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## ESTABLISHMENT OF A PILOT DEMONSTRATION PLANT FOR THE PRODUCTION OF VACCINES FOR APRICA

### XA/RAF/88/666

Technical report: Subcontract for remodelling, training and additional equipment required for LAMAVET, arous\*

Prepared for the Government of Cameroon by the United Nations Industrial Development Organization

## Based on the work of L. Hegedüs UNIDO Consultant

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United Nations Industrial Development O:ganization Vienna

<sup>\*</sup> This document has not been edited.

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### **ACKNOWLEDGEMENTS**

The consultant wishes to express his thankfulness to Dr.Maikano Abdoulaye, General Director of Lanavet and his staff with whom the consultant has been closely associated during the length of the mission.

The courtesy and cooperation of the officials of the Government of Cameroon institutions is deeply appreciated. Many thanks to Dr.C.Borredon who was staying at Lanavet on another World Bank mission and devoted his week-end to work together with the consultant.

Special thanks to Mr. M. Konare - SIDFA for his valuable assistance.

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### SUMMARY AND RECOMMENDATIONS

The purpose of the project is the establishment of a Pilot production Plant for the production of human vaccines at the premises of Lanavet in Cameroon.

- 2. Offer for the subcontract has been discussed with the subcontractor and the management of Lanavet. Strong efforts were mode to reduce the price below the budgeted amount. The new, revised offer from Enterprise Goulet was received. It is recommended that Goulet Enterprise be awarded the subcontract.
- 3. Orders and final specifications for machinery have been reviewed and discussed in detail. Comments are given in the report. Careful and well planed shipping is a very important factor for the implementation of the strict time-shedule of the project. Recommendations are given in the report for the shipping, clearing and forwarding arrangements.

- 4. Additional machinery, materials and services are required for the successfull implementation of the project amounting appr. USO 100.000.—. Detailed list of the requested materials and recommendation for generating the additional funds are given in the VI. paragraph of the report.
- 5. A proposal for time schedule for consultants and experts is given in the VII. paragraph of the report.
- 6. Revised project implementation time schedule is proposed in the VIII. paragraph of the report.

### I. INTRODUCTION

The present 10 days consultantship is meant to review the past 4 months progress of the project and to discuss and facilitate the critical areas of the first phase regarding remodelling of the facilities, pruchase of machinery and organizing the training for the selected Lanavet staff. The work undertaken at Lanavet, Garoua, Cameroon was prescribed by UNIDO job description XA/RAF/88/666.

### It comprised:

- To finalize nomination forms for trainees and schedule their fellowship at institute Human, Hungary.
- To finalize and be present at signing of subcontract for which the Substantive Backstopping Unit at UNIDO will obtain waiver of International Bidding at that date.
- To assist in preparatory activities to receive machinery and arrange inland transportation from Douala to Garoua.
- To discuss necessary budget revision if additional unforseen expenses may occur during implementation.

The duties described in the job description of the mission and the subsequent orientations outlined in the time of briefing period at the headquarters have been fulfilled. The contract started on 19th February with travel and briefing in Vienna-Work in Cameroon commenced on 21st February 1989 and ended on 1st March 1989.

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### II. PROJECT BACKGROUND AND HISTORY

Between September 1988 and January 1989 three Technical Reports have been prepared and published by UNIDO on the project.

Recommendations and the Project Implementation Scheduling have been accepted by Lanavet and the reports were presented to the relevant government authorities as revised documents for the realization of the project.

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## III. TO FINALIZE NOMINATION FORMS FOR TRAINEES AND SCHEDULE THEIR FELLOWSHIP AT INSTITUTE HUMAN, HUNGARY

7 trainees have been nominated by Lanavet for the training in Institute Human, Hungary and 2 traines in Phylaxia, Hungary. The Ministry of Livestock, Fisheries and Animal Industries approved the nominations

Fellowship Nomination Forms have been obtained from the UNIDO office in Yaounde and completed by Lanavet and the trainees. The 9 completed forms are attached to this report.

The following table contains the necessary information regarding the nominations, requested time and duration of the trainings.

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Name:	Occupation:	Training is reguested in the following fields	Proposed starting date:	Proposed duration of training:
Mr.Fokou Samuel	ingineur ensiac /new recruitment/	complete production of tetanus toxoid bulk, formulation and filling of Tetanus toxoid vacc., formulation and filling of DPT vaccine. Human Institute	April 1989	6 months /April-Sept.1989/
Mr.Youkuda Koeranga	<pre>docteur en pharmacie /new recruitment/</pre>	11	April 1989	6 months /April-Sept.1989/
Mr.Nengue Jean-Marie	infirmier veterinaire /Lanavet present/ staff	complete production of tetanus toxoid bulk, formulation of TT and DPT bulk vacc. Human Institute	April 1989	3 months /April-June 1989/
Mrs.Yaya Pierrette	lincence biochimie /Lanavet present/	Complete biological, biochemical and chemical QC of TT and OPT vaccines Human Institute	April 1989	3 months /April-June 1989/
Dr.Lotchuang Etiene	<pre>veterinaire /Lanavet present/ staff</pre>	complete biological, biochemical and chemical QC of TT and DPT vaccines. Human Institute	July 1989	3 months /July-Sept 1989/

Name:	Occupation:	Training is reguested in the following fields	Proposed starting date:	Proposed duration of training:
Miss.Tamon Constance	techniciene superieure /Lanavet present/ staff	Complete production of tetanus toxoid bulk, formulation of TT and DPT bulk vaccine. Human Institute	July 1989	3 months /July-Sept.1989/
Mr.Hadam Seket	<pre>bac mecanigue industriel /Lanavet present/ staff</pre>	maintenance of machinery Human Institute	July 1989	3 months
Dr.Hamadama Hassan	<pre>veterinaire /Lanavet present/ staff</pre>	production of chemical veteriner products Phylaxia, Budapest	to be specified later by Lanavet	to be specified later by Lanavet /maximum 3 months/
Mr.Némb Theodore	licence biochimie /Lanavet present/ staff	production of chemical veteriner products Phylaxia, Budapest	to be specified later by Lanavat	to be specified later by Lanavet /maximum 3 months/

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It is a specific reguest of Lanavet that

Mr. Fokou Samuel and

Mr. Youkuda Koreanga

should be trained for the complete production of the vaccines. This is why they will spend double time than the others.

After the completed training course Mr. Foku, S. will be in charge of fermentation, concentration and purification while mr. Youkuda, K will be responsible for the formulation, filling and finishing activities.

The same refers to the 2 quality controler

Mrs. Yaya Pierette and

Dr. Lotchuang Etien.

They should be trained for the complete QC.

After returning to Lanavet Dr. Lotchuang will be in charge of the biological QC while Mrs. Yaya will be responsible for the biochemical tests.

In addition of the above trainings Lanavet is requesting for a 2 weeks study tour for

Dr. Abdoulkaoiri Souley - Deputy General Manager and a short term consultancy for

Or. Jean-Jacques Tulasne - Head of Bacteriology in the second half of June 1989 /24th June - 9th July/

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### IV. SUBCONTRACT FOR THE REMODELLING

At the consultant's arrival to Garoua the position of the subcontract was the following;

- The budget of our project provided USO 150.000.- /appr. CFA 47.000.000.-/ for the remodelling plus USO 43.467.- /appr. CFA 13.450.000.-/ for the 3 controlled temperature rooms totaling CFA 60.450.000.- for the complete remodelling.
- UNIOO, Vienna mailed a contract proposal to the subcontractor /Enterprise Goulet/ which was not received so far /airmails take 3-5 weeks to Cameroon from Vienna/.
- Enterprise Goulet submitted 2 offers to Lanavet for the complete remodelling. The offer of 14th Febr. 198° contained all the necessary reconstruction works and materials which were based on the Terms of Reference proposed by C. Borredon,
   J. Zsidai and L.Gy. Hegedüs for an amount of CFA 62.501.527.—excluding tax.

An additional offer of 20th Febr. 1989 amounting CFA 3.329.340.— was prepared by Goulet for the reguired built—in laboratory furnitures. The same items would cost CFA 8.574.060.— in case of purchase from import. /All above prices are excluding  $\tan x_i$  which is 10.99 % in Cameroon/.

Summerizing the above; a Garoua based construction company which is owned and managed by French engineers quoted CFA 65.830.867.— for the remodelling.

This amount did not contain remodelling of the animal houses proposed by Dr.L.Hegedüs in his report. This report was handed over to Lanavet by the consultant on the 23rd Febr. 1989. Two meetings have been held with Goulet whereby it was agreed that Goulet will prepare a revised offer for UNIDO considering the followings.

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- Aluminium doors and partitioning elements represent a considerable past in the offer /CFA 12.750.254.-/ Therefore in order to reduce the offer it was agreed that the existing wooden doors will not be changed but repainted with resistant epoxy paint.
- Having in hand the final drawings of the KSF 1020 Bausch+ Stroebel filling machine it was established that room 61 is not big enough for the installation. Therefore it was agreed that rooms 64 and 65 will be reconstructed and attached to room 61.
- It was agreed that the absolute filters for the aircontrol of the filling area should be built into the offer. A proforma invoice for 2 terminal filters were handed over to Goulet /2x FF 11.890.- on FOB, France parity/
- Drawings for the remodelling of the animal house were given to Goulet asking him to built in the costs into the revised offer. It was agreed that the mouse test of tetanus toxin production will be carried out in the well separated room of the house of mice which is presently used for storage of animal food. In this room a fixed window and an airconditioning unit will be installed.
- In order to reduce cost it was agreed that the separation of the house of mice into 6 more rooms will be done by brick walls up to 1.5 meter and wire mesh above. In this case the already built in central airconditioning unit will serve these six rooms and no need to buy individual units for each single room.

The revised offer amounting CFA 59.012.760.- was presented on the 28th Febr. 1989.

This offer excludes the two terminal filters /2x FF 11.800.-/which should be purchased by UNIOO.

Based on Lanavet's opinion and the impression gained during the meetings it is recommended that Goulet enterprise be awarded with the contract.

The contract should be awarded in March and the complete remodelling should be carried out in three months time between May and July. /Procurement of some imported materials like inox pipes will take appr. 3 months time for Goulet/

### V. MACHINERY AND INLAND TRANSPORTATION

Copies of the orders sent by UNIOO have been received by Lanavet. The documents were studied carefully and the following comments, proposals were made.

### Purchase order 15-8-H1485

Item 38. Quantity should be ammended to 2 pes. The price is unchanged.

### Purchase order 15-8-H1614

Chemap offered a 400 lit. storage tank for the demineralized water and a 250 lit. storage tank for the osmosis water in its original offer for SFR 112.575.~.

Therefore the additionaly ordered jacketed mixing vessel is not necessary. This will reduce the cost by SFR 92.900.- and we can remain at the originally accepted SFR 112.575.-.

CHEMAP AG should be requested to send urgently detailed specification and drawing of the complete water system.

### Purchase order 15-8-H1499

Sofast informed Dr.C. Borredon that they received the drawing of the requested hot air steriliser only after they have quoted for one of their standard machines.

Upon receiving the drawing they have started to produce the requested equipment.

Sofast will be requested by Or. Borredon to confirm it in writting to UNIDO.

Dr. Borredon will also ask Sofast to reduce length of the boxes by 25 mm. /This is the recent request of Bausch + Ströbel/ In this case the final measurements will be the following

Lenght: 425 mm

Width: 310 mm

Height: 70 mm

in case the boxes have already been produced the originaly requested length of 450 mm is also acceptable.

### Purchase order 15-8-H1613

- It would be important to reduce the delivery time by at least one month from September to August 1989.
- Questionnarie of Electric Equipment is completed and enclosed to the report /3 copies/.
- Cleaning scheme for FAW 1000 is prepared and enclosed to the report. For the washing demineralized water will be used produced by Millipore ionpure machine equiped with a 400 liter storage tank.
- Supply magazine

FAW 1000 - localy produced trays will be used for this purpose. Bausch + Strobel is kindly requested to send proposal for the measurements and material.

KSF 1020 - Aluminium boxes complete with lid

Lenght: 450 mm /external/

Width: 310 mm

Height: 70 mm "

Material: 1.5 - 2.0 mm aluminium

Discharge magazine for FAW 1000 and KSF 1020

Aluminium boxes complete with lid

Lenght: 450 mm

Width: 310 mm

Height: 70 mm

Material: 1.5 - 2.00 mm aluminium

Samples of vials, stoppers and caps will be sent by the consultant before 7th of March 1989.

It is confirmed that for the KSF 1020 the trial runs can be done by water.

Based on the experiences of Lanavet shipping time could be 2-3 months between Europe and Garoua. This could badly affect the implementation time scheduling of the project.

It is important that the French companies should ship the goods in one consignment in container.

France: Etec SA

Biobloc

SGI

SOFAST

UNIOO in Yaounde should be informed by telex by the suppliers about the shipments giving all necessary detailes ie. name of vessel, container number, number of packages, value, etc. All documents necessary for the clearing of the consignments should be sent by DHL to the UNIDO office in Yaounde to the attention of Mr.M. Konare - SIDFA.

In case of air supply consignments should be directed to Garoua! .

Transportation of the goods from Douala to Garoua will be organized by the Yaounde UNIDO office. During the mission only one quotation has been obtained for the charges.

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MORY ENTERPRISE - Garoua

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Bulk consignment: CFA 95.000.-/ton 30 m<sup>3</sup> container: CFA 1.425.000.-

### VI. BUDGET REVISION

The following additional purchases and expenses are required for the successfull implementation of the project.

Quantity:	Description:	Proposed supplier:	Unit price /USD/	Total price /USD/
2 pcs	Laboratory thermostat for QC tests	ETEC	1.150	2.300
1 pc	Laminar Airflow Vertical Crystal 15, for QC tests	ETEC	5.710	5.710
	Laboratory Utensils			
80 pcs	Pyrex flacon lo lit.	<b>11</b>		
15 pcs	Pyrex flacon 15 lit.	81		
30 pcs	Erlenmeyer flask 3 lit.	11		
100 pcs	" " 1 lit.	**		
100 pcs	" " 0,5 lit.	11		
100 pcs	" 0,25 lit	. 11		
400 pcs	Tubes a hémolyse	88		
100 pcs	Manual security pipettes 0.5 ml	**		
100 pcs	" 1 ml	10		
100 pcs	" 2 ml	99		
50 pcs	" 5 ml	**		
50 pcs	" 10 ml	**		
25 pcs	" 20 ml	•		
25 pcs	" 100 ml	**		
500 pcs	Plastic Petri dishes	**		
			appr.	15.000
	Raw and packaging materials	ETEC		
150 kg	Ammonium sulphate pharm.qual.	11		

Quantity:	Description:	Proposed supplier:	Unit price /USO/	Total price /USD/
500 lit.	Alu.phosh.gel 2 % standard ADJU-PHOS	ETEC		
	Superfos Biosector a/s Denmark			
0.2 kg	Biotin pharm.qual	ETEC		
0.5 kg	Ca panthotenate "	**		
1.5 kg	Cystine "	81		
20 lit	Ethanol p.a.	Ħ		
24 lit	Hydrochloric acid 37 % p.a.			
l kg	Fe SO <sub>4</sub> /7 H <sub>2</sub> O/ pharm.qu	ıal "		
25 lit	Formaldehyde "	<b>11</b>		
50 kg	Glucose "	817		
l kg	KH <sub>2</sub> PO <sub>4</sub> p.a.	98		
l kg	MgS0 <sub>4</sub> /7H <sub>2</sub> 0/ "	98		
5 kg	NaOH "	**		
7 kg	Na <sub>2</sub> HPO <sub>4</sub> "	**		
100 kg	NZ-case standa Sheffield rharm USA	rd "		
0.5 kg	Pyrodoxine HCl pharm.q	ual "		
0.5 kg	Riboflavin "	16		
15 kg	Sodium chloride p.a.	16		
100 kg	Sodium chloride pharm.q	ual "		
0.5 kg	Thiamin "	**		
2 kg	Thioglycolate broth star			
2 kg	Thiomersal pharm.q	ual "		
3 kg	Tyrosine "	11	•	
1.5 kg	uracil "	89		
175000 pcs	Aluminium cap. /OM 7.7/3 Helvoet Pharma-Belgium Diam. inner: 20.3 mm Height: 7.5 mm Thickness: 0.2 mm	"		
	Surface: natural	**		

Quantity:	Description:	Proposed supplier:	Unit pr /USO		Total price /USD/
175000 pcs	Rubber stopper 20 mm Helvoet Pharma-Belgium V9034 FM 157 /DM 20.30/1000/	ETEC			
175000 pcs	11,5 ml vial DIN 58366-BR Hydrolitic class.l.	**			
5 pcs	Pall filter cartridge SLK 7002 NRP				
500 pcs	Seitz EK 20x20	n			
500 pcs	Seitz _K 40x40	Ħ			
150 pcs	Seitz EKS 20x20	m			
150 pcs	Seitz EKS 40x40	81			
2 lit	Silicon emulsion	ľ			
			appr.	35	- 40.000
	Clearing and Forwarding charges of the consignments for the project		appr.	20	- 25.000
	. •				
			Total:		88.010

The suppliers of the packaging materials should be requested to send the following quantities as samples free of charge for machine trial to Bausch + Strobel - Germany.

VIAL - 1000 pcs RUBBER STOPPER - 3000 pcs ALU. CAP - 3000 pcs

The above amount of appr. USO 100.000.- could be obtained from converting 5 short expert months to material purchase /USO 50.000.-/ and from the carcellation of the jacketed mixing vessel of the Chemap order No. 15-8-H1614 /SFR 92.900.-/

# VII. PROPOSED TIME SCHEDULE FOR CONSULTANTS AND SHORT TERM EXPERTS FOR 1989

Name:	Budget	line:		Duties required:	Period required:
				Production technics	24th June- 9 th July
Dr.C.Borredon	11-51	return	mission	Overall rewiw of the construction works	12-19 July
Dr.József Zsidai	11-01	return	mission	Validation of equipments	Sept- Oct 1989
Mr.Lajos Hegedüs	11-02	return	mission	Preparation of standard Operation Procedures Trial fermentation of tetanus toxin/toxoid Trial concentration and purification of tetanus toxoid Installation and validation of the filling+finishing equipments Preparation of production program for 1990.	
Short term expert from Human Insti- tute	11-53			Completion of the training under local conditions production of tetanus toxoid bulk.	Oct 1989
Or.Christian Borredon	11-51	return	mission	Overall rewiew of the installations and trial produc- tion.	19-25 Oct 1989
Or.László Hegedüs	11-03	return		Completion of the training under local conditions. Complete QC follow up of the tetanus toxin bulk and the Tetanus toxoid vaccine production.	Nov-Dec.1989

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Name:	Budget line:	Duties required:	Period required:
Short term expert from	11-54	Production of Tetanus toxoid	15th Nov- 15th Dec 1989.
Human Insti- tute		<pre>vacc. Filling and fi-</pre>	
3230		nishing.	

### Revised implementation sheduling time-programme

Yiming:	Remodelling/Reconstruction:	Machinery/Materials:	Training:	Production and QC:	Marketing:
Nov.1988	Final engineering layout should be prepared by international experts in coordination with national counterpart COMPLETED!	Invitation for machi- nery quotations from different suppliers. Final specification to agreed between supplier national counterpart and licensor. COMPLETED!	Selection of trainees by Lanavet COMPLETED!		Relevant Govern- ment Authorities should be infor- med about the project and the expected imple- mentation shedu- ling COMPLETEO!
Dec.1988	Governmental approval	Orders should be placed for machinery for July arrival at latest COMPLETED!	Recruitment of additional staff for the training. COMPLETED!	•	-
Jan.1989	Governmental approval	-	-	-	
Febr.1989	Selection of a local company for the execution of the job. COMPLETED!	-	-	-	- 1
March. 1989	UNIDO should finalize the subcontract with the contractor	Quotations should be requested for raw and packaging mate- rials by UNIDO		-	-

Timing:	Remodelling/Reconstruction:	Machinery/Materials:	Training:	Production and QC:	Marketing:
April 1989	-	Orders should be placed for raw and packaging materials for July arrival by UNIDO Orders for lab.utensils should be placed by UNIDO for July arrival	Training of the first team should be started	-	-
May 1989	Start up for the reconst- ruction/remodelling	-	-	-	Progress report should be prepared for MOH.
June 1989	Remodelling	-	Training for the first team is fi-nished	-	- - 24
July 1989	Completion of the construction work	Deadline for the arrival of the machinery	Training for the second team should be started	-	-
Aug 1989	-	Installation of the machinery	-	-	Demand forecast should be obtai- ned from MOH for 1990.

Timing:	Remodelling/Reconstruction:	Machinery/Materials:	Training:	Production and QC:	Merketing:
Sept. 1989		Validation and trial runs with the participation of the consultants. Orders should be placed for raw and packaging material for Jan. arrival by Lanavet	Training for the second group is finished	Production programme should be prepared for 1990.	Well drafted Memorandum sho- uld be sent to potential ex- port partners about the pro- duction unit, forecasting capacity figu- res
Oct 1990	-	Trial runs and pre- paration of SOP-s with the participa- rion of the consul- tants	-	Trial Tetanus toxoid produc- tion with comp- lete QC follow up	-
		Arrival and installa- tion of the washing and filling machine			25
Nov 1990	-	-	-	Trial formulation of Tetanus toxoid vacc. with complete QC follow up	
<b>Dec</b> 1990	_	Orders should be placed by Lanavet for raw and packa-ging materials for April arrival	-		Opening cere- mony with the participation of potential big purchase part- ners

Timing:	Remodelling/Reconstruction:	Machinery/Materials:	Training:	Production and QC:	Marketing: .
Jan. 1990	<b>-</b>	<b>-</b>	-	Routine production of Tetanus toxoid vacc. and trial formulation of DPT and DT vaccines with the participation of the consultants	Offer to be given to potential export partners and proper follow up.
Febr.1990	-	-	••	-	-
March 1990	-	Orders should be placed by Lanavet for raw and packa-ging materials for July arrival	-	-	-
April 1990	-	-	-	Routine formula- tion of CPT and DT vaccines	- 25 -