

# ***ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER***

**Contract title: Supporting control monitoring and eradication of rabies in wild animals**

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**Publication reference: NEAR/BEG/2023/EA-OP/0064**

**Columns 1-2 should be completed by the contracting authority**

**Columns 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 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 specified in Article 13 of Special Conditions for 4 rabies vaccination campaigns in 2024 and 2025 (spring, autumn campaigns).

<b>Rabies vaccines for oral vaccination</b>		
<b>Item n°</b>	<b>Item</b>	<b>Quantity</b>
1.1	<b>Rabies Vaccine Bait:</b> 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 the first campaign.	<b>1.364.700</b>
1.2	<b>Rabies Vaccine Bait:</b> 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 the second campaign.	<b>1.364.700</b>
1.3	<b>Rabies Vaccine Bait:</b> 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 the third campaign.	<b>1.364.700</b>
1.4	<b>Rabies Vaccine Bait:</b> 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 the fourth campaign.	<b>1.364.700</b>

The territory for vaccination shall be the territory of Republic of Serbia excluding the urban settlements, main roads and water areas. Total area is 78.998 km<sup>2</sup> and area designated for vaccination is approximately 75.210 km<sup>2</sup>.

The total planned number of baits is 1,364,700 per each campaign, in accordance with distribution list presented in section 1.4 of this Technical Specifications. Average density of vaccine baits in 23 districts will be 18 per km<sup>2</sup> and in 2 districts will be 20 per km<sup>2</sup>

### **1.1 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, 1.2, 1.3 and 1.4 may be performed either by helicopter or by fixed-wing airplane (please also see Article 9 of the Contract Special Conditions).

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 program 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.

The airplane should be equipped with devices for filming and recording of the interior of the airplane during flights in order to film and record delivery of vaccines. The contractor is obliged to deliver

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 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 Contactor 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. Item Number	2. SpecificationsRequired	3. SpecificationsOffered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
1.1	<p><b>Rabies Vaccine Bait:</b> 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 the first campaign.</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"> <li>• Regulation (EC) No 726/2004 of the European Parliament and of the Council in force, 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], In case of entering into force of the subject regulation amendment, the latter will be valid.</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>• Regulation (EU) 2019/6 of the European Parliament and of the Council, in force, as</li> </ul>			

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	<p>amended [however products that are only the subject of a marketing authorisation issued in accordance with Articles 25 and 26 of 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><i>or</i></p> <p>ii) Regulation (EU) 2019/6 of the European Parliament and of the Council, as amended (and is not only the subject of a marketing authorisation issued in accordance with Articles 25 and 26 of this Directive);</p>			

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	<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> <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"> <li>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</li> <li>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.</li> </ul> <p><i>Tenderers must include laboratory reports demonstrating compliance with these requirements</i></p>			

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	<p><i>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 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).</i></p> <p><i>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</i></p>			

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	<i>contract is financed (see item 22 of the Supply Contract Notice).</i>			
	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			
1.2	<b>Rabies Vaccine Bait:</b> 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 the second campaign.			
	Same as for item 1.1			
1.3	<b>Rabies Vaccine Bait:</b> 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 the third campaign.			
	Same as for item 1.1			

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1.4	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 the fourth campaign.			
	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 <sup>2</sup>	N° of settlements	Estimated vaccination area km <sup>2</sup>	Density of baits per district = 18 and 20 per km <sup>2</sup>	Items 1.1, 1.2 and 1.3 (Density of baits per district = 18 and 20 per km <sup>2</sup> )
Zapadnobački	2420	37	2,200	18	39600
Severnobački	1784	45	1,600	18	28800
Severnobanatski	2329	50	2,200	18	39600
Juznobački	4016	77	3,800	18	68400
Srednjebanatski	3256	55	3,100	18	55800
Sremski	3486	109	3,200	18	57600
Juznobanatski	4245	94	4,100	18	73800
Mačvanski	3268	228	3,130	20	62600
Beograd	3224	166	3,100	18	55800
Podunavski	1248	59	1,100	18	19800
Braničevski	3865	189	3,690	18	66420
Borski	4007	90	3,600	18	64800
Pomoravski	3614	191	3,350	18	60300
Sumadijski	2387	175	2,190	18	39420
Kolubarski	2474	218	2,330	20	46600
Zlatiborski	6140	438	5,820	18	104760
Moravički	3016	206	2,800	18	50400
Raski	3918	359	3,800	18	68400
Rasinski	2668	295	3,500	18	63000
Zaječarski	3623	173	3,400	18	61200
Pirotski	2761	214	2,600	18	46800
Nisavski	2729	285	2,600	18	46800
Toplički	2231	267	2,100	18	37800
Jablanički	2769	336	2,600	18	46800
Pčinjski	3520	363	3,300	18	59400
<b>Total</b>	<b>78,998</b>	<b>4,719</b>	<b>75,210</b>	<b>-</b>	<b>1.364.700</b>