

ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

Contract title: Supply of vaccines for eradication of rabies in wildlife population and against Classical Swine Fever

Lot 1: Supply and aerial distribution of rabies vaccines

p 1 / 14

Publication reference: EuropeAid/135620/IH/SUP/RS

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 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 subject of 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 2015, 2016 and 2017.

Rabies vaccines for oral vaccination		
Item n°	Item	Quantity
1.1	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn campaign 2015.	1.650.000
1.2	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn 2015 for selected risk areas in Belgrade.	21.000
1.3	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2016.	1.650.000
1.4	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2016 for selected risk areas in Belgrade.	21.000
1.5	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn 2016	1.650.000
1.6	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn 2016 for selected risk areas in Belgrade.	21.000
1.7	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring campaign	1.650.000

2017.	
1.8	<p>Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (<i>vulpes vulpes</i>) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2017 for selected risk areas in Belgrade.</p> <p style="text-align: right;">21.000</p>

The territory for vaccination shall be the whole territory of Serbia excluding the urban settlements, main roads and water areas. Total area of the country is 78.998 km². Area designated for vaccination is approximately 75.000 km².

The total planned number of baits is 1.671.000, per each campaign.

Reinforcement vaccination by the Contractor for selected risk areas in Belgrade shall be done via helicopter/airplane and/or manual distribution. The planned number of baits for additional reinforcement vaccination for selected risk areas in Belgrade is $4 \times 21.000 = 84.000$ vaccine baits in total distributed in 4 (four) vaccination campaigns (21.000 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 including maintenance of the cold chain throughout the vaccination campaign 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 1.1, 1.3, 1.5 and 1.7 may be performed either by helicopter or by fixed-wing airplane (please also see Article 9 of the Contract Special Conditions).

Items No. 1.2, 1.4, 1.6 and 1.8 are to be distributed by the Contractor via helicopter/airplanes 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.

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. 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.

Control of quality before realization in the field

Please refer to Articles 24 and 25 of the Contract Special Conditions.

Each batch of vaccine shall have expired date minimum 10 months from the date of delivery.

Contractors human resources

Please refer to Article 9 of the Contract Special Conditions.

The Contractor is obliged to assure 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, knowledge of the Serbian language would be considered as an advantage

Professional experience

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

The Contractor should ensure that the contact person and other 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	<p>Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (<i>vulpes vulpes</i>) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn campaign 2015</p>			
	<p>The Veterinary Medicinal Product offered must:</p> <p>a) be the subject of a Marketing Authorisation by competent authority in any EU Member State which is valid at the deadline for the submission of tenders (specified in section 19 of the supply procurement notice) in accordance with</p> <ul style="list-style-type: none"> • Regulation (EC) No 726/2004 of the European Parliament and of the Council, as amended [however products that are only the subject of a marketing authorisation issued in accordance with Article 39(7) of the Regulation shall not be considered compliant with the requirements of this tender], <p>or</p> <ul style="list-style-type: none"> • Directive 2001/82/EC of the European Parliament and of the Council, as amended [however products that are only the subject of a marketing authorisation issued in accordance with Article 26(3) of 			

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	<p>the Directive shall not be considered compliant with the requirements of this tender];</p> <p>Tenderers must include a copy of the relevant Marketing Authorisation issued by competent authority in any EU Member State, as well as a declaration issued by that competent authority that the offered product is fully compliant with the requirements outlined above in point a), i.e. that the authorisation issued is either in accordance with:</p> <p>i) Regulation (EC) No 726/2004 (and is not only the subject of a marketing authorisation issued in accordance with Article 39(7) of this Regulation).</p> <p>or</p> <p>ii) <i>Directive 2001/82/EC of the European Parliament and of the Council, as amended (and is not only the subject of a marketing authorisation issued in accordance with Article 26(3) of this Directive);</i></p> <p>b) - be the subject of a marketing authorisation (or the equivalent thereof) granted by the national competent authority in the Beneficiary Country (Republic of Serbia) prior to delivery of the vaccines</p>			

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	<p><i>Tenderers must include a copy of the relevant Marketing Authorisation in the Beneficiary Country [or equivalent] together with their tenders or prior to delivery (in case that the requirement described in point (b) is not issued).</i></p> <p>It is the sole responsibility of tenders to comply with the requirement in point b) to ensure implementation of the Contract in line with its terms and conditions.</p>			
	<p>The Veterinary Medicinal Product offered must conform to the following stability standards:</p> <ul style="list-style-type: none"> i. Following incubation of the bait at 25 °C for 5 days, the virus titre must be at least the minimum virus titre stated on the label; and ii. Following incubation of the bait at 40 °C for 1 h, the bait casing must remain in its original shape and adhere to the vaccine container. <p><i>Tenderers must include laboratory reports demonstrating compliance with these requirements together with their tenders. The laboratory responsible for performing the tests and preparing the reports must be independent of the rabies vaccines bait manufacturer and must be accredited by the national body with responsibility for the accreditation of laboratories in accordance with the relevant International Organisation for Standardisation ISO 17000</i></p>			

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	<p>series of standards and guides and/or the harmonised EN 45000 series of European standards in one of the Member States or in a country or territory of the regions covered and/or authorised by the specific instruments applicable to the programme under which the contract is financed (see item 22 of the Supply Contract Notice).</p> <p>Tenderer must include a declaration by a laboratory that performed the tests that it is i) independent of the rabies vaccines bait manufacturer, ii) is accredited by the national body with responsibility for the accreditation of laboratories in accordance with the relevant International Organisation for Standardisation ISO 17000 series of standards and guides and/or the harmonised EN 45000 series of European standards in one of the Member States or in a country or territory of the regions covered and/or authorised by the specific instruments applicable to the programme under which the contract is financed (see item 22 of the Supply Contract Notice).</p>			
1.2	<p>The Veterinary Medicinal Product offered must contain tetracycline as a biomarker that provides life-long marking of bones and teeth, which can be detected post mortem, in young and adult foxes that consume the baits</p> <p>Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a</p>			

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	matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn 2015 for selected risk areas in Belgrade.			
	Same as for item 1.1			
1.3	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2016.			
	Same as for item 1.1			
1.4	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2016 for selected risk areas in Belgrade.			
	Same as for item 1.1			
1.5	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn			

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	2016			
1.6	Same as for item 1.1 Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for autumn 2016 for selected risk areas in Belgrade.			
	Same as for item 1.1			
1.7	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2017.			
	Same as for item 1.1			
1.8	Rabies Vaccine Bait: Vaccine for the oral immunisation of red foxes (vulpes vulpes) to prevent infection by the rabies virus, enclosed in a matrix which is edible by and appealing to the target species and which is designed to be distributed by low altitude aerial drops for spring 2017 for selected risk areas in Belgrade.			
	Same as for item 1.1			

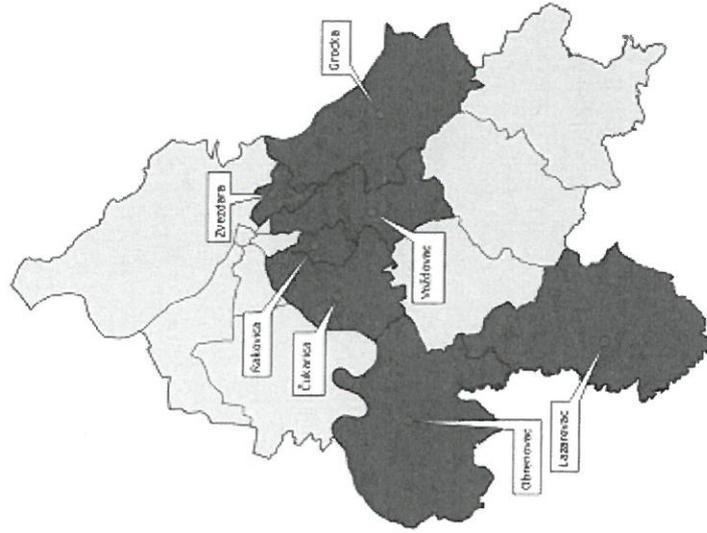
1.4. Distribution

District	Area km ²	N° of settlements	Estimated vaccination area km ²	Items 1.1, 1.3, 1.5 and 1.7 (Density of baits per district app 22 per km ²)
Zapadnobački	2.420	37	2.204	48.488
Severnobački	1.784	45	1.615	35.530
Severnobanatski	2.329	50	2.234	49.148
Juznobački	4.016	77	3.879	85.338
Srednjebanatski	3.256	55	3.090	67.980
Sremski	3.486	109	3.293	72.446
Juznobanatski	4.245	94	4.144	91.168
Mlačvanski	3.268	228	3.104	68.288
Beograd	3.224	166	3.172	69.784
Podunavski	1.248	59	1.193	26.246
Braničevski	3.865	189	3.695	81.290
Borski	4.007	90	3.640	80.080
Pomoravski	3.614	191	3.412	75.064
Sumadijski	2.387	175	2.152	47.344
Kolubarski	2.474	218	2.367	52.074
Zlatiborski	6.140	438	5.824	128.128
Moravički	3.016	206	2.862	62.964
Raski	3.918	359	3.749	82.478
Rasinski	2.668	295	2.544	55.968
Zajčarski	3.623	173	3.419	75.218
Pirotski	2.761	214	2.629	57.838
Nisavski	2.729	285	2.675	58.850
Toplički	2.231	267	2.143	47.146
Jablanički	2.769	336	2.637	58.014
Pčimjski	3520	363	3.324	73.128
Total			75.000	1.650.000

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

Additional distribution of 21.000 live cell cultural vaccines against rabies for oral vaccination of foxes x 4 vaccination campaign (**Items 1.2, 1.4, 1.6 and 1.8**) shall be done by **helicopter/airplane 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
- Obrenovac
- Lazarevac



Total area of referred municipalities is about 1453,30 km², however the risk area to be vaccinated is estimated at about 700 km² as shown on the following map. Therefore, the reinforcement distribution corresponds to additional density of baits per risk area of 21.000 vaccine baits / 700 km² = 30 baits per km².

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: https://ec.europa.eu/europeaid/communication-and-visibility-manual-eu-external-actions_en.

The Contractor shall ensure the highest visibility to the financial contribution of the European Union. To ensure such publicity the Contractor shall implement among other actions the specific activities described in the Special Conditions. All measures must comply with the rules in the Communication and Visibility Manual for EU External Actions published by the European Commission.