NATIONALLY AGREED STANDARD OPERATING PROCEDURE (NASOP)

Title: **Control of Foot and Mouth Disease vaccine at a Designated Vaccine Centre**

Version: **1.0**

Prepared by: **Subcommittee on Emergency Animal Diseases**

Approved by: **Animal Health Committee**

Revision history:

Version	Date of approval	Comments
1.0	02/05/11	AHC Approved

NASOPs support national consistency and provide guidance to response personnel undertaking operational tasks.

1. Purpose

- To provide jurisdictional operations centres and Vaccination Managers with information on the control of foot and mouth disease (FMD) vaccine at a Designated Vaccine Centre (DVC).

2. Application/scope

- This NASOP describes the procedures to be followed for the control of FMD vaccine at a DVC in a state or territory when emergency vaccination of livestock is to be carried out as part of a control program for FMD.
- NASOP 24: *Ordering of Foot and Mouth Disease vaccine and distribution to states and territories* describes the national processes for the ordering, delivery and control of FMD vaccine to the DVC.
- Vaccination will be carried out according to NASOP 17: *Vaccinating livestock on a property for Foot and Mouth Disease*
- This NASOP is written for an inactivated, non-genetically modified, oil-adjuvant vaccine as contained in Australia's FMD vaccine bank.

3. Resources/equipment

- DVC resources include:
  - a building located either within the Restricted Area (RA) or close to it, and approved by the Chief Veterinary Officer (CVO) or delegate
  - serves as the local storage and distribution point for all vaccines, cold chain apparatus, vaccine applicators, syringes, needles and related equipment
  - must have a security system to prevent unauthorised access
  - must have a reliable refrigeration system with appropriate alarms and backup power to maintain the temperature at +2°C to +8°C.
  - must have the capacity to provide sufficient ice-packs to be used for maintaining the cold chain in the field
  - must be equipped with sterilising apparatus (either a steam steriliser or facilities for boiling vaccination equipment in clean water for a minimum of 15 minutes. No chemical sterilisation is to be used for vaccinating equipment).
- To prevent cross contamination with the clean areas of the DVC, a separate area must be established to manage potentially contaminated materials including personal protective equipment (PPE) and vaccination wastes.

- The DVC must provide the following facilities for vaccination teams:
  - clean area for collection of vaccine and equipment

  - dirty area for return of wastes, contaminated material and waste vaccine
  - waste disposal system
  - clean area for return of all cold chain intact vaccine and equipment/supplies that have not been on a premises
  - appropriate area for completion, reconciliation and photocopying of all documentation including vaccine inventories, downloading electronic records of National Livestock Identification System (NLIS) identification codes and submission of these records
  - area for cleaning vehicles
  - entry and exit policy for DVC.
- Auditable inventory (amounts, batch numbers) system for use at each stage of vaccine distribution, storage, use and waste.
- Register system for issuing and receiving other supplies e.g. vaccine applicators, syringes, needles, cool-boxes, ice packs and PPE.
- AUSVETPLAN disease strategy for FMD manual and relevant NASOPs and work instructions.
- Vaccination plan that includes delegation authorities for the distribution of vaccine.

4. Warnings

- FMD vaccine must be used in accordance with the vaccination plan.
- FMD vaccine contains an oil emulsion adjuvant and should be used with great care.
- Maintain a cold chain at all stages of vaccine storage and transport. Data loggers should be used to monitor temperatures during transport and storage.
- Opening of cool-boxes should be minimised to keep temperatures in the range of +2°C to +8°C, without freezing, and to reduce vaccine vial exposure to light.
- If a vaccination team is suspected of being exposed to infectious field FMD virus (for example, through contact with infected animals) they will be withdrawn from the vaccination program for a designated period of time.
- The Australian Pesticides and Veterinary Medicines Authority (APVMA) requires that the vaccine may be released only on the authority of the CVO in each state or territory, and used only by authorised personnel acting under their direction or persons otherwise authorised under state/territory legislation. The product must be used in accordance with the label instructions and Standard Operating Procedures as may be specified by the Consultative Committee on Emergency Animal Diseases.
- Do not clear sessions on NLIS readers until the files have been saved, re-opened and checked complete and uncorrupted.
- Handling animals and some vaccines have Occupational Health and Safety (OHS) issues—arrangements need to be made for emergency medical treatment in case of injury.
- The operations centre should make arrangements with local medical facilities to prepare for treatment of accidental human vaccination.
- The contaminated area of the DVC must be treated as an infected place and requires the use of PPE and entry and exit decontamination protocols.

5. Description of activities

- Receive vaccine.
- Maintain accurate inventory control and documentation at all stages (see Appendix A Designated Vaccine Centre FMD Vaccine Inventory, and Appendix B FMD vaccination stock take Form (Electronic Balance Calculator)).
- Register DVC as a Property Identification Code (PIC) and have a number of orange post-breeder cattle NLIS 'emergency' tags issued to this PIC.
  - Download NLIS tag data from NLIS readers returning from field but do not clear sessions until the files have been saved, re-opened and checked complete and uncorrupted.
- Transfer NLIS codes of ‘emergency’ tags from DVC PIC to PIC on which they were applied.
- Ensure that the NLIS codes of all vaccinated cattle are registered against the PIC on which they were vaccinated.
- Ensure vaccinated cattle are flagged as FMD vaccinated on the NLIS database.
- Maintain appropriate storage of vaccine.
- Prepare a detailed vaccination plan, identify premises where vaccination is to be carried out, and determine the appropriate resources required.
- Determine the number of doses of vaccine required for each property where animals are to be vaccinated.
- For small numbers of animals, the appropriate number of doses of vaccine can be drawn up in a 50 ml plastic repeater injector for transfer onto the premises. An open bottle on the property must be disposed according to NASOP 17 *Vaccinating livestock on a property for Foot and Mouth Disease.*
- Establish and manage an appropriate number of field teams.
- Ensure that all personnel who handle vaccine have appropriate legislative authorisations to possess and administer FMD vaccine.
- Ensure that all personnel who handle or administer vaccine have had appropriate induction and training with special reference to the safety aspects of handling an oil emulsion vaccine, other OHS aspects, use of NLIS readers etc., and keep records of such induction and training.
- Issue all vaccine and equipment to field teams.
- Receive from returning field teams, and document, all unused vaccine, spoilt vaccine, used equipment, unused equipment/supplies and wastes in a biosecure manner.
- Clean and sterilise vaccination equipment that is to be reused.
- Store waste vaccine separately at the DVC and dispose of in accordance with the vaccination plan.
- Animal Health Australia (AHA) will arrange for the return of unused vaccine (see Appendix C for FMD vaccine return – cold chain intact form).
- AHA can also arrange through the return and destruction of unused vaccine where the cold chain has not been maintained (see Appendix D for FMD vaccine return – cold chain not maintained form). The Vaccination Manager can authorise and sign off on alternative means of destruction of such vaccine, as long as barcodes, batch numbers and estimated doses are appropriately accounted for.
- The operations centre should ensure that all vaccinated cattle are eventually handled in accordance with the State Coordination Centre policy and this may include vaccination for destruction or vaccination to live, the animals status must be recorded on the NLIS database or equivalent.

6. References

- AUSVETPLAN Disease Strategy Foot-and-Mouth Disease
  - AUSVETPLAN manuals are available at: www.animalhealthaustralia.com.au
- NASOP 17: *Management of Foot and Mouth Disease vaccination on a property*
- NASOP 24: *Ordering Foot and Mouth Disease vaccine and distribution to states and territories*
- Operational Procedures Guidelines. Vaccination for Contagious Disease. (Draft). National Animal Health Emergency Management System Guidelines - U.S. Department of Agriculture, 2003

7. Appendices

- Appendix A: Designated Vaccine Centre vaccine inventory
- Appendix B: FMD vaccination stock take form (electronic balance calculator; double-clicking on the spreadsheet will bring up the daily data sheet work sheets for editing in Microsoft Excel)
- Appendix C: FMD Outbreak - Request to AHA for authorisation to retun unused vaccine
- Appendix D: FMD Outbreak – Request to AHA for Authorisation to return spoilt vaccine

Designated Vaccine Centre FMD Vaccine Inventory

DVC name:_ _ _ _ _ _ _ _ _ _

Date	Event eg 'Vacc. PIC ABCD1234'	Doses* (CED) of Vaccine received ex AHA	No of bottles	Box number	AH bottle Barcodes	CED dispensed	CED in unopened bottles	CED in opened bottles	CED injected	CED wasted in field	Vaccine Balance (CED)	Temp 2-8°C	Team code	No. Ret. Empty bottles	Bar codes of empty bottles	Open bottle bar codes	CED in open bottle	No. cattle vacc.	No. sheep vacc.	No. pigs vacc.	No. other spp. vacc.	Store type (e.g. esky)	Checked in by (DVC officer name)
	Brought forward balance *(if any)*																						
*Note: all doses in Cattle Equivalent Doses (CED) of 2ml per cattle dose.																							

FMD VACCINATION STOCK TAKE FORM (ELECTRONIC BALANCE CALCULATOR)

Weekly summary

Date:

This is a summary page: Do not add stock on this page except carry over on first line!

Report vaccine in cattle equivalent doses (CED) 100 CED = 1 bottle vaccine (200 ml)

Number carried over from previous week:	Total doses:		Doses in Open Bottles:		
Number received into DVC:		**0**			
Stock throughput:		**0**			

Number issued to:

Vaccination Team	CED in Unopened Bottles	CED in Opened Bottles	Total Doses Issued
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
Total	**0**	**0**	**0**

Number returned to DVC:

Vaccination Team	CED in Unopened Bottles	CED in Opened Bottles	Total Doses Returned
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
Total	**0**	**0**	**0**

Number used:

Vaccination Team	CED injected into animals	CED wasted in field	Total Used
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
Total	**0**	**0**	**0**

Summary	Issued	Used	Discarded	Returned to store		**Difference**
				Whole Bottles	Opened Bottles	
	0	**0**	**0**	0	0	**0**

Amount of stock in DVC store to carry over to next week:	**0**	**Doses in Open Bottles:**	**0**

Place your DPI logo here for easy identification

CONTROL CENTRE:……..
ADDRESS:……
PHONE:…….FAX:…….

FACSIMILE MESSAGE

To: [*AHA officer*] FAX No. 02 6232 5511 Location: Animal Health Australia

From: _____ Date:

FMD Outbreak [*month/ year*]
Request to AHA for authorisation to Return Unused Vaccine

Request No.	**File**

1.**Person making request**	
Name	Contact no.
Location	Signature:

2. **Request details**

Number of bottles (200ml) of vaccine returned [*AFTOPOR DOE]*. This form is intended for the return of larger volumes of vaccine, from vaccination centres cold-chain intact. Vaccine in this category has NOT left the vaccination centre. Please contact [AHA officer] (02 6203 5522) to make complete arrangements, once this form has been faxed through to Animal Health Australia.

Bar Code (or bar code range)	Batch No.	Barcode (or bar code range)	Batch No.
Pick up at:	Contact person: Phone:	Opening hours for pick up:	Approximate pick up date:

3. AHA USE ONLY		
Acknowledged		Date
[*Name AHA officer*]	Manager Animal Health Standards	Signature:

Place your DPI logo here for easy identification

CONTROL CENTRE:……..
ADDRESS:……
PHONE:…….FAX:……

FACSIMILE MESSAGE

To: [*AHA officer*] FAX No. 02 6232 5511 Location: Animal Health Australia

From: _____

FMD Outbreak [*month/year*]
Request to AHA for authorisation to return Spoilt Vaccine

Request No.		**File**

1.**Person making request**	
Name	Contact no.
Location	Signature:

2. **Request details**

Number of doses of vaccine returned [*AFTOPOR DOE*]. This form is intended for the return of smaller volumes (<200 doses), or bottles (200ml), with cold chain not maintained. Please contact [AHA officer] (02 6203 5522) to complete arrangements, once this form has been faxed through to Animal Health Australia.

Estimate of CED doses with same barcode (max 200)	Barcode	Batch No.	Estimate of CED doses with same barcode (max 200)	Barcode	Batch No.

Deliver to:	Opening hours for delivery:	Approximate delivery date:

3. AHA USE ONLY		
Acknowledged		Date
[*Name AHA officer*]	Manager Animal Health Standards	Signature: