SCHEDULE 2: SPECIFICATION OF REQUIREMENTS

This Section sets out the Authority's requirements.

1. Strategic Overview and Scope of the Requirement

1.1 The Animal and Plant Health Agency (**APHA**) is an Executive Agency of the Department for Environment and Rural Affairs (**Defra or the Authority**) and delivers significant portions of the animal health and welfare policies of Defra, Welsh Government and Scottish Government across Great Britain (**GB**), and working in partnership with the Department of Agriculture, Environment and Rural Affairs (**DAERA**) in Northern Ireland. One of APHA's principal functions is the safeguarding of animal health and welfare and public health, which in turn supports economic growth and trade.

1.2 APHA has a critical role in the control and eradication of endemic diseases, most notably Bovine Tuberculosis (**TB**) - an infectious disease of bovines caused by *Mycobacterium bovis*, but which can also affect other mammals (**Non-Bovines**). The scale of infection and its eradication costs make bovine TB one of the biggest challenges that the food and farming industry faces. The Authority is committed to eradicating bovine TB to support the food and farming industry and to reduce costs to farmers and taxpayers.

1.3 The Authority, on behalf of the UK government and its devolved administrations, wishes to establish a supply of Purified Protein Derivatives (**PPD**) of avian and bovine Tuberculins (bovine PPD or PPD-B/PPDb and avian PPD or PPD-A/PPDa) for use in its bovine tuberculosis (**bTB**) testing programme, which is a critical part of the bTB eradication programmes in England, Wales and Northern Ireland, and in the surveillance programme in Scotland.

2. Quantity

2.1 The Contractor shall supply avian and bovine PPD Tuberculin (**the Goods**) to the Authority in the following quantities for the duration of the Contract:

2.1.1 a minimum of one hundred and forty (140) litres* of avian PPD Tuberculin per month up to a maximum of one hundred and ninety (190) litres per month; and

2.1.2 a minimum of one hundred and forty (140) litres* of bovine PPD Tuberculin per month up to a maximum of one hundred and ninety (190) litres per month.

*The Authority reserves the right to amend minimum and maximum order volumes of PPD Tuberculin, providing the Contractor with six (6) months' notice in writing, where changes to UK Government testing programmes (affecting PPD Tuberculin usage) are made.

2.2 The Contractor shall ensure that the production capacity and manufacturing facilities to be used are adequate for the production and supply of PPD Tuberculins in the quantities and in the packaging required by the Authority.

2.3 The Authority shall not be obliged to purchase more than the minimum quantity of avian and/or bovine PPD Tuberculin as set out in Paragraph 2.1 above provided that the Contractor shall be obliged to supply up to the maximum amounts set out in Paragraph 2.1 following notification from the Authority.

2.4 A minimum of nine (9) months reserve stock of avian and bovine PPD Tuberculin (i.e., 9 x 140 litres of each) is to be held between the parties on a continuous basis [redacted]

2.5 [redacted]

3. Product specification

3.1 The Contractor must hold current UK Marketing Authorisations (**MA**) for both bovine and avian PPD veterinary medicinal products, or an MA for a PPD Tuberculin kit comprising both bovine and avian PPD Tuberculin for the duration of the contract.

3.2 The Contractor's manufacturing facilities must hold a current Good Manufacturing Practice (**GMP**) certificate recognised by the UK's Veterinary Medicines Directorate (**VMD**) for the duration of the Contract.

3.3 The Goods must be tested according to, and, at the time of delivery, must be compliant with, the general standards defined in the European Pharmacopoeia Current Edition (and address the requirements of monographs 0536 and 0535)[1] and bovine TB chapter (3.4.6) of the WOAHs Manual for Diagnostic Tests and Vaccines for Terrestrial Animals, Specifically Section C1 ("Production of Tuberculin"). The certificates (see para 3.8) of analysis for each batch will be provided by the Contractor to the Authority at the time of the delivery of the Goods.

3.4 Each batch of the Goods must have a batch release certificate issued by the VMD - the UK competent authority for veterinary immunologicals batch release.

3.5 In addition to the skin testing the Goods are expected to be used within the APHA UKAS-accredited interferon-gamma (IFN-γ) blood testing delivery program and, therefore, must also conform to the quality requirements of that test. (Please see Section 2, Evaluation, for the sample testing criteria.)

3.6 In accordance with the MA, the Contractor shall ensure that the avian PPD Tuberculin is clearly distinguishable from the bovine PPD Tuberculin.

3.7 The Contractor shall ensure that bovine and avian PPD Tuberculin is supplied as a paired presentation by date of first supply (January 2023), and then every month thereafter. The estimated potency of a dose of bovine PPD Tuberculin shall be greater than the estimated potency of avian PPD Tuberculin divided by 1.2, but the difference shall not exceed 500IU per 0.1 ml dose, as assayed in guinea pigs.

The optimum Potency Levels in guinea pigs being:

[1] European Pharmacopoeia Current Edition, Monographs 0536 and 0535.

	Potency (I.U./dose)	Protein (mg/ml)
Bovine Tuberculin	3000 (+/- 30%)	1 (- 0.2/ + 0.5)
Avian Tuberculin	2500 (+/- 30%)	0.5 (-0.2/+ 0.35)
Potency Difference Bovine/ Avian	Max. 500	

3.8 As a minimum the Contractor shall ensure that the stated potency of the bovine PPD Tuberculin is 25,000 IU/ml or 30,000 IU/ml, and the stated potency of the avian PPD Tuberculin is 25,000 IU/ml. Specifically, the potency of bovine PPD Tuberculin batches must be assessed against the WOAH International Standard (ref. WHO 1st International Standard) or an in-house standard that has been calibrated against the WHO 1st International Standard for bovine PPD Tuberculin using guinea pigs previously sensitised with **live** *Mycobacterium bovis* according to the EP monographs 0536 and 0535[1]. Complete details must be provided in relation to a minimum of five guinea pig assays, i.e., those performed in a Good Manufacturing Practice (GMP) and Good Laboratory Practice (**GLP**)-compliant laboratory on guinea pigs sensitised (infected) by living *Mycobacterium bovis*, strain AN5, covering three production runs during the most recent two annual production periods on batches of PPD Tuberculin released for use in cattle. Details should include the number of guinea pigs used for each assay, the raw data obtained from which the potency was calculated (such that the calculation can be repeated), the specifics of the methodology used to calculate the potency, the calculated potency and a certificate of analysis for each batch.

3.9 The vials and Goods must all be compatible with McLintock tuberculin multi-dose syringes. Should there be a requirement to change the delivery device during the period of the Contract, the Contractor must ensure product presentation is adapted according to APHA's requirements as appropriate.

3.10 The Goods shall be presented in a minimum of twenty (20) x 0.1ml dose vials and maximum fifty (50) x 0.1ml dose vials.

3.11 The bovine and avian PPD Tuberculins must have a minimum of twenty-four (24) months shelf life. There should be a minimum of eighteen (18) months of shelf life remaining at the time of receipt at APHA (address detailed in Section 6 below). APHA will not accept delivery of any Goods from the Contractor which do not have a minimum of eighteen (18) months of shelf life remaining at the time of delivery at APHA and it will be the Contractor's responsibility to return and destroy those Goods at its own cost. Any Goods which have reached their expiry date whilst in the possession of the Contractor will be destroyed by the Contractor at its own cost.

3.12 The MA for bovine and avian PPD Tuberculin must be authorised for use in cattle.

3.13 The Authority must be copied into each batch release request submitted by the Contractor to the VMD.

3.14 As at the date of first supply (in January 2023) the MA must permit distribution outside of the cold chain, e.g., +2°C to +37°C for a period of at least fourteen (14) days.

3.15 The Authority reserves the right to include, in the scope of these requirements, the possibility of future purchase of bovine PPD Tuberculin only (without avian PPD Tuberculin). Procurement of this requirement would be subject to the product obtaining UK recognised Marketing Authorisations (**MA**) which would be supported under this contract where applicable.

4. Quality Control and assurance

4.1 The Tuberculin must be manufactured, stored and supplied in accordance with this Specification and any certified quality controls that are associated with its compliance shall be maintained through the life of the Contract, subject to any subsequent variations to the Marketing Authorisation of the Goods agreed with the Buyer.

4.2 A Business Continuity and Disaster Recovery plan, covering manufacturing and storage facilities including products and consumables, storage, and supply of the final products, is to be in place before the receipt of first Delivery to APHA in January 2023.

5 Product packaging and literature

5.1 Primary Packaging of goods shall:

5.1.1 Be packaged in equal pack sizes. Sizes can be between one hundred (100) doses to one thousand (1000) doses per pack, however these pack sizes must contain an equal number of avian and bovine PPD Tuberculin doses.

5.1.2 Be in matched paired /kits of equal vial sizes of PPDa and PPDb.

5.1.3 Contain avian PPD Tuberculin clearly distinguishable from the bovine PPD Tuberculin.

5.1.4 Have vial labels written in English and be in accordance with the MA.

5.1.5 Contain a product insert leaflet in accordance with the MA.

5.1.6 Be clearly labelled to demonstrate the content, number of vials and doses, product precautions, batch numbers and expiry as described in product details of the MA.

5.2 Secondary packaging of goods shall:

5.2.1 Contain the primary packaged PPD Tuberculin and shall only contain 2ml or 5ml kits and not a mixture of both.

5.2.2 Only contain primary packaged PPD Tuberculin from the same batch.

5.2.3 Be labelled in English and must be in accordance with the MA.

5.2.4 Display the storage temperature, the statement ‘do not freeze’, and the keep upright symbol.

5.3 Outer packaging (delivery pallet) will meet the following requirements:

5.3.1 Pallet sizes must be a maximum 1.0 metre x 1.2 metre and be wrapped in a clear (transparent) outer covering.

5.3.2 At least one side of every carton on the pallet must display a label written in English stating: the start and end location, carton number, product name and contents, i.e. volume, weight, order number, storage conditions, batch number and expiry date.

5.3.3 If the pallet contains batch numbers already received by APHA, these shall be packaged at the top of the pallet for ease of stock rotation at APHA.

5.3.4 The content of the pallet shall contain either the 2ml or the 5ml PPD Tuberculin and not a mixture of both.

5.3.5 Pallets must be of a suitable material to withstand cold storage conditions for many months.

5.3.6 Each pallet must have a data temperature control logger within one of the secondary packaged boxes. This shall be labelled as “control package” and placed at the top of the pallet for ease of access.

6 Delivery

6.1 The Goods must be available for delivery from 1st January 2023.

6.2 The Goods must be delivered to the following address:

APHA Weybridge – Central Stores
Animal and Plant Health Agency (APHA)
New Haw
Addlestone
Surrey
KT15 3NB

6.3 The Goods will only be issued each month following receipt of an official APHA Purchase Order, detailing the exact order quantity required.

6.4 The Contractor will Deliver the Goods to the address detailed at Paragraph 6.2, including clearance through UK customs, providing APHA with five (5) Working Days written notice prior to dispatch detailing product description, batch numbers, expiry dates, quantities and ensuring Delivery arrives on a Working Day between 9.00am and 2.00pm (UK time).

6.5 The Contractor must transport the Goods in compliance with GDP standards to APHA within a monitored +2°C to +8°C temperature-controlled unit. Data from the monitoring logger must be reported to APHA within ten (10) Working Days of receipt by the Contractor.

6.6 The Contractor shall (and shall ensure that any subcontractor shall) have in place and maintain adequate insurances having regard to their obligations under this Contract (including but not limited to goods in transit, public liability, product liability, employer’s liability and any other insurance required by law).

7 Performance Management

7.1 The Contractor's Service Manager (**SM**) or Deputy (**DSM**) is expected to respond to urgent queries from APHA within twenty-four (24) hours of request.

7.2 The Contractor's SM or DSM will respond to service requests or issues from APHA within five (5) days of receipt in accordance with the requirements of the Contract.

7.3 The Contractor shall produce monthly reports detailing stock levels, production and testing status of batches destined for the UK, and any threats to the continuity of supply to APHA's PPD Tuberculin Manager five (5) Working Days prior to each monthly review meeting.

7.4 Providing reasonable notice is given, the Authority or its representative shall be permitted unhindered access to the manufacturing facilities and distribution sites to conduct Contractor audits as necessary (including but not limited to access to the Contractor's / sub-contractor's facilities (production lines, Quality assurance processes/facilities and storage areas) and its production and manufacturing records, compliance records and certification of required standards).

7.5 Performance Management of this Contract will be as detailed in Schedules 10 and 13 of the Contract.