



EUROPEAN UNION

DELEGATION TO BOSNIA AND HERZEGOVINA

Clarification No. 1

Project Title: Supply of vaccines against rabies and classical swine fever for the State Veterinary Office of BiH

Publication reference: EuropeAid/128354/C/SUP/BA

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Question 1

2.1.2. Technical requirements

Lot 1 Rabies vaccine (live, oral) for foxes

Item Number 1.1

"Each vaccine should be tested and approved for the titer and stability by an acknowledge

quality control scheme according to OIE standards and WHO recommendation"

Please specify the quality control scheme since the cited OIE standards and WHO recommendations are not known resp. are not precise to understand the set requirements.

Answer 1

Please refer to Corrigendum No. 1 to the Technical Specifications

Question 2

2.1.2. Technical requirements

Lot 1 Rabies vaccine (live, oral) for foxes

"Distribution of baits should be performed on the entire territory of BiH with exception of urban areas, large water areas, mountainous areas (above 1.500 m).

Baiting density should be at least 20 baits per km².

Flight lines distance should not exceed 500 meters.

Distribution pattern per km²: linear 2 flight lines (2 x 9 baits).

Distance between each bait (along the same flight line): approx. 50 m.

Flight altitude: 100 - 500 m.

Flight speed: 100-150 km/h.

Flight distance and bait density may be recalculated due to specific field and ecological conditions"

Please specify the required baits density since based on above outlined specification, there are actually two different bait densities given:

either 18 baits per km² based on distribution pattern set above

or 40 baits per km² based on calculation 50 m distance between each bait resulting in 20 baits per km

and flight line distance of 500 m resulting in 40 baits per km².

Furthermore could you please explain the flight speed restriction to 100 - 150 km/h. What is the reason for setting a speed limit of 150 km/h? In case of backwind aircrafts used for aerial distribution of baits often reach ground speed up to 200 km/h.

Answer 2

The required minimum baiting density should be at least 20 baits per km².

The flight speed (100 – 150 km/h) indicated in the specifications is based on standard weather conditions. It is up to the aerial distributor to compensate the speed for any unforeseen circumstances, such as backwinds.

Question 3

Please clarify the absence of requirement of the labels and the instructions for use of the vaccines to be also in English and Bosnian language.

Answer 3

Please refer to *Item 3 General Requirements* of the Technical Specifications:

For Lot 1 and Lot 2

All supplies must be delivered, inspected and tested at designated places of delivery. Delivery on-site shall be as indicated in the Timetable above after the contract has been signed by both parties.

Supplier must provide all relevant documents regarding the requirements. Documents written in one of the official languages of Bosnia and Herzegovina, including the original set of users' manual of products.

Products must be in conformity with relevant CE regulation /norms where applicable.

The tenderer should prove that the supplies proposed is produced by a manufacturer who is accredited by ISO 9001:2000 or an equivalent European quality mark.

For lot 1 and 2

Product information for oral vaccine baits against rabies for foxes and vaccine for CSF in domestic pigs:

- For liability purposes every single packaging unit should be labelled with the following information; name of product, name of manufacturer, contact address, batch number and shelf-life.

- Every box / carton containing the goods should contain a SPC. In the same time, every box/carton should contain “Instruction for use” in one of the constitutive languages in BIH.
- Documentation of the cold-chain until delivery at delivery address must be provided by Supplier.
- Upon delivery the batch records should be presented to recipient of goods at delivery address.
- Transportation and storage of goods must be accordingly to manufacturer specification.

