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<https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs>

Lionex GmbH
Salzdahlumer Strasse 196
Geb. 1A 38126
Braunschweig
Germany

Attn: Prof. Dr [REDACTED]
By email to: purchase@lionex.de

Our ref: C28582
Date: 9 April 2025

Dear Prof. Dr [REDACTED]

Award of contract for the Supply of the DIVA (Discrimination of Infected from Vaccinated Animals) Skin Test Fusion protein (DST-F) for the BCG cattle vaccine Field Trials

Following your proposal for the Supply of the DIVA (Discrimination of Infected from Vaccinated Animals) Skin Test Fusion protein (DST-F) for the BCG cattle vaccine Field Trials to APHA, we are pleased to award this contract to you.

The attached contract details ("Order Form") and the Appendices set out the terms of the contract between Lionex GmbH and APHA for the provision of the deliverables set out in the Order Form.

We thank you for your co-operation to date and look forward to forging a successful working relationship resulting in a smooth and successful delivery of the deliverables.

Please confirm your acceptance of the Conditions by signing, by way of electronic signature, the Order Form within 7 days from the date of this letter, which will create a binding contract between us. No other form of acknowledgement will be accepted. Please remember to include the reference number above in any future communications relating to this contract.



We will then arrange for the Order Form to be countersigned so that you have a signed copy of the Order Form for your records.

Yours sincerely,

[REDACTED]
DgC Higher Category Officer - EG&S – Vets & Labs
Tel: [REDACTED]
Email: [REDACTED]@defra.gov.uk

Standard Contract for Goods and/or Services - Order Form

1. Purchase Order Number	To be Confirmed (following agreement of this Contract)	
2. Customer	The Secretary of State for Environment, Food and Rural Affairs, acting as part of the Crown 2 Marsham Street London SW1P 4DF United Kingdom	
3. Contractor(s)	Lionex GmbH Salzdahlumer Strasse 196 Geb. 1A 38126 Braunschweig Germany	
4. Defra Group Members	The following Defra Group members will receive the benefit of the Deliverables: Animal and Plant Health Agency (APHA)	
5. The Agreement	This Order is part of the Agreement and is subject to the terms and conditions Referenced at Appendix 1 and shall come into effect on the Start Date. Unless the context otherwise requires, capitalised expressions used in this Order have the same meanings as in the terms and conditions. The following documents are incorporated into the Agreement. If there is any conflict, the following order of precedence applies (in descending order): <ul style="list-style-type: none"> a) this Order; b) the terms and conditions at Appendix 1; and c) the remaining Appendices (if any) in equal order of precedence. 	
6. Deliverables	Applicable Deliverables	Goods Only: <input checked="" type="checkbox"/> Services Only: <input type="checkbox"/> Good and Services: <input type="checkbox"/>
	Goods	As set out in Appendix 2 – Specification
	Services	None
7. Start Date	9 April 2025	
8. Expiry Date	8 October 2025	

9. Charges	The Charges for the Goods and/or Services shall be as set out in Appendix 3 – Charges . The Charges are fixed for the duration of the Agreement.
10. Payment	<p>The Authority's preference is for all invoices to be sent electronically, in PDF format, quoting a valid Purchase Order Number (PO Number), to:</p> <p style="text-align: center;">APinvoices-APH-U@gov.sscl.com</p> <p>Alternatively, you may post to: Shared Services Connected Ltd DEF Procure to Pay PO Box 790 Newport Gwent NP10 8FZ</p> <p>Payment of valid and undisputed invoices will be made within 30 days of receipt of the invoice or, if later, the date by which the payment falls due in accordance with the invoice, which must be submitted promptly by the Contractor.</p> <p>Within 10 Working Days of receipt of your countersigned copy of this Order Form, we will send you a unique PO Number. You must be in receipt of a valid PO Number before submitting an invoice.</p> <p>To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, item number (if applicable) and the details (name, email, and telephone number) of your Buyer contact (i.e., Buyer Authorised Representative). Non-compliant invoices may be sent back to you, which may lead to a delay in payment.</p> <p>If you have a query regarding an outstanding payment, please contact: APinvoices-APH-U@gov.sscl.com</p>
11. Contractor's Liability Cap (Clause 13.2.1)	£500,000
12. Customer's Authorised Representative(s)	<p>For general liaison your contact will continue to be</p> <p style="text-align: center;">@apha.gov.uk</p> <p>or, in their absence,</p> <p style="text-align: center;">contractmanagement@apha.gov.uk</p>
13. Contractor's Authorised Representative	<p>For general liaison your contact will continue to be</p> <p style="text-align: center;">Prof. Dr  purchase@lionex.de</p>
14. Optional Intellectual Property Rights ("IPR") Clauses	The Customer has chosen Option B in respect of intellectual property rights provisions for the Agreement as set out in the terms and conditions.

15. Progress Meetings and Progress Reports	Not applicable										
16. Address for notices	<table border="0"> <tr> <td>Customer:</td> <td>Contractor:</td> </tr> <tr> <td>Animal and Plant Health Agency</td> <td>LIONEX GmbH</td> </tr> <tr> <td>Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB</td> <td>Salzdahlumer Strasse 196, Geb. 1A 38126 Braunschweig, Germany</td> </tr> <tr> <td>Attention: [REDACTED]</td> <td>Attention: Prof. Dr [REDACTED]</td> </tr> <tr> <td>Email: [REDACTED]@apha.gov.uk</td> <td>Email: purchase@lionex.de</td> </tr> </table>	Customer:	Contractor:	Animal and Plant Health Agency	LIONEX GmbH	Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB	Salzdahlumer Strasse 196, Geb. 1A 38126 Braunschweig, Germany	Attention: [REDACTED]	Attention: Prof. Dr [REDACTED]	Email: [REDACTED]@apha.gov.uk	Email: purchase@lionex.de
Customer:	Contractor:										
Animal and Plant Health Agency	LIONEX GmbH										
Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB	Salzdahlumer Strasse 196, Geb. 1A 38126 Braunschweig, Germany										
Attention: [REDACTED]	Attention: Prof. Dr [REDACTED]										
Email: [REDACTED]@apha.gov.uk	Email: purchase@lionex.de										
17. Key Personnel of the Contractor	Not Applicable										
18. Procedures and Policies	Not Applicable										
19. Special Terms	Not Applicable										
20. Additional Insurance	Not Applicable										
21. Further Data Protection Provisions	<p>The further data protection provisions contained within Annex 4 of the terms and conditions are applicable to this Agreement where indicated below:</p> <p>Yes: <input type="checkbox"/></p> <p>No: <input checked="" type="checkbox"/></p>										

Contractor Signature

[Redacted Signature]

Full Name: Prof. Dr. [Redacted]
Job Title/Role: Managing Director
Date Signed: 11.04.2025

Authority Signature

[Redacted Signature]

Full Name: [Redacted]
Job Title/Role: Category Officer
Date Signed: 11/04/2025

Appendix 1: Terms and Conditions

The Customer's Standard Good & Services Terms and Conditions which can be located on the [Defra Website](#) and which are called 'Standard Goods & Services Terms and Conditions (Core Defra)'

Appendix 2: Specification

This Section sets out the Authority's requirements.

Definitions

For the purposes of Appendix 2, unless the context otherwise requires, the following words shall have the meanings given to them below.

"APHA"	means Animal and Plant Health Agency
"ATC"	means Animal Test Certificate
"BCG"	means Bacillus Calmette-Guérin
"BTB"	means Bovine tuberculosis
"DIVA"	means Detection of Infected amongst Vaccinated Animals
"DST-F"	means DIVA Skin Test Fusion protein
"CMT"	means Contract Management Team
"GB"	means Great Britain
"KPIs"	means Key Performance Indicators
"PMF"	means Performance Management Framework
"TB"	means tuberculosis
"VMD"	means Veterinary Medicines Directorate
"Working Days"	means a day (other than a Saturday or Sunday) on which banks are open for general business in the City of London.

1 Overview

- 1.1 The Authority wishes to obtain supply of the DIVA (of Infected amongst Vaccinated Animals) Skin Test Fusion protein (DST-F) for use in the BCG cattle vaccine Field Trials

2 Background and Policy Context

- 2.1 The UK Government has invested heavily in research since 1998 to develop a cattle BTB vaccine and DIVA tests that can Detect infected amongst vaccinated animals. The government's primary BTB research goal is to develop a deployable cattle BTB vaccine within the next five years.
- 2.2 An ATC application has been authorised by the VMD and authorisation has been given to the APHA to conduct field trials on cattle herds in GB with the DST-F and the BCG Vaccine.
- 2.3 Field trials will commence in Summer 2025 to provide data for scientific assessment to ensure the necessary requirements of unauthorised veterinary medicines in a food producing species are met and to ensure safety.

3 Requirement

- 3.1 The Authority requires the supply of the DIVA Skin Test Fusion protein (DST-F) for use in the BCG cattle vaccine Field Trials, as detailed below:

NAME OF THE VETERINARY MEDICINAL PRODUCT

DST-F

Solution for intradermal injection for cattle.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.1 ml dose

Active substance:

Fusion protein of ESAT-6, CFP-10 and Rv3615c..... 300 µg/ml

Excipients: Phosphate Buffered Saline, pH 7.4

Disodium hydrogen phosphate

Potassium dihydrogen phosphate

Sodium chloride

Water for injections

Nature and composition of immediate packaging

Type I glass (Ph.Eur) vial with rubber stopper (Ph.Eur) and aluminium cap.

Suitable packaging with 10 vials of a 10 dose per vial presentation.

Special precautions for storage

Store and transport at 2 °C – 8 °C.

PHARMACEUTICAL FORM

Solution for intradermal injection for cattle.

Shelf-life of the veterinary medicinal product as packaged for sale is 12 months.

Shelf life after first opening the immediate packaging: Use within 10 hours

4 Delivery

- 4.1 The DST-F reagent will be delivered by 31 August 2025 to

F.A.O [REDACTED] APHA, New Haw, Addlestone, Surrey, KT15 3NB.

Delivery will take place one (1) week after the Goods are manufactured, which is estimated to take three (3) months. This must be delivered in suitable packaging. Cold packs capable of keeping the temperature at +2°C to +8°C for the duration of delivery and one Electronic Monitoring Device will be included in each shipping container.

- 4.2 If any of the shipment is damaged on arrival at APHA, Weybridge, or the cold-chain has been compromised, the Contractor will be notified within 3 Working Days of its arrival and evidence of any damage or temperature deviations provided.

- 4.3 Product that is unusable should be replaced within 3 months of the date of notification of the quality defect.

5 Performance Management Framework (including KPIs and Service Credits)

- 5.1 As part of the Authority's continuous drive to improve the performance of all Contracts, this PMF will be used to monitor, measure and control all aspects of the Contractor's performance of contract responsibilities.
- 5.2 The purpose of the PMF is to set out the obligations on the Contractor, to outline how the Contractor's performance will be evaluated and to detail the sanctions for performance failure. The Contractor is responsible for the performance of any sub-contractors.
- 5.3 Key Performance Indicators (KPIs) are essential in order to align Contractor performance with the requirements of the Authority and to do so in a fair and practical way. KPIs have to be realistic, measurable and achievable; they also have to be met otherwise indicating that the service is failing to deliver. Without the use of service credits in such a situation, this service failure places strain on the relationship as delivery falls short of agreed levels.
- 5.4 The proactive approach to correcting failures and addressing their cause improves the relationship and enables a partnership rather than a confrontational style of working. Its focus is on managing and improving service.
- 5.5 The Authority shall review performance against KPI's and, if appropriate, instigate meetings and work closely with the Supplier to agree action plans. The Authority expects the Contractor to agree and implement these plans. If this does not happen, only then shall service credit principles be applied. The KPIs for this Contract are set out at Table One (1) – Key Performance Indicators

Service Credit Principles

- 5.6 The use of service credits is governed by the following principles:

Service credits sit within the wide service management approach being pursued by the Contractor and the Authority. Use of service credits does not preclude any other remedy for failure of performance available to the Authority under the terms and conditions of the contract.

The service credit regime shall be instigated on each occasion where there is a service failure. Failure to meet a KPI may also give rise to a remediation plan.

- KPIs with a service credit rating of one (1) will have a service credit of three per cent (3%) of the invoice amount for the monitoring period, applied for each KPI failure.
- KPIs with a service credit rating of two (2) will have a service credit of five per cent (5%) of the invoice amount for the monitoring period, applied for each KPI failure.
- The maximum annual service credit to be applied will be no more than ten per cent (10%) of the total annual contract value per Contractor.

5.7 The Authority has full and complete discretion on whether to claim all, part or none of a service credit to which it is due.

5.8 Service credits claimed shall be paid to APHA as a credit note within one (1) month following the date at which the service credits were applied.

5.9 The full, agreed service credit regime will operate from the Contract start date until the end of the contract period. The KPIs may be adjusted to ensure that they are appropriate and achievable.

Table One (1) – Key Performance Indicators

KPI	Description	Measure	KPI Target	Service Credit Rating
KPI One (1) Delivery	Goods shall be delivered within the agreed timescales as stated in Condition 4.1.	Delivery against agreed timescales.	100%	2
KPI Two (2) Quality	The product is accepted as suitable by DEFRA and performs to the manufacturer's specifications.	The product meets the required standards as stated in the specification.	100%	2

Appendix 3: Charges

- 1. A fixed price of **€59,585 Euros** (Fifty-Nine Thousand Five Hundred Eighty-Five) will be paid for an initial order for a batch which produces approximately 150 vials as set out in the Contract.
- 2. The following prices have been confirmed and provided by the Contractor. This is the maximum unit price that can be charged during the contract period and shall not be exceeded without prior written agreement from the Customer. It is acknowledged that the GBP amount will vary based on the current exchange rate at the time of ordering.

Exchange rate of £1 GBP = 1.17253 EUR applied on 7th April 2025 using xe.com

- 3. The total contract value will not exceed £55,000.00 without prior written consent from the Authority.

Description Item no.	Art. No.	QTY	Price per Unit (EUR)	Discount	AMOUNT (EUR)	Total Price (GBP) as at 7 th April 2025
Cost of Production of purified DST-F:	LRP-0124.5	150				
International Shipment	HS-03	1				
Total					59,585.00	50,817.46

- All prices are exclusive of VAT.

- 4. Payment will be made once all Goods have been satisfactorily received and in accordance with this Contract.

Variations

- 5. The Authority may make reasonable changes to its invoicing requirements during the Term after providing 30 calendar days written notice to the Contractor. This may include the provision of additional goods which are not listed in the above table.
- 6. Any variation to the Charges payable under the Contract must be agreed between the Contractor and the Authority and implemented using the procedure set out in this Appendix.