VRA 23 - What are the risks of causing a new outbreak of foot and mouth disease (FMD) by authorising a premises to treat raw milk produced in the surveillance and/or protection zones and produce products from such milk?

1. SUMMARY OF OVERALL RISK & RECOMMENDED ACTION

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, assessed 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 collection and processing 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. Authorising a specified premises to receive such milk for treatment/processing may result in that premises becoming contaminated with FMDV and therefore becoming a source of infection for surrounding premises. Release of FMDV from the contaminated milk processing plant could occur: at unloading of delivery tankers through spillage of contaminated milk or aerosol of FMDV; during milk processing e.g. leakage of contaminated milk to adjacent land grazed by susceptible animals or on release of contaminated products/by-products/co-products from the premises for feeding to susceptible animals.

It is essential that milk continues to be collected from unrestricted dairy farms, as on-farm milk storage capacity is very limited. To reduce the risk of spreading FMDV, it is desirable that milk from the PZ is treated and processed within the PZ. Similarly, milk from the SZ would ideally be treated and processed within the SZ or associated PZ. However, due to the specialist facilities required to treat and process milk, there are relatively few such premises and it is likely that milk will have to be moved out of the PZ and SZ for treatment elsewhere ie to premises in RZs or free areas.

The FMD (Scotland) Order 2006, Schedule 4, requires that milk treatment/processing plants in the PZ/SZ are authorised by the Scottish Ministers. In the absence of such plants, the Ministers may direct milk treatment/processing plants in the RZ or free area to be used. In practical terms, both the authorisation of PZ/SZ plants and the direction of plants outside the PZ/SZ would be achieved by licensing.

4. POTENTIAL RISK PATHWAYS

Infection Sources:

A1 Tankers arriving at the milk treatment/processing plant are contaminated with FMDV.
A2 Milk delivered to the milk treatment/processing plant is contaminated with FMDV.

Risks of transmission:

B1 Virus passing to uninfected premises in the vicinity of the milk treatment/processing plant via airborne spread from milk spillages / aerosol transmission.
B2 Virus passing to uninfected premises from the milk treatment/processing plant, via contaminated personnel/fomites/vehicles.
B3 Virus passing to uninfected premises via contaminated 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 Tankers arriving at the milk treatment/processing plant are contaminated with FMDV**	
Requires tanker/driver to have become contaminated with FMDV at least once during the collection round. Contamination may come from: • Entering infected premises where	• Milk collection is not permitted from premises where FMD is suspected or confirmed. • Virus shedding is most likely around the

FMDV is present on surfaces, in livestock and milk/excretions	time of or shortly after the appearance of clinical signs (Charleston *et al.* 2011). However, infected livestock may excrete FMD virus for several days before the appearance of clinical signs, potentially leading to transmission or contamination prior to disease detection, particularly in cattle and pigs (Alexanderson *et al.* 2003, Orsel *et al.* 2009). Thus tankers collecting milk from apparently unaffected farms may become contaminated with FMDV. • The FMD (Scotland) Order 2006, Schedule 4 part 2 requires that the milk collection vehicle must be clean and disinfected before every loading. Thus the tanker is not a source of FMDV at the beginning of the round. • Full cleaning and disinfection of the outside of the tanker on leaving each farm, as required by the milk industry's code of practice, will reduce the risk of external contamination to a negligible level. • If any of the milk collected by the tanker contains FMDV, the interior of the tank will be contaminated. The usual cleaning and sterilising routine, carried out after discharge of every load, will reduce the risk of internal contamination to a negligible level. • While on the farm, the tanker driver must wear protective clothing that can be cleaned and disinfected prior to leaving the premises or, in the case of disposable overalls, left at the premises for disposal by the farmer. Careful use of protective clothing will reduce the risk of spreading FMDV off the farm to a very low level.
• Travelling on FMDV-contaminated roads near infected premises (i.e. in the PZ) may expose the vehicle to contamination	• Milk collection vehicles may become contaminated with FMDV through driving on roads that have been contaminated by fomite spread or aerosol dispersal from infected premises. • FMDV is very sensitive to approved disinfectants and appropriate cleansing and disinfection of the vehicle on arrival at each premises will reduce any FMDV contamination to negligible levels.
***Infection source*: A2 Milk delivered to the milk treatment/processing plant is contaminated with 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 from apparently unaffected herds may be contaminated with FMDV.

	• If all raw milk is treated in accordance with one of the methods detailed in FMD (Scotland) Order 2006, schedule 5 part 4, FMDV will be destroyed. The risk of disease spread is reduced to negligible
***Risk of transmission*: B1 Infection passing to uninfected premises in the vicinity of the milk treatment/processing plant via airborne spread.**	
• Milk contaminated with FMDV can give rise to infective aerosols when a milk tanker is loaded or unloaded (Dawson 1970).	• Use of approved air filters (detailed in the milk industry's code of practice) prevents dispersal of FMDV when the tanker unloads at the milk treatment/processing plant. The risk of spread is reduced to negligible.
***Risk of transmission:* B2 Infection passing to uninfected premises from the milk treatment/processing plant, via contaminated personnel/fomites/vehicles.**	
• Raw milk contaminated with FMDV is a potential source of infection to susceptible livestock.	• Raw milk could be moved out of the processing/treatment plant on fomites, items such as clothing, footwear, equipment and vehicles. If the milk contains FMDV and comes into contact with susceptible livestock, a new disease outbreak could follow. • Milk processing/treatment sites require approval to operate under Regulation EC 853/2004. This includes food hygiene measures such as complete separation of raw milk from treated/processed material. • In order to operate during a FMD outbreak, milk processing/treatment plants require additional licensing by the Scottish Ministers (or equivalent). The conditions of the licence include the requirement that staff take stringent biosecurity measures. Such measures would reduce the risk of spreading FMDV to a very low level. • Raw milk that is rejected for human consumption (e.g. due to positive antibiotic test result) is controlled under the Animal By-Product (Enforcement) (Scotland) Regulations 2011 and must be disposed of accordingly. If such milk is to be fed to livestock, it must be heat treated beforehand. Appropriate treatment would reduce the risk of spreading FMDV to negligible levels. • The operator of the milk treatment/processing plant is required to keep records of all consignments of milk received and dispatched. Also records of treatment to show that the required parameters have been met for each batch of milk.
***Risk of transmission*: B3 Infection passing to uninfected premises via contaminated vehicles**	
• Vehicles may become contaminated by picking up FMDV from contaminated	• FMDV is very sensitive to approved disinfectants and good biosecurity will

roads or premises in the PZ.	reduce risk of virus transfer via fomites such as personnel, vehicles and equipment. Provided that the vehicle is appropriately cleaned and disinfected on arrival at subsequent premises, FMDV will be deactivated and therefore will not pose a risk to livestock.

6. CONSEQUENCE ASSESSMENT

Spread of disease to uninfected premises.

7. RISK MANAGEMENT OPTIONS/ADVICE

The risk in removing milk from the PZ/SZ for processing outside those zones arises because FMDV-contaminated milk is a potential source of infection. However, it is necessary to establish regulated milk collections (licensed vehicles transporting milk to licensed premises) at a very early stage of an outbreak, in order to allow the dairy industry to continue to function. The milk industry's code of practice recognises the risks inherent in milk collection/ treatment/ processing and sets out the necessary mitigation. Additional measures to reinforce and clarify the requirements of the code can be made by conditions of the licence. Provided that the code and appropriate conditions are observed, there is very low risk of causing a new FMD outbreak by authorising a premises to treat and process milk from the PZ/SZ, whether the treatment/processing plant is inside the PZ/SZ or elsewhere. Given the impracticality of requiring all milk to be processed/treated in the zone of origin, it is suggested that authorisation of premises can be permitted, subject to compliance with licences and the milk industry's code of practice.

8. POTENTIAL OPTIONS FOR MITIGATING RISK

Authorisation of premises outside the SZ/PZ to treat and process milk presents a very low risk provided that safeguards are in place. The following risk mitigation measures are suggested:

A. prevent infection from reaching the treatment/processing plant

i) Milk is not collected from premises where FMD is suspected or confirmed.
ii) Milk tankers are cleaned and disinfected externally on leaving each milk collection point.
iii) While on the farm, the tanker driver wears protective clothing that is either cleaned and disinfected prior to re-entering the vehicle or is discarded at the farm for disposal by the farmer.

B. prevent infection from escaping from the treatment/processing plant

i) The treatment/processing plant must be both approved under EC 853/2004, Annex III, Section IX and licensed/directed by the Scottish Ministers under the FMD (Scotland) Order 2006, Schedule 4.
ii) Ensure that air filters are fitted to the milk tanker to prevent FMDV dispersal by aerosol when the milk is unloaded.
iii) Milk must be treated in accordance with FMD (Scotland) Order 2006, schedule 5 part 4.
iv) Records must be kept of milk received, treatment(s) carried out and milk/milk products dispatched and retained for at least 3 months ensuring the following information is recorded: (a) the amount of untreated milk the food business receives;(b) the treatments and processes applied to that milk; and (c)the amount of milk and/or milk products distributed since milk was first received from susceptible animals in a protection or surveillance zone.

v) Biosecurity protocols must be in place at the treatment/processing plant.
vi) The consignment note that accompanies each delivery of untreated milk must be retained by the Licensee for a minimum of six weeks.
vii) The licensee must, at that person's own expense, provide adequate facilities and equipment for cleaning and disinfection of vehicles, as per FMD (Scotland) Order 2006, article 46.

It is assumed that relevant legislation applicable during "peacetime" is followed, for example regarding food hygiene and consignment of animal-by-products (e.g. milk not intended for human consumption).

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

Jenny Purcell (temporary Veterinary Advisor, Scottish Government) Date: 28/12/2012.
Reviewed by: Martyn Blissitt (AH&WD, Scottish Government) Date: 10/01/2013

11. REFERENCES

Alexanderson S, Zhang Z, Donaldson AI, Garland AJM (2003) The pathogeneses and diagnosis of foot-and-mouth disease. *Journal of Comparative Pathology* 129, 1-36.

Burrows R (1968) Excretion of foot-and-mouth disease virus prior to the development of lesions. Veterinary Record 82, pp387-388

Charleston B, Bankowski BM, Gubbins S, Chase-Topping ME, Schely D, Howey R, Barnett PV, Gibson D, Juleff ND, Woolhouse MEJ (2011) Relationship Between Clinical Signs and Transmission of an Infectious Disease and the Implications for Control, *Science* 332, 6030, pp726-729.

Dawson PS (1970) The involvement of milk in the spread of foot-and-mouth disease: an epidemiological study *Veterinary Record* 87 pp543-548.

Donaldson AI and Alexanderson S (2001) Relative resistance of pigs to infection by natural aerosols of FMD virus. *Veterinary Record* 148, 19, pp600-602

Orsel K, Bouma A, Dekker A, Stegeman JA, de Jong MCM (2009) Foot and mouth disease virus transmission during the incubation period of the disease in piglets, lambs, calves, and dairy cows, *Preventive Veterinary Medicine* 88, 2, pp58-163.

12. NOTES

None