

# NATIONALLY AGREED STANDARD OPERATING PROCEDURE (NASOP)

**Title:** Ordering of Foot and Mouth Disease vaccine and distribution to States and Territories

**Version:** 1.0

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

**Approved by:** Animal Health Committee

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

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

## 1. Purpose

- To provide the Chief Veterinary Officer (CVO), the State Control Centre (SCC) and vaccination managers with guidelines to control distribution of foot and mouth disease (FMD) vaccine from the National FMD Vaccine Storage Facility in Australia to a Designated Vaccine Centre (DVC) and return of vaccine to the National FMD Vaccine Storage Facility.

## 2. Application/Scope

- This NASOP describes the procedures for the ordering and distribution of FMD vaccine from the National FMD Vaccine Storage Facility in Australia to a DVC in an affected State or territory, when vaccination of livestock is to be carried out as part of an approved FMD control program. It also describes the control of return of vaccine to the National FMD Vaccine Storage Facility.
- This NASOP must not be activated until:
  - the National Management Group (NMG) activates (upon the recommendation of the Consultative Committee on Emergency Animal Diseases (CCEAD)) the FMD vaccine supply arrangements immediately following the identification of the FMD virus strain at the commencement of an Australian outbreak; and
  - The Australian Pesticides and Veterinary Medicines Authority (APVMA) have issued an Emergency Use Permit to the supplier of FMD vaccine and a Consent to Import; and, the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) has issued an import permit.
- This NASOP does not cover vaccine control between the DVC and the field (see NASOP 14: *Control of Foot and Mouth Disease vaccine at a Designated Vaccine Centre*).

## 3. Resources/equipment

- National FMD Vaccine Storage Facility:
  - Animal Health Australia (AHA) has contracted a cold-chain distribution to store vaccine at their secure cold store facility.
  - This is a national storage point for all FMD vaccine.
- DVC: see NASOP 14: *Control of FMD vaccine at a Designated Vaccine Centre*
- auditable inventory (amounts, AHA barcodes, batch numbers) of vaccine for each stage of vaccine distribution, storage, use and waste
- AUSVETPLAN disease strategy for FMD
- Product label including leaflets

#### **4. Warnings**

- It is essential to maintain the cold chain (+2° to +8°C, without freezing) at all stages of vaccine acquisition, storage, transport and handling. 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° to +8°C, without freezing, and to protect vaccine vial from exposure to light.
- Security of vaccine stocks from theft, inappropriate distribution or the local effects of natural disaster must be assured at all times.
- The APVMA requires that the vaccine may be released only on the authority of the CVO in each state or territory, and used and handled only by authorised personnel acting under their direction or persons otherwise authorised under state/territory legislation. The product must be handled and used in accordance with the label instructions and Standard Operating Procedures as may be specified by the CCEAD.

## 5. Description of activities

- The SCC will determine the number of doses of FMD vaccine and FMD vaccine applicators required by that jurisdiction. This will be authorised by CCEAD. The jurisdiction will notify AHA of its vaccine requirements using an official AHA request form (see Appendix A FMD outbreak - Request to AHA for Supply of Emergency Vaccine, Appendix B for FMD Outbreak -Request to AHA for Supply of vaccine applicators Appendix C Equipment Required for FMD Vaccination).
- AHA will notify the National FMD Vaccine Storage Facility of the location of the DVC(s), contact details for the vaccination manager and number of doses of vaccine and applicators required.
- The National FMD Vaccine Storage Facility provider, through a courier, will transport FMD vaccine from the National FMD Vaccine Storage Facility to the DVC in secure vehicles or by air, with temperature controlled equipment equipped with data loggers to ensure the temperature is maintained at +2° to +8°C.
- Vaccine inventory control must be practised and recorded at all stages from vaccine arrival into Australia, transportation to and storage at the National FMD Vaccine Storage Facility, transportation to and storage at the DVC, transportation and use at the properties and transportation of any unused vaccine back to the DVC. This also includes transfer between DVCs within a jurisdiction.
- The vaccination manager will be responsible for receipt, inventory control and appropriate storage of vaccine at the DVC (see Appendix D for DVC FMD vaccine inventory, and Appendix E: FMD Vaccination stock take form (Electronic Balance Calculator)).
- AHA will arrange through the National FMD Vaccine Storage Facility provider for the return of unused vaccine (see Appendix F FMD Outbreak – Request to AHA for Authorisation to return unused vaccine).
- AHA can also arrange through the National FMD Vaccine Storage Facility for the return and destruction of unused vaccine where the cold chain has not been maintained (see Appendix G for FMD Outbreak – Request to AHA for Authorisation to return Spoilt Vaccine). 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.
- Persons handling vaccine will need to be trained and a record must be kept of this training.

## 6. References

- AUSVETPLAN Disease strategy Foot-and-Mouth Disease
  - AUSVETPLAN manuals are available at (<http://www.animalhealthaustralia.com.au>)
- NASOP 14: *Control of Foot and Mouth Disease vaccine at a Designated Vaccine Centre*
- NASOP 17: *Management of Foot and Mouth Disease vaccination on a property*

## 7. Appendices

- Appendix A: FMD Outbreak - Request to AHA for Supply of Emergency Vaccine
- Appendix B: FMD Outbreak – Request to AHA for Supply of Vaccine Applicators
- Appendix C: Equipment required for FMD vaccination
- Appendix D: Designated Vaccine Centre FMD vaccine inventory
- Appendix E: FMD vaccination stock take form (electronic balance calculator)
- Appendix F: FMD Out break- Request to AHA for Authorisation to return Unused
- Appendix G: FMD Out Break – Request to AHA for Authorisation to return Spoilt Vaccine

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:** \_\_\_\_\_ **Title:** \_\_\_\_\_  
**Date sent:** \_\_\_/\_\_\_/\_\_\_ **Time:** \_\_\_\_\_

<b>FMD Outbreak – [Month/ Year]</b>	
<b>Request to AHA for Supply of Emergency Vaccine</b>	
<b>Request No.</b>	<b>File</b>
<b>1. CVO/Deputy CVO making request</b>	
Name	Contact no.
Location	Signature:
<b>2. Request details</b>	
Number of doses of vaccine required in cattle equivalent doses [200 ml bottles, 100 CED per bottle]:	
Address for delivery:	
Name/position of person to sign for delivery (vaccine will only be delivered to vaccine manager on duty)	
Phone contact business hours:	
24 Hour contact number:	
Requested date & day for delivery or 'as soon as practicable'	
Receiving Centre's opening times for delivery:	
Any special requirements:	

<b>3. AHA USE ONLY</b>	
Approved	Date
[Name AHA officer]      Manager Animal Health Standards      Signature:	

**Pages sent:** \_\_\_\_\_ (including cover sheet)

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**FACSIMILE MESSAGE**

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

**From:** \_\_\_\_\_ **Title:** \_\_\_\_\_  
**Date sent:** \_\_\_/\_\_\_/\_\_\_ **Time:** \_\_\_\_\_

<b>FMD Outbreak – [Month/ Year]</b>	
<b>Request to AHA for Supply of Vaccine Applicators</b>	
Request No.	File
<b>1. CVO/Deputy CVO making request</b>	
Name	Contact no.
Location	Signature:
<b>2. Request details</b>	
<b>Item:</b>	<b>Number required:</b>
Order Code EAS1161. The 3ml variable plastic disposable injector.	
Order Code EAS1162. The 50ml plastic repeater injector.	
Order Code WX1111. Spare part kit for 50ml Repeater	
Order Code WX965. Draw-off and feed tube kit.	
Order Code SP150. Pack of 12 - 18G x ½ inch needles.	
Order Code SP***. Pack of 12 – 18G x 1 inch needles	
Address for delivery:	
24 Hour contact number:	
Receiving Centre’s opening times for delivery:	
Any special requirements:	

<b>3. AHA USE ONLY</b>	
Approved	Date
[Name AHA officer]      Manager Animal Health Standards      Signature:	

**Pages sent:** \_\_\_\_\_ (including cover sheet)

## EQUIPMENT REQUIRED FOR FMD VACCINATION

The vaccine equipment identified for use in FMD vaccination has been tested by the supplier - NJ Phillips - against the vaccine adjuvant (a light mineral oil) to ensure compatibility. In this case the off-the-shelf products are those best suited to the adjuvant.

1. Order Code EAS1161. The 3ml variable plastic disposable injector, complete with feed tube, draw-off and pack of 12 needles. No spare parts available.



2. Order Code EAS1162. The 50ml plastic repeater injector (1 ml increments) for use in small scale situations, complete with pack of 12 needles.



3. Order Code WX1111. Spare part kit for 50ml Repeater, consists of 1x barrel and 1 x Piston O-Ring.



4. Order Code WX965. Draw-off and feed tube kit.



5. Order Code SP150. Pack of 12 - 18G x ½ inch needles.

6. Order Code SP\*\*\*. Pack of 12 – 18G x 1 inch needles.



## 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)

<b>Number carried over from previous week:</b>	Total doses:			Doses in Open Bottles:		
<b>Number received into DVC:</b>	<b>0</b>					
<b>Stock throughput:</b>	<b>0</b>					
<b>Number issued to:</b>	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		
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>		
<b>Number returned to DVC:</b>	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		
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>		
<b>Number used:</b>	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		
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>		
<b>Summary</b>	Issued	Used	Discarded	Returned to store		<b>Difference</b>
	<b>0</b>	<b>0</b>	<b>0</b>	Whole Bottles	Opened Bottles	
				<b>0</b>	<b>0</b>	<b>0</b>
<b>Amount of stock in DVC store to carry over to next week:</b>			<b>0</b>	<b>Doses in Open Bottles:</b>	<b>0</b>	



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## FACSIMILE MESSAGE

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

From: \_\_\_\_\_ Date: \_\_\_\_\_

<b>FMD Outbreak [month/ year]</b> <b>Request to AHA for authorisation to Return Unused Vaccine</b>			
Request No. _____		File _____	
1. Person making request			
Name		Contact no.	
Location		Signature:	
2. Request details			
Number of <u>bottles (200ml)</u> of vaccine returned [AFTOPOR DOE]. This form is intended for the return of larger volumes of vaccine, from vaccination centres <u>cold-chain intact</u> . 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:

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

## FACSIMILE MESSAGE

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

**From:** \_\_\_\_\_    **Date:** \_\_\_\_\_

<b>FMD Outbreak [month/year]</b>					
<b>Request to AHA for authorisation to return Spoilt Vaccine</b>					
<b>Request No.</b>				<b>File</b>	
<b>1. Person making request</b>					
Name			Contact no.		
Location			Signature:		
<b>2. Request details</b>					
Number of <u>doses</u> 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:

<b>3. AHA USE ONLY</b>	
Acknowledged	Date
[Name AHA officer]    Manager Animal Health Standards	Signature: