

ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

Contract title: Supply of rabies vaccines

2011/S 195-316856 <to be checked by the F&C>

Location: Serbia

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Supply of Rabies vaccines

Column 1-2 should be completed by the Contracting Authority

Column 3-4 should be completed by the tenderer

Column 5 is reserved for the evaluation committee

Annex III - the Contractor's technical offer

The tenderers are requested to complete the template on the next pages:

- Column 2 is completed by the Contracting Authority shows the required specifications (not to be modified by the tenderer),
- Column 3 is to be filled in by the tenderer and must detail what is offered (for example the words “compliant” or “yes” are not sufficient)
- Column 4 allows the tenderer to make comments on its proposed supply and to make eventual references to the documentation

The eventual documentation supplied should clearly indicate (highlight, mark) the models offered and the options included, if any, so that the evaluators can see the exact configuration. Offers that do not permit to identify precisely the models and the specifications may be rejected by the evaluation committee.

The offer must be clear enough to allow the evaluators to make an easy comparison between the requested specifications and the offered specifications.

1.1. Description of the Supply

The contract is the supply, delivery, storage, transport and distribution by the Contractor of the following goods in given quantities for specified areas in Serbia according to the distribution list defined in this Technical Specifications, DDP (Delivery Duty Paid) within the periods or dates specified in Article 13 of Special Conditions for the rabies vaccination campaigns in the autumn of 2012 and 2013.

Rabies vaccines for oral vaccination		
Item n°	Item	Quantity
1.1	Vaccine bait - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2012 autumn campaign	1.610.000
1.2	Vaccine bait reinforcement for selected risk areas in Belgrade - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2012 autumn campaign	9.000
1.3	Vaccine bait - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2013 spring campaign	1.610.000
1.4	Vaccine bait reinforcement for selected risk areas in Belgrade - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2013 spring campaign	9.000
1.5	Vaccine bait - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2013 autumn campaign	1.610.000
1.6	Vaccine bait reinforcement for selected risk areas in Belgrade - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2013 autumn campaign	9.000

The territory for vaccination shall be the whole territory of Serbia excluding the urban settlements. Total area of the country is 78.998 km². Area designated for vaccination is about 70.000 km².

For each campaign, the vaccine dose should be approximately 23 pieces of vaccination baits per 1 km². The planned number of baits is 1.610.000 per each campaign.

Additional reinforcement vaccination by the Contractor for selected risk areas in Belgrade shall be done via helicopter and/or manual distribution. The planned number of baits for additional reinforcement vaccination for selected risk areas in Belgrade is $3 \times 9.000 = 27.000$ vaccine baits in total distributed in 3 vaccination campaigns (9.000 baits per campaign).

1.2. Technical requirements

The technical specifications are requirements based on the respective item's projected function or purpose.

Items non compliant with technical specifications will be rejected.

Delivery of the vaccines

The vaccine shall be delivered in the Contractor's storage facilities at the territory of Serbia, at the temperature and all other conditions specified by the vaccine producer.

Vaccines should be packed in cardboard boxes or in polyethylene bags and unless otherwise specified by the producer of vaccines kept in a dark place.

Vaccines handling and storage must fulfill all conditions and standards set by the vaccine producer.

Storage of the vaccines

Vaccine baits should be stored all the time in chillers equipped with temperature data loggers.

The storage facility should be equipped with device that is able to keep record of the temperature and other parameters specified by the producer during each day of the storage.

Storage facility shall be prepared also at the airports (-20 °C cooling trucks or freezers with sufficient capacity for a quantity of baits needed for at least one day of each daily flight activity at every airport).

Transport of the vaccines

The day before being distributed, baits are to be delivered to the places where they will be loaded on the helicopters / airplanes.

Transport of vaccines from storage facility to the airports shall be done by using adequate cooling trucks (-20 °C) so that the vaccine will be transported in a frozen condition.

Places for distribution of vaccines (airports) shall be equipped with suitable refrigerators. In an event that uploaded baits are not distributed during the same day (for justified reason like bad water, etc.), they should be stored at temperature of +1 to +8 °C, but not longer than 3 days.

Distribution of the vaccine baits

Aerial distribution by the Contractor of the baits for Items No 1.1, 1.3 and 1.5 may be performed either by helicopter or by fixed-wing airplane flying at 100 - 300 m altitude (or higher due to safety reasons) at a speed of 100 - 300 km/hr.

Items No. 1.2, 1.4 and 1.6 are to be distributed by the Contractor via helicopter and/or manual distribution.

The helicopters or airplanes shall be equipped with GPS system and supported by a computer program that will allow control of the ejection process of bait (number, time, location) used during the spread of the baits. The contractor is obliged to deliver detailed characteristics of the computer programme to be used.

The spread of baits from the helicopters or airplanes shall be done by special equipment. Therefore, the aircrafts shall be equipped with a system for spread of baits connected with GPS system in order to ensure the exact distribution depending on the speed and height of the flight and keep automatic record of the quantity and location of the spread baits.

An average distance between the flying lines (flying corridors) will be 500 m +/- 100 m and the baits will be dropped with the average distance of 100 m +/- 50 m.

Where manual distribution will be used, the persons distributing vaccine manually shall use appropriate GPS devices to register the walking routes and the position where each bait is placed.

At the end of each day, the records on number of distributed baits and the territory covered shall be submitted to the Beneficiary (Veterinary Directorate). The pilot and the responsible person shall sign a protocol for the completed vaccination that will be prepared by the Veterinary Directorate of Serbia.

The electronic records containing data about vaccine bait storage and temperature, the number of distributed vaccines and covered territory, weather conditions (air temperature, wind speed, direction, rainfall, humidity) shall be submitted to the Beneficiary (Veterinary Directorate) representative at the end of each working day. The information on the course of distribution shall be possible to be downloaded from the computer database after each flight or whole campaign. There should be a possibility to record distribution data in computer unit equipped with a slot for memory card. Date, time and position of each vaccine bait and real time cross country flight or distributor walking routes should be recorded / mapped.

Baits shouldn't be distributed in settlements and therefore pilots should stop with baits distribution 100 meters before the village / courtyards and continue the process at least 100 meters after transiting of settlement.

Seven (7) days before beginning of the vaccination, the Contractor is obliged to submit to the Beneficiary (Veterinary Directorate) general vaccine distribution plan and flying routes for each vaccination day.

Control of quality before realization in the field

Each vaccine batch shall be tested on virus titer and stability of virus observing at 25°C during 7 days and it shall be on the cost of the Contractor and approved by the relevant national authorities using an acknowledged quality control scheme according to the Technical Specifications.

Titre of rabies viruses, bait melting temperature and stability parameters shall be tested and confirmed by EU or OIE Reference laboratory before delivery of vaccine. All supporting documents shall be provided to competent authority at least 10 days before delivery of each vaccine batch.

Each batch of vaccine shall have expired date minimum 12 months from the date of delivery.

Contractors human resources

The Contractor is obliged to assure full time presence of the responsible person ("Contact person") in Serbia during both the pre-vaccination activities and vaccination campaign. He / she will be responsible for all contacts with the Contracting Authority / Beneficiary. His / her CV should comply with following requirements:

Qualifications and skills

- University level degree in veterinary science / pharmaceutical industry or similar or at least 10 years of professional experience in a relevant field
- Fluency in English and preferably knowledge of the Serbian language

Professional experience

- At least 3 years of working experience in the veterinary, pharmaceutical, medicine, or other relevant field

The contact person should ensure that the personnel involved in the vaccination campaign have necessary competences for successful implementation of the vaccination campaigns.

1.3. Technical specifications

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
1.1	Vaccine bait - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for autumn campaign 2012			
	The vaccine bait must comply with monograph no.0746 " <i>European monograph for live oral rabies vaccine for foxes</i> " of the European Pharmacopoeia.			
	Vaccine must have been registered by either the European Medicines Agency (EMA) or a competent/regulatory authority of any EU Member State.			
	Vaccine has to be licensed for use by the national Medicines and Medical Devices Agency of Serbia prior to delivery.			
	The vaccine baits shall contain a biomarker tetracycline allowing to identify the vaccinated foxes			
	The vaccine will allow differentiation of vaccine from wild (field) virus			
	The vaccine baits shall be adjusted (adapted) for spread by airplane or helicopter (therefore they shall be solid and not to break into pieces when dropped from the flying altitude, at list 100m on natural ground)			

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1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
	Each vaccine bait (blister) should be labeled with warning alert , batch number and expire date			
	The labels and the instructions for use of the vaccines to be also in English and Serbian language			
1.2	Vaccine bait reinforcement for selected risk areas in Belgrade - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for autumn campaign 2012			
	Same as for Item 1.1			
1.3	Vaccine baits - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for spring campaign 2013			
	Same as for Item 1.1			
1.4	Vaccine bait reinforcement for selected risk areas in Belgrade - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for spring campaign 2013			
	Same as for Item 1.1			
1.5	Vaccine baits - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for autumn campaign 2013			
	Same as for Item 1.1			



1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
1.6	Vaccine bait reinforcement for selected risk areas in Belgrade - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for autumn campaign 2013			
	Same as for Item 1.1			

1.4. Distribution

Distribution of live cell cultural vaccine against rabies for oral vaccination of foxes shall be done according to the enclosed distribution list.

District	Area km ²	N° of settlements	Vaccination area km ²	Item 1.1 Vaccine baits - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2012 autumn campaign (Density of baits per district = 23 per km²)	Item 1.3 Vaccine baits - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2013 spring campaign (Density of baits per district = 23 per km²)	Item 1.5 Vaccine baits - Supply of live cell cultural vaccine against rabies for oral vaccination of foxes for 2013 autumn campaign (Density of baits per district = 23 per km²)
Zapadnobački	2.420	37	2.217	51.000	51.000	51.000
Severnobački	1.784	45	1.635	37.600	37.600	37.600
Severnobanatski	2.329	50	2.134	49.100	49.100	49.100
Juznobački	4.016	77	3.679	84.600	84.600	84.600
Srednjebanatski	3.256	55	2.990	68.750	68.750	68.750
Sremski	3.486	109	3.193	73.440	73.440	73.440
Juznobanatski	4.245	94	3.888	89.400	89.400	89.400
Mačvanski	3.268	228	2.994	68.870	68.870	68.870
Beograd	3.224	166	2.952	67.900	67.900	67.900
Podunavski	1.248	59	1.143	26.300	26.300	26.300

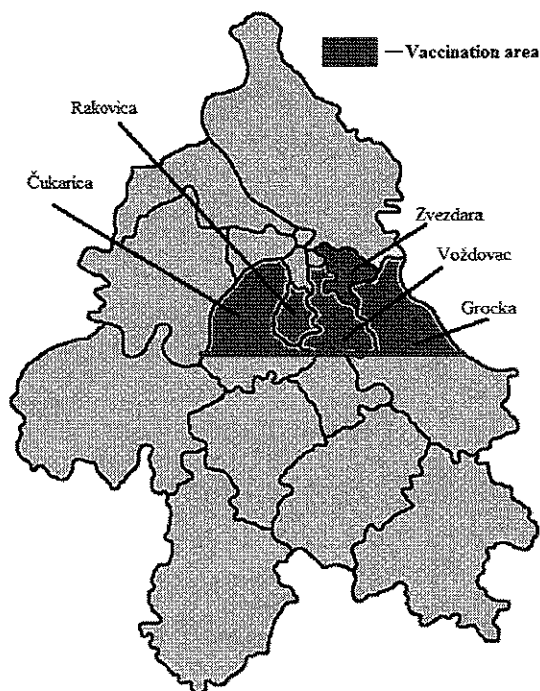
Braničevski	3.865	189	1.395	32.100	32.100	32.100
Borski	4.007	90	3.540	81.420	81.420	81.420
Pomoravski	3.614	191	3.212	73.870	73.870	73.870
Sumadijski	2.387	175	2.186	50.300	50.300	50.300
Kolubarski	2.474	218	2.267	52.100	52.100	52.100
Zlatiborski	6.140	438	5.624	129.400	129.400	129.400
Moravički	3.016	206	2.762	63.500	63.500	63.500
Raski	3.918	359	3.589	82.550	82.550	82.550
Rasinski	2.668	295	2.444	56.200	56.200	56.200
Zaječarski	3.623	173	3.319	76.300	76.300	76.300
Pirotski	2.761	214	2.529	58.200	58.200	58.200
Nisavski	2.729	285	2.500	57.500	57.500	57.500
Toplički	2.231	267	2.043	47.000	47.000	47.000
Jablanički	2.769	336	2.537	58.400	58.400	58.400
Pčinjski	3520	363	3.224	74.200	74.200	74.200
Total			69.996	1.610.000	1.610.000	1.610.000

Additional distribution of 9.000 live cell cultural vaccines against rabies for oral vaccination of foxes x 3 vaccination campaign (**Items 1.2, 1.4 and 1.6**) shall be done by helicopter and/or manual distribution in selected risk areas. The referred suburban areas in Belgrade include areas in the following municipalities:

- Cukarica
- Grocka
- Rakovica
- Voždovac
- Zvezdara

Total area of referred municipalities is about 658,30 km², however the risk area to be additionally vaccinated is estimated at about 300 km² as shown on the following map.

Therefore, the reinforcement distribution corresponds to additional density of baits per risk area of $9.000 \text{ vaccine baits} / 300 \text{ km}^2 = 30 \text{ baits per km}^2$.



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The oral vaccination campaigns in marked risk areas should be organized at the same times when oral vaccination program in whole Serbia is performed.

1.5. Visibility

All supplies must comply with the generic Visibility policies in force within the scope of external aid contracts financed from the EU general budget; tenderers will thus be aware that certain visibility rules apply and that the guidelines and manuals concerned may be found in the EUROPEAID website, at:
http://ec.europa.eu/europeaid/work/visibility/index_en.htm