SHORT FORM CONTRACT FOR THE SUPPLY OF SERVICES

LGC Limited
Queens Road
Teddington
TW11 0LY

[redacted]

Following your tender/proposal for the supply of Guidance for Point of Contact Technology to Food Standards Agency, we are pleased confirm our intention to award this Contract to you.

The attached Order Form, contract Conditions and the Annexes set out the terms of the Contract between Food Standards Agency and LGC Limited for the provision of the Deliverables set out in the Order Form.

We thank you for your co-operation to date, and look forward to forging a successful working relationship resulting in a smooth and successful Delivery of the Deliverables. Please confirm your acceptance of this Contract by signing and returning the Order Form. No other form of acknowledgement will be accepted. Please remember to include the reference number(s) above in any future communications relating to this Contract.

We will then arrange for the Order Form to be countersigned which will create a binding contract between us.

Yours faithfully,

[redacted]
Commercial Category Manager

I. Order Form

1. Contract Reference	C173168	
2. Buyer	Food Standards Agency Clive House 70 Petty France London SW1H 9EX	
3. Supplier	LGC Limited Queens Road Teddington TW11 0LY	
4. The Contract	This Contract between the Buyer and the Supplier is for the supply of Deliverables. The Supplier shall supply the Deliverables described below on the terms set out in this Order Form and the attached contract conditions ("**Conditions**") and ***Annexes***. Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in the Conditions. In the event of any conflict between this Order Form and the Conditions, this Order Form shall prevail. [Please do not attach any Supplier terms and conditions to this Order Form as they will not be accepted by the Buyer and may delay conclusion of the Contract.]	
5. Deliverables	**Goods**	None
	Services	as set out below in [Annex 2 – **Specification]** and in the Supplier's tender as set out in [Annex 4 – **Supplier Tender]**
6. Specification	The specification of the Deliverables is as set out in [Annex 2 – **Specification]**	
7. Start Date	01/08/2023	
8. Expiry Date	31/03/2024	

9. Extension Period	Not applicable
10. Optional Intellectual Property Rights ("IPR") Clauses	***Clause 10 of the Conditions provides that each Party retains its Existing IPR, and New IPR belongs to the Buyer (with a license granted to the Supplier for use).***
11. Charges	The Charges for the Deliverables shall be as set out in [Annex 3 – **Charges]**
12. Payment	Payment of undisputed invoices will be made within 30 days of receipt of invoice, which must be submitted promptly by the Supplier. All invoices must be sent, quoting a valid Purchase Order Number (PO Number), to: Accounts-Payable.fsa@gov.sscl.com Within [**10**] Working Days of receipt of your countersigned copy of this Order Form, we will send you a unique PO Number. You must be in receipt of a valid PO Number before submitting an invoice. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, item number (if applicable) and the details (name, email, and telephone number) of your Buyer contact (i.e. Buyer Authorised Representative). Non-compliant invoices may be sent back to you, which may lead to a delay in payment.
13. Data Protection Liability Cap	In accordance with clause 12.5 of the Conditions, the Supplier's total aggregate liability under clause 14.7(e) of the Conditions is no more than the Data Protection Liability Cap, being ***£1million***
14. Progress Meetings and Progress Reports	See Annex 4 – **Supplier Tender**
15. Buyer Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted]

16. Supplier Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted]
17. Address for notices	**Buyer:** Food Standards Agency Foss House Peasholme Green York YO1 7PR **Supplier:** LGC Limited Queens Road Teddington TW11 0LY
18. Key Staff	[redacted] – Head of GMO analytical unit and Principal Scientist (Project Lead - Principal Investigator) [redacted] – Science Leader: Food analysis (Operations Manager) [redacted] - Science Leader: Innovation, Molecular and Cell Biology (Specialist Support Officer) [redacted] – UK Deputy Government Chemist & Key Account Manager (Key Account Manager) [redacted] – Head of the Office of the Government Chemist and Referee (Analyst Association of Public Analysts Training Officer) [redacted] – Senior Project Manager (Senior Project Manager)
19. Procedures and Policies	For the purposes of the Contract the: The Buyer's additional sustainability requirements are: ***FSA Environmental Sustainability Strategy***.
20. Special Terms	Special Term 1 -

21. Incorporated /terms	The following documents are incorporated into the Contract. If there is any conflict, the following order of precedence applies: a) The cover letter from the Buyer to the Supplier dated *25/07/2023* b) This Order Form c) Any Special Terms (see **row 20 (Special Terms)** in this Order Form) d) Conditions e) The following Annexes in equal order of precedence: i. Annex 1 – Processing Personal Data ii. [Annex 2 – **Specification]** iii. [Annex 3 – **Charges]** iv. [Annex 4 – **Supplier Tender]**

Signed for and on behalf of the **Supplier**	Signed for and on behalf of the **Buyer**

Name: [redacted] NML Head of Commercial	Name: [redacted] Commercial Category Manager
Date: 29/08/23	Date: 30/08/2023
Signature: [redacted]	Signature: [redacted]

[Where appropriate, this Order Form may be signed electronically by both Parties.]

II. Annex 1 – Processing Personal Data

A. Part A - Authorised Processing Template

Contract:	**C173168 – Guidance for Point of Contact Technology**
Date:	**25/07/2023**
Description of authorised processing	**Details**
Identity of Controller and Processor for each category of Personal Data	The Buyer is the Controller and the Supplier is the Processor for the purposes of the Data Protection Legislation.
Subject matter of the processing	Guidance for Point of Contact Technology
Duration of the processing	Per dates of contract
Nature and purposes of the processing	LGC will use Stakeholder contact data arising from the professional networks of those delivering the project. Stakeholder's data will only be used and stored with their consent, and they have the right to withdraw this consent at any time. Data will be stored electronically in accordance with LGC's Information Security Management and Data Processing policies (copies of which were provided to the FSA as appendices to the tender for this contract).
Type of Personal Data	Stakeholder names, email addresses, and telephone numbers
Categories of Data Subject	Stakeholder contact details. Low risk. No special category data involved.
Plan for return and destruction of the data once the processing is complete UNLESS requirement under law to preserve that type of data	Data retention and destruction will be accordance with LGC's Information Security Management and Data Processing policies (copies of which were provided to the FSA as appendices to the tender for this contract).
Locations at which the Supplier and/or its Subcontractors process Personal Data under this Contract	Data will be stored and processed in the UK and the EU will be accordance with LGC's IT and Cyber Arrangements document (a copy of which was provided to the FSA as an appendix to the tender for this contract).

Protective Measures that the Supplier and, where applicable, its Subcontractors have implemented to protect Personal Data processed under this Contract against a breach of security (insofar as that breach of security relates to data) or a Personal Data Breach	Only approved suppliers will be used under this contract, in accordance with the LGC Supplier Code of Conduct (a copy of which was provided to the FSA as an appendix to the tender for this contract). This policy contains specific provisions on Cyber security and data privacy.

III. [Annex 2 – Specification]

Specification Reference
C173168
Specification Title
Guidance for Point of Contact Technology Research Project
Contract Duration
Until March 2024

This specification, which forms part of the Invitation to Tender (ITT), comprises of three individual sections: -

A. **SPECIFICATION:** An outline of the requirement

B. **PROCUREMENT TIMETABLE:** An estimated timetable for the procurement of the proposed requirement

C. **TENDER REQUIREMENTS AND EVALUATION CRITERIA:** Provides guidance to applicants on the information that should be included within tenders and on the evaluation criteria and weightings used by appraisers when assessing and scoring tenders

Tenders for FSA funded projects must be submitted through the FSA E-sourcing and contract management system, ECMS, using the following link: https://health-family.force.com/s/Welcome

Failure to do so may result in the tender response not being processed by the system or the response being automatically disqualified during the evaluation stage of the tender process.

THE SPECIFICATION, INCLUDING PROJECT TIMETABLE AND EVALUATION OF TENDERS

GENERAL INTRODUCTION

The Food Standards Agency is an independent Government department working across England, Wales and Northern Ireland to protect public health and consumers wider interest in food. We make sure food is safe and what it says it is.

The Agency is committed to openness, transparency and equality of treatment to all suppliers. As well as these principles, for science projects the final project report will be published on the Food Standards Agency website (www.food.gov.uk). For science projects we will encourage contractors to publish their work in peer reviewed scientific publications wherever possible. 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.

Central to FSA's vision for 2022-2027 of "food you can trust" is our guiding principle of being science and evidence led. We use science and evidence to tackle the challenges of today, to identify and address emerging risks, and to ensure the UK food and feed safety regulation framework is modern, agile and represents consumer interests.

The last ten years have witnessed significant advances in technology and applications for food testing, including a focus on the availability of an increasing number of Point-of-Contact (POC) technologies. POC instrumentation enables testing and screening of food in real time at the point of contact with a sample (field, roadside, factory, port-

side etc). To date, POC testing has been largely confined to clinical diagnostic and human forensics arenas, with limited application of POC instrumentation in the foods sector.

In November 2019, Defra commissioned the Project FA0178 with LGC, which aimed to establish the fitness for purpose of food authenticity testing deployed via POC instrumentation. This project has highlighted the promising capabilities of POC technology as well as several reasons why uptake has generally remained low. It was identified that very few, if any, official guidelines for developing, validating, and utilising POC testing in any environment exists and no standards from accredited bodies exist to govern this type of testing outside of the clinical setting. With the rise of consumer applied technologies such as smartphone-based food testing, it was concluded that these unregulated instruments may become increasingly problematic. Thus, recommendations for future work included the development of support mechanisms such as official guidance on sampling and results generation/interpretation. To help inform potential users and prevent undermining the great potential of POC technologies for improving food safety and standards, the FSA seeks to undertake follow-up research to support the development of the requirements for POC technology application in food testing, especially for enforcement purposes.

A. THE SPECIFICATION

1.0 Background

To support the harmonisation of POC methodologies and for the eventual establishment of an accredited standard, similar to ISO 17025 or the standards governing medical point of care testing, official guidance needs to be introduced to inform potential users. The Defra Project FA0178 highlighted that a similar level of regulation to that adopted by the Medicines and Healthcare Regulatory Agency for clinical POC testing, would greatly benefit the integration of non-targeted/multi-analyte detection approaches in food testing. Without such guidance, methodology using POC instrumentation can only be considered as a screening tool.

2.0 The Specification

Applicants are invited to carry out the research required to develop guidelines on the application of POC technology for the purpose of official controls in the food sector.

Tenders must demonstrate how the research being conducted will enable the development of guidelines. The supplier should consider including the following when developing the guidelines, but this is not an exhaustive list:

- A clear definition of instruments which are in the POC technology umbrella.
- An approach to validating a POC device being used for official controls.
- Clear guidelines on who is able to test food using POC technology for official controls and who the guidelines apply to.
- General guidelines on operating POC instruments.
- Reference to specific commodities testing with POC technology is suitable for.
- General guidelines on interpretation of results including the potential requirement of follow-up analysis.

The project is expected to be delivered in two phases, with a report to be submitted at the end of each phase.

Phase 1 – Horizon Scanning and Engagement

Requirements

- Horizon scanning activity to understand the potential for POC technology in the food sector for official controls and wider food sector (e.g. used by the public or FBOs).
- Engagement with UKAS for insight on accreditation requirements for POC.
- Engagement with key stakeholders including potential end-users such as local authority enforcement officers, Public Analyst Official Laboratories, National Reference Laboratories.
- Engagement with current POC users including MHRA as the regulators for POC technology application in the clinical setting.
- Interim report outlining the horizon scanning activity undertaken and stakeholder engagement.

Related POC work is ongoing in other projects within government including the Pathogen Surveillance in Agriculture, Food and Environment Programme (PATH-SAFE). As such foodborne pathogens are out of scope of the horizon scanning and connections must be made with relevant projects to ensure alignment of activities, and to avoid duplication of effort, throughout.

Phase 2 – Development of POC Technology Guidelines for Official Controls

Requirements

- Development of guidelines on requirements for validation of POC technology and requirements for underlying datasets they require for key technologies identified in Phase 1.
- Final report outlining the activities undertaken and rationale behind the development of the guidelines in the format detailed below. The guidelines may be included as an annex to the final report.

3.0 Deliverables

It is anticipated that this project will deliver the following:

- Draft interim report (1) consisting of a horizon scanning activity and stakeholder engagement to scope out the current application of POC technology.
- Draft interim report (2) detailing the approach to validating POC technology and requirements for underlying datasets they require.
- A final project report incorporating interim reports (1) and (2) to include guidance on the application of POC technology for the purpose of official controls in the food sector as an annex and recommendations for future work.

Usually reports require at least one round of substantive comments by FSA officials (and any other parties involved in the project as appropriate) and a final round to finalise minor outstanding comments. Unless otherwise agreed, the project manager

will co-ordinate comments and provide them to the contractor and all responses will be recorded. The final report will be subject to external peer review, following which further amendments may be required. Contractors should agree the timetable for reporting and publication with the project officer but should note that FSA normally expect two weeks to provide a co-ordinated response per round of substantive comments. Please confirm in your proposal how you will meet FSA's requirements for reporting.

The required timescales for delivery are listed below. Any risks to the delivery of the project must be highlighted in the expression of interest along with measures for mitigation. Quarterly meetings must be held between the contractor and the project officer to monitor the progress of the project.

4.0 Format

All reports must be formatted in line with FSA accessibility guidelines – the most up to date version of which should be checked prior to writing the report. They must be submitted in Microsoft word format. These requirements additionally include (but are not limited to):

- Use a sans serif font (for example Arial, Helvetica), with a minimum font size of 12 points
- Use left aligned text, not justified
- Avoid chunks of italicised or capitalised text
- Only use underlines to indicate links
- Use standard bullets for lists
- Use styles and headings to structure your content, and ensure these are in the right order (for example, in Microsoft Word, heading 1 followed by heading 2)
- Ensure that all tables are simple (no split/merged cells) and have column and row headers

The draft final report is required to be completed by **February 2024**, however the remaining timelines are negotiable.

5.0 Cost

The onus is on the contractor(s) to provide the costings they believe that is reasonable to meet the evidence gap as outlined in this survey specification and provide the justification of this within their proposal. The contractor(s) should be aware that one of the key criteria that all research proposals are evaluated against is 'value for money' which is delivering the survey asked for in this specification (including the anticipated outputs and benefits) at a competitive price'. At a competitive price this has been estimated between £30-50k.

6.0 Risk

The contractor to provide details of any relevant perceived risks in undertaking this project, as delays due to business or personnel needs to be mitigated.

7.0 Data protection

Handling published research may require you to comply with the copy right. Privacy Impact Assessment (PIA), and a privacy notice may be required, which will be reviewed by the FSA data security team.

Ensure the roles and responsibilities of the Controller, usually FSA, and the Processor, usually supplier, are set out clearly in this specification.

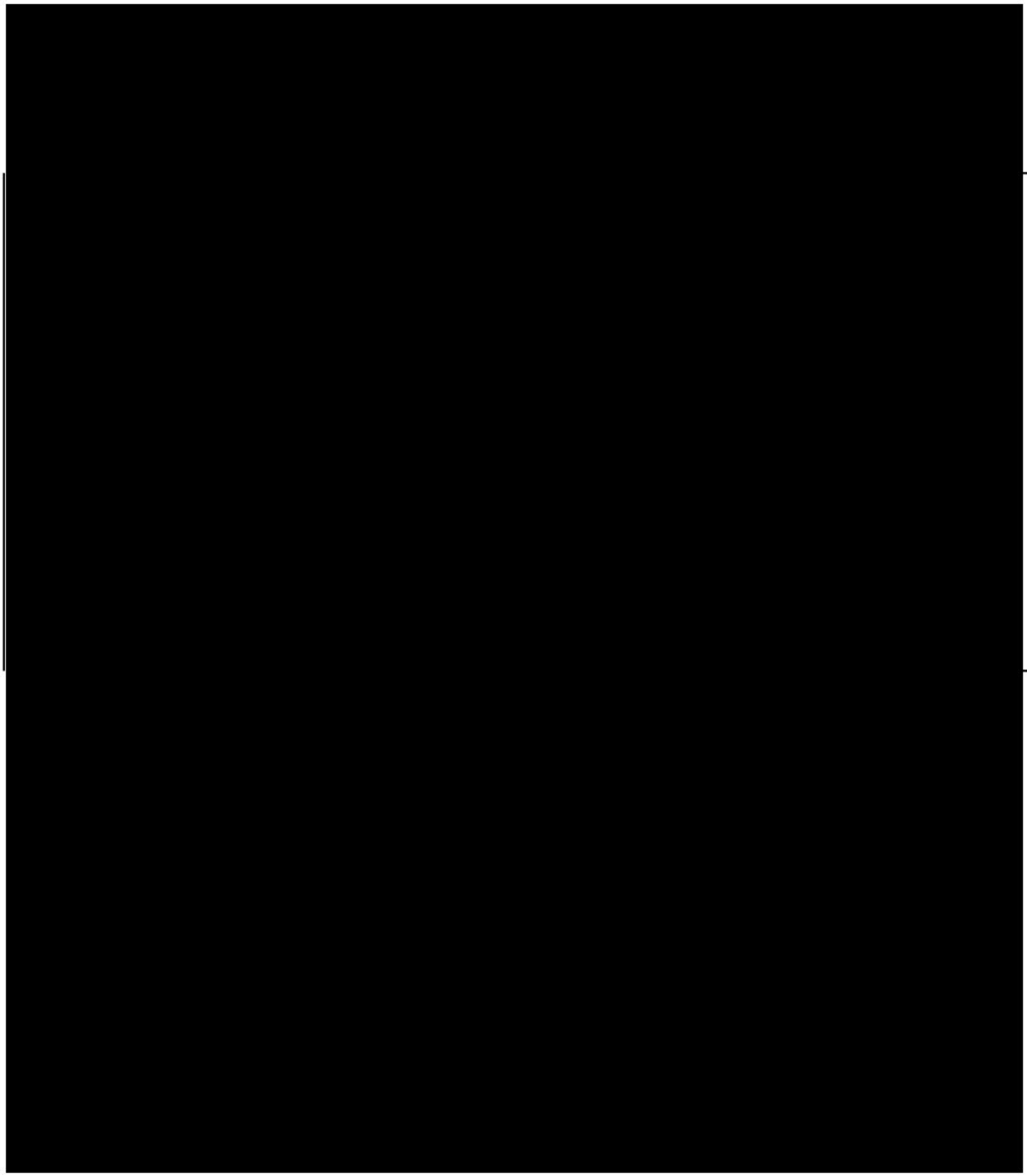
The contractor should outline within their tender whether they anticipate any Personal Data will be collected as part of the surveillance. If so, it should be included a description of how their tender will comply with the GDPR, recognising the commissioning authority's role as the 'data controller' and the contractors' role as the 'data processor', and responding to the sections below. If successful you may also be asked to carry out a Privacy Impact Assessment (PIA), and a privacy notice may be required, which will be reviewed by the FSA data security team.

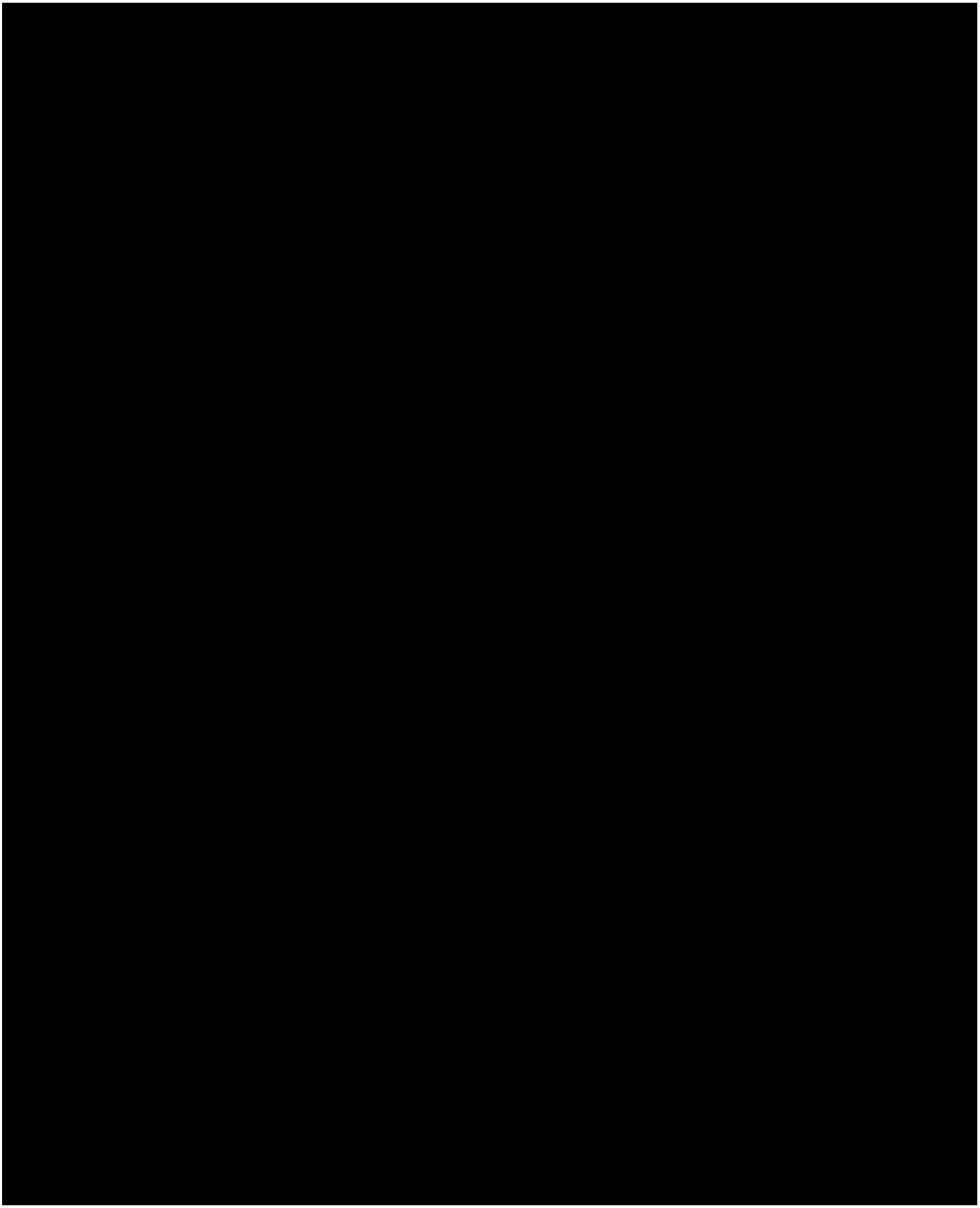
8.0 Data security

Please confirm in your tender that you have in place, or that you will have in place by contract award, the human and technical resources to perform the contract to ensure compliance with the General Data Protection Regulation and to ensure the protection of the rights of data subjects.

Please provide details of the technical facilities and measures (including systems and processes) you have in place, or will have in place by contract award, to ensure compliance with the General Data Protection Regulation and to ensure the protection of the rights of data subjects. Your response should include, but should not be limited to facilities and measures:

- to ensure ongoing confidentiality, integrity, availability and resilience of processing systems and services.
- to comply with the rights of data subjects in respect of receiving privacy information, and access, rectification, deletion and portability of personal data.
- to ensure that any consent-based processing meets standards of active, informed consent, and that such consents are recorded and auditable.
- to ensure legal safeguards are in place to legitimise transfers of personal data outside the EU (if such transfers will take place);
- to maintain records of personal data processing activities; and
- to regularly test, assess and evaluate the effectiveness of the above measures.'

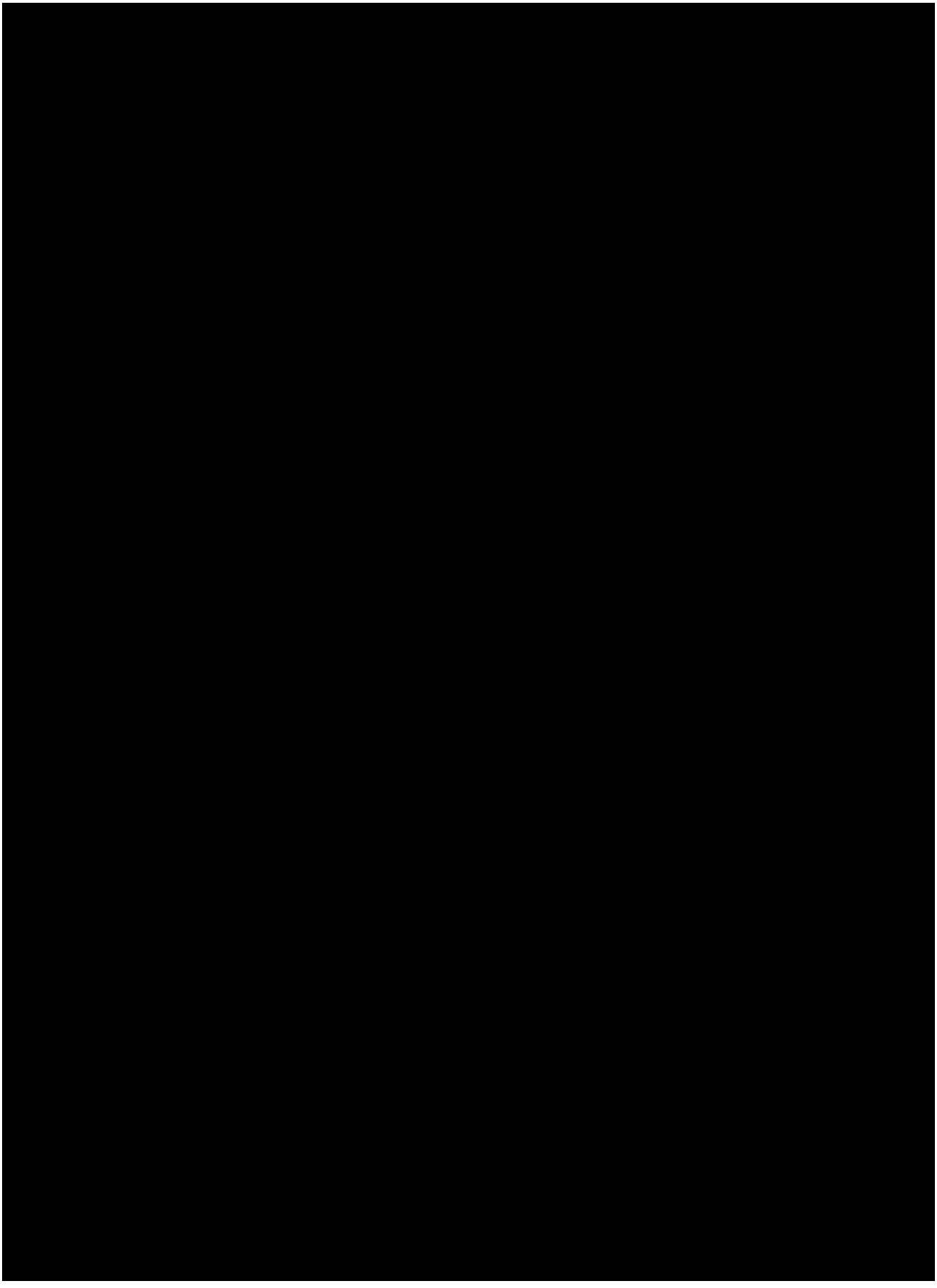


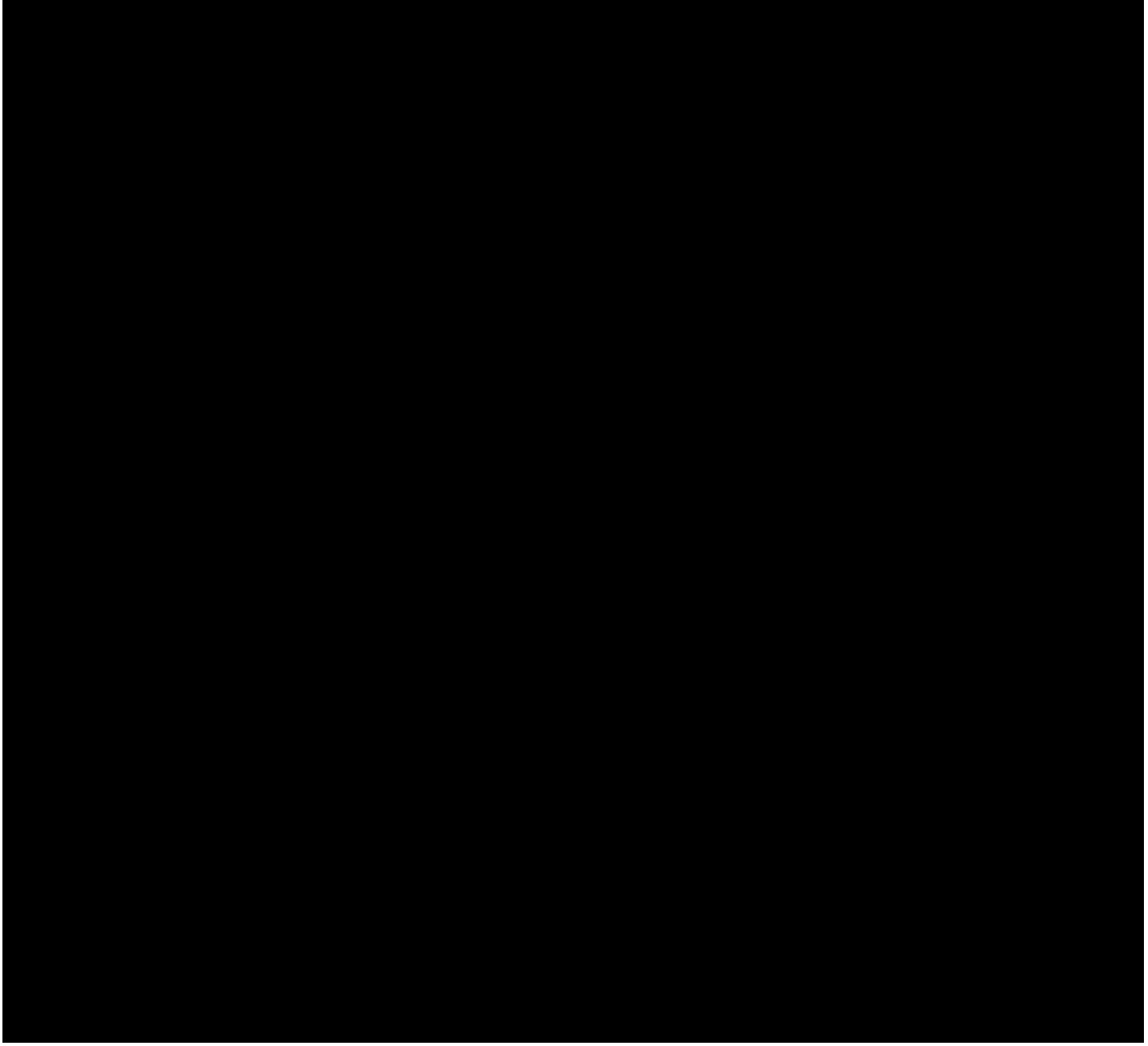


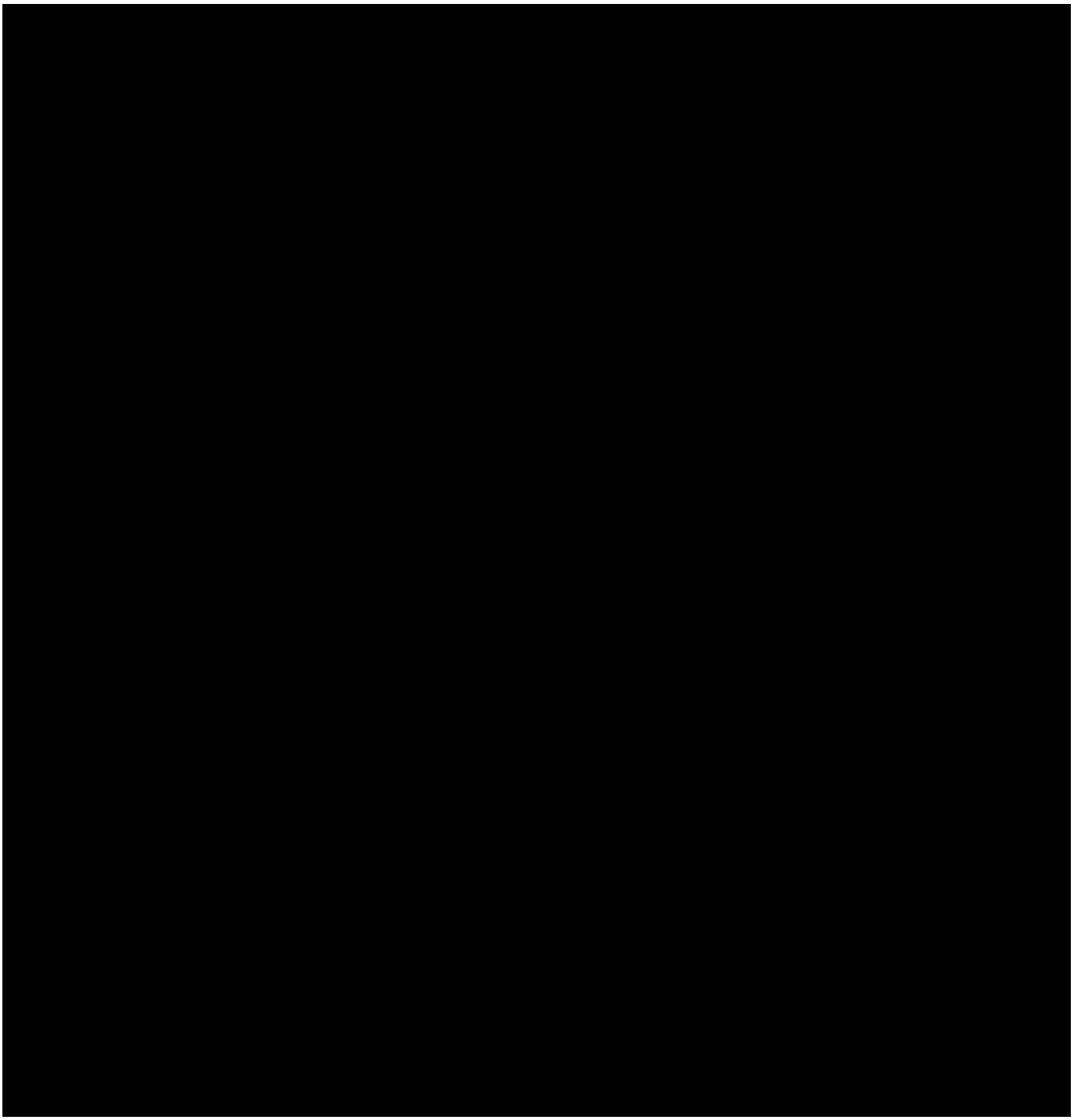
[redacted]

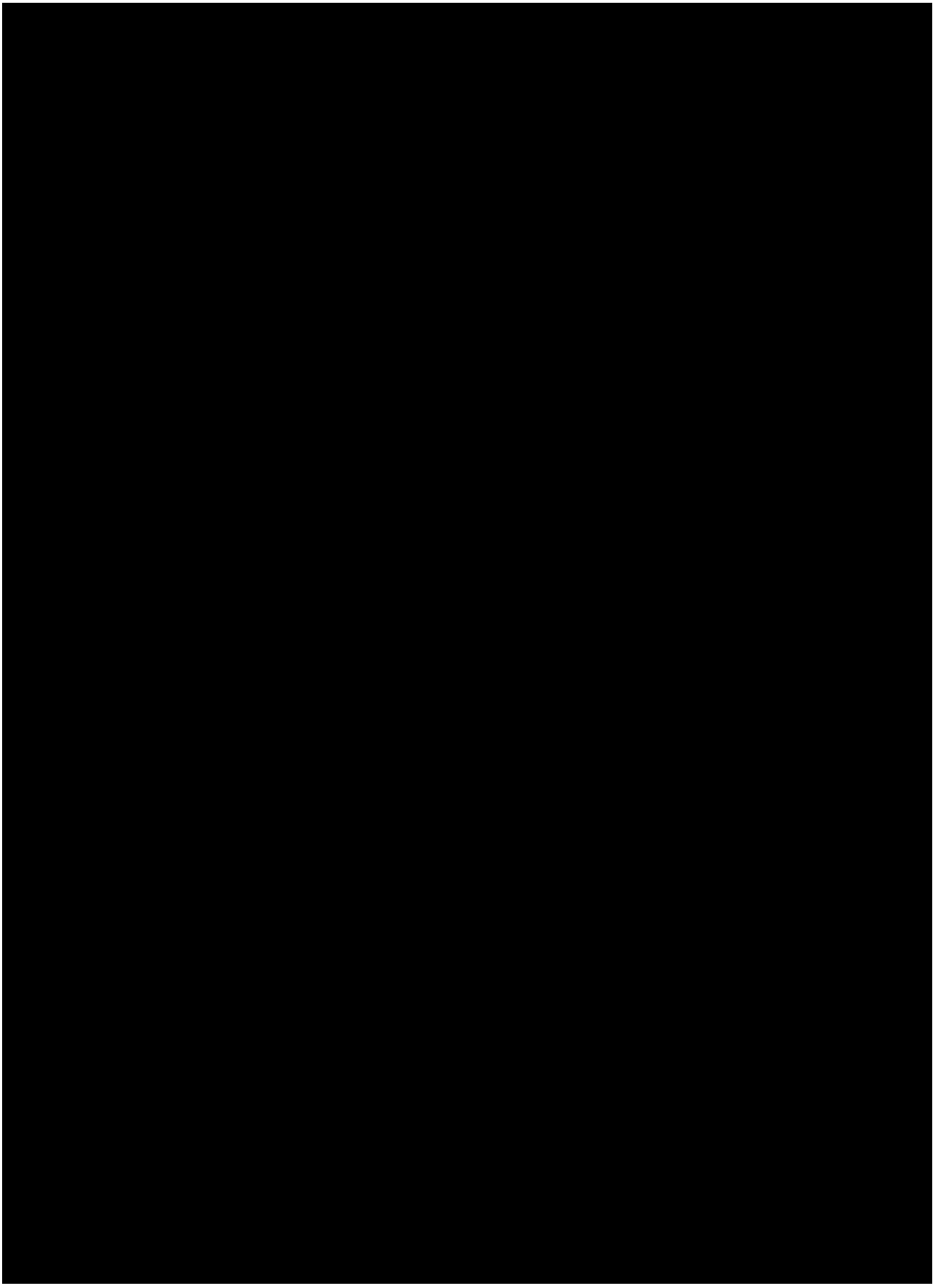
	£
Total Project Costs	49,987.00

[redacted]









[redacted]

	Year 1		
Financial Year (Update as applicable in YYYY-YY format)	2023-24	Retention	Total
Total Amount	£ 39,989.60	£ 9,997.40	£ 49,987.00

V. [Annex 4 – Supplier Tender]

Tender Application form for a project with the Food Standards Agency

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 (Atamis) by the deadline set in the invitation to tender document.

TENDER SUMMARY			
TENDER TITLE			
Guidance for Point of Contact Technology Research Project			
TENDER REFERENCE	C173168		
PROPOSED START DATE	01/08/2023	**PROPOSED**	31/03/2024

1: TENDER SUMMARY AND OBJECTIVES

TENDER SUMMARY

Please give a brief summary of the proposed work in no more than 400 words.

Within the last decade, Point of Contact (POC) technologies have gained increasing popularity for analytical diagnostics, fuelled in part by lower costs and increasing availability of miniaturised analytical equipment. However, a lack of guidance and harmonisation regarding validation, application and results interpretation for food testing have limited their full utilisation in the food supply chain.

This project proposes to use a two-phased approach to identify gaps and provide much needed guidance in this area, with a firm focus on utilisation for official controls.
Phase 01 will consist of a Horizon Scanning and Engagement activity, evaluating the current uses and gaps associated with the POC technology for food authenticity testing. Tasks include a deep-dive of responses to a POC questionnaire, alignment and input with national and international initiatives associated with POC technologies, stakeholder engagement and focus groups, use of virtual networks, and key contacts with UKAS, MHRA and PATH-SAFE to align with accreditation and published guidance, whilst ensuring no duplication of effort between projects. The stakeholder engagement exercise will assess which POC instrumentation is currently being used, as well as examine what specific commodities are being analysed using POC technology and where it can be used for the future.

Phase 02 consists of the generation of POC guidance, with a focus on its use for official controls. Account will be taken of both classic method validation parameters, as well as the concept of operations (CONOPS), recognising that the end-user is uniquely positioned to provide a more informed decision on what the requirements and validation parameters should be as informed through Phase 01. Recognising the plethora of technologies and different instruments that qualify as POC devices, this project proposes to provide both general validation guidance applicable across all instrumentation, as well as supportive guidance specific to core POC technology areas. Consideration will also be given to the generation and interpretation of results.

This project will provide general guidance on the validation of POC instrumentation and associated dataset requirements. A clear focus will be given on what needs to be done to validate POC instrumentation for use in an official control setting, to provide an infra-structure and supportive mechanism to promote uptake of this important technological tool by official laboratories as an additional approach in their analytical toolkit.

OBJECTIVES AND RELEVANCE OF THE PROPOSED WORK TO THE FSA TENDER

OBJECTIVES

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

OBJECTIVE NUMBER	OBJECTIVE DESCRIPTION
1.0	**HORIZON SCANNING AND ENGAGEMENT** To assess the current state of the art and availability of POC instrumentation an updated literature review will be performed. A series of stakeholder engagement exercises (focus groups and online survey) will be conducted to inform on end-user requirements. Alignment with synergistic activities through national and international related projects will be sought, to remain abreast of best measurement practice guidance and avoid duplication of effort. Engagement with key stakeholders at UKAS, MHRA and PATH-SAFE will ensure the project remains informed on published guidance, relevant road-maps for ISO 17025 accreditation, and validation of POC instrumentation. Information gained as a result of Objective 01 will inform the direction of travel and content of Objective 02.
2.0	**DEVELOPMENT OF POC TECHNOLOGY GUIDELINES FOR OFFICIAL CONTROLS** Information from Objective 01 on stakeholder engagement and Horizon Scanning will be combined with classic method validation approaches to provide guidance for application of POC technologies for food testing. It is foreseen that both general guidance applicable to all POC technologies, as well as specific bespoke guidance on a POC technology by technology

	basis will be provided. A focus will be given on the tailoring of guidance for the use of POC technology in support of official controls in the UK.

2: DESCRIPTION OF APPROACH/SCOPE OF WORK

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.

Scientific or technical problem being addressed in the proposal

Within the last decade, significant advances have been made in terms of analytical technology, application and best measurement practices in the area of food fraud detection. This evolution also includes advances in the capabilities and market availability of portable analytical instrumentation which can be deployed at the point of sample testing throughout the food and feed supply chains, often referred to as Point of Contact (POC) technologies.

Such POC technologies are often regarded as suitable instruments to use as an additional tool to help combat food fraud. Whilst the type and modes of actions of technologies that fit under the one umbrella term of POC instrumentation is vast and ever increasing, all of the instruments generally share common features inclusive of enabling testing of food to take place in near/real-time and at the point of contact with the sample. They thus offer the potential to screen samples quickly and cost effectively. However, whilst the potential benefits of POC technology are widely understood, the application of POC instrumentation has largely been confined to the clinical diagnostic and human forensic areas, as supported through the relevant published guidelines.

The previous Defra FA0178 project "Assessment of Point of Contact Testing Technologies to Verify Food Authenticity", led by LGC, evaluated the use of POC technologies for food authenticity testing, identifying practical barriers to uptake of these new technologies, as well as providing recommendations on support mechanisms to promote their use. Chief amongst some of these findings and recommendations was that the lack of guidance on the application of POC technologies and interpretation of the resultant data provided a significant challenge, and further guidelines and training/support were needed to promote POC technology uptake, particularly if this was to be used for control purposes as part of the analytical toolkit that official laboratories can apply. There was therefore a need for further work and guidance to be generated to help address this issue.

Through a phased approach of expert and end-user stakeholder engagement exercises, this tender response will assess what instrumentation is currently being used under the POC technology envelope as well as examine what specific commodities POC technology is being used for and may be suitable for. This project will provide general guidance on the validation of POC instrumentation and associated dataset requirements. A clear focus will be provided on what needs to be done to validate POC instrumentation for use in an official control setting, so as to develop an infra-structure and supportive mechanism to promote uptake of this important technological tool by official laboratories as an additional approach in their analytical toolkit.

State-of the art in the research area and scientific and technological basis for the proposed work

Towards the end of 2019, Defra commissioned project FA0178 "Assessment of Point of Contact Testing Technologies to Verify Food Authenticity" with LGC, whose aim was to help establish the fitness for purpose of food authenticity testing as enabled by POC technologies. The previous FA0178 project consisted of a two phased approach, conducting a landscape review (consisting of a literature review and online questionnaire completed by 170 participants) of current and emerging POC technologies, followed by an experimental pilot study of selected instrumentations' fitness for purpose. An initial list of practical barriers to uptake of POC technologies was provided, as well as support mechanisms (validation and training) to help promote uptake.

It was identified that very few, if any, official guidelines for developing, validating, and utilising POC testing in any environment existed and no standards from accredited bodies were present to govern this type of testing outside of the clinical setting. The Defra Project FA0178 highlighted that a similar level of regulation to that adopted by the Medicines and Healthcare Regulatory Agency (MHRA) for clinical POC testing, would greatly benefit the integration of non-targeted/multi-analyte detection approaches in food testing.

As a result of this initial project, it was clear that whilst the benefits of POC instrumentation were relatively well understood, its application in the food sector had been limited. Whilst method validation was a key factor in determining the fitness for purpose of POC instrumentation, the FA0178 project highlighted the need for relevant evaluation of the POC instrumentation in the field (at the point of application), as well as further engagement with end-users. Chief amongst these was that the fitness for purpose of POC technologies can only be fully realised through additional key stakeholder engagement of end-user requirements. The Concept of Operations (CONOPS) of "one size does not fit all" held true, as there is a plethora of instruments/technologies under the one "POC" heading, which often have bespoke applications and requirements, and effectively preclude the adoption of a single set of recommendations. One of the main recommendations for follow on work as a result of Defra project FA0178 was that further engagement with end-users and other stakeholders of the technologies was required, in order to inform on the understanding of what the requirements are to enable the full potential of POC instrumentation to be realised, particularly in an official control setting. There was a requirement for official guidance, as part of the natural road-map towards production of standards or inclusion in ISO 17025.
There was thus a need to develop further support mechanisms such as official guidance on sampling and results generation and interpretation. The current FSA tender seeks to undertake follow-up research to support the development of the requirements for POC technology application in food testing, especially for enforcement purposes, to help inform potential users and prevent undermining the great potential of POC technologies for improving food safety and standards.

Scientific approach, methodology and study design that will be used to address the specific evidence requirement and realise the scientific objectives outlined above
To best accommodate the project workflow, it is proposed to use a two-phased approach, as suggested in the project specifications document. Phase 01 will consist of a Horizon Scanning and Engagement activity, evaluating the current uses and gaps associated with the POC technology for food authenticity testing, as delivered through a series of activities inclusive of a deep-dive questionnaire, alignment and input with national and international initiatives associated with POC technologies, stakeholder engagement and focus groups, use of virtual networks, and key contacts with UKAS, MHRA and PATH-SAFE to align with accreditation and published guidance.
Phase 02 consists of the generation of POC guidance, with a focus on its use for official controls. Account will be taken of both classic method validation parameters, as well as the concept of operations (CONOPS), where the end-user helps provide a more informed decision on what the validation parameters should be. Both generic and technology/application specific guidance will be considered where appropriate as befits all of the technologies under the umbrella POC term, and consideration will also be given to the generation and interpretation of results.
Phase 01 (Horizon Scanning and Engagement) will naturally inform and flow into Phase 02 (Development of POC Technology Guidelines for Official Controls), but parts of Phase 02 can run concurrently with Phase 01, as detailed later in the Gantt chart and Project Flow diagram (please see Figure 2 in Section 3 of this form).

Phase 01 – Horizon Scanning and Engagement
To better understand the potential for POC technology in the food sector, with a focus on potential use for official controls and the wider food sector at large, it is proposed to conduct a horizon scanning and engagement activity as part of Phase 01.
As an initial activity, this tender response proposes to conduct a **deeper-dive into the pre-existing questionnaire** responses delivered as a result of the successful Defra FA0178 project recently delivered by LGC. Re-examination of the questionnaire data and responses in relation to tailoring relevant results from official controls and the wider food sector, will provide a firm infrastructure and springboard on which to base the current tender and add further value. LGC still has access to the original FA0178 questionnaire and responses, providing the potential to inform and refocus the Horizon Scanning and Engagement initiative as appropriate.
Following this, a thorough and **updated literature review** will be conducted, to provide the basis for the current understanding of POC technology potential for food testing as part of official controls and use in the wider food sector. This will not only include using key search terms across the major search engines (Google, Bing, Yahoo, Google scholar), but also on scientific publications, reports, Blogs, kit manufacturer commercial documents, conference reports, ISO/CEN standardisation activity, BSI, and Codex. This will be further supported by the very recently completed LGC led FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity", which it will take key learnings from in terms of a number of the synergistic aspects on the use of POC devices for the herbs and spices testing sector.

To further augment the Phase 01 Horizon Scanning and Engagement activity, **synergistic activities** from other related projects will also be used as key learning points and to help further inform on the direction of travel. Example activities from the recently awarded **Defra C5263 project on "Harmonisation and Standardisation in the Field of Next Generation Sequencing"** led by LGC, and the current **Government Chemist Programme 2023-2026 Capability Building project (CB5) "Next Generation Sequencing and supportive technologies to underpin food authenticity and safety"**, will be used, as these projects include distinct and fundamental elements associated with non-targeted and multi-analyte NGS approaches, portable instrumentation, and harmonisation and standardisation of analytical technologies inclusive of hand-held sensor/imaging based screening technologies. Key learning points associated with scope, limitations, harmonisation/standardisation and method validation guidance from these synergistic projects will be fed into the current FSA project to help inform and provide a fuller and more inclusive picture of the current state of the art and requirements for the future. Relevant guidance on standardisation/harmonisation activities delivered through these projects will be used to help align any resultant guidance from the current FSA project.

To help ensure the Horizon Scanning and Engagement initiatives of Phase 01 are truly representative of the current situation**,** key **international expert groups and global initiatives** with mandates associated with using Point Of Contact instrumentation for food authenticity testing will be contacted and accessed. These will include, but not be limited to, the **Food Authenticity Network** (FAN) to help canvas opinions on POC instrumentation, as well as provide access to expert individuals, learning experiences and **Centres of Expertise** associated with food analysis in general, and also the **"Global networking for food safety"**, which is a very recent European Commission (JRC) led initiative to develop a global network of laboratory experts using analytical technologies for a variety of health, safety and authenticity aspects related to food.

Insight on accreditation requirements for POC technologies will be assessed through engagement with the **United Kingdom Accreditation Service (UKAS)**. The contact point at UKAS associated with driving forwards the pilot study initiative on ISO 17025 accreditation for non-targeted food authenticity testing is know personally by LGC, through our input into this initiative at Defra's **Authenticity Methods Working Group** (AMWG) and via UKAS' regular and routine ISO 17025 audits of LGC's Teddington site. Such a contact will be used as part of the stakeholder engagement exercise, to ensure that any recommendations for validation guidance as a result of this project are fully in line and informed via the UKAS views on non-targeted approaches. Consultation with additional standardisation initiatives such as the CCQM Working Group on Nucleic Acid Analysis (CCQM-NAWG) will ensure a plurality of guidance and feedback. This is further augmented by LGC being the current chair of this international Working Group.

The central focus of this tender response is associated with CONOPS: the concept of operations. Whilst method validation in a controlled laboratory environment is essential for defining performance parameters and provision of analytical fitness for purpose, it is also imperative that stakeholders and end-users are consulted in terms of what their requirements are in the field. A core aspect of this proposal is therefore a thorough and intensive stakeholder engagement exercise with potential end-users inclusive of local authority enforcement officers, Public Analyst Official Laboratories, and National Reference Laboratories. Taking learnings from the recent and successful FSA FS900293 project which LGC led on, these engagement exercises will primarily be conducted as **on-line focus group meetings** to collate feedback from users, developers and regulators, where a pre-defined set of questions will be used to steer conversations as appropriate. The Project Team has close working relationships with food businesses, local authorities, and Government (FSA, Defra & FSS) and will engage with them via organised, category based, stakeholder focus groups to establish the needs in relation to the use of POC instrumentation for sampling and testing of food samples. A topic guide of questions will be prepared, in conjunction with the FSA, for use at the focus groups. A clear focus will be provided on stakeholder engagement with **Official Laboratories and National Reference Laboratories**, where **personal contacts** with the Heads of the relevant Laboratories are already established through frequent communications enabled by the Association of Public Analysts Training Officer [redacted] and the head of the UK National Reference Laboratory for GMO analysis [redacted] both of whom are based at LGC.

Stakeholder groups will be targeted, inclusive of (but not limited to) Local Authorities / Port Health Authorities (and associated laboratories), National Reference Laboratories, Central government, International counterparts and networks, Instrument manufacturers, relevant Centres of Expertise, and industry (retailers, manufacturers, etc.,).

The focus group meetings as part of the overall stakeholder engagement exercise will be further augmented through an **electronic survey** publicised through the Food Authenticity Network to collect broader stakeholder views. The stakeholder survey will build upon the focus group and previous FA0178 project survey to provide a more targeted assessment of current POC technologies. LGC has successfully

conducted e-Surveys through the FAN, with good response rates, as demonstrated through Defra project FA0178 and the recent FSA project FS900293. Building on the e-Survey conducted for the previous Defra FA0178 project, a list of questions specifically focused on recommendations for provision of guidelines for the validation and application of POC instrumentation for food authenticity testing will be developed, with a clear focus on applicability for UK official controls.
To further supplement this, initial steps have already been taken to engage with current POC users at the **Medicines & Healthcare products Regulatory Agency (MHRA)**, as the regulators for POC technology application in the clinical setting. The MHRA is an executive agency, sponsored by the Department of Health and Social Care, and is responsible for the regulation of medicines, medical devices and blood components for transfusion in the UK. They are one of the first expert groups to publish clear guidance on the use of POC instrumentation, albeit in relation to clinical diagnostic purposes. Key learnings from the MHRA guidance will be used and examined for transferability of the principles to the application of POC instrumentation for food authenticity testing, using the MHRA guidance to help inform and steer on the direction of travel for food testing. This will be facilitated through the unique position LGC holds in already hosting and operating the UK' Official Medicines Control Laboratory (OMCL) for chemical testing and British Pharmacopoeia Commission Laboratory, under contract to the MHRA. Initial contact has already been made with relevant experts and representatives within the MHRA, in order to engage with them further as part of this project proposal. By pre-contacting appropriate stakeholders at the MHRA, the Project Team have already ensured that relevant people at the MHRA will be available within the project timeframe and are already engaged with supporting the project.
Although the topic of foodborne pathogens is outside the scope of the current tender response, direct contact will be made with the **Pathogen Surveillance in Agriculture, Food and Environment Programme (PATH-SAFE)**. PATH-SAFE, a cross-government programme led by the FSA. PATH-SAFE is engaged in monitoring and tracking food borne pathogens and antimicrobial resistant (AMR) microbes in the UK, where Work Stream 3 of the PATH-SAFE programme involves testing the feasibility of using portable diagnostics as inspection tools and development of appropriate method validations workflows. Initial contact has already been made with appropriate staff at the FSA involved in the PATH-SAFE programme, and this tender response proposes to assess areas of synergy and learning opportunities to inform on the direction of travel for guidance supporting POC applications in the food authenticity testing sector. This will also help avoid any duplication of effort and ensure mutual complementarity between this current project and the PATH-SAFE programme.

Phase 02 - Development of POC Technology Guidelines for Official Controls
Results and conclusions from Phase 01 will be used in the establishment of appropriate validation guidance and associated dataset requirements, with a clear focus on transferability for official controls. The resultant guidance will also be informed based on the key recommendations and conclusions from Defra project FA0178.
Guidance on requirements is likely to be subdivided according to classical method validation parameters and the concept of operations, the latter of which will be steered by end-user requirements. The plethora of instrumentation which can be classified under the heading of a Point of Contact is ever expanding, and such instrumentation can differ in the technology type used, mode of action, method, application and generation of resultant datasets. From a pragmatic point of view, it is thus envisaged that two main sets of guidance may be produced: generic guidance which is universally applicable across all POC devices, but also core technology specific guidance which may be more bespoke and tailored to the individual performances and scopes of the different technologies. A likely demarcation of the technologies and associated guidance has already been highlighted in the Defra FA0178 project, which classified POC technologies into rotational vibrational spectroscopy platforms (NIR, FT-IR and Raman), spectral imaging platforms (multi- and hyperspectral imaging), mass spectrometry, NMR and biological analyte based platforms (proteins and nucleic acid-based). As the generation of data and interpretation of results will be tailored to the specific technology being used, it is envisaged that the guidance for requirements for the underlying datasets will also be technology specific and included as appropriate.

As per the project specifications, interim reports will be produced at two of the key stages during the project: an interim report outlining the Horizon Scanning and Engagement activity undertaken as part of Phase 01, and a second interim report detailing the approach to validating POC technology as part of Phase 02. To further augment this activity, we also propose an additional targeted stakeholder engagement exercise to present and discuss the draft guidance from the second interim report (Phase 02). This would consist of a brief "sanity check" with a select group of stakeholders, primarily official

laboratories, identified in Task 3 as part of the stakeholder engagement exercise, to ensure that the relevant views and recommendations have been captured correctly.
Following any feedback from this small stakeholder engagement exercise, a draft final report will be complied based on the outcomes and outputs of both Phase 01 and Phase 02, as detailed in the respective interim project reports, and further informed and refined following any feedback and comments received as part of the small stakeholder engagement exercise. This final report will outline the activities undertaken and the rationale behind the development of the guidelines.

Unique benefits that LGC affords to this tender

Project specific

Having delivered the Defra FA0178 project "Assessment of Point of Contact Testing Technologies to Verify Food Authenticity", LGC is uniquely positioned to immediately access the original FA0178 questionnaire, which contains feedback from over 170 respondents in relation to the utilization and gaps associated with the application of current POC instrumentation for food authenticity analysis. A deeper-dive into the responses associated with the original questionnaire with a focus on aspects associated with official controls and the wider food sector will provide the potential to update and refocus the Horizon Scanning and Engagement initiative as appropriate.
The recent FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity" which was led by LGC and completed in March 2023, very successfully implemented a range of stakeholder engagement activities and focus group meetings, which the current proposal will also mirror. Additionally, key learnings from the project in terms of a number of the synergistic aspects on the use of POC devices for the herbs and spices testing sector will be captured in the current project final report. Working further along the lines of synergistic activities and opportunities, LGC is also leading on the newly commissioned Defra project (C5263) on "Harmonisation and Standardisation in the Field of Next Generation Sequencing" as well as the core DNA and hand held imaging/spectroscopic technologies for food authenticity testing as part of a Capability Building project (CB5) in the new Government Chemist 2023-2026 programme. These projects include distinct and fundamental elements associated with non-targeted and multi-analyte approaches, portable instrumentation, and harmonisation and standardisation of analytical technologies inclusive of hand-held sensor/imaging based screening technologies. Key learning points associated with scope, limitations, harmonisation/standardisation and method validation guidance from these synergistic projects will be fed into the current FSA project to help inform and provide a fuller and more inclusive picture of the current state of the art and requirements for the future.
LGC also has access to related international expert groups and global initiatives with mandates associated with using Point Of Contact instrumentation for food authenticity testing. This includes running the Food Authenticity Network (FAN) to help canvas opinions on POC instrumentation, as well as provide access to expert individuals, learning experiences and Centres of Expertise associated with food analysis in general. Additionally, a recent European Commission (JRC) initiative has the mandate for a "Global networking for food safety", developing a global network of laboratory experts using analytical technologies for a variety of health, safety and authenticity aspects related to food, which LGC has been invited to be part of. Both areas have an interest in exploring the potential behind the use of POC technologies for food testing, and provide an unparalleled opportunity to source additional information, views and experiences from a targeted and expert audience. Consultation with additional standardisation initiatives such as the CCQM Working Group on Nucleic Acid Analysis (CCQM-NAWG) will help ensure that current best practice guidance/concepts are incorporated into project strategy and outputs. Discussions with the CCQM-NAWG will be further facilitated as LGC is the current chair of this international working group.

Part of the project specification is to remain abreast of and make contact with UKAS in relation to POC instrumentation, particularly so as part of the pilot study on non-targeted methods for food authenticity testing. The contact point at UKAS associated with driving forwards the pilot study initiative on ISO 17025 accreditation for non-targeted multi-analyte methods is know personally by LGC, through our input into this initiative at Defra's AMWG and via UKAS's regular and routine ISO 17025 audits of LGC's Teddington site. Such a contact will be used as part of the stakeholder engagement exercise, to ensure that any recommendations for validation guidance as a result of this project are fully in line and informed via the UKAS views on non-targeted approaches. The MHRA are also one of the few professional organisations that have developed published guidance on the use of POC instrumentation, albeit in a clinical diagnostics setting. LGC is in the unique position of hosting and operating one of the chemical testing laboratories under contract to the MHRA and has already made contact with relevant experts at MHRA who are happy to be made available for consultation within the proposed timeframe, facilitating a smooth start to the

project should this tender application be successful. Equally well, initial dialogue has been established with the FSA regarding suitable contact points and project officers for the POC aspects associated with Work Stream 3 of PATH-SAFE, ensuring that learning opportunities from PATH-SAFE can be capitalised upon to inform the direction of travel for guidance supporting POC application in the food authenticity testing sector, as well as ensuring no duplication of effort between projects.
Based on the published tender specifications, development of guidelines on the application of POC technology for the purpose of official controls in the food sector is a central theme. A clear focus will be provided on stakeholder engagement with Official Laboratories and National Reference Laboratories, where personal contacts with the Heads of the relevant Laboratories are already established through frequent communications enabled by the Association of Public Analysts Training Officer [redacted] and the head of the UK National Reference Laboratory for GMO analysis [redacted] both of whom are based at LGC and are included in this proposal.

Experience in Method validation and standardisation
Method validation principles and its practical implementation in a wide range of applications including food testing/authenticity are core to the proposed project team, the National Measurement Laboratory, the Government Chemist and LGC. Our expertise in the principles of method validation is demonstrated in a variety of ways:

- Our successful programme of method validation and measurement uncertainty courses delivered to over 5,000 participants, representing 775 organisations from 48 different countries over the past 20 years
- Publications including the EURACHEM guide "The Fitness for Purpose of Analytical Methods - A Laboratory Guide to Method Validation and Related Topics"
- Involvement in the revision of ISO17025:2017 (lab competency) with method validation and measurement uncertainty at its core.

We are also experts in the practical implementation of method validation, having validated hundreds of methods to ISO17025 or ISO9001 for various applications , including food testing/authenticity. We play a leading role in standardisation activities at both a national and international level. Our scientists are represented on over 60 committees providing worldwide authority on areas including standards and accreditation (ISO, CEN, BSI, ILAC, CITAC) and laboratory medicine (IFCC, JCTLM). We hold Chair or National Representative positions on over 20 of these, including ISO/TC 276 Biotechnology. We are typically involved in the production of around 30 documentary standards at any one time, with over 5 published per annum. Recently, our expertise in Metrology and Standardisation was recognised by the Biotechnology and Biological Sciences Research Council (BBSRC) who awarded £770k to National Measurement Laboratory to develop and deploy training opportunities in metrology and standardisation for engineering biology. The plans for this are to support (1) the provision of basic training on metrology, documentary standards and accreditation, (2) the provision of advanced training on engineering biology topics identified by key stakeholders and (3) review of documentary standards landscape and development of new 'flex standards'. Since October 2022 (project start), a steering committee was formed with representatives from 10 UKRI/BBSRC research centres, and a pilot training course run in February 2023.

General
LGC is uniquely positioned to deliver this project. Having acted as the UK National Reference Laboratory (NRL) for GMOs in food **and feed** since the establishment of the position in 2009, LGC has excellent relations with all UK based Official Laboratories, remaining aware of the technological capabilities of these and being in constant communication with them. The Heads of all Official Laboratories are known personally by LGC, which is further reinforced through the recent GMO analytical capability building exercises with the Official Laboratories, as part of the FSA Targeted Capability Building for UK controls. Additionally, the Head of the Office of the Government Chemist at LGC is also the appointed training officer for the Association of Public Analysts, further augmenting the relationships with all UK based Official Laboratories.

In addition to this, as a UK National Measurement Laboratory, LGC regularly participates in international metrology studies as part of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM). The mission of the CCQM includes responsibility for developing, improving and documenting the equivalence of national standards (certified reference materials and reference methods) for chemical and biological measurements, to establish global comparability of measurement results

through promoting traceability to the international system of units (SI) and other internationally agreed references, and to contribute to the establishment of a globally recognized system of national measurement standards, methods and facilities for chemical and biological measurements. The NML's international measurement claims are freely accessible.

Since 2002, the GMO National Reference Laboratory (held at LGC) has provided constant and consistent attendance at EC (JRC) led initiatives associated with method validation studies. This participation is above and beyond any other UK based laboratory, and all of the heads of EU GMO related NRLs are known personally by LGC. This helps facilitate continued national and international links, which are unsurpassed by any other UK based laboratory on the GMO front. LGC's core input into all GMO and method validation related activities has been acknowledged by the EU to such an extent that [redacted] (Principal Scientist at LGC) has been recognised as an independent international scientific expert in this area by the European Commission since EU exit in January 2021, facilitating consistent attendance at relevant scientific meetings, workshops, expert groups, advisory panels, conferences and training, continuing to allow free exchange of scientific information between the UK and EU, as well as provide a mechanism for foresight and horizon scanning.
LGC's scientific knowledge in the GMO area and method validation has further been demonstrated through the recent publication of the EU guidance on measurement uncertainty testing for GMO testing labs (3rd edition), which LGC is an author on, and the publication of the Royal Society of Chemistry book on molecular biology techniques, which LGC is an editor and author on, including significant content on portable technologies for food authenticity testing.

How this project fulfils the laboratory requirements listed as part of the specification
The focus of this project is on stakeholder engagement towards development of appropriate guidelines on the application of POC technology for official controls in the food sector. Hence there are no foreseen laboratory requirements or any practical requirements that are listed in the project specification.

However, the project specification states that all project reports must comply with the latest FSA accessibility guidelines in terms of formatting. LGC confirms that all reports (interim reports 1, 2 and the final report) will be formatted in line with the current version of the FSA accessibility guidelines. Demonstrable evidence of LGC preparing reports accordingly can be found in such examples as the published FSA FS301017 report on validation of multispectral imaging as well as the final report for FSA project FS900243 on the "Literature review on analytical methods for the detection of precision bred products" (in press).

The project specification also states that the tender must specify how FSA requirements will be met in terms of reporting. Following reception of a project report, the FSA will arrange a round of substantive comments as well as a subsequent round to finalise any minor outstanding comments, as part of the review process. The final report will be then subject to external peer review followed by additional amendments as necessary.
We propose to work with the appointed FSA project officer to ensure smooth delivery and agree a timetable for this. Delivery dates of the two interim reports and final report have been adopted accordingly, based on the published tender specifications and the FSA requirement for a normal expectation of two weeks to provide a coordinated response of substantiative comments. The smooth running of this process will be maintained through constant communication between the main project lead at LGC, the FSA Key Account Manager based at LGC, and the appointed FSA project officer. Communications will be facilitated by face-to-face meetings, email, telephone or Teams meeting as appropriate to ensure all parties are kept fully informed, as part of the overarching project management of the project. This will be augmented through regular catch-ups at monthly meetings and the scheduled quarterly review meetings.
A detailed description of how the Project Management Team will interact to deliver the desired outcomes can be found in the Section 5 "Project Management" part of this form.

Explanation of how the project advances knowledge in the area and provides the information indicated by the Specification Requirement document
How the project advances knowledge in the area
One of the main recommendations from the previous Defra FA0178 project was to further elaborate on the concept of operations (CONOPS), and to engage with end-users regarding what their requirements are.

This was in recognition that the end-users themselves are best qualified to state what the needs were, as well as recognising the end-users' expertise and experiences associated with POC technologies. Whilst classic laboratory-based method validation exercises are still a fundamental aspect underpinning the confidence in a method for provision of objective evidence that the method is fit for purpose, this is often conducted in a very controlled environment and may not necessarily be reflective of how the POC instrument is being used in reality in the field. It is further necessary to elaborate on the concept of operations, which would explore end-user requirements inclusive of expense, availability, capabilities, training, ease of use, size, portability, time to result, quantitative capability, food types, sample prep, and results interpretation.
This project directly addresses that issue through the proposed Phase 01 "Horizon Scanning and Engagement" activities, where a staged approach for evaluating the current uses and gaps associated with the POC technology for food authenticity testing will be conducted, as delivered through a series of a deep-dive questionnaire, alignment and input with national and international initiatives associated with POC technologies, stakeholder engagement and focus groups, use of virtual networks, and key contacts with UKAS, MHRA and PATH-SAFE to align with accreditation and published guidance.

Targeted questions will be used to explore in more detail the current purpose/deployment of POC instrumentation, as well as mitigation approaches of false positives when using POC instrumentation. This project will facilitate further engagement with end-users for a more informed understanding of what the requirements are to enable full potential of POC instrumentation to be realised.
This project advances current knowledge in the area by developing support mechanisms, focussing on method validation guidance associated with POC technologies, with a firm emphasis on how these can be applied for official controls. This will help inform potential users regarding the scope and utility of the POC instrumentation, providing additional confidence in results from this topical and growing sector, supporting its application as a further additional tool for fraud and authenticity testing in the food supply chain.

How the project provides the information indicated by the Specification Requirement document
In order to meet the specifications of the project, it is proposed to adopt the two-phased approach as suggested in the project specifications document. Phase 01 will consist of a Horizon Scanning and Engagement activity, evaluating the current uses and gaps associated with the POC technology for food authenticity testing, as delivered through a series of a deep-dive questionnaire, alignment and input with national and international initiatives associated with POC technologies, stakeholder engagement and focus groups, use of virtual networks, and key contacts with UKAS and MHRA to align with accreditation and published guidance.
Phase 02 consists of the generation of POC guidance, with a focus on its use for official controls. Account will be taken of both classic method validation parameters, as well as the aspects of the concept of operations (CONOPS), where the end-user helps provide a more informed decision on what the validation parameters should be. Both generic and technology/application specific guidance will be considered where appropriate as befits all of the technologies under the one POC umbrella term, and consideration will also be given to the generation and interpretation of results.
Phase 01 (Horizon Scanning and Engagement) will naturally inform and flow into Phase 02 (Development of POC Technology Guidelines for Official Controls), but parts of Phase 02 can run concurrently with Phase 01, as detailed later in the Gantt chart and Project Flow diagram ((please see Figure 2 in Section 3 of this form).

Page 3 of the Specification Requirement document explicitly states that proposals must demonstrate how the research being conducted will enable the development of guidelines. The supplier was advised to consider inclusion of a non-exhaustive list when developing the guidelines, which we have incorporated below with a detailed explanation of how each of these aspects will be directly addressed:

A clear definition of instruments which are in the POC technology umbrella.
The Phase 01 "Horizon Scanning and Engagement" activity will provide intelligence led evidence as to what current technologies (and instrumentation derived from) can be included under the blanket envelop of Point of Contact testing devices. This will consist of a deeper-dive into the responses from the FA0178 questionnaire, updated literature review, synergies with previous and supportive Defra/FSA projects, current synergistic projects (GC and Defra), international activities and expert groups, engagement with UKAS, MHRA and PATH-SAFE, and the stakeholder engagement exercise with focus group meetings. Equally well, the criteria defined in the previous Defra FA0178 project will be used to inform on the likely categories of POC technologies. At the current stage, it is envisaged that POC technologies can be split

broadly into 5 general subdivisions of rotational vibrational spectroscopy platforms (NIR, FT-IR and Raman), spectral imaging platforms (multi- and hyperspectral imaging), mass spectrometry, NMR and biological analyte based platforms (proteins and nucleic acid-based). Following the Phase 01 Horizon Scanning and Engagement activity, an informed decision will be made in relation to the generation of generic and/or technology specific guidance as appropriate.

An approach to validating a POC device being used for official controls.
Validation of a POC device in relation to official controls will be informed by taking into account the current capabilities of the Official Laboratories. This will be updated as part of the stakeholder engagement exercise and focus group meetings, but further augmented through the 2023 annual GC Survey of UK Public Analyst Official Laboratory capabilities: the 2022 survey contributed to a FSA Board paper on this topic. Validation will take into account classical method validation guidance and texts (e.g., ISO 9000, 9001 and 16140 series and related standards, and the EURACHEM guide "The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics"), but will also take into account the steer from the Phase 01 Horizon Scanning and Engagement activity on the concept of operations as informed by stakeholder engagement, where such criteria as expense, ease of use, time to result, portability, quantitative potential, sampling and results format/interpretation, may be of equal or greater importance.
Results from Phase 01 "Horizon Scanning and Engagement" activities and Phase 02 "Development of POC Technology Guidelines for Official Controls" will be used to inform on what generic validation guidance can be produced for POC devices in general, and whether guidance needs to be technology/instrument specific.

Clear guidelines on who is able to test food using POC technology for official controls and who the guidelines apply to.
As part of the validation approach, guidance will be provided to help inform end-users on the appropriate application of methodologies associated with POC technology for food testing. The remit associated with the specifications for this tender provide a firm focus on validation of POC technologies in the framework of official controls, so an emphasis will be placed on validation guidelines for official laboratories, Public Analysts, local authorities (including port health authorities), trading standards officers and environmental health officers.
Such guidance will be firmly founded in best measurement practice and steered as a result of the combined Phase 01 and 02 of the project, being influenced both by classic method validation standards but also informed by end-user requirements. The resultant guidance should have general applicability to any analytical laboratory, and the correct implementation of a validated method will be governed by a laboratory's own internal Quality Management System to ensure that the scope is fit for purpose.

General guidelines on operating POC instruments.
As outlined above, the plethora of types of technologies and number of instruments which can come under the umbrella term of Point of Contact is very broad. As a result of this, it is foreseen that the production of guidelines will form a two-tiered approach.
Firstly, any generic validation guidance which can be applied across all POC applications (irrespective of technology or instrument) will be examined, and relevant guidelines provided. Such guidance is likely to include minimum performance criteria, operating parameters, sampling, replication levels, training, adherence to instrument manufacturer's instructions, use of referee materials and databases, involvement of regulatory bodies, use of validated methods, and provision and adherence to WIs/SOPs/protocols, etc.,.
Secondly, recognising that the technologies, instrumentation and modes of operation can differ between POC devices, it is anticipated that technology/instrument specific guidelines will be provided where applicable, which are tailored to individual and specific applications. At the current stage, it is envisaged that POC technologies can be split broadly into 5 general subdivisions of rotational vibrational spectroscopy platforms (NIR, FT-IR and Raman), spectral imaging platforms (multi- and hyperspectral imaging), mass spectrometry, NMR and biological analyte based platforms (proteins and nucleic acid-based).

Reference to specific commodities testing which POC technology is suitable for.
As part of any method validation, the scope of operations of that method must be made explicit in the associated protocol e.g., if the method is applicable to liquids, agricultural commodities such as raw meat samples, flour, cereal grains, vegetable products, dairy products, starchy roots, sugar crops, sweeteners, oils, spices, wine, animal fat, fish and sea food, through packaging, etc. Where possible, guidelines will be

provided on the applicability of POC instrumentation to different commodity types, tailored according to the capabilities associated with each technology sector (e.g., NIR, FT-IR, Raman, MSI, HSI, mass spectrometry, NMR, genomics and proteomics). This will be further informed through the Phase 01 "Horizon Scanning and Engagement" activities, where end-user requirements and experiences/expertise with POC technologies and applications will be taken into account.

General guidelines on interpretation of results including the potential requirement of follow-up analysis.
The plethora of technologies and instrumentation which qualify as Point Of Contact devices is very wide and ever expanding, as advances are made in miniaturisation and portability of analytical equipment. This diversity also means that the mode of action of POC instrumentation will also be diverse, as will the generation of data and resultant outputs. To provide guidance for interpretation of results tailored to each technology may be beyond the remit and scope of the current project. However, general guidelines on interpretation of results will be addressed, focusing on the necessity for appropriate reference materials and databases to be used as the underlying comparators. Should the application of the POC instrument be regarded as a screening approach, recommendations will also be provided for appropriate follow-on analysis to be conducted in a laboratory environment using confirmatory approaches. This will be augmented through provision of clear recommendations regarding what would be needed to develop an infra-structure for developing unambiguous presentation of results and associated data interpretation, for each of the main POC areas under study.

Explanation of how the proposed objectives will meet FSA policy needs
The central theme of "Food you can trust" is described in the FSA Strategy 2022-2027 document. This central theme is supported by three pillars which encapsulate the FSA strategy, namely that food is safe, food is what it says it is, and food is healthier and more sustainable. A set of guiding principles are included in the FSA Strategy document, which set out how the FSA will work over the immediate future, one of which is that the FSA is science and evidence led: basing decisions on scientific evidence to help inform further work, policy and best practices in the food system. This science and evidence is used to tackle the challenges of today, to identify and address emerging risks, and to ensure the UK food and feed safety regulation framework is modern, agile and represents consumer interests.

Point of Contact (POC) technologies represent a new and innovative sector, gaining growing favour for their potential application in the food supply chain for food authenticity and fraud detection, becoming increasingly available as costs reduce and technological advancement means that scientific components are becoming increasing miniaturised and portable. However, whilst POC technologies have great potential for use in the field and at the point of application in the food supply chain, the sector is still somewhat in its infancy as applied to food analysis, and uncertainty can be generated in terms of how the POC instrumentation is being applied and how the results are to be interpreted. The scope and application of POC technologies need to be properly understood, so that relevant portable instruments can be applied with confidence for food analysis, and to help reduce the potential for false positive or false negative results.
The current project addresses this by providing a framework for horizon scanning activities and engagement with a range of stakeholders (end-users, official laboratories (NRLs and PA official laboratories), government, manufacturers, retailers, suppliers, expert working groups, food authenticity centres of expertise, the Food Industry Intelligence network, the National Food Crime Unit, the Scottish Food Crime and Incidents Unit, accreditation and standardisation bodies etc.,), as well as a questionnaire available through the Food Authenticity Network, to better assess the current gaps and requirements associated with POC technologies, and provide written guidance associated with validation of POC methods. Such harmonisation, informed through evidence led science and engagement, will provide the cornerstone for better understanding of POC technologies, inclusive of their scope and application.
Through the assessment of relevant performance characteristics and provision of objective evidence, method validation will ensure that approaches are fit for purpose, such that POC technologies can be applied with confidence, reducing any incidences of false positive and negative results.
Confidence in results generated through POC technologies will help inform potential users and prevent undermining the great potential of POC technologies for improving food safety and standards. This confidence in results generated through application of POC technologies in the food supply chain, will help ensure that food is safe and is what it says it is, further supporting the FSA policy and central theme of "Food you can Trust".

INNOVATION
Please provide details of any aspect of the proposed work which are considered innovative in design and/or application? E.g. Introduction of new or significant improved products, services, methods, processes, markets and forms of organization.
The utility of Point of Contact devices, being both portable and having application at specific points in the food supply chain, is innovative in itself. This project seeks to harmonise the application of POC technology, providing clear guidance in relation to method validation with a focus on the utility of POC instrumentation for official controls. As part of this tender response, an innovative project work-flow has been suggested, capitalising upon pre-established project links to data, networks and expert groups. Examples include having direct access to the original questionnaire responses as a result of the Defra FA0178 project, but also having established or made connections with key individuals and project officers as part of the Phase 01 "Horizon Scanning and Engagement" activities stakeholder engagement exercise, inclusive of the MHRA, UKAS and PATH-SAFE. Having made the pre-establish contacts helps ensure that the project can immediately start to run smoothly should this tender be successful, with no additional time being spent on having to request the FA0178 dataset or make new contacts with the listed stakeholders, further streamlining activities and providing value for money for the FSA. Synergistic activities will be capitalised upon through seeking opportunities with related projects and national/international initiatives, which also include development of POC technologies in their mandate. Examples include results from the recently completed LGC led FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity" on the use of POC devices for the herbs and spices testing sector, POC development and instrumentation use in the funded Defra C5263 project on "Harmonisation and Standardisation in the Field of Next Generation Sequencing" and the Government Chemist Programme 2023-2026 Capability Building project (CB5) "Next Generation Sequencing and supportive technologies to underpin food authenticity and safety", as well as international expert groups and global initiatives inclusive of the Food Authenticity Network (FAN), FAN Centres of Expertise, and the new European Commission JRC "Global networking for food safety" initiative. In this manner, informed learnings can be gained from related projects, ensuring that recommendations and guidance are aligned and harmonised, as well as avoiding any duplication of effort between the separate projects and initiatives. Focus group meetings with relevant stakeholders were an integral part of the recent FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity". These meetings were hugely successful, having likeminded stakeholders share their views, experiences and expertise on a central subject. It is proposed that such an innovative project design also be employed in the current project as part of the Phase 01 "Horizon Scanning and Engagement" activities, to maximise stakeholder engagement whilst streamlining resourcing inclusive of FSA funding and the project timeframe. Taking ley-learnings from the previous Defra FA0178 project which LGC led on, it is anticipated that two main sets of guidance may be produced as a result of Phase 02 "Development of POC Technology Guidelines for Official Controls". These will consist of generic guidance which is universally applicable across all POC devices, but also technology specific guidance which may be more bespoke and tailored to the individual performances of the different technologies. Such knowledge, gained from delivering the FA0178 project and appreciating the plethora of instrumentation which can be classified under the heading of a Point of Contact device, further streamlines the project work-flow and maximizes the use of FSA funding resources and time. From a more general and project supportive angle, EU exit has had a detrimental impact upon relations between the UK and EU, and a number of scientific services formally provided by the EU have been withdrawn to UK based entities, inclusive of access to training, workshops, working groups, meetings and proficiency test rounds. The lead applicant associated with this tender response [redacted] has continued to be fully involved in a number of EU related activities since EU exit, having been formally recognised as an independent international scientific expert in the areas of food and GMO analysis. This acknowledgement by the European Commission has facilitated [redacted] consistent attendance at relevant EU related scientific meetings and workshops. This provides unrivalled knowledge and continued

access to EU/EC intelligence and guidance on food analysis post the EU exit phase. Such a unique position will be captilised upon to seek continued awareness and alignment with related EU activities as part of the current tender (e.g., the new European Commission JRC "Global networking for food safety" initiative).

LGC houses the UK Government Chemist (GC) function, which has a role in helping safe-guard the quality of public science in relation to food analysis. The GC function has a statutory duty, underpinned by UK legislation, to provide impartial and independent referee analysis on a (food) sample as part of official controls, in cases of dispute between a trader/manufacturer and local authority. As such, this statutory role means that LGC needs to remain abreast of all modern analytical approaches and instrumentation, such that it can provide the necessary analysis and advice should a relevant referee case sample be referred to it. As a result of this, the National Measurement Laboratory at LGC is fully equipped with a range of all modern analytical instrumentation, inclusive of Point of Contact technologies (e.g., handheld FTIR, NIR and DNA instrumentation). Hence, LGC is already in a unique and innovative position regarding method validation of POC instrumentation and possesses an up-to-date awareness of what is currently available on the market.

3: THE PROJECT PLAN AND DELIVERABLES

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.

We propose the following project plan, further subdivided into tasks and sub-tasks as appropriate. Details for each task and sub-task can be found in the text beneath the table.

Phase 01 – Horizon Scanning and Engagement

	Phase 01 – Horizon Scanning and Engagement
Task/Sub-task	**Description**
1.0	Horizon scanning activity to understand the potential for POC technology in the food sector for official controls and wider food sector (e.g., used by the public or FBOs).
1.1	Deep-dive into questionnaire responses associated with Defra FA0178 project to inform direction of travel
1.2	Updated literature review
1.3	Alignment with synergistic activities from related projects
1.4	Scientific international engagement and global initiatives
2.0	Engagement with UKAS for insight on accreditation requirements for POC
3.0	Engagement with key stakeholders including potential end-users such as local authority enforcement officers, Public Analyst Official Laboratories, National Reference Laboratories
4.0	E-Survey on the Food Authenticity Network to collect broad stakeholder views
5.0	Engagement with current POC users including MHRA as the regulators for POC technology application in the clinical setting.
6.0	Monitoring and alignment of activities with PATH-SAFE
7.0	Interim report outlining the horizon scanning activity undertaken and stakeholder engagement.

Requirements

Task 1.0 - Horizon scanning activity to understand the potential for POC technology in the food sector for official controls and wider food sector (e.g. used by the public or FBOs).

Task 1.1 – Deep-dive into questionnaire responses associated with Defra FA0178 project to inform direction of travel

As part of the previous Defra FA0178 project, an on-line questionnaire was used to augment the landscape review via a stakeholder engagement exercise. This questionnaire looked at end-user requirements and was developed to target individuals involved in the food supply and associated diagnostics sectors, including primary production, supply and manufacturing, The questionnaire was advertised and published via relevant networks, with support from the FSA, Defra, IAEA, IFST and the FAN, and over 170 participants responded to the questionnaire.

Whilst primarily the responses to the questionnaire were used to assess views on the current applications of POC technology for food testing, it is proposed that this dataset (directly available both at LGC and Defra) should be further examined for its potential to inform on key food authenticity aspects tailored to the current tender, inclusive of the potential for POC technology use for official controls and the wider food sector. This will help provide a value-added springboard and infrastructure alongside objective led intelligence on the direction of travel and a steer for Task 1.2 on the literature review.

Task 1.2 – Updated literature review

An updated and thorough literature review will be conducted, to provide the basis for the current understating of POC technology potential for food testing as part of official controls and use in the wider food sector. As part of this literature review, the following information sources will be used:

Output from Task 1.1 (described above)

Key learnings from the recently completed LGC led FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity", which ran a synergistic study and literature review focussing on similar key terms and concepts inclusive of portable technologies, authenticity testing, method validation, targeted, and non-targeted approaches.

Electronic searches of the academic literature, including case studies, will be conducted using appropriate citation databases such as Scopus, Web of Science and PubMed.

A search, using search engines such as Google or Bing or Yahoo, supplemented by scholar.google.co.uk, to identify relevant professional, industry and governmental literature, including reports and Blogs, to include kit manufacturer commercial documents, conference reports, ISO/CEN standardisation activity, BSI, Codex, etc. The scope will be global in terms of English language publications.

It is proposed that the main focal point of the time period will be from 2019 onwards (since the original Defra project FA0178 was commissioned), to represent the growing interest and uptake in POC technologies and applications and to avoid duplication of effort since the previous review.

Task 1.3 – Alignment with synergistic activities from related projects

The scientific field of the use and scope of Point of Contact devices and applications is a very topical one, supported through a number of related projects. One of these includes the recently funded Defra C5263 project on "Harmonisation and Standardisation in the Field of Next Generation Sequencing" led by LGC, which will also focus on specific aspects associated with non-targeted and multi-analyte NGS approaches, with a potential emphasis on portable instrumentation, Additionally, the current Government Chemist Programme 2023-2026 includes a Capability Building project (CB5) on "Next Generation Sequencing and supportive technologies to underpin food authenticity and safety", which will focus on harmonisation and standardisation of analytical technologies inclusive of hand-held sensor/imaging based screening technologies.

Key learning points associated with scope, limitations, harmonisation/standardisation and method validation guidance from these synergistic projects will be fed into the current FSA project to help inform and provide a fuller and more inclusive picture of the current state of the art and requirements for the future. Relevant guidance on standardisation/harmonisation activities delivered through these projects will be used to help align any resultant guidance from this project.

Task 1.4 – Scientific international engagement and global initiatives

At a recent meeting, the European Commission (JRC) have proposed support for a "Global networking for food safety". This initiative seeks to develop a global network of experts that have a common goal in using DNA-based methodologies for a variety of health, safety and authenticity aspects related to food. Such a network will be invaluable in helping provide guidance on method validation parameters for related POC instrumentation for food analysis, providing an expert resource to help inform the current project. Equally well, the Food Authenticity Network (FAN), led by LGC, will be used to help canvas opinions on POC instrumentation where appropriate, as well as provide access to expert individuals, learning experiences and Centres of Expertise associated with food analysis in general.

Alongside these two networks, other international expert groups and global initiatives with mandates associated with using Point Of Contact instrumentation for food authenticity testing will be contacted and accessed, to help ensure the Horizon Scanning and Engagement initiative of Phase 01 is representative of the current situation.

Task 2.0 - Engagement with UKAS for insight on accreditation requirements for POC.
UKAS are currently developing and providing a pilot study initiative on ISO 17025 accreditation for non-targeted food authenticity methods, with a focus on screening applications and quality control processes associated with databases. LGC is aware of this initiative, having contributed towards the development of these guidelines via such routes as the AMWG, and the contact point at UKAS driving this forward is also known personally at LGC through attending routine and recent ISO 17025 audits of the LGC premises. LGC will continue to keep abreast of progress in this developing area, and has a named contact point at UKAS who is known personally by LGC and is directly involved in the pilot study work. UKAS guidance on non-targeted food authenticity methods will be directly incorporated into validation guidance as a result of the current project, but the two-way exchange of information will also be used to keep UKAS informed of this project's findings.

Task 3.0 - Engagement with key stakeholders including potential end-users such as local authority enforcement officers, Public Analyst Official Laboratories, National Reference Laboratories.
Task 3 comprises the core aspect of the stakeholder engagement exercise. Based on the very successful strategy for organising and conducting focus group meetings as part of the previous FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity", the same team will help prepare and run a series of stakeholder engagement exercises. Taking learnings from the FS900293 project, these engagement exercises will primarily be conducted as on-line focus group meetings to collate feedback from users, developers and regulators, where a pre-defined set of questions will be used to steer conversations as appropriate. Following participants' agreement, meeting transcripts will be used to provide outputs to inform on the end-user requirements.
The Project Team has close working relationships with food businesses, local authorities, and Government (FSA, Defra & FSS) and will engage with them via organised stakeholder focus groups to establish the needs in relation to the use of POC instrumentation for sampling and testing of food samples. A topic guide of questions will be prepared, in conjunction with the FSA, for use at the focus groups and it is anticipated that it will include but not be limited to those questions shown below. This approach was used successfully as part of the previous FSA FS900293 project "Review of methods for the analysis of culinary herbs and spices for authenticity" (final report submitted).
Example questions:
What are the main sectors that are using POC instrumentation for food authenticity testing?
What are the high priority food testing applications and samples that POC are currently being used for?
What are the technologies that are commonly being used for POC testing?
What do end-users see as some of the main gaps and limitations associated with the application of POC instrumentation?
What needs to be done in order to overcome some of these barriers and help promote uptake of POC instrumentation?
What are the requirements in order to help validate the technology for specific food authenticity applications?
What are the requirements from official laboratories in order that POC instrumentation can be used for control purposes?
What do end-users need in terms of general requirements for operating POC instrumentation?
Where do end-users see POC instrumentation being best applied in the future?
What aspects associated with interpretation of results would benefit more from further refinement, harmonisation and guidelines?
What confidence do end-users see in results from POC instrumentation, and is there a need for further confirmatory analysis?

A focus will be provided on stakeholder engagement with Official Laboratories and National Reference Laboratories, where personal contacts with the Heads of the relevant Laboratories is already established through frequent communications enabled by the Association of Public Analysts Training Officer [redacted] and the head of the UK National Reference Laboratory for GMO analysis [redacted] both of whom are based at LGC and are part of this project. Frequent contact with the relevant laboratories is already maintained on a regular and routine basis by these means, particularly so by the UK NRL for

GMOs as part of the current FSA GMO analytical capability building exercise in support of FSA targeted funding for Official Laboratories.

Stakeholder groups will be targeted, inclusive of (but not limited to):

Local Authorities / Port Health Authorities (and associated laboratories)
- Public Analysts, Official Laboratories and Association of Public Analysts
- Trading Standards (e.g., Buckinghamshire and Surrey Trading standards)
- Environmental Health officers
- Port Health Authorities (e.g., Suffolk Coastal Port Health Authority)

National Reference Laboratories
- (Interactions with this stakeholder group could also be augmented through further engagement at the annual NRL networking meeting, which was first established and organised successfully by Rashmi Seneviratne (FSA) in autumn 2022)

Central government
- Defra (main contact point as part of previous FA0178 project)
- FSA
- FSS
- The National Food Crime Unit
- The Scottish Food Crime and Incidents Unit
- MHRA

International counterparts and networks
- EC-JRC and Global Network for Food Safety

Instrument manufacturers
- LGC already has pre-established links with a range of POC instrument manufacturers, as facilitated through the previous Defra FA0178 project, which will be further built upon, and the current GC Programme 2023/2026 Capability Building 4 project

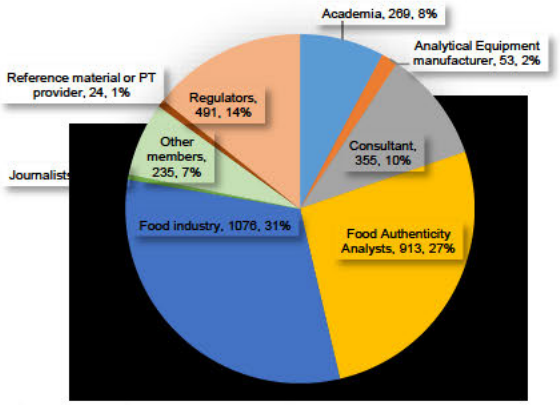
Relevant Centres of Expertise
- Food Authenticity Network designated Centres of Expertise for food analysis
- University of Strathclyde whom LGC has a long standing working relationship with, has a recognised Centre for Signal & Image Processing. Strathclyde have a world class reputation for innovative research into new algorithms, architectures and applications, providing a platform for the development of tools, techniques and systems used for the acquisition, analysis and extraction of information. Such imaging approaches form a fundamental part of many non-targeted and multianalyte applications.

Industry
- McCormick and Company
- The British Retail Consortium (BRC)
- Food and Drinks Federation (FDF)
- Food Industry Intelligence Network (FIIN)

Task 4.0 - E-Survey on the Food Authenticity Network to collect broad stakeholder views

FAN membership is currently at 3,440 people from ninety-three different countries. Membership by stakeholder category is shown in the figure below.

Figure 1: Membership by category of the Food Authenticity Network



FAN gives the Project Team access to a very large number of highly engaged stakeholders (as they have signed up to be members of a network that focuses on food authenticity testing and food fraud prevention), from whom, broad views on the applicability of POC instrumentation for food authenticity testing, will be sought.
LGC has successfully conducted e-Surveys on FAN, with good response rates, for three recent projects:
Defra food fraud project (report pending publication) – this survey was posted on FAN in June 2020 and attracted 330 responses.
Review of the National Food Crime Unit (NFCU) – Selvarani Elahi is currently part of a three-person team undertaking a review of the NFCU. The report of the Review will be discussed at the December 2022 FSA Board meeting. An e-Survey was sent to the 1,013 Food Industry members in September 2022 and 106 responses were received.
Defra POC Project (report pending publication). This e-Survey consisted of forty-two questions including where POC instrumentation was being used, what the high priority food applications were, and what the common technologies were e.g. NIR, FT-IR, Spectral Imaging (MSI/HSI) and Raman spectroscopy; MS; NMR; nucleic acids (PCR and NGS); Proteomics. It was posted in July 2020 on FAN and 1,702 responses were received from a range of stakeholders.
Building on the e-Survey conducted for the previous Defra FA0178 POC project, a list of questions specifically focused on recommendations for provision of guidelines for the validation and application of POC instrumentation for food authenticity testing will be sought, with a clear focus on applicability for UK official controls.

Task 5.0 - Engagement with current POC users including MHRA as the regulators for POC technology application in the clinical setting.
The Medicines & Healthcare products Regulatory Agency (MHRA) is an executive agency, sponsored by the Department of Health and Social Care, and is responsible for the regulation of medicines, medical devices and blood components for transfusion in the UK. As a result of this, the MHRA have a keen interest in the application of point-of-care testing devices (POCT): those transportable and portable instrumentation which can be used in the field at the point of application for diagnostic purposes. Recognising that both the instrumentation itself and the use of it can introduce additional variability into a diagnostic test, the MHRA were one of the first agencies to publish clear guidance on the use of POC, both in forms of the management and use of POCT technologies. Whilst this guidance is primarily aimed at medical health care professionals from a clinical standpoint, it also contains overarching principles and key learnings associated with the relevant application of a number of Point Of Contact devices for food analysis. Thus, the published guidance provides an invaluable resource on which to base additional conclusions for portable analytical technologies as applied in the different field of food authenticity testing. We therefore propose to inspect and use the published MHRA guidance on the POCT technologies, extracting key information relevant to the application of POC instrumentation for food authenticity testing, using the MHRA guidance to help inform and steer on the direction of travel for food testing.

To facilitate this, initial contact has already been made with relevant experts and representatives within the MHRA, in order to engage with them further as part of this project proposal. This has been facilitated through LGC hosting and operating the UK' Official Medicines Control Laboratory (OMCL) for chemical testing and British Pharmacopoeia Commission Laboratory, under contract to the MHRA. By pre-contacting appropriate stakeholders at the MHRA, the Project Team have already ensured that relevant

people at the MHRA will be available within the project timeframe and are already engaged with supporting the project.

Task 6.0 – Monitoring and alignment of activities with PATH-SAFE
As stated in the published project specifications, although the topic of foodborne pathogens is outside the scope of the current tender response, direct contact will be made with the Pathogen Surveillance in Agriculture, Food and Environment Programme (PATH-SAFE). PATH-SAFE ,a cross-government programme led by the FSA, is engaged in monitoring and tracking food borne pathogens and antimicrobial resistant (AMR) microbes in the UK. PATH-SAFE aims at improving existing surveillance exercises through investigating the use of new technologies such as whole-genome sequencing and a national sampling database.
Work Stream 3 of the PATH-SAFE programme involves testing the feasibility of using portable diagnostics as inspection tools. This includes testing the technology readiness levels (TRL) of portable diagnostic devices for rapid testing as well as developing appropriate method validations workflows. Whilst it is recognised that the evaluation of foodborne pathogens is outside the scope of the current tender response, it is proposed that direct contact will be made with PATH-SAFE through contacting and communicating with the appropriate FSA project officer(s), to assess areas of synergy, learning opportunities and to inform on the direction of travel for guidance supporting POC applications in the food authenticity testing sector. Initial contact with the appropriate FSA project officers has been made to this effect, through the recent Government Chemist conference at the Royal Society of Chemistry in London in June 2023, at which key LGC and FSA representatives were in attendance. The aim will be to both avoid any duplication of effort but also ensure mutual complementarity between this current project and the PATH-SAFE programme, further demonstrating good value for money for the FSA.

Task 7.0 - Interim report outlining the horizon scanning activity undertaken and stakeholder engagement.
An interim project report will be submitted to the FSA, detailing activities from the above tasks inclusive of Task 1 on the horizon scanning work (deep-dive questionnaire, literature review, synergies with other projects and global initiatives), Task 2 on monitoring and keeping abreast of relevant UKAS advice in this area, Task 3 on key stakeholder engagement and focus groups, Task 4 on the additional targeted questionnaire, Task 5 on learning opportunities on published MHRA guidance on POCT, and Task 6 on monitoring and alignment with related PATH-SAFE activities on portable instrumentation.

Phase 02 – Development of POC Technology Guidelines for Official Controls

	Phase 02 – Development of POC Technology Guidelines for Official Controls
Task/Sub-task	**Description**
8.0	**Development of guidelines on requirements for validation of POC technology and requirements for underlying datasets associated with key technologies identified in Phase 01**
9.0	**Draft interim report (2) detailing the approach to validating POC technology**
10.0	**Small stakeholder engagement exercise to present and discuss draft guidance**
11.0	**Final report outlining the activities undertaken and rationale behind the development of the guidelines**

Task 8.0 - Development of guidelines on requirements for validation of POC technology and requirements for underlying datasets associated with key technologies identified in Phase 01
Results and conclusions from Phase 01 will be used in the establishment of appropriate validation guidance and associated dataset requirements, with a focus on applicability for official controls. The resultant guidance will also be informed based on the key recommendations and conclusions from Defra project FA0178.
It is envisaged that two main sets of guidance will be produced: generic guidance which is universally applicable across all POC devices, but also technology specific guidance which may be more bespoke and tailored to the individual performances of the different technologies. Demarcation of the technologies and associated guidance, as informed by Defra project FA0178, is likely to include rotational vibrational spectroscopy platforms (NIR, FT-IR and Raman), spectral imaging platforms (multi- and hyperspectral

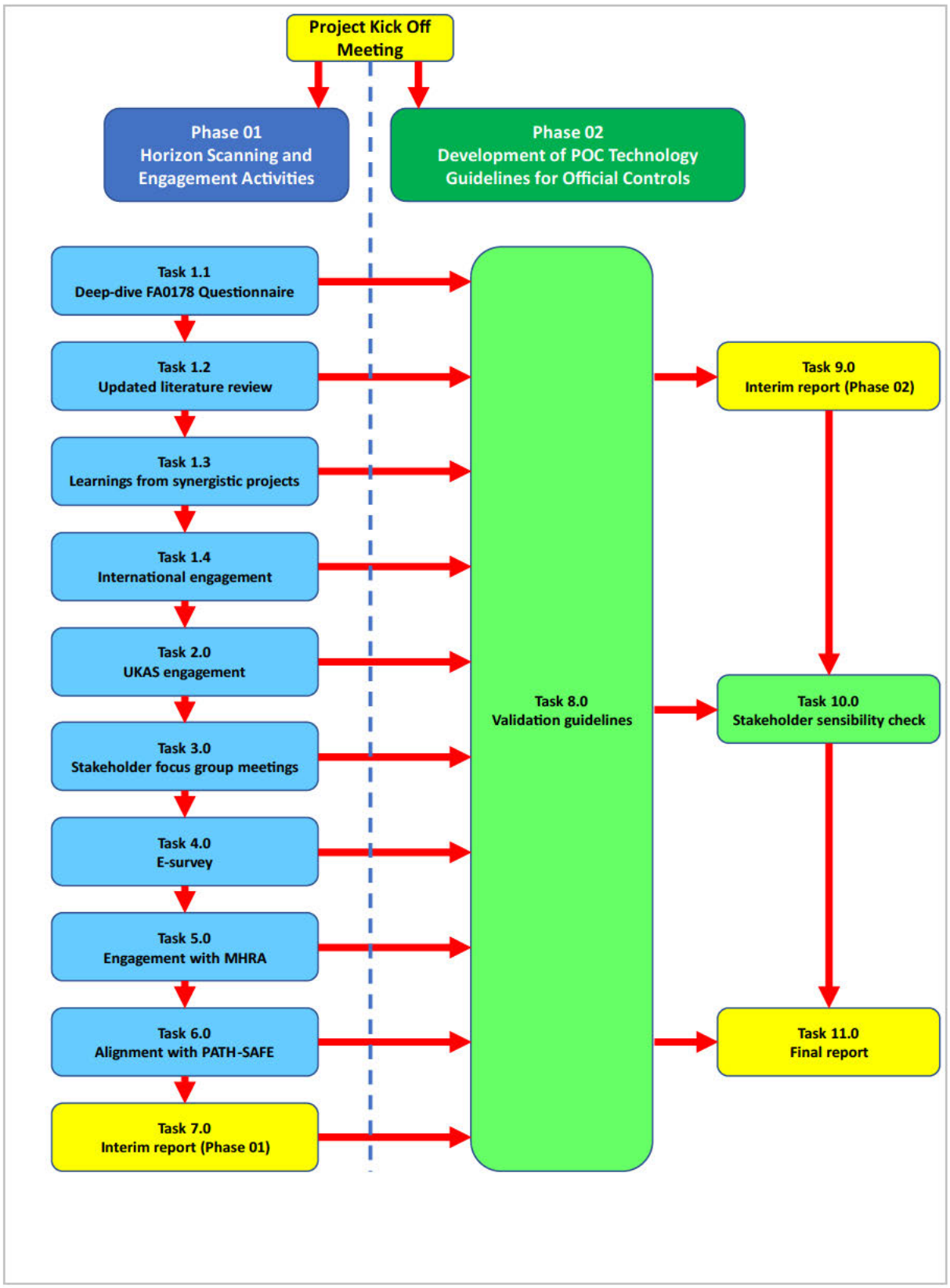
imaging), mass spectrometry, NMR and biological analyte based platforms (proteins and nucleic acid-based).
It is proposed that guidance on requirements be subdivided according to classical method validation parameters and the concept of operations/end-user requirements. For classical method validation, key texts and publications inclusive of the ISO 9000, 9001 and 16140 series and related standards associated with food analysis (performance parameters associated with single laboratory and interlaboratory validation), and the EURACHEM guide on validation of analytical methods, will be followed. Where appropriate, guidance will be provided on the assessment and minimum acceptance criteria of laboratory-based evaluation of parameters such as trueness (bias), precision (repeatability, intermediate precision, reproducibility), sensitivity, specificity, robustness, limit of detection, limit of quantitation and scope. Informed further through end-user requirements as assessed through Phase 01 of the study, guidance for requirements of POC technology is likely to include instrument expense, analytical capabilities, availability, ease of use, weight and dimensions, portability, time to result, quantitative capability, food types, sample preparation and results format and interpretation.

Task 9.0 - Draft interim report (2) detailing the approach to validating POC technology
An interim project report will be submitted to the FSA, providing details on the approach to use for validating POC technologies with a focus on official controls, as outlined in the previous task. As per Task 8.0, because of the breadth of instrumentation which can be included under the one envelope of "Point of Contact", it is envisaged that validation guidelines will be provided which are universally applicable across all of the technologies, as well as those more tailored towards the specific individual technologies themselves.

Task 10.0 - Small stakeholder engagement exercise to present and discuss draft guidance
As an appropriateness check, a small meeting will be held with key stakeholder groups identified in Phase 01 (particularly official laboratories), to request feedback and as an additional "sanity check" on the proposed validation guidance included in Task 9.0 for the draft interim report. These comments will be taken into account when preparing the draft final report in the next task (Task 11), providing the FSA with an additional level of peer review on the appropriateness of the proposed guidance and any further refinement which may be necessary.

Task 11.0 - Final report outlining the activities undertaken and rationale behind the development of the guidelines
A draft final report will be complied based on the outcomes and outputs of both Phase 01 (Horizon Scanning and Engagement) and Phase 02 (Development of POC Technology Guidelines for Official Controls), which were previously detailed in the interim reports as part of Tasks 7 and 9 respectively. These will be further refined based on any comments received by the stakeholder review (Task 10), as well as outlining the activities and rationale behind the development of the guidelines.

Figure 2. Flow chart illustrating the proposed project plan.


Project Kick Off Meeting
Phase 01
Horizon Scanning and Engagement Activities
Phase 02
Development of POC Technology Guidelines for Official Controls
Task 1.1
Deep-dive FA0178 Questionnaire
Task 1.2
Updated literature review
Task 1.3
Learnings from synergistic projects
Task 1.4
International engagement
Task 2.0
UKAS engagement
Task 3.0
Stakeholder focus group meetings
Task 4.0
E-survey
Task 5.0
Engagement with MHRA
Task 6.0
Alignment with PATH-SAFE
Task 7.0
Interim report (Phase 01)
Task 8.0
Validation guidelines
Task 9.0
Interim report (Phase 02)
Task 10.0
Stakeholder sensibility check
Task 11.0
Final report

Gantt chart to show activities carried out on a monthly basis.

Phase	Task	Brief Description	Month							
			1 Aug	2 Sept	3 Oct	4 Nov	5 Dec	6 Jan	7 Feb	8 Mar
01		**Horizon scanning activities**								
	1.1	Deep-dive FA0178 questionnaire								
	1.2	Updated literature review								
	1.3	Learnings from synergistic projects								
	1.4	International engagement								
	2.0	Engagement with UKAS								
	3.0	Stakeholder focus group meetings								
	4.0	E-survey								
	5.0	Engagement with MHRA								
	6.0	Alignment with PATH-SAFE								
	7.0	Interim report (Phase 01)								
02		**Development of POC guidelines**								
	8.0	Validation guidelines								
	9.0	Interim report (Phase 02)								
	10.0	Stakeholder sensibility check								

	11.0	Final report								

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:
no more 100 characters in length
self-explanatory
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 prosed work will automatically be calculated on the financial template.

DELIVERABLE NUMBER OR MILESTONE IN ORDER	TARGET DATE	TITLE OF DELIVERABLE OR MILESTONE
1.1	30/09/2023	DEEP-DIVE OF FA0178 QUESTIONNAIRE COMPLETE
1.2	30/09/2023	UPDATED LITERATURE REVIEW COMPLETE
1.4	27/10/2023	INTERNATIONAL ENGAGEMENT ACTIVITIES COMPLETE
2.9	27/10/2023	ENGAGEMENT WITH UKAS COMPLETE
3.0	27/10/2023	STAKEHOLDER FOCUS GROUPS HELD
4.0	27/10/2023	E-SURVEY ON STAKEHOLDER VIEWS COMPLETE
5.0	27/10/2023	ENGAGEMENT WITH MHRA COMPLETE
6.0		ENGAGEMENT WITH PATH-SAFE COMPLETE
7.0	27/10/2023	DELIVERY OF PHASE 01 INTERIM REPORT (1) ON HORIZON SCANNING AND ENGAGEMENT
8.0	19/01/2024	VALIDATION GUIDELINES FOR POC TECHNOLOGIES COMPLETE
9.0	19/01/2024	DELIVERY OF PHASE 02 INTERIM REPORT (2) ON APPROACHES FOR VALIDATING POC TECHNOLOGIES
10.0	29/02/2024	STAKEHOLDER SENSIBILITY CHECK COMPLETE
11.0	22/02/2024	DELIVERY OF DRAFT FINAL REPORT

4: 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.

Example #01
Contract Name: Defra project (FA0178) 'Assessment of Point of Contact Testing Technologies to Verify Food Authenticity'
Contract Number: FA0178
Organisation name: Department for Environment, Food and Rural Affairs (Defra)

[redacted]

Contract Start Date: November 2019
Contract Completion Date: July 2021
Contract Value (£): £134,582
A brief description of the work carried out, demonstration of relevant skills and expertise, and what skills the team used to ensure the project was successfully delivered:
Point of contact technologies (POC) represent an emerging suite of tools to support food authenticity testing. Whilst the application of POC technologies is well developed in the clinical diagnostic community, a variety of systemic and structural challenges exist within the foods testing area.
The Defra FA0178 project comprised an initial comprehensive landscaping review that included a literature assessment and engagement with a broad range of stakeholders through activities such as online questionnaires, discussions with technology developers/users and industry bodies, and discussions with UK Government departments and agencies. The outputs from this phase of the project informed a feasibility study focused on evaluating the performance of three instrument platforms representative of priority analytical technologies mass spectrometry, Next Generation Sequencing and Near-infrared spectroscopy). A topical meat adulteration testing scenario was employed across all three test platforms which allowed for comparative performance to be investigated and for key functionality and capabilities to be assessed. Core project outputs included individual reports covering the technology landscape, an assessment of step-changes/barriers to uptake, an assessment of support mechanisms and a practical feasibility study. A comprehensive set of guidance and recommendations were developed as part of the project to help support POC within the foods sector.
The project required a broad set of skills ranging from engaging effectively with stakeholders (crucial to the success of the project) across multiple areas (demonstrating flexibility and networking capabilities) to the capability to evaluate multiple analytical technologies with active developer support (technical and scientific expertise). The breadth of reports generated as part of the project highlighted the ability to effectively collate, condense and analyse large amounts of information resources from publications and stakeholder feedback. The project effectively applied communication skills and strategies which ensured good stakeholder engagement and supported project dissemination activities to help ensure successful project completion.

Example #02
Contract Name: FSA project (FS900293) "Review of methods for the analysis of culinary herbs and spices for authenticity"
Contract Number: FS900293
Organisation name: Food Standards Agency

[redacted]
Contract Start Date: December 2022
Contract Completion Date: March 2023
Contract Value (£): £59,385
A brief description of the work carried out, demonstration of relevant skills and expertise, and what skills the team used to ensure the project was successfully delivered:
This project provided an up-to-date review of the current use and applicability of analytical methods for the determination of culinary herbs and spices. A review of current and emerging method for the analysis of herbs and spices was conducted, comparing and contrasting analytical methods. As part of this, broader stakeholder views on methods were collected and collated via a series of successful engagement and focus group exercises, in order to get a representative cross-section of views from target groups inclusive of industry, local authorities, central government, and instrument manufacturers.
Delivery to time and budget was achieved for this project, despite the tight turn around time, as facilitated through active project management between the FSA appointed officer and the LGC project management team, as supported through regular catch-ups. The literature review was augmented through sub-contracting the work to Queen's University Belfast.
Skills and expertise from this project, inclusive of organisational and operational aspects associated with focus group meetings and links with industry, manufacturers, Official Laboratories and central government, will be capitalised upon for delivery of the current C173168 tender proposal. A number of the stakeholders from the above FS900293 project and the C173168 tender proposal are similar, working in areas using POC technology for herbs and spices testing, so contacts have already been established and will be used accordingly.

[redacted]
Contract Start Date: December 2014
Contract Completion Date: February 2016
Contract Value (£): £118,895
A brief description of the work carried out, demonstration of relevant skills and expertise, and what skills the team used to ensure the project was successfully delivered:
This project evaluated the applicability of modern molecular biology methods to detect and quantify meat species around the 1% (w/w) level for enforcement action with a focus on processed food materials. Three techniques were evaluated: real-time PCR, droplet digital PCR and a label-free mass-spectrometry (MS) approach. Good quantitative performance (down to 0.1% (w/w) limit of quantitation and applicable for detection of adventitious contamination) was observed for the PCR-based methodologies, with ddPCR demonstrating the best analytical precision particularly associated with the 0.1% (w/w) canned meat test material. The chosen label-free MS technique, whilst simple and cost effective, did not perform as well in terms of identification and quantitative capability when applied to processed food materials.
Technical capability in this area was demonstrated through managing this multidisciplinary project, preparing gravimetric meat samples, applying advanced molecular biology approaches and subsequent data analysis and interpretation of balanced experimental designs. Core method validation skills were use to objectively evaluate and compare and contrast the performance characteristics of the different analytical technologies and instruments. Measurement uncertainty estimates were made for each of the core technologies, and hands-on experience and knowledge gained as a result of this project in terms of an appreciation of the applicability of a wider range of analytical technologies suitable for supporting food testing and controls, as well as how best to summarise and present scientific results from a range on analytical platforms.

Additional LGC Experience
LGC provides a range of consultancy and research services in support of Government policy. These include statutory functions such as the Government Chemist (GC) Function. The role of the UK GC has existed formally

since the 1875. Under the provisions of many Acts of Parliament, but significantly the Food Safety Act 1990 and the Agriculture Act 1970, the GC acts as an independent referee in cases of dispute between enforcement authorities and industry.

LGC also delivers National Reference Laboratory (NRL) functions for the following areas:

- Genetically modified organisms (GMOs) in food and feed – control and authorisation;
- Added water in poultry;
- Feed Additives – Authorisation;
- Feed Additives – Control;

Consequently, LGC staff are very familiar with the enforcement system in the operation in the UK for chemical contaminants because of the statutory and advisory responsibilities of the GC. LGC staff are in regular dialogue with Port Health officials, Trading Standards Officers, PAs, Agency officials and industry representatives in relation to possible, impending or actual official action regarding food contaminants.

Furthermore, the GC regularly produce documents in the form of guidance notes or other briefing notes that offer advice and procedure to reinforce current practice, examples include published papers on evaluation of data in the absence of statutory limits, a toolkit for adopting a weight of evidence evaluation procedure (in production) and guidance on sampling of rice and rice products for genetically modified organisms.

The housing of the GC and the National Measurement Laboratory and Designated Institute for Chemical and Bio-measurement (NML) in the same organisation is of enormous benefit as they are synergistic statutory roles. In addition, the NRL and GC functions have been mutually complimentary and have augmented each other in terms of provision of expert advice and guidance: for the Chinese GM rice issue (EU Commission Implementing Decision 2011/884) the NRL position provided the knowledge regarding the legislation and guidance on the approved approaches for analysis, whilst the GC function has provided advice regarding the hands-on and practical application of the techniques required for analysis and the associated experience from experimental application. The resultant combined advice and experience, uniquely facilitated through the collective knowledge of the NRL and GC functions, has been disseminated to the benefit of stakeholders within the UK, and as the NRL, LGC is assisting in the upskilling of PA OLs in relation to GMO measurement capability.

LGC deploying the statutory functions of GC, NML for chemical measurements and NRL avoids technical duplication thus offering an efficient use of Government funds.

Method validation is key to method robustness and successful transfer and adoption of novel methods and technologies for routine applications. The NML is an expert in method validation as a training provider and the Designated Institute for Chemical and Bio-measurement. Method validation and transferability are at the core of our measurement research activities. As a training provider, we have been running method validation and measurement uncertainty courses for the past 25 years (755 Organisations in 47 countries and 4820 delegates).
With regards, to laboratory expertise, our scientists develop and validate analytical methods for a wide range of applications such as diagnostics, therapeutics, food and environment. Those methods are developed and validated in accordance with ISO17025 or follow its principles. Over the years, we have validated 100's of methods that were published or transfer to third party laboratories. Below are some examples.
With such an experience, we are well aware of challenges around sample matrices, sensitivity and selectivity, validation status, costs (for set up, accreditation and maintenance of testing), transferability (including training, ease of use), availability of reference materials and proficiency testing.

Additional activities at LGC that will benefit the project

Programme Management and Commercial team & Key Account Management team
LGC's National Laboratories operate a dedicated Key Account Management function, and together with the Programme management and commercial Team, they are responsible for managing government contracts and relationships. Selvarani Elahi, Deputy Government Chemist, and Will Webster, the contract manager will function as the primary points of contact for commercial or contractual matters. This would include contract onboarding, the management of commercial reviews, contract variations, as well as performance reporting and route of escalation for issues arising.

The Programme Management and Commercial Team is part of the National Measurement Laboratory (NML) and is office-based providing programme, contract and commercial management to support to LGC's national roles as the NML and the GC. The team is composed of very experienced programme and project managers, commercial service managers (measurements, training and consultancy) and a continuous improvement manager. The team manages large Government programmes (>£12m per year) i.e. monitoring cost/progress, reporting and invoicing using our Enterprise Resource Management system. The team also deals with more than one hundred commercial projects per year, facilitating all the steps i.e. initial discussion, quotation, delivery, reporting and invoicing for the NML products and services. The delivery of this contract will be supported by this team.

As key account manager, Selvarani will also continue to ensure excellent communication between the FSA and teams within LGC ensuring the Agency is briefed on all aspects of this project and any relevant novel technologies, pilots and innovation taking place across the organisations that may be of interest.

Horizon scanning
At LGC, the GC programme conducts a review of food and agriculture legislation to assess the likely impact on the analytical capabilities required by the GC, with key changes and developments captured in quarterly reports to the UK Department for Business, Energy & Industrial Strategy (BEIS). As part of the horizon scanning activities, the GC also monitors worldwide food notifications for emerging trends. These reports provide a review of developments in food and feed law and related scientific and regulatory issues that affect the UK, and are easily accessible via the GC website at: https://www.gov.uk/government/organisations/government-chemist This allows LGC to keep up-to-date on impending revision of legislation and intelligence on emerging legislative issues regarding contaminants and safety, which might impinge on market acceptability of products.

LGC Training
LGC has been providing training courses for analytical scientists worldwide for over 25 years. Our long history and role as the UK's National Measurement Laboratory for chemical and bio-measurement means that we have a wide range of expertise in analytical techniques such as chromatography, mass spectrometry and hyphenated techniques. We offer live courses both face-to-face and online, as well as web based eLearning modules. Our courses cover topics such as quality systems, statistics, method validation and measurement uncertainty. We offer a scheduled programme of courses, as well as delivering training for individual customers (both in-person and virtually). Details of our courses can be found at https://www.lgcgroup.com/measurement-services/training-and-consultancy/our-training-courses/

LGC also operates the Joint Knowledge Transfer Framework for Food Standards and Food Safety Analysis, which is a cross-government project (funded by the Department for Environment, Food and Rural Affairs, the Food Standards Agency, Food Standards Scotland and the GC) aimed at disseminating knowledge from government funded research to stakeholders to support UK laboratory capability and promote best practice in food safety and standards analysis. The project commenced in April 2017 and by March 2023, it is anticipated that twenty-nine knowledge transfer outputs will be delivered. Food authenticity related outputs can be found on the Training pages of the Food Authenticity Network, whilst all output (food safety and food authenticity) can be found on the Knowledge Resources section of the Government Chemist website.

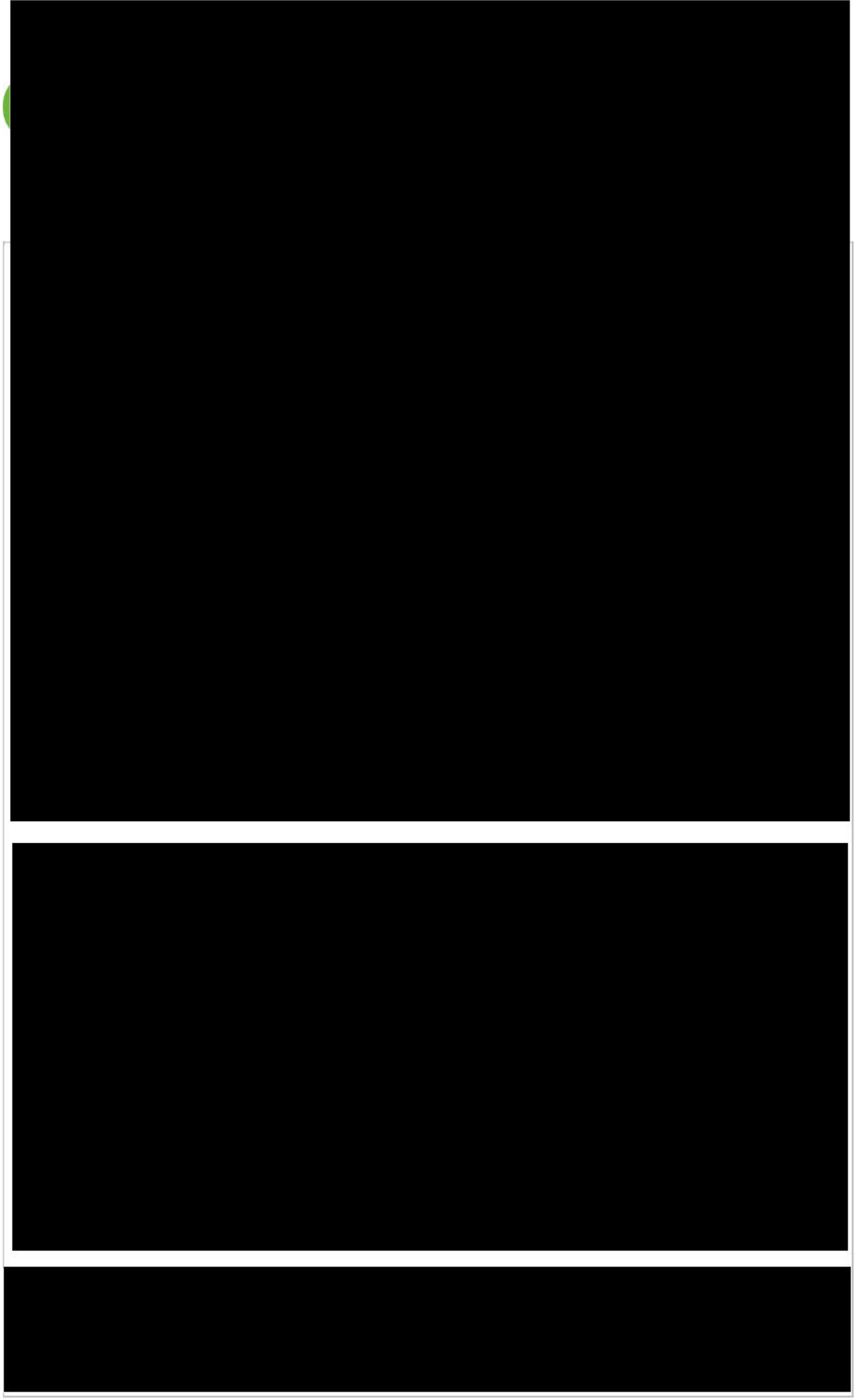
B. NAMED STAFF MEMBERS AND DETAILS OF THEIR SPECIALISM AND EXPERTISE

Lead Applicant	LGC Limited
Named staff members, details of specialism and expertise.	

LGC is a leading, global life science tools company, providing mission-critical components and solutions into high-growth application areas across the human healthcare and applied market segments. Our high quality product portfolio is comprised of mission-critical tools for genomic analysis and for quality assurance applications, which are typically embedded and recurring within our customers' products and workflows and are valued for their performance, quality and range.

LGC has extensive experience in successfully managing multidisciplinary projects (at both a National and European level), with the quality of project management and analytical research assured through certification to ISO 9001.

Selvarani Elahi MBE BSc, CChem, FRSC, FIFST
UK Deputy Government Chemist



[redacted]

Participant Organisation 1	
Named staff members, details of specialism and expertise.	

Participant Organisation 2	
Named staff members, details of specialism and expertise.	

Participant Organisation 3	
Named staff members, details of specialism and expertise.	

C. STAFF EFFORT

In the table below, please detail the staff time to be spent on the project (for every person named in section above) and their role in delivering the proposal If new staff will be hired in order to deliver the project please include their grade, name and the staff effort required.

Name and Role of Person where known/ Role of person to be recruited	Working hours per staff member on this project
[redacted]	37.5
	187.5
	120
	15
	15
	37.5
Total staff effort	412.5

5: PROJECT MANAGEMENT

Please fully describe how the project will be managed to ensure that objectives and deliverables will be achieved on time and on budget. Please describe how different organisations/staff will interact to deliver the desired outcomes.
Highlight any in-house or external accreditation for the project management system and how this relates to this project.

How the project will be managed to ensure objectives and deliverables are achieved on time and to budget

The concept and practice of project management is well established within LGC and the organisation considers its implementation to be fundamental to the successful planning, execution and delivery of work programmes to complete customer satisfaction. LGC has accumulated considerable experience in the management and delivery of complex work programmes for its customers. LGC's proven track record of good delivery on customer projects owes much to careful planning and the systems in place for monitoring progress towards objectives.

LGC uses the following mechanisms for performance monitoring/measuring:

- Project Management Tools (IFS)
- Specific milestones and performance targets
- Contingency plans (including a Business Continuity Plan)

By comparing actual against planned progress on a frequent basis, (by regular meetings of Team Leader, project managers and other relevant staff) responsible staff are able to assess progress towards deliverables and, if necessary, make any adjustments to the resources required to ensure delivery within the specified time frame of the project as a whole.

In addition to the formal monitoring of project progress, all LGC staff work to an annual individually tailored forward job plan (FJP) agreed with their line managers. These in turn are linked to the business objectives and targets of the company and individual Teams. Individual objectives in a forward job plan at the team level will include work on specific customer programmes, expected outputs, and key performance indicators to monitor performance against the objectives set. FJPs are reviewed periodically and if necessary adjusted so that they remain aligned to our business and the services we provide to our customers.

Running in parallel to the operational performance programme, the financial performance of the project is monitored on a regular basis so that we remain competitive and provide value for money to the customer. LGC's financial reporting tools allow project managers to obtain detailed information on all financial aspects of each project.

Project management processes will adhere to the LGC Group Quality Manual and applicable local quality procedures. These set out the scope, objectives, responsibilities, and procedures required to delivered effective project management. To support this the NML operates a regime of regular internal audits conducted by our pool trained auditors to ensure that all quality control and quality assurance requirements are fully implemented.

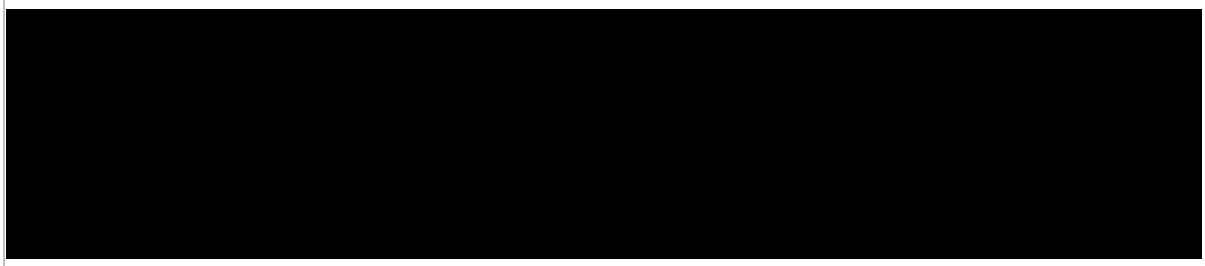
All staff at LGC are trained following documented knowledge transfer programs and procedures. Their training and development needs are regularly reviewed. All instrumentation at LGC is appropriately calibrated and maintained. Local work instructions (WIs) are used in laboratories to provide detailed instructions for the calibration and operation of equipment such as daily temperature checks on fridges and freezers, daily balance checks and also to assess the suitability of use.

External accreditation associated with Quality and Project Management Systems

All of LGC's activities are registered under BS EN ISO 9001 (2002). The majority of analyses routinely offered by LGC are accredited by UKAS to ISO 17025 and specific areas are compliant with Good Laboratory Practice. The quality procedures followed by LGC are in line with the guidelines outlined in the Joint Code of Practice for Research. Members of the official project management etam at LGC hold PRINCE2® Practitioner certificates in project management.

Project Management Team

A project management team shall be constituted which will make day to day technical decisions regarding the delivery of the project. Official titles and roles at LGC are provide next to the names of the project team below, with anticipated roles tailored for the project proposal provided in parentheses and in italics.
The project team will consist of:



How the Project Management Team will interact to deliver the desired outcomes

The Principal Investigator will remain responsible for the overall project as well as for planning and decisions associated with it. They will act as the key Principal Scientist in relation to the quality of the science delivered, and will provide technical oversight and consultancy on the scientific activities carried out under the project.

The Operations Manager will have responsibility for the day-to-day management, co-ordination and delivery of the overall project. The Operations Manager will be the key contact with the Food Standards Agency's Project Officer and will take direction from the Principal Investigator in terms of planning and quality of the science. They will be assisted in their role by the following members of the proposed project management team.

The FSA Key Accounts Manager is responsible for managing government contracts and relationships, acting as one of the primary points of contact for commercial and contractual matters, inclusive of contract onboarding, the management of commercial reviews, contract variations, as well as performance reporting and a route of escalation for any issues should they arise. The key account manager will continue to ensure excellent communication between the FSA and teams within LGC ensuring the Agency is briefed on all aspects of this project and any relevant novel technologies, pilots and innovation taking place across the organisations that may be of interest.

The Specialist Support Officer, having experience of working in the field with POC instrumentation, will provide scientific, technical and administrative assistance to the Operations Manager. They will provide core assistance for the literature review and help establish key contacts and focus group meetings as part of Phase 01 "Horizon Scanning and Engagement" of the project, as well as helping develop the key validation criteria as described in Phase 02 "Development of POC Technology Guidelines for Official Controls".

The Head of the Office of the Government Chemist, also having the role of the Association of Public Analyst Training Officers, will interact with the Operations Manager through using pre-existing links and communication channels with UK Official Laboratories (Public Analysts). They will promote and encourage engagement as part of Task 3 "Stakeholder focus group meetings" and throughout Phase 01 "Horizon Scanning and Engagement" of the project. Furthermore, they will invite feedback from Official Laboratories as part of the draft method validation guidance which is being produced in Phase 02 "Development of POC Technology Guidelines for Official Controls", helping ensure recommendations have captured and are representative of the requirements of this Key Stakeholder group.

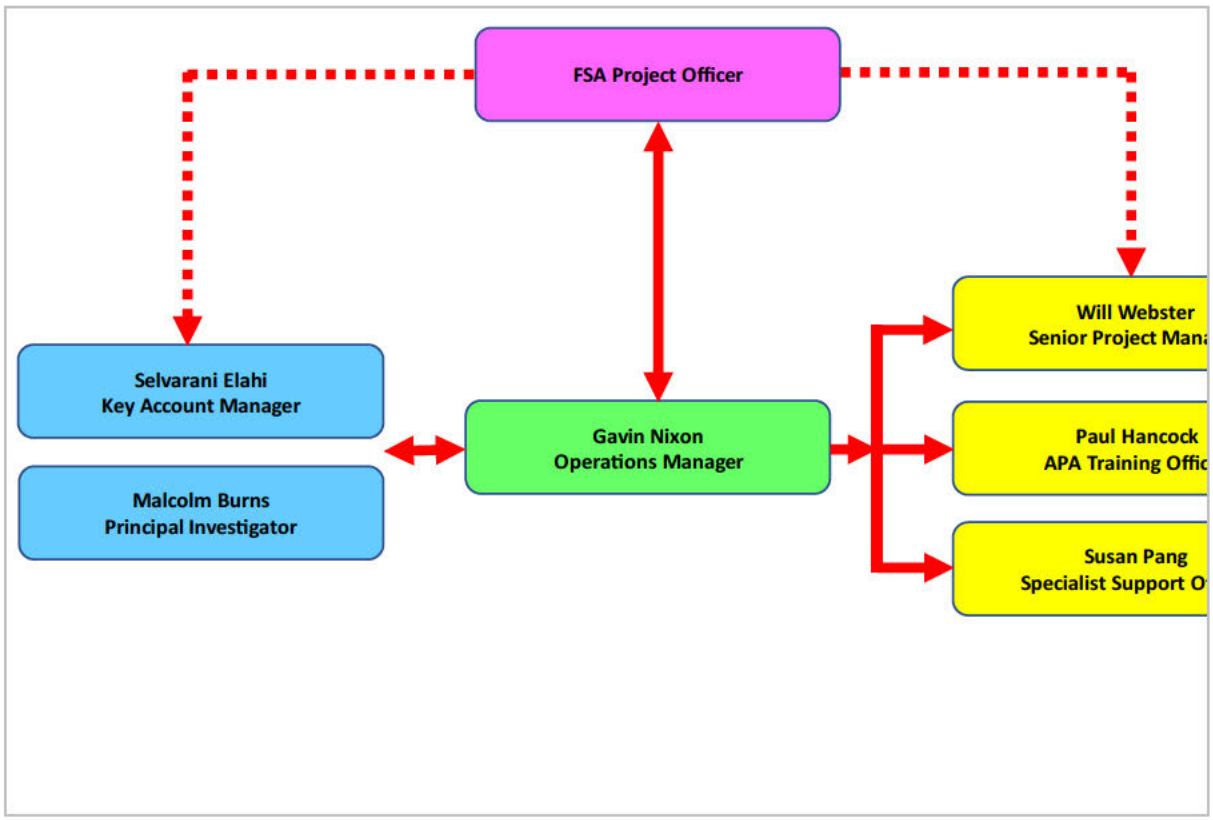
The Senior Project Manager will be responsible for administrative project management support to the team, particularly in relation to the financial project and contract management support. This will include regular monitoring of actual against planned progress for the project, making any resource adjustments as appropriate to ensure delivery to time and budget. The Senior Project Manager will take direction from the FSA Project Officer in relation to release of invoices as part of this project.

All staff at LGC are trained following documented knowledge transfer programs and procedures. Their training and development needs are regularly reviewed. All instrumentation at LGC is appropriately calibrated and maintained. Local work instructions (WIs) are used in laboratories to provide detailed instructions for the

calibration and operation of equipment such as daily temperature checks on fridges and freezers, daily balance checks and also to assess the suitability of use.

Should additional personnel be required to help address or organise any of the events described as part of the tasks in this proposal, a pool of 25 other qualified researchers and research analysts from within the Molecular Biology Team at LGC can be called upon.

Figure 3. Project delivery organogram illustrating the interactions between the proposed Project Team.



6. 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
Personnel	low	medium	No difficulties in personnel availability are foreseen at the current time. However, deputy Project Leads (Gavin Nixon and Susan Pang) have been identified and will be appointed in case of the primary project lead being unavailable. LGC possesses broad technical expertise to allow evaluation of methods across multiple techniques and platforms, and this expertise does not lie exclusively with those named in this tender. As such alternative experts will be able to assist if required. The project will be based within a team of around 25 experienced researchers in the molecular biology field, enabling sufficient coverage in the event of staff loss. All staff are cross trained so that we have multiple staff qualified in relation to knowledge and scope of associated analytical instrumentation.

Insufficient capacity due to COVID-19 / other sickness absences	low	medium	1.) Staff provided with laptops and secure two-step log in authentication (including independent user verification stage) to enable and encourage work from home if necessary, minimising footfall on site. 2.) LGC encourage staff to adhere to national self-isolation/quarantining requirements. LGC has introduced a global policy allowing employees to request up to 10 days paid emergency leave to deal with exceptional, unplanned emergency situations that arise out of COVID-19. 3.) All staff are cross trained so that we have multiple staff qualified to work on analytical projects at any one time.
Catastrophic incident	low	high	LGC maintains corporate and local registers to regularly review, prevent and mitigate the impact of anticipated risks, including critical supplier or facility loss. Approved secondary suppliers are in place for key items. LGC is a global business with multiple UK and international sites and could, if necessary, relocate delivery capabilities (staff, kit and consumables) to alternative location(s). As indicated above, staff are provided with laptops and remote access to LGC system to enable homeworking. Laboratory facilities are not required for this project.
IT system failure	low	medium	LGC's Risk Steering Committee conducts a quarterly review of risk-related matters, including cyberattacks. Extensive measures are in place to prevent system failure (e.g. firewalls, Forcepoint web filtering, Sophos anti-malware, 'Splunk' network traffic monitoring, Darktrace network scanning), SOP3956 'IT Disaster Recovery and Contingency Planning' sets out LGC's approach. Commvault software manages a three- tier data backup: daily on-site disk storage, daily replication between 2 physical data centres, monthly backups copied to Amazon Web Services (AWS) for long term retention. More broadly, LGC's in-house IT Team has over 20 years of experience of working with LIMS systems and is part of our day-to-day practical processes at LGC. Once an issue has been resolved, a ticket is released to the team informing them that the system is now fully functional and can be used. The National Laboratories Division, where this project will be conducted, also has a dedicated IT manager to provide support on a local basis.
Availability of stakeholders for interviews	Low	Medium	A number of stakeholders have been pre-contacted and have indicated their agreement in principle to participate in the project. By pre-contacting stakeholders, the Project Team will ensure the relevant people will be available within the project timeframe and are engaged with supporting the project. A number of key

			stakeholders to this project (e.g. Public Analyst Laboratories) are known personally by the Project Lead and the APA Training Officer at LGC. In cases where a personal contact cannot is not available, an alternate person will be sought through personal contacts or the relevant trade association / professional body. Virtual meetings will be used in order to facilitate the widest possible stakeholder engagement.
Delivery of project reports on time	Low	Medium	LGC employs robust Project Management strategies to ensure that progression associated with customer projects are constantly monitored, and should there be a likelihood that delivery may be detrimentally impacted, additional resources will be employed as a corrective action. The proposed Project Team in response to this tender are experienced project managers, being involved on a regular basis with delivery of FSA projects.
Readiness of POC technology transfer to Official Laboratories	Low	Medium	The plethora of technologies which fit under the umbrella term of POC devices is large and ever expanding. Given this diversity in technology/instrumentation and current POC technology readiness, there may be some likelihood that bespoke validated methods may not be available for all appropriate POC instrumentation suitable for transfer for official control use. Should this be the case, this project will still seek to provide clear guidance and recommendations on what requirements and infra-structure need to be met regarding any outstanding POC instrumentation which can be developed further for use in an enforcement setting.

LGC routinely employs a set of techniques and standards which are used to assess and mitigate risks across its business. These include:

- Managing Risk Management - version 1.1
- LGC Risk Management Process (based on ISO31000:2009 Risk Management Process)
- LGC Security Management System Policy and Arrangements
- LGC DPL Policy: Dealing with Denied Persons, Politically Exposed Persons and other sanctions lists.
- Anti-corruption and Anti-Bribery Policy
- Risk register for National Laboratories
- Business Continuity Disaster Recovery plan (BCDR) for Office of the Government Chemist team
- Sub-contracting process
- LGC group ISMS 2001 – Data Privacy and processing Policy 2021*
- LGC NML Cyber arrangements*

Copies of these documents are available for inspection by the FSA upon request.

LGC's risk management infrastructure and implementation are managed by two key appointments; the Senior Information Risk Owner and the Group Head of Security. They are supported by a Risk Steering Committee, which has representation from key functions across LGC. LGC's National Laboratories' Teams are experienced in the management of risk for government Customers and stakeholders and have enhanced their risk monitoring and mitigation activities as a response to the challenges posed by the COVID-19 pandemic and EU Exit transition.

Security
LGC's security policy is included as a supplementary document to this tender.

7. 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

LGC's reputation is built on quality. The services required for this contract can best be fulfilled effectively by an organisation with a commitment to total quality and a track record of delivering impartial advice. LGC's track record of, and commitment to, quality is reflected in its being among the first laboratories to achieve accreditation under:

- **BS EN ISO 9001:2015 (BS5750 Part 1)**
  Granted March 1994, all Laboratory activities are covered, i.e. both scientific and support activities, e.g. customer relations and financial services.
- **ISO17034:2016**
  Granted in 2006 (ISO Guide 34) for the general requirements for the competence of Reference Materials producers
- **Additional UK Accreditation Service, UKAS**
  Granted April & November 1984 (testing & calibration respectively), LGC was one of the first laboratories to achieve this foremost assurance of analytical quality and reliability, and now has one of the most extensive scopes of accreditation to the requirements of ISO/IEC 17025:2015 of any laboratory in Europe.
    - LGC is also accredited by UKAS for the provision of proficiency testing (PT) schemes to ISO Guide 1743:20101, and for the production of Certified Reference Materials (CRMs) to ISO/IEC 17025:2015 in combination with ISO 17034:2016, being in the first tranche of accredited organisations for both these activities.
    - LGC has ISO17025 accreditation to provide statements of opinions and interpretation in relation to referee analyst. This accreditation covers the interpretation of analytical data derived from prescribed methods of analysis and the expression of opinions with regard to product compliance with the relevant legislation.

The quality systems are formally documented in a Quality Manual as Quality Procedures and Work Instructions. Although these are controlled documents their inspection by customers and other interested parties can be arranged on request.

The Total Quality approach to all aspects of LGC's work is also characterised by:

- All of LGC's operations comply with the requirements of ISO 9001:2015;

- Recognition of LGC as the Government's Referee Analyst and cited explicitly in Acts of Parliament;
- Management of, and participation in, proficiency testing schemes, such as Aquacheck, CONTEST, FAPAS, Toytest, Quartz, Aims, DAPS, BAPS, UKNEQAS, UKFSLG, CTS, EUPTS and Asia
- Production, and use, of certified reference materials (CRMs) for traceability and calibration;
- A continuous improvement cycle to all aspects of service, including technical, commercial and customer relations;
- Regular internal audits to ensure that the highest standards of quality are maintained.

LGC is committed to continual improvement in quality and efficiency through a system of regular internal audits. These programs aim to identify areas where procedures can be improved to meet the needs of our customers and other stakeholders more effectively. In working towards continual improvement LGC is following the EFQM Excellence model to identify gaps and possible solutions.

The quality of the results we provide to our customers is a cornerstone of the service LGC provides. To help protect this high quality of service LGC ensures that competent staff are recruited to conduct its work. Further, a comprehensive training program is in place for all employees.

LGC is further committed to promoting QA within the whole of the analytical community. As the UK's designated Institute for chemical and biochemical measurements, LGC has a major role to play in helping to improve the accuracy and reliability of chemical and bio-measurements that are important to the UK's industrial competitiveness and quality of life. LGC's measurement science is recognised throughout the world and many of our experts represent UK metrology interests on European and international organisations.

Copies of LGC's UKAS and BS EN ISO 9001 certification, ISO 17025 for testing and certification laboratories (UKAS_17025_testing_&_calibration (quality assurance)) the UKAS testing schedule (Schedule of accreditation (quality assurance)), and LGC's ESG Policy (LGC's policies and management systems) have been submitted as part of this tender as additional attachments. The LGC Quality Manual is a controlled document but can also be made available for inspection upon request.

LGC fully complies with the Joint Code of Practice for Research (JCoPR). In the case of this contract, no laboratory work is envisaged – therefore the JCoPR would only apply to any laboratory work undertaken in response to an emerging issue.

Specific quality management requirements for this project

To help ensure the quality of the outputs throughout the project, LGC will:

1. Ensure that the outcomes of the **literature review (Task 1.2)** are robust in the following manner:
    - Using sources that will detect both UK and international items.
    - The findings of the literature review will be stored in an Excel database giving the details, key findings/conclusions and methods used for each document reviewed.
    - The literature review will be validated by peer review within LGC. The initial data collection will be checked for completeness by other investigators at LGC.
    - The robustness of the findings from the literature review and will be cross-checked with the other outputs of Phase 01, specifically the deep-dive of the Defra FA0178 questionnaire (Task 1.1), alignment with other projects and national;/international activities associated with POC development and analysis (Tasks 1.3 and 1.4), engagement with professional bodies involved in provision of guidance and accreditation for POC technologies (UKAS, MHRA and PATH-SAFE as part of Tasks 2.0, 5.0 and 6.0), and alignment with key take-home messages as a result of the focus group meetings (Task 3.0) and the e-survey (Task 4.0).
    - Comprehensive key search terms intended to be used, including but not limited to**:**
        - Point Of Contact
        - Point of Test
        - Point of Care
        - Point of Care testing devices
        - Non-targeted

- Untargeted
- Targeted
- Multi-analyte
- Food authenticity
- Food fraud
- Food labeling
- Method validation
- Measurement Uncertainty estimation

- The search terms will be applied across a range of scholarly databases and the internet to ensure that both academic and grey literature publications are captured.

2. **Stakeholder focus groups (Task 3.0)**
   - The stakeholder focus groups will be conducted in a manner that is compliant with the General Data Protection Regulation.
   - The final list of organisations to be invited to attend the stakeholder focus groups will be agreed with the FSA.
   - Stakeholder focus groups will be conducted to include the following range of stakeholder categories to cover the food industry, local authorities, central government, instrument manufacturers and testing laboratories.
   - The stakeholder focus groups will be conducted, using topic guide questions as guidance (to be agreed with FSA), to identify the required information on POC requirements and method validation.
   - All stakeholder focus groups will be recorded, subject to the agreement of the participants, and transcribed (non-attributed) to formally document the data collected.
     Two researchers will be involved in the stakeholder focus groups and interpreting the data collected to enhance the trustworthiness and credibility of the qualitative analysis.

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
All activities undertaken by LGC will be conducted under the LGC Code of Ethics (a copy of which is included in the appendices to this tender). This code places the LGC values of “integrity” and “respect” at the heart of LGC’s mission of “Science for a Safer World” and outlines the high ethical standards expected by LGC from its employees, consultants, and contractors. A commitment to high ethical standards has been at the heart of LGC since we started as the UK ‘Laboratory of the Board of Excise’ testing the integrity of products in 1842. Today, as an international leader in the extended life sciences sector it is important our commitment to the highest professional and ethical standards is understood and embedded throughout our business. We expect our employees, consultants and contractors to do the right thing. This is integral to our purpose of “Science for a Safer World” and is reflected in our core values of “integrity” and “respect”. Our commitment to high ethical standards: • Raise a concern • Following laws and regulations • Anti-bribery and corruption – including gifts and hospitality and charitable and political donations and sponsorship • Fair competition – anti-trust and competition

- Trade sanctions
- Handling information – personal data and customer inside information
- Financial records – accurate records which do not mislead or misrepresent
- Anti-facilitation of tax evasion
- Supplier management - what we expect from our suppliers
- Treating people with respect – harassment, bullying, victimisation and discrimination
- Our staff responsibility.

LGC also has a central Bio-Ethics Committee to provide consistent and formal advice to staff on the compliance of all work undertaken with respect to the Human Tissue Act the in the UK. However, there are no bio-ethical issues ethical anticipated under this project.

All stakeholder interviews will be conducted in compliance with the General Data Protection Regulation (see 'QUALITY MANAGEMENT' above, and 'DATA PROTECTION' below).

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) 2018 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.

To protect its business information and that of its customers, LGC's official Information Security Policy ensures that information assets (internal and external) are protected from threats and used appropriately. LGC is well versed in dealing with confidential information. All staff are bound by confidentiality agreements and LGC's long history of customs and forensic science work makes security and confidentiality arrangements commonplace.

LGC operates a policy of performing suitability checks on new staff to ensure their eligibility for appointment. This includes checks to ensure suitability, integrity and experience and the methods employed are:
– Character references
– Health declaration form, supplemented as required by examination/referral to occupational health service
– Nationality, birth certificate, passport and other relevant certificates such as marriage, alien etc.
– Education and professional attainment – relevant certificates of qualification

In certain cases, LGC staff involved in particularly sensitive activities are cleared to Security Check (SC) or Developed Vetting (DV) level as appropriate. It is recognised that for the delivery of this contract, background checks on new staff will need to be implemented.
Job descriptions exist for each category of role and there is a clear differentiation between the job responsibilities, the skills required to carry out the role, and the purpose of the specific role. Access to sensitive data is managed according to the individual's role and authorisation level.
It is also recognized that access to mobile devices might be prohibited for staff delivering unless encrypted devices are used.

Sub-contractors/Consultants are required to sign a comprehensive Consultancy Agreement containing Confidentiality and Non-Disclosure clauses and consultants' access to facilities and material is controlled. Subcontractors, including maintenance staff, who are not able to demonstrate that they have suitable security clearance are supervised at all times whilst on site. Selection of subcontractors will be in accordance with LGC HS&I quality procedure 'QM MI 006', a copy of which can be provided upon request.

Control of documents including (but not limited to) Standard Operating Procedures, Work Instructions, Experimental Data, and reports will be undertaken in accordance HS&I quality procedure 'QM QI 001', a copy

of which can be provided upon request. Documents under ISO 9001, 17025, and 17034 will created, issued, and controlled in accordance with the requirements of the management systems in operation.

GDPR policy

We perform Personal Information Assessments and Risk Assessments for all our contracts and arrangements are summarised in QM MI 018 GDPR Management.

Information security
LGC uses its information systems to process a range of commercially sensitive information. As such, the information systems and the data processed therein are to be afforded a level of protection commensurate with its sensitivity. The purpose of the information systems is to collect, store and allow the authorised retrieval of data. It is therefore imperative that the confidentiality, integrity and availability of the information systems and associated data are protected at all times.

- LGC has a well-established security organisation and information security management system which is supported by senior management and is aligned with the principles of ISO 27001.
- LGC holds a Cyber Essentials certificate, a copy of which is included as a supplementary document to this tender.
- LGC's Enterprise Risk Steering Committee is responsible for management of risk throughout the organisation. It is chaired by the Group CFO who acts as Senior Information Risk Owner.
- The Computer Security Incident Response Team is responsible for responding to cyber security incidents and reporting outcomes to the Enterprise Risk Management team. Incident details are reported to the LGC Board on a monthly basis.
- Cyber security is embedded within LGC's IT processes, including change management.
- LGC has a well-defined security architecture and associated technologies.
- A multi-layer vulnerability management programme is in operation with regular assessments conducted by both internal personnel and external specialists.
- LGC operates a comprehensive staff security training and awareness programme, including mandatory annual refresher training and monthly phishing simulations.

LGC's IT and cyber security arrangements are summarised in QM MI 017 'LGC IT and Cyber arrangements', a copy of which is included as a supporting document to this tender.

Specific GDPR requirements for this project:
LGC will comply with General Data Protection Regulation (GDPR) and ensure that any information collected, processed and transferred on behalf of the FSA will be managed, held, handled and transferred securely. LGC understands that it will be assigned the role of 'Data Processor' for the duration of the contract and the FSA will act as the 'Data Controller'.

Compliance with GDPR will be an agenda item for the project kick off meeting. All subcontractors will be asked to attend this meeting to ensure that they are aware of their obligations. GDPR requirements from the header contract between LGC and FSA will be flowed down to subcontracts as appropriate.

The Data Processor (LGC) will:
- Process any personal data only on the documented instructions of the Controller (the FSA).
- Comply with security obligations equivalent to those imposed on the Controller (implementing a level of security for the personal data appropriate to the risk).
- Ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- Only appoint Sub-processors with the Controller's prior specific or general written authorisation, and impose the same minimum terms imposed on it on the Sub-processor; and the original Processor will remain liable to the Controller for the Sub-processor's compliance. The Sub-processor must provide sufficient guarantees to implement appropriate technical and organisational measures to demonstrate compliance. In the case of general written authorisation, Processors must inform Controllers of intended changes in their Sub-processor arrangements.

- Make available to the Controller all information necessary to demonstrate compliance with the obligations laid down in Article 28 GDPR and allow for and contribute to audits, including inspections, conducted by the Controller or another auditor mandated by the Controller - and the Processor shall immediately inform the controller if, in its opinion, an instruction infringes GDPR or other EU or member state data protection provisions.
- Assist the Controller in carrying out its obligations with regard to requests by data subjects to exercise their rights under chapter III of the GDPR, noting different rights may apply depending on the specific legal basis for the processing activity (and should be clarified by the Controller up-front).
- Assist the Controller in ensuring compliance with the obligations to implementing a level of security for the personal data appropriate to the risk, considering the nature of processing and the information available to the Processor.
- Assist the Controller in ensuring compliance with the obligations to carry out Data Protection Impact Assessments, considering the nature of processing and the information available to the Processor; and
- Notify the Controller without undue delay after becoming aware of a personal data breach.

For this contract, it is proposed to use a Microsoft 365 platform (SharePoint online or Teams, as appropriate) to exchange information between FSA, LGC, and subcontractors Access to this be granted only to authorised staff. LGC's M355 solution ensures that data will be stored within one of three different Microsoft UK data centres and backed-up to different physical location within the UK. LGC uses Microsoft's 365 portal to authenticate user accounts. Use of Multi-Factor Authentication (MFA) is mandatory on all user accounts used to access LGC's network. MFA is via text message or an authentication app.

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)

Summaries of LGC's Environmental and Sustainability policies are included below. The full policy is included as a supporting document to this tender.

LGC Environmental Policy
LGC is a company with 175 years' experience in analytical science acting on behalf of both government and private sector clients. As such, LGC is aware of and accepts the environmental responsibilities placed upon it, in particular those that relate to the operation of laboratories. LGC is committed to the continual improvement of its environmental performance and operates an Environmental Management System (EMS) aligned with ISO 14001 principles. This Environmental Management System provides the framework for setting and reviewing environmental objectives and targets. LGC is committed to complying with all legal and other environmental requirements, as well as with ISO 14001 standards. LGC is also committed to the prevention of pollution and to minimising the environmental impact of its business operations. LGC has an Environmental Team with a remit to advise on and monitor compliance with statutory requirements, instigate the adoption of best practice, actively manage LGC's waste streams and seek ways in which LGC can reduce its environmental impact. The control of both energy and materials consumption, along with the responsible management of our waste are key to LGC's efforts to improve environmental performance and reduce its Carbon Footprint. LGC endeavours to match its energy usage to its business requirements, making sure that loss is minimised and patterns of demand are optimised. All staff are required to play a full part in reducing energy consumption. The laboratory operates a waste minimisation and segregation policy. Where possible, waste is sent for re-cycling rather than landfill. The reduction in the generation of waste materials, particularly chemicals and solvents, is at the forefront of LGC's operating procedures in reducing our impact on the environment. The Environmental Policy is communicated to all employees and made publicly available.
LGC helps its customers respect the environment and reduce waste by providing accurate measurement and quality control systems. We also work to reduce the impact of our own activities have on the environment, including energy consumption and waste production. LGC's commitment to maintaining and enhancing the

environment is captured and governed by the following policies and systems: the LGC Environmental Policy; LGC's Sustainability Policy and Group EP2005 Sustainable Procurement; CRC reporting.

LGC Sustainability Policy

LGC is committed to a policy of sustainable development that meets the needs of the present, without compromising the ability of future generation to meet their own needs. LGC has set specific goals and targets for sustainability. LGC recognises that its activities have the potential for both positive and negative impacts upon the environment at local, national and global levels. LGC acknowledges the importance of delivering a sustainable service that will contribute to an increase in the quality of life and of the environment. To deliver our goals and strategies LGC will: Communicate LGC's Sustainability Policy and strategy to staff and stakeholders and raise awareness of their sustainability responsibilities and the requirement to commit to environmental improvements; Set continuous improvement targets by which LGC's performance can be measured, demonstrated and reported to LGC's Board; Identify opportunities and take action where practicable to improve the sustainability of LGC's activities, products and operations; Reduce waste created and where possible reuse and recycle before responsible disposal of surplus materials; Comply fully and where possible exceed standards set in relevant UK, EU and international regulatory requirements and agreements; Deliver a travel plan to implement measures to encourage walking, cycling, the use of public transport and a car share scheme as the principle means for commuting to LGC sites; Provide the right level of advice, awareness and competency to staff and to our contractors' employees; Work with our suppliers to ensure that goods and services procured by LGC are sourced in a sustainable manner. LGC recognises that is has an important part to play in society in the way that it carries out its business. Much of our work is aimed at improving the quality of life within society. LGC has a significant role in the analytical chemistry community as well as having an effect on the safety of society. In order for LGC to behave in a socially responsible manner, it is vital that staff are aware of LGC's current activities and take an active part in developing LGC's sustainability activities. **The importance of being able to deliver a reliable and continuous service to customers is guided and governed by LGC's ESG Policy.**

- **LGC COMMITMENTS TOWARDS REDUCING CARBON FOOTPRINT**
- We are in the process of setting a 2050 carbon net zero target.
- We currently working with an external agency to measure our group carbon footprint, this will include
    - Direct emissions e.g. from use of natural gas (scope 1)
    - Indirect energy emissions e.g. from electricity (scope 2)
    - Wider emissions associated with our supply chains and business activities (Scope 3)
- We will report on our carbon footprint annually
- Renewable electricity: Currently, at UK sites where LGC is responsible for purchasing electricity 100% of electricity is from certified renewable sources.
- Energy efficiency investment is a priority across LGC, examples include
    - installation of carbon filtered ventilation hoods for workstations. This helps in two ways. First it significantly lowers the amount of electricity required to heat and cool the facility which reduces our carbon footprint. The second is that it traps the VOC's in the carbon media instead of releasing them into the environment.
    - New fume hoods with technology that allows flow rates to be turned down by 40%,Natural gas saving of 70,210 Mw/year

- **LGC BUILDING SUSTAINABILITY INTO OUR ANALYTICAL METHODS, LAB CONSUMABLES, AND TECHNOLOGY**

In our analytical laboratories, we focus on developing shorter, more efficient methods, to actively reduce the amount of electricity, gasses and solvents used. Examples of specific projects include:

- Corporately funded development project concerning the use of Hydrogen as a carrier gas for gas chromatography to reduce impact on the dwindling global Helium supply
- Implementation of a GMP compliant SFC system to aid the migration away from normal phase LC.
- The use of UPLC to reduce solvent consumption relative to HPLC.
- Energy efficient equipment, for example
    - Planned replacement of chillers This work is essential to allow lab temperature to be kept within correct working and process approved range and will later allow removal of redundant split units.

The proposed new chillers will have an energy efficiency of about 3.3, the existing at best are running at 2 so for every kW of cooling we need to put in 1/3rd less power to achieve this.

- increasing our recycling capacity
- monitoring site electric and water usage
- working with suppliers to reduce packaging
- working with building contractors to improve sustainability of new builds
- weekly environmental awareness emails and much more.
- Energy survey – to understand the energy demands of different equipment and identify opportunities to improve energy management
- Motion sensors – to ensure lights are not on unnecessarily (and reminder labels to turn off lights)
- Recycling of gloves
- Recycling of pipette tips
    - Replacement of taps with push ones that automatically turn-off to reduce water waste
    - Introduced our Sustainability Ninja tips
    - Replaced inefficient boilers and associated pumps to reduce energy consumption
    - Currently investigating a green labs certification program
    - Corporate LGC project investigating the installation of electric vehicle charge points

LGC ESG silver award
In 2022, LGC have been awarded a silver medal for improving our ESG score, as part of our 2022 EcoVadis sustainability assessment. The award places LGC in the top 25% of the 90,000+ companies assessed by EcoVadis.

Established in 2007, EcoVadis is an evidence-based online platform for evaluating and rating sustainable business and procurement practices. Their methodology is built on international sustainability standards, including the Global Reporting Initiative (which we use for our latest ESG report), the United Nations Global Compact and ISO 26000. The assessment covers approximately 200 questions, each which require an evidence-based answer, across four areas: environment, labour and human rights, ethics, and sustainable procurement. Read more on the EcoVadis website to learn more about the assessment (https://ecovadis.com/).

E. DISSEMINATION AND EXPLOITATION

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

The work of the National Measurement Laboratory at LGC addresses the measurement challenges facing the UK and the wider world. We have a strong track record in disseminating and exploiting our work to influence policy, protect consumers, and enhance quality of life.

The below table (**NML Indicators 2016 – 2021**) summarises the centrality of dissemination to the NML's mission.

Theme		Indicator	AIM	ACHIEVED	2021	2020	2019	20
Research	1.1	Number of academic collaborators	Grow		**141**	136	105	7
	1.2	Number of peer reviewed papers	Maintain		**43**	40	34	3
Trade & Regulation	2.1	Number of active measurement services and reference materials	Maintain		**142**	128	120	12
	2.2	Income from measurement services and reference materials	Grow		**£0.64M**	£0.58M	£0.52M	£0.5
	2.3	Publication of new or amended standards with an NMS contribution	Maintain		**9**	5	8	7
Innovation	3.1	Number of business collaborations	Grow		**217**	143	150	10
	3.2	Number of new active measurement services and reference materials	Maintain		**27**	6	11	6
	3.3	Leveraged income from collaborative R&D and consultancy	Grow		**£3.65M**	£3.29M	£3.00M	£2.8
Skills	4.1	Number accessing measurement training through web resources	Grow		**2650**	1840	275	20
	4.2	Participation in face to face training	Grow		**223**	171	446	37

Figure 3: NML Indicators, 2016-2021

LGC operates many technical websites (see examples below) so it is very familiar with disseminating to a wide range of different stakeholders:
The Government Chemist website
The Food Authenticity Network
The Eurachem website
The iKANN website
The CAMS website

Dissemination/Knowledge Exchange Plans for This Project
Approval to publish any results from this project will be agreed with the FSA in advance, and all publications will acknowledge financial support from the FSA.

Communication of results to raise awareness and encourage adoption
A range of communication and dissemination routes will be used to maximise exposure of the project and its associated results, best measurement practice guidance and recommendations. The output of this project will be disseminated through multiple routes:

- Posted on the Food Authenticity Network website and included in the Monthly Summary Report, which is emailed to its ~3,500 members in 93 countries.
- Posted on the Government Chemist website, which has a dissemination list of over 1,000 people.
- Subject to FSA approval, the report or a summary can be disseminated via FSA's Smarter Comms platform and at relevant scientific conferences or meetings as presentations/posters.
- An article will be written for the Food Authenticity Network newsletter.
- An article will be posted on the Food Authenticity Network social media accounts (LinkedIn and Twitter).
- Subject to FSA approval, It is also suggested that the rationale/plan and the final results associated with this project be presented to Defra's Authenticity Methods Working Group (AMWG), to incorporate feedback and raise awareness of the project outputs with key representatives from government, regulators, laboratories, food manufacturers and retailers..

- With prior agreement from the FSA, every effort will be made to publish results and guidance from this project in the public domain as a peer reviewed paper (LGC has an excellent track-record of publishing FSA work as scientific papers (e.g. qPCR and use of plasmid DNA, measurement uncertainty estimation, collaborative trial of qPCR approach for horse DNA,)
- Use of the FSA/FSS/Defra/Government Chemist (GC)) Joint Knowledge Transfer Framework for Food Standards and Food Safety Analysis

Brief description of how results will be used and by whom

Key audiences will include Government and Regulatory bodies (e.g. FSA, Defra and associated working groups such as the AMWG); Enforcement agencies and Public Analysts and Official Laboratories; Industry, instrument manufacturers, testing labs, food retailers, food manufacturers and consumer bodies etc. All stakeholders have a key interest in food labelling, traceability and testing for food authenticity, as well as application of emerging technologies inclusive of POC instrumentation.

Intellectual Property (IP)

It is not anticipated that any Intellectual Property (IP) will be generated as a result of this project.

Clarification Questions 19/07/2023

C173168 Guidance for Point of Contact Technology Research Project
Clarification Responses
19/07/2023
LGC

1. Does the bid cover both authenticity and chemical testing?

At the current stage, the scope of the project will be kept broad and includes both "authenticity" and "chemical testing" applications.

The exact testing approaches to focus on in Phase 2, will be informed by Phase 01 "Horizon Scanning and Engagement", which will help identify POC technologies being used, how they are being applied (analytical question they are addressing / "authenticity" and "chemical testing"), and where the gaps are.
This will also be dependent upon type of technology being used as part of the POC testing, the latter of which can be broadly split into rotational vibrational spectroscopy platforms (NIR, FT-IR and Raman), spectral imaging platforms (multi- and hyperspectral imaging), mass spectrometry, NMR and biological analyte based platforms (proteins and nucleic acid-based).

2. As stated, the panel felt that the bid described a more general approach to project management – how do LGC intend to specifically tailor their approach to this project whilst engaging with the FSA?

The details of how the LGC team intend to tailor their approach to this specific project can be found on page 28 of the tender response. In particular:

- "The Operations Manager will have responsibility for the day-to-day management, co-ordination and delivery of the overall project. The Operations Manager will be the key contact with the Food Standards Agency's Project Officer and will take direction from the Principal Investigator in terms of planning and quality of the science"
- "The key account manager will continue to ensure excellent communication between the FSA and teams within LGC ensuring the Agency is briefed on all aspects of this project and any relevant novel technologies, pilots and innovation taking place across the organisation that may be of interest."
- "The Specialist Support Officer, having experience of working in the field with POC instrumentation, will provide scientific, technical and administrative assistance to the Operations Manager. They will provide core assistance for the literature review and help establish key contacts and focus group meetings as part of Phase 01 "Horizon Scanning and Engagement" of the project, as well as helping develop the key validation criteria as described in Phase 02 "Development of POC Technology Guidelines for Official Controls"."

- "The Head of the Office of the Government Chemist, also having the role of the Association of Public Analyst Training Officers, will interact with the Operations Manager through using pre-existing links and communication channels with UK Official Laboratories (Public Analysts). They will promote and encourage engagement as part of Task 3 "Stakeholder focus group meetings" and throughout Phase 01 "Horizon Scanning and Engagement" of the project. Furthermore, they will invite feedback from Official Laboratories as part of the draft method validation guidance which is being produced in Phase 02 "Development of POC Technology Guidelines for Official Controls", helping ensure recommendations have captured and are representative of the requirements of this Key Stakeholder group."

In terms of engagement with the FSA:

- The Operations Manager will be the key contact with the Food Standards Agency's Project Officer (p28).
    - Communications will be facilitated by face-to-face meetings, email, telephone or Teams meeting as appropriate to ensure all parties are kept fully informed, as part of the overarching project management of the project. (p7)
    - This will be augmented through regular catch-ups at monthly meetings and any scheduled quarterly review meetings. (p7)
    - In addition, the following deliverables will be submitted:
        - Task 7.0 – Interim project report (1)
        - Task 9.0 – Draft interim report (2) detailing the approach to validating POC technology
- The smooth running of this project will be maintained through constant communication between the Operations Manager and the FSA Key Account Manager, both based at LGC, and the appointed FSA project officer. (p7)

3. The bid referred to 25 researchers in the molecular biology field and suggested that their availability could help mitigate the risk of key staff being required for urgent projects

Within the Molecular Biology team (the local team charged with delivering the technical aspects of this project), a pool of 25 expert scientists are available, all of whom are cross trained in modern genomic/proteomic based technologies inclusive of DNA extraction, DNA quantification, PCR, real-time PCR, digital PCR, DNA sequencing, Next Generation Sequencing, etc., and core staff with additional specialist expertise within crucial POC areas such as imaging (e.g., MSI) and spectroscopy (e.g., NIR).

Outside of the Molecular Biology team and in a broader context, skilled scientists from the Office of the Government Chemist, Inorganic analysis, and Organic mass-spectrometry teams can be called upon. These scientists encapsulate a representative cross section of all technologies which can fall under the POC heading, inclusive of

stable isotope ratio and trace analysis; GC and LC field flow fractionation; nanoparticle tracking; speciation; Nuclear Magnetic Resonance spectroscopy and optical/bright field/phase contrast/fluorescence microscopy; ELISA immunoassays, Western blotting, mass spectrometry, capillary electrophoresis; NIR, FTIR and multispectral imaging.

In total, the teams represent a pool of 65 experienced scientists with more than half holding PhD i.e. able to perform critical literature reviews.

4. Can a detailed breakdown of staffing costs be provided?

Staff members names and project roles added to financial template 'Staff costs' tab in 'Financial Template FSA POC v2'.

5. Is the licence for Survey Monkey being purchased exclusively for this project?

Yes, a suitable time limited licence, to provide access for three core members of the project team to design questionnaires, analyse data and interpret results, is required for delivery of this project. Output from Survey Monkey will be immediately transferable to the FSA, inclusive of appropriate graphs that require no additional processing, in a similar format to the previous projects delivered for UK government e.g. FSA project FS900293 on a 'Review of methods for the analysis of culinary herbs and spices for authenticity' and the Defra FA0178 project.

Other platforms are available with different levels of functionality, but the cost implications in being trained on these more bespoke platforms would offset any short-term gains.

6. Could the costs be reduced by removing face to face meetings where possible and instead hosting some online via MS Teams?

Face-to-face meetings are one option which can be deployed as one of the mechanisms for stakeholder engagement as part of the Phase 01 "Horizon Scanning and Engagement". This option could be removed, but it could limit the scope of the work in terms of a deeper-dive with some targeted stakeholders and would only realise a small cost saving.

Face-to-face meetings have been planned with the FSA, for example as part of any kick-off meetings, project round up meetings, presentation at AMWG or, where necessary, as part of any quarterly reviews or monthly catchups. A small travel budget has been allocated for these purposes. Should travel into central London for any meetings not be required as part of this project (for example, meetings will be solely done via MS Teams or the FSA were happy to travel to the LGC Teddington/Guildford sites), then the associated travel budget (£250) can be removed.

VI. Short form Terms ("Conditions")

1. Definitions used in the Contract

In this Contract, unless the context otherwise requires, the following words shall have the following meanings:

"Affiliates"	in relation to a body corporate, any other entity which directly or indirectly Controls (in either of the senses defined in sections 450 and 1124 of the Corporation Tax Act 2010 and "**Controlled**" shall be construed accordingly), is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;
"Audit"	the Buyer's right to: (a) verify the accuracy of the Charges and any other amounts payable by the Buyer under the Contract (including proposed or actual variations to them in accordance with the Contract); (b) verify the costs of the Supplier (including the costs of all Subcontractors and any third party suppliers) in connection with the provision of the Deliverables; (c) verify the Supplier's and each Subcontractor's compliance with the applicable Law; (d) identify or investigate actual or suspected breach of clauses 4 to 35, impropriety or accounting mistakes or any breach or threatened breach of security and in these circumstances the Buyer shall have no obligation to inform the Supplier of the purpose or objective of its investigations; (e) identify or investigate any circumstances which may impact upon the financial stability of the Supplier and/or any Subcontractors or their ability to provide the Deliverables; (f) obtain such information as is necessary to fulfil the Buyer's obligations to supply information for parliamentary, ministerial, judicial or administrative purposes including the supply of information to the Comptroller and Auditor General; (g) review any books of account and the internal contract management accounts kept by the Supplier in connection with the Contract; (h) carry out the Buyer's internal and statutory audits and to prepare, examine and/or certify the Buyer's annual and interim reports and accounts;

	(i) enable the National Audit Office to carry out an examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Buyer has used its resources;
"Buyer"	the person named as Buyer in the Order Form. Where the Buyer is a Crown Body the Supplier shall be treated as contracting with the Crown as a whole;
"Buyer Cause"	any breach of the obligations of the Buyer or any other default, act, omission, negligence or statement of the Buyer, of its employees, servants, agents in connection with or in relation to the subject-matter of the Contract and in respect of which the Buyer is liable to the Supplier;
"Central Government Body"	a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency;
"Charges"	the charges for the Deliverables as specified in the Order Form;
"Claim"	any claim which it appears that the Buyer is, or may become, entitled to indemnification under this Contract;
"Compliance Officer"	the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its legal obligations;
"Conditions"	means these short form terms and conditions of contract;
"Confidential Information"	all information, whether written or oral (however recorded), provided by the disclosing Party to the receiving Party and which (i) is known by the receiving Party to be confidential; (ii) is marked as or stated to be confidential; or (iii) ought reasonably to be considered by the receiving Party to be confidential;
"Conflict of Interest"	a conflict between the financial or personal duties of the Supplier or the Supplier Staff and the duties owed to the Buyer under the Contract, in the reasonable opinion of the Buyer;

"Contract"	the contract between (i) the Buyer and (ii) the Supplier which is created by the Supplier's counter signing the Order Form and includes the cover letter (if used), Order Form, these Conditions and the Annexes;
"Controller"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Crown Body"	the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the National Assembly for Wales), including, but not limited to, government ministers and government departments and particular bodies, persons, commissions or agencies from time to time carrying out functions on its behalf;
"Data Loss Event"	any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach;
"Data Protection Impact Assessment"	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
"Data Protection Legislation"	(a) the UK GDPR, (b) the DPA 2018; (c) all applicable Law about the processing of personal data and privacy and guidance issued by the Information Commissioner and other regulatory authority; and (d) (to the extent that it applies) the EU GDPR (and in the event of conflict, the UK GDPR shall apply);
"Data Protection Liability Cap"	has the meaning given to it in row 13 of the Order Form;
"Data Protection Officer"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Data Subject"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Data Subject Access Request"	a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data;
"Date of Delivery"	that date by which the Deliverables must be Delivered to the Buyer, as specified in the Order Form;
"Deliver"	hand over of the Deliverables to the Buyer at the address and on the date specified in the Order Form, which shall include unloading and any other specific arrangements agreed in accordance with clause 4.2. **"Delivered"** and

	"Delivery" shall be construed accordingly;
“Deliverables”	means the Goods and/or Services to be supplied under the Contract as set out in the Order Form;
"DPA 2018"	the Data Protection Act 2018;
"EU"	the European Union;
"EU GDPR"	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as it has effect in EU law;
"Existing IPR"	any and all intellectual property rights that are owned by or licensed to either Party and which have been developed independently of the Contract (whether prior to the date of the Contract or otherwise);
"Expiry Date"	the date for expiry of the Contract as set out in the Order Form;
"FOIA"	the Freedom of Information Act 2000 together with any guidance and/or codes of practice issued by the Information Commissioner or relevant Government department in relation to such legislation;
"Force Majeure Event"	any event, circumstance, matter or cause affecting the performance by either the Buyer or the Supplier of its obligations arising from: (a) acts, events, omissions, happenings or non-happenings beyond the reasonable control of the Party seeking to claim relief in respect of a Force Majeure Event (the “**Affected Party**”) which prevent or materially delay the Affected Party from performing its obligations under the Contract; (b) riots, civil commotion, war or armed conflict, acts of terrorism, nuclear, biological or chemical warfare; (c) acts of a Crown Body, local government or regulatory bodies; (d) fire, flood or any disaster; or (e) an industrial dispute affecting a third party for which a substitute third party is not reasonably available but excluding: (i) any industrial dispute relating to the Supplier, the Supplier Staff (including any subsets of them) or any other failure in the Supplier or the Subcontractor's supply chain;

	(ii) any event, occurrence, circumstance, matter or cause which is attributable to the wilful act, neglect or failure to take reasonable precautions against it by the Party concerned; and (iii) any failure of delay caused by a lack of funds, and which is not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party;
"Goods"	the goods to be supplied by the Supplier to the Buyer under the Contract;
"Good Industry Practice"	standards, practices, methods and procedures conforming to the Law and the exercise of the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged within the relevant industry or business sector;
"Government Data"	(a) the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, including any of the Buyer's confidential information, and which: (i) are supplied to the Supplier by or on behalf of the Buyer; or (ii) the Supplier is required to generate, process, store or transmit pursuant to the Contract; or (b) any Personal Data for which the Buyer is the Controller;
"Independent Controller"	a party which is Controller of the same Personal Data as the other Party and there is no element of joint control with regards to that Personal Data;
"Information"	has the meaning given under section 84 of the FOIA;
"Information Commissioner"	the UK's independent authority which deals with ensuring information relating to rights in the public interest and data privacy for individuals is met, whilst promoting openness by public bodies;
"Insolvency Event"	in respect of a person: (a) if that person is insolvent; (b) where that person is a company, LLP or a partnership, if an order is made or a resolution is passed for the winding up of the person (other than

	voluntarily for the purpose of solvent amalgamation or reconstruction); (c) if an administrator or administrative receiver is appointed in respect of the whole or any part of the person's assets or business; (d) if the person makes any composition with its creditors; or (e) takes or suffers any similar or analogous action to any of the actions detailed in this definition as a result of debt in any jurisdiction;
"IP Completion Day"	has the meaning given to it in the European Union (Withdrawal Agreement) Act 2020;
"Joint Controller Agreement"	the agreement (if any) entered into between the Buyer and the Supplier substantially in the form set out in ***Error! Reference source not found.*** of Annex 1 – *Processing Personal Data*;
"Joint Controllers"	Where two or more Controllers jointly determine the purposes and means of processing;
"Key Staff"	any persons specified as such in the Order Form or otherwise notified as such by the Buyer to the Supplier in writing, following agreement to the same by the Supplier;
"Law"	any law, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, right within the meaning of the European Union (Withdrawal) Act 2018 as amended by European Union (Withdrawal Agreement) Act 2020, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Supplier is bound to comply;
"Month"	a calendar month and "**Monthly**" shall be interpreted accordingly;
"National Insurance"	contributions required by the Social Security Contributions and Benefits Act 1992 and made in accordance with the Social Security (Contributions) Regulations 2001 (SI 2001/1004);
"New IPR"	all and intellectual property rights in any materials created or developed by or on behalf of the Supplier pursuant to the Contract but shall not include the Supplier's Existing IPR;
"New IPR Items"	means a deliverable, document, product or other item within which New IPR subsists;
"Open Licence"	means any material that is published for use, with rights to access and modify, by any person for free, under a

	generally recognised open licence including Open Government Licence as set out at http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/ and the Open Standards Principles documented at https://www.gov.uk/government/publications/open-standards-principles/open-standards-principles;
"Order Form"	the order form signed by the Buyer and the Supplier printed above these Conditions;
"Party"	the Supplier or the Buyer (as appropriate) and "**Parties**" shall mean both of them;
"Personal Data"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Personal Data Breach"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires and includes any breach of Data Protection Legislation relevant to Personal Data processed pursuant to the Contract;
"Prescribed Person"	a legal adviser, an MP or an appropriate body which a whistle-blower may make a disclosure to as detailed in 'Whistleblowing: list of prescribed people and bodies', 24 November 2016, available online at: https://www.gov.uk/government/publications/blowing-the-whistle-list-of-prescribed-people-and-bodies--2/whistleblowing-list-of-prescribed-people-and-bodies as updated from time to time;
"Processor"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Processor Personnel"	all directors, officers, employees, agents, consultants and suppliers of the Processor and/or of any Subprocessor engaged in the performance of its obligations under the Contract;
"Protective Measures"	technical and organisational measures which must take account of: (a) the nature of the data to be protected; (b) harm that might result from Data Loss Event; (c) state of technological development; (d) the cost of implementing any measures; including pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating

	the effectiveness of the such measures adopted by it;
"Purchase Order Number" or "PO Number"	the Buyer's unique number relating to the order for Deliverables to be supplied by the Supplier to the Buyer in accordance with the Contract;
"Rectification Plan"	the Supplier's plan (or revised plan) to rectify its material default which shall include: (a) full details of the material default that has occurred, including a root cause analysis; (b) the actual or anticipated effect of the material default; and (c) the steps which the Supplier proposes to take to rectify the material default (if applicable) and to prevent such material default from recurring, including timescales for such steps and for the rectification of the material default (where applicable);
"Regulations"	the Public Contracts Regulations 2015 and/or the Public Contracts (Scotland) Regulations 2015 (as the context requires) as amended from time to time;
"Request For Information"	has the meaning set out in the FOIA or the Environmental Information Regulations 2004 as relevant (where the meaning set out for the term "request" shall apply);
"Services"	the services to be supplied by the Supplier to the Buyer under the Contract;
"Specification"	the specification for the Deliverables to be supplied by the Supplier to the Buyer (including as to quantity, description and quality) as specified in the Order Form;
"Staff Vetting Procedures"	vetting procedures that accord with Good Industry Practice or, where applicable, the Buyer's procedures or policies for the vetting of personnel as specified in the Order Form or provided to the Supplier in writing following agreement to the same by the Supplier from time to time;
"Start Date"	the start date of the Contract set out in the Order Form;
"Sub-Contract"	any contract or agreement (or proposed contract or agreement), other than the Contract, pursuant to which a third party: (a) provides the Deliverables (or any part of them);

	(b) provides facilities or services necessary for the provision of the Deliverables (or any part of them); and/or (c) is responsible for the management, direction or control of the provision of the Deliverables (or any part of them);
"Subcontractor"	any person other than the Supplier, who is a party to a Sub-Contract and the servants or agents of that person;
"Subprocessor"	any third party appointed to process Personal Data on behalf of the Processor related to the Contract;
"Supplier"	the person named as Supplier in the Order Form;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor of the Supplier engaged in the performance of the Supplier's obligations under the Contract;
"Transparency Information"	In relation to Contracts with a value above the relevant threshold set out in Part 2 of the Regulations only, the content of the Contract, including any changes to this Contract agreed from time to time, as well as any information relating to the Deliverables and performance pursuant to the Contract required to be published by the Buyer to comply with its transparency obligations, including those set out in Public Procurement Policy Note 09/21 (update to legal and policy requirements to publish procurement information on Contracts Finder) (https://www.gov.uk/government/publications/ppn-0921-requirements-to-publish-on-contracts-finder) and Public Procurement Policy Note 01/17 (update to transparency principles) where applicable (https://www.gov.uk/government/publications/procurement-policy-note-0117-update-to-transparency-principles) except for: (a) any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Buyer; and (b) Confidential Information;
"Term"	the period from the Start Date to the Expiry Date as such period may be extended in accordance with clause 11.2 or terminated in accordance with the Contract;
"Third Party IPR"	intellectual property rights owned by a third party which is or will be used by the Supplier for the purpose of providing the Deliverables;
"UK GDPR"	has the meaning as set out in section 3(10) of the DPA

	2018, supplemented by section 205(4);
"VAT"	value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"Worker"	any one of the Supplier Staff which the Buyer, in its reasonable opinion, considers is an individual to which Procurement Policy Note 08/15 (Tax Arrangements of Public Appointees) (https://www.gov.uk/government/publications/procurement-policynote-0815-tax-arrangements-of-appointees) applies in respect of the Deliverables; and
"Working Day"	a day (other than a Saturday or Sunday) on which banks are open for business in the City of London.

2. Understanding the Contract

In the Contract, unless the context otherwise requires:

2.1 references to numbered clauses are references to the relevant clause in these Conditions;

2.2 any obligation on any Party not to do or omit to do anything shall include an obligation not to allow that thing to be done or omitted to be done;

2.3 the headings in this Contract are for information only and do not affect the interpretation of the Contract;

2.4 references to "writing" include printing, display on a screen and electronic transmission and other modes of representing or reproducing words in a visible form;

2.5 the singular includes the plural and vice versa;

2.6 a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time and to any legislation or byelaw made under that Law;

2.7 the word "including", "for example" and similar words shall be understood as if they were immediately followed by the words "without limitation";

2.8 any reference which, immediately before IP Completion Day (or such later date when relevant EU law ceases to have effect pursuant to section 1A of the European Union (Withdrawal) Act 2018), is a reference to (as it has effect from time to time):

(a) any EU regulation, EU decision, EU tertiary legislation or provision of the EEA agreement ("**EU References**") which is to form part of domestic law by application of section 3 of the European Union (Withdrawal) Act 2018 and which shall be read on and after IP Completion Day as a reference to the EU References as they form part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 as modified by domestic law from time to time; and

(b) any EU institution or EU authority or other such EU body shall be read on and after IP Completion Day as a reference to the UK institution, authority or body to which its functions were transferred.

3. How the Contract works

3.1 The Order Form is an offer by the Buyer to purchase the Deliverables subject to and in accordance with the terms and conditions of the Contract.

3.2 The Supplier is deemed to accept the offer in the Order Form when the Buyer receives a copy of the Order Form signed by the Supplier.

3.3 The Supplier warrants and represents that its tender (if any) and all statements made and documents submitted as part of the procurement of Deliverables are and remain true and accurate.

4. What needs to be delivered

4.1 All Deliverables

(a) The Supplier must provide Deliverables: (i) in accordance with the Specification, the tender in Annex 4 – Supplier Tender (where applicable) and the Contract; (ii) using reasonable skill and care; (iii) using Good Industry Practice; (iv) using its own policies, processes and internal quality control measures as long as they don't conflict with the Contract; (v) on the dates agreed; and (vi) that comply with all Law.

(b) The Supplier must provide Deliverables with a warranty of at least 90 days (or longer where the Supplier offers a longer warranty period to its Buyers) from Delivery against all obvious defects.

4.2 Goods clauses

(a) All Goods delivered must be new, or as new if recycled, unused and of recent origin.

(b) All manufacturer warranties covering the Goods must be assignable to the Buyer on request and for free.

(c) The Supplier transfers ownership of the Goods on completion of Delivery (including off-loading and stacking) or payment for those Goods, whichever is earlier.

(d) Risk in the Goods transfers to the Buyer on Delivery, but remains with the Supplier if the Buyer notices damage following Delivery and lets the Supplier know within 3 Working Days of Delivery.

(e) The Supplier warrants that it has full and unrestricted ownership of the Goods at the time of transfer of ownership.

(f) The Supplier must Deliver the Goods on the date and to the location specified in the Order Form, during the Buyer's working hours (unless otherwise specified in the Order Form).

(g) The Supplier must provide sufficient packaging for the Goods to reach the point of Delivery safely and undamaged.

(h) All deliveries must have a delivery note attached that specifies the order number, type and quantity of Goods.

(i) The Supplier must provide all tools, information and instructions the Buyer needs to make use of the Goods.

(j) The Supplier will notify the Buyer of any request that Goods are returned to it or the manufacturer after the discovery of safety issues or defects that might endanger health or hinder performance and shall indemnify the Buyer against the costs arising as a result of any such request.

(k) The Buyer can cancel any order or part order of Goods which has not been Delivered. If the Buyer gives less than 14 days' notice then it will pay the Supplier's reasonable and proven costs already incurred on the cancelled order as long as the Supplier takes all reasonable endeavours to minimise these costs.

(l) The Supplier must at its own cost repair, replace, refund or substitute (at the Buyer's option and request) any Goods that the Buyer rejects because they don't conform with clause 4.2. If the Supplier doesn't do this it will pay the Buyer's costs including repair or re-supply by a third party.

(m) The Buyer will not be liable for any actions, claims, costs and expenses incurred by the Supplier or any third party during Delivery of the Goods unless and to the extent that it is caused by negligence or other wrongful act of the Buyer or its servant or agent. If the Buyer suffers or incurs any damage or injury (whether fatal or otherwise) occurring in the course of Delivery or installation then the Supplier shall indemnify the Buyer from any losses, charges, costs or expenses which arise as a result of or in connection with such damage or injury where it is attributable to any act or omission of the Supplier or any of its Subcontractors or Supplier Staff.

4.3 **Services clauses**

(a) Late Delivery of the Services will be a default of the Contract.

(b) The Supplier must co-operate with the Buyer and third party suppliers on all aspects connected with the delivery of the Services and ensure that Supplier Staff comply with any reasonable instructions including the security requirements (where any such requirements have been provided).

(c) The Buyer must provide the Supplier with reasonable access to its premises at reasonable times for the purpose of supplying the Services

(d) The Supplier must at its own risk and expense provide all equipment required to deliver the Services. Any equipment provided by the Buyer to the Supplier for supplying the Services remains the property of the Buyer and is to be returned to the Buyer on expiry or termination of the Contract.

(e) The Supplier must allocate sufficient resources and appropriate expertise to the Contract.

(f) The Supplier must take all reasonable care to ensure performance does not disrupt the Buyer's operations, employees or other contractors.

(g) On completion of the Services, the Supplier is responsible for leaving the Buyer's premises in a clean, safe and tidy condition and making good any damage that it has caused to the Buyer's premises or property, other than fair wear and tear.

(h) The Supplier must ensure all Services, and anything used to deliver the Services, are of good quality and free from defects.

(i) The Buyer is entitled to withhold payment for partially or undelivered Services, but doing so does not stop it from using its other rights under the Contract.

5. Pricing and payments

5.1 In exchange for the Deliverables, the Supplier must invoice the Buyer for the charges in the Order Form.

5.2 All Charges:

(a) exclude VAT, which is payable on provision of a valid VAT invoice; and

(b) include all costs and expenses connected with the supply of Deliverables.

5.3 The Buyer must pay the Supplier the charges within 30 days of receipt by the Buyer of a valid, undisputed invoice, in cleared funds to the Supplier's account stated in the invoice or in the Order Form.

5.4 A Supplier invoice is only valid if it:

(a) includes all appropriate references including the Purchase Order Number and other details reasonably requested by the Buyer; and

(b) includes a detailed breakdown of Deliverables which have been delivered.

5.5 If there is a dispute between the Parties as to the amount invoiced, the Buyer shall pay the undisputed amount. The Supplier shall not suspend the provision of the Deliverables unless the Supplier is entitled to terminate the Contract for a failure to pay undisputed sums in accordance with clause 11.6. Any disputed amounts shall be resolved through the dispute resolution procedure detailed in clause 37.

5.6 The Buyer may retain or set-off payment of any amount owed to it by the Supplier under this Contract or any other agreement between the Supplier and the Buyer if notice and reasons are provided.

5.7 The Supplier must ensure that all Subcontractors are paid, in full, within 30 days of receipt of a valid, undisputed invoice. If this doesn't happen, the Buyer can publish the details of the late payment or non-payment.

6. The Buyer's obligations to the Supplier

6.1 If Supplier fails to comply with the Contract as a result of a Buyer Cause:

(a) the Buyer cannot terminate the Contract under clause 11;

(b) the Supplier is entitled to reasonable and proven additional expenses and to relief from liability under this Contract;

(c) the Supplier is entitled to additional time needed to deliver the Deliverables; and

(d) the Supplier cannot suspend the ongoing supply of Deliverables.

6.2 Clause 6.1 only applies if the Supplier:

(a) gives notice to the Buyer within 10 Working Days of becoming aware;

(b) demonstrates that the failure only happened because of the Buyer Cause; and

(c) mitigated the impact of the Buyer Cause.

7. Record keeping and reporting

7.1 The Supplier must ensure that suitably qualified representatives attend progress meetings with the Buyer and provide progress reports when specified in the Order Form.

7.2 The Supplier must keep and maintain full and accurate records and accounts on everything to do with the Contract for 7 years after the date of expiry or termination of the Contract and in accordance with the UK GDPR or the EU GDPR as the context requires.

7.3 The Supplier must allow any auditor appointed by the Buyer access to its premises to verify all contract accounts and records of everything to do with the Contract and provide copies for the Audit.

7.4 During an Audit, the Supplier must provide information to the auditor and reasonable co-operation at their request.

7.5 The Parties will bear their own costs when an Audit is undertaken unless the Audit identifies a material default by the Supplier, in which case the Supplier will repay the Buyer's reasonable costs in connection with the Audit.

7.6 If the Supplier is not providing any of the Deliverables, or is unable to provide them, it must immediately:

(a) tell the Buyer and give reasons;

(b) propose corrective action; and

(c) provide a deadline for completing the corrective action.

7.7 If the Buyer, acting reasonably, is concerned as to the financial stability of the Supplier such that it may impact on the continued performance of the Contract then the Buyer may:

(a) require that the Supplier provide to the Buyer (for its approval) a plan setting out how the Supplier will ensure continued performance of the Contract and the Supplier will make changes to such plan as reasonably required by the Buyer and once it is agreed then the Supplier shall act in accordance with such plan and report to the Buyer on demand; and

(b) if the Supplier fails to provide a plan or fails to agree any changes which are requested by the Buyer or fails to implement or provide updates on progress with the plan, terminate the Contract immediately for material breach (or on such date as the Buyer notifies).

7.8 If there is a material default, the Supplier must notify the Buyer within 3 Working Days of the Supplier becoming aware of the material default. The Buyer may request that the Supplier provide a Rectification Plan within 10 Working Days of the Buyer's request alongside any additional documentation that the Buyer requires. Once such Rectification Plan is agreed between the Parties (without the Buyer limiting its rights) the Supplier must immediately start work on the actions in the Rectification Plan at its own cost.

8. Supplier Staff

8.1 The Supplier Staff involved in the performance of the Contract must:

(a) be appropriately trained and qualified;

(b) be vetted in accordance with the Staff Vetting Procedures; and

(c) comply with all conduct requirements when on the Buyer's premises.

8.2 Where the Buyer decides one of the Supplier's Staff isn't suitable to work on the Contract, the Supplier must replace them with a suitably qualified alternative.

8.3 If requested, the Supplier must replace any person whose acts or omissions have caused the Supplier to breach clause 29.1 to 29.3 .

8.4 The Supplier must provide a list of Supplier Staff needing to access the Buyer's premises and say why access is required.

8.5 The Supplier indemnifies the Buyer against all claims brought by any person employed or engaged by the Supplier caused by an act or omission of the Supplier or any Supplier Staff.

8.6 The Supplier shall use those persons nominated (if any) as Key Staff in the Order Form or otherwise notified as such by the Buyer to the Supplier in writing, following agreement to the same by the Supplier to provide the Deliverables and shall not remove or replace any of them unless:

(a) requested to do so by the Buyer or the Buyer approves such removal or replacement (not to be unreasonably withheld or delayed);

(b) the person concerned resigns, retires or dies or is on parental or long-term sick leave; or

(c) the person's employment or contractual arrangement with the Supplier or any Subcontractor is terminated for material breach of contract by the employee.

8.7 The Supplier shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Contract, relevant to the work of the Buyer, or is of a type otherwise advised by the Buyer (each such conviction a "**Relevant Conviction**"), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a disclosure and barring service check or otherwise) is employed or engaged in the provision of any part of the Deliverables.

9. Rights and protection

9.1 The Supplier warrants and represents that:

(a) it has full capacity and authority to enter into and to perform the Contract;

(b) the Contract is executed by its authorised representative;

(c) it is a legally valid and existing organisation incorporated in the place it was formed;

(d) there are no known legal or regulatory actions or investigations before any court, administrative body or arbitration tribunal pending or threatened against it or its affiliates that might affect its ability to perform the Contract;

(e) all necessary rights, authorisations, licences and consents (including in relation to IPRs) are in place to enable the Supplier to perform its obligations under the Contract and the Buyer to receive the Deliverables;

(f) it doesn't have any contractual obligations which are likely to have a material adverse effect on its ability to perform the Contract; and

(g) it is not impacted by an Insolvency Event.

9.2 The warranties and representations in clause 3.3 and clause 9.1 are repeated each time the Supplier provides Deliverables under the Contract.

9.3 The Supplier indemnifies the Buyer against each of the following:

(a) wilful misconduct of the Supplier, any of its Subcontractor and/or Supplier Staff that impacts the Contract; and

(b) non-payment by the Supplier of any tax or National Insurance.

9.4 If the Supplier becomes aware of a representation or warranty made in relation to the Contract that becomes untrue or misleading, it must immediately notify the Buyer.

9.5 All third party warranties and indemnities covering the Deliverables must be assigned for the Buyer's benefit by the Supplier.

10. Intellectual Property Rights (IPRs)

10.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Supplier's Existing IPR to enable the Buyer and its sub-licensees to both:

(a) receive and use the Deliverables; and

(b) use the New IPR.

10.2 Any New IPR created under the Contract is owned by the Buyer. The Buyer gives the Supplier a licence to use any Existing IPRs and the New IPR which the Supplier reasonably requires for the purpose of fulfilling its obligations during the Term or using or exploiting the New IPR developed under the Contract.

10.3 Where a Party acquires ownership of intellectual property rights incorrectly under this Contract it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.

10.4 Neither Party has the right to use the other Party's intellectual property rights, including any use of the other Party's names, logos or trademarks, except as provided in clause 10 or otherwise agreed in writing.

10.5 If any claim is made against the Buyer for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an "**IPR Claim**"), then the Supplier indemnifies the Buyer against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.

10.6 If an IPR Claim is made or anticipated the Supplier must at its own expense and the Buyer's sole option, either:

(a) obtain for the Buyer the rights in clauses 10.1 and 10.2 without infringing any third party intellectual property rights; and

(b) replace or modify the relevant item with substitutes that don't infringe intellectual property rights without adversely affecting the functionality or performance of the Deliverables.

10.7 The Supplier shall not use in the Delivery of the Deliverables any Third Party IPR unless it has notified the Buyer that the owner or an authorised licensor of the relevant Third Party IPR will grant a direct licence to the Buyer for the Third Party IPR and that licence has been granted. The Buyer, in its absolute discretion, shall have 10 Working Days following the Supplier's notification to reject the grant of the licence. If the Supplier cannot obtain for the Buyer a licence in respect of any Third Party IPR, for whatever reason, the Supplier shall:

(a) notify the Buyer in writing; and

(b) use the relevant Third Party IPR only if the Buyer has provided authorisation in writing, with reference to the acts authorised and the specific intellectual property rights involved.

10.8 In spite of any other provisions of the Contract and for the avoidance of doubt, award of this Contract by the Buyer and the ordering of any Deliverable under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Sections 240 – 243 of the Copyright, Designs and Patents Act 1988.

11. Ending the contract

11.1 The Contract takes effect on the Start Date and ends on the earlier of the Expiry Date or termination of the Contract, or earlier if required by Law.

11.2 The Buyer can extend the Contract where set out in the Order Form in accordance with the terms in the Order Form.

11.3 **Ending the Contract without a reason**

The Buyer has the right to terminate the Contract at any time without reason or liability by giving the Supplier not less than 90 days' written notice, and if it's terminated clause 11.5(a)(ii) to 11.5(a)(viii) applies.

11.4 **When the Buyer can end the Contract**

(a) If any of the following events happen, the Buyer has the right to immediately terminate its Contract by issuing a termination notice in writing to the Supplier:

(i) there's a Supplier Insolvency Event;

(ii) if the Supplier repeatedly breaches the Contract in a way to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms and conditions of the Contract;

(iii) the Supplier is in material breach of any obligation which is capable of remedy, and that breach is not remedied within 30 days of the Supplier receiving notice specifying the breach and requiring it to be remedied;

(iv) there's a change of control (within the meaning of section 450 of the Corporation Tax Act 2010) of the Supplier which isn't pre-approved by the Buyer in writing; which will not be unreasonably withheld or delayed.

(v) the Buyer discovers that the Supplier was in one of the situations in 57 (1) or 57(2) of the Regulations at the time the Contract was awarded;

(vi) the Supplier or its affiliates embarrass or bring the Buyer into disrepute or diminish the public trust in them; or

(vii) the Supplier fails to comply with its legal obligations in the fields of environmental, social, equality or employment Law when providing the Deliverables.

(b) The Buyer also has the right to terminate the Contract in accordance with clauses 7.7(b), 21.3, 29.4(b), 34.3 and Paragraph **Error! Reference source not found.** of ***Error! Reference source not found.*** of Annex 1 – *Processing Personal Data* (if used).

(c) If any of the events in 73(1) (a) or (b) of the Regulations happen, the Buyer has the right to immediately terminate the Contract and clause 11.5(a)(ii) to 11.5(a)(viii) applies.

11.5 **What happens if the Contract ends (Buyer termination)**

(a) Where the Buyer terminates the Contract under clause 11.4(a), 7.7(b), 29.4(b), or Paragraph **Error! Reference source not found.** of ***Error! Reference source not found.*** of Annex 1 – *Processing Personal Data* (if used), all of the following apply:

(i) the Supplier is responsible for the Buyer's reasonable costs of procuring replacement Deliverables for the rest of the term of the Contract;

(ii) the Buyer's payment obligations under the terminated Contract stop immediately;

(iii) accumulated rights of the Parties are not affected;

(iv) the Supplier must promptly delete or return the Government Data except where required to retain copies by Law;

(v) the Supplier must promptly return any of the Buyer's property provided under the Contract;

(vi) the Supplier must, at no cost to the Buyer, give all reasonable assistance to the Buyer and any incoming supplier and co-operate fully in the handover and re-procurement;

(vii) the Supplier must repay to the Buyer all the Charges that it has been paid in advance for Deliverables that it has not provided as at the date of termination or expiry; and

(viii) the following clauses survive the termination of the Contract: 4.2(j), 7, 8.5, 10, 12, 14, 15, 16, 19, 20, 37 and 38 and any clauses which are expressly or by implication intended to continue.

11.6 **When the Supplier can end the Contract and what happens when the contract ends (Buyer and Supplier termination)**

(a) The Supplier can issue a reminder notice if the Buyer does not pay an undisputed invoice on time. The Supplier can terminate the Contract if the Buyer fails to pay an undisputed invoiced sum due and worth over 10% of the total Contract value or £1,000, whichever is the lower, within 30 days of the date of the reminder notice.

(b) Where the Buyer terminates the Contract in accordance with clause 11.3 or the Supplier terminates the Contract under clause 11.6(a) or 24.4:

(i) the Buyer must promptly pay all outstanding charges incurred by the Supplier;

(ii) the Buyer must pay the Supplier reasonable committed and unavoidable losses as long as the Supplier provides a fully itemised and costed schedule with evidence - the maximum value of this payment is limited to the total sum payable to the Supplier if the Contract had not been terminated; and

(iii) clauses 11.5(a)(ii) to 11.5(a)(viii) apply.

(c) The Supplier also has the right to terminate the Contract in accordance with Clauses 21.3 and 24.4.

11.7 **Partially ending and suspending the Contract**

(a) Where the Buyer has the right to terminate the Contract it can terminate or suspend (for any period), all or part of it. If the Buyer suspends the Contract it can provide the Deliverables itself or buy them from a third party.

(b) The Buyer can only partially terminate or suspend the Contract if the remaining parts of it can still be used to effectively deliver the intended purpose.

(c) The Parties must agree (in accordance with clause 26) any necessary variation required by clause 11.7, but the Supplier may not either:

(i) reject the variation; or

(ii) increase the Charges, except where the right to partial termination is under clause 11.3.

(d) The Buyer can still use other rights available, or subsequently available to it if it acts on its rights under clause 11.7.

12. How much you can be held responsible for

12.1 Each Party's total aggregate liability under or in connection with the Contract (whether in tort, contract or otherwise) is no more than 125% of the Charges paid or payable to the Supplier.

12.2 No Party is liable to the other for:

(a) any indirect losses; and/or

(b) loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect).

12.3 In spite of clause 12.1, neither Party limits or excludes any of the following:

(a) its liability for death or personal injury caused by its negligence, or that of its employees, agents or Subcontractors;

(b) its liability for bribery or fraud or fraudulent misrepresentation by it or its employees; or

(c) any liability that cannot be excluded or limited by Law.

12.4 In spite of clause 12.1, the Supplier does not limit or exclude its liability for any indemnity given under clauses 8.5, 9.3(b), 10.5, or 33.2(b).

12.5 Notwithstanding clause 12.1, but subject to clauses 12.1 and 12.3, the Supplier's total aggregate liability under clause 14.7(e) shall not exceed the Data Protection Liability Cap.

12.6 Each Party must use all reasonable endeavours to mitigate any loss or damage which it suffers under or in connection with the Contract, including any indemnities.

12.7 If more than one Supplier is party to the Contract, each Supplier Party is fully responsible for both their own liabilities and the liabilities of the other Suppliers.

13. Obeying the Law

13.1 The Supplier must, in connection with provision of the Deliverables:

(a) comply and procure that its Subcontractors comply with the Supplier Code of Conduct: (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779660/20190220-Supplier_Code_of_Conduct.pdf) as such Code of Conduct may be updated from time to time, and such other sustainability requirements as set out in the Order Form;

(b) comply with the provisions of the Official Secrets Acts 1911 to 1989 and section 182 of the Finance Act 1989;

(c) support the Buyer in fulfilling its Public Sector Equality duty under section 149 of the Equality Act 2010;

(d) comply with the model contract terms contained in Example 1 of Annex C of the guidance to PPN 05/19 (Tackling Modern Slavery in Government Supply Chains) shall apply to the Contract, as such clauses may be amended or updated from time to time; and

(e) meet the applicable Government Buying Standards applicable to Deliverables which can be found online at: https://www.gov.uk/government/collections/sustainable-procurement-the-government-buying-standards-gbs.

13.2 The Supplier indemnifies the Buyer against any costs resulting from any default by the Supplier relating to any applicable Law to do with the Contract.

13.3 The Supplier must appoint a Compliance Officer who must be responsible for ensuring that the Supplier complies with Law, clause 13.1 and clauses 28 to 35.

14. Data Protection

14.1 The Supplier must not remove any ownership or security notices in or relating to the Government Data.

14.2 The Supplier must make accessible back-ups of all Government Data, stored in an agreed off-site location and send the Buyer copies every 6 Months.

14.3 The Supplier must ensure that any Supplier system holding any Government Data, including back-up data, is a secure system that complies with the security requirements specified in writing by the Buyer (where any such requirements have been provided).

14.4 If at any time the Supplier suspects or has reason to believe that the Government Data is corrupted, lost or sufficiently degraded, then the Supplier must immediately notify the Buyer and suggest remedial action.

14.5 If the Government Data is corrupted, lost or sufficiently degraded so as to be unusable the Buyer may either or both:

(a) tell the Supplier to restore or get restored Government Data as soon as practical but no later than 5 Working Days from the date that the Buyer receives notice, or the Supplier finds out about the issue, whichever is earlier; and/or

(b) restore the Government Data itself or using a third party.

14.6 The Supplier must pay each Party's reasonable costs of complying with clause 14.5 unless the Buyer is at fault.

14.7 The Supplier:

(a) must provide the Buyer with all Government Data in an agreed open format within 10 Working Days of a written request;

(b) must have documented processes to guarantee prompt availability of Government Data if the Supplier stops trading;

(c) must securely destroy all storage media that has held Government Data at the end of life of that media using Good Industry Practice;

(d) securely erase all Government Data and any copies it holds when asked to do so by the Buyer unless required by Law to retain it; and

(e) indemnifies the Buyer against any and all losses incurred if the Supplier breaches clause 14 or any Data Protection Legislation.

14.8 The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under the Contract dictates the status of each party under the DPA 2018. A Party may act as:

(a) “Controller” in respect of the other Party who is “Processor”;

(b) “Processor” in respect of the other Party who is “Controller”;

(c) “Joint Controller” with the other Party;

(d) “Independent Controller” of the Personal Data where the other Party is also “Controller”,

in respect of certain Personal Data under the Contract and shall specify in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data* which scenario they think shall apply in each situation.

14.9 **Where one Party is Controller and the other Party its Processor**

(a) Where a Party is a Processor, it must only process Personal Data if authorised to do so in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data* by the Controller. Any further written instructions relating to the processing of Personal Data are incorporated into Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data*.

(b) The Processor must give all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment before starting any processing, including:

(i) a systematic description of the expected processing and its purpose;

(ii) the necessity and proportionality of the processing operations;

(iii) the risks to the rights and freedoms of Data Subjects; and

(iv) the intended measures to address the risks, including safeguards, security measures and mechanisms to protect Personal Data.

(c) The Processor must notify the Controller immediately if it thinks the Controller's instructions breach the Data Protection Legislation.

(d) The Processor must put in place appropriate Protective Measures to protect against a Data Loss Event which must be approved by the Controller.

(e) If lawful to notify the Controller, the Processor must promptly notify the Controller if the Processor is otherwise required to process Personal Data by Law before processing it.

(f) The Processor must use all reasonable endeavours to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:

(i) are aware of and comply with the Processor's duties under this clause 14;

(ii) are subject to appropriate confidentiality undertakings with the Processor or any Subprocessor;

(iii) are informed of the confidential nature of the Personal Data and do not provide any of the Personal Data to any third party unless directed in writing to do so by the Controller or as otherwise allowed by the Contract; and

(iv) have undergone adequate training in the use, care, protection and handling of Personal Data.

(g) Where the Personal Data is subject to UK GDPR, the Processor must not transfer Personal Data outside of the UK unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:

(i) the transfer is in accordance with Article 45 of the UK GDPR (or section 73 of DPA 2018); or

(ii) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with UK GDPR Article 46 or section 75 of the DPA 2018) as determined by the Controller which could include relevant parties entering into the International Data Transfer Agreement (the "**IDTA**"), or International Data Transfer Agreement Addendum to the European Commission's SCCs (the "**Addendum**"), as published by the Information Commissioner's Office from time to time as well as any additional measures determined by the Controller;

(iii) the Data Subject has enforceable rights and effective legal remedies when transferred;

(iv) the Processor meets its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred; and

(v) the Processor complies with the Controller's reasonable prior instructions about the processing of the Personal Data.

(h) Where the Personal Data is subject to EU GDPR, the Processor must not transfer Personal Data outside of the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:

(i) the transfer is in accordance with Article 45 of the EU GDPR; or

(i) the Controller or Processor has provided appropriate safeguards in relation to the transfer in accordance with Article 46 of the EU GDPR as determined by the Controller which could include relevant parties entering into Standard Contractual Clauses in the European Commission's decision 2021/914/EU or such updated version of such Standard Contractual Clauses as are published by the European Commission from time to time as well as any additional measures determined by the Controller;

(ii) the Data Subject has enforceable rights and effective legal remedies;

(iii) the Processor complies with its obligations under the EU GDPR by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and

(iv) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the processing of the Personal Data.

(j) The Processor must notify the Controller immediately if it:

(i) receives a Data Subject Access Request (or purported Data Subject Access Request);

(ii) receives a request to rectify, block or erase any Personal Data;

(iii) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

(iv) receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract;

(v) receives a request from any third Party for disclosure of Personal Data where compliance with the request is required or claims to be required by Law; and

(vi) becomes aware of a Data Loss Event.

(k) Any requirement to notify under clause (j) includes the provision of further information to the Controller in stages as details become available.

(i) The Processor must promptly provide the Controller with full assistance in relation to any Party's obligations under Data Protection Legislation and any complaint, communication or request made under clause (j). This includes giving the Controller:

(ii) full details and copies of the complaint, communication or request;

(iii) reasonably requested assistance so that it can comply with a Data Subject Access Request within the relevant timescales in the Data Protection Legislation;

(iv) any Personal Data it holds in relation to a Data Subject on request;

(v) assistance that it requests following any Data Loss Event; and

(vi) assistance that it requests relating to a consultation with, or request from, the Information Commissioner's Office or any other regulatory authority.

(l) The Processor must maintain full, accurate records and information to show it complies with this clause 14. This requirement does not apply where the Processor employs fewer than 250 staff, unless either the Controller determines that the processing:

(i) is not occasional;

(ii) includes special categories of data as referred to in Article 9(1) of the UK GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the UK GDPR; or

(iii) is likely to result in a risk to the rights and freedoms of Data Subjects.

(m) The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.

(n) Before allowing any Subprocessor to process any Personal Data, the Processor must:

(i) notify the Controller in writing of the intended Subprocessor and processing;

(ii) obtain the written consent of the Controller;

(iii) enter into a written contract with the Subprocessor so that this clause 14 applies to the Subprocessor; and

(iv) provide the Controller with any information about the Subprocessor that the Controller reasonably requires.

(o) The Processor remains fully liable for all acts or omissions of any Subprocessor.

(p) At any time the Buyer can, with 30 Working Days' notice to the Supplier, change this clause 14 to replace it with any applicable standard clauses (between the controller and processor) or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to the Contract).

(q) The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office or any other regulatory authority.

14.10 **Joint Controllers of Personal Data**

In the event that the Parties are Joint Controllers in respect of Personal Data under the Contract, the Parties shall implement paragraphs that are necessary to comply with UK GDPR Article 26 based on the terms set out in ***Error! Reference source not found.*** of Annex 1 – *Processing Personal Data*.

14.11 **Independent Controllers of Personal Data**

In the event that the Parties are Independent Controllers in respect of Personal Data under the Contract, the terms set out in **Error! Reference source not found.** of Annex 1 – *Processing Personal Data* shall apply to this Contract.

15. What you must keep confidential

15.1 Each Party must:

(a) keep all Confidential Information it receives confidential and secure;

(b) not disclose, use or exploit the disclosing Party's Confidential Information without the disclosing Party's prior written consent, except for the purposes anticipated under the Contract; and

(c) immediately notify the disclosing Party if it suspects unauthorised access, copying, use or disclosure of the Confidential Information.

15.2 In spite of clause 15.1, a Party may disclose Confidential Information which it receives from the disclosing Party in any of the following instances:

(a) where disclosure is required by applicable Law, a regulatory body or a court with the relevant jurisdiction if the recipient Party notifies the disclosing Party of the full circumstances, the affected Confidential Information and extent of the disclosure;

(b) if the recipient Party already had the information without obligation of confidentiality before it was disclosed by the disclosing Party;

(c) if the information was given to it by a third party without obligation of confidentiality;

(d) if the information was in the public domain at the time of the disclosure;

(e) if the information was independently developed without access to the disclosing Party's Confidential Information;

(f) on a confidential basis, to its auditors or for the purposes of regulatory requirements;

(g) on a confidential basis, to its professional advisers on a need-to-know basis; and

(h) to the Serious Fraud Office where the recipient Party has reasonable grounds to believe that the disclosing Party is involved in activity that may be a criminal offence under the Bribery Act 2010.

15.3 The Supplier may disclose Confidential Information on a confidential basis to Supplier Staff on a need-to-know basis to allow the Supplier to meet its obligations under the Contract. The Supplier shall remain responsible at all times for compliance with the confidentiality obligations set out in this Contract by the persons to whom disclosure has been made.

15.4 The Buyer may disclose Confidential Information in any of the following cases:

(a) on a confidential basis to the employees, agents, consultants and contractors of the Buyer;

(b) on a confidential basis to any other Central Government Body, any successor body to a Central Government Body or any company that the Buyer transfers or proposes to transfer all or any part of its business to;

(c) if the Buyer (acting reasonably) considers disclosure necessary or appropriate to carry out its public functions;

(d) where requested by Parliament; and

(e) under clauses 5.7 and 16.

15.5 For the purposes of clauses 15.2 to 15.4 references to disclosure on a confidential basis means disclosure under a confidentiality agreement or arrangement including terms as strict as those required in clause 15.

15.6 Transparency Information, and Information which is exempt from disclosure by clause 16 is not Confidential Information.

15.7 The Supplier must not make any press announcement or publicise the Contract or any part of it in any way, without the prior written consent of the Buyer and must take all reasonable endeavours to ensure that Supplier Staff do not either.

16. When you can share information

16.1 The Supplier must tell the Buyer within 48 hours if it receives a Request For Information.

16.2 In accordance with a reasonable timetable and in any event within 5 Working Days of a request from the Buyer, the Supplier must give the Buyer full co-operation and information needed so the Buyer can:

(a) comply with any FOIA request;

(b) comply with any Environmental Information Regulations ("**EIR**") request;

(c) if the Contract has a value over the relevant threshold in Part 2 of the Regulations, comply with any of its obligations in relation to publishing Transparency Information.

16.3 To the extent that it is allowed and practical to do so, the Buyer will use reasonable endeavours to notify the Supplier of a Request For Information and may talk to the Supplier to help it decide whether to publish information under clause 16. However, the extent, content and format of the disclosure is the Buyer's decision in its absolute discretion.

17. Insurance

The Supplier shall ensure it has adequate insurance cover for this Contract.

18. Invalid parts of the contract

If any part of the Contract is prohibited by Law or judged by a court to be unlawful, void or unenforceable, it must be read as if it was removed from the Contract as much as required and rendered ineffective as far as possible without affecting the rest of the Contract, whether it's valid or enforceable.

19. No other terms apply

The provisions incorporated into the Contract are the entire agreement between the Parties. The Contract replaces all previous statements, or agreements whether written or oral. No other provisions apply.

20. Other people's rights in the contract

No third parties may use the Contracts (Rights of Third Parties) Act ("**CRTPA"**) to enforce any term of the Contract unless stated (referring to CRTPA) in the Contract. This does not affect third party rights and remedies that exist independently from CRTPA.

21. Circumstances beyond your control

21.1 Any Party affected by a Force Majeure Event is excused from performing its obligations under the Contract while the inability to perform continues, if it both:

(a) provides written notice to the other Party; and

(b) uses all reasonable measures practical to reduce the impact of the Force Majeure Event.

21.2 Any failure or delay by the Supplier to perform its obligations under the Contract that is due to a failure or delay by an agent, Subcontractor and/or Supplier Staff will only be considered a Force Majeure Event if that third party is itself prevented from complying with an obligation to the Supplier due to a Force Majeure Event.

21.3 Either Party can partially or fully terminate the Contract if the provision of the Deliverables is materially affected by a Force Majeure Event which lasts for 90 days continuously.

21.4 Where a Party terminates under clause 21.3:

(a) each Party must cover its own losses; and

(b) clause 11.5(a)(ii) to 11.5(a)(viii) applies.

22. Relationships created by the contract

The Contract does not create a partnership, joint venture or employment relationship. The Supplier must represent themselves accordingly and ensure others do so.

23. Giving up contract rights

A partial or full waiver or relaxation of the terms of the Contract is only valid if it is stated to be a waiver in writing to the other Party.

24. Transferring responsibilities

24.1 The Supplier cannot assign, novate or in any other way dispose of the Contract or any part of it without the Buyer's written consent, which will not be unreasonably withheld or delayed.

24.2 The Buyer can assign, novate or transfer its Contract or any part of it to any Crown Body, public or private sector body which performs the functions of the Buyer.

24.3 When the Buyer uses its rights under clause 24.2 the Supplier must enter into a novation agreement in the form that the Buyer specifies.

24.4 The Supplier can terminate the Contract novated under clause 24.2 to a private sector body that is experiencing an Insolvency Event.

24.5 The Supplier remains responsible for all acts and omissions of the Supplier Staff as if they were its own.

25. Supply Chain

25.1 The Supplier cannot sub-contract the Contract or any part of it without the Buyer's prior written consent. The Supplier shall provide the Buyer with the name of any Subcontractor the Supplier proposes to engage for the purposes of the Contract. The decision of the Buyer to consent or not will not be unreasonably withheld or delayed. If the Buyer does not communicate a decision to the Supplier within 10 Working Days of the request for consent then its consent will be deemed to have been given. The Buyer may reasonably withhold its consent to the appointment of a Subcontractor if it considers that:

(a) the appointment of a proposed Subcontractor may prejudice the provision of the Deliverables or may be contrary to its interests;

(b) the proposed Subcontractor is unreliable and/or has not provided reliable goods and or reasonable services to its other customers; and/or

(c) the proposed Subcontractor employs unfit persons.

25.2 If the Buyer asks the Supplier for details about Subcontractors, the Supplier must provide details of all such Subcontractors at all levels of the supply chain including:

(a) their name;

(b) the scope of their appointment; and

(c) the duration of their appointment.

25.3 The Supplier must exercise due skill and care when it selects and appoints Subcontractors.

25.4 The Supplier will ensure that all Sub-Contracts in the Supplier's supply chain entered into after the Start Date wholly or substantially for the purpose of performing or contributing to the performance of the whole or any part of this Contract contain provisions that:

(a) allow the Supplier to terminate the Sub-Contract if the Subcontractor fails to comply with its obligations in respect of environmental, social, equality or employment Law;

(b) require the Supplier to pay all Subcontractors in full, within 30 days of receiving a valid, undisputed invoice; and

(c) allow the Buyer to publish the details of the late payment or non-payment if this 30-day limit is exceeded.

25.5 The Supplier will take reasonable endeavours to ensure that all Sub-Contracts in the Supplier's supply chain entered into before the Start Date but made wholly or substantially for the purpose of performing or contributing to the performance of the whole or any part of this Contract contain provisions that:

(a) allow the Supplier to terminate the Sub-Contract if the Subcontractor fails to comply with its obligations in respect of environmental, social, equality or employment Law;

(b) require the Supplier to pay all Subcontractors in full, within 30 days of receiving a valid, undisputed invoice; and

(c) allow the Buyer to publish the details of the late payment or non-payment if this 30-day limit is exceeded.

25.6 At the Buyer's request, the Supplier must terminate any Sub-Contracts in any of the following events:

(a) there is a change of control within the meaning of Section 450 of the Corporation Tax Act 2010 of a Subcontractor which isn't pre-approved by the Buyer in writing;

(b) the acts or omissions of the Subcontractor have caused or materially contributed to a right of termination under Clause 11.4;

(c) a Subcontractor or its Affiliates embarrasses or brings into disrepute or diminishes the public trust in the Buyer;

(d) the Subcontractor fails to comply with its obligations in respect of environmental, social, equality or employment Law; and/or

(e) the Buyer has found grounds to exclude the Subcontractor in accordance with Regulation 57 of the Regulations.

25.7 The Supplier is responsible for all acts and omissions of its Subcontractors and those employed or engaged by them as if they were its own.

26. Changing the contract

Either Party can request a variation to the Contract which is only effective if agreed in writing and signed by both Parties. The Buyer is not required to accept a variation request made by the Supplier.

27. How to communicate about the contract

27.1 All notices under the Contract must be in writing and are considered effective on the Working Day of Delivery as long as they're delivered before 5:00pm on a Working

Day. Otherwise the notice is effective on the next Working Day. An email is effective at 9am on the first Working Day after sending unless an error message is received.

27.2 Notices to the Buyer or Supplier must be sent to their address or email address in the Order Form.

27.3 This clause does not apply to the service of legal proceedings or any documents in any legal action, arbitration or dispute resolution.

28. Dealing with claims

28.1 If the Buyer becomes aware of any Claim, the Buyer must:

(a) notify the Supplier as soon as reasonably practical becoming aware of a Claim;

(b) at the Supplier's cost, allow the Supplier to conduct all negotiations and proceedings to do with a Claim;

(c) at the Supplier's cost, give the Supplier reasonable assistance with the Claim if requested; and

(d) not make admissions about the Claim without the prior written consent of the Supplier which cannot be unreasonably withheld or delayed.

28.2 The Supplier must:

(a) consider and defend the Claim diligently and in a way that does not damage the Buyer's reputation; and

(b) not settle or compromise any Claim without the Buyer's prior written consent which it must not unreasonably withhold or delay.

29. Preventing fraud, bribery and corruption

29.1 The Supplier shall not:

(a) commit any criminal offence referred to in 57(1) and 57(2) of the Regulations; or

(b) offer, give, or agree to give anything, to any person (whether working for or engaged by the Buyer or any other public body) an inducement or reward for doing, refraining from doing, or for having done or refrained from doing, any act in relation to the obtaining or execution of the Contract or any other public function or for showing or refraining from showing favour or disfavour to any person in relation to the Contract or any other public function.

29.2 The Supplier shall take all reasonable endeavours (including creating, maintaining and enforcing adequate policies, procedures and records), in accordance with Good Industry Practice, to prevent any matters referred to in clause 29.1 and any fraud by the Supplier Staff and the Supplier (including its shareholders, members and directors) in connection with the Contract and shall notify the Buyer immediately if it has reason to suspect that any such matters have occurred or is occurring or is likely to occur.

29.3 If the Supplier notifies the Buyer as required by clause 29.2, the Supplier must respond promptly to their further enquiries, co-operate with any investigation and allow the Audit of any books, records and relevant documentation.

29.4 If the Supplier or the Supplier Staff engages in conduct prohibited by clause 29.1 or commits fraud in relation to the Contract or any other contract with the Crown (including the Buyer) the Buyer may:

(a) require the Supplier to remove any Supplier Staff from providing the Deliverables if their acts or omissions have caused the default; and

(b) immediately terminate the Contract.

30. Equality, diversity and human rights

30.1 The Supplier must follow all applicable employment and equality Law when they perform their obligations under the Contract, including:

(a) protections against discrimination on the grounds of race, sex, gender reassignment, religion or belief, disability, sexual orientation, pregnancy, maternity, age or otherwise; and

(b) any other requirements and instructions which the Buyer reasonably imposes related to equality Law.

30.2 The Supplier must use all reasonable endeavours, and inform the Buyer of the steps taken, to prevent anything that is considered to be unlawful discrimination by any court or tribunal, or the Equality and Human Rights Commission (or any successor organisation) when working on the Contract.

31. Health and safety

31.1 The Supplier must perform its obligations meeting the requirements of:

(a) all applicable Law regarding health and safety; and

(b) the Buyer's current health and safety policy while at the Buyer's premises, as provided to the Supplier.

31.2 The Supplier and the Buyer must as soon as possible notify the other of any health and safety incidents or material hazards they're aware of at the Buyer premises that relate to the performance of the Contract.

32. Environment and sustainability

32.1 In performing its obligations under the Contract, the Supplier shall, to the reasonable satisfaction of the Buyer:

(a) meet, in all material respects, the requirements of all applicable Laws regarding the environment; and

(b) comply with its obligations under the Buyer's current environmental policy, which the Buyer must provide.

32.2 The Supplier must ensure that Supplier Staff are aware of the Buyer's environmental policy.

33. Tax

33.1 The Supplier must not breach any tax or social security obligations and must enter into a binding agreement to pay any late contributions due, including where applicable, any interest or any fines. The Buyer cannot terminate the Contract where the Supplier has not paid a minor tax or social security contribution.

33.2 Where the Supplier or any Supplier Staff are liable to be taxed or to pay National Insurance contributions in the UK relating to payment received under the Contract, the Supplier must both:

(a) comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations relating to income tax, the Social Security Contributions and Benefits Act 1992 (including IR35) and National Insurance contributions; and

(b) indemnify the Buyer against any Income Tax, National Insurance and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made during or after the Term in connection with the provision of the Deliverables by the Supplier or any of the Supplier Staff.

33.3 If any of the Supplier Staff are Workers who receive payment relating to the Deliverables, then the Supplier must ensure that its contract with the Worker contains requirements that:

(a) the Buyer may, at any time during the term of the Contract, request that the Worker provides information which demonstrates they comply with clause 33.2, or why those requirements do not apply, the Buyer can specify the information the Worker must provide and the deadline for responding;

(b) the Worker's contract may be terminated at the Buyer's request if the Worker fails to provide the information requested by the Buyer within the time specified by the Buyer;

(c) the Worker's contract may be terminated at the Buyer's request if the Worker provides information which the Buyer considers isn't good enough to demonstrate how it complies with clause 33.2 or confirms that the Worker is not complying with those requirements; and

(d) the Buyer may supply any information they receive from the Worker to HMRC for revenue collection and management.

34. Conflict of interest

34.1 The Supplier must take action to ensure that neither the Supplier nor the Supplier Staff are placed in the position of an actual, potential or perceived Conflict of Interest.

34.2 The Supplier must promptly notify and provide details to the Buyer if an actual, potential or perceived Conflict of Interest happens or is expected to happen.

34.3 The Buyer will consider whether there are any appropriate measures that can be put in place to remedy an actual, perceived or potential Conflict of Interest. If, in the reasonable opinion of the Buyer, such measures do not or will not resolve an actual or potential conflict of interest, the Buyer may terminate the Contract immediately by giving notice in writing to the Supplier where there is or may be an actual or potential Conflict of Interest and clauses 11.5(a)(ii) to 11.5(a)(viii) shall apply.

35. Reporting a breach of the contract

35.1 As soon as it is aware of it the Supplier and Supplier Staff must report to the Buyer any actual or suspected breach of Law, clause 13.1, or clauses 28 to 34.

35.2 The Supplier must not retaliate against any of the Supplier Staff who in good faith reports a breach listed in clause 35.1 to the Buyer or a Prescribed Person.

36. Further Assurances

Each Party will, at the request and cost of the other Party, do all things which may be reasonably necessary to give effect to the meaning of this Contract.

37. Resolving disputes

37.1 If there is a dispute between the Parties, their senior representatives who have authority to settle the dispute will, within 28 days of a written request from the other Party, meet in good faith to resolve the dispute by commercial negotiation.

37.2 If the dispute is not resolved at that meeting, the Parties can attempt to settle it by mediation using the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure current at the time of the dispute. If the Parties cannot agree on a mediator, the mediator will be nominated by CEDR. If either Party does not wish to use, or continue to use mediation, or mediation does not resolve the dispute, the dispute must be resolved using clauses 37.3 to 37.5.

37.3 Unless the Buyer refers the dispute to arbitration using clause 37.4, the Parties irrevocably agree that the courts of England and Wales have the exclusive jurisdiction to:

(a) determine the dispute;

(b) grant interim remedies; and

(c) grant any other provisional or protective relief.

37.4 The Supplier agrees that the Buyer has the exclusive right to refer any dispute to be finally resolved by arbitration under the London Court of International Arbitration Rules current at the time of the dispute. There will be only one arbitrator. The seat or legal place of the arbitration will be London and the proceedings will be in English.

37.5 The Buyer has the right to refer a dispute to arbitration even if the Supplier has started or has attempted to start court proceedings under clause 37.3, unless the Buyer has agreed to the court proceedings or participated in them. Even if court proceedings have started, the Parties must do everything necessary to ensure that the court proceedings are stayed in favour of any arbitration proceedings if they are started under clause 37.4.

37.6 The Supplier cannot suspend the performance of the Contract during any dispute.

38. Which law applies

This Contract and any issues or disputes arising out of, or connected to it, are governed by English law.