



RFP/RABIESVB/2021

A.TENDER PROCEDURE RULES

RABIES VACCINE BANK

WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

FEBRUARY 2021

Contracting authority

World Organisation for Animal Health (OIE)

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F-75017 Paris

France

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1. GENERAL TENDER RULES

1.1. DEFINITIONS

Awarded Tenderer: the economic operator having, through the call for tender process, been awarded the contract, prior to its signature.

Contract: the definitive agreement for Services entered into by the OIE and the Supplier, including any annexes attached thereto, as amended, modified and supplemented from time to time.

Supplier: the economic operator having signed the contract with the OIE for the provision of the services detailed in this call for tender. This operator will be the sole interlocutor of the OIE.

Services: the services, functions, responsibilities, tasks and deliverables to be carried out by the Supplier, as described in the Contract.

Tenderers: all economic operators responding to this tender procedure.

RFP: Request for Proposal

1.2. PURPOSE

This tender procedure is an invitation for interested service providers to submit a proposal regarding the establishment of a new Rabies Vaccine Bank which will allow (i) purchase by the OIE (donor funding), (ii) direct purchase by countries or governmental Agencies, and (iii) direct purchase by international organisations and implementing partners, such as WHO, FAO and NGOs.

1.3. NON-BINDING EFFECT

The information included in the tender documents are provided to Tenderers so they may prepare a proposal in response. This tender procedure may lead to the signature of a Contract between the OIE and up to two tenderers selected by the OIE. However, the transmission of the tender documents to tenderers does not imply any legal obligation on the part of the OIE to entrust the provision of the services to any tenderer. The OIE has the right to reject any proposal in its sole discretion. The OIE remains strictly independent of any tenderer, and none of the provisions of the tender documentation may be interpreted as creating a contractual relation of any sort.

The OIE is under no obligation to accept a given tenderer's proposal and reserves the right not to proceed with or to terminate negotiations with any tenderer, at any time prior to the signature of a Contract.

In this case, the OIE shall not have any liability whatsoever and tenderers who have not signed a Contract with the OIE waive their right to claim any compensation or damages.

1.4. CONFIDENTIALITY

Unless otherwise authorised in writing by the OIE, all information, whether disclosed either directly or indirectly, formally or informally, in writing, orally, or by visual inspection, which are part of the tender procedure or provided for its purpose or any amendment thereto, shall not be disclosed, copied, used or modified in any manner and shall only be used for the sole purpose of the tender procedure.

Consequently, tenderers agree to take all the necessary steps to ensure compliance with such confidentiality obligations by its directors, officers and employees who need to know such information for purposes of the tender procedure.

All information received in response to this initiative that is marked proprietary will be handled accordingly. Responses will not be returned.

1.5. COSTS OF RESPONSES

Tenderers are responsible for all costs and expenses, including professional fees, incurred in connection with the preparation and submission of responses to, and generally their participation in, the tender procedure.

1.6. CONDITIONS OF PARTICIPATION

Natural and legal persons as well as consortia (either officially established or constituted specifically for this call for tender) may apply.

No more than one tender may be submitted by a person whether as a natural or legal person or member of a consortium. If a person submits more than one response, all responses in which they participate will be excluded from the selection process.

In participating to this call for tender, a tenderer represents and warrants by doing so that:

- is not bankrupt or under mandatory liquidation, is not having its affairs administered by the courts, has not entered into an arrangement with creditors, is not the subject of proceedings concerning its business activities, or is not in any similar situation arising from a procedure provided for in national legislation or regulations;
- it or a person having powers of representation, decision-making or control over it or a member of an administrative, a management or a supervisory body has not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization, money laundering, offences linked to terrorist activities, child labour, human trafficking, creating or being a shell company or any other irregular or illegal activity ;
- it or persons having powers of representation, decision-making or control over it have not been guilty of professional misconduct, including misrepresentation.
- it is in compliance with all its obligations relating to the payment of social security contributions and of taxes in accordance with the national legislation or regulations of the country in which the Tenderer is established;

Tenderers undertake to provide documentary evidence related to the items mentioned above upon request by the OIE at any point during the tender procedure and/or contracting process. Should a tenderer fail to produce reasonable evidence, the OIE reserves the right to reject the tenderer's response and, in the event it has already entered into a Contract with the tenderer as a result of the tender process, to terminate such Contract with immediate effect.

1.7. CONFLICTS OF INTEREST

Under no circumstances is a tenderer to contact any person employed by or representing the OIE. regarding the tender procedure other than the person(s) mentioned in this document.

In participating to this call for tender, a tenderer represents and warrants that:

- It does not have any conflict of interest arising from economic interests, political or national affinities, family or emotional ties, or any other relevant connection or shared interest in connection with any Contract that may be entered into between the tenderer and the OIE as a result of the call for tender;
- It will inform, without delay, of any situation constituting a conflict of interest or which could give rise to a conflict of interest;
- No offer of any type whatsoever from which an advantage can be derived under the Contract has been or will be made;
- It has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or

- in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to the award of the Contract;
- It has not misrepresenting, either knowingly or negligently, in supplying any of the information requested by the OIE.

1.8. PERIOD OF PROPOSAL VALIDITY

Tenderers are bound by their proposals for 180 days after the deadline for submission or until they have been notified of non-award.

1.9. APPEAL

Tenderers believing, they have been harmed by an error or irregularity during the award process may lodge a complaint with the OIE who will be required to reply within ten working days after receipt of the complaint. If the OIE fails to address the complaint, the unsuccessful tenderer may request arbitration by the Permanent Court of Arbitration (PCA) at The Hague, governed by the PCA arbitration rules 2012 and the PCA Optional Rules for Arbitration between International Organisations and Private Parties.

1.10. SIGNING OF THE CONTRACT

1.10.1. General provisions

Any Awarded Tenderer represents and warrants that it is authorised to bind its affiliates to the Contract it will sign with the OIE and shall cause such affiliates to comply with all commitments set out in the Contract and any purchase orders signed within the framework of the Services. Awarded Tenderers will undertake to inform their affiliates, potential suppliers and subcontractors of the existence of the Contract within thirty (30) calendar days from its signature by the parties.

Awarded Tenderers will appoint a contact person having the right and authority to ensure compliance with the commitments set out in the Contract and the purchase orders signed within the framework of the Services. S/He will be the sole contact person of the OIE.

1.10.2. Notification of award

The OIE will notify the Awarded Tenderers that their tender has been retained. At the same time, the OIE will inform every other unsuccessful tenderer in writing that its tender has been rejected. Tenderers having submitted a tender before the deadline will receive, within ten (10) working days of their written request, information relating to the rejection of their tender.

1.10.3. Signing of the Contract

The Awarded Tenderers will be notified in writing of the selection. The contract award decision shall be published and contract negotiations based on the draft Contract submitted by the OIE shall be conducted. These negotiations will involve, at least, the OIE representatives from the Legal Affairs Unit and the Administration Directorate and the Awarded Tenderer's authorised representative.

2. GENERAL TENDER PROVISIONS

2.1. CONTRACT TYPE

Supply Agreement.

2.2. CONTRACT NATURE

Unit price contract.

2.3. LOTS

Single lot.

2.4. VARIANTS

Variants are not authorised.

2.5. ADDITIONAL SERVICES

The Contract may be extended by agreement of both parties through consecutive amendments if:

- additional operations have, due to unforeseen circumstances, become necessary for the performance of the Services as described in the initial Contract;
- these operations cannot be dissociated from the initial Contract without presenting major drawbacks or costs or additional expenses for the OIE; and
- the extension of the Contract is clearly more economical and more efficient, and the organisation of a new tendering process would not provide any advantage.

2.6. SUBCONTRACTING

Subcontracting is not allowed.

2.7. DURATION OF THE CONTRACT

The Contract is expected to be performed from 01/01/2022 to 31/12/2025.

It may be extended.

2.8. INVOICING

Payment throughout the Contract will be made upon receipt of the corresponding undisputed invoice, which should be raised after vaccines have been delivered.

In the case of the OIE purchasing vaccines, the OIE will proceed to the payment of undisputed invoices after the delivery of the vaccines and within 45 days of the reception of the invoices by bank transfer or cheque.

Invoice currency will be agreed-upon with each requesting entity (OIE, implementing partners or any other third party). By default, invoices should be established in EUR, or in USD. However, it must be noted that in order to facilitate customs clearance, some beneficiary countries may require invoices in a currency differing from the currency of the contract signed (e.g. contract signed in EUR and invoice in USD on a case-by-case basis for some countries).

3. CONTRACTUAL FRAMEWORK OF THE SERVICES

The services contract (supply agreement) is attached in annex 3 and will serve as basis for the contract negotiation.

4. RESPONSE PROCEDURE

4.1. OIE CONTACT POINTS

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Engagement and Investment Department
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Ms Andrea Rivera Valdez
Direction of Administration
Email: a.rivera@oie.int

4.2. SCHEDULE

RFP sent to suppliers	19 February 2021
Questions/Answers session (by email)	19 February 2021 – 13 April 2021
Deadline for submission	19 April 2021
Evaluation of offers*	20 April 2021 – 15 July 2021
Contract award and notification	25 July 2021
Contract finalisation with the selected manufacturers	01 September 2021 – 15 December 2021
Deadline for contract signature and official start of the services	31 December 2021

* The OIE may ask tenderers to provide clarifications needed to evaluate their tender; tenderers will be requested to reply in writing.

Should the OIE change any of these dates, all tenderers having notified their interest will be informed.

4.3. TENDER DOCUMENTS

The tender documents are the following:

- A. Tender procedure rules and its annexes:
 - o Annex 1, Declaration of interest and integrity (to be provided as part of the response)
 - o Annex 2, Financial and economic capacity assessment (to be provided as part of the response)
 - o Annex 3, Draft Contract (for information only)
- B. Tender terms of reference

4.4. NOTIFICATION OF INTEREST AND QUESTIONS/ANSWERS

Tenderers wishing to respond to the call for tender should notify the OIE contact points of their interest to do so, by sending by email the Declaration of interest and integrity document filled out and signed (Annex 1), within fifteen days of the receipt of the call for tender, and by **01 April 2021** at the latest.

If necessary, tenderers may request additional information, in English, to establish their responses. Questions must be sent exclusively by email to the OIE contact points until **13 April 2021** (Paris local time). Questions should make precise reference to the relevant tender document, chapter, page and paragraph. In order to ensure fair and equal treatment of all interested suppliers, the questions and the answers will be centralised and shared with all tenderers.

Note: commercial information will not be shared with other tenderers.

The OIE reserves the right to introduce non-substantial modifications to the tender documents. In the event that the OIE, either following a request from a tenderer or on its own initiative, introduces a modification of the tender documents, all tenderers having notified the OIE of their interest to respond will be informed simultaneously and a corrigendum will be published at least six working days before the deadline for submission of the tenders. The OIE may extend the deadline for submission of tenders to all tenderers to allow tenderers to take into account these changes.

4.5. RESPONSE FORMAT REQUIREMENTS

Tenders, namely the envelope including the technical offer and the envelope including the financial offer, must be submitted in English in a sealed package bearing in large bold letters as follows:

CONFIDENTIEL - NE PAS OUVRIR A LA RECEPTION
Rabies Vaccine Bank Call for tender

Madame la Directrice Générale
Organisation Mondiale de la Santé Animale (OIE)
12, rue de Prony
F-75017 Paris
France

The wording on the package should also appear on the outside of the external wrapping if the responses are sent by post or by couriers. If necessary, the OIE will provide the required acknowledgment of receipt. Tenders may be deposited at the OIE reception desk, from Monday to Friday and from 9:00 to 17:00.

Tenders should include:

- **Technical envelope:**

- All call for tender addenda signed;
- Annexes 1 and 2 of document A. *Tender Procedure Rules* duly completed and signed;
- One hard copy of the technical offer (valid for 180 days from the day of tender submission), providing the information required in document B. *Terms of Reference*, including all annexes and signed by the authorised person;
- A USB key containing the electronic copy of the technical offer.

The tender response should be provided with a table of contents and in the most succinct format possible for efficient evaluation. The OIE states its preference to receive only the information requested to specifically demonstrate compliance of the manufacturer and vaccine with technical requirements, along

with evidence of certification/validation by reputable Regulatory Authorities or GMP certifiers, thereby avoiding unnecessary and unhelpful additional documentation. Responses padded with unnecessary and unhelpful additional documentation that complicate the evaluation process will be taken as evidence of a supplier's inability to efficiently comply with supply requirements.

- **Financial envelope:**

- The financial offer (valid for 180 days from the day of tender submission), providing the information required in document *B. Terms of Reference*;
- A USB key containing the electronic copy of the financial offer;

Please make specific reference in the response to any legitimately and appropriately confidential or proprietary material contained in the response. Such information included in the responses to the RFP will be kept confidential by the OIE.

Reminder: responses should be submitted by **19 April 2021 COB (Paris local time)**. Any tender received past this deadline, or within a non-sealed package, will be excluded from the tendering process.

4.6. **MODIFICATION OR WITHDRAWAL OF TENDERS**

Tenders may be modified or withdrawn prior to the deadline for submission through a written notification sent to the OIE contact points. Notification of a modification or withdrawal must comply with the requirements specified in paragraphs 4.5 Response format, with outer envelopes bearing the word "Modification" or "Withdrawal".

4.7. **INITIAL EVALUATION OF TENDERS**

A tender Opening Committee will proceed to open tenders received at the beginning of the selection process. The Opening Committee is responsible for verifying that the tenders received have complied with the procedures for the submission and presentation of tenders described in this call for tender and for preparing the list of tenders deemed eligible.

A tender Selection Committee will then proceed to award the contract. In view of the technical complexity of the proposed contract, it will include several qualified persons internal and external to the OIE. The Selection Committee will evaluate the technical and financial offers and will proceed to a selection based on the following criteria:

- Company capacity to deliver and sustainability
- Adequacy of the vaccine nature and quality proposed with requirements presented in the Terms of reference
- Adequacy of the vaccine service proposed with requirements presented in the Terms of reference
- Cost

The OIE may ask tenderers to provide clarifications needed to evaluate their tender; tenderers will be requested to reply in writing.

4.8. **FINAL EVALUATION AND AWARD OF THE CONTRACT**

The OIE will proceed to an evaluation of all final offers according to the criteria described above. The award criteria will be the most economically advantageous tender, based on a ratio of 70% for the technical offer and 30% for the financial offer.

Tenderers will be informed through electronic correspondence of the results of the selection process.



ANNEX 1 - DECLARATION OF INTEREST AND INTEGRITY

To be completed and sent back upon receipt of the tender documentation to the OIE contact points.

Call for tender: RFP/RABIESVB/2021

..... (the Tenderer) acknowledges receipt of the tender documentation and hereby notifies the OIE of its intention to respond to this call for tender. The designated point of contact for the call for tender process is:

- Name:
- Surname:
- Email:
- Phone number:

The Tenderer further declares that:

- is not bankrupt or under mandatory liquidation, is not having its affairs administered by the courts, has not entered into an arrangement with creditors, is not the subject of proceedings concerning its business activities, or is not in any similar situation arising from a procedure provided for in national legislation or regulations;
- it or a person having powers of representation, decision-making or control over it or a member of an administrative, a management or a supervisory body has not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization, money laundering, offences linked to terrorist activities, child labour, human trafficking, creating or being a shell company or any other irregular or illegal activity ;
- it or persons having powers of representation, decision-making or control over it have not been guilty of professional misconduct, including misrepresentation.
- it is in compliance with all its obligations relating to the payment of social security contributions and of taxes in accordance with the national legislation or regulations of the country in which the Tenderer is established;
- it does not have any conflict of interest arising from economic interests, political or national affinities, family or emotional ties, or any other relevant connection or shared interest in connection with any definitive agreement that may be entered into between the Tenderer and the OIE ("Contract") as a result of the tendering process;
- it will inform, without delay, the World Organisation for Animal Health (OIE) of any situation constituting a conflict of interest or which could give rise to a conflict of interest;
- no offer of any type whatsoever from which an advantage can be derived under the Contract has been or will be made;
- it has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to the award of the Contract;
- it is not misrepresentating, either knowingly or negligently, in supplying any of the information requested by the OIE.



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de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

The Tenderer acknowledges and agrees that the OIE reserves the right to check the above-mentioned declarations and to request further information to its satisfaction, and undertakes to provide documentary evidence upon request. The Tenderer further acknowledges that failure to disclose relevant information or a false statement may result in the disqualification of the Tenderer from the tendering process, the withdrawal of any proposition of a Contract by the OIE, or the termination with immediate effect of the Contract if it has already been awarded.

Entity name:

Address:
.....
.....

Name and Title of duly authorized representative:

Date:

Signature:



ANNEX 2 - FINANCIAL AND ECONOMIC CAPACITY ASSESSMENT

RFP N°	
Company name	

Regarding the last two years for which the accounts are closed:		
2020	Start of the fiscal year	/...../...../2020
	End of the fiscal year	/...../...../2020
2019	Start of the fiscal year	/...../...../2019
	End of the fiscal year	/...../...../2019
Currency used for accounting:		

Simplified balance sheet/financial position		
	2020	2019
Assets (total), including:		
Cash and cash equivalents		
Liabilities (total), including:		
Equity (reserves, investment subsidies and others)		
Total liabilities, including:		
Total of medium and long-term debts (> 1 year)		
Total of short-term debts (< 1 year)		

Simplified statement of financial performance		
	2020	2019
Total expenses, including:		
Personnel costs (amount)		
Personnel costs (% of the total expenses)		
Revenue:		
Operating income		

[Date]

SUPPLY AGREEMENT

This Agreement is concluded between

The OIE (World Organisation for Animal Health) with its headquarters at 12 rue de Prony, F-75017 PARIS, FRANCE

Represented by its Director General, Dr Monique ELOIT,

Hereinafter referred to as:

“the OIE”

And

[Company name], a company with its headquarters at **[address]**

Represented by its Director General, **[Company name representative]**

Hereinafter referred to as:

“**[short Company name if relevant]**”

WHEREAS

In **[Date]**, the OIE expressed, through an international call for tender (“Call for Tender”), the wish to establish a new rabies Vaccine Bank managed by the OIE.

In **[Date]**, **[Company name]** replied by offering its services as defined in the Technical and Financial offers sent by **[Company name]**.

An independent Selection Committee including renowned international experts was formed to analyse the offers received.

On **[Date]**, the OIE, based on the recommendation of the Selection Committee, selected **[Company name]** for the supply of inactivated parenteral (injectable) rabies vaccines in **[size of vial]** vials for dogs.

The OIE and **[Company name]** agreed in consequence to start the following cooperation.

THE PARTIES HEREWITH AGREE TO THE FOLLOWING

ARTICLE 1 – PURPOSE/SCOPE

1-1 In accordance with the provisions and technical specifications of the Call for Tender, the OIE entrusts [Company name] with the task of:

- Manufacturing a [type of vaccine] against rabies for carnivores (dogs and cats) as set out in **Annex 5** (the “Vaccines”);
- Implementing a supply plan and a minimum inventory of Vaccines for the OIE managed through rolling stocks and replenishment principles to allow as much flexibility as possible for an effective and efficient supply and provide access to Vaccines with sufficient shelf life;
- Upon receipt of a production & delivery order or delivery order, triggering production and/or delivery within the delivery periods specified in this Agreement;
- Delivering the ordered Vaccines to an international airport at the delivery location as designated by the OIE. Depending on quantities ordered, deliveries may be fragmented.
- [add information on planned leadtimes]

1-2 The Annexes and the Call for Tender form an integral part of this Agreement and are to be taken as mutually explanatory. If there is any inconsistency between the provisions of this Agreement a descending order of precedence will be accorded to:

- the Agreement clauses;
- the Annexes, including the [Company name] offers; and
- the Call for Tender,

so that the provision in the higher ranked document, to the extent of the inconsistency, will prevail.

In case any ambiguity or discrepancy or inconsistency still prevails, the parties hereto will discuss in good faith with the purpose of clarifying them.

ARTICLE 2 – VACCINE MANUFACTURE

2-1 - Term

[Company name] and the OIE will maintain a rabies Vaccine Bank to be used as described in **Article 1**. The Agreement will come into force on the date it is signed by both parties hereto (i.e., the Commencement Date), and will remain in full force until **31 December 2025** (the “Initial Term”). This Initial Term may be extended for periods of one year (or other duration agreed upon by the parties hereto) through a written agreement.

If the OIE requires additional doses beyond the maximum doses as defined in **article 2-2** below, [Company name] will give the best timeline possible based on volume and manufacturing capacity.

2-2 - Volume

[Company name] will guarantee availability of Vaccines as set out in this Agreement.

The maximum capacity of [Company name] is [number of doses] doses per annum. Should a greater volume be required, the parties hereto will discuss in good faith such requirement.

The Vaccines available from [Company name] under the terms of this Agreement are inactivated injectable rabies vaccine for carnivores (dogs and cats), [brand name of the vaccine], packaged in [size/specification of vials] vials.

In every case, depending on available stocks, [Company name] will use its best endeavours to deliver the Vaccines in the shortest time frame within the yearly quantities.

2-3 - Technical Warranties

[brand name of the vaccine] provides at least [number] months of immunity to dogs vaccinated with one single injection of [number] ml. Protective immunity was demonstrated in vaccinated animals for up to [number] years post vaccination in dogs and cats.

[Company name] warrants that all Vaccines and packaging shall be manufactured, tested and stored in accordance with the conditions set forth in **Annex 5**.

All Vaccines in accordance with good manufacturing practices (GMPs) and the Technical Specifications shall be packed and labelled in compliance with the Technical Specifications and requirements set forth in **Annex 5**.

ARTICLE 3 – STORAGE/PRESERVATION OF THE VACCINES

3-1 - Technical Warranties

The Vaccines to be manufactured within the quantities indicated in **Article 2** will remain in [Company name] inventory and stored by [Company name] at its manufacturing facilities of [address]. The finished Vaccines are kept in cold storage by [Company name] until the day of dispatch.

The Vaccines will be kept in cold-storage in outer boxes until the day of dispatch. Upon reception of a valid delivery order from the OIE (as defined in **Annex 1**) and confirmed by [Company name], the Vaccines will be packed and shipped to the international airport designated by the OIE and it is expected that the beneficiary country (or beneficiary country's agent) will collect them from there.

[Company name] warrants that all measures will be taken to ensure the quality and purity of the Vaccines, to ensure traceability and to minimize the risk of cross contaminations between the Vaccines and any other products.

3-2 - Ownership of the Vaccines

[Company name] shall store the volume agreed upon on its premises for the OIE, with no fixed costs and for the whole duration of this Agreement. [Company name] represents and warrants that this stock shall always be compliant with the Technical specifications of the Call for Tender. The doses will remain [Company name]'s property until they are delivered to the international airport designated by the OIE.

Transfer of property is described in **Article 4-2**. At the expiration and or termination of this Agreement, the Vaccines which have not been shipped to an eligible country shall remain the property of [Company name] and not be charged to the OIE.

3-3 - Insurance

The Vaccines stored by [Company name] will be insured against general and product liability by [Company name] at all times as from the Commencement Date and through the expiration or termination of this Agreement against loss/damage in accordance with the conditions indicated in the certificate of insurance issued by [Company name]'s insurance company (and provided to the OIE prior to the execution of this Agreement);

further details can be found in the Technical offer of **Annex 5**. [Company name] may be requested by the OIE to provide a valid insurance certificate at any time during the duration of this agreement, or any other duration mutually agreed upon after subsequent modifications of this Agreement.

3-4 - Inspections and Audits

The OIE and/or the purchasing entities shall be entitled to either visit by itself or to request that its funding entities be entitled to inspect or audit the [Company name] facilities within the framework of a confidentiality agreement as often as duly appropriate for the purpose of conducting technical inspections of the conditions under which [Company name] maintains Vaccines. The OIE and/or the purchasing entities shall have access to any documents, data and procedure related to the purpose of the Agreement. [Company name] shall ensure that all documents and records relating to the manufacture, testing and delivery of the Vaccines are maintained in accordance with the applicable laws and regulations.

Subject to reasonable notice given to [Company name] in writing (at least one month for routine audits/inspections but could be shortened to 48h/72h for specific causes), the OIE and/or the purchasing entities may carry out an inspection or audit at [Company name] facilities, up to one (1) time in any twelve-month period.

The inspections or audits shall be conducted during working days and hours.

The OIE and/or the purchasing entities will be entitled to examine (through a Confidentiality Agreement to be executed with [Company name]'s documents, data and procedure related to the purpose of the Agreement.

3-5 - Replenishment Mechanism

Within the Maximum Annual Quantity as defined in **article 2-2** and during the term of this Agreement, [Company name] will offer the OIE a replenishment schedule after the inventory draw down.

ARTICLE 4 – PREPARATION AND DELIVERY OF THE VACCINES

4-1 - Order of Production/Delivery

The implementation of this Agreement will be done through the OIE Headquarters in Paris.

In order to avoid any error in the transmission of the message which might result in an inadvertent or unwanted depletion of Vaccines, the OIE will inform in writing the [Company name] persons listed in **Annex 2**. Only written communications endorsed by the Director General of the OIE (or her representative as communicated by the Director General) or the Director of Administration will be deemed as valid written communications.

A "Delivery Order" must be issued for triggering the delivery of vaccines from the [Company name] physical stock.

A "Production & Delivery Order" must be issued for the manufacturing of Vaccines and their delivery when they become available.

Upon submission of a valid Production & Delivery Order or Delivery Order, the order will be scheduled, and the quantities agreed upon will be prepared for shipment according to the lead times described in Article 1.

Template orders are provided in **Annex 1** to this Agreement.

The Orders must specify:

- the number of doses requested;

- the beneficiary country/shipping destination;
- the maximum date of delivery of the shipment.

All Production & Delivery Order or Delivery Orders shall be deemed accepted and binding upon [Company] five (5) days from reception of the Delivery Order by [Company]. If an Order is not accepted by [Company], [Company] shall indicate in writing no later than five (5) days from reception of the Production & Delivery Order or Delivery Order, the reasons of refusal and the date of the possible delivery.

Obtaining import permits (if necessary) and other requirements for acceptance of the Vaccines and transfer to and from the OIE designated international airport are the responsibility of the Veterinary Authority of the country of destination and not [Company name].

As per **Annex 3**, the OIE shall provide [Company name] with the information related to the recipient of the Vaccines, including possible Third Party customer details, if applicable (see **Article 4-3**).

The following information may be transferred to [Company name] as a secondary step when finalising the logistics arrangements:

- a copy of the import permit (when relevant);
- the international airport designated in the beneficiary country;
- the details of the Veterinary Authority to which ownership will be transferred upon arrival,
- the details of the contact person in charge of the consignment upon arrival, and
- the details of the storage facility of destination (when known).

4-2 - Delivery of the vaccines

[Company name] will deliver the vaccines in compliance with the terms of this Agreement and taking into account the constraints set out in **Annex 4** as well as embargoes and trade compliance. [Company name] shall notify the OIE of any possible change to the shipping constraints thereof.

[Company name] is fully responsible for making the corresponding flight reservations and confirmations.

Once transport is organised by [Company name], the Incoterm that will govern the delivery of the Vaccines will be CIP Incoterms® (Carriage and Insurance Paid to; "CIP (insert named place of destination/international airport) Incoterms® 2010") with the transportation services organised by [Company name] or its freight forwarder / forwarding agent.

The risk of loss and transfer of property for the Vaccines will take place at the arrival airport (the "Delivery") as soon as the beneficiary country (or beneficiary country's agent) collects them from there or any representatives duly empowered by the OIE or by the National Authorities to do so. In such cases, the OIE will inform [Company name] in advance. [Company name] will not be responsible for the storage conditions and risks after the Delivery.

The Vaccines shall be delivered with a minimum remaining shelf life of [number] months as from the date of arrival of the Vaccines at the airport of final destination.

[Company name] will provide all the necessary information to allow customs clearance in the beneficiary country. Documents to be provided by [Company name] with the delivery of each shipment are:

- invoice;

- certificate of analysis;
- packing list;
- airway bill (AWB);
- any other documents depending on the beneficiary country regulations.

4-3 - Exceptional orders

During the term of this Agreement, a funding entity ("Third Party") may approach the OIE and request permission to order Vaccines through the OIE Rabies Vaccine Bank. In this circumstance such Third Parties will be approved in writing by both the OIE and [Company name] prior to the placement of an order. The delivery timelines and terms of payment (except price per dose) will need to be agreed to by all parties OIE, [Company name] and Third Party).

If Parties agree for [Company name] to supply Vaccines directly to a Third Party, an agreement between [Company name] and the Third Party containing the same terms and conditions of this Agreement may be entered into if needed. The timelines will be in working days between the date of an executed contract and availability of the Vaccines at factory gate.

Corresponding invoices will be paid directly to [Company name] by the Third Party unless other arrangements are agreed to in writing between the OIE and [Company name] prior to placing the order (see **Article 6-4** regarding warranty of payment by Third Parties).

The WHO (and the organizations eligible to purchase through WHO) is not considered as a Third Party according to this section.

4-4 - WHO orders

In agreement with the World Health Organization (WHO) acting in collaboration with OIE, the direct purchase by WHO will be subject to the following terms:

[Company name] shall offer the same prices and terms as those agreed with OIE to WHO and other organizations eligible to purchase through WHO (it being understood WHO and other organizations eligible to purchase through WHO will be responsible for independently entering into and administering its own contract with [Company name] as much as possible exclusively based on the conditions of the present Agreement and the template attached in **Annex 1**).

ARTICLE 5 – LIABILITY AND INDEMNITY

[Company name] agrees to indemnify and to hold the OIE, and each of its respective directors, officers and employees, harmless from and against, and shall compensate and reimburse, from all liabilities, damages, claim, suit, loss or expenses caused by, arising out of, or resulting from failure by [Company name] or its affiliates to comply with the terms of this Agreement, the non-compliance of the Vaccines with this Agreement, the negligence or willful misconduct of [Company name] or its affiliates or as a result of [Company name]'s performance of its obligations hereunder.

[Company name] shall be liable for any direct and indirect damages, whether based on warranty, contract, negligence or tort. During the Initial Term, the liability of [Company name] and its affiliates for all losses/damages will be limited to a maximum amount of 3,000,000 Euros per year; provided that the cumulative total of damages will not exceed 5,000,000 Euros during the Initial Term. In the event the Initial Term is extended for periods of one year (or other duration agreed upon) through a written agreement, the liability of [Company name] and its affiliates for all losses/damages will be limited to a maximum amount of 3,000,000 Euros per year.

[Company name] shall be solely responsible for compliance with all laws, rules and regulations concerning protection of its personnel and the environment from any damage due to active ingredients, raw materials and packaging elements.

ARTICLE 6 – PRICES - TERMS OF PAYMENT

6-1 - Price for the Establishment of the rabies Vaccine Bank

The prices are firm and non-revisable during the Initial Term.

Prices of the Vaccines for the vaccine bank during the duration of this Agreement are set as follows:

[price]

Prices listed do not encompass the shipment costs. Price for the delivery cannot be defined in advance.

Prices are quoted in [currency], per dose and are VAT excluded.

6-2 - Miscellaneous

[price for data logger, syringe or other potential additional services]

6-3 - Price of Delivery/Transportation

[Company name] agrees to present a financial proposal regarding the cost for shipment including transportation and freight to the departure airport under temperature control. [Company name] will also provide to the best of its ability the estimated delivery date and time before proceeding to any shipment of vaccines.

As soon as the OIE places a Production & Delivery order or a Delivery order and such order is accepted by [Company name], [Company name] will promptly undertake the preparation of the shipment of the ordered Vaccines. [Company name] will endeavour to keep the overall lead time as short as possible.

To avoid complications caused by flight connections while maintaining the cold chain, [Company name] shall use direct flights as often as possible (or a limited number of connecting flights).

In order not to delay the shipment, [Company name] will promptly seek the OIE's approval to ship the Vaccines rapidly. The OIE shall confirm its agreement to [Company name] as soon as possible or ask [Company name] to make another proposal if the first proposal is not acceptable (price or time/date of arrival). [Company name] shall be responsible for corresponding flight reservations and confirmations.

The price of the delivery of the vaccines will depend on the beneficiary country. Goods are sent to the international airport requested by the OIE or the Third Party, as the case may be, as designated in the Production & Delivery order or Delivery order and it is expected that the OIE or the Third Party (or their agent) will collect the shipment from there.

The leadtime of delivery between factory gate and airport of final destination will depend on the beneficiary country and on flight availability as specified in the Technical offer in **Annex 5**.

[Company name] will invoice the OIE for the cost of shipment from the [Company name] factory or warehouse to the international airport designated by the country after each shipment arrives.

6-4 - Terms of payment

All the prices are quoted in [Currency] and VAT excluded. The relevant VAT should be the French VAT, if any.

Within the maximum annual quantities, [Company name] will grant access to large quantities of vaccines at no additional fixed costs.

[Company name] will invoice the price of the vaccines when delivered to the recipient country.

The invoice will stipulate:

- the cost of the vaccines,
- the cost for the freight, transportation and insurance,

The invoices will be issued in [Currency]. Upon request, [Company name] will provide an invoice in another currency.

The OIE shall notify [Company name] in writing of any dispute with any invoice (along with a reasonably detailed description of the dispute) within fifteen (15) working days from receipt of such invoice. The parties shall seek to resolve any such disputes expeditiously and in good faith. Notwithstanding anything to the contrary, the parties shall continue performing their obligations under the Agreement during any such dispute, and the OIE will pay all due and undisputed invoice amounts (or when only part of the invoice is disputed, all due and undisputed part of the invoice amounts) according to the above schedule and within 45 days of receipt.

In the event of a direct purchase from [Company name] by a Third Party as set in **Article 4-3** or WHO as set in **Article 4-4**, [Company name] will directly invoice the Third Party and/or WHO.

With the exception of the OIE and WHO, all countries or international organizations eligible to the OIE rabies vaccine bank shall be presented to and accepted by [Company name] according to **Article 4-3**. Terms and conditions of payment (excluding Price perdose) might be different than in this Agreement.

[Company name] may refuse to accept a direct purchase order for the following reasons:

- if the conditions are different from those defined in this Agreement, or
- if the quantities exceed the maximum volume per year, or
- for Force Majeure events such as embargos, civil wars, or
- for trade compliance issues.

If there is any reasonable doubt regarding the financial situation of a Third Party, [Company name] may choose to delay the manufacture of the Vaccines or their delivery or not to proceed at all to their delivery to the Third Party, and will inform the OIE accordingly until a payment guarantee is secured by the Third Party.

Any other case will be examined in good faith by [Company name] and the OIE.

ARTICLE 7 – PENALTIES

In the event of late delivery of Vaccines compared to the speed of delivery set forth in Production & Delivery order or Delivery Order accepted by [Company] (as per timelines defined in **Article 1**), [Company name] will pay a penalty of zero point five percent (0.5%) daily penalty calculated on the basis of the total amount of the not fully delivered Delivery Order. In any case the maximum amount of penalty shall not exceed 20% of the amount due for the delivery.

Penalties do not apply to the delivery of the Vaccines paid directly by Third Parties.

Force Majeure events such as wars and embargos will exonerate [Company name] from these penalties. Any Force Majeure event shall as soon as possible be notified by [Company name] in writing and provide all the particulars of the event and date of its first occurrence.

In a potential recall situation of Vaccines, [Company name] shall bear all costs and expenses of such recall, including, without limitation, expenses or obligations to third parties, the cost of notifying customers and costs associated with the shipment of recalled Vaccines from customers, except if such recall is not due to a fault or a negligence of [Company name] in the manufacture, storage, handling and delivery of the Vaccines.

ARTICLE 8 - SCIENTIFIC COLLABORATION

Upon request by the OIE, [Company name] will provide scientific collaboration [to be described] as described in the Technical offer.

ARTICLE 9 – TERMINATION

This Agreement can be terminated at any time by either Party if the other has breached its obligations hereunder and failed to remedy within 30 days following receipt of the other party's written notice.

ARTICLE 10 – AMENDMENTS

This Agreement can be amended or extended subject to the signing of an addendum between the parties hereto.

ARTICLE 11 – FORCE MAJEURE

[Company name] shall assume no responsibility for the consequences of non-fulfilment or delayed fulfilment of obligations under this Agreement, if such fulfilment or delayed fulfilment is due to Force Majeure events.

A Force Majeure event is defined as a cause or an event that [Company name] can neither control, predict or resist and which may prevent [Company name] from totally or partially fulfilling its obligations.

Such events include: wars, insurrections, social unrest or riots, acts of terrorism, earthquakes, floods, explosions, volcanic eruptions and fires.

Should any Force Majeure event occur, [Company name] agrees to notify the OIE immediately and provide specific facts within eight days by registered mail containing all the details known to [Company name]. Should such Force Majeure events be of long duration (more than one month), both parties hereto will discuss any necessary modifications to this Agreement.

ARTICLE 12 - ETHICAL BUSINESS

Both parties will comply by all laws, rules and regulations that apply to the performance of the obligations under this Agreement.

[Company name] and the OIE will adhere to business practices in connection with this Agreement which are in accordance with the letter and spirit of applicable laws and ethical principles. The OIE and [Company name] agree that all transactions related to this Agreement will be accurately reflected in their books and records, and that no funds or other assets will be paid directly or indirectly to government officials (or persons acting on their behalf) for the purpose of influencing government decisions or actions. Violation of this Article will result in the immediate termination of this Agreement.

No employee or agent of [Company name] will have authority to give any direction, written or oral, relating to the making of any commitment by the OIE or its agents to any third party in violation of the provisions of this Article.

ARTICLE 13 – ASSIGNMENT AND SUBCONTRACTING

Neither party shall assign or subcontract any part of this Agreement.

ARTICLE 14 – CONFIDENTIALITY

Each party must keep confidential all terms and conditions of this Agreement and not disclose to any third party, information relating to the quantities, prices or other relevant business information regarding the Vaccines held or supplied by [Company name] as well as any technical or business information provided by the other Party.

A copy of the Agreement will be provided in confidence to WHO by the OIE to facilitate the use of the Agreement provisions by WHO.

Any public communication shall be subject to both parties' consent and should refer whenever appropriate to the fact that the OIE Rabies Vaccine Bank is co-funded by donors and partners of the OIE.

ARTICLE 15 – LEGAL DISPUTES

This Agreement shall be governed by French law. Any dispute, controversy or claim arising out of or relating to the interpretation, application or performance of this Agreement, will first be dealt with through amicable consultations between the parties hereto. In the event that such attempt at amicable consultations is not successful within thirty (30) days after the date of a notice stating a dispute, controversy or claim, the parties shall have the right to resolve such dispute through the exclusive jurisdiction of the courts of Paris in France.

MADE IN DUPLICATE

FOR the OIE

FOR [Company name]

Date:

Date:

Signature:

Signature:

Name: Monique ELOIT

Name:

Position: Director General

Position:

ANNEX 1 - Templates for Production & Delivery orders and Delivery Orders

ANNEX 2 - Contact details of [Company name] and the OIE

ANNEX 3 – Contact Information and Financial Details to be provided to [Company name]

ANNEX 4 - List of countries for vaccine delivery

ANNEX 5 - [Company name] Technical Offer which includes all Technical Specifications

ANNEX 6 – [Company name] Financial Offer

CONFIDENTIAL

ANNEX 1 - Templates for Production & Delivery Order and Delivery Order

N°

PRODUCTION & DELIVERY ORDER OF RABIES VACCINES

Ref: [name of the supply agreement]

Date: Ref:	<input checked="" type="checkbox"/> Production and Delivery of rabies vaccines
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Country of destination
Speed of availability of the vaccines at factory gate requested
Size of vials
Number of <u>doses</u> requested _____ doses

* Cold Chain (5°C±3°C) must be maintained during transportation and storage at all times.

Date

Director General of the OIE
(or the Director of Administration)

DELIVERY ORDER OF RABIES VACCINES

Ref: [name of the supply agreement]

Date: Ref:	<input checked="" type="checkbox"/> Delivery of rabies vaccines
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Country of destination
Speed of availability of the vaccines at factory gate requested
Size of vials
Number of <u>doses</u> requested <div style="text-align: center;"> <hr style="width: 150px; border: 1px solid black;"/> doses </div>

* Cold Chain (5°C±3°C) must be maintained during transportation and storage at all times.

Date

 Director General of the OIE
 (or the Director of Administration)

ANNEX 2

Contacts

[Company name]

Name:
Address:
Office:
Mobile:
E-mail:

Other [Company name] Contacts:

Name:
Contact No:
Mobile:
Email:

Name:
Contact No:
Email:

OIE HQ

Name:
Address:
Contact No:
Email:

Name:
Contact No:
Email:

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ANNEX 3

Contact information and financial details to be provided to [Company name]

For each order, the following information will be provided by the OIE (or by a Third Party) to [Company name].

Contact details of person in charge of the consignment upon arrival:

Name:

Position:

Email:

Telephone (office):

Telephone (mobile):

Fax:

Contact details of the Veterinary Authority to which ownership is transferred upon arrival:

Name:

Position:

Full Postal address:

Email:

Telephone (office):

Telephone (mobile):

Fax:

Organisation to which vaccines are delivered (if different than above):

Name:

Address:

Financial Information (Payment terms are described in **Article 6** of this Agreement)

- Invoicing address (Name, address, country)
- Language
- Phone number
- Fax number (when relevant)
- OIE or Third Party Financial Contact name (and e-mail address)
- Currency (USD – EUR)
- Mode of payment
- Copy of Import license/Permit (when relevant)

ANNEX 5 - TECHNICAL OFFER

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ANNEX 6 - FINANCIAL OFFER

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