susceptible
animals

 Laboratory staff handling milk samples have a low risk of transferring FMDV from contaminated samples to livestock, even if they use PPE and follow disinfection procedures correctly. Milk samples from the PZ/SZ must only be handled by staff who do not have contact with susceptible animals outside the laboratory. This measure reduces the risk of spreading FMDV to a very low level.

6. CONSEQUENCE ASSESSMENT

Spread of disease to uninfected premises.

7. RISK MANAGEMENT OPTIONS

The risk in handling raw milk samples from the PZ/SZ in a laboratory is that some of the samples may be internally and/or externally contaminated with FMDV. The virus may be disseminated via lab equipment and/or staff and result in further FMD outbreaks. However, raw milk testing is an essential part of quality control for the milk industry so it is necessary to allow testing to continue under controlled conditions at a very early stage of an outbreak. The milk industry's code of practice recognises the risks inherent in dealing with milk samples, and sets out the necessary mitigation. Additional measures to reinforce and clarify the requirements of the code can be made conditions of the laboratory licence. Provided that the code and appropriate conditions are observed, there is a very low risk of causing a new FMD outbreak through the laboratory testing of milk from the SZ/PZ. Given that milk must be collected, sampled and tested during an outbreak, it is suggested that collection and sampling of milk from the PZ and SZ can be permitted, subject to compliance with licences and the milk industry's code of practice.

8. SPECIFIED RISK MITIGATION STRATEGIES

Authorisation of laboratories to test raw milk samples from the SZ/PZ presents a very low risk provided that safeguards are in place. The following risk mitigation measures are suggested:

A. prevent transfer of infection from the laboratory

- i) Milk samples are received and unwrapped in a dedicated reception area where any leaks or spills can be cleansed and disinfected immediately.
- ii) When testing is complete **and** before the material leaves the laboratories, all milk samples/residues resulting from testing are treated in accordance with FMD (Scotland) Order 2006, Schedule 5.
- iii) Laboratory records must account for all milk samples received and must state the treatment, decontamination and/or disposal process to destroy FMDV for each sample.
- iv) Sample containers are disposed of in such a way that any FMDV is destroyed prior to the container leaving the laboratory, or for reusable containers, autoclaved.
- v) Those laboratory staff who handle milk samples do not have contact with susceptible livestock outside the laboratory.

B. prevent transfer of infection within the laboratory

- i) All personnel involved in handling milk samples must wear clean, dedicated protective clothing at all times.
- ii) All spills/leaks of milk are cleansed and disinfected immediately. Protective clothing is cleansed or disposed-of after use. All equipment used in handling/storing/testing milk samples is cleansed and disinfected after use.
- iii) No susceptible livestock are kept at the laboratory.

It is assumed that relevant legislation applicable during "peacetime" is followed, for example regarding good laboratory practice, disposal of animal by-products.

9. SOURCES OF EXPERT ADVICE

This VRA was based on:

Great Britain Foot and Mouth Disease Code of Practice for hauliers, processors and buyers of milk, produced by Dairy UK, dated June 2008.

VRA E840077 "What is the risk of spreading FMD by permitting the collection and movement of milk samples from premises in the Restricted Zone to a laboratory for routine quality analysis? Produced by the Veterinary Division, Rural Directorate, December 2009.

10. AUTHORS

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11. REFERENCES

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12. NOTES

None