K-11053(5313)/15/2019-LH

Government of India Ministry of Fisheries, Animal Husbandry & Dairying Department of Animal Husbandry & Dairying

Krishi Bhawan, New Delhi Dated: 21-11-2019

To,

The Principal Secretary/Secretary Animal Husbandry Department All States/UTs

Subject: Forwarding of Minutes of Second National Steering Committee meeting for National Animal Disease Control Programme for FMD and Brucellosis (NADCP) held on 20th November, 2019 at Krishi Bhawan, New Delhi – reg.

Sir/Madam,

The undersigned is directed to forwarded herewith the Minutes of Second National Steering Committee meeting for National Animal Disease Control Programme for FMD and Brucellosis held on 20th November, 2019 at Krishi Bhawan, New Delhi under Chairmanship of Secretary (AHD) for favour of your kind information and necessary action.

Yours faithfully

(R. G. Bambal)

Joint Commissioner (RGM) Emai: <u>rajendrabambal@hotmail.com</u>

Enclosed: a/a

Copy to:

- 1. PPS to Secretary (AHD)
- 2. PPS to AS & FA, AHC
- 3. PPS to JS (C&DD)/(LH)
- 4. PPS to DDG (AS), ICAR
- 5. JC(LH)
- 6. All concerned officers of NADCP

MINUTES OF THE SECOND MEETING OF THE NATIONAL STEERING COMMITTEE FOR NATIONAL ANIMAL DISEASE CONTROL PROGRAMME (NADCP) HELD UNDER CHAIRMANSHIP OF SECRETARY (AHD), DEPARTMENT OF ANIMAL HUSBANDRY & DAIRYING, MINISTRY OF FISHERIES, ANIMAL HUSBANDRY & DAIRYING ON 20th NOVEMBER, 2019 AT KRISHI BHAWAN, NEW DELHI

A. The second meeting of National Steering Committee (NSC) for National Animal Disease Control Programme (NADCP) was held on 20th November, 2019 under the Chairmanship of Shri Atul Chaturvedi, Secretary (AHD), Department of Animal Husbandry & Dairying, Ministry of Fisheries, Animal Husbandry & Dairying, Government of India.

B. The list of participants is placed at Annexure I. The States of Andhra Pradesh, Telangana, Maharashtra and Gujarat also joined through Video Conferencing.

C. At the outset, the Chairman welcomed the participants and urged all to have a concerted effort for successful implementation of National Animal Disease Control Programme for control of Foot & Mouth Disease (FMD) and Brucellosis (NADCP).

D. The minutes of the first meeting of the NSC were confirmed. Thereafter, each of the agenda item was discussed in detail and the following decisions were taken by the NSC:

E. Agenda item 2: Discussions and finalization on mode of procurement of FMD and Brucella vaccine and Tender document prepared by PLA for procurement of FMD vaccine.

Various pros and cons of mode of procurement of FMD and Brucella vaccine by PLA (NAFED) through Central Public Procurement Portal (CPPP) and GeM was deliberated. It was observed that procurement through GeM would incur a substantial amount of cost to the bidder which will result in increased cost of the vaccine. Further, it was mentioned that GeM portal necessitates release of 100% payments within 10 days after issue of consignee receipt cum acceptance certificate and this fund gets blocked in advance. Since requirement of vaccine etc. requires release of payment in two installments based on quality test results, therefore GeM procurement process is not suitable for such procurement. As CPP portal does not have any such compulsion

mentioned above and as available funds can be better utilized for any programme objective including procurement, therefore after detailed discussions, NSC approved the CPPP mode to procure the FMD and Brucella vaccines etc. to be used under NADCP.

The NSC also discussed the major aspects of the tender document viz. technical specifications of the FMD vaccine to be used, payment conditions, penalty clauses and special terms and conditions included in the draft tender document as enclosed in agenda item and the NSC approved the technical specifications and terms and conditions of payment etc. for inclusion in the tender document by PLA (enclosed at **Annexure II**)

F. Agenda item 3 : Discussions and finalization on Ear Tags :

- a. Specifications for ear tags for large and small animals were approved (Annexure IIIa)
- b. Total fund requirement for purchase of ear tags alongwith applicators to the tune of **Rs. 30370.12 lakh** was approved (**Annexure IIIb**)
- c. Remuneration for eartagging @ Rs. 2.50/- per tagging and Rs. 0.50/- per animal health card and the fund requirement for ear tagging including health card amounting to Rs. 15295.65 lakh was approved (Annexure IIIc). This amount also includes the remuneration cost for eartagging with ear tags which are already available with the States as on 01/11/2019 under RGM/ Pashu Sanjivini.
- d. As FMD vaccination is to be started from January, 2020 under NADCP and as very little time is left for purchase of eartags through PLA-NAFED before vaccination starts, for States where FMD vaccination has to be undertaken during January-February, 2020. It was decided that the aforesaid States may procure the ear-tags on already approved pre-existing standard rates tendered by States. For this funds should be released to State SIAs concerned. The anticipated requirement of **Rs. 4099.88 lakh** was also approved which, however, may undergo change based on actual approved rates.

G. Agenda item 4: Cold chain infrastructure requirement by the States and proposal for fund release.

Detailed assessment of requirement of cold chain infrastructure has been done by the department state-wise / district-wise based on demand received from States.

Mission Director briefed that the cold chain requirement received from States was Rs. 213.57 crores, while on a very strict assessment it has been arrived at Rs. 97.47 crores based on cold chain equipment capacity and doses requirement in the district. As per detail assessment various types of cold chain infrastructure Walk-in-Coolers (at district level), Cold Cabinets (at district/ block level), Ice line Refrigerators (ILR), refrigerators (at block level) and vaccine carriers an amount of **Rs. 9747 lakh** was approved for cold chain infrastructure to be released to various States (**Annexure IV**).

H. Agenda item 5: Proposal for release of funds to states for purchase of accessories to be used under NADCP.

The accessories to be provided under NADCP for FMD and Brucellosis vaccination @ Rs. 3/- for the former and Rs. 6.50/- for the latter were approved. The total funds to be released for the same to the States amounting to Rs. 15592.12 lakh were also approved (**Annexure V**).

1. Agenda item 6: Appraisal on vaccine dosage of Brucella vaccine (S-19) to be used by states for Brucellosis vaccination

NSC approved the use of vaccine with minimum 4 x 10^9 CFU based on the decision of the technical experts committee and minutes of the meeting dated 18/10/2019.

J. Additional Agenda item 7: Constitution of the National Steering Committee

Joint Secretary (CDD) who is Mission Director, was approved to be included as the Member Secretary of the NSC. It was further decided that Joint Secretary (LH) and Joint Commissioner (LH) shall continue to be members of NSC.

The meeting concluded with vote of thanks to the Chair.

SECOND MEETING OF THE NATIONAL STEERING COMMITTEE FOR NATIONAL ANIMAL DISEASE CONTROL PROGRAMME (NADCP) HELD UNDER CHAIRMANSHIP OF SECRETARY (AHD), DEPARTMENT OF ANIMAL HUSBANDRY & DAIRYING, MINISTRY OF FISHERIES, ANIMAL HUSBANDRY & DAIRYING ON 20th NOVEMBER, 2019 AT KRISHI BHAWAN, NEW DELHI

SI.	SI. Name Designation			
No.		-		
1.	Sh. Atul Chaturvedi	Secretary, AHD, Gol		
2.	Sh. B. Pradhan	AS & FA, Gol		
3.	Sh. Mihir Kumar Singh	JS (Cⅅ), MD (NADCP), DAHD, Gol		
4.	Sh. Upamanyu Basu	JS (LH), DAHD		
5.	Sh. Anoop Kumar	Principal Secretary, AHD&F		
6.	G. Krishna Kishore	Director (Fin)		
7.	Dr. Ashok Kumar	ADG (AH & ANP), ICAR		
8.	Dr. Anil Kumar Sharma	Joint Director, Animal Husbandry, UP		
9.	Dr. Sanjeev Khosla	Joint Director, AH, Punjab		
10.	Dr. Nitant Pannikar	DAHO, Animal Husbandry Unit, GNCTD		
11.	Dr. Anil Kumar Sharma	Joint Director, Animal Husbandry, UP		
12.	Dr. P. Blahwar	JC (LH), DAHD, Gol		
13.	Dr. R G Bambal	JC (Cattle)		
14.	Dr. Rajiv Khosla	RO (NADCP)		
15.	Dr. Sujit Nayak	AC (LH)		
16.	Dr. Anirban Guha	LO(LH)		

List of participants

Annexure-II

TECHNICAL SPECIFICATIONS

SPECIFICATIONS OF FMD VACCINES:

- I.A. Trivalent ('A', 'O' and 'Asia-1') FMD oil adjuvant vaccine with the following strains
 - (i) Serotype 'O'- Strain IND R2/1975
 - (ii) Serotype 'A'- Strain IND 40/2000
 - (iii) Serotype 'Asia 1'- Strain IND 63/72
 - B. Oil- adjuvant (safe and of proven efficacy)
 - C. Routes of administration: Intra muscular (I/M)
 - D. Period of immunity: Not less than 9months
 - *E.* The shelf life of the vaccine should be at least 24 months from the date of manufacture and m*inimum* one year at the time of supply
 - F. One dose of vaccine should have at least 3PD₅₀ as per IP (Vet) and whenever tested, the FMD vaccines should satisfy the quality parameters of safety and sterility as per IP in vogue and generate a minimum of 1:64 SNT titre for Serotype 'O' and 1:48 each for serotype 'Asia-1' & 'A'.
 - G. The vaccine should be Non-structural protein (NSP) free. The manufacturer has to self-certify that their vaccine is NSP free.

II Special terms and conditions for Foot & Mouth Disease (FMD) Vaccine:

- 1. The FMD Vaccine manufacturers shall have valid license from DCGI (Drug Controller General Of India) and the vaccines shall be manufactured having their quality assured as per the extant Indian Pharmacopoeia (IP) Veterinary. All provisions of Drugs & Cosmetics Act 1940, as amended till date and Rules made there under will always be applicable. If revalidation of drug license has been applied for, the buyer should be informed accordingly and the copy of application to Licensing authority must be submitted with a certificate that application for renewal was made within the time frame as per Drugs & Cosmetics Act as amended up to date and that has not been deleted by licensing authority.
- **2.** In-house Certification of Analysis (COA) of each batch should be accompanied with supply.
- **3.** Temperature Monitoring Card shall be provided in each box by the manufacturer to assess the cold chain maintenance

4. 10 (ten) vials of each batch of FMD vaccine produced by the manufacturer will be collected on random basis out of the whole lot of each batch by the officials authorized by DAHD. Vaccine manufacturer will facilitate for such collection of the vaccine samples and for maintenance of the cold chain for transportation to the designated institute by DAHD.

5 (A). MECHANISM FOR QUALITY CONTROL TESTING OF INACTIVATED FOOT AND MOUTH DISEASE VACCINE

- a. Ten vials of every batch of FMD vaccine produced by the manufacturers will be collected on random basis out of the whole lot of each batch by the officials authorised by DAHD/NAFED. Vaccine manufacturer will facilitate for such collection of vaccine samples and for maintenance of cold chain for transportation. Samples of all the batches collected by officer will be submitted to designated institute.
- b. The sample vials will be coded and any one out of every 5 batches will be randomly selected and will be sent to three laboratories designated by DAHD for testing of FMD vaccine. 16 cattle for potency, 2 cattle for safety and 2 cattle as control of 6 to 8 months of age will be used for quality control testing by these laboratories.
- c. Each designated laboratory for testing will undertake testing of FMD vaccine as under:

(i) **Sterility:** Sterility testing of each batch of vaccine will be conducted as per Indian Pharmacopoeia (IP)

(ii) Safety: Safety testing of each batch of vaccine will be conducted as per Indian Pharmacopoeia (Vet).

(iii) **Potency:** The *in vitro* serotype based alternate assay SNT will be used for testing the efficacy of FMD vaccine under NADCP for FMD. The personnel of respective laboratories will vaccinate the animals and collect pre and post vaccinate serum samples at 0 and 28 days post vaccination.

- d. Besides the satisfactory results in sterility and safety testing, the vaccines inducing SN₅₀ antibody titre (1:64 for Serotype O and 1:48 for Serotype A and Asia-1) in 75% (12 out of 16) animals of each potency testing group will satisfy the criteria for acceptance of the vaccine quality.
- e. The result of testing will be communicated by the designated institute to DAHD/NAFED within 40 days.

5 (B). MECHANISM OF PURITY TESTING OF INACTIVATED FOOT AND MOUTH DISEASE VACCINE UNDER NADCP:

- a) The same samples will be subjected to purity of the vaccine by the designated laboratory for testing NSP antibodies using 3AB3 ELISA kit provided by ICAR-DFMD laboratory.
- b) For this, 8 numbers of animals for each batch subjected for potency testing will be boostered at 28th -30th days after first vaccination. Serum samples will be collected at 0 day and 28-30 days of booster vaccination (60 days of first vaccination) by respective labs and as per requirements and guidelines provided by ICAR-DFMD.
- c) Result will be submitted by the designated institute immediately within two days after completion of testing.
- 6 Any information regarding vaccine if necessary shall be available to access by DAHD, Gol.

7 STORAGE TEMPERATURE; COLD CHAIN MAINTENACE

The vaccine shall be stored and/or transported between $+2^{\circ}$ C and $+8^{\circ}$ C and not to be frozen. The cold chain maintenance of the supply of vaccine shall be ensured by the seller up to the designated destination.

8 **DOSAGE SIZE**:

The vaccine should be packed in a bottle of 50 doses each of vaccine, one

standard dose consisting of 2 ml of liquid vaccine

- 9 The quantitative lot(s) of the vaccines supplied shall preferable be of the same batch.
- 10 **POST DELIVERY SURVEILLANCE:** The batch/batches of the vaccine(s) which fail(s) Quality Control tests as prescribed in I.P. and by the Department of Animal Husbandry, GoI shall be considered as failed and action shall be taken on the manufacturer concerned as under:
 - i. Un-utilized dose(s) of the failed vaccine, if any, shall stand written off from all departmental stores and the manufacturer shall be responsible for immediate lifting the un-utilized vaccine in all respect. If vaccine batched taken for testing at designated laboratories are delivered in the field but fail the test(s) then that batch of vaccine supplied shall be replaced by the manufacturer at its own cost and the cost of vaccination shall also be recovered from the manufacturer.

- ii. If 03 (three) consecutive batched of vaccines of a particular manufacturer fail QC tests, then purchaser/ Nafed shall not take supply from the vaccine manufacturer concerned and this information shall be shared with the Department (DADH) so that DCGI is informed for taking necessary further action.
- iii. Vaccine manufacturer shall comply with the testing requirements for subsequent two consecutive batched for testing at designated laboratories at their own expense and only after due compliance of testing, the manufacturer(s) shall approach the Government concerned for its (their) readiness to supply the vaccines as per the extant procedure.
- 11 The Buyer may carry out either Pre-dispatch inspection at manufacturer place or post-dispatch inspection at its warehouses at district level sending the samples to accredited labs for testing at their own cost.
- 12 Maximum delivery time for supply of vaccine will be 60 days from the date of placing the order.

13 LABELING:

- a. Packing and labeling shall be appear in English language and shall confirm to provisions of applicable Indian Pharmacopeia and as specified under Drugs and Cosmetics Act, 1940 as amended to date. The vaccine vial labels/inserts shall include strains of the virus to be used against, adjuvant, dosage and route of administration, precautions, batch numbers, date of manufacture, date of expiry, name of manufacturer, etc.
- b. All vial and other packing should contain label/ stamped

"NADCP, GOVT OF INDIA"

"NOT FOR SALE" in English.

Qualification Criteria:

- 1. The bidder must be a manufacturer and should have drug license issued by DCGI for commercial manufacture and supply of FMD vaccine in the country.
- 2. The Bidder should be in relevant business for at least past 3 years. In support of this, the bidder shall furnish performance statement in the enclosed Proforma
- 3. The bidder shall furnish a brief write-up including:
 - a) Production Capacity (Monthly and Yearly)
 - b) Expansion Plan

- c) Present Commitments
- d) Location of Plants
- e) Capacity/capability to perform the contract (if awarded) within the stipulated time period, after meeting all its current/present commitments.
- 4. Notwithstanding anything stated above, the purchaser reserves the right to assess the bidder's capability and capacity to perform the contract satisfactorily before deciding on award of contract, should circumstances warrant such an assessment in the overall interest of the purchaser.
- 5. Bidder should not be blacklisted by DCGI.

PAYMENT CONDITIONS

The approved rate shall be paid to the supplier on fulfillment of the following conditions:

On submission of a claim supported by the acceptance certificate issued by the consignee/purchaser's representative in the proforma.

The following documents shall be provided by the supplier before release of payment

The supplier's request for payment shall be made to the Paying authority specified in the notification of award/contract in writing accompanied by an invoice indicating the quantity of goods delivered.

Approved consolidated unit price.

Consolidated due amount.

The supplier shall also enclose manufacturer's test certificate of each batch/lot of vaccine supplied, guarantee certificate, certificate of origin, certificate of analysis along with the bill/invoice.

Self-certification from the manufacturer/supplier that the vaccine supplied is free from NSP

While claiming payment, the supplier shall also certify in the bill that the payment being claimed is strictly as per terms of the contract and the entire obligation on the part of the supplier for claiming that payment has been fulfilled as required under the contract.

Payment of 75% of the supplied goods will be released by the purchaser on receipt of all required documents within 7 working days. On receipt of Quality Control Test as specified in clause 5(A) and receipt of NSP test results from DAHD/ designated lab as specified in clause 5(B) "TECHNICAL SPECIFICATIONS" of the bid, the balance payment of 25% will be released.

If NSP test is failed, only 40% of the Balance payment amount (25%), i.e. 10% of the total payment will be given to the manufacturer. Remaining 15% will be the penalty imposed on the manufacturer.

Payment will be made subject to recoveries, if any, by way of liquidity damages or any other charges/ recoveries as per terms of the contract.

The supplier will not claim any interest on payment under the contract.

Specification on Ear Tags for large animals NDDB has provided the following specification for Ear tags for cattle buffalo which is already being used in the RGM programme.

Sr. No.	Description: Specification for ear tags of Large animals (Cattle and Buffalo)						
1	Description: The ear tag composed of two parts (Male + Female). The male part is a button with a diameter of 27 mm (+2mmd). The male part should have a metal point. The size of the female piece should be comprised between 55x65 mm and 58x 69 mm with a closed head.						
2	• <u>Raw material</u> : The tag should be made from Ether grade Thermoplastic polyurethane Elastomer material that should be resistant to ultraviolet light, high and low temperature, impossible to reopen by wrench and should be tamperproof.						
	• The manufacturer should provide documentation from the independent and recognized sources to demonstrate the non-resolvability of its tags. Pull test certificate for the ear tag with minimum 28kgf pull test force shall be furnished at the time of submitting technical bid.						
3	Weight: The weight of the ear tag (male +female)should be 7 grams (+/-10%).						
4	Printing Laser): 1 st : One dimensional Barcode with encoding 128, Line 10mm high (+/-1mm). 2 nd : A row of 6 digits, 10mm high (+/-mm).						
	Line : A row of 6 digits, 18mm high (+/-mm). 3 rd : A row of 6 digits, 18mm high (+/-mm).						
5	Numbers and bar code should be covering full size of the female tag and leaving 2 mm margin on all sides.						
6	The printing must be as dark as possible to ensure the readability of the bar code over the years. The manufacturer should provide documentation to demonstrate the readability of its numbers to be laser printed on ear tags.						
7	<u>Colour</u> : The colour of the tag should be lemon yellow						
8	<u>Packing</u> : In order to manage the tag inventory the eartag should be packed in batches of 100 pieces in a good quality polyethylene bags indicating beginning and ending numbers and further packed in a corrugated box containing 500 Pieces of ear tags i.e. 5 polyethylene bags each containing 100 pieces of ear tags.						
9	Ear tag Applicator: Compatible Universal applicator with 1 extra pin along with the ear tags should also be supplied.						
10	Ear tag-Test Report- a) Ether Grade Test Report is required to be provided at the time of supply (finished good) b) Manufacturer' test certificate should be attached						
	with the proposal (Raw Material)						

Specification for ear tags of small animals (Sheep, Goat and Pig):

- i. Two part (Male and Female) plastic ear tag will be used
- Single, uniform, global medium female ear tag of dimension 15/8" x2" (41.27mm x 50.8 mm) will be used for ear tagging all species of animals. The male part button will have diameter of 27mm.
- iii. The weight of the ear tag (Male + Female) will be 6 gms (±10%)
- iv. The colour of the tag will be deep violet.
- v. The 12 digit unique number will be laser printed on ear tag in 2 rows of 6 digit each, with 15mm and 8mm font size.
- vi. The barcode of the number will be printed on the tag. (However, QR code could be explored later for optimal utilization of the space).
- vii. Other specification will be same as being used for cattle / buffalo.

Annexure-III(b)

Fund requirement for ear tags and applicators:

(in Lakhs)

Cattle	Total Ear	Ear Tags	Gaps for	Total	Total Ear	Fund
and	Тад	available	Ear Tags	Sheep	Тад	requirement
Buffalo	requirement	with states		Goat and		for purchase of
populatio				Pig		Ear tags @
n				Populatio		Rs. 7 per tag
				n	5	(4+6) x Rs.7
						(Rs. In lakh)
1	2	3	4	5	6	7
3023.35	3023.35	1006.76	2016.58	2322.01	2322.01	30370.13

Annexure-III(c)

Fund requirement for ear tags for which remuneration to be paid:

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								(in La	khs)
Total	Ear	Ear tag	Total Ear	Total I	Ear	Total	Ear	Remune	ratio
Ear	tagging	left with	Tag Gap	Tags	for	Tag	for	n for	Ear
Tags	already	the	Cattle &	cattle a	and	Sheep	Goat	Tagging	per
available	done	States	Buffalo	buffalo	for	and Pig	3	animal	-
Cattle &	under	as on		which				including	
Buffalo	INAPH	01-11-		remuneration				health ca	ard
	till 31-	2019		is to be pai	id			(5+6) x 3	3
	10-2019	(1-2)		(3+4)				(Rs.	in
								Lakhs)	
1	2	3	4	5		6		7	
1006.76	246.80	759.96	2016.58	2776.54	ŀ	2322	.01	15295.	65

Annexure IV

Fund requirement for cold chain infrastructure:

(Rs. In lakh)

						()
Walk-in	Cold	ILRs	Refrigerators/	Vaccine	Total	Total
Coolers/ Cabinet		(300	Deep Freezer	Carriers	Funds	Funds
Cold (1.5 lakh		litres	(300 lt cap -	2 lit @	Cold	appraised
Rooms	Rooms doses) @		15000 doses @	Rs.	Chain	(Rs. in
(4.5 lakh	Rs. 2	20,000	Rs. 40,000)	1000/-	sought	Lakh)
doses) @	lakh	doses)			(Rs. in	
Rs. 6 lakh		@ Rs.			Lakh)	
		80,000				
1109	773	3436.1	3639	790	21357	9747.1

Annexure V

Fund requirement for purchase of accessories to be used under NADCP:

Rs. in Lakh

Total FMD vacc doses (in million doses)	Brucella vaccines required (in million doses)	Accessories Cost- FMD (@Rs.3 per Dose) for one round	Accessories - Brucella @ Rs 6.50 per dose	Total Cost implication for accessories
452.57	30.98	13578.31	2013.81	15592.12