



Belgrade, 20.09.2013.

Ref:

CONTRACTING AUTHORITY'S CLARIFICATIONS

Supply and aerial distribution of rabies vaccines

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No.	Question	Answer
1	<p>- <i>To Article 13 (Programme of implementation of tasks), paragraph 13.1 in context of Article 9 (General Information), paragraph 9.1, eighth bullet of the Special Conditions:</i></p> <p>According to the Article 13, for spring 2014 vaccination campaign, the vaccine shall be delivered to Serbia during February 2014 and for spring 2015 vaccination campaign, the vaccine shall be delivered to Serbia during February 2015. Each vaccination campaign must be completed within 45 days starting from the day of issuance of the delivery order by the Contracting Authority.</p> <p>According to the Article 9, paragraph 9.1, eighth bullet (i.e. last bullet on page 9), the Contractor shall specifically ensure, that the rabies vaccine baits are not sited when ambient ground temperatures are, on the basis of official meteorological data, forecast within the following 5 days to be within 5C of freezing or within 5C below the maximum temperature at which the rabies vaccine baits have been proven to be stable in accordance with Article 25 of these Special Conditions. However, this condition may be varied, allowing the upper limit of this temperature range to be raised to a specified higher temperature, in the following circumstances:</p> <p>- the Contractor can supply to the Project Manager evidence from an independent, accredited laboratory, with which the</p>	<p>Please refer to the Special Conditions, which require <u>delivery</u> of the vaccines for spring 2014 campaign in February 2014, while further in the same Article you will find that "all pre-vaccination activities must be timely completed by the Contractor so that vaccination campaigns could start respectively during April 2014, October 2014, and April 2015".</p> <p>The temperatures in the relevant time of the year in Serbia may vary and will be for the Contractor to follow this as per the terms and conditions of the Contract, and to assess the eventual risks and modify the activities accordingly.</p>

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	<p>manufacturer has no commercial links, showing that the virus titre of representative samples of the rabies vaccine baits are equal to or exceed the minimum virus titre stated on the product label following incubation for a minimum period of 5 days at the specified higher temperature. This temperature must remain constant throughout the incubation period; and</p> <p>- the Contractor shall not apply this variation without express, written authorisation in advance issued by the Project Manager;</p> <p><i>Question: Usual weather prevailing in Serbia in the period of 45 days following the (expected) issuance of the delivery order for spring campaign enables compliance with the conditions laid down in paragraph), paragraph 9.1, eighth bullet? What is the usual ambient ground temperature in Serbia in this time period?</i></p>	
2	<p><i>- To Article 25 (Inspection and testing), paragraph 25.2 of the Special Conditions:</i></p> <p>25.2 Following delivery to interim storage facilities in Serbia and prior to siting (by low altitude aerial drops), at least 5 randomly selected samples from each separate lot of each separately produced batch (as identified by the manufacturer's lot and batch numbers) of the supplies delivered shall, at the expense of the Contractor, be tested at an EU or OIE reference laboratory for rabies or at the national reference laboratory for rabies of Serbia for</p> <ul style="list-style-type: none"> - titre of rabies vaccine virus, - bait melting temperature, - stability of the bait when incubated at 25°C for 5 days (see Technical Specification), and - <u>inclusion of tetracycline as a biomarker.</u> <p>The contractor shall make all necessary arrangements to enable representatives of the Contracting Authority and/or the</p>	<p>Testing vaccine baits to verify the inclusion of tetracycline demands equipment and expertise that may not be available in the EU and OIE reference laboratories. An acceptable alternative is for this specific analysis to be performed in a laboratory equipped to carry out the required tests and accredited in accordance with the International Standard EN ISO/IEC 17025.</p>

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	<p>Beneficiary to be present during the selection and collection of the above-mentioned samples and to ensure that test results issued by the laboratory undertaking the tests specifically indicate the batch / lot numbers of the rabies vaccine baits tested.</p> <p><i>Question: According to our findings, laboratories most commonly used for testing of rabies vaccine baits samples (namely EU RL for Rabies - ANSES, France and OIE and NRL for Rabies - Friedrich Loef β er Institute, Germany) do not perform tests proving the presence of tetracycline as a biomarker in rabies vaccine baits. Does the National Reference Laboratory for Rabies of Serbia perform this kind of test.</i></p>	
3	<p><i>- To Article 29 (Delivery), paragraph 29.5. of the Special Conditions:</i></p> <p>29.5 The outer packaging materials, vaccine sachets and baits shall as an absolute minimum bear all the details as required by the authorisations, approvals, licences, permits (or equivalent) issued by the competent authorities of Serbia.</p> <p>Unless otherwise specifically forbidden by the competent authorities of Serbia the details appearing on the vaccine sachets and baits will, following the words "Informative phone number", provide the telephone number which members of the public may telephone free of all charges to obtain specific information in relation to the vaccines and baits such as human or veterinary medical information as provided for in Article 9.1 of these Special Conditions.</p> <p><i>Question: Is it a sole task of the Contractor to establish an information phone line in question or the line will be established by the Contracting Authority/Beneficiary/another subject and appropriate phone number will then be communicated to the Contractor? When will this happen?</i></p>	<p>Provision of the information phone line is the sole responsibility of the Contractor. However, the specific arrangements are to be developed in strict coordination with the Beneficiary after the Contract signature, and will be subject to their written approval.</p> <p>The Beneficiary reserves the right to nominate person(s) who could assist in responding to the queries of the public.</p> <p>Informative phone number should thus be based in Belgrade.</p>

No.	Question	Answer
4	<p data-bbox="320 248 735 309"><i>- To Annex II +III - Technical Specifications + Technical Offer;</i></p> <p data-bbox="320 349 842 510"><i>Question: Please, is it possible to obtain this electronic file also in fillable format (*. doc, *.rif)? It would greatly facilitate the processing of the tender offer. Thank you in advance.</i></p>	<p data-bbox="874 264 1441 633">The published file in PDF format is the official version of the document. The editable version of Annex II+III: Technical specifications + Technical offer, to facilitate the preparation of the offers by the Tenderers, is attached to (and published together with) these clarifications. Please note however that in case of any inconsistency between the two versions of the document, the file in PDF format, published together with the Tender Dossier, is the one prevailing.</p>

Attachment:

1. Editable version of Annex II+III: Technical Specifications + Technical Offer.
Please note that in case of any inconsistency between this version and the PDF version published together with the Tender Dossier, the PDF version will prevail!

