

Annex C. Call Off Agreement Form

MoU between the FSA and UK Health Security Agency: CALL OFF AGREEMENT		
<p>This Form is to be used by the FSA when requesting that work be undertaken or a Variation is required within the terms of the MOU. The Parties agree that each completed and approved Form will form part of and be interpreted in accordance with the terms and conditions of that MOU.</p>		
Project Title: National Reference Laboratory for Microbiology Lot 1-6	UK Health Security Agency Reference:	
	Purchase Order Number :	TBC
FSA – Project Representative: [REDACTED]	Tel:	[REDACTED]
	E-mail:	[REDACTED]
UK Health Security Agency – Project Representative: [REDACTED]	Tel:	[REDACTED]
	E-mail:	[REDACTED]
Project Number:	FS431167	
Project Start Date:	1 st April 2023	
Project Completion Date:	31 st March 2027 (subject to a break clause after two years) – See special terms	
Project Summary NRLs are specialist laboratories responsible for maintaining standards for the routine testing of feed, food and animal health. They provide advice and support on methods for official control testing, ensuring the delivery of risk-based and proportionate food enforcement to protect consumers.		
Specification/ Scope of Work: GENERAL INTRODUCTION The Food Standards Agency (FSA) is a non-ministerial Government department governed by a Board appointed to act in the public interest, with the task of protecting consumers in relation to food. The FSA work across England, Wales and Northern Ireland and collaborate closely with		

colleagues in Food Standards Scotland (FSS) to make sure food is safe, what it says it is and is healthier and more sustainable.

The National Reference Laboratories (NRLs) designated are a critical part of our national infrastructure for delivering a safe and authentic food system. The NRLs play a pivotal role in food safety enforcement by providing support and impartial expert advice to Official Laboratories (OLs) for microbiology testing of food and feed, identifying new areas of research interest and emerging threats, developing novel analytical methods and providing advice and testing capability during an emergency incident.

The FSA and FSS are committed to openness and transparency of our evidence and its use, and equality of treatment to all suppliers. As well as these principles, the FSA and FSS approve the annual report of NRL work programmes can be published on their own dedicated website.

Also, in line with the Government's Transparency Agenda which aims to encourage more open access to data held by government, the Agency is developing a policy on the release of underpinning data from all of its science- and evidence-gathering projects. Data should be made freely available in an accessible format, as fully and as promptly as possible. Consideration should be given to data management as new contracts are being negotiated. Resource implications for this should be taken into account. The mechanism for publishing underpinning data should allow the widest opportunity for to enable its re-use. Where possible, underpinning data should be included in the final project report. Where data are included in the final report in pdf format, they should also be published separately in a format that can be used for further analysis. Large data sets can be provided separately in an annex to the report, and published, where possible, alongside the final report online. Where it is more appropriate to publish underpinning data in an existing database, archive, repository or other community resource, or for data to be saved in a specialist proprietary format, information will be provided on how the data can be accessed. There will be some circumstances where release of data may need to be restricted or anonymised for reasons of commercial and/or personal sensitivities.

A. THE SPECIFICATION

Background

The FSA and FSS are responsible for Official Feed and Food Controls across the UK. The UK has a legal obligation to appoint NRLs for Food and Feed. NRLs provide advice and support to food, feed and materials and articles in contact with food enforcement laboratories and government bodies responsible for food policy (FSA and FSS) to ensure a harmonised approach to food enforcement. NRLs are responsible for setting standards for routine procedures and reliable testing methods in the regulated areas of feed and food. This delivers consumer protection and effective, risk-based and proportionate regulation and enforcement.

This project is to re-procure the contract for the UK National Reference Laboratory for Microbiology from the 1st April 2023 for four years (incorporating a two-year break point for

review in 2025). The FSA will confirm if they wish to proceed with the break point by variation to the contract, confirming intentions and any changes to the requirement.

Laboratories may only be designated as an NRL if they are accredited in accordance with

- EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories".

The applicant is required to operate in accordance with the standard EN ISO/IEC 17025 and be accredited in accordance with that standard by a national accreditation body operating in accordance with Retained Regulation (EC) No 765/2008.

The scope of the accreditation must cover the following:

- shall include those methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses, when it operates as an official laboratory;
- may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
- may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods

Where the applicant does not have the required accreditation, they must outline how they will obtain this as part of the contract.

The Specification

This is a multiple lot tender. Tenders are invited to bid for all lots, several lots or one lot; please provide details of any applicable discount for multiple awards within the Financial Template.

The appointed laboratory will carry out the provision of services for the UK National Reference Laboratory for Microbiology for the following areas in food:

- **Lot 1** - NRL for Antimicrobial Resistance (AMR)
- **Lot 2** - NRL for *Campylobacter*
- **Lot 3** - NRL for Coagulase positive *Staphylococci*, including *Staphylococcus aureus*
- **Lot 4** - NRL for *Escherichia coli*, including Shiga-toxin producing *E.coli* (STEC)

- **Lot 5** - NRL for *Listeria monocytogenes*
- **Lot 6** - NRL for the analysis and testing of Zoonoses (*Salmonella*)

The basic duties of National Reference Laboratories are, but not limited to, the following:

- (a) co-operate internationally in their area of competence, including collaborating and participating in training courses and inter-laboratory comparative tests organised by international laboratories (where appropriate);
- (b) co-ordinate, for their area of competence, the activities of UK OLS responsible for the analysis of official controls samples to ensure the verification of compliance with feed and food law;
- (c) where appropriate, organise comparative tests between the UK OLS and ensure an appropriate follow-up of such comparative testing;
- (d) ensure the dissemination of any information required by the FSA and FSS;
- (e) provide scientific and technical assistance to the FSA and FSS, especially for the implementation of the Multi Annual National Control Plans;
- (f) participate in relevant national and international workshops and training courses and, where necessary, conduct training courses for the staff of UK OLS;
- (g) upon request by the FSA and FSS, actively assist in relevant foodborne incident and outbreak situations, should be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations and in cases of non-compliance of consignments, by carrying out confirmatory analysis;
- (h) carry out research, evaluation and development of new and existing methods for the analysis of UK regulated and officially monitored foods and feed and emerging new risks to UK food safety;
- (i) provide advice and expertise on standardisation of methods at CEN and ISO;
- (j) obtain and maintain accreditation for official reference and other relevant regulatory methods for microbiology testing of food, feed within the NRL area of competence;
- (k) be responsible for carrying out other specific duties as required by the FSA and FSS, where appropriate and by prior agreement;

- (l) cascade information and learning to commercial labs, at the request of the FSA and FSS.

The laboratory is required, but not limited, to the following:

- (a) be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as NRLs;
- (b) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;
- (c) possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;
- (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national and international level are taken into account in their work;
- (e) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents and secure access to any reference materials required in order to fulfil their responsibilities and support the relevant OLs;
- (f) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and where appropriate, assist the FSA and FSS in food incidents by carrying out diagnosis and/or testing of samples, when necessary;
- (g) where relevant, be equipped to comply with relevant biosecurity standards;
- (h) maintain a list of the accreditation for the relevant OLs;
- (i) liaise with other NRLs (as and when required);
- (j) have experience of, and be able to operate in accordance with, the relevant sampling and analysis legislation, including maintaining specific UK Accreditation Service (UKAS) accreditation (or equivalent) for the relevant analytes, and satisfactory performance in proficiency test schemes;
- (k) be familiar with the enforcement system in operation in the UK.

The duties of the NRL are grouped according to its core functions, but are not limited to the following:

1. Secretariat services

- (a) disseminating relevant information/advice to the FSA and FSS, when required, UK OLs and other relevant laboratories in a timely and effective manner;
- (b) co-ordinating the activities of UK OLs and other relevant laboratories in food in relation to the core functions described below;
- (c) creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation;
- (d) providing regular updates to the FSA and FSS on NRL activities, and up-to-date information on UK OLs and other relevant laboratories to the FSA and FSS as requested;
- (e) organising quarterly network meetings to allow NRLs to engage with OLs and the FSA and FSS. Feedback from attendees must be requested and any appropriate changes implemented for the following meetings. This meeting can be in-person, however attendees must be able to attend online as well;
- (f) creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OLs, information on methods of analyses, Standard Operating Procedures (SOPs), latest developments and other background information. The FSA and FSS must have access to this website.

2. Advice and representation within the UK and internationally

- (a) providing impartial expert advice as requested to the FSA and FSS, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment;
- (b) representing the UK at relevant international meetings, and working groups, consulting the FSA and FSS on objectives and requirements before each meeting and providing the FSA and FSS with an internal report of the meeting within 10 working days of each meeting;
- (c) participating in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledge;
- (d) advising the FSA and FSS, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in

consultation with the FSA and FSS that facilitate and promote their application in the UK within the policy aims of the FSA and FSS;

- (e) keeping abreast of and advising the FSA and FSS, OLs and other relevant laboratories of developments and research for the sampling, testing and detection of food contaminants, including horizon scanning for future developments in this space;
- (f) identifying and informing the FSA and FSS, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommending action to address them;
- (g) where appropriate, partake and/or keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area;

3. Research and development, including production of standard operating procedures, codes of practice and guidance documents

- (a) contribute to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLs and other relevant laboratories, as requested by the FSA and FSS.
- (b) reports, data and results from research, development or sampling surveys conducted by the lab in its capacity as an NRL to be shared with FSA and FSS.
- (c) identify reports, sampling data and results available from within the NRL organisation and externally that could be shared with FSA/FSS

4. Compliance assessment via audits and ring trials

- (a) ensuring consistency and quality of testing approaches applied by UK OLs and other relevant laboratories, including advising on corrective action following adverse reports on OLs from UKAS;
- (b) planning and co-ordinating proficiency tests for UK OLs and other relevant laboratories as appropriate (taking into account the number of relevant laboratories), analysing and evaluating the outcome, informing the FSA and FSS and OLs of the results and advising on further action;
- (c) co-ordinating the participation of UK OLs and other relevant laboratories in international method validation studies and other initiatives, informing the FSA and FSS and OLs of the results and advising on further action;

- (d) where relevant, participating in proficiency tests and method validation studies organised by international organisations, informing the FSA and FSS of the results and implementing any corrective measures required;
- (e) co-ordinating training exercises to promote best laboratory practice in respect of analysis. Feedback from attendees at training events must be requested and any appropriate changes implemented for following events.;
- (f) providing OLs with advanced notification of proficiency testing rounds to enable OLs to implement such activities in a timely manner.
- (g) assessing the capability and capacity of OLs conducting microbiology testing across the UK every two years, informing FSA and FSS of results.

5. Co-ordination within the UK of international initiatives

- (a) where appropriate, co-ordinating the recommendations of international organisations related to the standardisation of testing methods.

6. Communication of results and data use

- (a) the supplier shall ensure that the FSA and FSS receives regular updates of any developments related to the core functions of the NRL;
- (b) the supplier shall notify the FSA and FSS immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual work programme;
- (c) the supplier shall notify the FSA and FSS immediately by email of any unusual occurrences resulting from any of the core functions of the NRL;
- (d) The supplier shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the FSA and FSS by 31st March each year. Annual reports will be approved by the FSA and FSS prior to publication by NRLs on NRL dedicated websites. If requested by the FSA and FSS, the supplier may also need to provide interim reports during the annual work programme;
- (e) any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the FSA and FSS;
- (f) the use of the data for presentations and/or papers will not be permitted unless written permission has been sought and given by the FSA and FSS;

- (g) the supplier will maintain records. Retention periods will be agreed and defined in the contract and if necessary, the supplier will assist with transfer of archived reference material;
- (h) in other work related to the core functions of the NRL, the specified deadlines agreed between the FSA and FSS and the Contractor should be met;
- (i) if necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the FSA and FSS. This will include assisting with transfer of archived reference materials;
- (j) provide an internal report of meetings with other organisations within 10 working days of the meeting;
- (k) the supplier will engage in quarterly dialogues with the FSA and FSS to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the FSA and FSS may also be organised to ensure any potential or evolving issues are flagged and work is kept on track. While these meetings can be in-person, attendees must be able to attend in an online format as well;
- (l) the supplier will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and FSA and FSS on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results. Feedback from attendees must be requested and any appropriate changes implemented for the following meetings. While these meetings can be in-person, attendees must be able to attend in an online format as well;
- (m) the Contractor will review NRL finances regularly and communicate spending, including a break-down of costs, with the FSA and FSS on a quarterly basis.

7. Incident management

- (a) Supply of scientific advice and guidance to FSA, FSS, LAs and PA OLs for incident matters and wider issues related to NRL microbiological area in food and feed.
- (b) Should a major food or feed incident occur where there is currently no method associated with the 6 NRL responsibilities, the NRL will prioritise and dedicate effort towards developing the new methods required.
- (c) Conduct rapid sampling under direction of FSA and FSS and the FSA incident management team in the event of a food or feed incident relating to NRL microbiological area in food and feed. This may include training of staff and ensuring appropriate staff resources in event of food or feed incident.

- (d) Conduct analyses on official control samples for PAs in the event of an incident relating to the NRL's microbiological area.

Tender Application Form

The 'Tender Application Form' requests the supplier to complete information in the following headers. Please state in your application which lots you are bidding for (details at Scope of Services section).

- Project summary
- Description of approach/scope of work
- The project plan and deliverables
- Participating Organisations and sub-contractors
- Project and staff management
- Risk management
- Quality management
- Social Value

Cost

The proposal must identify all anticipated costs of conducting the work, providing a cost breakdown of staff involvement and days dedicated to the project for each staff member, and all other associated overheads and expenses. Quarterly invoicing must be specified.

Examples of the costs which should be included in the cost breakdown, in addition to the main analysis, include:

- The charge for presentations and meetings
- Costs for delivering workshops
- A breakdown for any proposed sub-contractor involvement (if relevant)
- Any costs associated with making data available for further use (e.g. archiving)
- Access to other datasets, as necessary

Costs should be provided for the life of the contract exclusive of VAT and should clearly state whether VAT will be charged.

Special Terms:

To include any terms or conditions not covered in the overarching MoU or any terms amended for the purposes of this Call Off Agreement

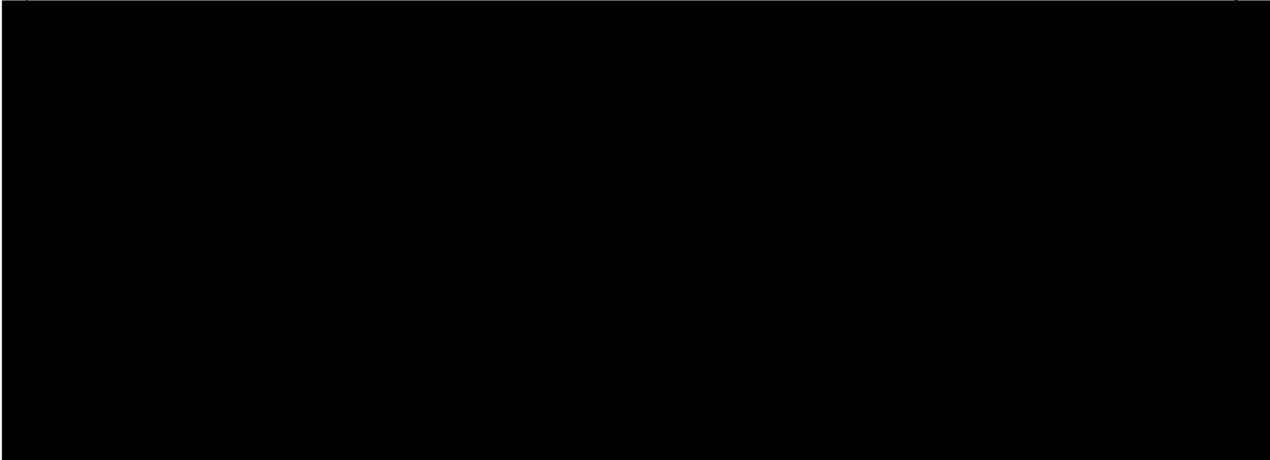
This agreement is subject to a break point after 31st March 2025 with 3 months' notice. At this break point either party can by notice in writing terminate the agreement.

Deliverables:	See Annex 1 – Suppliers Technical Application Form	
Progress Reporting (frequency & details):	As per The Project Plan and Deliverables of Annex 1 – Suppliers Technical Application form for a project with the Food Standards Agency.	
Key Personnel:	See Annex 1 – Technical Application Form	
Foreground IPR – Ownership	As detailed in the MoU.	
Price	Total costs for the period 1 April 2023 to 31 st March 2027 subject to a break clause – see special terms, is £1,443,675.18.	
Payments & Invoicing	<p>Please submit invoices to [REDACTED] for work with FSA.</p> <p>Please include the referring FSA purchase order number in the email title and within the invoice to allow Invoice/Purchase Order matching.</p> <p>Note that invoices that do not include reference to FSA Purchase Order number will be returned unpaid with a request for valid purchase order through email.</p>	
Data sharing	Personal Data	Biological/ Sampling & Station Data
What data is being shared and why is it being collected?	<i>UK Food Examiner's contact details for FSA to hold in case of incident in particular area of the UK.</i>	<i>Proficiency testing data to adhere to OCRs, laboratory capability information to attain UK's capability</i>

	<i>[e.g. Names and addresses of collectors 2017 onwards for the purpose of the work specified in this Call Off Form]</i>	<i>[e.g. resulting report and findings of specified work in the Call Off Form]</i>
How will the data be shared	<i>secure email systems, MS Teams upload (secure file transfer protocol portal), in closed meetings (e.g: encrypted digital copy, transfer of the required data to an IT system accessed solely by a party via a secure file transfer protocol portal, providing access to IT systems via a secure login)</i>	<i>secure email systems, MS Teams upload (secure file transfer protocol portal), in closed meetings (e.g: encrypted digital copy, transfer of the required data to an IT system accessed solely by a party via a secure file transfer protocol portal, providing access to IT systems via a secure login)</i>
How will the data be stored	<i>Secure UKHSA network server, where access is password protected and limited to NRL staff (Include any security requirements for data storage eg: secure servers to a minimal level meeting cyber essentials, ensuring access is only granted to those employees with a need to use it)</i>	<i>Secure UKHSA network server, where access is password protected and limited to NRL staff (Include any security requirements for data storage eg: secure servers to a minimal level meeting cyber essentials, ensuring access is only granted to those employees with a need to use it)</i>
Role of the Parties	<i>Data Controller: UKHSA [specify whether FSA or UKHSA] Processor: UKHSA [specify whether FSA or UKHSA]</i>	<i>Data owner: UKHSA [specify whether FSA or UKHSA] Data originator: UKHSA [specify whether FSA or Hampshire County Council] Data receiver: UKHSA, FSA, FSS [specify whether FSA or UKHSA]</i>
How long will access to the data be permitted	<i>Personal information: 6 years [Clearly set out the duration of the processing including dates]</i>	<i>Biological and sampling data: 6 years [Clearly set out the duration of the processing including dates]</i>
How can the data be used	<i>For contact purposes [Please be as specific as possible, but make sure that you cover all intended purposes. The nature of the processing means any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval,</i>	<i>In reports; at closed meetings (invited participants only) [e.g. For completing the Party's obligations under the Call Off Form or Publish reports, is it to be restricted in any way e.g. raw data or methods of working? Also include restrictions on access e.g. read only for some people]</i>

	<p><i>consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means) etc.</i></p> <p><i>The purpose might include: statutory obligation, refer to work being completed under the Call Off Form]</i></p> <p><i>Include identifying the source of the data and any appropriate copyright notice</i></p>	
What is the nature of the Personal Data?	<p><i>Name, email address, work address, work phone number</i></p> <p><i>[Examples here include: name, address, date of birth, NI number, telephone number, pay, images, biometric data, law enforcement data, Vessel or skipper details]</i></p>	<i>e.g. associated location data</i>
If personal data is being provided please detail Categories of Data Subject	<p><i>NRL Staff, UK Food Examiners</i></p> <p><i>[Examples include: Staff (including volunteers, agents, and temporary workers), customers/clients, suppliers, students, members of the public, users of a particular website etc]</i></p>	<i>Not applicable</i>
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	<p><i>6 years</i></p> <p><i>[Describe how long the Data Processor may retain the data for, how it be returned or destroyed or if legally it needs to be retained the applicable legislation for retaining it]</i></p>	<p><i>6 years</i></p> <p><i>[Describe how long the Data receiver (& originator if not the owner) may retain the data for, how it be returned or destroyed or if legally it needs to be retained the applicable legislation for retaining it]</i></p>

Transfers to third countries or international organisations (if applicable)	<i>EURLs – contact details of UK NRL staff [Insert any details about transfers to third countries or international organisations]</i>	<i>EURLs – PT data, survey information [Insert any details about transfers to third parties]</i>
Commercially sensitive information	N/A	Third party laboratories if NRL receives request to evaluate method/performance
<p>We agree that the goods and/or services requested will be provided according to the terms and conditions set out in the MoU between UK Health Security Agency and the FSA supported by this Call-Off Agreement/Variation Form.</p>		



Annex 1 – Technical Application Form

<h2>Tender Application form for a project with the Food Standards Agency</h2>		 Food Standards Agency food.gov.uk	
<ul style="list-style-type: none"> Applicants should complete each part of this application as fully and as clearly as possible Brief instructions are given in the grey boxes at the start of each section. Please submit the application through the Agency's eSourcing Portal (Bravo) by the deadline set in the invitation to tender document. 			
LEAD APPLICANT'S DETAILS			
[REDACTED]			
Is your organisation is a small and medium enterprise . (EU recommendation 2003/361/EC refers http://www.hmrc.gov.uk/manuals/cirdmanual/cird92800.htm)		Yes	No <input checked="" type="checkbox"/>
TENDER SUMMARY			
TENDER TITLE			
National Reference Laboratory for Microbiology			
TENDER REFERENCE	FS516010-6		
PROPOSED START	[01/04/2023]	PROPOSED	[31/03/2027]
1: TENDER SUMMARY AND OBJECTIVES			
A. TENDER SUMMARY			
Please give a brief summary of the proposed work in no more than 400 words.			
<p>This application is to provide a service to the Food Standards Agency (FSA) for the United Kingdom's National Reference Laboratory (NRL) for food microbiology as a multi-lot bid, according to the duties detailed in Article 101 of Regulation (EC) 2017/625, and additional functions as required by the FSA and FSS. UK Health Security Agency (UKHSA) will propose to draw on expertise from the UKHSA FW&E Microbiology Services and the national facilities at UKHSA Colindale which has specialist experience in all of the required areas. UKHSA has also had experience of undertaking the NRL function for FSA since August 2011 (Contract References PAU222/Micro and FS516010). There will be access to appropriate laboratory facilities to perform all aspects of the work including all analytical reference methods for the specific targets as outlined in Commission Regulation EC No. 2073/2005, as well as disseminating information (via written communications, a dedicated area on the UKHSA Web Site, laboratory training facilities and face-to-face meetings), and for the performance of ring trials and comparative analyses together with IT, statistical and quality support. The proposed service will be project managed by a Steering Group which will meet quarterly and review the activities of the NRL. An Annual Work Plan will be proposed and agreed, and this will be included in an Annual Report. Budget statements will be prepared on a quarterly basis by UKHSA and sent to the FSA and will coincide</p>			

with the deliverables. Completion of the project will include the completion of all deliverables signed off by the management group and funder as well as a final annual report.

The UKHSA Food Water and Environmental Microbiology Service is a designated Official Laboratory (OLs) and consequently accredited to the ISO 17025 standard (General Requirements for the Competence of testing and Calibration laboratories) and is audited by United Kingdom Accreditation Service (UKAS) annually. It is a multisite laboratory with UKAS number 1645. The NRL function will be embedded within this network of laboratories.

Three dedicated full-time staff will be employed within this activity; an NRL Lead Scientist (G7), NRL Scientist (AFC7) and an NRL Administrator (AFC5) and supported by various experienced staff at UKHSA. The project will benefit from existing strong relationships in the participating Reference Laboratories as well as the OLs and all participants share a clear public health focus and commitment to Official Control functions in line with the purpose and ethos of this bid.

B. OBJECTIVES AND RELEVANCE OF THE PROPOSED WORK TO THE FSA TENDER

OBJECTIVES

Please detail how your proposed work can assist the agency in meeting its stated objectives and policy needs.. Please number the objectives and add a short description. Please add more lines as necessary.

OBJECTIVE NUMBER	OBJECTIVE DESCRIPTION
1	SECRETARIAT SERVICES.
2	ADVICE AND REPRESENTATION WITHIN THE UK AND INTERNATIONALLY
3	RESEARCH AND DEVELOPMENT, INCLUDING PRODUCTION OF STANDARD OPERATING PROCEDURES, CODES OF PRACTICE AND GUIDANCE DOCUMENTS
4	COMPLIANCE ASSESSMENT VIA AUDITS AND RING TRIALS
5	CO-ORDINATION WITHIN THE UK OF INTERNATIONAL INITIATIVES
6	COMMUNICATION OF RESULTS AND DATA USE
7	INCIDENT MANAGEMENT

DESCRIPTION OF APPROACH/SCOPE OF WORK

C. APPROACH/SCOPE OF WORK

Please describe how you will meet our specification and summarise how you will deliver your solution. You must explain the approach for the proposed work. Describe and justify the approach, methodology and study design, where applicable, that will be used to address the specific requirements and realise the objectives outlined above. Where relevant (e.g. for an analytical survey), please also provide details of the sampling plan..

The UK has a legal obligation (through adopting the Official Food and Feed Controls Regulations 2009; UK SI 3255) to appoint National Reference Laboratories (NRLs) to support the food enforcement laboratories (Official Laboratories; OLs) and government bodies responsible for food safety. The specification requests NRL services for the following areas in food microbiology as single lots:

- Antimicrobial resistance (AMR)
- *Campylobacter*
- Coagulase positive *Staphylococci* including *Staphylococcus aureus*
- *Escherichia coli*, including Shiga-toxin producing *E. coli* (STEC)
- *Listeria monocytogenes*
- Analysis and testing of Zoonoses (*Salmonella*)

Core functions and duties of the appointed NRL are based on article 101 of the EC Regulation 2017/625, retained by UK Statutory Instrument 2019 No. 665:

- (a) co-operate internationally in their area of competence, including collaborating and participating in training courses and inter-laboratory comparative tests organised by international laboratories (where appropriate);
- (b) coordinate, for their area of competence, the activities of UK OLs responsible for the analysis of official control samples in to ensure the verification of compliance with feed and food law;
- (c) where appropriate, organise comparative tests between the UK OLs and ensure an appropriate follow-up of such comparative testing;
- (d) ensure the dissemination of any information required by the FSA and FSS;
- (e) provide scientific and technical assistance to the FSA and FSS, especially for the implementation of the Multi Annual National Control Plans;
- (f) participate in relevant national and international workshops and training courses and, where necessary, conduct training courses for the staff of UK OLs;
- (g) upon request by the FSA and FSS, actively assist in relevant foodborne incident and outbreak situations, should be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations and in cases of non-compliance of consignments, by carrying out confirmatory analysis;
- (i) provide advice and expertise on standardisation of methods at CEN and ISO;
- (j) obtain and maintain accreditation for official reference and other relevant regulatory methods for microbiology testing of food, feed within the NRL area of competence;
- (k) be responsible for carrying out other specific duties as required by the FSA and FSS, where appropriate and by prior agreement;
- (m) cascade information and learning to commercial labs, at the request of the FSA and FSS.

UKHSA will deliver this service by:

- providing impartial expert advice to the FSA and FSS, OLs and other relevant laboratories, including comprehensive advice and guidance on methodology, testing of samples and legislation;
- providing qualified staff who have a high level of scientific expertise, experience and proficiency in the area of Official Control and international standards, and to support them with continued development
- having access to suitable laboratory facilities with appropriate equipment and products to achieve the NRL tasks
- performing standardisation activities (e.g. CEN, ISO etc.) relevant to the work area, including method development and improvement
- validating and maintain relevant reference controls and reagents to support the OLs
- responding to emergency situations and assisting and communicating with the FSA and FSS in food incidents, providing testing when necessary
- complying with relevant biosecurity standards
- maintaining a list of the accreditation status for the relevant OLs;
- liaising with other FSA-appointed foodborne disease NRLs (e.g., Animal and Plant Health Agency and the **Centre for Environment, Fisheries and Aquaculture Science (CEFAS)**) to ensure overall adherence and complementary activities for Official Controls
- possessing experience of, and being able to operate in accordance with, the relevant sampling and analysis legislation, including maintaining specific UKAS accreditation (or equivalent) for the relevant analytes, and satisfactory performance in proficiency test schemes
- being familiar with the enforcement system in operation in the UK
- where available, collaborating with the EURLs ensuring communication and dissemination of information to the FSA, FSS and OLs
- maintaining competence in all areas of the NRL by participating in training courses and inter-laboratory comparative tests organized by international laboratories
- organizing comparative tests between the UK OLs and supporting those that report poor performance
- identifying capability gaps in the UK's microbiological testing in food and feed and delivering training to OLs and other supporting information
- when appropriate, evaluating new and existing methods for appropriate testing of food and feed to support UK food safety
- when appropriate, giving support to commercial laboratories

The proposed NRL will draw on expertise from the National Network of three laboratories in the UKHSA Food Water and Environmental Microbiology Service, as well as the expertise within the National Microbiology Reference facilities at UKHSA Colindale, which has specialist experience in all of the required areas. There will be access to appropriate laboratory facilities to perform all aspects of the work including all analytical reference methods for the specific targets as outlined in Commission Regulation EC No. 2073/2005 (Microbiological Criteria for Foodstuffs), as well as methods for dissemination of information (via written communications, a dedicated area on the UKHSA Web Site, laboratory training facilities and face-to-face meetings), and for the performance of ring trials and comparative analyses together with IT, statistical and quality support.

In consultation with the FSA & FSS, the NRL will produce and agree an annual work programme and agree milestones, deadlines and key target dates via annual timelines. The NRL will deliver these milestones, deadlines and key target dates unless otherwise agreed with FSA & FSS. Services will be formally reviewed at regular planning and yearly review meetings. A minimum of four meetings will be held during the year between representatives of the NRL and the FSA & FSS to review the volume, cost and activities of the contractor services provided. The date of these meetings will be agreed between the NRL and the FSA & FSS. Other ad-hoc meetings may be arranged as required.

UKHSA has the capability and capacity to conduct focussed testing and method development which can be utilised at the request of FSA and FSS and with prior agreement by all parties. UKHSA is also equipped to identify, investigate and communicate foodborne incidents as part of the UK response for public health and food security. Due to the unpredictable nature of these activities, examples have been given separately in the financial template and can be agreed as and when the event/activity is required.

In addition, UKHSA has currently successfully provided the NRL service for all the above work areas since August 2011, and this experience has demonstrated the required infrastructure and competencies and strengthened the links between the NRL, the FSA & FSS, the OLs and other relevant laboratories.



2: THE PROJECT PLAN AND DELIVERABLES

A. THE PLAN

Please provide a detailed project plan including, the tasks and sub-tasks required to realise the objectives (detailed in Part 1). The tasks should be numbered in the same way as the objectives and should be clearly linked to each of the objectives. Please also attach a flow chart illustrating the proposed plan.

The service for the provision of the core functions for all six microbiological areas will be delivered as follows (also see supporting document 1):

1) Core Function One: Secretariat services

- a) *Disseminating relevant information/advice FSA and FSS, when required, UK OLs and other relevant laboratories in a timely and effective manner.* The NRL will achieve this by regular communication, where possible, with the EURLs and other international organisations (representation to at least one meeting each year) and frequent monitoring of the EURL websites for new information. Information from the EURLs will be disseminated via written communications, a dedicated area on the UKHSA Web Site and at least one network ('User Day') meeting (either face-to-face in Colindale or via Microsoft Teams), with representatives from the FSA and FSS, the NRL and all OLs for each of the required areas (i.e. antimicrobial resistance (AMR), *Campylobacter*, Coagulase positive *Staphylococci*, including *Staphylococcus aureus*, *Escherichia coli*, including Shiga-toxin producing *E. coli* (STEC), *Listeria monocytogenes* and *Salmonella*). A quarterly newsletter will be produced to update OLs, the FSA and FSS, and other UK laboratories of relevant methodologies, legislation and events from the EURLs, the EU and other international organisations. The other UK laboratories include the relevant reference laboratories within UKHSA, the Scottish *E. coli* O157/VTEC Reference Laboratory, the **Scottish Salmonella, Shigella & C. difficile Reference Laboratory**, the **Animal and Plant Health Agency (APHA)** and the **Centre for Environment, Fisheries and Aquaculture Science (CEFAS)**. The Newsletter will also list changes to the NRL web site, including addition of new documents, reports, SOPs, etc. The annual 'User Day' will be open to all interested parties and will provide a further communication route for information to other relevant UK laboratories involved in the testing of food and activities of the NRL.
- b) *Co-ordinating the activities of UK OLs and other relevant laboratories in food in relation to the core functions described below.* The NRL will maintain a list of OLs' accreditation status by regular audits of the OLs together with information on accreditation scope available from the UKAS website. This, together with feedback from the OLs after network meetings and training activities, will be used to appropriately arrange NRL activities to support and strengthen the UK capability of microbiology testing in food. The NRL will co-ordinate using written communications, a dedicated area on the UKHSA website and at annual network meetings, to UK OLs and other relevant UK laboratories in food for the core functions. In addition, the annual 'User Day' will provide a further communication route for information to other relevant UK laboratories involved in the testing of food.
- c) *Creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation.* An efficient two-way channel of communication with the UK OLs and relevant laboratories and international organisations will be achieved by using the above-mentioned mechanisms, to disseminate information on analytical methods and UK and EU Regulations. The annual 'User Day' is a further two-way means of communication for information to UK OLs and other relevant UK laboratories involved in the testing of food and provides a forum to discuss specific areas including proficiency testing (PT) results as well as results of other comparative analyses and methodological advances.
- d) *Providing regular updates to the FSA and FSS on NRL activities, and up-to-date information on UK OLs and other relevant laboratories to the FSA and FSS as requested.* The NRL will provide monthly logs of activity and an extended annual report to the FSA and FSS on NRL activities, together with up-to-date information on UK OLs and other relevant UK laboratories to the FSA and FSS as requested.
- e) *Organising quarterly network meetings to allow NRLs to engage with OLs and the FSA and FSS. Feedback from attendees must be requested and any appropriate changes implemented for the following meetings.* The NRL will meet with the FSA and FSS on a quarterly basis, to review past deliverables, discuss progress on work and identify new activities. The OLs will be invited to a network meeting at least once a year, along with FSA and FSS, and other relevant UK laboratories to update in participation to proficiency testing, method developments, training needs and other relevant NRL activities. Feedback will be sought after the annual network meetings to improve the content and management of the meetings and to tailor the NRL's other activities to support the OL network.
- f) *Creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OLs, information on methods of analyses, SOPs, latest developments and other background information.* The NRL will provide a dedicated area on the UKHSA website to support and advise the OLs, and SOPs will be accessible. Various documents and news items will also be available or signposted (e.g., Annual Reports, new legislations). All

SOPs that are related to the NRL activities will be available on the NRL webpage. Content will be regularly checked for accuracy and updated where necessary. The website will have unrestricted access to maximise support to all relevant parties, including the FSA and FSS.

2. Core Function Two: Advice and representation within the UK and internationally

- a) *Providing impartial expert advice as requested to the FSA and FSS, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment.* The NRL will provide impartial expert advice in relation to the required areas (i.e. antimicrobial resistance (AMR), *Campylobacter*, Coagulase positive *Staphylococci*, including *Staphylococcus aureus*, *Escherichia coli*, including Shiga-toxin producing *E. coli* (STEC), *Listeria monocytogenes* and *Salmonella*) via written communications, a dedicated area on the UKHSA website, laboratory training, tutorial sessions and an annual 'User Day'. Any advice requested by the FSA and FSS will be given by experts within the NRL in their relevant areas of work.
- b) *Representing the UK at relevant international meetings, and working-groups, consulting the FSA and FSS on objectives and requirements before each meeting and providing the FSA and FSS with an internal report of the meeting within 10 working days of each meeting.* Staff of the NRL will provide representation of the UK at relevant international meetings including attending the annual workshops and collating views and comments from interested parties as appropriate. The NRL will (where available) send agendas, objectives and requirements to the FSA and FSS before each meeting and an internal report of the meeting will be provided to the FSA and FSS after each meeting. Communications and information from the international meetings will be disseminated to the OLs and other relevant UK laboratories.
- c) *Participating in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledge.* Staff of the NRL will participate and contribute to the scientific input at international meetings in a manner which supports UK policy based on best available scientific knowledge. Where relevant, the strategy to best support UK policy will be discussed and agreed with the FSA and FSS before each meeting as described above in 2.b.
- d) *Advising the FSA and FSS, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in consultation with the FSA and FSS that facilitate and promote their application in the UK within the policy aims of the FSA and FSS.* The NRL will inform the FSA and FSS of international recommendations related to harmonised testing methods for microbiological contaminants in food and within the UK for Official Controls, and co-ordinate their implementation. Information on the implementation of these harmonised testing methodologies will be disseminated via written communications, a dedicated area on the UKHSA website, and at least one network meeting with representatives from the FSA and FSS, the NRL and all OLs for each of the required areas. Face to face meetings may also include laboratory demonstration and training as necessary. The implementation of harmonised testing methods will also be facilitated by the provision of validation data resulting from PT results as well as those from ring trials and other comparative analyses.
- e) *Keeping abreast of and advising the FSA and FSS, OLs and other relevant laboratories of developments and research for the sampling, testing and detection of food contaminants, including horizon scanning for future developments in this space.* Staff of the NRL will enact this by attending EURL meetings, where possible, regular monitoring of EURL and EU websites, attending international scientific meetings and through being a member of the BSI AW/9 'Microbiology of the food chain' committee. Information will then be disseminated via written communications, a dedicated area on the UKHSA website, and at network meetings, with the FSA and FSS, OLs and other relevant UK laboratories.
- f) *Identifying and informing the FSA and FSS, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommending action to address them.* The NRL will achieve this using a similar approach to 2 e) above. The NRL will identify these via two way communication with OLs, the FSA and FSS, and other relevant UK laboratories, as well as from a number of different sources including; CEN and ISO working groups; local and national human and veterinary surveillance; links with other national and international organisations (e.g. ECDC, EFSA, CDC, WHO); contact with the EURLs, and other NRLs in both the UK and other EU Member States, etc. current contacts and activities of the UKHSA make this organisation particularly well placed to identify emerging analytical issues or developments.
- g) *Where appropriate, partake and/or keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area.* Staff of the NRL will engage in the relevant working groups of the CEN and ISO organisations, where relevant. BSI meetings will be attended by the NRL, and updates from the ISO/CEN meetings will be gained from existing UK attendees. The FSA will be updated of any developments through either written communication or the quarterly meetings.

3. Core Function Three: Research and development, including production of standard operating procedures, codes of practice and guidance documents

- a) *Contributing to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLS and other relevant laboratories, as requested by the FSA and FSS.* The NRL will produce SOPs that are related to the NRL activities and make them available on the UKHSA website, as stated previously in 1.f). Other documents will be made available, such as codes of practice and guidance material to be used by the OLS. This can include advice on testing plans, reference methods, appropriate target selection and acceptability criteria. Advice will also be provided on acceptability of alternatives to testing plans, micro-organisms, microbiological limits and microbiological methods which differ to those outlined in EC No 2073/2005.
- b) *Conduct sampling and method development activities at the request of the FSA and FSS, informing the FSA and FSS of the outcome. Training OLS to perform the methods if required.* The NRL will conduct focussed testing and method development activities on a case-by-case basis, with additional resources where necessary and at the request of the FSA and FSS. The sampling plan would be developed and agreed by the NRL and FSA and FSS and the number of samples would be dependent on the matrix type, expected contamination rates and/or the number of target organisms being sought [see supporting document 2]. UKHSA has experience in targeted surveys and works closely with Local Authorities who may assist with collection of the relevant samples. UKHSA FW&E staff also have experience in working with sub-contracted sampling companies in order to provide suitable samples for more specialised surveillance activities.
Method development can be undertaken by the NRL, where a need is identified. UKHSA FW&E staff have experience of developing and validating a range of microbiological methods (both culture-based and molecular methods), and introducing them into routine use, including gaining UKAS accreditation for them. Subsequent training in the new or updated method can be delivered to the OLS to roll out the method and increase UK's testing capacity.
- c) *Reports, data and results from research, development or sampling surveys conducted by the lab in its capacity as an NRL to be shared with FSA and FSS.* Reports, data and results from targeted surveys and method development will be produced by the NRL and these will be shared with FSA and FSS by joint agreement between all parties on a case-by-case basis.
- d) *Identify reports, sampling data and results available from within the NRL organisation and externally that could be shared with FSA/FSS.* Targeted surveys are performed by UKHSA and some of the generated data and reports may be useful to share with the FSA and FSS to inform further sampling plans, food monitoring, risk assessment and identifying future threats. The NRL will be kept informed of these surveys and when permitted and relevant, will pass on reports to the FSA and FSS. The NRL also maintains awareness of surveys and studies carried out by external organisations which may have relevance to food microbiology in the UK, and is able to disseminate this information as required.

4. Core Function Four: Compliance assessment via audits and ring trials

- a) *Ensuring consistency and quality of testing approaches applied by UK OLS and other relevant laboratories, including advising on corrective action following adverse reports on OLS from UKAS.* The NRL will be staffed by microbiologists with expertise in all the relevant areas specified. Staff for the NRL will be available to provide OLS with advice on request, regarding accreditation requirements including adverse reports during UKAS inspections. A specific update on maintenance of accreditation will be included at the annual 'User Day'.
- b) *Planning and co-ordinating proficiency tests for UK OLS and other relevant laboratories as appropriate (taking into account the number of relevant laboratories), analysing and evaluating the outcome, informing the FSA and FSS and OLS of the results and advising on further action.* To allow for adequate participation in proficiency tests (PTs) by the OLS, this activity will be subcontracted to the UKHSA Food and Environmental Proficiency Testing Unit (FEPTU) as a costed activity paid for from the NRL budget directly to the external quality assurance (EQA) provider and allowing 'free' participation for each OL. The European Food Microbiology Legislation (EFL) Scheme delivered by FEPTU is best suited to the OLS, as this concurrently compares and assesses participants' ability to test and interpret laboratory results in accordance with EU food safety and process hygiene criteria. FEPTU will prepare bespoke LENTICULE discs with known levels of wild type target organisms to be tested by the OLS. The NRL will receive an anonymous report of each PT distribution to monitor performance and identify any concerns with specific methods or individual laboratories and will offer advice where necessary. Due to the nature of FEPTU's management and organisation of PT schemes, the NRL will remain independent and objective and will only intervene after repeated poor performance and support has been sought via FEPTU. The FEPTU EFL PT scheme is organised as four proficiency tests annually, with each distribution focusing on specific matrix types. This will provide validation data for implementation of analytical reference methods fit for accreditation by UKAS. Reporting on outcomes of comparative testing and ring trials will be discussed with the FSA and FSS and disseminated via written communications, reports on a dedicated area on the UKHSA website, quarterly newsletters and at the annual 'User Day'.
- c) *Coordinating the participation of UK OLS and other relevant laboratories in international method validation studies and other initiatives, informing the FSA and FSS and OLS of the results and advising*

- on further action.* Coordination, and the outcomes, advice and summaries of these comparative and validation studies will be disseminated via written communications, at the annual 'User Day', the annual reports and in meetings with the FSA and FSS. The NRL will support and advise the OLs if any corrective measures are required.
- d) *Participating in proficiency tests and method validation studies organised by international organisations, informing the FSA and FSS of the results and implementing any corrective measures required.* The NRL, where possible, will participate as the UK-NRL in ring trials including method comparison or validation studies and other initiatives organised by the EURLs and international organisations, informing the FSA and FSS of the results and implementing any corrective measures required. Outcomes, advice and summaries of these comparative and validation studies will be disseminated via written communications, at the annual 'User Day', the annual reports and in meetings with the FSA.
 - e) *Co-ordinating training exercises to promote best laboratory practice in respect of analysis. Feedback from attendees at training events must be requested and any appropriate changes implemented for following events.* The NRL will co-ordinate training workshops to promote best laboratory practice for the areas listed. These training exercises will be performed at face-to-face meetings in Colindale, where there is a dedicated training laboratory facility available for this activity. Areas for training will be identified via a variety of sources, for example, from information and activities resulting from the EURLs and international organisations, communication with other NRLs, two-way communication and feedback from OLs and other relevant UK laboratories involved in the testing of food, results of ring trials and PT results. Non-practical training issues, such as Measurement Uncertainty, validation/verification of alternative methods, and interpretation of the microbiological criteria can also be addressed by organising on-line meetings for OLs and other relevant UK laboratories to attend remotely.
 - f) *Providing OLs with advanced notification of proficiency testing rounds to enable OLs to implement such activities in a timely manner.* Notification of proficiency testing will be performed by the NRL by arranging in advance with the OLs their participation in the FEPTU EFL PT scheme and the OLs will be sent the dates of dispatch and result submission. Reminders will be sent at regular intervals directly from FEPTU and via the quarterly newsletters from the NRL with at least two months' notice of the dispatch date of the next distribution.
 - g) *Assessing the capability and capacity of OLs conducting microbiology testing across the UK every two years, informing FSA and FSS of results.* The NRL will conduct capability and capacity audits of the UK OLs for food microbiology by using an online survey tool and these will align with the EU 2073/2005 Microbiological Criteria legislation, as well as laboratory infrastructure and other testing and service needs. Results and reports will be produced and shared with the FSA and FSS and uploaded on the dedicated area of the UKHSA website, and at network meetings. The NRL will also review the accreditation status of the OLs to assess the capability and capacity of the UK's testing of microbiology in food.

5. Co-ordination within the UK of international initiatives

- a) *Where appropriate, co-ordinating the recommendations of international organisations related to the standardisation of testing methods.* Staff of the NRL will co-ordinate recommendations from international organisations to the FSA and FSS, the OLs and other relevant laboratories by regular communications. This will be strengthened by the drafting of national SOPs, organisation of specific meetings and practical workshops, and further support, advice and guidance to the OLs, to obtain standardisation of testing methods.

6. Communication of results and data use

- a) *The supplier shall ensure that the FSA and FSS receives regular updates of any developments related to the core functions of the NRL.* The NRL will send regular updates of all the relevant activities by way of monthly logs and annual reports.
- b) *The supplier shall notify the FSA and FSS immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual work programme.* If the NRL experiences either adverse events or a newly identified activity related to one of the specified areas (e.g., via international organisation recommendation or new legislation), the NRL will immediately notify the FSA and FSS of this change and an update of the costs, specifications and/or timings of the planned work will be provided.
- c) *The supplier shall notify the FSA and FSS immediately by email of any unusual occurrences resulting from any of the core functions of the NRL.* Staff of the NRL will email the FSA if any results from the activities have deviated from the intended, especially where extra activities may be generated (similar to point 6.b, above).
- d) *The supplier shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the FSA and FSS by 31st March each year. Annual reports will be approved by the FSA and FSS prior to publication by NRLs on NRL dedicated websites. If requested by the FSA and FSS, the supplier may also need to provide interim reports during the annual work programme.* The NRL will prepare annual reports to be approved by the FSA and FSS before being uploaded on the

- dedicated NRL website. Reports for specific activities (e.g., audit of the OLs, workshop report) will be produced and sent to the FSA and FSS, if requested.
- e) *Any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the FSA and FSS.* Staff of the NRL will ensure that all results or reports that will be communicated either via the UKHSA website or directly to OLs and other relevant laboratories will initially be sent to the FSA and FSS for approval. The NRL will then not send or publish these reports/results until a written permission or approval is received.
 - f) *The use of the data for presentations and/or papers will not be permitted unless written permission has been sought and given by the FSA and FSS.* The NRL will seek permission to use data for presentations and/or papers from the FSA and FSS as explained above in 6.e.
 - g) *The supplier will maintain records. Retention periods will be agreed and defined in the contract and if necessary, the supplier will assist with transfer of archived reference material.* Staff of the NRL will maintain records, both hard and electronic, as agreed and defined in the contract. UKHSA have adequate facilities, infrastructure and experience in archiving records related to external and internal projects, for audit, legal and publication reasons.
 - h) *In other work related to the core functions of the NRL, the specified deadlines agreed between the FSA and FSS and the Contractor should be met.* The NRL will adhere to the specified deadlines as agreed with the FSA and FSS by planning the activities throughout the year (e.g., annual 'User Day', training workshops, attendance of international meetings).
 - i) *If necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the FSA and FSS. This will include assisting with transfer of archived reference materials.* Where necessary, the NRL will transfer any information and data generated from the NRL function to the FSA and FSS at the end of the contract.
 - j) *Provide an internal report of meetings with other organisations within 10 working days of the meeting.* The NRL will provide internal reports of other organisation meetings, within ten working days of the meeting.
 - k) *The supplier will engage in quarterly dialogues with the FSA and FSS to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the FSA and FSS may also be organised to ensure any potential or evolving issues are flagged and work is kept on track. While these meetings can be in-person, attendees must be able to attend in an online format as well.* The NRL will meet with the FSA and FSS on a quarterly basis, to review past deliverables, discuss progress on work and identify new activities. If there is a compelling need, the NRL will arrange additional meetings with the FSA and FSS to discuss matters or specific activities.
 - l) *The supplier will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and FSA and FSS on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results. Feedback from attendees must be requested and any appropriate changes implemented for the following meetings. While these meetings can be in-person, attendees must be able to attend in an online format as well.* The OLs will be invited to the network meeting organised by the NRL, along with FSA and FSS, and other relevant UK laboratories to update in participation to proficiency testing, method developments, training needs and other relevant NRL activities. Feedback will be sought after these network meetings to improve the content and management of the meetings and to tailor the NRL's other activities to support the OL network. These meetings can be arranged as a hybrid format, allowing attendees to come to Colindale face-to-face or to join online.
 - m) *The Contractor will review NRL finances regularly and communicate spending, including a break-down of costs, with the FSA and FSS on a quarterly basis.* The NRL will review finances quarterly and send a quarterly break-down of costs to the FSA and FSS along with a monthly log of NRL activities performed.

7. Incident management

- a) *Supply of scientific advice and guidance to FSA, FSS, LAs and PA OLs for incident matters and wider issues related to NRL microbiological area in food and feed.* The NRL can be contacted to provide scientific advice and guidance to the FSA, FSS, LAs and OLs in the six areas covered in this tender, including any urgent matters concerning food safety or public health.
- b) *Should a major food or feed incident occur where there is currently no method, the NRL will prioritise and dedicate effort towards developing the new methods required.* The NRL will have the capability to develop a new method if there was no method to respond to a major food or feed incident. Initially, communication with the ISO committee, EURLs and wider scientific community and a review of their websites and scientific publications would be performed to avoid duplication of effort and enhance harmonisation, particularly if the incident was also affecting countries other than the UK. The NRL would then form close links with the identified organisation to develop a new method if available and appropriate and would collaborate with relevant international organisations for a rapid outcome.
- c) *Conduct rapid sampling under direction of FSA and FSS in the event of a food or feed incident relating to NRL microbiological area in food and feed. This may include training of staff and ensuring appropriate staff resources in event of food or feed incident.* The NRL will conduct rapid testing of samples from a

food or feed incident on a case-by-case basis, where appropriate and at the request of the FSA and FSS. UKHSA has close links with and routinely supports LAs and PHAs. Accordingly, UKHSA has the infrastructure to receive and test relevant samples related to a public health, food or feed incident. The NRL will ensure training of staff in the relevant procedures to support and deliver rapid testing, where appropriate.

Method development can be undertaken by the NRL, where a need is identified. Subsequent training in the new or updated method can be delivered to the OLs to roll out the method and increase UK's testing capacity.

- d) *Conduct analyses on official control samples for PAs in the event of an incident relating to the NRL's microbiological area* In the event of an incident, where an OL does not have the capability of a novel method to test official samples, the NRL can conduct analyses or locate an appropriate UK OL to perform the relevant testing.

B. DELIVERABLES

Please outline the proposed project milestones and deliverables. Please provide a timetable of key dates or significant events for the project (for example fieldwork dates, dates for provision of research materials, draft and final reporting). Deliverables must be linked to the objectives.

For larger or more complex projects please insert as many deliverables /milestones as required.

Each deliverable should be:

- i. no more 100 characters in length
- ii. self-explanatory
- iii. cross referenced with objective numbers i.e. deliverables for Objective 1 01/01, 01/02 Objective 2 02/01, 02/02 etc

Please insert additional rows to the table below as required.

A final deliverable pertaining to a retention fee of 20 % of the total value of the proposed work will automatically be calculated on the financial template.

DELIVERABLE NUMBER OR MILESTONE IN ORDER OF EXPECTED ACHIEVEMENT	TARGET DATE	TITLE OF DELIVERABLE OR MILESTONE
D1	30/06/2023	DELIVERY OF 3 MONTHLY REPORTS; YR 1; QTR 1 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D2	30/09/2023	DELIVERY OF 3 MONTHLY REPORTS; YR 1; QTR 2 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D3	31/12/2023	DELIVERY OF 3 MONTHLY REPORTS; YR 1; QTR 3 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D4	31/03/2024	DELIVERY OF 3 MONTHLY REPORTS & ANNUAL REPORT; YR 1; QTR 4 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D5	30/06/2024	DELIVERY OF 3 MONTHLY REPORTS; YR 2; QTR 1 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D6	30/09/2024	DELIVERY OF 3 MONTHLY REPORTS; YR 2; QTR 2 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D7	31/12/2024	DELIVERY OF 3 MONTHLY REPORTS; YR 2; QTR 3 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D8	31/03/2025	DELIVERY OF 3 MONTHLY REPORTS & ANNUAL REPORT; YR 2; QTR 4 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D9	30/06/2025	DELIVERY OF 3 MONTHLY REPORTS; YR 3; QTR 1 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)

D10	30/09/2025	DELIVERY OF 3 MONTHLY REPORTS; YR 3; QTR 2 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D11	31/12/2025	DELIVERY OF 3 MONTHLY REPORTS; YR 3; QTR 3 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D12	31/03/2026	DELIVERY OF 3 MONTHLY REPORTS & ANNUAL REPORT; YR 3; QTR 4 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D13	30/06/2026	DELIVERY OF 3 MONTHLY REPORTS; YR 4; QTR 1 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D14	30/09/2026	DELIVERY OF 3 MONTHLY REPORTS; YR 4; QTR 2 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D15	31/12/2026	DELIVERY OF 3 MONTHLY REPORTS; YR 4; QTR 3 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)
D16	31/03/2027	DELIVERY OF 3 MONTHLY REPORTS & FINAL REPORT; YR 4; QTR 4 ACTIVITIES PERFORMED AS AGREED WITH FSA AND FSS (RELEVANT OBJECTIVES)

3: ORGANISATIONAL EXPERIENCE, EXPERTISE and STAFF EFFORT

A. PARTICIPATING ORGANISATIONS' PAST PERFORMANCE

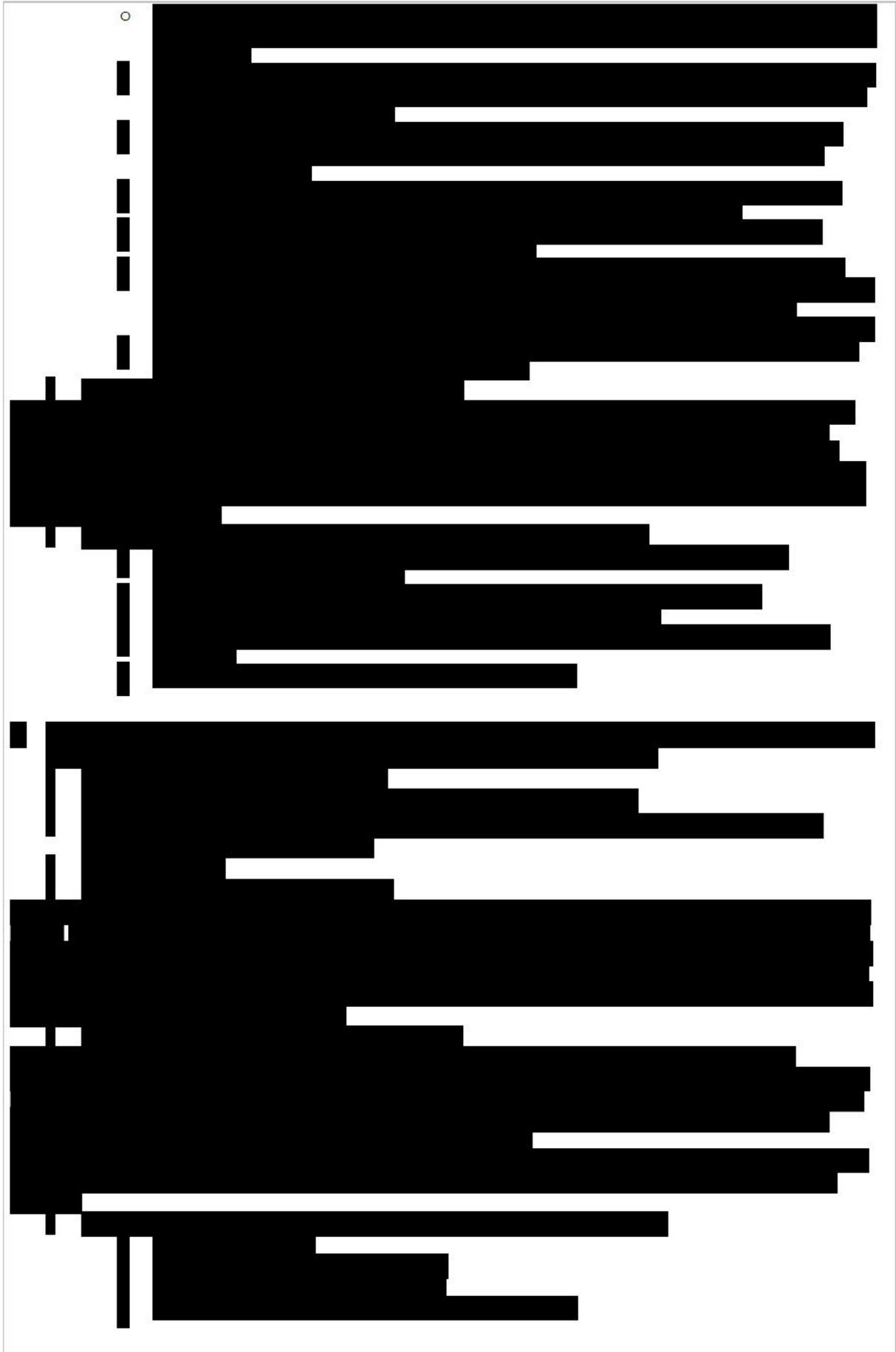
Please provide evidence of up to three similar projects that the project lead applicant and/or members of the project team are currently undertaking or have recently completed. Please include:

- The start date (and if applicable) the end date of the project(s)
- Name of the client who commissioned the project?
- Details of any collaborative partners and their contribution
- The value
- A brief description of the work carried out.
- How the example(s) demonstrate the relevant skills and/or expertise.
- What skills the team used to ensure the project (s) were successfully delivered.

UK Health Security Agency (UKHSA) has a proven record in being awarded grant funding, leading and participating in large-scale, scientifically important studies and delivering outputs from those studies within defined timescales. This includes a particularly strong reputation for public health microbiology. Within the Science Group of UKHSA, the Food, Water and Environmental Microbiology Services provide routine public health testing of food and supporting parties in Official Food Control in England.

Evidence of the required competencies from three projects:

1) [REDACTED]



3)

[Redacted content]

B. NAMED STAFF MEMBERS AND DETAILS OF THEIR SPECIALISM AND EXPERTISE

For each participating organisation on the project team please list:- the names and grades of all staff who will work on the project together with details of their specialism and expertise, their role in the project and details of up to 4 of their most recent, relevant published peer reviewed papers (where applicable). If new staff will be hired to deliver the project, please detail their grade, area/(s) of specialism and their role in the project team.

Lead Applicant UK Health Security Agency

Named staff members, details of specialism and expertise.

[Principal Investigator's name and details 1st]

[Redacted content]

[Redacted content]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

- [REDACTED]

- [Redacted]
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- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

[Redacted]

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Participant Organisation 1

Named staff members, details of specialism and expertise.

Management Groups.

The proposed service will be coordinated in the first instance by a **Steering Group** comprising nominated personnel from the FSA and FSS and UKHSA which will meet quarterly and review the activities of the NRL. The Steering Group membership will comprise of a Chair from the FSA, the project lead from the UKHSA, the NRL Scientists plus additional members nominated by the FSA and FSS, and staff directly involved with the operation of the NRL. An **Annual Work Plan** will be proposed and agreed at the steering group, and this will be included in an **Annual Report**.

Actions from the Steering Group will feed into a **Local Management Group** headed by [REDACTED] which will meet at least monthly and be attended by staff directly involved with the operation of the NRL. **Minutes of the Steering Group and Management Group** can be made available to the FSA and FSS and a **monthly activity report** will be sent to the FSA and FSS which identifies activity under all the work areas (i.e. Secretarial services; Advice and representation within the UK and internationally; Research and development, including production of standard operating procedures, codes of practice and guidance documents; Compliance assessment via audits and ring trials; Co-ordination within the UK of international initiatives; Communication of results and data use; and Incident management). Budget statements will be prepared on a quarterly basis by UKHSA and sent to the FSA and will coincide with the payment schedule.

People

The lead applicant has worked in UKHSA (previously PHE, HPA and PHLS) for more than 20 years and has experience in project management and successful delivery of externally funded projects. She has experience of co-ordination of Official Laboratories and of delivering the National Reference Laboratory for Microbiology function. The project lead will be responsible for assuring the outputs which require up to date data inputs from all aspects of the project. The project lead will follow up any gaps identified and resolve them with the relevant site or centre or share with the management group if wider input is needed. The NRL senior scientist and administrator both have several years' experience and are proficient to support the project lead in delivering the NRL activities.

The project will benefit from existing strong relationships in the participating Reference Laboratories as well as the OLs and all the applicants share a clear public health focus and commitment to Official Control functions in line with the purpose of the tender and ethos of this bid.

Project completion

Completion of the project will include the completion of all deliverables signed off by the management group and funder as well as a final project report.

Accreditation

The National Reference Laboratory for Microbiology will comply with all requirements for National reference laboratories as set out in Article 101 of EC Regulation No. 2017/625 (as retained by UK SI 2019 No. 665) on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The UKHSA applies a **total Quality Management** system to all laboratory activities which is designed to meet the general requirements of all the relevant standards which is **equivalent to BS EN ISO 9000**. Accreditation is held across the organisation with relevant bodies to ensure compliance. Due to the range of activities undertaken by the UKHSA a range of accreditation is held with a range of bodies, including against ISO 17025 through United Kingdom Accreditation Service (UKAS).

5. RISK MANAGEMENT

In the table provided, please identify all relevant risks in delivering this project on time and to budget. Briefly outline what steps will be taken to minimise these risks and how they will be managed by the project team. Please add more lines as required

Identified risk	Likelihood of risk (high, medium, low)	Impact of Risk (high, medium, low)	Risk management strategy

6. QUALITY MANAGEMENT

A. QUALITY MANAGEMENT

Please provide details of the measures that will be taken to manage and assure the quality of work. You should upload your Quality Assurance policy in the supporting documents section of your application.

This should include information on the quality assurance (QA) systems, , which have been implemented or are planned, and should be appropriate to the work concerned. All QA systems and procedures should be clear and auditable, and may include compliance with internationally accepted quality standards specified in the ITT e.g. ISO 9001 and ISO17025.

Specific to science projects and where relevant, applicants must indicate whether they would comply with the [Joint Code of Practice for Research \(JCoPR\)](#). If applicants do not already fully comply with the JCoPR please provide a statement to this effect to provide an explanation of how these requirements will be met. The FSA reserves the right to audit projects against the code and other quality standards

The lead principle investigator is responsible for all work carried out in the project; (including work supplied by sub-contractors) and should therefore ensure that the project is carried out in accordance with the Joint Code of Practice

UKHSA Quality Assurance

UKHSA applies a total Quality Management system to all laboratory activities which is designed to meet the general requirements of all the relevant standards ISO 17025 and ISO 15189 which covers the requirements for quality and competence in laboratories [supporting documents 12, 13, 14 & 15]. Accreditation is held across the organisation with relevant bodies to ensure compliance. Due to the range of activities undertaken by the UKHSA a range of accreditation is held with a range of bodies.

The UKHSA Food Water and Environmental Microbiology Service laboratories are designated Official Control Laboratories and consequently accredited to the ISO 17025 standard whilst the Bacteriology Reference Department (which GBRU and AMRHAI are situated) is accredited to ISO 15189 standard. The NRL function will be embedded within this network of laboratories. Microbiological testing performed in the laboratories is audited by UK Accreditation Service (UKAS) annually to ensure compliance with the International Standard – General Requirements for the Competence of testing and Calibration laboratories (ISO/IEC 17025:2017) and Medical laboratories – Requirements for quality and competence (ISO 15189:2012). This standard specifies requirements for quality and competence particular to medical laboratories and is for use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognising the competence of medical laboratories. The Gastrointestinal Bacteria Reference Unit is also accredited through UKAS Accreditation to ISO 17025 for *Clostridium botulinum* (and botulinum neurotoxin testing). Isolation and identification of the bacteria tested for in this project will be covered under these accreditation schemes. Details about the UKAS accreditation and the accreditation schedules of the UKHSA laboratories can be found on the UKAS website at: www.ukas.com

The Food and Environmental Proficiency Testing Unit (FEPTU), is accredited to ISO/IEC ISO 17043:2010 (Conformity assessment – General requirements for proficiency testing) by UKAS for the provision of all the UKHSA food and water microbiology PT schemes. The scope of accreditation is available from the UKAS website (link above). Copies of the UKAS accreditation certificate are available on request. The organisers within FEPTU are supported by the UKHSA Executive Steering Group for Food and Water Microbiology Schemes, which includes participant representatives, scheme consultants with expertise in specific aspects of food and/or water microbiology and representatives from the food and water industries. The Steering Group meets twice every year; participants are contacted by email prior to each meeting and invited to submit queries and comments regarding scheme development and strategy for consideration by the Group.

Each laboratory holds accreditation for the isolation and identification of some of the bacteria to be tested for this project, but not all parameters. Where tests are not included in the scope of accreditation (e.g. method development), they are generally still included in internal quality assurance checks and internal audit procedures, and staff training, equipment monitoring and non-conformance monitoring apply equally to accredited and unaccredited tests.

All laboratory protocols, laboratory equipment and results are subject to documented quality control procedures internally and externally. Details of such procedures will be made known to the FSA and FSS and be available for audit by the FSA and FSS on request. All other aspects of the work will be available for audit by the FSA and FSS (or a nominated representative). All work will comply with the Joint Code of Practice for Research.

B. ETHICS

Please identify the key ethical issues for this project and how these will be managed. Please respond to any issues raised in the Specification document

Please describe the ethical issues of any involvement of people, human samples, animal research or personal data in this part. In addition, please describe the ethical review and governance arrangements that would apply to the work done.

Applicants are reminded that, where appropriate, the need to obtain clearance for the proposed project from their local ethics committee. This is the responsibility of the project Lead Applicant. However, if a sub-contractor requires such clearance the project Lead Applicant should ensure that all relevant procedures have been followed. If there are no ethical issues please state this

No formal ethics approval is required. All NRL and UKHSA staff with access to sensitive commercial data in the study are aware of confidentiality as part of their professional duties and this shall be governed by the relevant contracts, should UKHSA be successful.

C. DATA PROTECTION

Please identify any specific data protection issues for this project and how these will be managed. Please respond to any specific issues raised in the Specification document.

Please note that the successful Applicant will be expected to comply with the Data Protection Act (DPA) 1998 and ensure that any information collected, processed and transferred on behalf of the FSA, will be held and transferred securely.

In this part please provide details of the practices and systems which are in place for handling data securely including transmission between the field and head office and then to the FSA. Plans for how data will be deposited (i.e. within a community or institutional database/archive) and/or procedures for the destruction of physical and system data should also be included in this part (this is particularly relevant for survey data and personal data collected from clinical research trials). The project Lead Applicant will be responsible for ensuring that they and any sub-contractor who processes or handles information on behalf of the FSA are conducted securely.

UKHSA is committed to achieving a high standard of performance against the Cabinet Office's information standards. No Personal Confidential Data is envisaged to be handled in this project; however, advice can be sought from the UKHSA Caldicott Guardian where needed.

All staff are mandated to complete and pass, on an annual basis, defined minimum information governance training as detailed in the UKHSA Mandatory Training Schedule. All staff must mark documents and correspondence in accordance with the Government Security Classification scheme and supporting guidance. UKHSA will comply with relevant data protection legislation and this will be covered in the agreement between the FSA and FSS and UKHSA, should UKHSA be successful.

UKHSA recognises that a key aspect of the project is dissemination of results, as defined in one of the project objectives above.
All data (including laboratory performance data) will be treated as confidential and will not be released without written permission from the FSA

D. SUSTAINABILITY

The Food Standards Agency is committed to improving sustainability in the management of operations. Procurement looks to its suppliers to help achieve this goal. You will need to demonstrate your approach to sustainability, in particular how you will apply it to this project taking into account economic, environmental and social aspects. This will be considered as part of our selection process and you must upload your organisations sustainability policies into the eligibility criteria in Bravo.
 Please state what(if any) environmental certification you hold or briefly describe your current Environmental Management System (EMS)

UKHSA is committed to protecting the environment and reducing carbon emissions arising from its activities. To do this it has developed a carbon reduction delivery plan, as part of its overall carbon management programme. UKHSA policy has been developed to help staff to consider their impact on the environment for example when travelling, purchasing goods and using energy. Where staff are working on sites that are not managed by UKHSA, there is encouragement to contribute to the sites owners efforts to minimise their own carbon footprint. The UKHSA has developed Environmental Sustainability Policy documents that minimises the impact on the environment and which have been uploaded as attached document to this application. These include an overarching Environmental Policy as well as policies for Procurement, Travel and Waste [supporting documents 16, 17, 18 and 19]. All UKHSA staff participate in Environmental Sustainability training as part of their portfolio of mandatory training.

E. DISSEMINATION AND EXPLOITATION (Science Projects Only)

Where applicable please indicate how you intend to disseminate the results of this project, including written and verbal communication routes if appropriate. Applicants are advised to think carefully about how their research aligns with the FSA strategy, what is the impact that their research has on public health/ consumers and decide how the results can best be communicated to the relevant and appropriate people and organisations in as cost-effective manner as possible. Please provide as much detail as possible on what will be delivered. Any costs associated with this must be documented in the Financial Template.

The applicant should describe plans for the dissemination of the results for the project team as a whole and for individual participants. Details should include anticipated numbers of publications in refereed journals, articles in trade journals etc., presentations or demonstrations to the scientific community, trade organisations and internal reports or publications. Plans to make any information and/or reports available on the internet with the FSA's permission are also useful, however, this does not remove the requirement for Tenderers to think how best to target the output to relevant groups.

If a final report is part of the requirement, please make sure, as part of the executive summary, that aims and results are clear to the general audience and that the impact of the research on public health/consumers and it's alignment to FSA priorities is clearly stated.

Please note that permission to publish or to present findings from work supported by the FSA must be sought in advance from the relevant FSA Project Officer. The financial support of the FSA must also be acknowledged.

Please indicate whether any Intellectual Property (IP) may be generated by this project and how this could be exploited. Please be aware the FSA retains all rights to the intellectual property generated by any contract and where appropriate may exploit the IP generated for the benefit of public health.

In this part Applicants should demonstrate the credibility of the partnership for exploitation of the results and explain the partnership's policy in respect of securing patents or granting licenses for the technology (if applicable). It should deal with any possible agreements between the partners to extend their co-operation in the exploitation phase and with relevant agreements with companies, in particular users, external to the partnership

To the FSA and FSS

For communication and dissemination of information to the FSA and FSS, the NRL will:

- prepare an Annual report which will contain a proposed Annual Work Plan for agreement of activity by the FSA and FSS
- prepare Minutes of the Steering Group and Management Group and disseminate to the FSA and FSS, and a monthly activity report will be sent to the FSA and FSS at the end of each month

- notify the FSA and FSS immediately by email or telephone of any deviations which may affect the specifications and timing of the annual work programme.
- notify the FSA and FSS immediately of any unusual occurrences resulting from any of the core functions of the UK-NRL.
- not communicate to any external parties without the written permission of the FSA and FSS representative, results or reports arising from the work of the UK-NRL.
- not use data for presentations and/ or papers unless written permission has been sought and given by the FSA and FSS.
- maintain records for a period of 3 years from the end of the contract.
- ensure that all relevant papers are distributed to the customer one week prior to UK-NRL network meetings.
- provide minutes of international meetings within two weeks of the date of the meetings.
- ensure all communications relating to the NRL work will be conducted through the FSA's representative.
- make available a suitably qualified contact person or system at the laboratory to answer telephone or email queries from the FSA and FSS.
- provide scientific advice on matters concerning functions of the UK NRL when requested by the Authorities representative
- provide scientific and technical assistance to the FSA for implementation of co-ordinated control plans adopted in accordance with Regulation EC No 2017/625 Article 109 as adopted by UK SI 665
- advise on alternative methods as required by EC Regulation 2017/625 as adopted by UK SI 665
- maintain a list of accreditation for the relevant OLs as well as a register of Food Examiners
- if necessary, at the end of the contract, hand over all information gained from and required for, the NRL function.

To Official Laboratories

For communication and dissemination of information to the OLs, the NRL will:

- hold at least one 'User Day' per year for all OLs to gain knowledge of the activities and expertise of the NRL, as well as provide information from the international laboratories.
 - send quarterly newsletters to all OLs to inform of recent legislation and method updates, PT schedules, NRL events and other organisations' relevant activities
 - communicate results of any comparative tests and ring trials
 - provide confidential advice on the results of external quality assessment and UKAS assessment results such that an environment of continuous improvement is achieved
 - provide advice on best scientific practice in microbiological testing within OLs for official control of food
 - maintain and develop an NRL web site which will contain:
 - further information on the six areas where service is provided (i.e. antimicrobial resistance (AMR), *Campylobacter*, Coagulase positive *Staphylococci*, including *Staphylococcus aureus*, *Escherichia coli*, including Shiga-toxin producing *E. coli* (STEC), *Listeria monocytogenes* and *Salmonella*)
 - regular updates on international laboratories' activities for all six areas of service
 - develop and maintain an accessible portfolio of SOPs to cover areas of Official Food Control.
 - provide a continuation process of education to Food Examiners and trainee Food Examiners through a Food Examiner Update training day (available twice yearly). This is offered as a joint activity with UKHSA FW&E Microbiology Services and cover areas integral to Food Control, including:
 - review of public health incidents
 - practice in production of Witness Statements and legal processes
 - visits to food production facilities
 - review of public health incidents and legislation updates
- Representation by the FSA and FSS has been encouraged at these events.

To Other laboratories and relevant organisations

For communication and dissemination of information to other laboratories and relevant organisations, the NRL will:

- maintain links with appropriate British Standards, CEN and ISO committees
- maintain links and appropriate communication with Reference Laboratories within UKHSA and other relevant Reference Laboratories including the Scottish *E. coli* Reference Laboratory and the **Scottish Salmonella, Shigella & C. difficile Reference Laboratory**
- maintain links with other relevant Reference laboratories associated with microbiological testing for Official Control including the Cefas laboratory on shellfish hygiene and the Defra (APHA) laboratories for Salmonella, *Campylobacter* and antibiotic resistance
- maintain links with the EURLs for the six areas in order to keep dialogue open with the UK-NRL since EU Exit to further participate in EURL activities
- establish and maintain links with the Northern Ireland (NI) NRLs to agree on support to the NI OL
- provide, where relevant, ad-hoc facilities for independently-funded evaluations of alternative methods from other organisations

It is not expected that any foreground intellectual property that will be generated by this project will be commercially exploitable however the results and reports will be widely disseminated, following approval from the FSA and FSS, to maximise research impact and benefit to public health.

7. SOCIAL VALUE

Social value has a lasting impact on individuals, communities and the environment. Government has a huge opportunity and responsibility to maximise benefits effectively and comprehensively through its commercial activity. To be effective it is essential that the FSA consider social value at all stages of the procurement life cycle. In order to do this, we are applying the Government Commercial Functions social value model PPN 06/20 Procurement Policy Note - Taking account of social value in the award of government contracts. [The Social Value Quick Reference Table](#) provides a useful summary of the criteria and the reporting metrics for each of the criteria, including examples.

In order to evaluate this, we ask that you answer the following:

A. A. FIGHTING CLIMATE CHANGE: Provide evidence of how you will deliver additional environmental benefits in the performance of the contract including working towards net zero greenhouse gas emissions.

A model response should include activities that demonstrate and describe the tenderer's existing or planned:

- Understanding of additional environmental benefits in the performance of the contract, including working towards net zero greenhouse gas emissions.

Illustrative example: conducting pre-contract engagement activities with a diverse range of organisations in the market to support the delivery of additional environmental benefits in the performance of the contract.

- Collaborative way of working with the supply chain to deliver additional environmental benefits in the performance of the contract, including working towards net zero greenhouse gas emissions.
- Delivery of additional environmental benefits through the performance of the contract, including working towards net zero greenhouse gas emissions.

Illustrative examples:

- Enhancing the natural environment such as habitat creation, increasing biodiversity such as increased numbers of pollinators.
- Green space creation in and around buildings in towns and cities, e.g. green walls, utilising roof tops for plants and pollinators.
- Improving air quality.

Responses should not exceed 750 words.

The UKHSA, as a public body, will embed sustainable development and environmental management into every facet of its operation, as set out in the government's 'Greening Government Commitment' document. As part of this, there will be an introduction of targets to reduce UKHSA's carbon footprint and therefore meet its commitments to Net Zero Carbon (NZC). These are:

- Reduce greenhouse gas emissions by 3% annually from the whole estate and its business-related transport
- reduce the amount of total waste going to landfill to less than 2% annually
- reduce water consumption by 2% annually
- continue to buy more sustainable and efficient products and services with the aim of achieving the best long-term, overall value for money for society

For the UKHSA to contribute to meeting the government's carbon zero target of 78% by 2035, UKHSA will put in train a variety of carbon reduction measures, starting with all new and refurbishment building projects to UKHSA owned estate.

Due to the specialist nature of UKHSA's work, laboratories, plug in general lab equipment and individual specialist equipment are used. Decarbonising the national grid and moving away from gas is the governments priority, therefore UKHSA will be looking at what it uses gas for and start looking now at alternatives to help meet NZC.

The UKHSA's Environment Policy [see supporting document 16] states a number of objectives related to sustainable development and are:

- Ensure compliance with all relevant UK government environmental policies, legislation and guidance
- Ensure that sustainability is considered in all UKHSA policy decisions
- Identify, assess and manage environmental risks to our staff, and others, affected by our activities
- Advocate the health co-benefits of a sustainable healthcare system by providing scientific expertise, leadership and guidance to our stakeholders
- Focus on the way we do business, including our role in coordinating science, policy, actions, and advocacy in this area
- Undertake environmental compliance audits to ensure the organisation is meeting its legal and environmental management obligations
- Reduce our carbon impact in line with the governments and our own Net Zero Carbon agenda, developing and implementing strategies for water, waste, energy, transport and procurement, where appropriate
- Put control measures in place to prevent pollution from our owned estate
- Assess and include sustainable options for all new and refurbished developments as an integral part of our estate's strategy
- Expect our suppliers and contractors to demonstrate a high standard of environmental performance and social value
- Ensure continual improvement of our environmental performance, through the implementation of a dedicated Environmental Management System, and our SDMP
- Allocate reasonable resources to support this policy.

All UKHSA staff are expected to comply with the UKHSA's Environmental Policy and the associated management arrangements, and to comply with identified practices and procedures. It is important that all members of staff develop an awareness of the environmental impact of their activities. This will be achieved by online mandatory training on a 3-yearly basis. Other activities to support fighting climate change includes arranging online meetings in place of face-to-face, or hybrid meetings, to off-set other participants need to travel to a meeting.

Annex 2 – Revised (29/03/23) Financial Template

Application form for a project with the Food Standards Agency Commercial Template

Applicants should complete each part of this application as fully and as clearly as possible

Brief instructions are given in the boxes at the start of each section.

Some boxes have **blue** text and this indicates that the value is calculated automatically

Some boxes are shaded **red** and these boxes **must** be completed

Guidance notes on completion of fields can be removed from view by pressing the ESC key

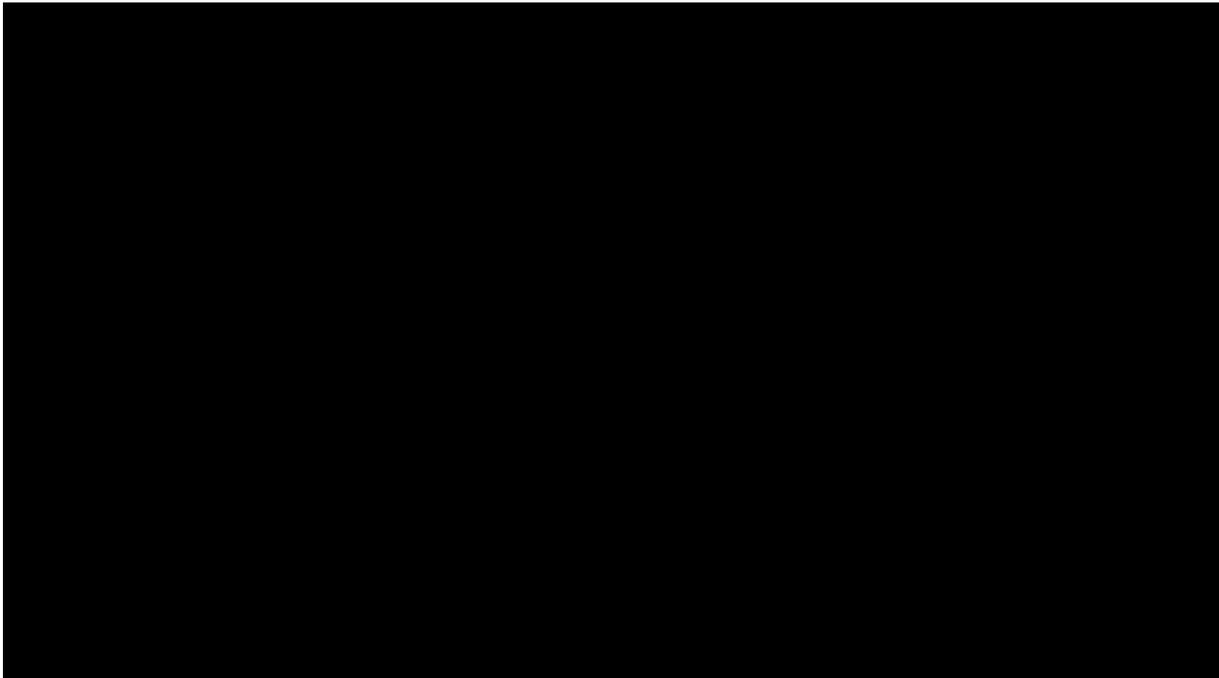
Please submit the application through the Agency's eSourcing portal by the deadline detailed within the specification.

This form should be completed by the project lead applicant and must include the collated costs

Tender Reference	FS516016-6 MULTI LOT
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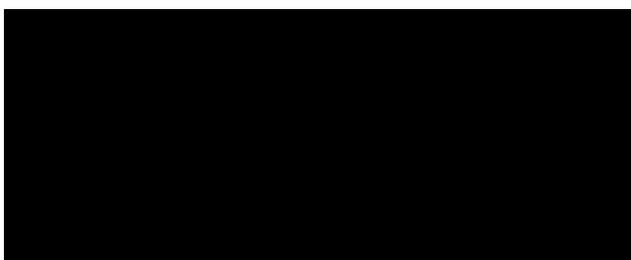
Tender Title	National Reference Laboratory for Microbiology – Multi-lot bid
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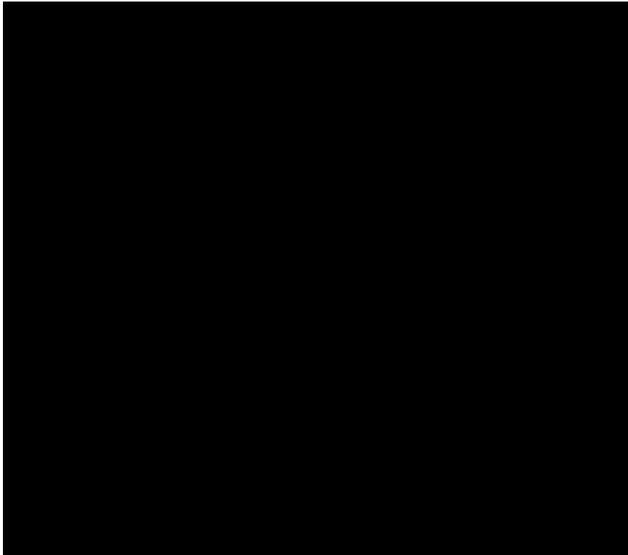
Full legal organisation name	UK Health Security Agency (UKHSA)
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Project Costs Summary Breakdown by Participating Organisations

Please include only the cost to the FSA.
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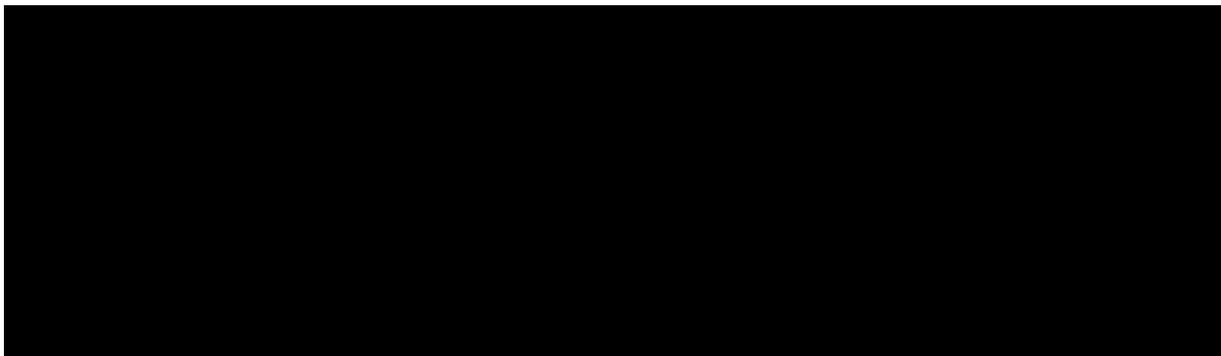
Total Project Costs (excluding VAT) **	£ 1,443,675.18
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* Please indicate zero, exempt or standard rate. VAT charges not identified above will not be paid by the FSA

** The total cost figure should be the same as the total cost shown in table 4

** The total cost figure should be the same as the total cost shown below and in the Schedule of payments tab.

Project Costs Summary (Automatically calculated)



Total Project Costs	£	1,443,675.18
----------------------------	----------	---------------------

COST OR VOLUME DISCOUNTS - INNOVATION

The Food Standards Agency collaborates with our suppliers to improve efficiency and performance to save the taxpayer money.

A tenderer should include in his tender the extent of any discounts or rebates offered against their normal day rates or other costs during each year of the contract. Please provide full details below:

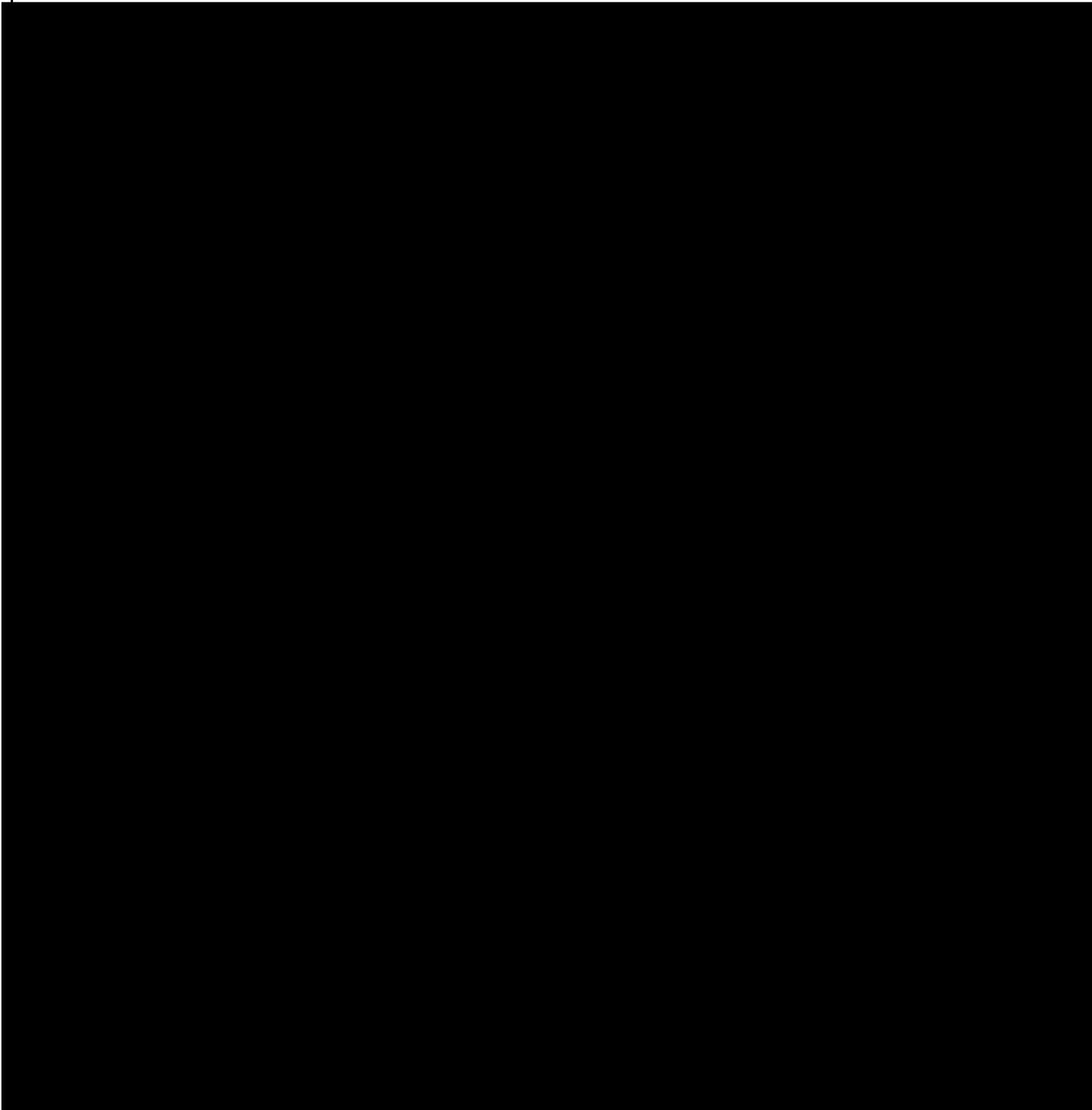


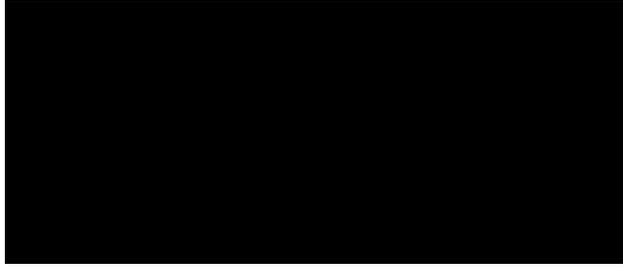
Staff Costs Table

*This should reflect details entered in your technical application section 4C.

Please insert as many lines as necessary for the individuals in the project team.

Please note that FSA is willing to accept pay rates based upon average pay costs. You will need to indicate where these have been used.





Consumable/Equipment Costs

Please provide a breakdown of the consumables/equipment items you expect to consume during the project



Please provide, in the table below, estimates of other costs that do not fit within any other cost headings

Description and justification of the cost	Estimate

Travel and Subsistence Costs	
-------------------------------------	--

Please provide a breakdown of the travel and subsistence costs you expect to incur during the project

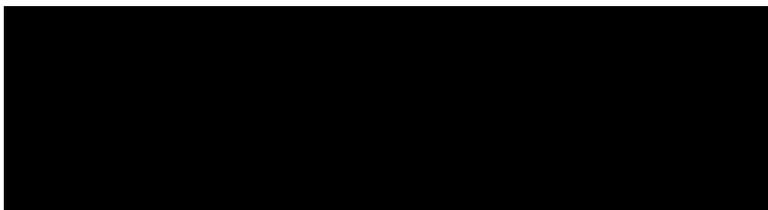
Purpose of journey or description of subsistence cost	Frequency	Cost each (£)	Total Cost
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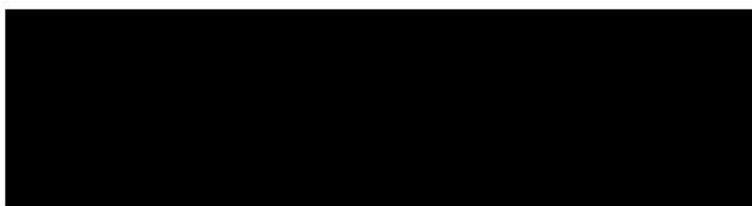


Please provide, in the table below, estimates of other costs that do not fit within any other cost headings

Description and justification of the cost	Estimated
A large, solid black rectangular redaction covers the entire content area of the table, obscuring all data and descriptions.	

Project Costs Summary





Total Project Costs	£ 1,443,675.18
----------------------------	-----------------------

The Pricing Schedule

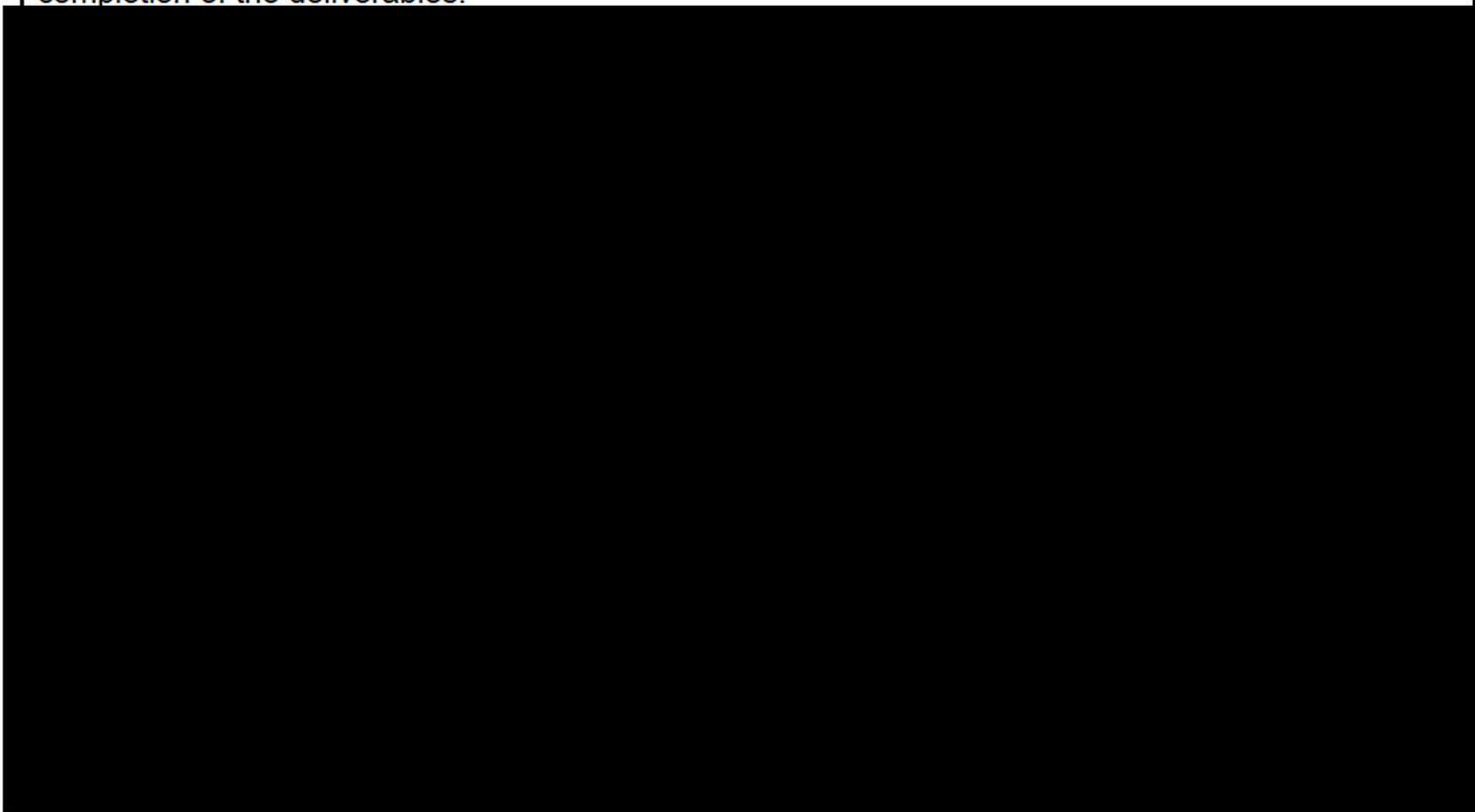
Please complete a proposed schedule of payments below, excluding VAT to be charged by any subcontractors to the project lead applicant.

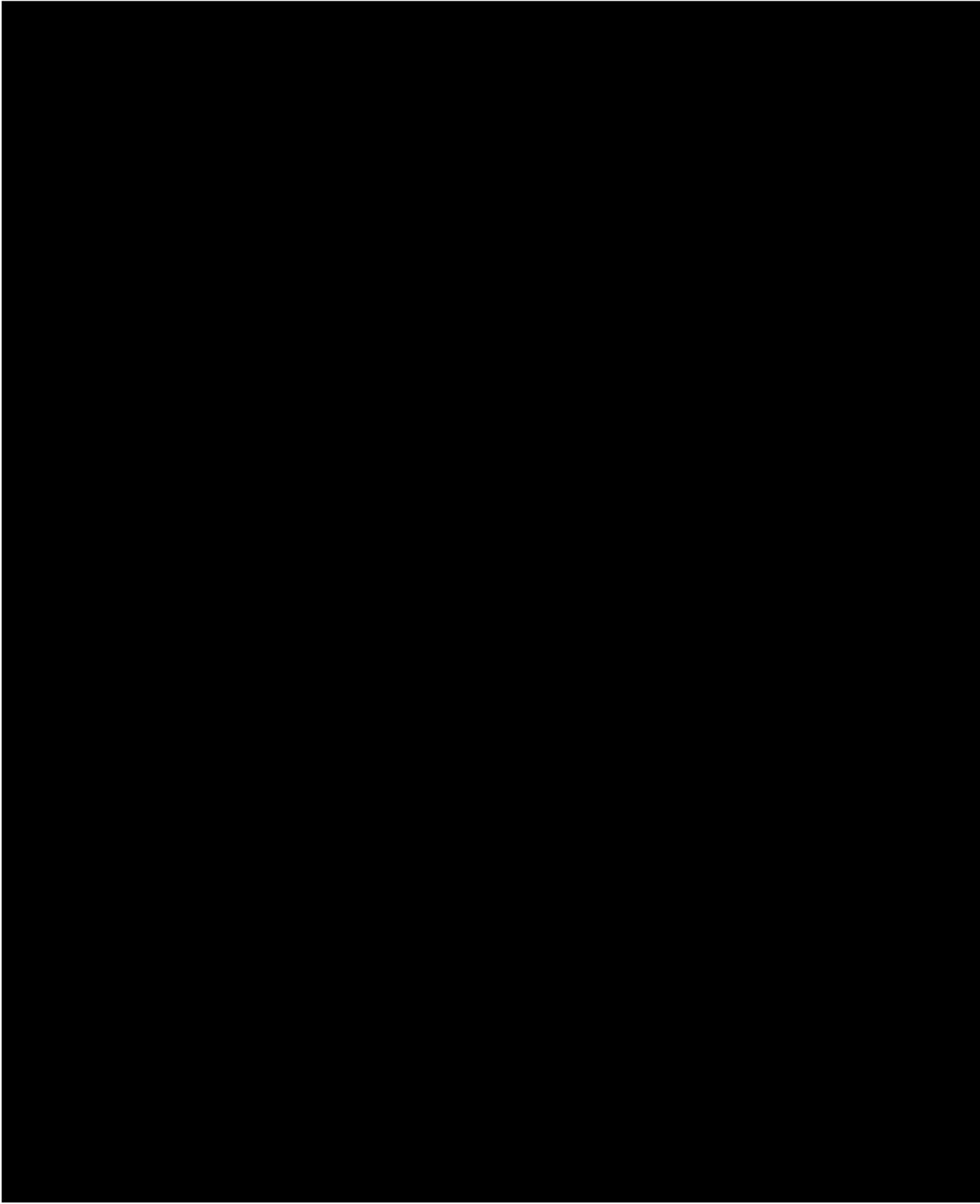
This must add up to the same value as detailed in the Summary of project costs to FSA including participating organisation costs.

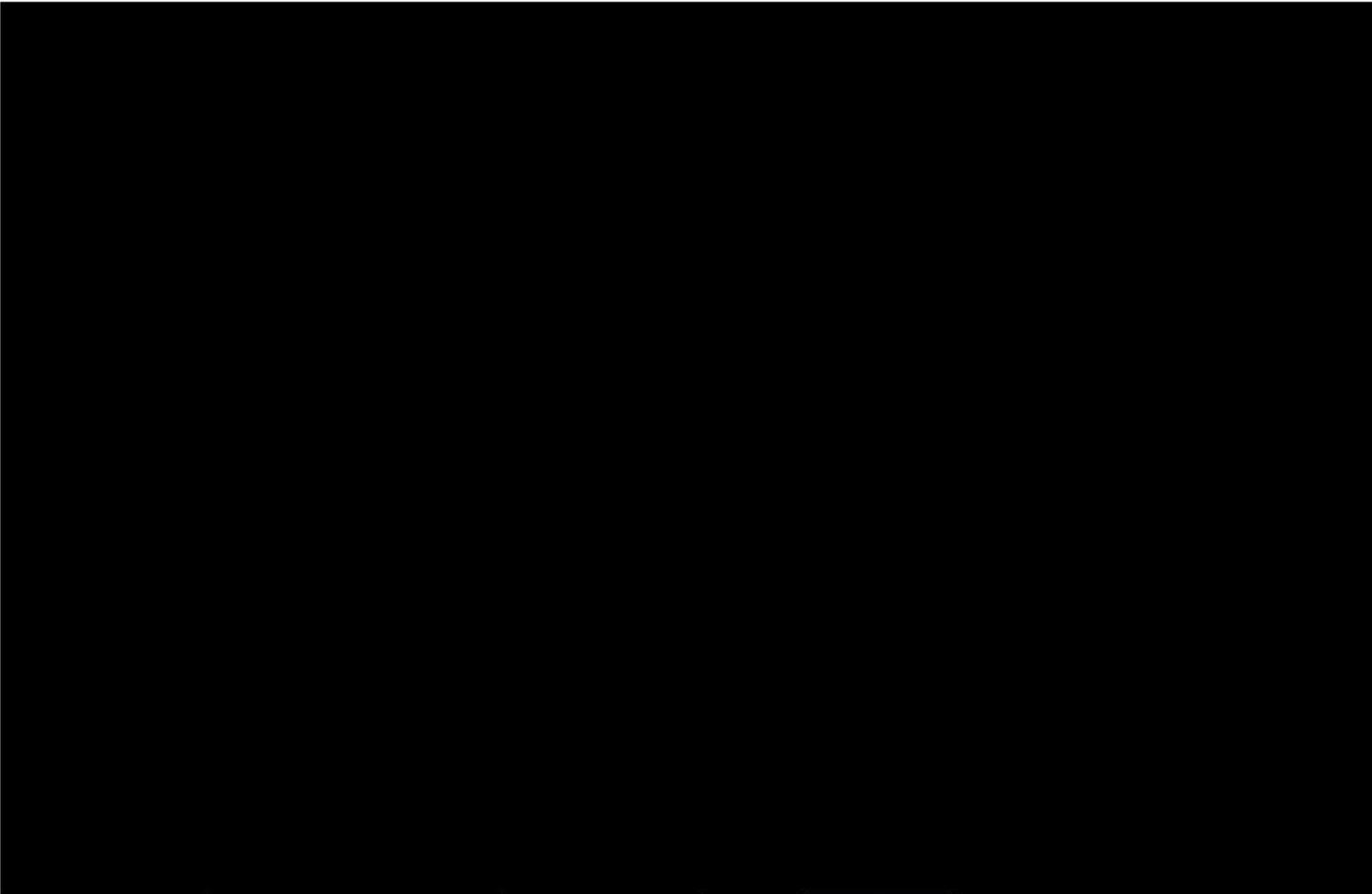
Where differing rates of VAT apply against deliverables, please provide details on separate lines.

Please link all deliverables (singly or grouped) to each payment. Please ensure that deliverable numbers are given as well as a brief description e.g., Deliverable 01/02: interim report submitted to the FSA, monthly report, interim report, final report.

Payment will be made to the Contractor, as per the schedule of payments upon satisfactory completion of the deliverables.







Total	£ 1,443,675.18	Totals Agree
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Summary of Payments

	Year 1	Year 2	Year 3	Year 4		
Financial Year	2023-24	2024-25	2025-26	2026-27	Retention	Total

(Update
as
applicab
le in
YYYY-
YY
format)

Total
Amount

	£ 1,443,675 .18

Annex 3 – Clarification Questions and Responses

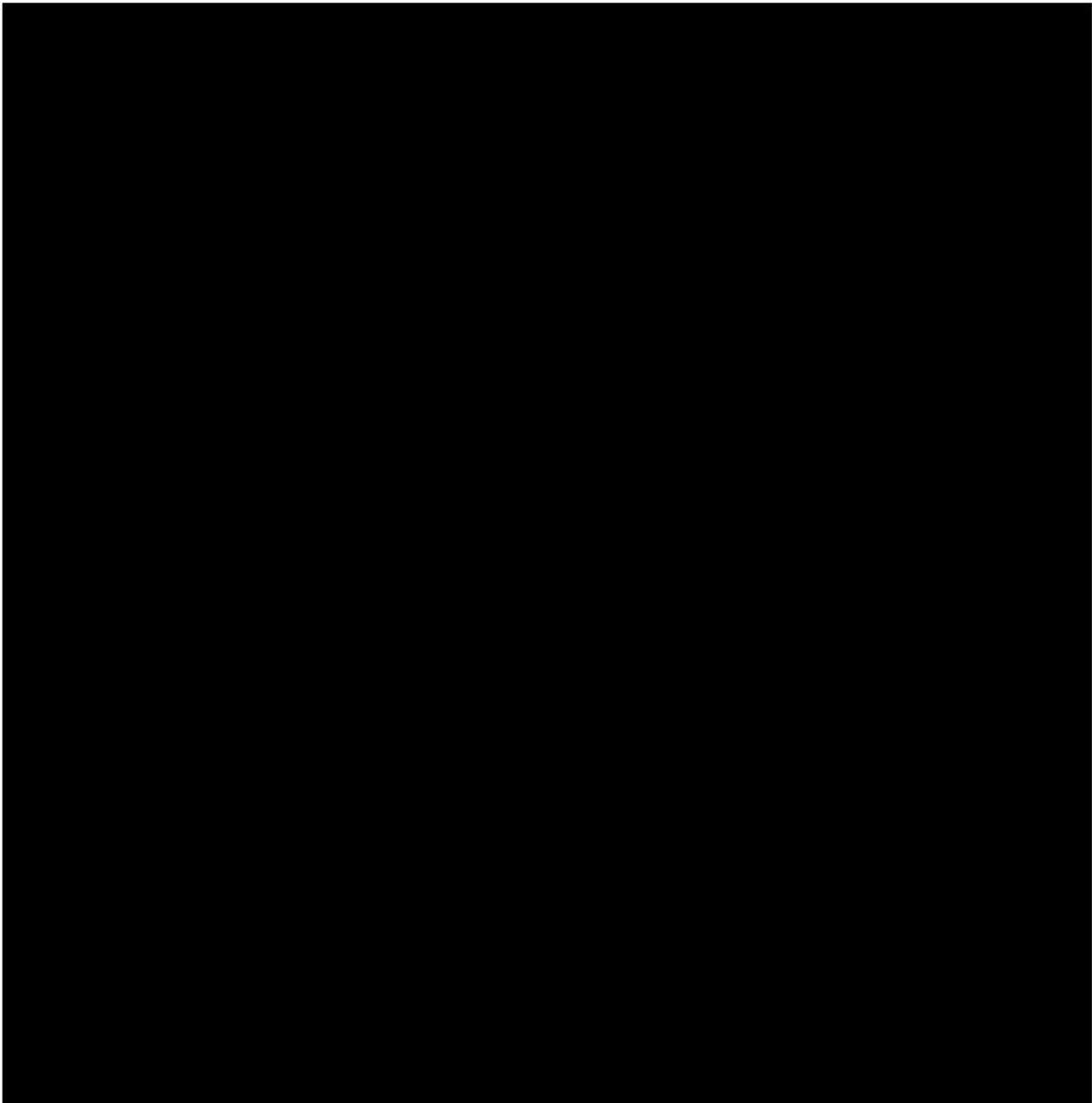
Tender reference number	Tenderers Name
FS431167 (previously FS516010-6)	UK Health Security Agency,
Tender title	
National Reference Laboratory for Microbiology	

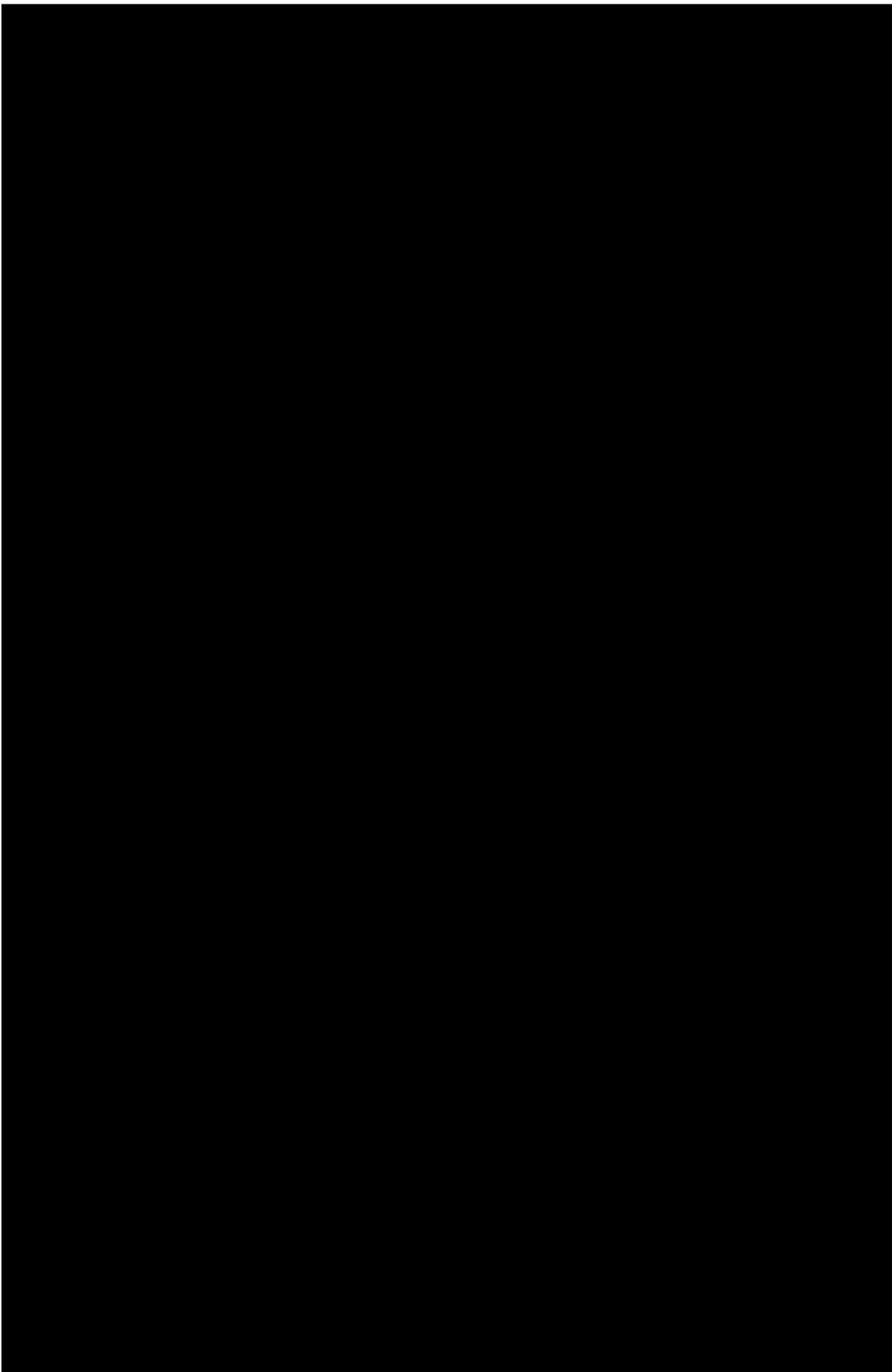
Evaluator name

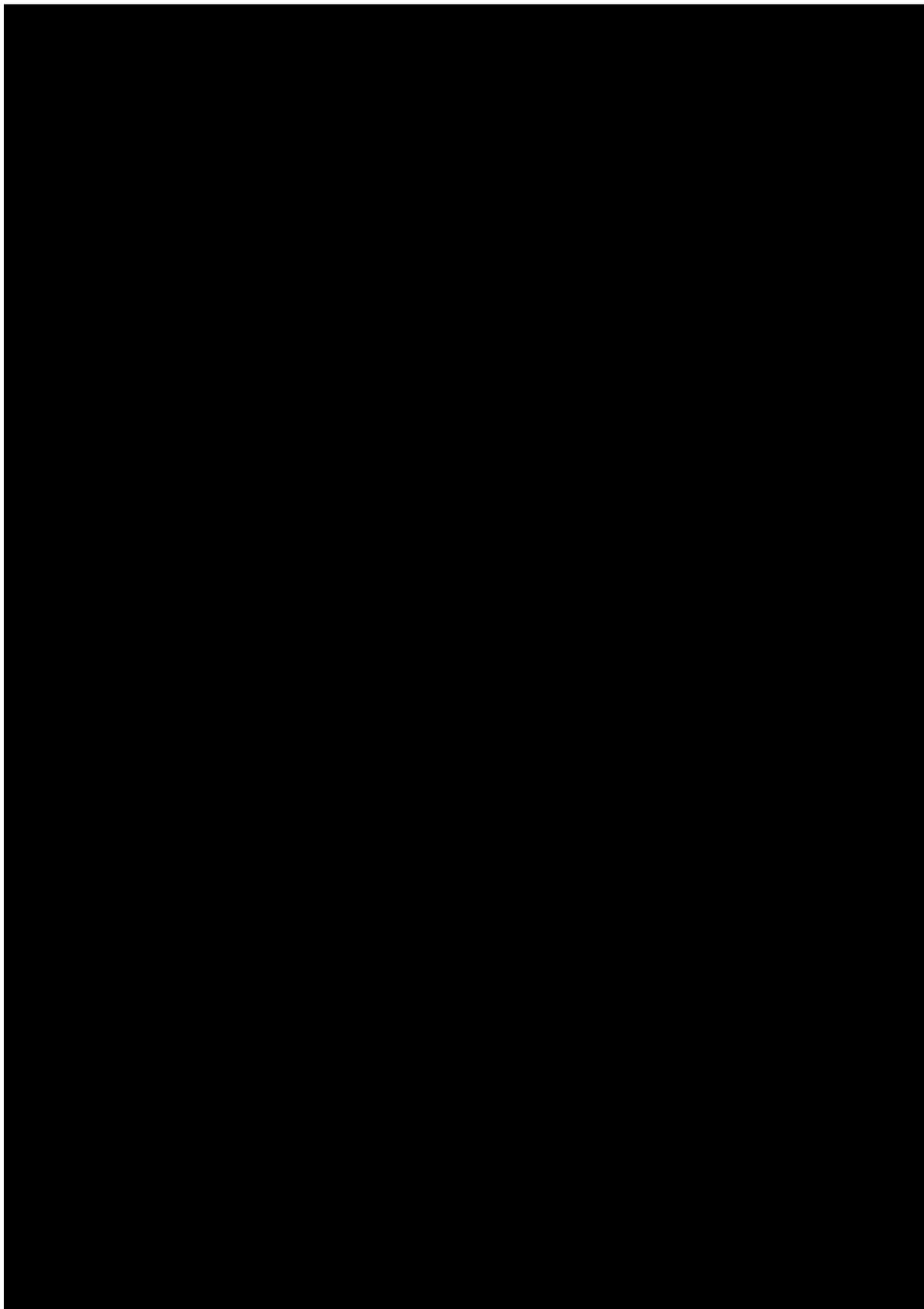
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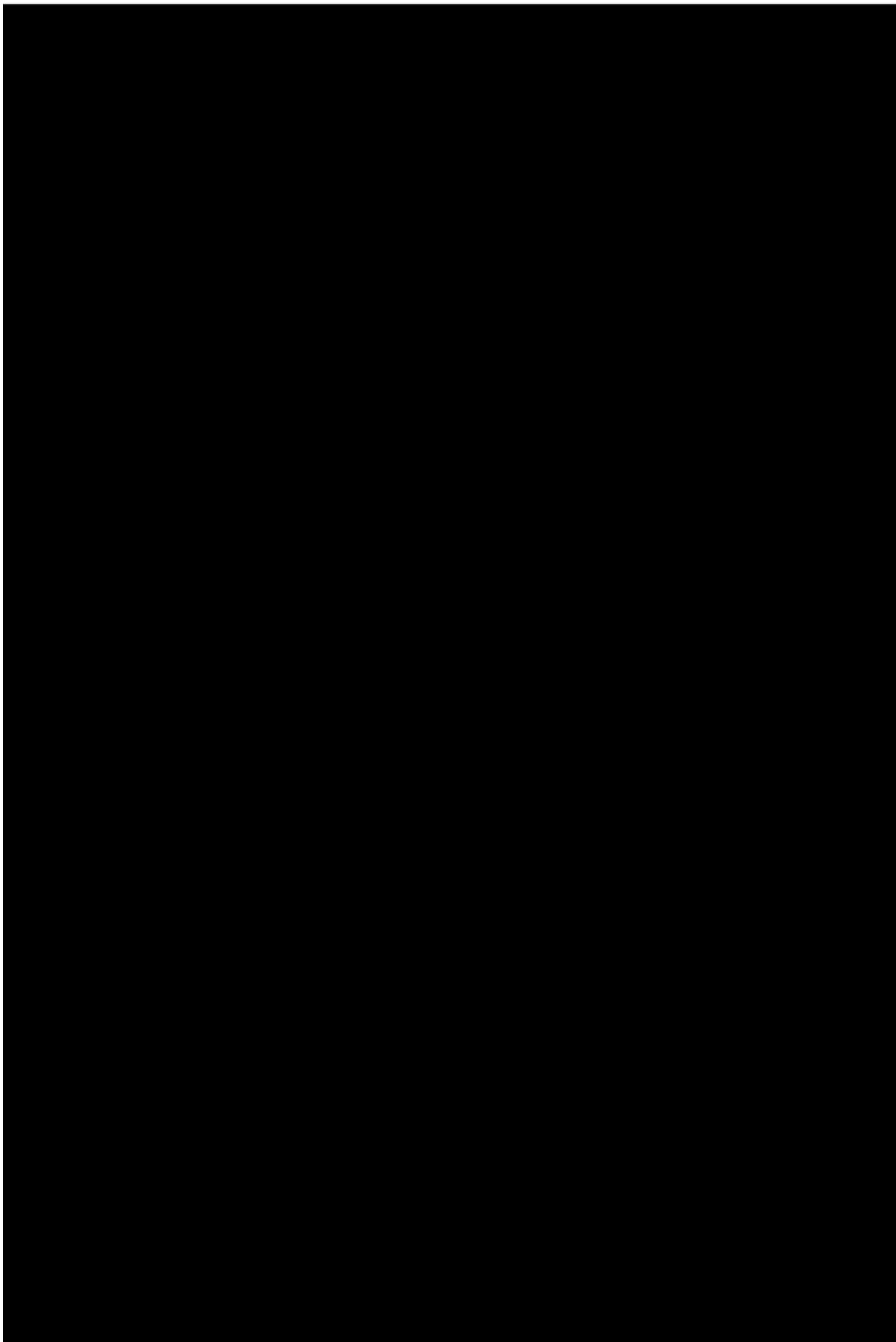
- The evaluation panel will be meeting shortly to make a decision about the tenders received for this requirement. To help the panel to evaluate your proposal fairly and accurately, **you are invited to comment or respond to the clarification questions highlighted below** which have been made by the panel members after initial evaluation of your tender. Your response should only relate to the issues raised.
- **Please note this is not an opportunity or request to submit a revised or amended proposal. This is to assist the tender evaluation panel in their assessment**
- Please respond via the eSourcing portal, **no later than 12 noon on Monday 30th January 2023.**
- If you have any queries please submit these via the eSourcing portal.

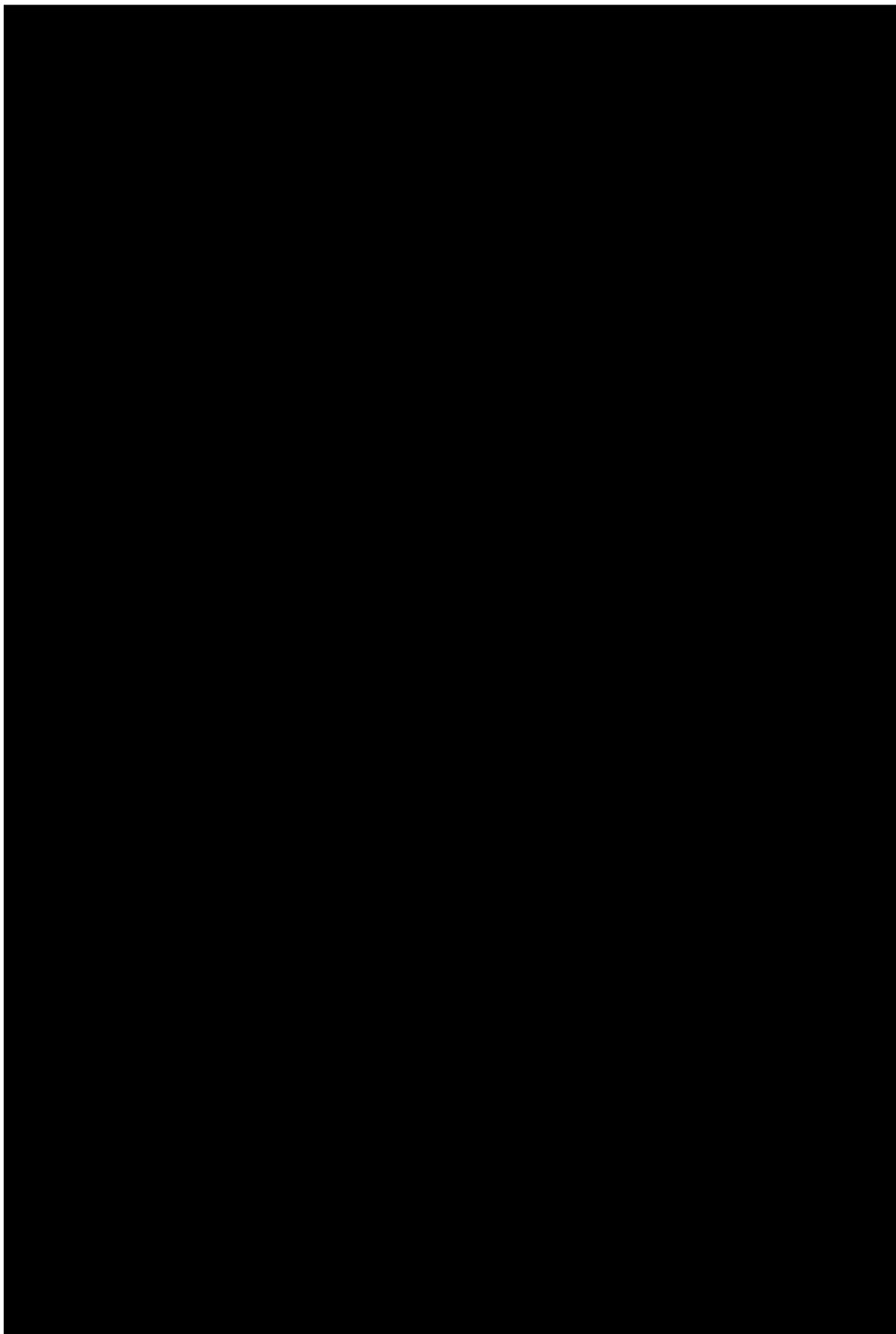
Requests for clarification and additional information

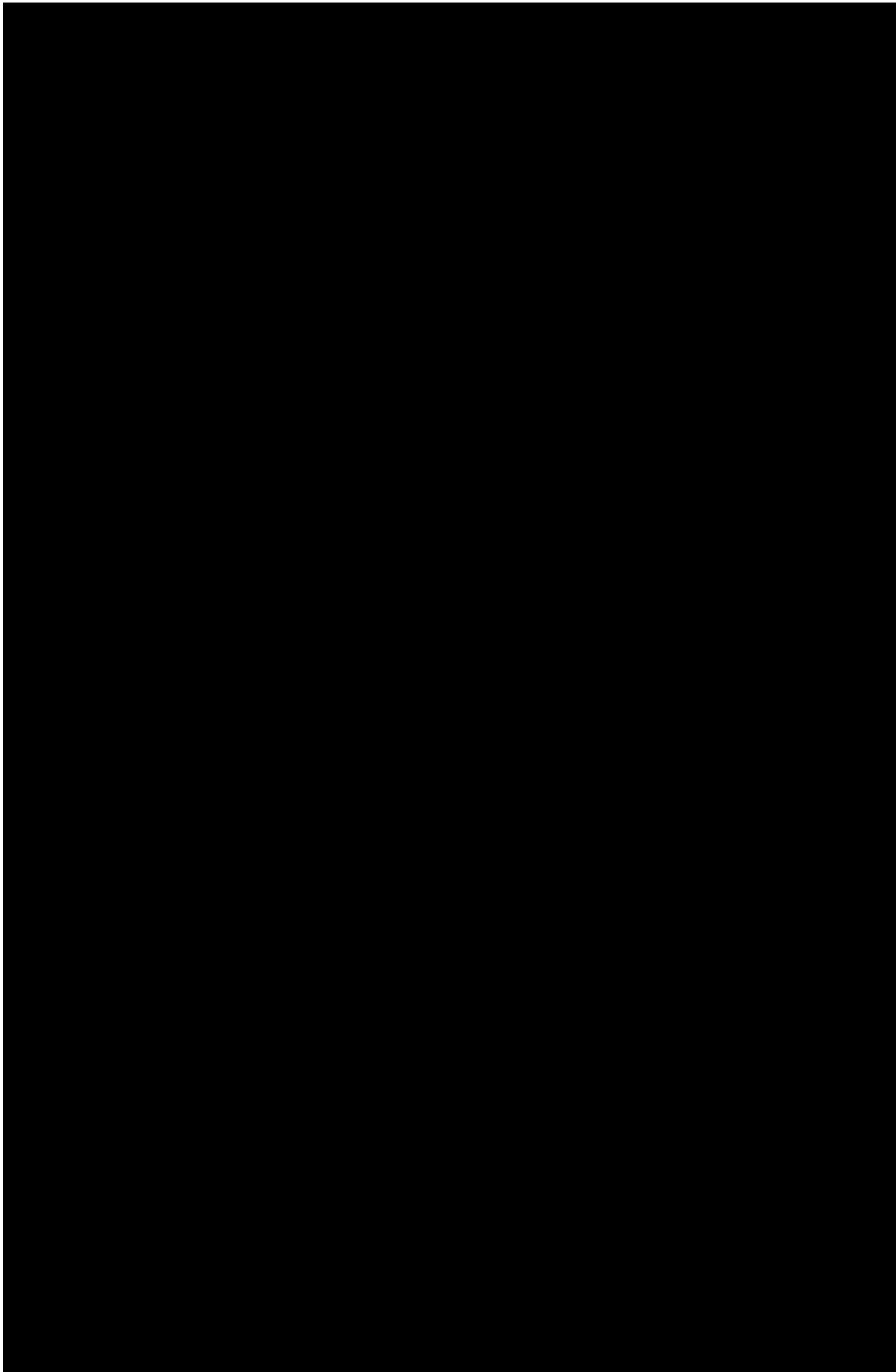


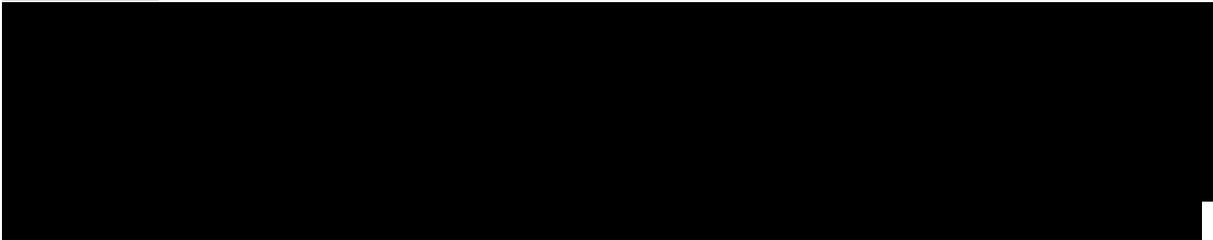


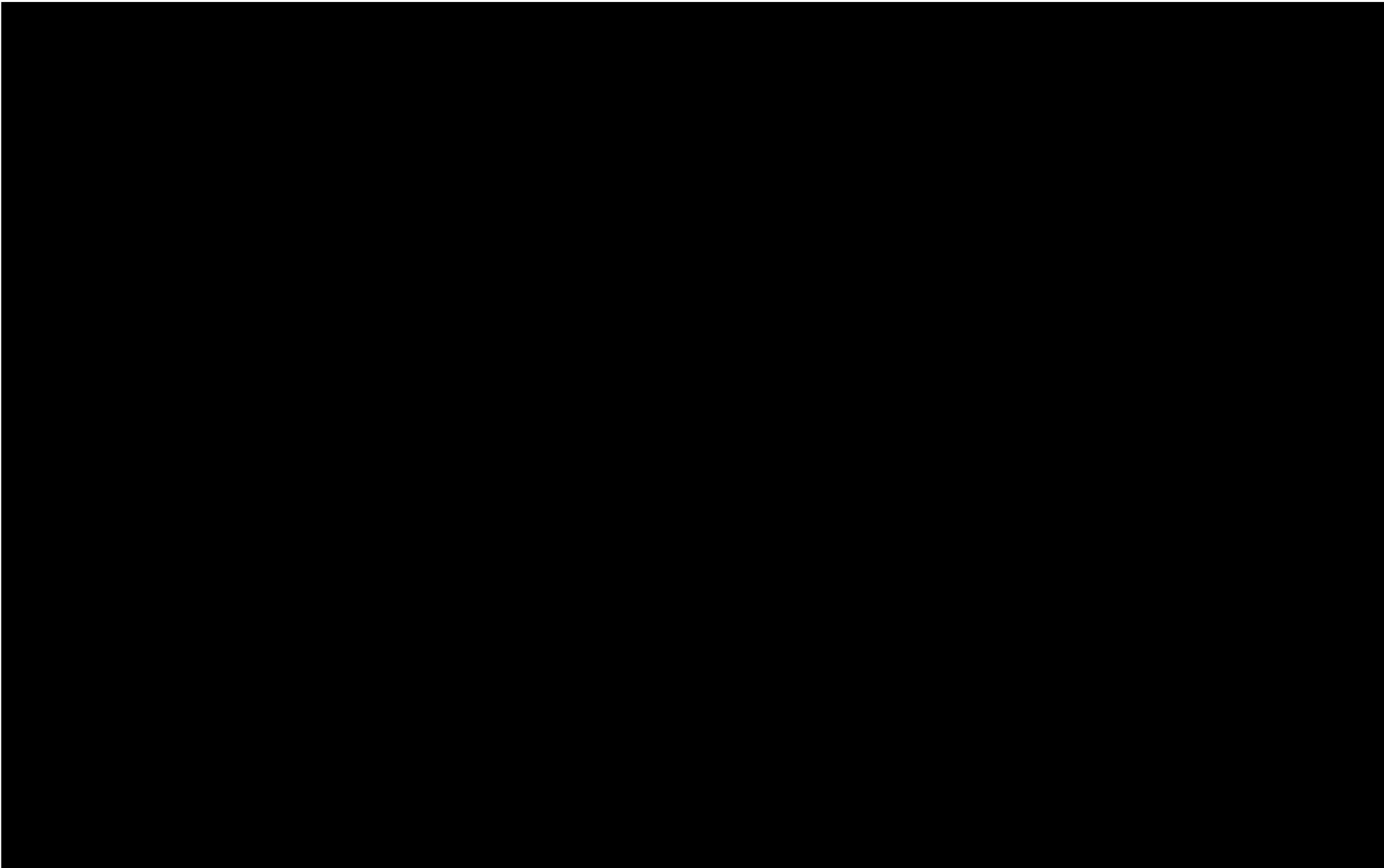






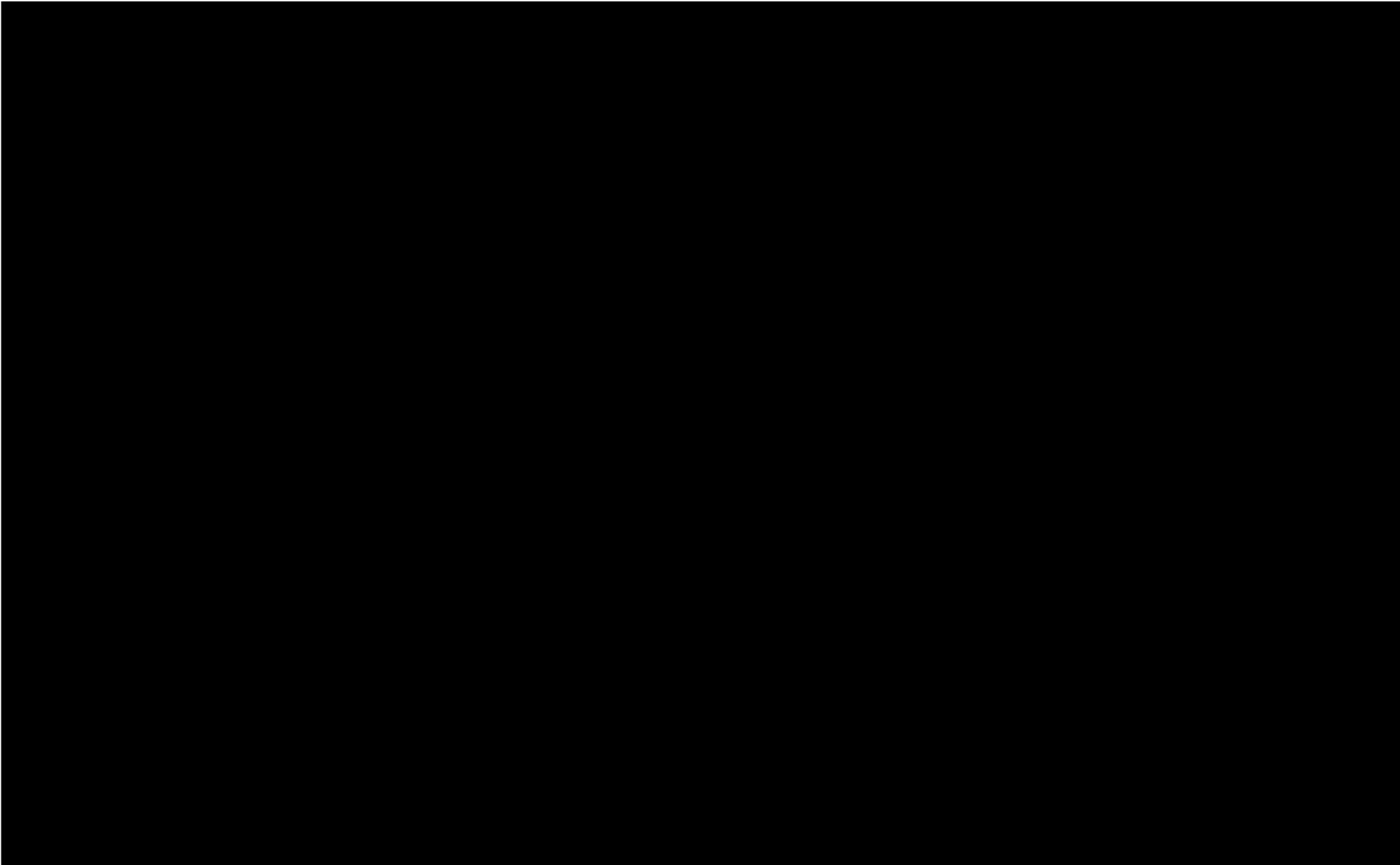


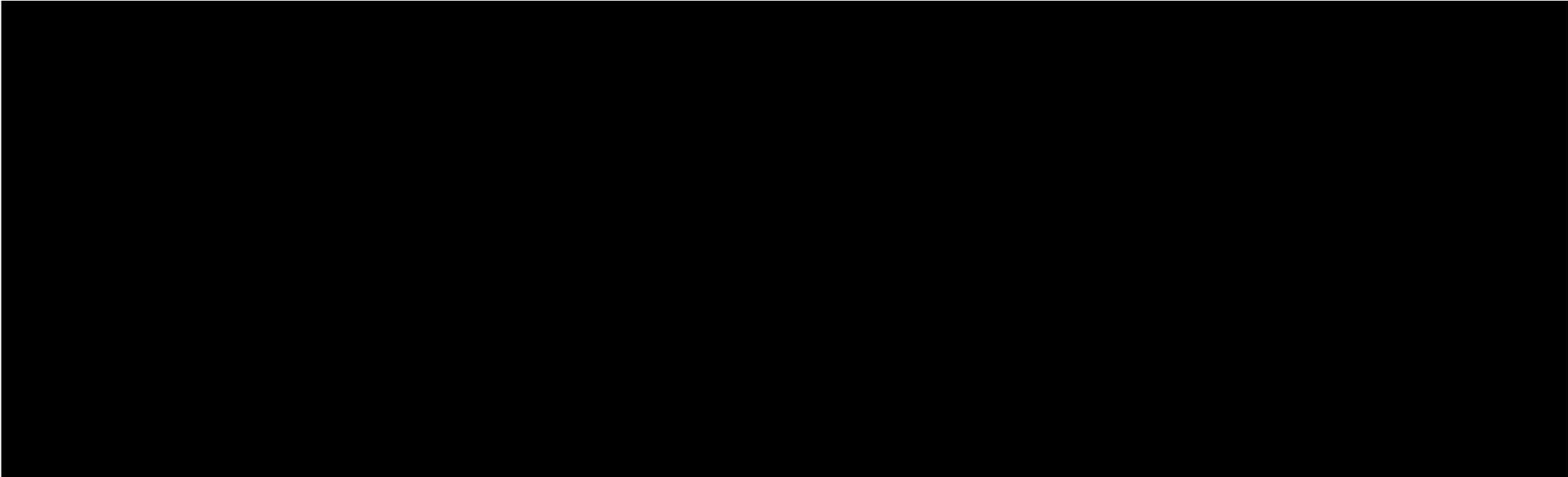




Proposed NRL activities for April 2023 to March 2024







[Redacted]

[Redacted text block]

[Redacted text block]

Tender reference number	Tenderers Name
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FS431167	UKHSA
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Tender title

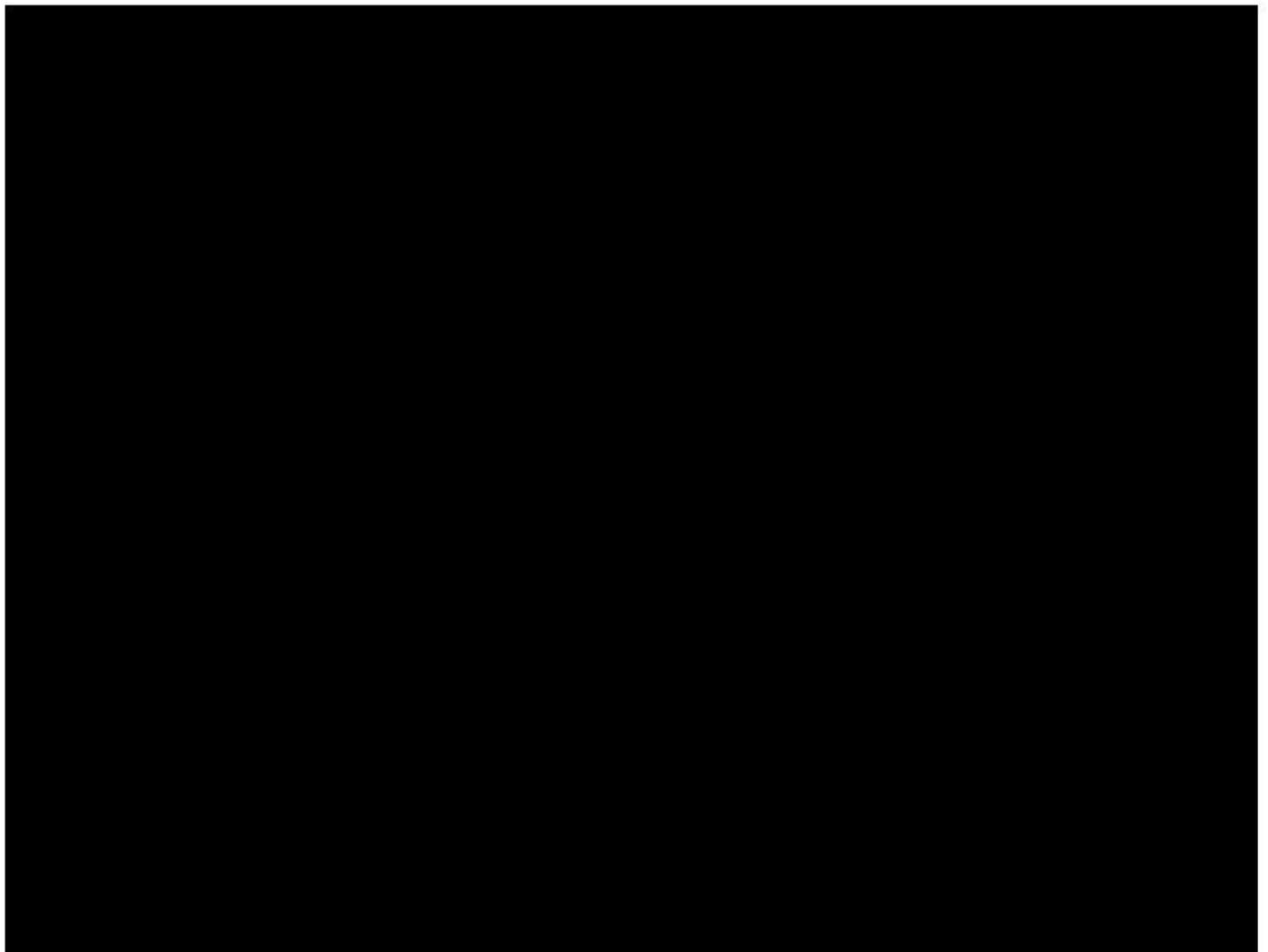
National Reference Laboratories for Microbiology
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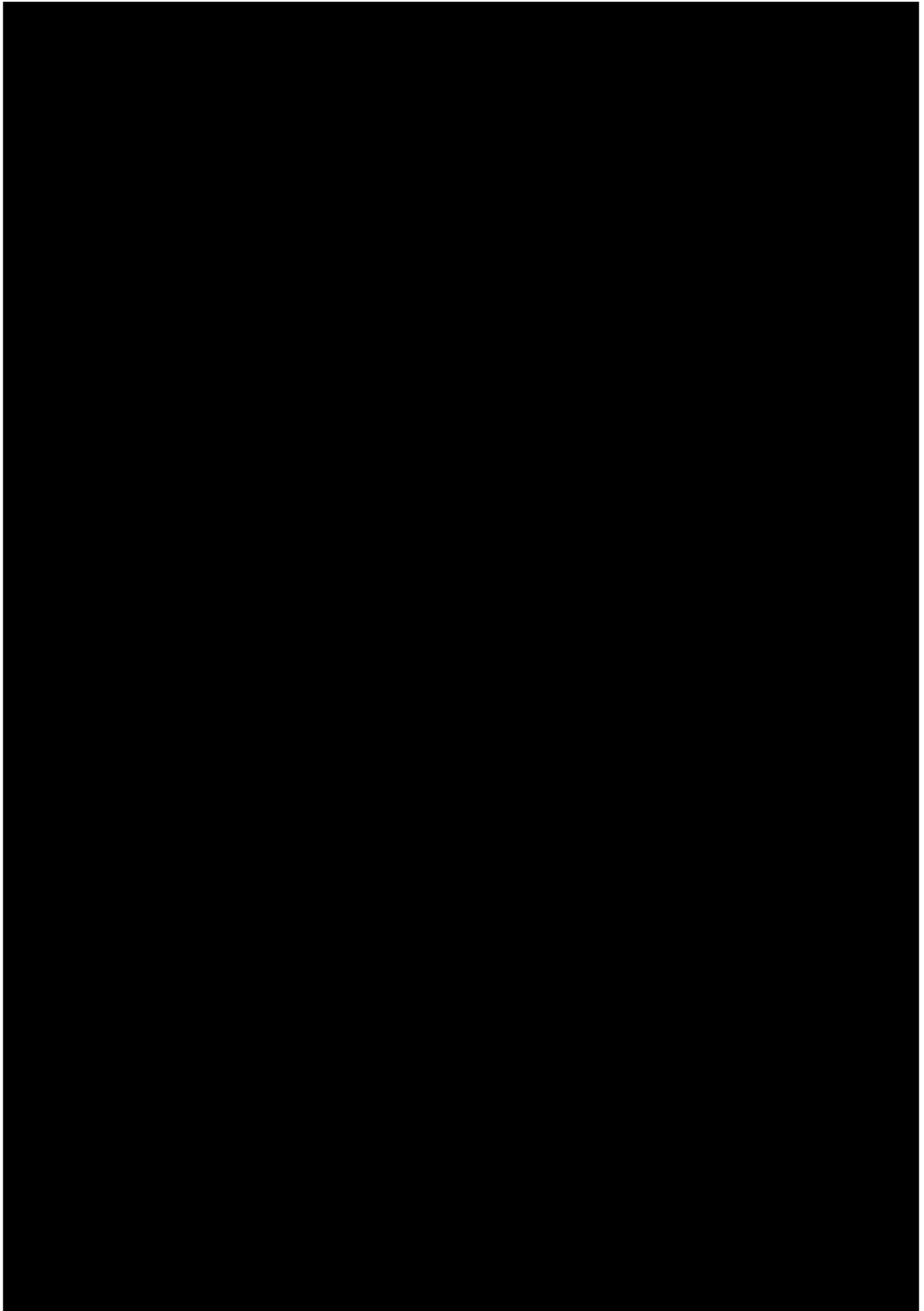
Evaluator name

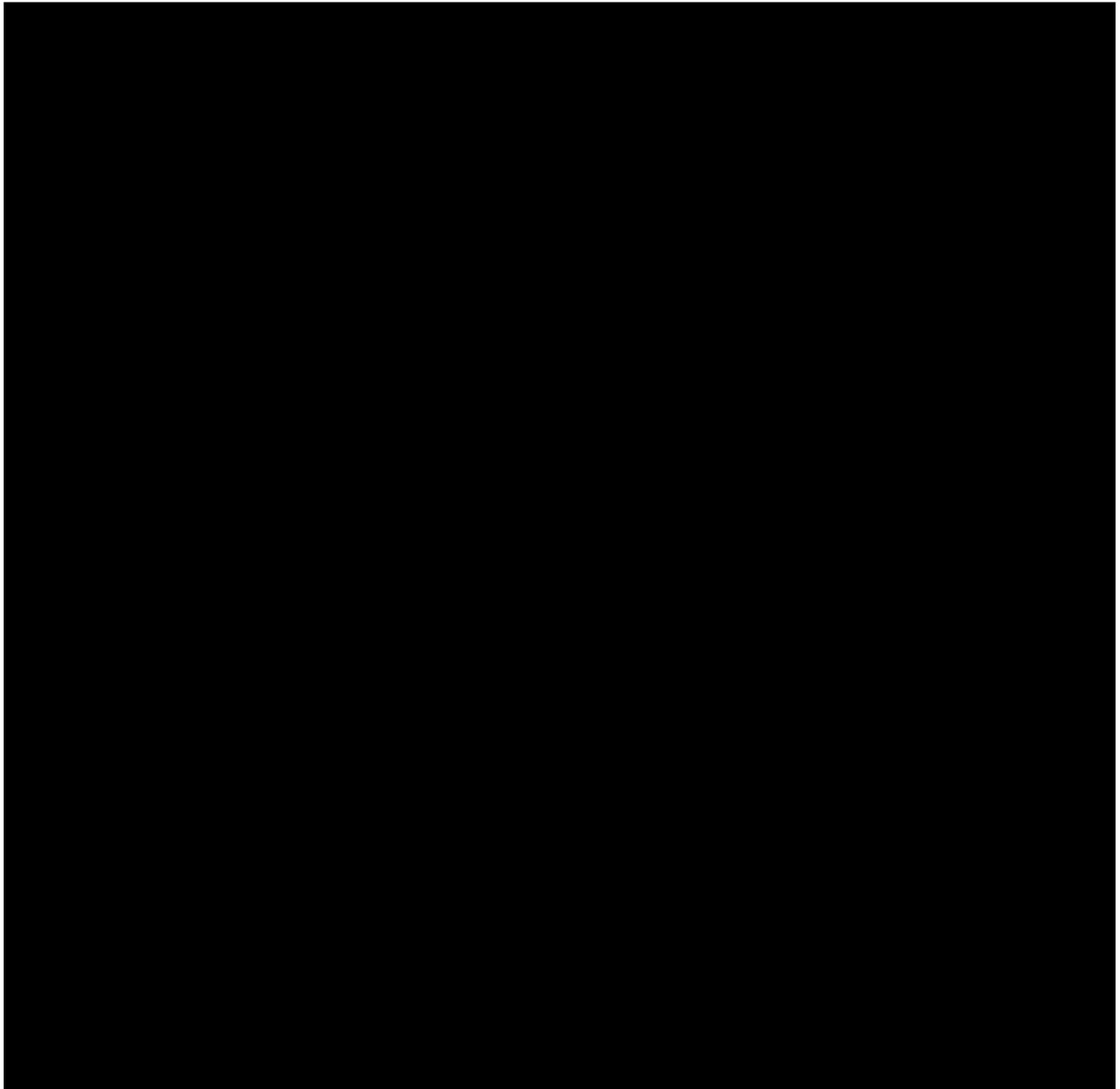
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Requests for clarification and additional information







[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]