Award Form

This Award Form creates the Contract. It summarises the main features of the procurement and includes the Buyer and the Supplier's contact details.

1.	**Buyer**	Food Standards Agency (the Buyer) Its offices are on: Clive House 70 Petty France London, SW1H 9EX
2.	**Supplier**	Name: LGC Address: Queens Road, Teddington, TW11 0LY Registration number: 2991879 SID4GOV ID: NA
3.	**Contract**	This Contract between the Buyer and the Supplier is for the supply of Deliverables. This opportunity is advertised in the Contract Notice in the Official Journal of the European Union reference 2020/S 227-560607 (OJEU Contract Notice).
4.	**Contract Reference**	**FS430418 -** GMO Food and Feed Authorisation GB
5.	**Deliverables**	Delivering the provision of laboratory services for the authorisation of new GMO applications for Great Britain (GB), renewal GMO applications for GB and the review and re-validation of existing and ongoing applications as and when necessary on behalf of the FSA. See Schedule 2 (Specification) for further details.
6.	**Start Date**	1st April 2021
7.	**End Date**	31st March 2026 (with a review point break clause at 3 Years
8.	**Extension Period**	Review point break clause at 3 years 31st March 2024.
9.	**Incorporated Terms** (together these documents form the 'the Contract')	The following documents are incorporated into the Contract. Where numbers are missing we are not using these Schedules. If the documents conflict, the following order of precedence applies: 1. This Award Form

		2. Any Special Terms (see **Section 10 Special Terms** in this Award Form) 3. Core Terms (version 1.0) 4. Schedule 1 (Definitions) 5. Schedule 20 (Processing Data) 6. The following Schedules (in equal order of precedence): ● Schedule 2 (Specification) ● Schedule 3 (Charges) ● Schedule 4 (Tender) ● Schedule 5 (Commercially Sensitive Information) ● Schedule 13 (Contract Management) ● Schedule 16 (Security) ● Schedule 20 (Processing Data) ● Schedule 21 (Variation Form) ● Schedule 22 (Insurance Requirements) ● Schedule 27 (Key Subcontractors)
10.	**Special Terms**	Special Term 1 set forth in in Annex 1 – amendments to the Agreement
11.	**Social Value Commitment**	Not applicable
12.	**Commercially Sensitive Information**	Supplier's Commercially Sensitive Information**:** Schedule 5
13.	**Charges**	Details in Schedule 3 (Charges)
14.	**Reimbursable expenses**	Recoverable as set out in Schedule 3 (Charges)
15.	**Payment Method**	All invoices must be sent, quoting a valid purchase order number (PO Number), to: [redacted] Within 10 Working Days of receipt of your countersigned copy of this letter, 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, PO Number item number (if applicable)

		and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment. [redacted]
16.	**Insurance**	Details in Annex of Schedule 22 (Insurance Requirements).
17.	**Liability**	In accordance with Clause 11.1 of the Core Terms each Party's total aggregate liability in each Contract Year under the Contract (whether in tort, contract or otherwise) is no more than £2 million
18.	**Supplier Contract Manager**	[redacted]
19.	**Key Subcontractors**	Key Subcontractor 1 Name (Registered name if registered) [insert name] Registration number (if registered) [insert number] Role of Subcontractor [insert role] [Guidance: copy above lines as needed]
20.	**Buyer Authorised Representative**	[redacted]

Signed for and on behalf of the **Supplier**	Signed for and on behalf of the **Buyer**
[redacted]	

Core Terms – Mid-tier

1. Definitions used in the contract

1.1 Interpret this Contract using Schedule 1 (Definitions).

2. How the contract works

2.1 If the Buyer decides to buy Deliverables under the Contract it must state its requirements using the Award Form). If allowed by the Regulations, the Buyer can:

- make changes to Award Form
- create new Schedules
- exclude optional template Schedules
- use Special Terms in the Award Form to add or change terms

2.2 The Contract:

- is between the Supplier and the Buyer
- includes Core Terms, Schedules and any other changes or items in the completed Award Form

2.3 The Supplier acknowledges it has all the information required to perform its obligations under the Contract before entering into it. When information is provided by the Buyer no warranty of its accuracy is given to the Supplier.

2.4 The Supplier won't be excused from any obligation, or be entitled to additional Costs or Charges because it failed to either:

- verify the accuracy of the Due Diligence Information
- properly perform its own adequate checks

2.5 The Buyer will not be liable for errors, omissions or misrepresentation of any information.

2.6 The Supplier warrants and represents that all statements made and documents submitted as part of the procurement of Deliverables are and remain true and accurate.

3. What needs to be delivered

3.1 All deliverables

3.1.1 The Supplier must provide Deliverables:

- that comply with the Specification, the Tender Response and the Contract
- using Good Industry Practice
- using its own policies, processes and internal quality control measures as long as they don't conflict with the Contract
- on the dates agreed
- that comply with Law

3.1.2 In the event that a level of warranty is not specified in the Award Form, the Supplier must provide Deliverables with a warranty of at least 90 days from Delivery against all obvious defects.

3.2 Goods clauses

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

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

3.2.3 The Supplier transfers ownership of the Goods on Delivery or payment for those Goods, whichever is earlier.

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

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

3.2.6 The Supplier must deliver the Goods on the date and to the specified location during the Buyer's working hours.

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

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

3.2.9 The Supplier must provide all tools, information and instructions the Buyer needs to make use of the Goods.
3.2.10 The Supplier must indemnify the Buyer against the costs of any Recall of the Goods and give notice of actual or anticipated action about the Recall of the Goods.

3.2.11 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 steps to minimise these costs.

3.2.12 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 3. If the Supplier doesn't do this it will pay the Buyer's costs including repair or re-supply by a third party.

3.3 Services clauses

3.3.1 Late Delivery of the Services will be a Default of the Contract.

3.3.2 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 of the Buyer or third party suppliers.

3.3.3 The Supplier must at its own risk and expense provide all Supplier Equipment required to Deliver the Services.

3.3.4 The Supplier must allocate sufficient resources and appropriate expertise to the Contract.

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

3.3.6 The Supplier must ensure all Services, and anything used to Deliver the Services, are of good quality and free from defects.

3.3.7 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.

4 Pricing and payments

4.1 In exchange for the Deliverables, the Supplier must invoice the Buyer for the Charges in the Award Form.

4.2 All Charges:

- exclude VAT, which is payable on provision of a valid VAT invoice

- include all costs connected with the Supply of Deliverables

4.3 The Buyer must pay the Supplier the Charges within 30 days of receipt by the Buyer of a valid, undisputed invoice, in cleared funds using the payment method and details stated in the Award Form.

4.4 A Supplier invoice is only valid if it:

- includes all appropriate references including the Contract reference number and other details reasonably requested by the Buyer
- includes a detailed breakdown of Delivered Deliverables and Milestone(s) (if any)

4.5 The Buyer may retain or set-off payment of any amount owed to it by the Supplier if notice and reasons are provided.

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

4.7 If the Buyer can get more favourable commercial terms for the supply at cost of any materials, goods or services used by the Supplier to provide the Deliverables and that cost is reimbursable by the Buyer, then the Buyer may either:

- require the Supplier to replace its existing commercial terms with the more favourable terms offered for the relevant items; or
- enter into a direct agreement with the Subcontractor or third party for the relevant item

4.8 If the Buyer uses Clause 4.7 then the Charges must be reduced by an agreed amount by using the Variation Procedure.

4.9 The Buyer's right to enter into a direct agreement for the supply of the relevant items is subject to both:

- the relevant item being made available to the Supplier if required to provide the Deliverables
- any reduction in the Charges excludes any unavoidable costs that must be paid by the Supplier for the substituted item, including any licence fees or early termination charges

4.10 The Supplier has no right of set-off, counterclaim, discount or abatement unless they’re ordered to do so by a court.

5. The buyer's obligations to the supplier

5.1 If Supplier Non-Performance arises from a Buyer Cause:

- the Buyer cannot terminate the Contract under Clause 10.4.1
- the Supplier is entitled to reasonable and proven additional expenses and to relief from Delay Payments, liability and Deduction under this Contract
- the Supplier is entitled to additional time needed to make the Delivery
- the Supplier cannot suspend the ongoing supply of Deliverables

5.2 Clause 5.1 only applies if the Supplier:

- gives notice to the Buyer of the Buyer Cause within 10 Working Days of becoming aware
- demonstrates that the Supplier Non-Performance only happened because of the Buyer Cause
- mitigated the impact of the Buyer Cause

6. Record keeping and reporting

6.1 The Supplier must attend Progress Meetings with the Buyer and provide Progress Reports when specified in the Award Form.

6.2 The Supplier must keep and maintain full and accurate records and accounts in respect of the Contract for 7 years after the End Date and in accordance with the UK GDPR.

6.3 The Supplier must allow any Auditor access to their premises to verify all contract accounts and records of everything to do with the Contract and provide copies for an Audit.

6.4 The Supplier must provide information to the Auditor and reasonable co-operation at their request.

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

- tell the Buyer and give reasons
- propose corrective action
- provide a deadline for completing the corrective action

7. Supplier staff

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

- be appropriately trained and qualified
- be vetted using Good Industry Practice and the Security Policy
- comply with all conduct requirements when on the Buyer's Premises

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

7.3 If requested, the Supplier must replace any person whose acts or omissions have caused the Supplier to breach Clause 27.

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

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

8. Rights and protection

8.1 The Supplier warrants and represents that:

- it has full capacity and authority to enter into and to perform the Contract
- the Contract is executed by its authorised representative
- it is a legally valid and existing organisation incorporated in the place it was formed
- 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
- it maintains all necessary rights, authorisations, licences and consents to perform its obligations under the Contract
- it doesn't have any contractual obligations which are likely to have a material adverse effect on its ability to perform the Contract
- it is not impacted by an Insolvency Event

8.2 The warranties and representations in Clauses 2.6 and 8.1 are repeated each time the Supplier provides Deliverables under the Contract.

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

- wilful misconduct of the Supplier, Subcontractor and Supplier Staff that impacts the Contract
- non-payment by the Supplier of any tax or National Insurance

8.4 All claims indemnified under this Contract must use Clause 26.

8.5 The Buyer can terminate the Contract for breach of any warranty or indemnity where they are entitled to do so.

8.6 If the Supplier becomes aware of a representation or warranty that becomes untrue or misleading, it must immediately notify the Buyer.

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

9. Intellectual Property Rights (IPRs)

9.1 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 it to both:

- receive and use the Deliverables
- make use of the deliverables provided by a Replacement Supplier

9.2 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 New IPRs for the purpose of fulfilling its obligations during the Contract Period.

9.3 Where a Party acquires ownership of IPRs 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.

9.4 Neither Party has the right to use the other Party's IPRs, including any use of the other Party's names, logos or trademarks, except as provided in Clause 9 or otherwise agreed in writing.

9.5 If there is an IPR Claim, the Supplier indemnifies the Buyer against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result.

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

- obtain for the Buyer the rights in Clause 9.1 and 9.2 without infringing any third party IPR
- replace or modify the relevant item with substitutes that don't infringe IPR without adversely affecting the functionality or performance of the Deliverables

10. Ending the contract

10.1 The Contract takes effect on the Start Date and ends on the End Date or earlier if required by Law.

10.2 The Buyer can extend the Contract for the Extension Period by giving the Supplier no less than 3 Months' written notice before the Contract expires.

10.3 Ending the contract without a reason

10.3.1 The Buyer has the right to terminate the Contract at any time without reason or liability by giving the Supplier at least 90 days' notice and if it's terminated Clause 10.5.2 to 10.5.7 applies.

10.4 When the Buyer can end the Contract

10.4.1 If any of the following events happen, the Buyer has the right to immediately terminate the Contract by issuing a Termination Notice to the Supplier:

- there's a Supplier Insolvency Event
- there's a Default that is not corrected in line with an accepted Rectification Plan
- the Buyer rejects a Rectification Plan or the Supplier does not provide it within 10 days of the request
- there's any material Default of the Contract
- there's any material Default of any Joint Controller Agreement relating to the Contract
- there's a Default of Clauses 2.6, 9, 14, 15, 27, 32 or Schedule 19 (Cyber Essentials) (where applicable) relating to the Contract
- there's a consistent repeated failure to meet the Service Levels in Schedule 10 (Service Levels)

- there's a Change of Control of the Supplier which isn't pre-approved by the Buyer in writing
- there's a Variation to the Contract which cannot be agreed using Clause 24 (Changing the contract) or resolved using Clause 34 (Resolving disputes)
- 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
- the Court of Justice of the European Union uses Article 258 of the Treaty on the Functioning of the European Union (TFEU) to declare that the Contract should not have been awarded to the Supplier because of a serious breach of the TFEU or the Regulations
- the Supplier or its Affiliates embarrass or bring the Buyer into disrepute or diminish the public trust in them

10.4.2 If there is a Default, the Buyer can, without limiting its other rights, request that the Supplier provide a Rectification Plan.

10.4.3 When the Buyer receives a requested Rectification Plan it can either:

- reject the Rectification Plan or revised Rectification Plan, giving reasons
- accept the Rectification Plan or revised Rectification Plan (without limiting its rights) and the Supplier must immediately start work on the actions in the Rectification Plan at its own cost, unless agreed otherwise by the Parties

10.4.4 Where the Rectification Plan or revised Rectification Plan is rejected, the Buyer:

- must give reasonable grounds for its decision
- may request that the Supplier provides a revised Rectification Plan within 5 Working Days

10.4.5 If any of the events in 73 (1) (a) to (c) of the Regulations happen, the Buyer has the right to immediately terminate the Contract and Clause 10.5.2 to 10.5.7 applies.

10.5 What happens if the contract ends

Where the Buyer terminates the Contract under Clause 10.4.1 all of the following apply:

10.5.1 The Supplier is responsible for the Buyer's reasonable costs of procuring Replacement Deliverables for the rest of the Contract Period.

10.5.2 The Buyer's payment obligations under the terminated Contract stop immediately.

10.5.3 Accumulated rights of the Parties are not affected.

10.5.4 The Supplier must promptly delete or return the Government Data except where required to retain copies by law.

10.5.5 The Supplier must promptly return any of the Buyer's property provided under the terminated Contract.

10.5.6 The Supplier must, at no cost to the Buyer, co-operate fully in the handover and re-procurement (including to a Replacement Supplier).

10.5.7 The following Clauses survive the termination of the Contract: 3.2.10, 6, 7.2, 9, 11, 14, 15, 16, 17, 18, 34, 35 and any Clauses and Schedules which are expressly or by implication intended to continue.

10.6 When the supplier can end the contract

10.6.1 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 within 30 days of the date of the Reminder Notice.

10.6.2 If a Supplier terminates the Contract under Clause 10.6.1:

- the Buyer must promptly pay all outstanding Charges incurred to the Supplier
- 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
- Clauses 10.5.4 to 10.5.7 apply

10.7 When subcontracts can be ended

At the Buyer's request, the Supplier must terminate any Subcontracts in any of the following events:

- there is a Change of Control of a Subcontractor which isn't pre-approved by the Buyer in writing
- the acts or omissions of the Subcontractor have caused or materially contributed to a right of termination under Clause 10.4

- a Subcontractor or its Affiliates embarrasses or brings into disrepute or diminishes the public trust in the Buyer

10.8 Partially ending and suspending the contract

10.8.1 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.

10.8.2 The Buyer can only partially terminate or suspend the Contract if the remaining parts of that Contract can still be used to effectively deliver the intended purpose.

10.8.3 The Parties must agree any necessary Variation required by Clause 10.8 using the Variation Procedure, but the Supplier may not either:

- reject the Variation
- increase the Charges, except where the right to partial termination is under Clause 10.3

10.8.4 The Buyer can still use other rights available, or subsequently available to it if it acts on its rights under Clause 10.8.

11. How much you can be held responsible for

11.1 Each Party's total aggregate liability in each Contract Year under the Contract (whether in tort, contract or otherwise) is no more than the greater of £5 million or 150% of the Estimated Yearly Charges unless specified in the Award Form.

11.2 No Party is liable to the other for:

- any indirect Losses
- Loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect)

11.3 In spite of Clause 11.1, neither Party limits or excludes any of the following:

- its liability for death or personal injury caused by its negligence, or that of its employees, agents or Subcontractors
- its liability for bribery or fraud or fraudulent misrepresentation by it or its employees
- any liability that cannot be excluded or limited by Law

11.4 In spite of Clause 11.1, the Supplier does not limit or exclude its liability for any indemnity given under Clauses 7.5, 8.3, 9.5, 12.2 or 14.8 or Schedule 7 (Staff Transfer)

of the Contract.

11.5 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.

11.6 When calculating the Supplier's liability under Clause 11.1 the following items will not be taken into consideration:

- Deductions
- any items specified in Clause 11.4

11.7 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.

12. Obeying the law

12.1 The Supplier must use reasonable endeavours to comply with the provisions of Schedule 26 (Corporate Social Responsibility).

12.2 The Supplier indemnifies the Buyer against any costs resulting from any Default by the Supplier relating to any applicable Law.

12.3 The Supplier must appoint a Compliance Officer who must be responsible for ensuring that the Supplier complies with Law, Clause 12.1 and Clauses 27 to 32.

13. Insurance

The Supplier must, at its own cost, obtain and maintain the Required Insurances in Schedule 22 (Insurance Requirements).

14. Data protection

14.1 The Supplier must process Personal Data and ensure that Supplier Staff process Personal Data only in accordance with Schedule 20 (Processing Data).

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

14.3 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.

14.4 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 Policy and any applicable Security Management Plan.

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

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

- 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
- restore the Government Data itself or using a third party

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

14.8 The Supplier:

- must provide the Buyer with all Government Data in an agreed open format within 10 Working Days of a written request
- must have documented processes to guarantee prompt availability of Government Data if the Supplier stops trading
- must securely destroy all Storage Media that has held Government Data at the end of life of that media using Good Industry Practice
- 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
- indemnifies the Buyer against any and all Losses incurred if the Supplier breaches Clause 14 and any Data Protection Legislation.

15. What you must keep confidential

15.1 Each Party must:

- keep all Confidential Information it receives confidential and secure
- 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
- 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:

- where disclosure is required by applicable Law or by 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
- if the Recipient Party already had the information without obligation of confidentiality before it was disclosed by the Disclosing Party
- if the information was given to it by a third party without obligation of confidentiality
- if the information was in the public domain at the time of the disclosure
- if the information was independently developed without access to the Disclosing Party's Confidential Information
- to its auditors or for the purposes of regulatory requirements
- on a confidential basis, to its professional advisers on a need-to-know basis
- 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 Staff must enter into a direct confidentiality agreement with the Buyer at its request.

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

- on a confidential basis to the employees, agents, consultants and contractors of the Buyer
- 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
- if the Buyer (acting reasonably) considers disclosure necessary or appropriate to carry out its public functions
- where requested by Parliament
- under Clauses 4.7 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 any 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 Contracts or any part of them in any way, without the prior written consent of the Buyer and must take all reasonable steps 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 Within the required timescales the Supplier must give the Buyer full co-operation and information needed so the Buyer can:

- publish the Transparency Information
- comply with any Freedom of Information Act (FOIA) request
- comply with any Environmental Information Regulations (EIR) request

16.3 The Buyer 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, which does not need to be reasonable.

17. 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 that 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.

18. No other terms apply

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

19. 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.

20. Circumstances beyond your control

20.1 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:

- provides a Force Majeure Notice to the other Party
- uses all reasonable measures practical to reduce the impact of the Force Majeure Event

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

20.3 Where a Party terminates under Clause 20.2:

- each party must cover its own Losses
- Clause 10.5.2 to 10.5.7 applies

21. 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.

22. 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.

23. Transferring responsibilities

23.1 The Supplier cannot assign the Contract without the Buyer's written consent.

23.2 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.

23.3 When the Buyer uses its rights under Clause 23.2 the Supplier must enter into a novation agreement in the form that the Buyer specifies.

23.4 The Supplier can terminate the Contract novated under Clause 23.2 to a private sector body that is experiencing an Insolvency Event.

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

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

- their name
- the scope of their appointment
- the duration of their appointment

24. Changing the contract

24.1 Either Party can request a Variation to the Contract which is only effective if agreed in writing and signed by both Parties

24.2 The Supplier must provide an Impact Assessment either:

- with the Variation Form, where the Supplier requests the Variation
- within the time limits included in a Variation Form requested by the Buyer

24.3 If the Variation to the Contract cannot be agreed or resolved by the Parties, the Buyer can either:

- agree that the Contract continues without the Variation
- terminate the affected Contract, unless the Supplier has already provided part or all of the provision of the Deliverables, or where the Supplier can show evidence of substantial work being carried out to provide them
- refer the Dispute to be resolved using Clause 34 (Resolving Disputes)

24.4 The Buyer is not required to accept a Variation request made by the Supplier.

24.5 If there is a General Change in Law, the Supplier must bear the risk of the change and is not entitled to ask for an increase to the Charges.

24.6 If there is a Specific Change in Law or one is likely to happen during the Contract Period the Supplier must give the Buyer notice of the likely effects of the changes as soon as reasonably practical. They must also say if they think any Variation is needed either to the Deliverables, the Charges or the Contract and provide evidence:

- that the Supplier has kept costs as low as possible, including in Subcontractor costs
- of how it has affected the Supplier's costs

24.7 Any change in the Charges or relief from the Supplier's obligations because of a Specific Change in Law must be implemented using Clauses 24.1 to 24.4.

25. How to communicate about the contract

25.1 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 when sent unless an error message is received.

25.2 Notices to the Buyer must be sent to the Buyer Authorised Representative's address or email address in the Award Form.

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

26. Dealing with claims

26.1 If a Beneficiary is notified of a Claim then it must notify the Indemnifier as soon as reasonably practical and no later than 10 Working Days.

26.2 At the Indemnifier's cost the Beneficiary must both:

- allow the Indemnifier to conduct all negotiations and proceedings to do with a Claim
- give the Indemnifier reasonable assistance with the claim if requested

26.3 The Beneficiary must not make admissions about the Claim without the prior written consent of the Indemnifier which cannot be unreasonably withheld or delayed.

26.4 The Indemnifier must consider and defend the Claim diligently using competent legal advisors and in a way that doesn't damage the Beneficiary's reputation.

26.5 The Indemnifier must not settle or compromise any Claim without the Beneficiary's prior written consent which it must not unreasonably withhold or delay.

26.6 Each Beneficiary must take all reasonable steps to minimise and mitigate any losses that it suffers because of the Claim.

26.7 If the Indemnifier pays the Beneficiary money under an indemnity and the Beneficiary later recovers money which is directly related to the Claim, the Beneficiary must immediately repay the Indemnifier the lesser of either:

- the sum recovered minus any legitimate amount spent by the Beneficiary when recovering this money
- the amount the Indemnifier paid the Beneficiary for the Claim

27. Preventing fraud, bribery and corruption

27.1 The Supplier must not during any Contract Period:

- commit a Prohibited Act or any other criminal offence in the Regulations 57(1) and 57(2)
- do or allow anything which would cause the Buyer, including any of their employees, consultants, contractors, Subcontractors or agents to breach any of the Relevant Requirements or incur any liability under them

27.2 The Supplier must during the Contract Period:

- create, maintain and enforce adequate policies and procedures to ensure it complies with the Relevant Requirements to prevent a Prohibited Act and require its Subcontractors to do the same
- keep full records to show it has complied with its obligations under Clause 27 and give copies to the Buyer on request
- if required by the Buyer, within 20 Working Days of the Start Date of the Contract, and then annually, certify in writing to the Buyer, that they have complied with Clause 27, including compliance of Supplier Staff, and provide reasonable supporting evidence of this on request, including its policies and procedures

27.3 The Supplier must immediately notify the Buyer if it becomes aware of any breach of Clauses 27.1 or 27.2 or has any reason to think that it, or any of the Supplier Staff, has either:

- been investigated or prosecuted for an alleged Prohibited Act
- been debarred, suspended, proposed for suspension or debarment, or is otherwise ineligible to take part in procurement programmes or contracts because of a Prohibited Act by any government department or agency
- received a request or demand for any undue financial or other advantage of any kind related to the Contract

- suspected that any person or Party directly or indirectly related to the Contract has committed or attempted to commit a Prohibited Act

27.4 If the Supplier notifies the Buyer as required by Clause 27.3, 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.

27.5 In any notice the Supplier gives under Clause 27.4 it must specify the:

- Prohibited Act
- identity of the Party who it thinks has committed the Prohibited Act
- action it has decided to take

28. Equality, diversity and human rights

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

- protections against discrimination on the grounds of race, sex, gender reassignment, religion or belief, disability, sexual orientation, pregnancy, maternity, age or otherwise
- any other requirements and instructions which the Buyer reasonably imposes related to equality Law

28.2 The Supplier must take all necessary steps, 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.

29. Health and safety

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

- all applicable Law regarding health and safety
- the Buyer's current health and safety policy while at the Buyer's Premises, as provided to the Supplier

29.2 The Supplier 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.

30. Environment

30.1 When working on Site the Supplier must perform its obligations under the Buyer's current Environmental Policy, which the Buyer must provide.

30.2 The Supplier must ensure that Supplier Staff are aware of the Buyer's Environmental Policy.

31. Tax

31.1 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.

31.2 Where the Charges payable under the Contract are or are likely to exceed £5 million at any point during the relevant Contract Period, and an Occasion of Tax Non-Compliance occurs, the Supplier must notify the Buyer of it within 5 Working Days including:

- the steps that the Supplier is taking to address the Occasion of Tax Non-Compliance and any mitigating factors that it considers relevant
- other information relating to the Occasion of Tax Non-Compliance that the Buyer may reasonably need

31.3 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:

- 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
- 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 Contract Period in connection with the provision of the Deliverables by the Supplier or any of the Supplier Staff

31.4 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 the following requirements:

- the Buyer may, at any time during the Contract Period, request that the Worker provides information which demonstrates they comply with Clause 31.3, or why those requirements do not apply, the Buyer can specify the information the Worker must provide and the deadline for responding
- 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
- 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 31.3 or confirms that the Worker is not complying with those requirements
- the Buyer may supply any information they receive from the Worker to HMRC for revenue collection and management

32. Conflict of interest

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

32.2 The Supplier must promptly notify and provide details to the Buyer if a Conflict of Interest happens or is expected to happen.

32.3 The Buyer can terminate its Contract immediately by giving notice in writing to the Supplier or take any steps it thinks are necessary where there is or may be an actual or potential Conflict of Interest.

33. Reporting a breach of the contract

33.1 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 12.1
- Clauses 27 to 32

33.2 The Supplier must not retaliate against any of the Supplier Staff who in good faith reports a breach listed in Clause 33.1 to the Buyer or a Prescribed Person.

34. Resolving disputes

34.1 If there is a Dispute, the senior representatives of the Parties 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.

34.2 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 34.3 to 34.5.

34.3 Unless the Buyer refers the Dispute to arbitration using Clause 34.4, the Parties irrevocably agree that the courts of England and Wales have the exclusive jurisdiction to:

- determine the Dispute
- grant interim remedies
- grant any other provisional or protective relief

34.4 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.

34.5 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 34.3, 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 34.4.

34.6 The Supplier cannot suspend the performance of the Contract during any Dispute.

35. Which law applies

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

Schedule 1 (Definitions)

1.1 In the Contract, unless the context otherwise requires, capitalised expressions shall have the meanings set out in this Schedule 1 (Definitions) or the relevant Schedule in which that capitalised expression appears.

1.2 If a capitalised expression does not have an interpretation in this Schedule or any other Schedule, it shall, in the first instance, be interpreted in accordance with the common interpretation within the relevant market sector/industry where appropriate. Otherwise, it shall be interpreted in accordance with the dictionary meaning.

1.3 In the Contract, unless the context otherwise requires:

1.3.1 the singular includes the plural and vice versa;

1.3.2 reference to a gender includes the other gender and the neuter;

1.3.3 references to a person include an individual, company, body corporate, corporation, unincorporated association, firm, partnership or other legal entity or Crown Body;

1.3.4 a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time;

1.3.5 the words "including", "other", "in particular", "for example" and similar words shall not limit the generality of the preceding words and shall be construed as if they were immediately followed by the words "without limitation";

1.3.6 references to "writing" include typing, printing, lithography, photography, display on a screen, electronic and facsimile transmission and other modes of representing or reproducing words in a visible form, and expressions referring to writing shall be construed accordingly;

1.3.7 references to "representations" shall be construed as references to present facts, to "warranties" as references to present and future facts and to "undertakings" as references to obligations under the Contract;

1.3.8 references to "Clauses" and "Schedules" are, unless otherwise provided, references to the clauses and schedules of the Core Terms and references in any Schedule to parts, paragraphs, annexes and tables are, unless otherwise provided, references to the parts, paragraphs, annexes and tables of the Schedule in which these references appear;

1.3.9 references to "Paragraphs" are, unless otherwise provided, references to the paragraph of the appropriate Schedules unless otherwise provided; and

1.3.10 references to a series of Clauses or Paragraphs shall be inclusive of the clause numbers specified.

1.3.11 the headings in the Contract are for ease of reference only and shall not affect the interpretation or construction of the Contract; and

1.3.12 where the Buyer is a Crown Body it shall be treated as contracting with the Crown as a whole.

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

"Achieve"	in respect of a Test, to successfully pass such Test without any Test Issues and in respect of a Milestone, the issue of a Satisfaction Certificate in respect of that Milestone and "**Achieved**", "**Achieving**" and "**Achievement**" shall be construed accordingly;
"Affected Party"	the party seeking to claim relief in respect of a Force Majeure Event;
"Affiliates"	in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;
"Annex"	extra information which supports a Schedule;
"Approval"	the prior written consent of the Buyer and "**Approve**" and "**Approved**" shall be construed accordingly;
"Audit"	the Buyer's right to: a) verify the accuracy of the Charges and any other amounts payable by the Buyer under a 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 Services; c) verify the Open Book Data; d) verify the Supplier's and each Subcontractor's compliance with the applicable Law; e) identify or investigate actual or suspected breach of Clauses 27 to 33 and/or Schedule 26 (Corporate Social Responsibility), 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; f) identify or investigate any circumstances which may impact upon the financial stability of the Supplier, any Guarantor, and/or any Subcontractors or their ability to provide the Deliverables; g) 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; h) review any books of account and the internal contract management accounts kept by the Supplier in connection with the Contract; i) 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; j) 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. a)
"Auditor"	a) the Buyer's internal and external auditors; b) the Buyer's statutory or regulatory auditors; c) the Comptroller and Auditor General, their staff and/or any appointed representatives of the National Audit Office; d) HM Treasury or the Cabinet Office; e) any party formally appointed by the Buyer to carry out audit or similar review functions; and f) successors or assigns of any of the above;
"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;
"BACS"	the Bankers' Automated Clearing Services, which is a scheme for the electronic processing of financial transactions within the United Kingdom;
"Beneficiary"	a Party having (or claiming to have) the benefit of an indemnity under this Contract;
"Buyer Assets"	the Buyer's infrastructure, data, software, materials, assets, equipment or other property owned by and/or licensed or leased to the Buyer and which is or may be used in connection with the provision of the Deliverables which remain the property of the Buyer throughout the term of the Contract;
"Buyer Authorised Representative"	the representative appointed by the Buyer from time to time in relation to the Contract initially identified in the Award Form;

"Buyer Premises"	premises owned, controlled or occupied by the Buyer which are made available for use by the Supplier or its Subcontractors for the provision of the Deliverables (or any of them);
"Contract"	the contract between the Buyer and the Supplier, which consists of the terms set out and referred to in the Award Form;
"Contract Period"	the Contract Period in respect of the Contract;
"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;
"Change in Law"	any change in Law which impacts on the supply of the Deliverables and performance of the Contract which comes into force after the Start Date;
"Change of Control"	a change of control within the meaning of Section 450 of the Corporation Tax Act 2010;
"Charges"	b) the prices (exclusive of any applicable VAT), payable to the Supplier by the Buyer under the Contract, as set out in the Award Form, for the full and proper performance by the Supplier of its obligations under the Contract less any Deductions;
"Claim"	any claim which it appears that a Beneficiary is, or may become, entitled to indemnification under this Contract;
"Commercially Sensitive Information"	the Confidential Information listed in the Award Form (if any) comprising of commercially sensitive information relating to the Supplier, its IPR or its business or which the Supplier has indicated to the Buyer that, if disclosed by the Buyer, would cause the Supplier significant commercial disadvantage or material financial loss;
"Comparable Supply"	the supply of Deliverables to another Buyer of the Supplier that are the same or similar to the Deliverables;
"Compliance Officer"	the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its legal obligations;
"Confidential Information"	means any information, however it is conveyed, that relates to the business, affairs, developments, trade secrets, Know-How, personnel and suppliers of the Buyer or the Supplier, including IPRs, together with information derived from the above, and any other information clearly designated as being confidential (whether or not

	it is marked as **"confidential"**) or which ought reasonably to be considered 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"	c) the contract to be entered into between the Buyer and the Supplier for the provision of the Deliverables;
"Contracts Finder"	the Government's publishing portal for public sector procurement opportunities and contract data;
"Contract Period"	the term of the Contract from the earlier of the: a) applicable Start Date; or b) the Effective Date until the applicable End Date;
"Contract Value"	the higher of the actual or expected total Charges paid or payable under the Contract where all obligations are met by the Supplier;
"Contract Year"	a consecutive period of twelve (12) Months commencing on the Start Date or each anniversary thereof;
"Control"	control in either of the senses defined in sections 450 and 1124 of the Corporation Tax Act 2010 and "**Controlled**" shall be construed accordingly;
"Controller"	has the meaning given to it in the UK GDPR;
"Core Terms"	d) the Buyer's standard terms and conditions for common goods and services which comprise one part of the Contract the full title of which is Core Terms – Mid-tier version 1.0;
"Costs"	the following costs (without double recovery) to the extent that they are reasonably and properly incurred by the Supplier in providing the Deliverables: a) the cost to the Supplier or the Key Subcontractor (as the context requires), calculated per Work Day, of engaging the Supplier Staff, including: i) base salary paid to the Supplier Staff; ii) employer's National Insurance contributions; iii) pension contributions; iv) car allowances; v) any other contractual employment benefits; vi) staff training; vii) work place accommodation;

	viii) work place IT equipment and tools reasonably necessary to provide the Deliverables (but not including items included within limb (b) below); and ix) reasonable recruitment costs, as agreed with the Buyer; b) costs incurred in respect of Supplier Assets which would be treated as capital costs according to generally accepted accounting principles within the UK, which shall include the cost to be charged in respect of Supplier Assets by the Supplier to the Buyer or (to the extent that risk and title in any Supplier Asset is not held by the Supplier) any cost actually incurred by the Supplier in respect of those Supplier Assets; c) operational costs which are not included within (a) or (b) above, to the extent that such costs are necessary and properly incurred by the Supplier in the provision of the Deliverables; and d) Reimbursable Expenses to the extent these have been specified as allowable in the Award Form and are incurred in delivering any Deliverables; but excluding: a) Overhead; b) financing or similar costs; c) maintenance and support costs to the extent that these relate to maintenance and/or support Deliverables provided beyond the Contract Period whether in relation to Supplier Assets or otherwise; d) taxation; e) fines and penalties; f) amounts payable under Schedule 12 (Benchmarking) where such Schedule is used; and g) non-cash items (including depreciation, amortisation, impairments and movements in provisions);
"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;
"CRTPA"	the Contract Rights of Third Parties Act 1999;
"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"	(i) the UK General Data Protection Regulation (UK GDPR), the LED and any applicable national implementing Laws as amended from time to time (ii) the Data Protection Act 2018 (DPA) to the extent that it relates to Processing of personal data and privacy; (iii) all applicable Law about the Processing of personal data and privacy;
"Data Protection Officer"	has the meaning given to it in the UK GDPR;
"Data Subject"	has the meaning given to it in the UK GDPR
"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;
"Deductions"	all Service Credits, Delay Payments (if applicable), or any other deduction which the Buyer is paid or is payable to the Buyer under the Contract;
"Default"	any breach of the obligations of the Supplier (including abandonment of the Contract in breach of its terms) or any other default (including material default), act, omission, negligence or statement of the Supplier, of its Subcontractors or any Supplier Staff howsoever arising in connection with or in relation to the subject-matter of the Contract and in respect of which the Supplier is liable to the Buyer;
"Delay Payments"	the amounts (if any) payable by the Supplier to the Buyer in respect of a delay in respect of a Milestone as specified in the Implementation Plan;
"Deliverables"	Goods and/or Services that may be ordered under the Contract including the Documentation;
"Delivery"	delivery of the relevant Deliverable or Milestone in accordance with the terms of the Contract as confirmed and accepted by the Buyer by the either (a) confirmation in writing to the Supplier; or (b) where Schedule 8 (Implementation Plan and Testing) is used issue by the Buyer of a Satisfaction Certificate. "**Deliver**" and "**Delivered**" shall be construed accordingly;
"Disaster"	the occurrence of one or more events which, either separately or cumulatively, mean that the Deliverables, or a material part thereof will be unavailable (or could reasonably be anticipated to be unavailable) for the period specified in the Award Form (for the purposes of this definition the **"Disaster Period**");
"Disclosing Party"	the Party directly or indirectly providing Confidential Information to the other Party in accordance with Clause 15 (What you must keep confidential);

"Dispute"	any claim, dispute or difference arises out of or in connection with the Contract or in connection with the negotiation, existence, legal validity, enforceability or termination of the Contract, whether the alleged liability shall arise under English law or under the law of some other country and regardless of whether a particular cause of action may successfully be brought in the English courts;
"Dispute Resolution Procedure"	the dispute resolution procedure set out in Clause 34 (Resolving disputes);
"Documentation"	descriptions of the Services and Service Levels, technical specifications, user manuals, training manuals, operating manuals, process definitions and procedures, system environment descriptions and all such other documentation (whether in hardcopy or electronic form) is required to be supplied by the Supplier to the Buyer under the Contract as: a) would reasonably be required by a competent third party capable of Good Industry Practice contracted by the Buyer to develop, configure, build, deploy, run, maintain, upgrade and test the individual systems that provide the Deliverables b) is required by the Supplier in order to provide the Deliverables; and/or c) has been or shall be generated for the purpose of providing the Deliverables;
"DOTAS"	the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HMRC of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions;
"Due Diligence Information"	any information supplied to the Supplier by or on behalf of the Buyer prior to the Start Date;
"Effective Date"	the date on which the final Party has signed the Contract;
"EIR"	the Environmental Information Regulations 2004;
"Employment Regulations"	the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) as amended or replaced or any other Regulations implementing the European Council Directive 77/187/EEC;
"End Date"	the earlier of: a) the Expiry Date (as extended by any Extension Period exercised by the Buyer under Clause 10.2); or

	b) if the Contract is terminated before the date specified in (a) above, the date of termination of the Contract;
"Environmental Policy"	to conserve energy, water, wood, paper and other resources, reduce waste and phase out the use of ozone depleting substances and minimise the release of greenhouse gases, volatile organic compounds and other substances damaging to health and the environment, including any written environmental policy of the Buyer;
"Estimated Year 1 Charges	the anticipated total Charges payable by the Buyer in the first Contract Year specified in the Award Form;
"Estimated Yearly Charges"	means for the purposes of calculating each Party's annual liability under clause 11.2 : i) in the first Contract Year, the Estimated Year 1 Charges; or ii) in any subsequent Contract Years, the Charges paid or payable in the previous Contract Year; or e) f) iii) after the end of the Contract, the Charges paid or payable in the last Contract Year during the Contract Period; g)
"Equality and Human Rights Commission"	the UK Government body named as such as may be renamed or replaced by an equivalent body from time to time;
"Existing IPR"	any and all IPR that are owned by or licensed to either Party and which are or have been developed independently of the Contract (whether prior to the Start Date or otherwise);
"Expiry Date"	the date of the end of the Contract as stated in the Award Form;
"Extension Period"	such period or periods beyond which the Initial Period may be extended up to a maximum of the number of years in total specified in the Award Form;
"FOIA"	the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time 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: h) acts, events, omissions, happenings or non-happenings beyond the reasonable control of the Affected Party which prevent or

	materially delay the Affected Party from performing its obligations under a Contract; a) riots, civil commotion, war or armed conflict, acts of terrorism, nuclear, biological or chemical warfare; b) acts of a Crown Body, local government or regulatory bodies; c) fire, flood or any disaster; or d) 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;
"Force Majeure Notice"	a written notice served by the Affected Party on the other Party stating that the Affected Party believes that there is a Force Majeure Event;
"Award Form"	the document outlining the Incorporated Terms and crucial information required for the Contract, to be executed by the Supplier and the Buyer;
" Incorporated Terms"	the contractual terms applicable to the Contract specified in the Award Form;
" Special Terms"	any additional terms and conditions specified in the Award Form incorporated into the Contract;
" Tender Response"	the tender submitted by the Supplier to the Buyer and annexed to or referred to in Schedule 4 (Tender);
"UK GDPR"	the UK General Data Protection Regulation (UK GDPR)
"General Anti-Abuse Rule"	a) the legislation in Part 5 of the Finance Act 2013 and; and b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid National Insurance contributions;
"General Change in Law"	a Change in Law where the change is of a general legislative nature (including taxation or duties of any sort affecting the Supplier) or which affects or relates to a Comparable Supply;
"Goods"	goods made available by the Supplier as specified in Schedule 2 (Specification) and in relation to a Contract as specified in the Award Form;
"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"	the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the National Assembly for Wales), including government ministers and government departments and other bodies, persons, commissions or agencies from time to time carrying out functions on its behalf;
"Government Data"	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;
"Government Procurement Card"	the Government's preferred method of purchasing and payment for low value goods or services https://www.gov.uk/government/publications/government-procurement-card--2;
"Guarantor"	the person (if any) who has entered into a guarantee in the form set out in Schedule 23 (Guarantee) in relation to this Contract;
"Halifax Abuse Principle"	the principle explained in the CJEU Case C-255/02 Halifax and others;
"HMRC"	Her Majesty's Revenue and Customs;
"ICT Policy"	the Buyer's policy in respect of information and communications technology, referred to in the Award Form, which is in force as at the Start Date (a copy of which has been supplied to the Supplier), as updated from time to time in accordance with the Variation Procedure;
"Impact Assessment"	an assessment of the impact of a Variation request by the Buyer completed in good faith, including: a) details of the impact of the proposed Variation on the Deliverables and the Supplier's ability to meet its other obligations under the Contract; b) details of the cost of implementing the proposed Variation; c) details of the ongoing costs required by the proposed Variation when implemented, including any increase or decrease in the Charges (as applicable), any alteration in the resources and/or expenditure required by either Party and any alteration to the working practices of either Party;

	d) a timetable for the implementation, together with any proposals for the testing of the Variation; and e) such other information as the Buyer may reasonably request in (or in response to) the Variation request;
"Implementation Plan"	the plan for provision of the Deliverables set out in Schedule 8 (Implementation Plan and Testing) where that Schedule is used or otherwise as agreed between the Supplier and the Buyer;
"Indemnifier"	a Party from whom an indemnity is sought under this Contract;
"Independent Control"	where a Controller has provided Personal Data to another Party which is not a Processor or a Joint Controller because the recipient itself determines the purposes and means of Processing but does so separately from the Controller providing it with Personal Data and "**Independent Controller**" shall be construed accordingly;
"Indexation"	the adjustment of an amount or sum in accordance with the Award Form;
"Information"	has the meaning given under section 84 of the Freedom of Information Act 2000;
"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;
"Initial Period"	the initial term of the Contract specified in the Award Form;
"Insolvency Event"	a) in respect of a person: b) a proposal is made for a voluntary arrangement within Part I of the Insolvency Act 1986 or of any other composition scheme or arrangement with, or assignment for the benefit of, its creditors; or c) a shareholders' meeting is convened for the purpose of considering a resolution that it be wound up or a resolution for its winding-up is passed (other than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation); or d) a petition is presented for its winding up (which is not dismissed within fourteen (14) Working Days of its service) or an application is made for the appointment of a provisional liquidator or a creditors' meeting is convened pursuant to section 98 of the Insolvency Act 1986; or e) a receiver, administrative receiver or similar officer is appointed over the whole or any part of its business or assets; or f) an application order is made either for the appointment of an administrator or for an administration order, an administrator is appointed, or notice of intention to appoint an administrator is given; or

	g) it is or becomes insolvent within the meaning of section 123 of the Insolvency Act 1986; or h) being a "small company" within the meaning of section 382(3) of the Companies Act 2006, a moratorium comes into force pursuant to Schedule A1 of the Insolvency Act 1986; or i) where the person is an individual or partnership, any event analogous to those listed in limbs (a) to (g) (inclusive) occurs in relation to that individual or partnership; or j) any event analogous to those listed in limbs (a) to (h) (inclusive) occurs under the law of any other jurisdiction;
"Installation Works"	all works which the Supplier is to carry out at the beginning of the Contract Period to install the Goods in accordance with the Contract;
"Intellectual Property Rights" or "IPR"	a) copyright, rights related to or affording protection similar to copyright, rights in databases, patents and rights in inventions, semi-conductor topography rights, trade marks, rights in internet domain names and website addresses and other rights in trade or business names, goodwill, designs, Know-How, trade secrets and other rights in Confidential Information; b) applications for registration, and the right to apply for registration, for any of the rights listed at (a) that are capable of being registered in any country or jurisdiction; and c) all other rights having equivalent or similar effect in any country or jurisdiction;
"Invoicing Address"	the address to which the Supplier shall Invoice the Buyer as specified in the Award Form;
"IPR Claim"	any claim of infringement or alleged infringement (including the defence of such infringement or alleged infringement) of any IPR, used to provide the Deliverables or otherwise provided and/or licensed by the Supplier (or to which the Supplier has provided access) to the Buyer in the fulfilment of its obligations under the Contract;
"IR35"	the off-payroll rules requiring individuals who work through their company pay the same tax and National Insurance contributions as an employee which can be found online at: https://www.gov.uk/guidance/ir35-find-out-if-it-applies;
"Joint Controller Agreement"	the agreement (if any) entered into between the Buyer and the Supplier substantially in the form set out in Annex 2 of Schedule 20 (*Processing Data*);
"Joint Controllers"	where two or more Controllers jointly determine the purposes and means of Processing;
"Key Personnel"	the individuals (if any) identified as such in the Award Form;

"Key Sub-Contract"	each Sub-Contract with a Key Subcontractor;
"Key Subcontractor"	any Subcontractor: a) which is relied upon to deliver any work package within the Deliverables in their entirety; and/or b) which, in the opinion of the Buyer performs (or would perform if appointed) a critical role in the provision of all or any part of the Deliverables; and/or c) with a Sub-Contract with the Contract value which at the time of appointment exceeds (or would exceed if appointed) 10% of the aggregate Charges forecast to be payable under the Contract, and the Supplier shall list all such Key Subcontractors in section 29 of the Award Form;
"Know-How"	all ideas, concepts, schemes, information, knowledge, techniques, methodology, and anything else in the nature of know-how relating to the Deliverables but excluding know-how already in the other Party's possession before the applicable Start Date;
"Law"	any law, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of Section 2 of the European Communities Act 1972, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements with which the Supplier is bound to comply;
"LED"	i) Law Enforcement Directive (Directive (EU) 2016/680)
"Losses"	all losses, liabilities, damages, costs, expenses (including legal fees), disbursements, costs of investigation, litigation, settlement, judgment, interest and penalties whether arising in contract, tort (including negligence), breach of statutory duty, misrepresentation or otherwise and "**Loss**" shall be interpreted accordingly;
"Lots"	the number of lots specified in Schedule 2 (Specification), if applicable;
"Marketing Contact"	shall be the person identified in the Award Form;
"Milestone"	an event or task described in the Implementation Plan;
"Milestone Date"	the target date set out against the relevant Milestone in the Implementation Plan by which the Milestone must be Achieved;
"Month"	a calendar month and "**Monthly**" shall be interpreted accordingly;
"National Insurance"	contributions required by the National Insurance Contributions Regulations 2012 (SI 2012/1868) made under section 132A of the Social Security Administration Act 1992;

"New IPR"	a) IPR in items created by the Supplier (or by a third party on behalf of the Supplier) specifically for the purposes of the Contract and updates and amendments of these items including (but not limited to) database schema; and/or b) IPR in or arising as a result of the performance of the Supplier's obligations under the Contract and all updates and amendments to the same; but shall not include the Supplier's Existing IPR;
"Occasion of Tax Non – Compliance"	where: a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 which is found on or after 1 April 2013 to be incorrect as a result of: i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation in any jurisdiction that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime in any jurisdiction; and/or b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 which gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Start Date or to a civil penalty for fraud or evasion;
"Open Book Data"	complete and accurate financial and non-financial information which is sufficient to enable the Buyer to verify the Charges already paid or payable and Charges forecast to be paid during the remainder of the Contract, including details and all assumptions relating to: a) the Supplier's Costs broken down against each Good and/or Service and/or Deliverable, including actual capital expenditure (including capital replacement costs) and the unit cost and total actual costs of all Deliverables; b) operating expenditure relating to the provision of the Deliverables including an analysis showing: i) the unit costs and quantity of Goods and any other consumables and bought-in Deliverables; ii) manpower resources broken down into the number and grade/role of all Supplier Staff (free of any contingency) together with a list of agreed rates against each manpower grade;

	iii) a list of Costs underpinning those rates for each manpower grade, being the agreed rate less the Supplier Profit Margin; and iv) Reimbursable Expenses, if allowed under the Award Form; c) Overheads; d) all interest, expenses and any other third party financing costs incurred in relation to the provision of the Deliverables; e) the Supplier Profit achieved over the Contract Period and on an annual basis; f) confirmation that all methods of Cost apportionment and Overhead allocation are consistent with and not more onerous than such methods applied generally by the Supplier; g) an explanation of the type and value of risk and contingencies associated with the provision of the Deliverables, including the amount of money attributed to each risk and/or contingency; and h) the actual Costs profile for each Service Period;
"Overhead"	those amounts which are intended to recover a proportion of the Supplier's or the Key Subcontractor's (as the context requires) indirect corporate costs (including financing, marketing, advertising, research and development and insurance costs and any fines or penalties) but excluding allowable indirect costs apportioned to facilities and administration in the provision of Supplier Staff and accordingly included within limb (a) of the definition of "Costs";
"Parliament"	takes its natural meaning as interpreted within by Law;
"Party"	the Buyer or the Supplier and "**Parties**" shall mean both of them where the context permits;
"Personal Data"	has the meaning given to it in the UK GDPR;
"Personal Data Breach"	has the meaning given to it in the UK GDPR;
"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;
"Progress Meeting"	a meeting between the Buyer Authorised Representative and the Supplier Authorised Representative;
"Progress Meeting Frequency"	the frequency at which the Supplier shall conduct a Progress Meeting in accordance with Clause 6.1 as specified in the Award Form;

"Progress Report"	a report provided by the Supplier indicating the steps taken to achieve Milestones or delivery dates;
"Progress Report Frequency"	the frequency at which the Supplier shall deliver Progress Reports in accordance with Clause 6.1 as specified in the Award Form;
"Prohibited Acts"	a) to directly or indirectly offer, promise or give any person working for or engaged by the Buyer or any other public body a financial or other advantage to: i) induce that person to perform improperly a relevant function or activity; or ii) reward that person for improper performance of a relevant function or activity; b) to directly or indirectly request, agree to receive or accept any financial or other advantage as an inducement or a reward for improper performance of a relevant function or activity in connection with the Contract; or c) committing any offence: i) under the Bribery Act 2010 (or any legislation repealed or revoked by such Act); or ii) under legislation or common law concerning fraudulent acts; or iii) defrauding, attempting to defraud or conspiring to defraud the Buyer or other public body; or d) any activity, practice or conduct which would constitute one of the offences listed under (c) above if such activity, practice or conduct had been carried out in the UK;
"Protective Measures"	technical and organisational measures which must take account of: j) a) the nature of the data to be protected k) b)harm that might result from Data Loss Event; l) c) state of technological development m) d) the cost of implementing any measures including but not limited to 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;
"Recall"	a request by the Supplier to return Goods to the Supplier or the manufacturer after the discovery of safety issues or defects (including defects in the IPR rights) that might endanger health or hinder performance;

"Recipient Party"	the Party which receives or obtains directly or indirectly Confidential Information;
"Rectification Plan"	the Supplier's plan (or revised plan) to rectify it's breach using the template in Schedule 25 (Rectification Plan Template) which shall include: a) full details of the Default that has occurred, including a root cause analysis; b) the actual or anticipated effect of the Default; and c) the steps which the Supplier proposes to take to rectify the Default (if applicable) and to prevent such Default from recurring, including timescales for such steps and for the rectification of the Default (where applicable);
"Rectification Plan Process"	the process set out in Clause 10.4.2 to 10.4.4 (Rectification Plan Process);
"Regulations"	the Public Contracts Regulations 2015 and/or the Public Contracts (Scotland) Regulations 2015 (as the context requires);
"Reimbursable Expenses"	the reasonable out of pocket travel and subsistence (for example, hotel and food) expenses, properly and necessarily incurred in the performance of the Services, calculated at the rates and in accordance with the Buyer's expenses policy current from time to time, but not including: a) travel expenses incurred as a result of Supplier Staff travelling to and from their usual place of work, or to and from the premises at which the Services are principally to be performed, unless the Buyer otherwise agrees in advance in writing; and b) subsistence expenses incurred by Supplier Staff whilst performing the Services at their usual place of work, or to and from the premises at which the Services are principally to be performed;
"the Buyer's Confidential Information"	c) all Personal Data and any information, however it is conveyed, that relates to the business, affairs, developments, property rights, trade secrets, Know-How and IPR of the Buyer (including all Buyer Existing IPR and New IPR); d) any other information clearly designated as being confidential (whether or not it is marked "confidential") or which ought reasonably be considered confidential which comes (or has come) to the Buyer's attention or into the Buyer's possession in connection with the Contract; and information derived from any of the above;
"Relevant Requirements"	all applicable Law relating to bribery, corruption and fraud, including the Bribery Act 2010 and any guidance issued by the Secretary of State pursuant to section 9 of the Bribery Act 2010;

"Relevant Tax Authority"	HMRC, or, if applicable, the tax authority in the jurisdiction in which the Supplier is established;
"Reminder Notice"	a notice sent in accordance with Clause 10.6 given by the Supplier to the Buyer providing notification that payment has not been received on time;
"Replacement Deliverables"	any deliverables which are substantially similar to any of the Deliverables and which the Buyer receives in substitution for any of the Deliverables , whether those goods are provided by the Buyer internally and/or by any third party;
"Replacement Subcontractor"	a Subcontractor of the Replacement Supplier to whom Transferring Supplier Employees will transfer on a Service Transfer Date (or any Subcontractor of any such Subcontractor);
"Replacement Supplier"	any third party provider of Replacement Deliverables appointed by or at the direction of the Buyer from time to time or where the Buyer is providing Replacement Deliverables for its own account, shall also include the Buyer;
"Request For Information"	a request for information or an apparent request relating to the Contract for the provision of the Deliverables or an apparent request for such information under the FOIA or the EIRs;
"Required Insurances"	the insurances required by Schedule 22 (Insurance Requirements);
"Satisfaction Certificate"	the certificate (materially in the form of the document contained in Annex 2 of Part B of Schedule 8 (Implementation Plan and Testing) or as agreed by the Parties where Schedule 8 is not used in this Contract) granted by the Buyer when the Supplier has Achieved a Milestone or a Test;
"Schedules"	any attachment to the Contract which contains important information specific to each aspect of buying and selling;
"Security Management Plan"	the Supplier's security management plan prepared pursuant to Schedule 16 (Security) (if applicable);
"Security Policy"	the Buyer's security policy, referred to in the Award Form, in force as at the Start Date (a copy of which has been supplied to the Supplier), as updated from time to time and notified to the Supplier;
"Serious Fraud Office"	the UK Government body named as such as may be renamed or replaced by an equivalent body from time to time;
"Service Levels"	any service levels applicable to the provision of the Deliverables under the Contract (which, where Schedule 10 (Service Levels) is used in this Contract, are specified in the Annex to Part A of such Schedule);
"Service Period"	has the meaning given to it in the Award Form;

"Services"	services made available by the Supplier as specified in Schedule 2 (Specification) and in relation to a Contract as specified in the Award Form;
"Service Transfer"	any transfer of the Deliverables (or any part of the Deliverables), for whatever reason, from the Supplier or any Subcontractor to a Replacement Supplier or a Replacement Subcontractor;
"Service Transfer Date"	the date of a Service Transfer;
"Sites"	any premises (including the Buyer Premises, the Supplier's premises or third party premises) from, to or at which: a) the Deliverables are (or are to be) provided; or b) the Supplier manages, organises or otherwise directs the provision or the use of the Deliverables; c) those premises at which any Supplier Equipment or any part of the Supplier System is located (where ICT Services are being provided)
"SME"	an enterprise falling within the category of micro, small and medium sized enterprises defined by the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium enterprises;
"Special Terms"	any additional Clauses set out in the Award Form which shall form part of the respective Contract;
"Specific Change in Law"	a Change in Law that relates specifically to the business of the Buyer and which would not affect a Comparable Supply where the effect of that Specific Change in Law on the Deliverables is not reasonably foreseeable at the Start Date;
"Specification"	the specification set out in Schedule 2 (Specification), as may, in relation to the Contract, be supplemented by the Award Form;
"Standards"	any: a) standards published by BSI British Standards, the National Standards Body of the United Kingdom, the International Organisation for Standardisation or other reputable or equivalent bodies (and their successor bodies) that a skilled and experienced operator in the same type of industry or business sector as the Supplier would reasonably and ordinarily be expected to comply with; b) standards detailed in the specification in Schedule 2 (Specification); c) standards detailed by the Buyer in the Award Form or agreed between the Parties from time to time;

	d) relevant Government codes of practice and guidance applicable from time to time;
"Start Date"	the date specified on the Award Form;
"Storage Media"	the part of any device that is capable of storing and retrieving data;
"Sub-Contract"	any contract or agreement (or proposed contract or agreement), other than a 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 Supplier related to the Contract;
"Supplier"	the person, firm or company identified in the Award Form;
"Supplier Assets"	all assets and rights used by the Supplier to provide the Deliverables in accordance with the Contract but excluding the Buyer Assets;
"Supplier Authorised Representative"	the representative appointed by the Supplier named in the Award Form, or later defined in a Contract;
"Supplier's Confidential Information"	a) any information, however it is conveyed, that relates to the business, affairs, developments, IPR of the Supplier (including the Supplier Existing IPR) trade secrets, Know-How, and/or personnel of the Supplier; b) any other information clearly designated as being confidential (whether or not it is marked as "confidential") or which ought reasonably to be considered to be confidential and which comes (or has come) to the Supplier's attention or into the Supplier's possession in connection with the Contract; c) Information derived from any of (a) and (b) above;
"Supplier's Contract Manager	the person identified in the Award Form appointed by the Supplier to oversee the operation of the Contract and any alternative person whom the Supplier intends to appoint to the role, provided that the Supplier informs the Buyer prior to the appointment;
"Supplier Equipment"	the Supplier's hardware, computer and telecoms devices, equipment, plant, materials and such other items supplied and used by the Supplier (but not hired, leased or loaned from the Buyer) in the performance of its obligations under this Contract;

"Supplier Non-Performance"	where the Supplier has failed to: a) Achieve a Milestone by its Milestone Date; b) provide the Goods and/or Services in accordance with the Service Levels ; and/or c) comply with an obligation under the Contract;
"Supplier Profit"	in relation to a period, the difference between the total Charges (in nominal cash flow terms but excluding any Deductions and total Costs (in nominal cash flow terms) in respect of the Contract for the relevant period;
"Supplier Profit Margin"	in relation to a period or a Milestone (as the context requires), the Supplier Profit for the relevant period or in relation to the relevant Milestone divided by the total Charges over the same period or in relation to the relevant Milestone and expressed as a percentage;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor engaged in the performance of the Supplier's obligations under the Contract;
"Supply Chain Information Report Template"	the document at Annex 1 of Schedule 18 Supply Chain Visibility;
"Supporting Documentation"	sufficient information in writing to enable the Buyer to reasonably assess whether the Charges, Reimbursable Expenses and other sums due from the Buyer under the Contract detailed in the information are properly payable;
"Termination Notice"	a written notice of termination given by one Party to the other, notifying the Party receiving the notice of the intention of the Party giving the notice to terminate the Contract on a specified date and setting out the grounds for termination;
"Test Issue"	any variance or non-conformity of the Deliverables or Deliverables from their requirements as set out in the Contract;
"Test Plan"	a plan: a) for the Testing of the Deliverables; and b) setting out other agreed criteria related to the achievement of Milestones;
"Tests and Testing"	any tests required to be carried out pursuant to the Contract as set out in the Test Plan or elsewhere in the Contract and "**Tested**" shall be construed accordingly;
"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;
"Transferring Supplier Employees"	those employees of the Supplier and/or the Supplier's Subcontractors to whom the Employment Regulations will apply on the Service Transfer Date;

"Transparency Information"	the Transparency Reports and the content of the Contract, including any changes to this Contract agreed from time to time, except for – n) (i) any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Buyer; and (ii) Commercially Sensitive Information;
"Transparency Reports"	the information relating to the Deliverables and performance pursuant to the Contract which the Supplier is required to provide to the Buyer in accordance with the reporting requirements in Schedule 6 (Transparency Reports);
"Variation"	has the meaning given to it in Clause 24 (Changing the contract);
"Variation Form"	the form set out in Schedule 21 (Variation Form);
"Variation Procedure"	the procedure set out in Clause 24 (Changing the contract);
"VAT"	value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"VCSE"	a non-governmental organisation that is value-driven and which principally reinvests its surpluses to further social, environmental or cultural objectives;
"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-policy-note-0815-tax-arrangements-of-appointees) applies in respect of the Deliverables; and
"Working Day"	any day other than a Saturday or Sunday or public holiday in England and Wales unless specified otherwise by the Parties in the Award Form.
"Work Day"	7.5 Work Hours, whether or not such hours are worked consecutively and whether or not they are worked on the same day;
"Work Hours"	the hours spent by the Supplier Staff properly working on the provision of the Deliverables including time spent travelling (other than to and from the Supplier's offices, or to and from the Sites) but excluding lunch breaks;

Schedule 2 (Specification)

This Schedule sets out what the Buyer wants.

For all Deliverables, the Supplier must help the Buyer comply with any specific applicable Standards of the Buyer.

Specification Reference
FS430418
Specification Title
GMO Food and Feed Authorisation GB
Contract Duration
5 years with a review point break clause at 3 years

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://food.bravosolution.co.uk/web/login.html. 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.

A. THE SPECIFICATION

Background

The Food Standards Agency (FSA) is the Competent Authority for the purpose of the Regulation (EU) 2017/625 on Official Feed and Food Controls in the UK.

To fulfil the FSAs obligation under Article 8 of Commission Implementing Regulation (EU) No 503/2013, the FSA is seeking a provider to deliver the functions currently performed

by the EU Reference Laboratory (EURL) for supporting the authorisation of Genetically Modified Organisms (GMO) for food and feed uses, in Great Britain (England, Wales and Scotland). Applications for authorisations may include analysis of genetic material derived from plant, animal and microorganism sources.

The Specification

The appointed organisation will be responsible for delivering the provision of laboratory services for the authorisation of new GMO applications for Great Britain (GB), renewal GMO applications for GB and the review and re-validation of existing and ongoing applications as and when necessary on behalf of the FSA.

Length of Agreement

This Agreement is for five years, subject to a Break Point after 3 years, 2021-2024. We will confirm whether we wish to proceed by issuing a Variation to Contract confirming our intention and any changes to our requirements.

Delivery requirements

The basic duty is to deliver the document review and method validation stage of the GMO Food and Feed authorisation process which forms part of the risk assessment for the FSA. The validation process must include the following six steps:

1. Application received including documentation and data on method and samples.
2. Scientific assessment of documentation and data.
3. Experimental testing of samples and methods.
4. Method validation through collaborative ring trials.
5. Reporting to the Authority (FSA).
6. Secure storage for GMO food and feed samples and control materials for the duration of the contract. The supplier will work with the FSA to ensure secure transfer of these samples to any new contractor when required.

The number of applications will vary each year for both new applications and renewals. For new applications, its estimated to be within the range of 10-30 applications requiring authorisation each year. For renewals, it’s expected to be up to 10 per year, but this is dependent on the companies wanting to renew their products for GB. The contractor must be able to meet the maximum number of new application and the expected number of renewals per year.

The validation of methods process must be conducted within 3 months from the date by which the application is received, concluding when the validation report is complete, allowing the appointed laboratory time to provide its opinion to the FSA. By exception, the FSA may agree to a longer timescale, but this must be requested by the contractor. If further information or amendments are required from the applicant, the laboratory may suspend the validation process, effectively pausing the indicative 3 month timescale, until

the application meets the requirements. The contractor will notify the FSA of deviations which may affect the review period and testing timeframe.

A breakdown of the requirements for each step is as follows:

Step 1:

A complete application will consist of four sections a) method(s) for detection, identification and quantification of the GMO being submitted and the data which satisfies the method acceptance criteria (Regulation (EC) No 1829/2003); b) control samples and the samples of food or feed; c) annotated GM insert(s) and flanking sequences; and, d) proof of payment provided by the laboratory. The contractor is required to receive the sample and method directly from the applicant and provide a document receipt which the applicant will include in their submission to the FSA. The contractor will charge the applicant directly for the initial and any subsequent fees based upon the validation process. The contractor is required to provide details of payment amounts to ensure the application costs do not exceed the costs incurred in carrying out the validation process.

Charging approach: For each application for a GMO containing a single transformation event, a flat-rate contribution shall be paid by the applicant to the laboratory at this stage.

Step 2:

Based on the evidence provided by the applicant, the laboratory verifies that the method(s) and samples meet the requirements of Certified Reference Materials for samples (Directive 2001/18/EC and Regulation (EC) No 1829/2003).

Step 3:

Using the samples provided, experimental testing of method(s) by the contractor should be conducted using the following steps; a) design of the process for full method(s) validation or method verification if method(s) have already been validated b) check quantity and quality of control samples c) prepare samples for in-house verification d) test detection methods provided by the applicant e) test extraction methods provided by the applicant if not already validated.

The results of experimental testing aims to verify that the methods(s) fulfil(s) the acceptance criteria according to the guidance on*: Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing* and that the methods and control samples are suitable to undergo the full validation process. If the method submitted has already been validated through a ring trial and is submitted as a stacked GMO, then it is subjected to single laboratory verification.

Step 4:

Experimental testing for the method validation study should involve a ring trial with a suitable number of accredited laboratories, or laboratories which meet the contractor's requirements for the validation process. It would be beneficial if these labs are based in the UK due to the logistics of transporting samples and the laboratories holding UK

accreditations. Validation must be conducted in accordance with the principles of IOA 5725 international standards and/or the international union of pure and applied chemistry (IUPAC) protocol.

Charging approach: Step 4 (collaborative trial) of the validation process shall not be started before those contributions for full validation are received.

Step 5:

The contractor must ensure all data and results collected during the ring trial is reported back to the FSA. Results and protocols will be published on the FSA website including; validation report, validated protocols and in-house validation of the DNA extraction process. The contractor will notify the FSA of any deviations which may affect cost, specification and timings to the method validation stage of the authorisation process.

Step 6:

The contractor must retain the methods, samples and control materials for the duration of the contract. At the end of contract, all samples and related materials must be transferred to the next contractor, as detailed in the contractors exit plan, as the GMO authorisation is valid for 10 years. On exiting, the contractor will be expected to work with the FSA to ensure a smooth transition of all samples and related materials to new provider, ensuring the integrity of these. The exit plan should detail the requirements for this transportation for both laboratories involved and how these will be met. The new contractor will be responsible for meeting any reasonable costs incurred for the transportation of samples and related materials.

The contractor will be required to provide and an annual report to the FSA summarising the applications process, applications received, adherence to timelines and financial costs. The report is to be provided each year for the duration of the contract, no later than for weeks after the contract year end date.

Laboratory requirements

The laboratory will be required to:

(a) be impartial, free from any conflict of interests, and declare this in the application;

(b) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;

(c) possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;

(d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national and international level are taken into account in their work;

(e) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

(f) be equipped with adequate and secure storage facility to store GMO food and feed samples and control materials that have been submitted for authorisation, for the duration of the contract.

(g) where relevant, be equipped to comply with relevant biosecurity standards;

(h) liaise with the FSA appointed NRL for GMO (as and when required);

(j) have experience of, and be able to operate in accordance with, the relevant sampling and analysis legislation, including maintaining specific UKAS accreditation (or equivalent) for the relevant analytes/methods, and satisfactory performance in proficiency test schemes;

(k) be familiar with the enforcement system in operation in the GB.

Pipeline applications

Once the transition period for the UK's exit from the EU has ended, there will be GMOs for which an authorisation has been requested but the assessment has not yet been completed in the EU regulatory pipeline. Handling will be dependent on how far the application has progressed by the end of the transition period and the wish for the applicant to market in GB. For GMO applications, it is expected that pipeline applications at the start of Commission and EFSA process will require laboratory method validation. These will typically be applications that have been received by the Commission but not yet submitted to EFSA. Pipeline applications midway through the start of the process may require method validation, which is to be decided on a case by case basis. It is expected that pipeline applications at the very end of Commission and EFSA process will not require laboratory method validation to be carried out. These will typically be applications where legislation has been drafted and discussed or those with a published EFSA opinion. For pipeline applications the FSA will be requesting dossiers and any validation reports.

Database

The contractor is required to have the capacity and capability to create a national GMO database including the storing and archiving of samples. This database should be accessible to all GB OCLs, GMO NRL and the FSA as they will be required to share the methods and control materials and hold samples for the duration of the contract.

Application Fees and costings

Applicants for authorisation of GM food and feed will be expected to contribute to cost which support the duties and tasks of the reference laboratory. The contribution from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

In the financial template please outline your proposed payment model for reimbursement of costs and the total cost per application (steps 1-6). An upfront cost for all applications should be outlined which will cover the cost of steps 1-3, the additional cost of the subsequent phases should then be outlined to be paid when this step can be completed.

If costings vary due to the nature of the application, such as additional costs per change required, please outline this.

Illustration only - Charging examples:

For each application for a GMO containing a single transformation event, a flat-rate contribution of ~£35,000 shall be paid by the applicant to the laboratory.

The laboratory shall request the applicant to pay an additional contribution of ~£55,000 where a full validation procedure of a method of detection and identification for a GMO containing a single transformation event is required.

For each application for a GMO containing stacked transformation events, where the method of detection and identification of each single transformation event that constitutes the GMO has been validated by the laboratory or where the validation is pending, the flat-rate contribution depends on the number (N) of single transformation events that constitute the GMO and shall be calculated as ~£18,000 + (N x 4500). Only the GMO containing stacked transformation events with the highest number of single transformation events is to be considered in this calculation.

“Full validation procedure” means the assessment, through a ring trial according to international standards, involving national reference laboratories of the method performance criteria.

Set up and ongoing running costs

Please provide a summary of any set up costs required in order to deliver the document review and method validation stage process outlined above (steps 1-5), alongside ongoing overhead costs (step 6).

Guidance

The contractor is required to produce guidance for applicants wishing to submit GMO Food and Feed samples for validation. The guidance should outline the necessary procedures that will guide applicants through the process in making their submissions to the contractor. Guidance information may include but is not exhaustive with; how to submit an application, expected timeframes, payment procedure, document templates and any other relevant information required.

Continued interactions with international partners

The contractor is expected to identify, participate and engage with relevant international partners when necessary to ensure access and retrieval of information remains at the forefront in this sector. Please identify international stakeholders you are likely engage with, and how often as part of this contract. All rates for travel and accommodation should be in line with FSA’s Travel Policy:

Expenses	Reimbursement
Rail travel	Standard class
Mileage	£0.45 per mile for the first 10,000 miles in a financial year
Overnight hotel accommodation	Up to £100 per night outside London Up to £130 per night in London (including breakfast and VAT)
Subsistence	Up to a maximum of £25 for a 24-hour period plus up to £5 for breakfast if not included in room rate (based on actual receipts)

Innovation

If the contractor is currently in ownership to highly specialised laboratory equipment that is likely to find notable benefit offered by the task of validating the varied methods provided by applicants. This may be briefly summarised as supplementary information. The contractor is expected to keep up to date with the latest processes, technologies, reference materials and any other areas of relevance to the field of GMO laboratory analysis.

Risk

The contractor is required to provide details on any relevant perceived risks including mitigation of those risks.

Ethics

The contractor is required to provide any details on ethical issues relating to the handling of samples derived from genetically modified plants, animals and microorganisms, to include upholding a legal responsibility to the deliberate release and transboundary movement of GMOs.

Data protection

The contractor is required to provide details on how they will securely store applications and physical samples. The contractor is also expected to uphold provisions set out in Article 30 and 31 of Regulation (EC) No 1829/2003 as this will be retained in GB, on genetically modified food and feed, relating to confidentiality and data protection.

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.'

The Supplier hereby assigns (where relevant by present assignment of future rights) absolutely and irrevocably to the FSA with full title guarantee all right, title and interest including all copyright, database rights and other intellectual property or related rights in and to the Database throughout the world absolutely for the full period or periods of protection conferred by law including all renewals, extensions and revivals of such period(s). The Supplier agrees and undertakes that it shall (at its cost and expense) do all such acts and execute such further documents as the FSA may request to ensure that all such rights in and to the Database are vested in the FSA including without limitation confirmatory assignments by all personnel and contractors working in relation to the Database. The FSA hereby grants to the Supplier during the term of its appointment a non-exclusive licence of the FSA's rights in and to the Database to the extent and for so long as is reasonably necessary for the performance of the Supplier's obligations under its appointment.

Dissemination and exploitation

The contractor is to produce the validation report once the validation processes has been completed, within 3 months as specified in the specification unless agreed by exception with the FSA. This is to be sent to the Authority (FSA) who can be expected to host the appropriate data and relevant reports to its website.

Sustainability

The contractor is required to provide details on its sustainability management practises.

Quality

- EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories";
- EN ISO/IEC 17011:2004 “Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.
- UKAS Accreditation (or equivalent)

Schedule 3 (Charges)

1. **How Charges are calculated**

    1.1 The Charges:

        1.1.1 shall be calculated in accordance with the terms of this Schedule;

        1.1.2 if not applicable: cannot be increased except as specifically permitted by this Schedule and in particular shall only be subject to Indexation where specifically stated in the Award Form; and

    1.2 Any variation to the Charges payable under a Contract must be agreed between the Supplier and the Buyer and implemented using the procedure set out in this Schedule.

2. **The pricing mechanisms**

    2.1 The pricing mechanisms and prices set out in Annex 1 shall be available for use in calculation of Charges in the Contract.

3. **Are costs and expenses included in the Charges**

    3.1 Except as expressly set out in Paragraph 4 below, or otherwise stated in the Award Form the Charges shall include all costs and expenses relating to the provision of Deliverables. No further amounts shall be payable in respect of matters such as:

        3.1.1 incidental expenses such as travel, subsistence and lodging, document or report reproduction, shipping, desktop or office equipment costs, network or data interchange costs or other telecommunications charges; or

        3.1.2 costs incurred prior to the commencement of the Contract.

4. **When the Supplier can ask to change the Charges**

4.1 The Charges will be fixed for the first **4** years following the Contract Commencement Date (the date of expiry of such period is a "**Review Date**"). After this Charges can only be adjusted on each following yearly anniversary (the date of each such anniversary is also a "**Review Date**").

4.2 The Supplier shall give the Buyer at least three (3) Months' notice in writing prior to a Review Date where it wants to request an increase. If the Supplier does not give notice in time then it will only be able to request an increase prior to the next Review Date.

4.3 Any notice requesting an increase shall include:

4.3.1 a list of the Charges to be reviewed;

4.3.2 for each of the Charges under review, written evidence of the justification for the requested increase including:

(a) a breakdown of the profit and cost components that comprise the relevant part of the Charges;

4.4 The Buyer shall consider each request for a price increase. The Buyer may grant Approval to an increase at its sole discretion.

4.5 Where the Buyer approves an increase then it will be implemented from the first (1st) Working Day following the relevant Review Date or such later date as the Buyer may determine at its sole discretion and Annex 1 shall be updated accordingly.

5. **Other events that allow the Supplier to change the Charges**

5.1 The Charges can also be varied (and Annex 1 will be updated accordingly) due to:

5.1.1 a Specific Change in Law in accordance with Clause 24;

5.1.2 a review in accordance with insurance requirements in Clause 13;

5.1.3 a request from the Supplier, which it can make at any time, to decrease the Charges; and indexation, where Annex 1 states that a particular Charge or any component is “subject to Indexation” in which event Paragraph 7 below shall apply.]

6. When you will be reimbursed for travel and subsistence]

6.1 Expenses shall only be recoverable where:

6.1.1 the Time and Materials pricing mechanism is used; and

6.1.2 the Award Form states that recovery is permitted; and

6.1.3 they are Reimbursable Expenses and are supported by Supporting Documentation.

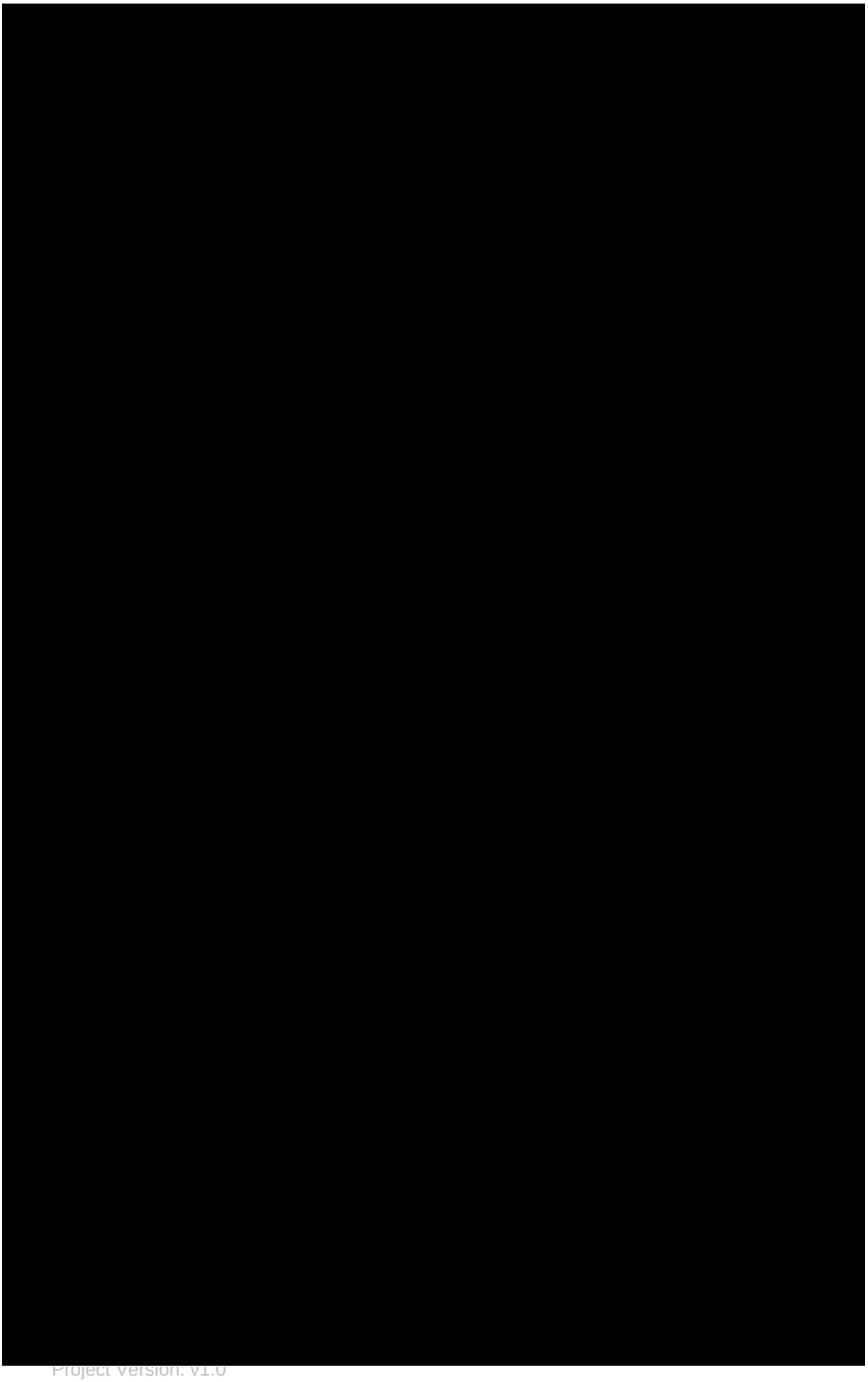
6.2 The Buyers expenses policy is as set out in the table below:

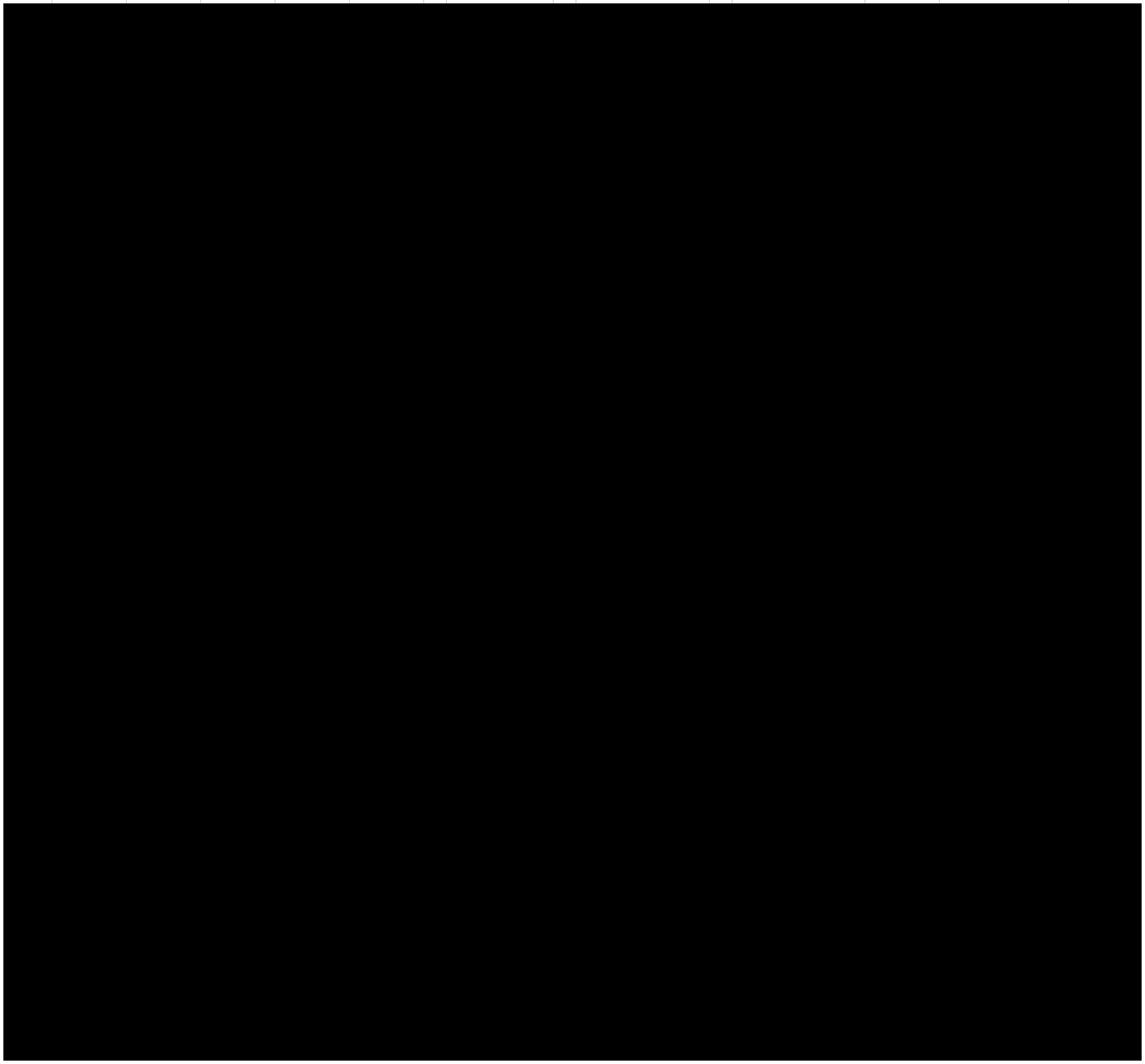
Expenses	Reimbursement
Rail travel	Standard class
Mileage	£0.45 per mile for the first 10,000 miles in a financial year £0.25 per mile for any mileage in excess of 10,000 miles in a financial year
Overnight hotel accommodation	Up to £85 per night outside London Up to £130 per night in London
Subsistence	Up to a maximum of £21 for a 24-hour period

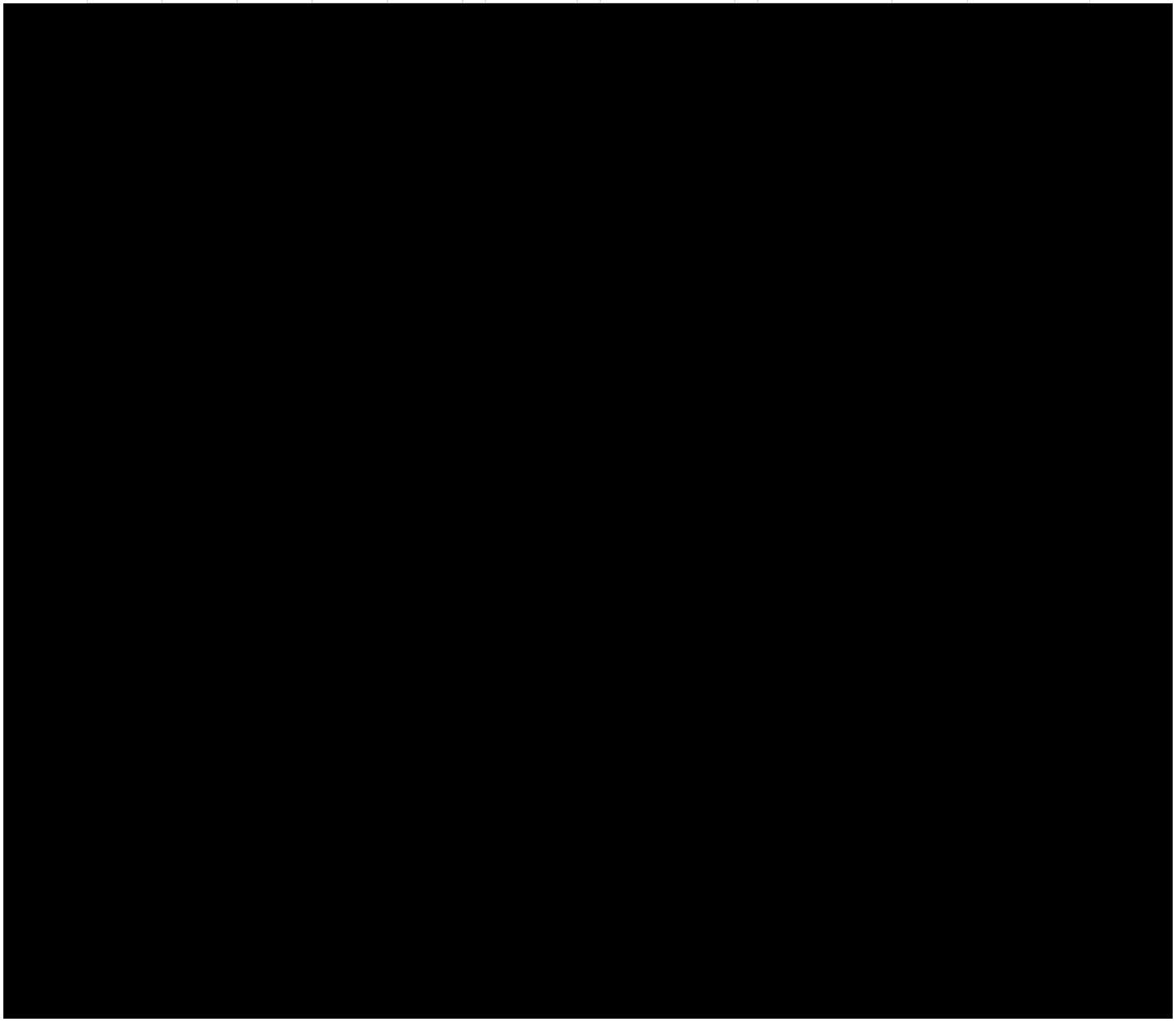
Annex 1: Rates and Prices

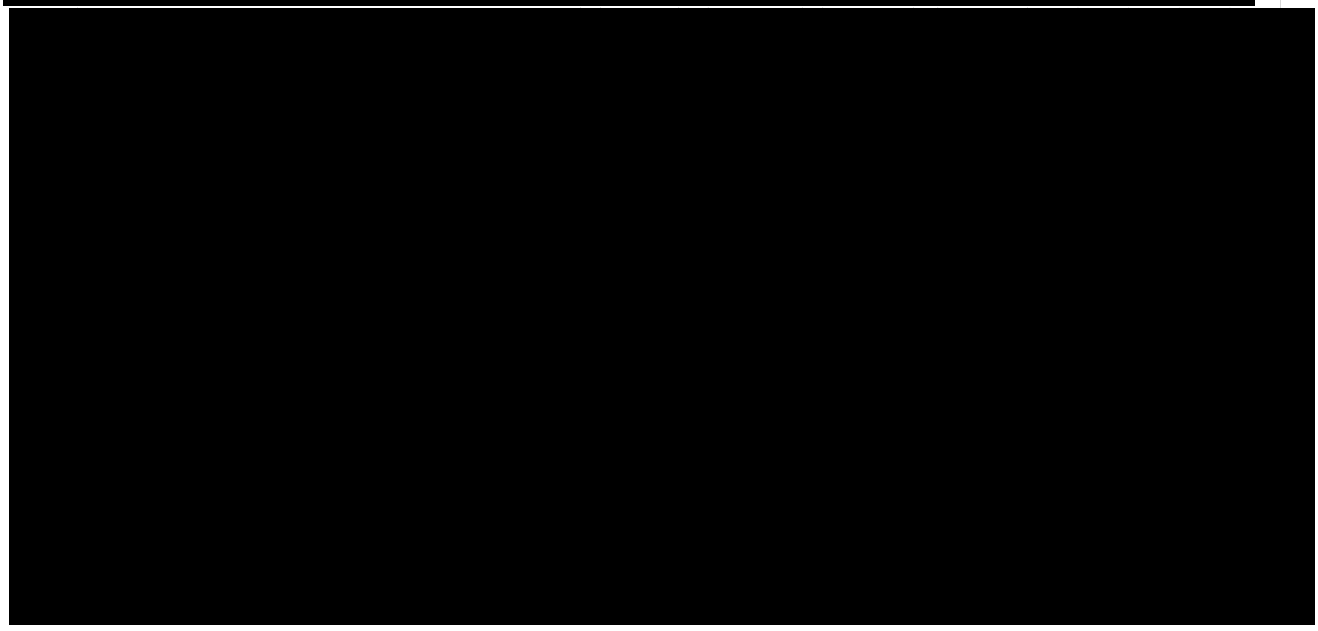
Ramp-up costs are one-off costs associated with increasing the supplier's capacity to support a higher annual average volume of applications."

Ramp-down costs reflect the maximum one-off cost chargeable to the buyer in the event that there is a sustained reduction (measured over a six-month period) in the volume of applications. The supplier will make every reasonable effort to off-set these costs and will only pass on those costs which could not be mitigated. Examples of this could be the redeployment of staff to other activities and/or the appointment of staff on short fix-term contracts. The buyer and supplier are committed to regularly reviewing upcoming application volumes to support effective resource planning and minimise the impact on either party that could arise from volumetric changes"









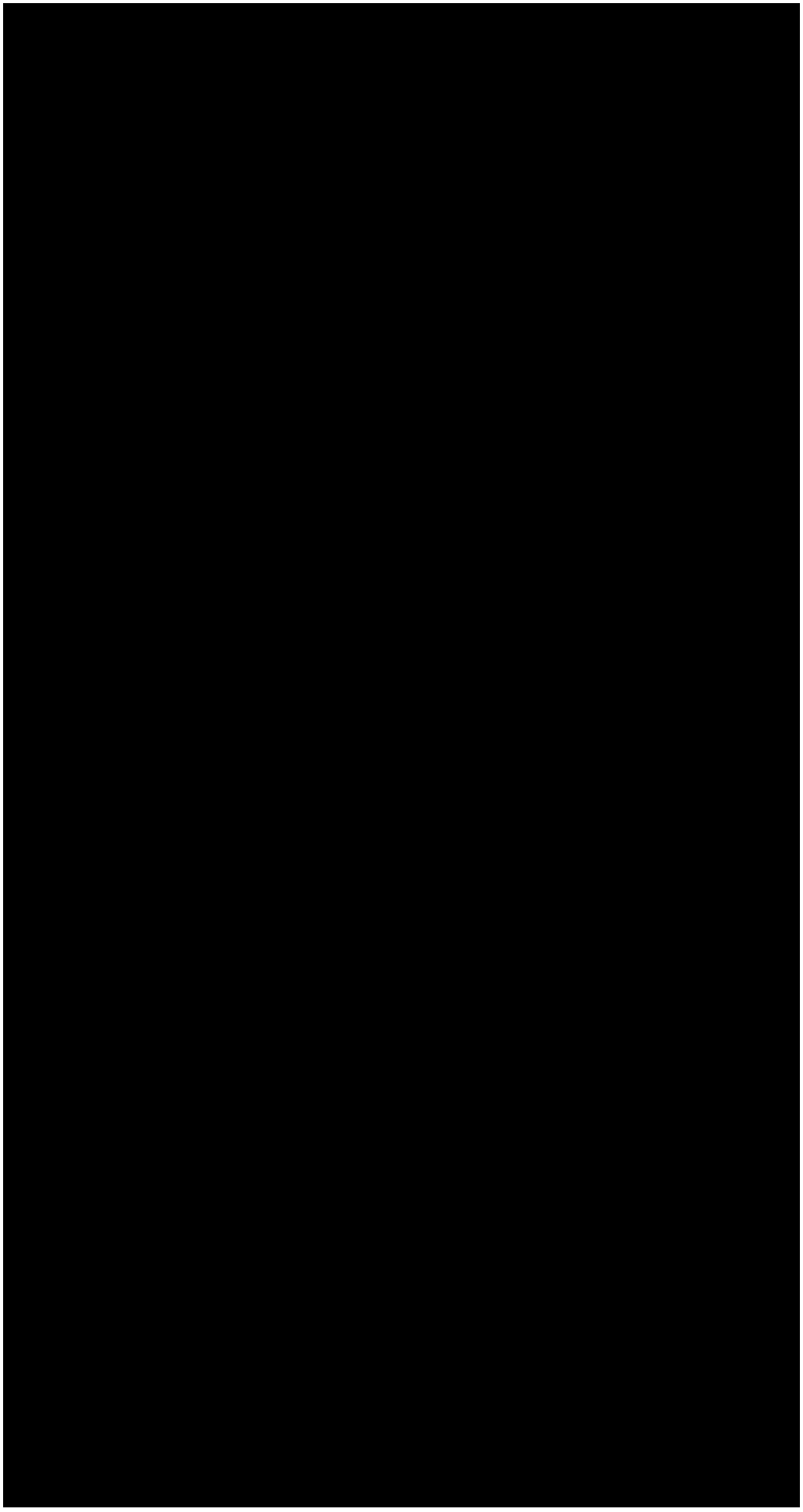
Staff Costs Table

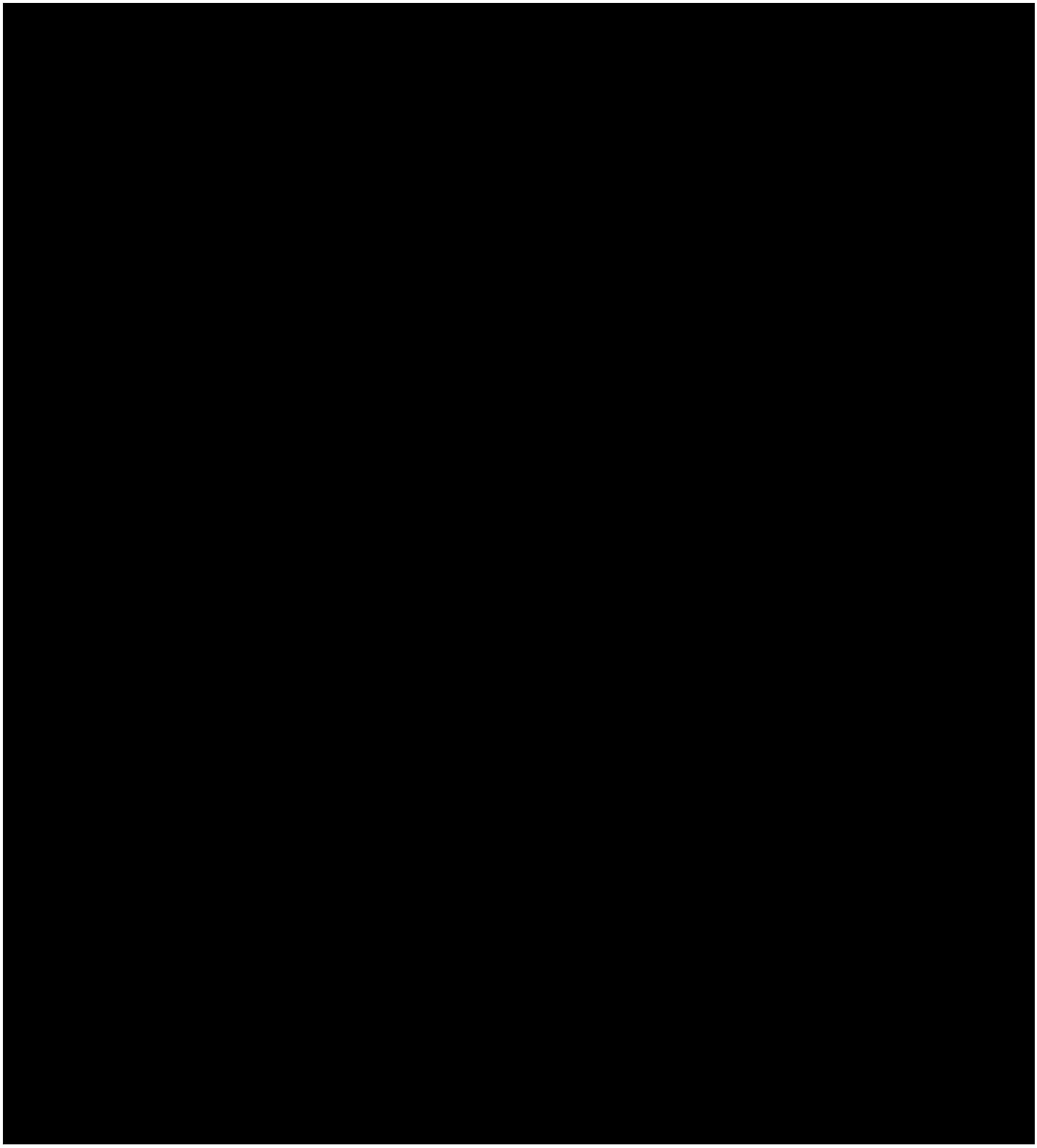
[redacted]

Consumable/Equipment Costs

[redacted]

Travel and Subsistence Costs (In line with FSA policy)
[redacted]





Schedule 4 (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 (Bravo) by the deadline set in the invitation to tender document.

Lead Applicant's details

[redacted]	[redacted]	First Name	[redacted]	Initial	[redacted]	Title	Dr
Organisation	LGC	Department	Health Science & Innovation				
Street Address	Queens Road						
Town/City	Teddington	Country	UK	Postcode	TW11 0LY		
Telephone No	[redacted]	E-mail Address	[redacted]				

Is your organisation is a **small and medium enterprise**. (EU recommendation 2003/361/EC refers http://www.hmrc.gov.uk/manuals/cirdmanual/cird92800.htm)	Yes		No	X

TENDER SUMMARY

GMO Food and Feed Authorisation GB

	[01/04/2021]		[31/03/2026]

1: TENDER Summary AND OBJECTIVES

A. TENDER SUMMARY

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

This project provides key scientific method validation services in support of authorisations for GMO applications in Great Britain. This is delivered through expert document reviews and practical method validation exercises, facilitated through three objectives:

1) **Develop and underpin the provision of a support structure** to build a resilient base for all GMO method validation authorisations (renewals, EU pipeline applications and UK applications) and provision of guidance for applicants;
2) **Provide core support activities to** maintain competency (annual report; lists of validated reagents and reputable suppliers; maintenance of appropriate storage facilities to ISO 9001; maintenance of ISO/IEC 17025:2017; maintenance of a national GMO compendium “database” containing control materials and methods; and continued international stakeholder engagement);
3) **Core authorisation activities** consisting of scientific evaluation and reporting of results to the FSA. To accommodate this, the six point plan suggested by the FSA will be adopted:
    I. Application reception;
    II. Scientific assessment of dossiers and data;
    III. Experimental testing of samples and methods;
    IV. Method validation through collaborative ring trials;
    V. Reporting to the Authority;
    VI. Secure storage of GMO control materials.

Added value and unique benefits afforded through this tender to ensure the FSA specifications are fully met include:

- The UK National Reference Laboratory position for GMOs;
- Excellent established links with UK official control network (particularly OCLs with proven qPCR and GMO capability);
- in-depth knowledge of GMO method validation trials (both as a participant and organising these through previous FSA/Defra tenders, fully meeting combined ENGL, IUPAC and IOA 5725 guidance and standards);
- Certification to ISO 9001 with an approved quality management system for all operations, inclusive of secure storage facilities for GMO control materials;
- ISO/IEC 17025:2017 accreditation for GMO related activities and dPCR operations;
- Accreditation to ISO 17034 for the production, distribution and housing of reference materials
- Unsurpassed proficiency test round results and international measurement claims (CCQM) for GMOs;
- Unequalled knowledge and continued access to EU/EC intelligence and guidance on GMO analysis post the EU transition phase;
- Full membership on EC GMO expert meeting and working groups;
- Production of peer reviewed GMO publications and EC guidance documents;
- Expert knowledge of pipeline GMO developments inclusive of committees on digital PCR, genetically modified microorganisms and products of gene editing.

This bid recognises the significant operational uncertainty regarding the number of authorisations that may be required to be assessed per year. This is addressed through using a phased and modular approach of different financial envelopes to accommodate the varied number of authorisations. This will enable maintenance of core capability and delivery in this area, seeking synergy with pre-existing NRL activities, providing increased flexibility to the FSA and demonstrating value for money.

Furthermore, it is the expectation that LGC will be delivering work for UK based GMO authorisations on behalf of the FSA for the interim period 1st January to 31st March 2021. This will have provided invaluable insight into the delivery of the authorisations function, facilitating establishment of the infra-structure for the service. Any cost-

savings during this period will be recognised against this full FSA GMO authorisations tender, off-setting any additional costs, and providing further value for money for the FSA.

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

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	**infrastructure development** Underpins support structure and builds a resilient base for all GMO method validation authorisations (renewals, EU pipeline applications and UK applications) and provision of guidance for applicants as part of UK centric authorisations
2	**core support activities** Ensures maintenance of competency through production of annual report, validating reagents, list of suppliers, storage of materials, maintenance of ISO/IEC 17025:2017 accreditation, reporting of PT rounds, maintain the national GMO compendium “database”, dedicated project and account management teams, international stakeholder engagement and establishment of the process for setup and overhead costs associated with each UK centric authorisation
3	**core authorisation activities** Encompasses the scientific evaluation and reports to the FSA associated with GMO renewals, EU pipeline applications and new UK applications requiring intra- and inter- lab practical evaluation. To keep costs low to the FSA, a realistic modular approach and synergy with pre-existing NRL activities have been sought

2: DESCRIPTION OF APPROACH/SCOPE OF WORK

A. 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

The Food Standards Agency (FSA) is the Competent Authority for the purpose of the Regulation (EU) 2017/625 on Official Feed and Food Controls in the UK. To fulfil the FSA's obligation under Article 8 of Commission Implementing Regulation (EU) No 503/2013, the FSA is seeking a provider to deliver the functions currently performed by the EU Reference Laboratory (EURL) for supporting the authorisation of Genetically Modified Organisms (GMO) for food and feed uses, in Great Britain (England, Wales and Scotland).

Authorisation of genetically modified food and feed (EU) is granted for a period of ten years (Regulation (EC) No 1829/20031)) in the European Union. This authorisation, in accordance with the procedure referred to in this Regulation is renewable (Art. 11 and 23. Regulation (EC) No 641/20042), as amended by Regulation (EU) No 503/20133), which set the requirements for the submission of applications. An application for authorisation permitting the placing on the market of the product in question within the EC must be filed with the Competent Authority of a Member State. Based on pre-existing EU legislation, the notification must include the particulars listed in part C of Directive 2001/18/EC (see Article 13), in particular:

- Detailed information on the GMO (in line with Annexes III and IV, including amongst others, information which can be used for the detection and identification of particular GMO products;
- Environmental risk assessment (in line with Annex II)
- Proposed period of consent not exceeding ten years
- Post-market monitoring plan (in line with Annex VII)
- Proposal for labelling (in line with Annex IV), including the words "This product contains genetically modified organisms";
- Summary of the notification

As part of the authorisation procedure, validation of the detection method submitted for the GM food/feed is an integral part of the assessment process, since the validated detection method is to be included in the final authorisation opinion. Consequently a GM food/feed cannot be authorised in the UK/EU before a relevant detection method has been validated.

Within the EU, the method validation process is conducted by the European Commission's Joint Research Centre (JRC) in its capacity as the European Union Reference Laboratory (EURL) for GMOs in food and feed, assisted by the European Network of GMO Laboratories (ENGL) as per articles 32 and Annex of Regulation (EC) No 1829/2003.

Since leavening the European Union, the UK needs to have in place procedures for the rigorous assessment of applications for authorisation of placing on the UK market of products containing GMOs. The FSA, as the relevant Competent Authority, will assume the role of the European Food Safety Authority (EFSA) in relation to the responsibility for the main authorisation route and role, but there is a requirement for a laboratory to provide expert scientific services for the purposes of the method validation to contribute towards the overall authorisation procedure.

This project will provide services for the scientific support for the detection of GMOs as part of the authorisation process for new GMO applications (food and feed) in Great Britain.

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

At the date of writing, the EC has an established and rigorous procedure in place for the authorisation of placing GMOs on the market place. Applications for authorisation for the placing on the market of genetically modified food and feed (as well as provision of samples for official control), is described in Commission Regulation (EC) 1829/2003 on genetically modified food and feed.

Briefly, the authorisation procedure consists of a number steps, inclusive of submission of an application to the National Competent Authority of a member state detailing safety studies and methods for detection of the GMO in the dossier, EFSA checking the validity of the application and conducting the scientific risk assessment, practical method validation for detection of the GMO being conducted by the EURL, production of a validation report, and finally EFSA issuing a scientific opinion on the findings to be ratified by the EU Member States.

From the 1st January 2021, the UK will have completed the EU transition/implementation period and will be responsible for processing and approving its own GMO authorisations. This project proposes to use the tried-and-tested approach provided by the EC as a template for implementation within the UK in the initial instances, supporting the FSA's role in replacing EFSA and LGC replacing the EURL for matters associated with the method validation of the authorisation process, allowing successful delivery of authorisations on day one. The method validation process is an integral part of the GMO authorisation procedure, which LGC is best positioned to deliver in the UK through proven track record associated with GMO validation and analysis, and LGC suggests working with the FSA to manage and adapt the established EU GMO method validation procedure (and the GMO authorisation process as a whole) to best support UK policy, legislation and interests in this important area.

LGC's unique placement of the only UK laboratory to consistently attending all European Network of GMO Laboratories (ENGL) plenary meetings since the ENGL inauguration ceremony of 2002, the only UK laboratory to be an active participant/leader in EC GMO expert Working Groups, workshops and meetings, and its position as the UK National Reference Laboratory (NRL) for GMOs in food and feed under Regulation 2017/625, provide bespoke and unsurpassed UK skill sets in support of the GMO method validation process. This includes participating in EURL method validation trials (providing knowledge and access to applicable reporting templates); demonstrable and published evidence of organising its own method validation trails on a national and international basis according to the exact specifications for the current project inclusive of IUPAC, ENGL MPR and ISO 17025 guidance (Defra projects FA0146[1]/FA0171[2] and FSA project FS126001[3]); housing of LGC Standards as an internationally accredited reference materials producer and proficiency test provider; participation in ENGL scientific Working groups on genetically modified microorganisms (GMM), products of gene editing (GE), digital PCR (dPCR), Next Generation Sequencing (NGS), etc.; recognition of its Principal Scientist as an independent and international expert in GMOs; ISO/IEC 17025:2017 accreditation for all GMO related activities inclusive of DNA extraction, quantitative real-time PCR (qPCR) and dPCR, supported through proficiency test (PT) round participation in over 54 PT rounds; author on a number of EC guidance documents inclusive of the recent guidance for measurement uncertainty estimation on GMO testing laboratories (3rd edition, 2020); horizon scanning initiatives including participation in the first dPCR method validation of a GMO authorisation (Dec., 2020); and dedicated cold-rooms and supplementary secure storage facilities for GMO control and reference materials.

[1] Defra project (FA0146) "Method validation of the real-time PCR approach for the quantitation of horse DNA" http://sciencesearch.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=19109

[2] Defra project (FA0171) "Validation of Methods to Quantify Horse and Pork Meat Adulteration in Raw and Processed Beef" (final report submitted to Defra 21/05/2020)

[3] FSA project (FS126001) "International Collaborative Trial of a Real-Time PCR Method for the Relative Quantitation of Horse DNA" https://www.food.gov.uk/sites/default/files/media/document/fs126001finrep.pdf

Unique benefits that LGC affords to the project

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 positions establishment in 2009, LGC has excellent relations with all UK based Official Control Laboratories, remaining aware of the technological capabilities of these and hence facilitating the smooth running of any UK based method validation trials which are required as part of the authorisation process. As part of this application, a number of UK Official Control Laboratories with demonstrable qPCR capability (include Edinburgh Scientific Services, Tayside Scientific services, Glasgow Scientific Services, , Hampshire Scientific Services, Lancashire Scientific Services and Minton Treharne & Davies) have expressed their support for being involved in the GMO authorisation process going forward. This core set of OCLs will be supplemented with other Public Analyst Laboratories such as PASS. In order to meet the minimum criterion for participants in an inter-laboratory method validation trial as per the IUPAC guidance, additional UK based labs can be recruited from the UK ENGL network with proven qPCR and GMO analytical capabilities that LGC has strong links with as part of the NRL position (e.g. Fera and SASA) or from appropriate UK based industry labs (e.g. Premier Analytical Services) with proven capability in GMO analysis to ISO/IEC 17025:2017

In current and previous FSA/Defra projects, LGC has in-depth knowledge of running **method validation collaborative trials** (this being distinct for standard proficiency test programmes which are also supported and provided more generally as part of LGC standards as an accredited PT provider, reference material producer and distributer), in accordance with and utilising the exact ENGL MPR document, the international union of pure and applied chemistry (IUPAC) protocol and ISO/IEC 17025:2017 accreditation as stipulated as part of the current contract specification. Examples include the LGC/Defra/FSA method of real-time PCR for the relative quantitation of horse DNA, which was based on best-measurement practice guidance from the GMO area (Defra projects FA0135/FA0146 and FSA project FS126001). This method, which was qualified as fit for purpose via a collaborative trial based on the ENGL MPR guidance, is now being considered for international standardisation via the relevant CEN sub-committee. Other projects include the LGC/Defra/FSA meat speciation trials (Defra project FA0171) which were organised within the UK based on method validation trials fully compliant with the ENGL MPR documents, which are also being considered further for downstream international standardisation.

In terms of **external quality assessment exercises** associated with GMO activities, LGC has successfully participated in 54 of these since 2000, being a mixture of both EURL Comparative Tests and GeMMA proficiency test rounds. In all 54 proficiency test rounds, LGC has received satisfactory (z<[2]) scores based on 95 different GM targets analysed. LGC has **ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis**.

In addition to this, as a UK National Measurement Laboratory, we regularly participate 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 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. Three of the NML's **international measurement claims** (https://www.bipm.org/kcdb/) are associated with GMO analysis, providing independent verification of LGC operating at the highest possible global standards for GMO analysis.

LGC is well versed in delivery of method validation studies and data, regularly participating in EURL led **method validation studies** as part of the GMO authorisation process, hence having excellent experience in this area and having knowledge of what is to be expected and the quality and formatting of resultant data.

Furthermore, having been present at all ENGL plenary meetings since the establishment of the ENGL in 2002, consistently so by the same staff member, all of the heads of EU 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. These international relations and ability to remain at the forefront of all GMO related activities is further cemented through LGC acting as the **nominated UK representative** on the ENGL Steering Committee (SC), which regularly meet twice yearly, as well as LGC being the only active UK participant and leader on all

current ENGL scientific working groups, inclusive of dPCR, DNA extraction, the new ENGL Minimum Performance Requirements(2), gene editing, genetically modified microorganisms (GMM) and Next Generation Sequencing (NGS). This ensures that LGC continues to remain up to date with the latest processes, technologies, reference materials and any other areas of relevance to the field of GMO laboratory analysis, which is a requirement stipulated in the specifications associated with this project.

LGC's core input into these scientific working groups has been acknowledged by the EU to such an extent that **Malcom Burns (Principal Scientist at LGC)** has been recognised as an independent scientific expert in this area, hence facilitating continued attendance at these scientific meetings in the future, for example, should agreements still be under negotiations between the EU and UK for the future. LGC's scientific knowledge in the GMO area 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 an RSC book on molecular biology techniques, which LGC is an editor on, including significant content on GMO detection strategies.

Based on current knowledge of the area and applications, it is the current expectation that the majority of applications will be for qPCR based approaches. However, LGC is aware that digital PCR (dPCR) applications for GMO authorisations are becoming increasingly more common in the future, LGC already having participated in the **first two EU dPCR GMO authorisations** based on the ENGL MPR and evolving guidelines in this area, as well as having knowledge and access to harmonised templates for reporting results from dPCR method validation studies. LGC has **ISO/IEC 17025:2017 accreditation for dPCR** activities in this area, being one of the first laboratories in the UK to acquire this, and has in-depth knowledge of method validation requirements for GMO using this technology, having participated in these exercises and also being a member on the EU Working Group set to provide published guidance on the minimum performance requirements for this in the near future.

Equally well, **genetically modified microbes (GMM)** and **products of gene editing (GE)** are beginning to gain additional traction, and it may be foreseen that an application for these GMO products may be required in the UK for the future. Whilst this is very much uncharted territory and their authorisations have yet to be formalised in the EU, LGC sits on bespoke EU committees and working groups associated with providing advice for these, and hence will be bets placed to advise on appropriate authorisation mechanisms to the FSA and work with these in order to best accommodate these for the future.

LGC's suite of dPCR instruments is housed within the National Measurement Laboratory (NML) facility on-site at Teddington, which is a recently refurbished laboratory facility (opened on 2019) fully equipped with all modern pieces of equipment including a range of qPCR and dPCR machines, manual and automated DNA extraction techniques, all of which are instrumental in developing and validation methods for GMO detection. The laboratory has access to four real-time PCR machines (1 x Applied Biosystems QuantStudio 7 Flex real-time PCR instrument; 1 x ABI 7900HT Real-Time PCR System (Thermo Fisher Scientific); 2 x CFX96 Touch Real-Time PCR Detection System (Bio-Rad)) which are all maintained under contract, providing sufficient coverage and contingency for all method validation studies as part of this proposal.

LGC houses multiple dedicated secure walk-in cold room facilities (paired with GMO NRL position for **storage of control materials**), as well as many independent fridges and freezers and -80ºC storage facilities. In fulfilment of ISO/IEC 17025:2017 and ISO 17034, all of these are independently serviced and monitored to ensure they are fit for purpose and maintain their temperature. The joint knowledge and experience of LGC Standards and the **National Measurement Laboratory** reference material production team (being accredited to ISO 17034 for reference material production and storage, with over 30 years' experience in this inclusive of distribution and characterisation of reference materials through inter-laboratory trials), will be used to help ensure samples are kept safely and appropriately.

The NML has a dedicated team of statisticians (3 staff) and advanced statistical tools. If required, support from this team will be available to deal with advance data analysis. Our Teddington site hosts some storage and distribution facilities for LGC Standards. These facilities and LGC What about Stats team and lead CCQM studies (distribution of materials across the world)

In relation to keeping costs low for this project, LGC has won and retained the UK GMO NRL position via competitive tender since the position's original inception in 2009. Part of the current project specification is for the contractor to liaise with the FSA appointed NRL. This will incur no additional charge on the assumption that the NRL position will be retained at LGC for the future duration of the contract.

Scientific approach, methodology and study design that will be used to address the specific evidence requirement and realise the scientific objectives outlined above

How LGC meets the project specifications (pages 6-8 of FS430418 specification)

Pipeline applications

"*Once the transition period for the UK's exit from the EU has ended, there will be GMOs for which an authorisation has been requested but the assessment has not yet been completed in the EU regulatory pipeline. Handling will be dependent on how far the application has progressed by the end of the transition period and the wish for the applicant to market in GB. For GMO applications, it is expected that pipeline applications at the start of Commission and EFSA process will require laboratory method validation. These will typically be applications that have been received by the Commission but not yet submitted to EFSA. Pipeline applications midway through the start of the process may require method validation, which is to be decided on a case by case basis. It is expected that pipeline applications at the very end of Commission and EFSA process will not require laboratory method validation to be carried out. These will typically be applications where legislation has been drafted and discussed or those with a published EFSA opinion. For pipeline applications the FSA will be requesting dossiers and any validation reports."*

The project specification requires flexibility to accommodate and deliver fit for purpose assessments of EU pipeline applications: those GMO applications that are part way through their authorisation within the EU, but will not be complete prior to the commencement of this contract.

LGC is well equipped to administer and deliver pipeline applications, which will predominantly occur more towards the start of the contract duration. LGC is well versed in organising method validation trials on a national and international basis (e.g. Defra project (FA0171) and FSA project (FS126001)) as well as regularly delivering these as part of pre-existing EURL validation trails, which are all fully compliant with ISO/IEC 17025/2017 accreditation, IUPAC and ENGL guidelines which are stipulated in the specifications. LGC routinely inspects and uses the EURL validated methods and associated method validation ring trial results as part of its GMO activities and quality management system to ISO/IEC 17025:2017, and is therefore well versed in assessing the fitness for purpose the supporting scientific documentation.

In terms of experience in delivering and managing commercial measurement services LGC routinely delivers over 100 of these per year (amounting to over £1m worth of contract value), across multiple operations and commercial areas inclusive of the chemical and molecular biology fields. Additionally, strength and resilience is demonstrated in our National Measurement Laboratory products and services team, managing 100's of projects and dealing with 100's of customers, resulting in an income of greater than £14m per annum. This team provides project management support for regularly planning, costing, reviewing and invoicing commercial projects for service provision and reference materials.

Handling of data is likely to be impacted by EU exit and is being further considered as this will require transfer of data from the EU to the UK.

This bid recognises there may be significant operational uncertainty regarding the total number of GMO renewals, pipeline applications and full UK centric authorisations that may be required to assessed per year. **This project addresses this by proposing a phased approach and financial envelope to accommodate the varied number of authorisations, whilst maintaining core capability and delivery in this area, providing flexibility to the FSA and demonstrating value for money.**

One of the main risks is the unknown demand over the life the contract and the maintenance of the capacity if demand drops unexpectedly. To mitigate this, increase in capacity will be achieved through a series of incremental 'ramp up' steps which can be implemented as necessitated by case volume and discussed and agreed with the FSA on a regular basis. Each small increment will be for 2 full time equivalents (FTEs) giving LGC the extra capacity to deal with an additional 4 applications per year. This cost will depend on existing capacity and total yearly volume of applications. The diagram below illustrates this phased approach, and further information can be found in the financial template.

Figure 1: Proposed phased approach to increase in capacity, showing increment costs, cumulative costs, and timescale. Ramp up steps are contingent upon case volume and are incremental. Ramp up costs also include an associated Ramp down cost should case volume fall unexpectedly subsequent to a ramp up step in a given year. This ramp down costs are only to be used in the case of a sudden drop in demand and they are kept to a minimum by the use of fixed term employment contracts and re-assigning staff to other contracts whenever possible. For further information, please see the financial template. Illustrative timeline only – actual timelines to be agreed on an individual basis.

Another option would be to have a **rolling contract** with the FSA where required capacity is agreed at the beginning of each year/contract.

Database

"*The contractor is required to have the capacity and capability to create a national GMO database including the storing and archiving of samples. This database should be accessible to all GB OCLs, GMO NRL and the FSA as they will be required to share the methods and control materials and hold samples for the duration of the contract."*

Project specifications require the contractor to have the capacity and capability to create a national GMO database including the storing and archiving of samples.

A "database" will be developed, referred to more simply as a Compendium as it will list all UK validated methods for GMOs authorised in the UK along with relevant control materials. This format will mitigate potential issues regarding GDPR and IP of housing of data in an official database, as information will be simply listed in a searchable format, saving the FSA costs associated with setting up an official database as part of this project.

This Compendium will be actively curated and maintained, housing all of the methods validated as part of the authorisation process, providing secured access to all GB Official Control Laboratories, the UK NRL for GMOs in food and feed and the FSA. This will house a searchable list of methods which will be made available to the stakeholders via clickable links which will forward the user to .pdf versions of the validated method, the related method validation trial report (encompassing the intra- and inter- laboratory validation results), and the DNA extraction report. In addition, the Compendium will provide a list of the relevant control materials supplied by the applicants as part of the authorisation process which can be distributed to UK stakeholders for the purposes of GMO controls.

LGC has demonstrable expertise and in-depth knowledge of providing such Compendiums in a secure manner, as illustrated by the list of FSA and Defra validated methods and research projects associated with food analysis, as housed on the Food Authenticity Network website (http://www.foodauthenticity.uk/methods). It is proposed that such a user-friendly interface be adopted as part of this project to promote easy (but secured) access to validated methods without being overly complex.

A proto-type example of the user-interface on the Compendium is provided below. Pertinent information on the validated method (Unique ID, version and date, GM event, species and a clickable link to the method) will be included for each entry. The screen shot below is a simple mock-up of an area within a SharePoint site that shows a list (Figure 1) containing direct links to validated methods housed within a document library (Figure 2).

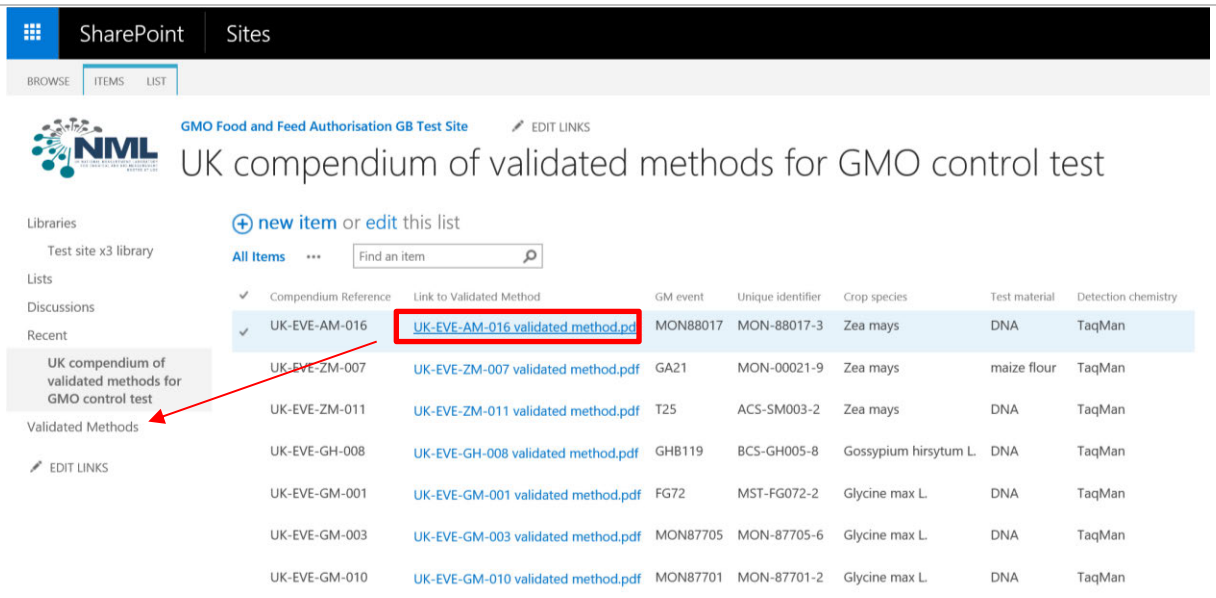


Figure 2: Screen shot of a SharePoint list housing a compendium of validated methods

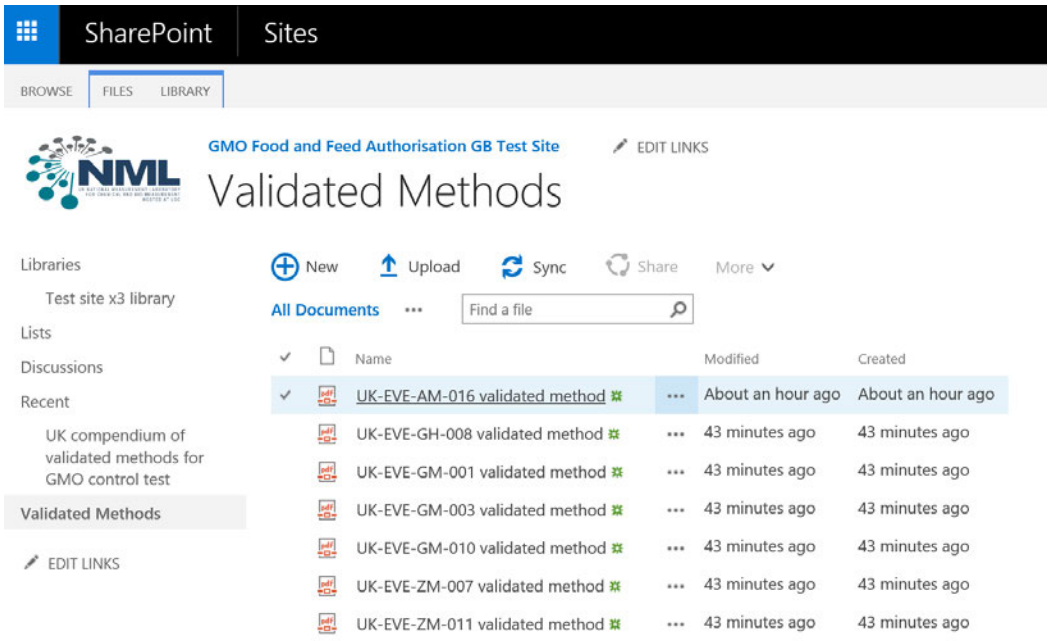


Figure 3: Screen shot of a SharePoint Library containing pdf versions of the validated methods that are linked to the compendium.

Depending upon the exact nature of the information held, and in discussions with the FSA, this information can be housed in a variety of formats, for example as a searchable Excel workbook or work sheets. LGC has a number of options available to enable restricted sharing of the Compendium to external parties. Platforms routinely used across the business that would meet the immediate needs of this requirement include both Microsoft SharePoint and Nextcloud. These products are housed on LGC's datacentres so conform to the necessary security requirements. User names and unique passwords can be generated to prevent unauthorised access. The screen

shot below shows a simple mock-up of an area within Nextcloud demonstrating a home page interface with associated folders.

In terms of storage of control materials provided by applicants as part of the authorisation process, LGC houses multiple dedicated secure walk-in cold room facilities (paired with GMO NRL position for storage of control materials), as well as many independent fridges and freezers and -80^{o}C storage facilities. All of these are independently serviced and monitored to ensure they are fit for purpose and maintain their temperature. As part of an accepted quality management system to ISO 9001 certification, samples stored in these facilities will be given unique ID numbers for traceability and also entered onto a secure electronic register.

Primary temperature monitoring and recordings are conducted on a daily basis using traceable ISO 9001 digital calibrated fridge/freezer sensors and documented appropriately as part of an audit trail. As a secondary system, a real-time online (Haier invisible monitoring) system based on a wireless temperature monitoring system (using individually ISO 9001 calibrated sensors) log data in real-time and store these on a cloud platform and accessible interface. The system is available 24 hours a day therefore providing a greater resilience to act accordingly especially with out of standard working hours – should the temperature fall outside pre-defined operating limits, audible alarms are triggered and dedicated appropriate members of staff are alerted via automatic text messages and email. This system has a 24 hour service contract in place. A further layer of resilience is applied to our walk in cold room which is also monitored 24 hours by our overall BMS temperature monitoring system and recorded by our in-house building services system.

Provision and handling of reference materials for inter-laboratory trials is further augmented through the National Measurement Laboratory reference material production team, as well as a recent FSA project (FS101206) regarding Development of Quality Control Materials for Food Allergen Analysis.

Storage and maintenance of control materials and samples will be augmented and supported by the vast knowledge and experience of LGC Standards and the National Measurement Laboratory reference material production team. LGC Standards operate across 120 countries worldwide, as an authorised distributor and producer of reference materials under ISO/IEC 17025:2017 and accredited to ISO 17034. LGC Standards supports a portfolio of 300,000+ reference materials and analytical standards, to check the quality and metrological traceability of products, to validate analytical measurement methods, for research and development, and for the calibration of instruments. As the UK's designated institute for chemical and bio-measurement, LGC uses the most advanced analytical techniques to characterise reference standards, ensuring the scientific integrity of the data contained in any Certificate of Analysis can be relied upon. LGC provides proficiency testing schemes accredited to ISO 17043 which are used by more than 13,000 participant labs worldwide. The knowledge provided by LGC Standards will be used to help ensure samples are kept safely, securely and appropriately.

Application Fees and costings

"Applicants for authorisation of GM food and feed will be expected to contribute to cost which support the duties and tasks of the reference laboratory. The contribution from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

In the financial template please outline your proposed payment model for reimbursement of costs and the total cost per application (steps 1-6). An upfront cost for all applications should be outlined which will cover the cost of steps 1-3, the additional cost of the subsequent phases should then be outlined to be paid when this step can be completed. If costings vary due to the nature of the application, such as additional costs per change required, please outline this."

The project specifications state that the applicant will provide costs towards the method validation tasks as part of the authorisation process.

[redacted]

For stacked events, the example quoted for illustration of costs in the original FSA specifications state:

"*For each application for a GMO containing stacked transformation events, where the method of detection and identification of each single transformation event that constitutes the GMO has been previously validated by the laboratory or where the validation is pending, the flat-rate contribution depends on the number (N) of single transformation events that constitute the GMO and shall be calculated as ~£18,000 + (N x 4500).*"

The costs for validating stacked events are complicated, as the text quoted in the FSA specifications can only be valid when there is a **UK approved validated method for each single transformation event** that constitutes the stacked event. In these instances, LGC proposes to adopt the above costing model.

However, as currently there are no such validated methods for UK approved GMOs, then there is a strong likelihood that a stacked event submitted by an applicant will contain single events for which no pre-existing UK validated method has been produced. In these instances, the costs are likely to be much higher with a tiered approach for having to validate all single events within the stacked event.

In such instances, and as this is unchartered territory for the UK and the EU, LGC proposes to work closely with the FSA and the applicant to agree on appropriate costs for authorisation of stacked events where no UK validated methods exist for the individual single events, on a case by case basis. In reality, the costs of authorising such stacked events will most likely be borne by the applicant, but additional administration costs will also be incurred in order to produce the necessary paperwork for the validation of multiple events within the same GMO.

In order to provide true value for money to the FSA, LGC proposes to support the FSA's recommendation of using a tiered approach regarding different costs for renewals, pipeline application and full UK centric authorisations, as detailed in the financial template. This bid also recognises there may be significant operational uncertainty regarding the total number of GMO renewals, pipeline applications and full UK centric authorisations that may be required to be assessed per year. This project addresses this by proposing a financial envelope to accommodate the varied number of authorisations, whilst maintaining core capability and delivery in this area, providing flexibility to the FSA and demonstrating value for money.

Being an active member of a number of EC scientific expert groups, inclusive of working groups on genetically modified microorganisms (GMM), digital PCR, stacked events and products of gene editing, LGC continually conducts horizon scanning initiatives in terms of what GM authorisations may be forth coming for the future. Digital PCR is becoming increasingly common within the EU and it is expected that future UK authorisations may include the use of dPCR instruments instead of just real-time PCR instrumentation – LGC is currently a participant in the first EURL led validation exercise using dPCR proposed by an applicant for authorisation of a new GMO event within the EU. LGC is thus well paced to advise the FSA on developing and administering GMO authorisations in this maturing technical field.

The use and incidences of Genetically Modified Microorganisms (GMM) (used for the production of food enzymes as part of food fermentation processes) and products as a result of gene editing, are increasing with a lot of support

from the research and development side of the scientific community. Alerts on the presence of GMM in food enzyme preparations have recently been published in 2020 on the RASFF by the Belgian authorities. Whilst the validation of such organisms and products will be complicated, and there are currently no EU approved guidelines for the approval process for GMM and GE organisms, LGC is best placed to advise and work with the FSA in order to further define a relevant UK authorisation process to accommodate these, due to LGC's membership of the relevant EC scientific expert working groups addressing this issue within the EU and status as an invited expert on related workshops

Set up and ongoing running costs

"Please provide a summary of any set up costs required in order to deliver the document review and method validation stage process outlined above (steps 1-5), alongside ongoing overhead costs (step 6)."

Project specifications require that set-up costs for the authorisation process be provided.

As advised by the FSA project specifications, ongoing costs have been included to administer the initial scientific dossier review and intra-lab validation exercise (Steps 1 to 5) as well as the subsequent inter-lab trials (Step 6). Set-up costs would involve setting up an ISO 9001 application process, lab capacity, a method catalogue, storage and distribution processes, reporting templates, contract management processes, and dissemination and communications strategies. The initial set up will allow LGC to undertake **a maximum of 4 full authorisations and 10 renewals per annum in the first instance**. This capacity will then be increased by a series of incremental 'ramp up' steps as necessitated by case volume. For further information, see Figure 1 (above) and the financial template.

Guidance

"The contractor is required to produce guidance for applicants wishing to submit GMO Food and Feed samples for validation. The guidance should outline the necessary procedures that will guide applicants through the process in making their submissions to the contractor. Guidance information may include but is not exhaustive with; how to submit an application, expected timeframes, payment procedure, document templates and any other relevant information required."

Project specifications require the contractor to provide guidance for applicants as part of the GMO authorisation process.

LGC is well versed in the authorisation procedure and knowledgeable regarding the available published guidance for the method validation process. We propose to initially adopt the relevant forms and processes already in place in the EU but also would work with the FSA to tailor these according to UK needs, policy, legislation and best measurement practice guidance.

The European Union (Withdrawal) Act 2018, which repeals The European Communities Act 1972, provides retention of existing EU laws in the domestic statute book, inclusive of GMO related legislation of Regulation (EC) No 1829/2003 on GM food and feed, Regulation (EC) No 1830/2003 on traceability and labelling, and Regulation (EU) No 503/2013 on applications for authorisation. The inherited regulatory framework will allow the FSA to take a risk-based, proportionate approach for GMO sampling and control.

This tender proposes to provide guidance which will include, but is not limited to, addressing the following relevant pre-existing EU published guidance:

- Description of the method validation process;
- The submission process and expected timeframes;
- Note to the applicants on the type and nature of control samples provided in the context of applications for authorisation;
- Explanatory note to applicants regarding practical instructions concerning the method validation task of the authorisation laboratory pursuant to relevant UK legislation (e.g. retained Regulation (EU) No 503/2013 on applications for authorisation;
- Explanatory note for the payment of financial contributions under Commission implementing regulation (EU) No 120/2014 of 7th February 2014, amending Regulation (EC) No 1981/2006, on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003;
- Document templates for submission of method validation data.

Following agreement and confirmation from the FSA as to the templates and pro-formas used as part of the application process, LGC will provide written guidance for help during the authorisation process for the stages including the initial application, submission and appraisal of the scientific dossier regarding the method, expected turnaround times, payment procedure from the applicant, document templates, payment procedure for participating laboratories, and other related information.

Continued interactions with international partners

"The contractor is expected to identify, participate and engage with relevant international partners when necessary to ensure access and retrieval of information remains at the forefront in this sector. Please identify international stakeholders you are likely engage with, and how often as part of this contract. All rates for travel and accommodation should be in line with FSA's Travel Policy"

Project specifications state that the contractor is expected to identify, participate and engage with relevant international partners to help ensure access and retrieval of information remains a priority.

LGC is uniquely placed to facilitate this and continue to maintain international relations. The European Network of GMO Laboratories (ENGL) was formed as by the European Union and the National Reference Laboratories NRLs which, in the context of the enforcement of the European Union (EU) regulations of GMOs are responsible for the correct detection, identification and quantification of GMOs by the enforcement authorities in the EU-Member States. LGC was part of the 2002 ENGL inauguration and has been the only UK participant present at all 31 ENGL plenary meetings since then, moreover consistently so by the same staff member. This has further helped cement excellent relations within the EU regarding GMOs, where the heads of EU NRLs are known personally by the manager of the NRL position at LGC, Dr. Malcolm Burns. This helps facilitate continued national and international links, which are unsurpassed by any other UK based laboratory on the GMO front.

These international relations and ability to remain at the forefront of all GMO related activities is further cemented through LGC acting as the nominated UK representative on the ENGL Steering Committee (SC), which regularly meet twice yearly, as well as LGC being the most active UK participant and leader on all ENGL scientific expert Working Groups, inclusive of dPCR, DNA extraction, the new ENGL Method Performance Requirements working group, genetically modified microorganism, products of gene editing GE and NGS, all of which are extremely pertinent to the UK and potentially the GMO authorisation process. This ensures that LGC continues to remain up to date with the latest processes, technologies, reference materials and any other areas of relevance to the field of GMO laboratory analysis, which is a requirement stipulated in the specifications associated with this project.

LGC's core input into these scientific working groups has been acknowledged by the EU to such an extent that Dr. Burns (Head of the GMO unit at LGC) has been recognised and approved as an independent scientific expert by the EU in this area. This is extremely beneficial to continued interactions with international partners, as this unique status maintains Dr. Burns' continued attendance at these scientific meetings post 1st January 2021, for example,

should UK – EU agreements still be under negotiations for the future and no agreement between the EU and UK is yet in place prior to or at the start of this contract.

Under current conditions, the contractor is likely to meet with control laboratory representatives from all 28 EU member states (plus Norway, Turkey and Switzerland) on a regular basis through ENGL meetings and invited scientific expert status to contribute to related EC Working Groups to which Dr. Burns is a member (MPR(2), dPCR, DNA extraction, GMM, GE and NGS), as well as relevant training and workshops. These typically will meet on a routine basis at least 25 times a year by a variety of physical and virtual meetings. LGC also maintains close connections with the EURL GMFF and the European Commission, the Secretariat and head of the EURL being known personally by LGC, where they collaborate on a routine basis for harmonisation of GMO analytical strategies (e.g. latest collaborative effort being published as "*Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition*" (2020) European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565)

How this project fulfils the laboratory requirements (page 6 of FS430418 specification)

(a) Be impartial, free from any conflict of interests, and declare this in the application;
LGC is recognised globally for 'setting standards in analytical science' and also for the manner in which it successfully executes three statutory functions within a private organisation; independence and impartiality are critical for this success. LGC is very well versed in performing a wide range of activities and compartmentalising those, as required, to overcome any perceived conflicts of interest. The Government Chemist underpins industry and public confidence in the food and feed official control system through a series of steps approved by BEIS to guarantee independent impartial technical appeal to the highest standards. Additionally, we routinely demonstrate our impartiality and independence in the running of the virtual Food Authenticity Network, co-funded by the FSA, and other FSA/Defra projects. Such steps will be adopted as part of the GMO authorisation contract to ensure impartiality is maintained at all stages of the process.

(b) Have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;
The National Measurement Laboratory (NML) facility at LGC is staffed by a team of 25 molecular biologists, who have a wide range of experience in all areas of DNA and protein based measurement, specialising in the development of sensitive and specific analytical procedures using state of the art technology. The team has in excess of 27 years research experience in house specialising in the development of sensitive and specific analytical procedures and boasts a combined CV comprising in excess of 400 publications representing research in a variety of different sectors. This ensures that the GMO authorisation function has a large pool of analytical support and provides for continuity of service where required.

The expertise of LGC staff has been demonstrated through such exercises as demonstrating compliance with the Maede *et al*., protocol for detection of the original Bt63 Chinese rice by practical implementation in the laboratory, and then disseminating this knowledge to OCLs. In support of this expertise LGC was the only UK based laboratory to assist the EU-RL in the initial validation of the "ENGL 96 well screening plates" for GMOs, which is described in the publication "Real-Time PCR-Based Ready-to-Use Multi-Target Analytical System for GMO Detection" in Food Analytical Methods in 2009. This expertise is further reinforced through LGC acting in its official capacity as the referee analyst in twelve cases of Official Control for Chinese GM rice from 2012 to 2020 inclusive.

The GMO unit at LGC has ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis, inclusive of DNA extraction, real-time PCR and digital PCR instrumentation. In terms of external quality assessment exercises associated with GMO activities, LGC has participated in 54 of these since 2000, being a mixture of both EURL Comparative Tests and GeMMA proficiency test rounds. In all 54 proficiency test rounds, LGC has received satisfactory (z<[2]) scores based on 95 different GM targets analysed.

The Head of the GMO unit at LGC, Dr. Malcolm Burns, has been acknowledged by the European Commission as a recognised independent scientific expert in the area of GMO analysis, heralding from the UK with unsurpassed knowledge of GMO analytical approaches. These international relations and ability to remain at the forefront of all GMO related activities is further cemented through LGC acting as the nominated UK representative on the ENGL Steering Committee (SC), which regularly meet twice yearly, as well as LGC being the only active UK participant and leader on all current ENGL scientific working groups, inclusive of dPCR, DNA extraction, the new ENGL Minimum Performance Requirements(2), gene editing, genetically modified microorganisms (GMM) and Next Generation Sequencing (NGS). This ensures that LGC continues to remain up to date with the latest processes, technologies, reference materials and any other areas of relevance to the field of GMO laboratory analysis, which is a requirement stipulated in the specifications associated with this project. LGC's scientific knowledge in the GMO area 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 an RSC book on molecular biology techniques, which LGC is an editor on, including significant content on GMO detection strategies. Dr. Burns has published over 60 articles, peer reviewed papers and EU guidance reports, mostly associated with GMO analysis, and heads up a team of experienced scientists dedicated to supporting all GMO related analytical activities. Dr. Burns has helped organise, co-chair, present and deliver a DNA extraction workshop with the EU Reference Laboratory (EURL) for GMOs in feed and food in 2017, held at the Joint Research Centre (JRC) in Ispra (Italy) This three day event was attended by over 30 experts representing 19 EU member states and other countries as far afield as Mexico, Ecuador and Brazil.

LGC has extensive experience in successfully managing multidisciplinary projects (at both a National and European level), with quality of project management and analytical research assured through certification to ISO 9001. The LGC staff who will work on this project are graduates in chemical and biological disciplines, and have extensive analytical experience of current and emerging molecular biology techniques. 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 to operate an instrument at any one time.

(c) Possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;

A complete range of all modern analytical equipment necessary for development, optimisation and validation of GMO methods is housed within the National Measurement Laboratory (NML) facility at LGC, which has recently been refurbished and equipped with the latest pieces of analytical equipment including a range of qPCR and dPCR machines, DNA spectrophotometers, and manual and automated DNA extraction instruments. This includes the Applied Biosystems QuantStudio 7 Flex real-time PCR instrument, and a range of other real-time and standard PCR machines. These are augmented by an epMotion 5075 liquid handling robot, Illumina MiSeq Next Generation Sequencer (NGS), Oxford Nanopore MinION NGS, BioMark Fluidigm digital PCR and dynamic array system, Bio-Rad QX200 droplet digital PCR and an Agilent LabChip Capillary Electrophoresis instrument. The laboratory facilities at LGC have dedicated rooms and areas for specific tasks (separating DNA extraction, PCR setup and PCR analysis) which are protected by distinct airflow regimes, all operating to an approved quality management systems as part of certification to ISO 9001 for all operations carried out at LGC.

LGC uses the modern Applied Biosystems QuantStudio 7 Flex real-time PCR instrument on a routine basis for GMO method validation and inclusion in proficiency test exercises (GeMMA and EURL Comparative Tests). As part of ISO 9001 certification and accreditation to ISO/IEC 17025:2017, this instrument is under service contract and regularly maintained and inspected by the manufacturer. Should this instrument not be performing optimally, the instrument will be replaced by the manufacturer. Additional real-time PCR capacity is further afforded through a suite of additional qPCR machines available at the Teddington site, which can be utilized should the situation demand.

LGC has cutting-edge, up-to-date laboratory equipment for the analysis of GMOs including end-point real-time, and digital PCR, Capillary Electrophoresis instrumentation (e.g. Agilent Bioanalyser), demonstrable expertise in SYBR®Green and TaqMan detection and quantitation systems, and future-proofed in terms of Next Generation Sequencing (NGS) on-site.

Quality procedures and practices underpin all work conducted. All laboratory equipment is routinely monitored and subject to contract service agreements and routine testing and calibration to ensure that it is fit for purpose. Where a piece of equipment becomes irrecoverably damaged, the service contract provides contingency for a replacement. Equipment performance and maintenance is routinely monitored and part of LGC imbedded quality management system, in line with ISO 9001 certification and LGC's ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis.

In terms of other approaches to bring to bear to benefit GMO analysis, LGC teaches regular courses on method validation and making measurement uncertainty estimates. Both of these areas are fundamental issues involved in accurate GMO determination. LGC rregularly participates in EURL GMFF method validation exercises so have great experience of this and what the expectations are, as well as using the laboratory facilities for regular participation in EURL GMFF and GeMMA proficiency test schemes, having a track record of generating acceptable z-scores (z<[2]) for all PT schemes it has participated in, involving 95 different GM targets analysed across 54 different PT rounds.

(d) Ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national and international level are taken into account in their work;

As part of the staff induction programme at LGC, all staff are required to comply with ISO 9001 quality procedures (inclusive of policies; network access; timesheets; training courses; IT best practices; workstation set-up; security systems and procedures; health, safety, quality and security practices; incident handling; working arrangements; internet usage; and data privacy (GDPR)) through a thorough training and induction programme. Quality underpins all aspects of delivery at LGC and a recognised quality management system is imbedded within the work we provide, including maintenance of staff training records, in accordance with ISO 9001 certification and ISO/IEC 17025:2017 accreditation for GMO analysis.

LGC is aware of all international standard and practices, and remains aware of all of the latest developments in research through his close contact with the European Commission and EU National Reference Laboratories for GMOs. Dr. Burns is an recognised expert in this, acknowledged as an international scientific expert on GMO analysis, and has recognised membership as an active member on all GMO related EC scientific Working Groups post the EU transition/implementation period, regularly helping produce and author best measurement guidance advice in the area of GMO analysis (e.g. "Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition" (202) European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565; EC Guidance document. Overview and recommendations for the application of digital PCR., ISBN 978-92-76-00180-5, doi:10.2760/192883) as well as being an author and editor on a recent RSC commissioned book involving best measurement practice guidance in food authenticity techniques (Malcolm Burns, Lucy Foster, Michael Walker (editors) (2019) "DNA Techniques to Verify Food Authenticity: Applications in Food Fraud" Royal Society of Chemistry, doi: 10.1039/9781788016025, ISBN: 978-1-78801-178-5)

(e) Where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

LGC maintains a list of reputable commercial suppliers of reagents and materials for real-time PCR and GMO analysis. There are only two authorised producers of Certified Reference Materials for GMOs, whom jointly share the responsibility for provision of these: AOCS in America and the JRC (Geel). Although analytical laboratories are responsible for verifying commercially available reagents and reference materials are fit for purpose in their own laboratory according to their quality management system, LGC has always provided advice and guidance to UK stakeholders (the FSA and Official Control Laboratories) on where to purchase such consumables as part of the NRL function. On the assumption that LGC retains the NRL position for the duration of this proposed tender

contract, then no additional costs will be charged, and the provision of advice will continue as part of the NRL function, providing value for money for the FSA.

(f) Be equipped with adequate and secure storage facility to store GMO food and feed samples and control materials that have been submitted for authorisation, for the duration of the contract.

In terms of storage of any control materials and samples provided by applicants as part of the authorisation process, LGC houses multiple dedicated secure walk-in cold room facilities (paired with GMO NRL position for storage of control materials), as well as many independent fridges and freezers and -80ºC storage facilities. All of these are independently serviced and monitored to ensure they are fit for purpose and maintain their temperature. As part of an accepted quality management system to ISO 9001 certification, samples stored in these facilities will be given unique ID numbers for traceability and also entered onto a secure electronic register. Storage and maintenance of control materials and samples will be augmented and supported by the vast knowledge and experience of LGC Standards and the National Measurement Laboratory reference material production team. LGC Standards operate across 120 countries worldwide, as an authorised distributor and producer of reference materials under ISO/IEC 17025:2017 and accredited to ISO 17034. LGC Standards supports a portfolio of 300,000+ reference materials and analytical standards, to check the quality and metrological traceability of products, to validate analytical measurement methods, for research and development, and for the calibration of instruments. As the UK's designated institute for chemical and bio-measurement, LGC uses the most advanced analytical techniques to characterise reference standards, ensuring the scientific integrity of the data contained in any Certificate of Analysis can be relied upon. LGC provides proficiency testing schemes accredited to ISO 17043 which are used by more than 13,000 participant labs worldwide. The knowledge provided by LGC Standards will be used to help ensure samples are kept safely and appropriately.

These activities are augmented by the Referee function of the Government Chemist at LGC, which acts as an impartial referee analyst in case of dispute between a Food Business operator and an enforcement agency over the nature or provenance of a food sample, prescribed in several Acts of UK Parliament. The Government Chemist function operates to ISO/IEC 17025:2017 inclusive of sample receipt, sample registration and traceable and secure sample storage and disposal, further augmenting any sample storage capability and competency at LGC.

(g) Where relevant, be equipped to comply with relevant biosecurity standards;

The National Measurement Laboratory facility at LGC, where the majority of the intra-laboratory method validation will take place, is a designated Class 2 laboratory (Biosafety Category 2 conditions), fully equipped to handle and analyse nucleic acid material and non-viable cell material, as well as working with moderate-risk infectious agents or toxins that pose a moderate danger if accidentally inhaled, swallowed, or exposed to human skin. Design requirements for BSL-2 laboratories include hand washing sinks, eye washing stations, and doors that close and lock automatically. All GM material which will be analysed in the laboratory environment will not represent a significant risk to human health, particularly so as DNA on its worn cannot self-replicate or otherwise propagate outside of the cellular environment. However, should additional biosafety requirements be required as part of future GMO authorisations, the modular nature of the new National Measurement Laboratory facility at LGC can be easily expanded to accommodate additional containment measures, and LGC would work with the FSA to implement this.

Whilst Genetically Modified Microorganisms are gaining increasing exposure and traction on the EU front, it is very unlikely that authorisations will be required for live GMM in the immediate future in the context of food enzyme preparations, mainly for two reasons. Firstly, food manufactures are not looking to authorise GMM but are focussed on the authorisation of the associated food enzyme, where the GMM used to produce that enzyme should not be present in the final food enzyme preparation, To date, no authorisations for GMM have been received by EFSA or the EURL-GMFF in respect of this. Secondly, potential propagation of any genetically modified organism, inclusive of GMM, is under strict regulatory control in the UK and a licence is necessary in order to do this, as prescribed by The Health and Safety Executive in the UK.

Page 3 of the project tender FS430418 specifications stipulate that the contractor will analyse genetic material derived from plant, animal and microorganism sources. It is thus expected that the material received will not pose health or safety risk. Nevertheless, should additional biosecurity measures need to be developed in the future as part of any relevant GMO authorisations, LGC will work with the FSA to introduce these and furthermore is well placed to respond to these through consultation with other parts of the LGC business where such measures are already in place for routine operations (e.g. approved COVID-19 testing).

(h) Liaise with the FSA appointed NRL for GMO (as and when required);

In relation to keeping costs low for this project, LGC has won and retained the UK GMO NRL position via open competitive tender since the position's original inception in 2009. Part of the current project specification is for the contractor to liaise with the FSA appointed NRL. It is foreseen that this aspect will incur no additional charge on the assumption that the NRL position will be retained at LGC for the future duration of the contract, further giving value for money to the FSA.

Whilst it is the aim for the GMO NRL function and the GMO authorisation function to be performed by LGC, steps will be taken to continue to maintain no conflict of interest. Dr. Burns will oversee the operations of both areas whilst an Operations Manager will be appointed for the routine delivery of the authorisations aspects, as is befitting a more service based project offering (please see proposed organogram on page 49).

(i) Have experience of, and be able to operate in accordance with, the relevant sampling and analysis legislation, including maintaining specific UKAS accreditation (or equivalent) for the relevant analytes/methods, and satisfactory performance in proficiency test schemes;

LGC is well versed in the EU and UK legislation on sampling and analysis of GMOs, being the UK representative on the ENGL Steering Committee, attending all ENGL plenary sessions, and being the only active UK participant on all EURL/ENGL related scientific working groups keeping abreast of the science in relation to the legislation.

LGC has in-depth knowledge of the key EU legislation in relation to GMOs (many of which will be retained in the UK), the major ones of which are:

- Directive 2001/18/EC - outlines the principles for, and regulates the deliberate release of GMOs into the environment in the EU;
- Regulation (EC) No 1829/2003 - outlines the principles for, and regulates the placing on the market of food and feed consisting of, containing or produced from GMOs (referred to as genetically modified food and feed). This key text provides the general framework for regulating GM food and feed in the EU;
- Regulation (EC) No 1830/2003 -. traceability requirements of GMOs;
- Regulation (EC) No 65/2004 - details the system for the assignment and the format of Unique Identifiers for GMOs;
- Regulation (EC) No 503/2013 – (detailed implementation of Regulation (EC) No 1829/2003) governs the applications for authorisation of GM food and feed, including the method(s) of detection, sampling and event specific identification of the transformation event;
- Regulation (EC) No 1981/2006 provides further detailed rules specific for the implementation of article 32 of Regulation (EC) No 1829/2003 on the European Reference for Genetically Modified Organisms;
- Commission Recommendation 2004/787/EC - provides technical guidance for sampling and detection of GMOs, in particular about sampling protocols and analytical test protocols;
- Regulation (EC) No 2017/625 – details Official controls for feed and food law;
- Cartagena Protocol on Biosafety (Decision 2002/628/EC) and Regulation (EC) No 1946/2003 may be of particular relevance to the UK as these texts refer to the international environment with respect to GMOs and also govern transboundary movements across the EU border.

As a direct consequence of this UK based GMO authorisation tender, it is envisaged that the methods which will be successfully validated as part of the UK authorisation process will be referred to as part of the UK legislation on relevant sampling and analysis of GMOs.

LGC maintains ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis, inclusive of real-time PCR methods and extensive DNA extraction approaches, and has recently applied to UKAS for an extension to scope of ISO 17025 to incorporate automated DNA extraction approaches, in line with modern analytical approaches for food analysis. Additionally, LGC was the first laboratory in the country to acquire ISO/IEC 17025:2017 accreditation for its digital PCR facility, inclusive of analysing nucleic acids derived from GMOs.

LGC regularly and routinely participates in in EURL GMFF and GeMMA proficiency test schemes. We have an extensive and unblemished track record in relation to results from these, generating acceptable z-scores (z<[2]) for all PT schemes across 54 PT rounds and 95 different GM targets since the establishment of GMO proficiency testing in the year 2000.

In addition to this, as a UK National Measurement Laboratory, we regularly participate 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 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. Three of the NML's international measurement claims are associated with GMO analysis, providing independent verification of LGC operating at the highest possible global standards for GMO analysis.

(j) Be familiar with the enforcement system in operation in the GB.

As part of LGC's pre-existing position as the UK National Reference Laboratory for GMOs in food and feed, we liaise closely and on a regular basis with the FSA regarding GMO enforcement in the UK. LGC has very close links with all of the named Public Analysts and Heads of Laboratories in the UK, regularly meeting with these as part of the NRL function, the Government Chemist function, and communicating with the labs through the Association of Public Analyst Training Officer, who is also stationed at LGC.

In order to augment, remain abreast of, and input into GB enforcement related activities, LGC regularly delivers the following aspects:

- LGC houses the UK Government Chemist function, a role underpinned by a number of UK Acts of Parliament to act as an independent referee analyst in cases of dispute between a Food Business Operator and a UK enforcement laboratory;
- LGC remains abreast of the successive quarterly open access publication of Food and feed law, having knowledge of the changes in food and feed legislation and associated activity affecting the UK;
- Regular Knowledge Transfer exercises, jointly funded by the GC/FSA/Defra/FSS facilitate up to date communication of UK enforcement policies as these are regularly attended by Environmental Health Officers, Trading's Standard Officers, Public Analysts and Public Health Officers;
- As part of the Office of the Government Chemist and recognised UK Referee Analyst positions, two members of LGC staff were part of the enforcement system in operation in Great Britain (Dr. Michael Walker and Paul Hancock) and continue to retain expert knowledge of these;
- LGC regularly published in the Journal of the Association of Public Analysts (JAPA), relevant publications including GMO screening approaches and GMO decision support systems (http://www.apajournal.org.uk/2016_0040-0050.pdf ; http://www.apajournal.org.uk/2017_0023-0040.pdf);
- As part of the Elliott Review into the Integrity and Assurance of Food Supply Networks, LGC was a lead author on 'Chapter 5: Laboratory Services' in the final report;
- LGC maintains membership of relevant committees associated with EU and UK enforcement operations, inclusive of the Food Safety and Information Focus Group (FSIFG) enforcement committee, and committees for the European Network of GMO Laboratories (ENGL) and the European Network of Food European Network of Food Allergen Detection Laboratories (ENFADL), representing UK/GB enforcement laboratories;

- LGC also publishes widely in relation to UK based enforcement control, relevant examples including M. Woolfe, *et al*., (2013) "*Can Analytical Chemists do Molecular Biology? A Survey of the Up skilling of the UK Official Food Control System in DNA Food Authenticity Techniques*" J Food Control, 33, 385 – 392 and M. Walker *et al*., (2017) "*Resolution of a disputed albendazole result in the UK Official Control System–time for more guidance?*" . Food Additives & Contaminants: Part A, 34(4), pp.489-493.

Scope of Services to be provided to the FSA

This project will provide scientific support services for the detection of GMOs as part of the authorisation process for new GMO applications (food and feed) in Great Britain. This will be delivered through a series of document reviews and practical method validation:

Objective 01 – infrastructure development

This objective will underpin the provision of a support structure to build a resilient base for all GMO method validation authorisations (renewals, EU pipeline applications and UK applications) and provision of guidance for applicants as part of UK centric authorisations.

Objective 02 – Core support activities

This objective will ensure maintenance of competency through production of an annual report; reviewing and maintaining a list of validated reagents; keeping list of reputable suppliers; maintain appropriate storage facilities to house materials; maintenance of support for ISO/IEC 17025:2017 accreditation; reporting of PT round results to the FSA as part of recognised external quality assessment exercises; maintenance of a national GMO compendium "database" containing lists of control materials and methods; continued international stakeholder engagement; and establishment of the process for setup costs and overhead costs associated with each UK centric authorisation

Objective 03 – Core authorisation activities

This objective encompasses the scientific evaluation and reporting of results to the FSA associated with GMO renewals, pipeline GM authorisations running in parallel with the EU, and UK centric authorisations requiring intra- and inter-lab practical evaluation. To keep costs low to the FSA, a realistic modular approach and synergy with pre-existing NRL activities have been sought

In fulfilment of Objective 3, the six stage modular process suggested by the FSA in the original tender specifications will be adopted:

1) Reception of the application;

2) Scientific assessment of scientific dossiers and data;

3) Experimental testing of samples and methods;

4) Method validation through collaborative ring trials;

5) Reporting to the Authority (FSA);

6) Secure storage for GMO food and feed samples and control materials.

Whilst this project will be focussed mainly on the delivery of the full UK centric GMO authorisations (requiring document appraisal and intra- and inter-laboratory trials), flexibility will also be afforded to accommodate GM renewals (those GMO authorisations that have passed their 10 year authorisation status in the EU) as well as EU pipeline authorisations (those GMO applications which are part-way through the EU authorisation process). Because of the variable nature of what stage any GMO renewals of pipeline authorisation may be at when they are received, the modular approach proposed above through the six stages can be used to accommodate the scientific requirements of each authorisation on a case by case basis.

The project specification states that 10-30 applications requiring authorisation are to be expected each year, with additional applications for renewals of up to 10 per year .This bid recognises the significant operational uncertainty regarding the number of renewals, EU and UK centric authorisations that may be required to assess per year. This project addresses this by proposing a financial envelope to accommodate the varied number of authorisations based on an average of the expected applications per year, whilst maintaining core capability and delivery in this area, providing flexibility to the FSA and demonstrating value for money.

This unique benefits afforded through this tender and LGC (inclusive of the UK National Reference Laboratory (NRL) for GMOs in food and feed, string established links with the UK official control network (particularly those OCLs with proven qPCR and GMO capability who support this tender), in-depth knowledge of GMO method validation trials (both as a participant and organising these through previous FSA/Defra tenders according to combined ENGL, IUPAC and IOA 5725 guidance and standards), certification to ISO 9001 with an approved quality management system for all operations at LGC, ISO/IEC 17025:2016 accreditation for GMO related activities and dPCR operations, accreditation to ISO 17034 for the production and distribution of reference materials, unsurpassed results for external quality assessment exercises as qualified through analysis of 95 GMO targets across 54 proficiency test rounds, unique status as a recognised scientific expert in GMOs facilitating continuity through personal invitation to EC GMO expert meeting and working groups, breadth of coverage through peer reviewed GMO publications and EC guidance documents, expert knowledge of pipeline GMO developments inclusive of genetically modified microorganisms and products of gene editing (sitting on the relevant EC working groups), and secure storage facilities for GMO control materials operating to ISO 9001), will ensure that the information and outcomes listed in the specification document are met.

B. 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

LGC's core scientific input into relevant EC/EU working groups related to GMO analysis has been acknowledged by the EU to such an extent that Dr. Malcom Burns (Principal Scientist at LGC) has been recognised as an independent scientific expert in this area. This facilitates continued attendance at relevant EU scientific meetings in the future, for example, should agreements still be under negotiations between the EU and UK for the future. This provides this tender with unequalled knowledge and continued access to EU/EC intelligence and guidance on GMO analysis post the EU transition phase.

Specifically regarding the concept of innovation. Page 9 of the specifications to this FS430418 project tender also state: "*If the contractor is currently in ownership to highly specialised laboratory equipment that is likely to find notable benefit offered by the task of validating the varied methods provided by applicants. This may be briefly*

summarised as supplementary information. The contractor is expected to keep up to date with the latest processes, technologies, reference materials and any other areas of relevance to the field of GMO laboratory analysis."

Based on in-depth knowledge of the GMO area and relevant analytical methods, it is the current expectation that the majority of applications will be based on qPCR approaches. However, LGC is aware that digital PCR (dPCR) applications for GMO authorisations are becoming increasingly common, being the only UK based laboratory having already participated in the first two EU dPCR GMO authorisations in full compliance with the ENGL Minimum Performance Requirements (2015) guidance. **LGC thus has operational knowledge and access to harmonised templates for reporting results from dPCR method validation studies.** LGC also has ISO/IEC 17025:2017 accreditation for dPCR activities in this area, being one of the first laboratories in the UK to acquire this, thus future proofing the UK GMO authorisation process as a whole should a related application be received by the FSA.

LGC's suite of dPCR instruments is housed within the National Measurement Laboratory (NML) facility on-site at Teddington, which is a recently refurbish laboratory facility equipped with all modern pieces of equipment including a full range of different qPCR and dPCR machines, manual and automated DNA extraction techniques, all of which are instrumental in developing and validating methods for GMO detection. Our newest dPCR instrument is less than 18 months old, and the NML has a proactive CAPEX policy to ensure that our capabilities remain at the cutting edge of measurement science.

Genetically modified microbes (GMM) and products of gene editing (GE) are becoming more common in the EU, and it would be sensible to foresee that a future application based on these novel GMO products may be required in the UK. LGC is the only UK based laboratory to sits on bespoke EU committees and working groups associated with providing advice for these, and hence is best placed to help advise the FSA on appropriate authorisation mechanisms and work with the FSA in order to best accommodate these for the future.

Having acted as the UK National Reference Laboratory (NRL) for GMOs in food and feed since the position's establishment in 2009, LGC has excellent relations with all UK based Official Control Laboratories, remaining aware of the technological capabilities of these and hence facilitating the smooth running of any UK based method validation trials which are required as part of the authorisation process.

As part of this application, a number of UK Official Control Laboratories with demonstrable qPCR capability (include Edinburgh Scientific Services, Tayside Scientific services, Glasgow Scientific Services, , Hampshire Scientific Services, Lancashire Scientific Services and Minton Treharne & Davies) have expressed their support for being involved in the GMO authorisation process going forward. This core set of OCLs will be supplemented with other Public Analyst Laboratories such as PASS. In order to meet the minimum criterion for participants in an inter-laboratory method validation trial as per the IUPAC guidance, additional UK based labs can be recruited from the UK ENGL network with proven qPCR and GMO analytical capabilities that LGC has strong links with as part of the NRL position (e.g. Fera and SASA) or from appropriate UK based industry labs (e.g. Premier Analytical Services) with proven capability in GMO analysis to ISO/IEC 17025:2017

In current and previous FSA/Defra projects, LGC has in-depth knowledge of running method validation collaborative trials (this being distinct for standard proficiency test programmes which are also supported and provided more generally as part of LGC standards as an accredited PT provider, reference material producer and distributer), in accordance with and utilising the exact ENGL MPR document, the international union of pure and applied chemistry (IUPAC) protocol and ISO/IEC 17025:2017 accreditation as stipulated as part of the current contract specification.

Examples include the LGC/Defra/FSA method of real-time PCR for the relative quantitation of horse DNA, which was based on best-measurement practice guidance from the GMO area (Defra projects FA0135/FA0146 and FSA project FS126001). This method, which was qualified as fit for purpose via a collaborative trial based on the ENGL MPR guidance, is now being considered for international standardisation via the relevant CEN sub-committee.

Other projects include the LGC/Defra/FSA meat speciation trials (Defra project FA0171) which were organised within the UK based on method validation trials fully compliant with the ENGL MPR documents, which are also being considered further for downstream international standardisation.

In terms of, LGC has participated successfully in 54 external quality assessment exercises associated with GMO activities since the establishment of these in the year 2000, being a mixture of both EURL Comparative Tests and GeMMA proficiency test rounds. In all 54 proficiency test rounds, LGC has received satisfactory (z<[2]) scores based on 95 different GM targets analysed.

In addition to this, as a UK National Measurement Laboratory, we regularly participate 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 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. Three of the NML's international measurement claims are associated with GMO analysis, providing independent verification of LGC operating at the highest possible global standards for GMO analysis.

LGC has ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis. A recent application for extension to scope of this accreditation has been submitted by LGC to UKAS, to also incorporate automated DNA extraction approaches. It is expected that such accreditation will lend itself well to routine and high-throughput sample extraction, further supporting the GMO authorisation process.

Having been present at all ENGL plenary meetings since the establishment of the ENGL in 2002, consistently so by the same staff member, all of the heads of EU 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. These international relations and ability to remain at the forefront of all GMO related activities is further cemented through LGC acting as the nominated UK representative on the ENGL Steering Committee (SC).

LGC is the only active UK participant and leader on all current ENGL scientific working groups, inclusive of dPCR, DNA extraction, the new ENGL Minimum Performance Requirements(2), gene editing, genetically modified microorganisms (GMM) and Next Generation Sequencing (NGS). This ensures that LGC continues to remain up to date with the latest processes, technologies, reference materials and any other areas of relevance to the field of GMO laboratory analysis, which is a requirement stipulated in the specifications associated with this project.

LGC's scientific knowledge in the GMO area 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 an RSC book on molecular biology techniques, which LGC is an editor on, including significant content on GMO detection strategies.

LGC houses multiple dedicated secure walk-in cold room facilities (paired with GMO NRL position for storage of control materials), as well as many independent fridges and freezers and -80^{o}C storage facilities. In fulfilment of ISO/IEC 17025:2017 and ISO 17034, all of these are independently serviced and monitored to ensure they are fit for purpose and maintain their temperature. The joint knowledge and experience of LGC Standards and the

National Measurement Laboratory reference material production team (being accredited to ISO 17034 for reference material production and storage, with over 30 years' experience in this inclusive of distribution and characterisation of reference materials through inter-laboratory trials), will be used to help ensure samples are kept safely and appropriately.

In relation to keeping costs low for this project, LGC has won and retained the UK GMO NRL position via competitive tender since the position's original inception in 2009. Part of the current project specification is for the contractor to liaise with the FSA appointed NRL. This will incur no additional charge on the assumption that the NRL position will be retained at LGC for the future duration of the contract.

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 Group has accumulated considerable experience in the management and delivery of complex work programmes for its customers. The Group'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 project managers, account 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 operation at 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 database allows project managers to obtain detailed information on all financial aspects of each project.

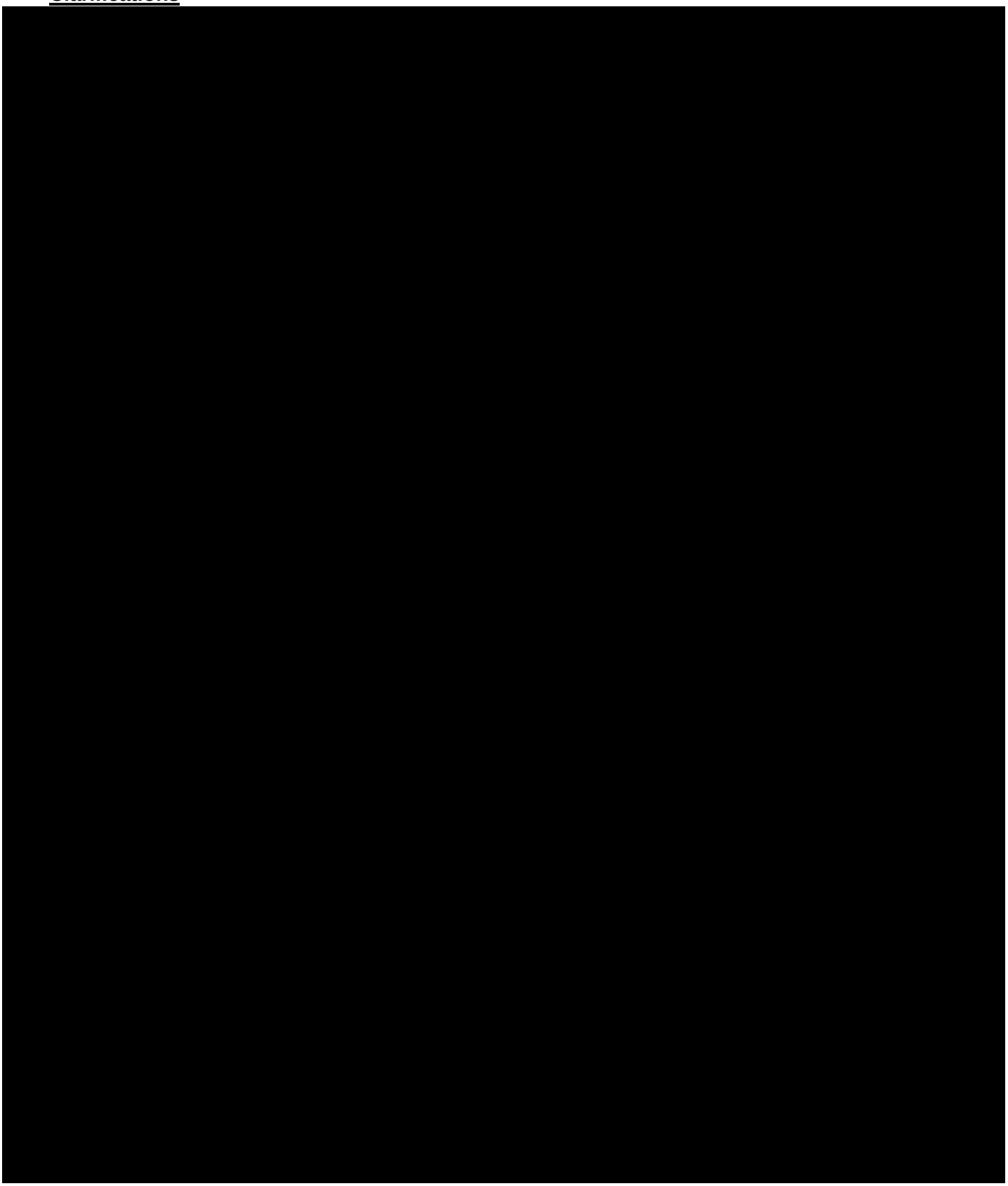
This bid recognises the significant operational uncertainty regarding the number of authorisations that may be required to be assessed per year. This is addressed through using a phased and modular approach of different financial envelopes to accommodate the varied number of authorisations. This will enable maintenance of core capability and delivery in this area, seeking synergy with pre-existing NRL activities, providing increased flexibility to the FSA and demonstrating value for money.

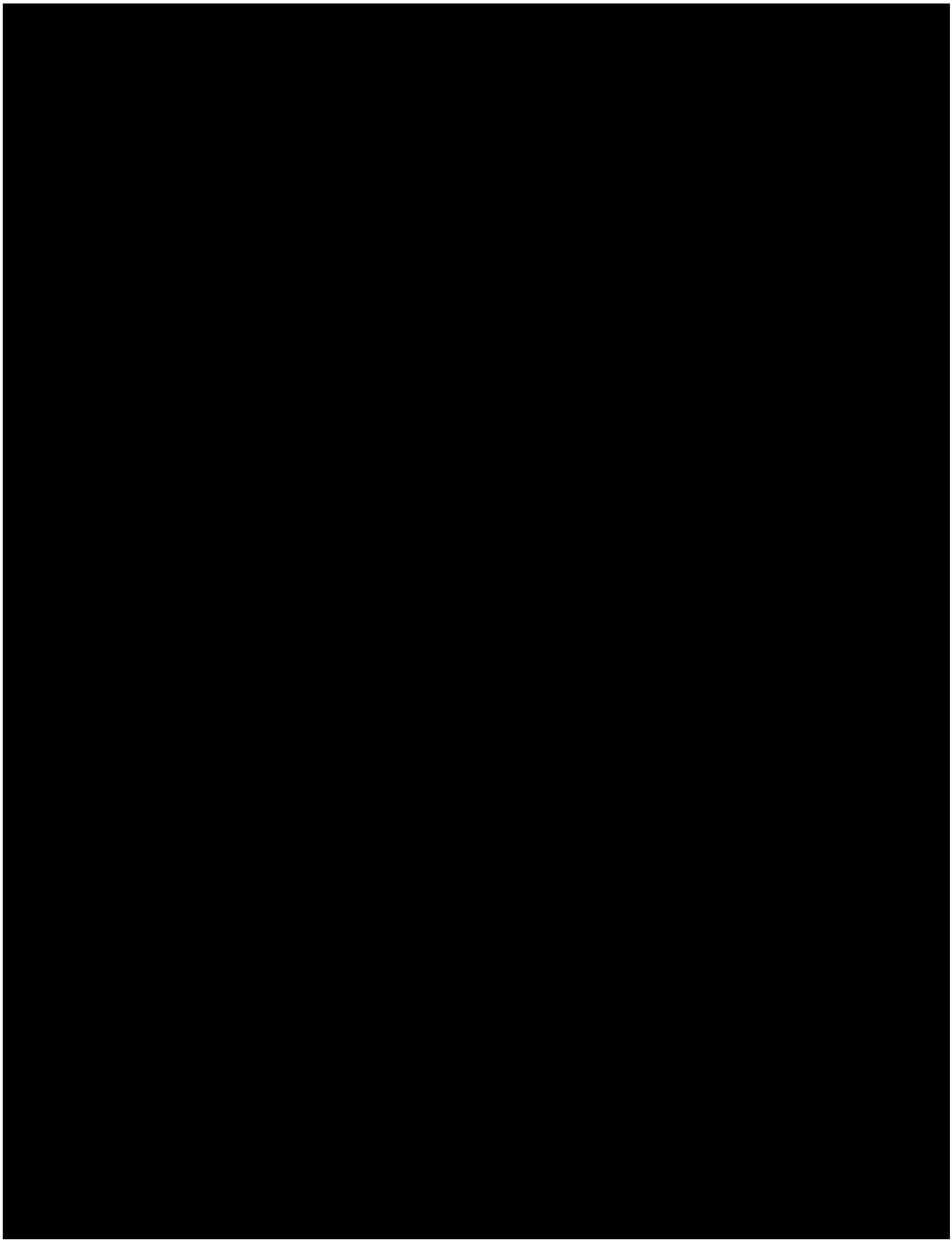
Furthermore, it is the expectation that LGC will be delivering work for UK based GMO authorisations on behalf of the FSA for the interim period 1st January to 31st March 2021. This will have provided invaluable insight into the delivery of the authorisations function, facilitating establishment of the infrastructure for the service and expected

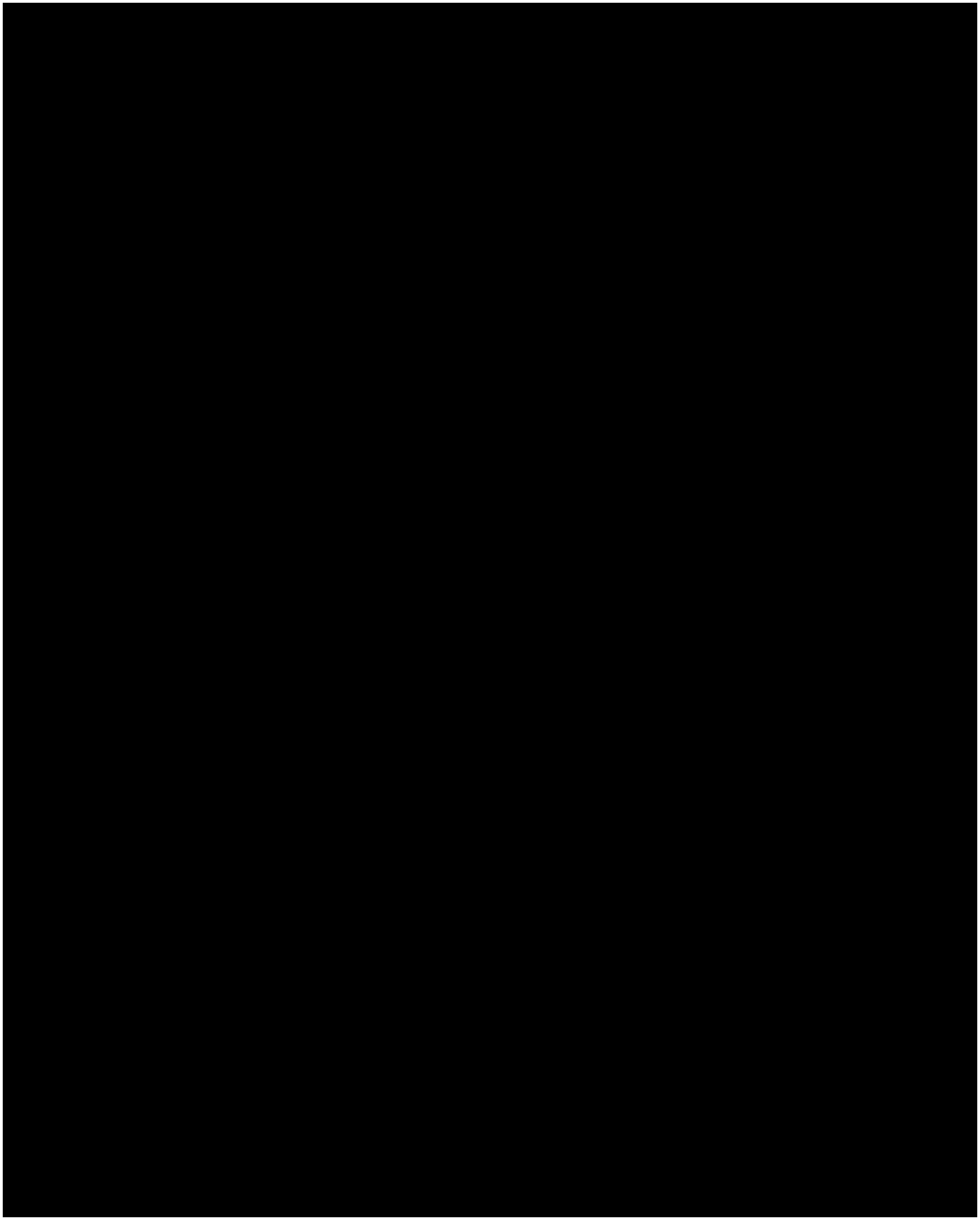
volume of applications. Any cost-savings during this period will be recognised against this full FSA GMO authorisations tender, off-setting any additional costs, and providing further value for money for the FSA.

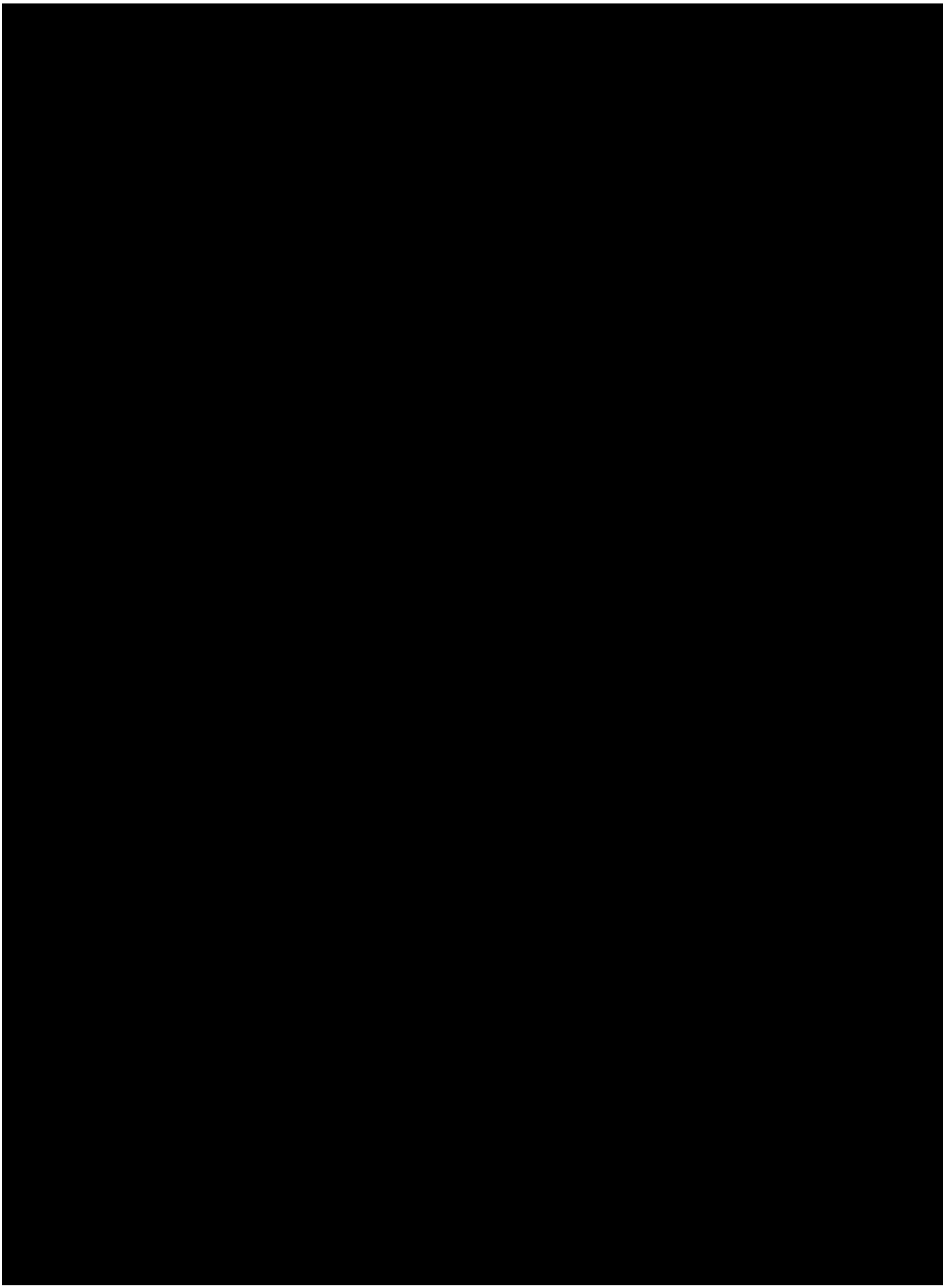
Clarifications

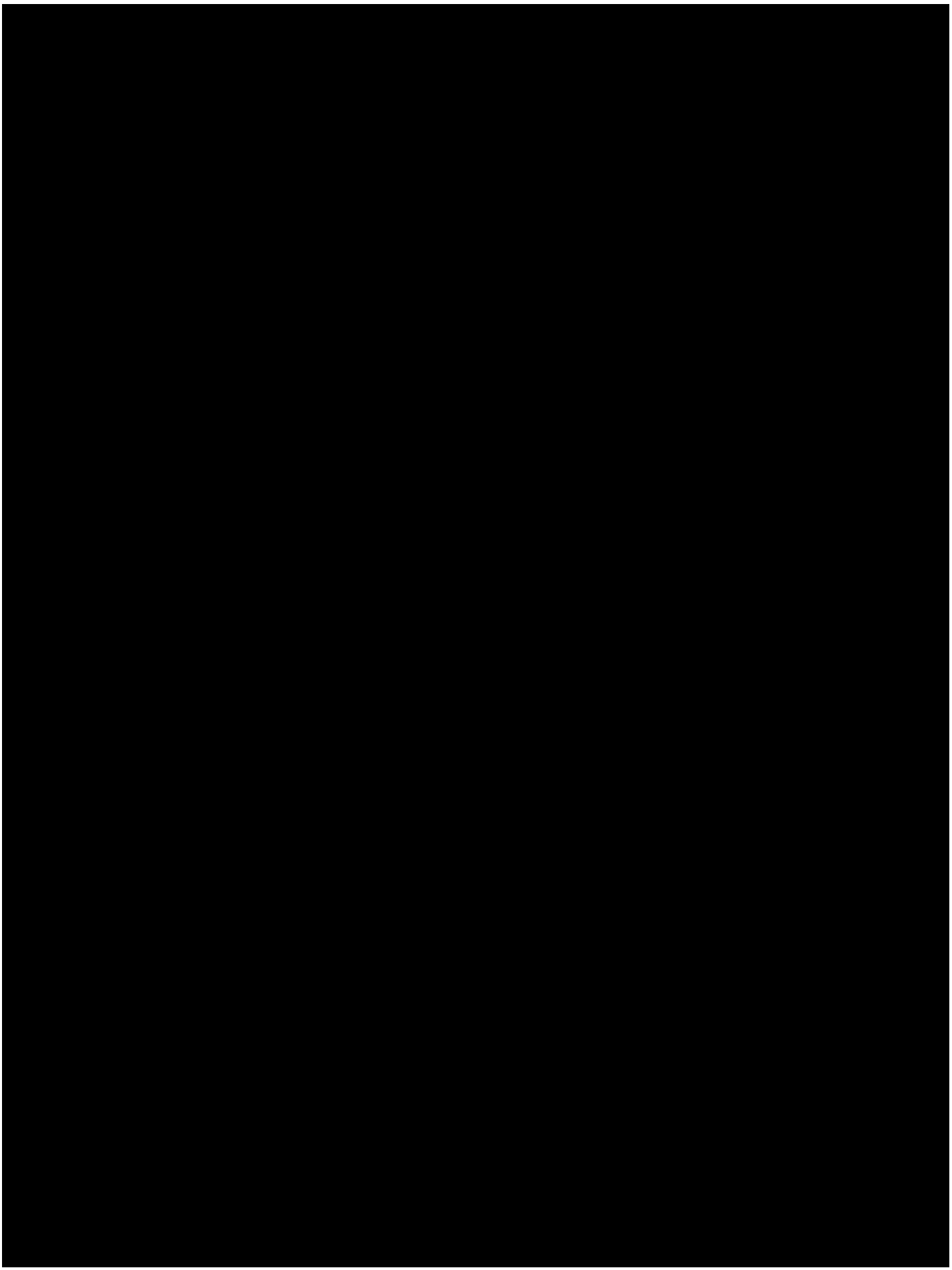
Clarifications

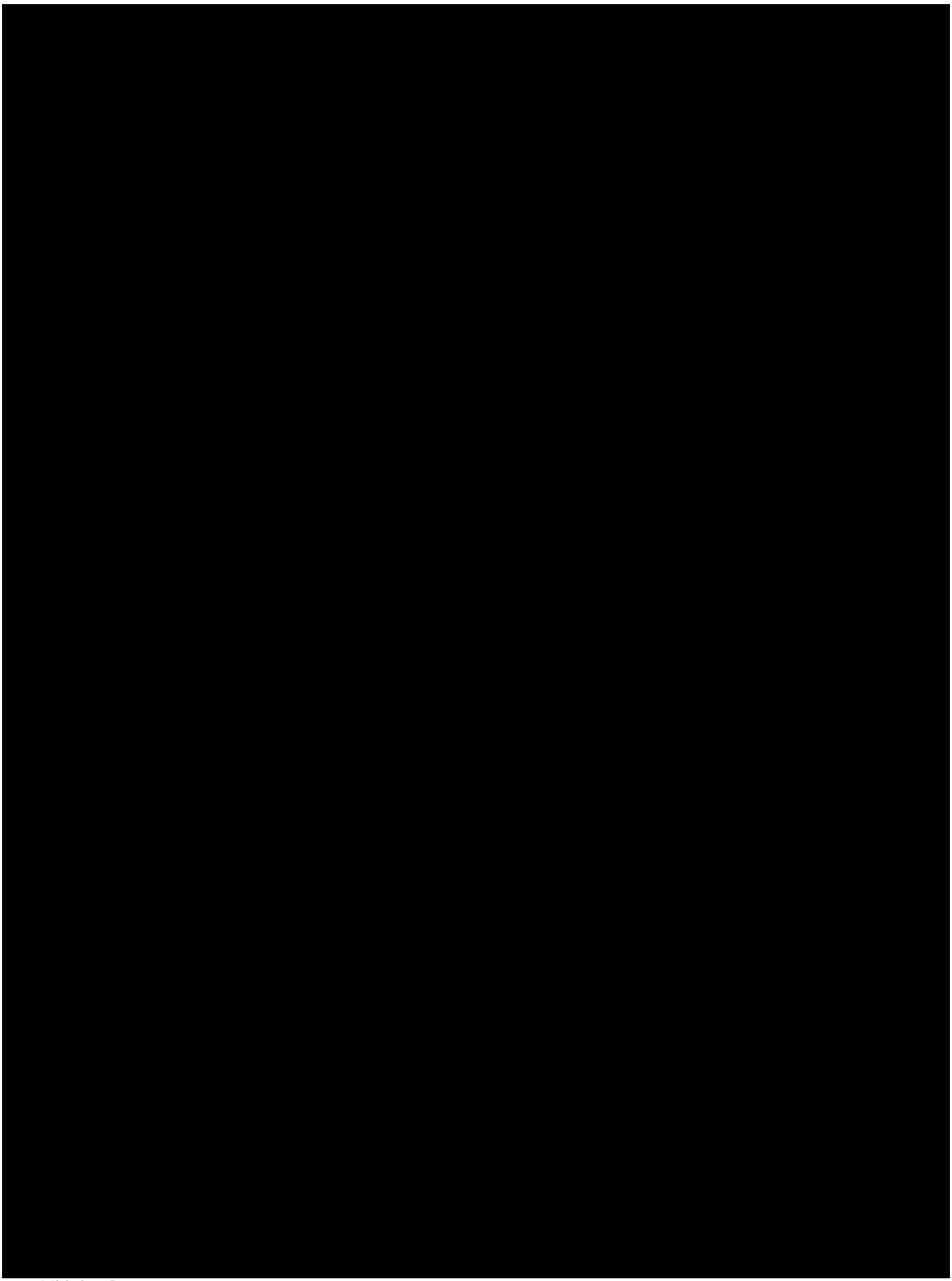












Schedule 5 (Commercially Sensitive Information)

1. What is the Commercially Sensitive Information?

1.1 In this Schedule the Parties have sought to identify the Supplier's Confidential Information that is genuinely commercially sensitive and the disclosure of which would be the subject of an exemption under the FOIA and the EIRs.

1.2 Where possible, the Parties have sought to identify when any relevant Information will cease to fall into the category of Information to which this Schedule applies in the table below and in the Award Form (which shall be deemed incorporated into the table below).

1.3 Without prejudice to the Buyer's obligation to disclose Information in accordance with FOIA or Clause 16 (When you can share information), the Buyer will, in its sole discretion, acting reasonably, seek to apply the relevant exemption set out in the FOIA to the following Information:

No.	Date	Item(s)	Duration of Confidentiality
	[insert date]	[insert details]	[insert duration]

Schedule 13 (Contract Management)

1. Definitions

1.1 In this Schedule, the following words shall have the following meanings and they shall supplement Schedule 1 (Definitions):

"Operational Board"	the board established in accordance with paragraph 4.1 of this Schedule;
"Project Manager"	the manager appointed in accordance with paragraph 2.1 of this Schedule;

2. Project Management

2.1 The Supplier and the Buyer shall each appoint a Project Manager for the purposes of this Contract through whom the provision of the Services and the Deliverables shall be managed day-to-day.

2.2 The Parties shall ensure that appropriate resource is made available on a regular basis such that the aims, objectives and specific provisions of this Contract can be fully realised.

2.3 Without prejudice to paragraph 4 below, the Parties agree to operate the boards specified as set out in the Annex to this Schedule.

3. Role of the Supplier Project Manager

3.1 The Supplier Project Manager shall be:

3.1.1 the primary point of contact to receive communication from the Buyer and will also be the person primarily responsible for providing information to the Buyer;

3.1.2 able to delegate his position to another person at the Supplier but must inform the Buyer before proceeding with the delegation and it will be delegated person's responsibility to fulfil the Project Manager's responsibilities and obligations;

3.1.3 able to cancel any delegation and recommence the position himself; and

3.1.4 replaced only after the Buyer has received notification of the proposed change.

3.2 The Buyer may provide revised instructions to the Supplier's Project Manager in regards to the Contract and it will be the Supplier Project Manager's responsibility to ensure the information is provided to the Supplier and the actions implemented.

3.3 Receipt of communication from the Supplier Project Manager by the Buyer does not absolve the Supplier from its responsibilities, obligations or liabilities under the Contract.

4. Contract Risk Management

4.1 Both Parties shall pro-actively manage risks attributed to them under the terms of this Contract.

4.2 The Supplier shall develop, operate, maintain and amend, as agreed with the Buyer, processes for:

4.2.1 the identification and management of risks;

4.2.2 the identification and management of issues; and

4.2.3 monitoring and controlling project plans.

4.3 The Supplier allows the Buyer to inspect at any time within working hours the accounts and records which the Supplier is required to keep.

4.4 The Supplier will maintain a risk register of the risks relating to the Contract which the Buyer and the Supplier have identified.

Schedule 16 (Security)

Part B: Long Form Security Requirements

1. Definitions

1.1 In this Schedule the following words shall have the following meanings and they shall supplement Schedule 1 (Definitions):

"Breach of Security"	means the occurrence of: a) any unauthorised access to or use of the Goods and/or Deliverables, the Sites and/or any Information and Communication Technology ("ICT"), information or data (including the Confidential Information and the Government Data) used by the Buyer and/or the Supplier in connection with this Contract; and/or b) the loss and/or unauthorised disclosure of any information or data (including the Confidential Information and the Government Data), including any copies of such information or data, used by the Buyer and/or the Supplier in connection with this Contract, in either case as more particularly set out in the security requirements in the Security Policy where the Buyer has required compliance therewith in accordance with paragraph 3.4.3 d;
"ISMS"	the information security management system and process developed by the Supplier in accordance with Paragraph 3 (ISMS) as updated from time to time in accordance with this Schedule; and
"Security Tests"	tests to validate the ISMS and security of all relevant processes, systems, incident response plans, patches to vulnerabilities and mitigations to Breaches of Security.

2. Security Requirements

2.1 The Parties acknowledge that the purpose of the ISMS and Security Management Plan are to ensure a good organisational approach to security under which the specific requirements of this Contract will be met.

2.2 The Parties shall each appoint a security representative to be responsible for Security. The initial security representatives of the Parties are:

2.2.1 [redacted]

2.2.2 [redacted]

2.3 The Buyer shall clearly articulate its high level security requirements so that the Supplier can ensure that the ISMS, security related activities and any mitigations are driven by these fundamental needs.

2.4 Both Parties shall provide a reasonable level of access to any members of their staff for the purposes of designing, implementing and managing security.

2.5 The Supplier shall use as a minimum Good Industry Practice in the day to day operation of any system holding, transferring or processing Government Data and any system that could directly or indirectly have an impact on that information, and shall ensure that Government Data remains under the effective control of the Supplier at all times.

2.6 The Supplier shall ensure the up-to-date maintenance of a security policy relating to the operation of its own organisation and systems and on request shall supply this document as soon as practicable to the Buyer.

2.7 The Buyer and the Supplier acknowledge that information security risks are shared between the Parties and that a compromise of either the Supplier or the Buyer's security provisions represents an unacceptable risk to the Buyer requiring immediate communication and co-operation between the Parties.

3. Information Security Management System (ISMS)

3.1 The Supplier shall develop and submit to the Buyer, within twenty (20) Working Days after the Start Date, an information security management system for the purposes of this Contract and shall comply with the requirements of Paragraphs 3.4 to 3.6.

3.2 The Supplier acknowledges that the Buyer places great emphasis on the reliability of the performance of the Deliverables, confidentiality, integrity and availability of information and consequently on the security provided by the ISMS and that the Supplier shall be responsible for the effective performance of the ISMS.

3.3 The Buyer acknowledges that;

3.3.1 If the Buyer has not stipulated that it requires a bespoke ISMS, the ISMS provided by the Supplier may be an extant ISMS covering the Services and their implementation across the Supplier's estate; and

3.3.2 Where the Buyer has stipulated that it requires a bespoke ISMS then the Supplier shall be required to present the ISMS for the Buyer's Approval.

3.4 The ISMS shall:

3.4.1 if the Buyer has stipulated that it requires a bespoke ISMS, be developed to protect all aspects of the Deliverables and all processes associated with the provision of the Deliverables, including the Buyer Premises, the Sites, the Supplier System, the Buyer System (to the extent that it is under the control of the Supplier) and any ICT, information and data (including the Buyer's Confidential Information and the Government Data) to the extent used by the Buyer or the Supplier in connection with this Contract;

3.4.2 meet the relevant standards in ISO/IEC 27001 and ISO/IEC27002 in accordance with Paragraph **Error! Reference source not found.**;

3.4.3 at all times provide a level of security which:

(a) is in accordance with the Law and this Contract;

(b) complies with the Baseline Security Requirements;

(c) as a minimum demonstrates Good Industry Practice;

(d) where specified by a Buyer, complies with the Security Policy and the ICT Policy;

(e) complies with at least the minimum set of security measures and standards as determined by the Security Policy Framework (Tiers 1-4) (https://www.gov.uk/government/publications/security-policy-framework/hmg-security-policy-framework)

(f) takes account of guidance issued by the Centre for Protection of National Infrastructure (https://www.cpni.gov.uk)

(g) complies with HMG Information Assurance Maturity Model and Assurance Framework (https://www.ncsc.gov.uk/articles/hmg-ia-maturity-model-iamm)

(h) meets any specific security threats of immediate relevance to the ISMS, the Deliverables and/or Government Data;

(i) addresses issues of incompatibility with the Supplier's own organisational security policies; and

(j) complies with ISO/IEC27001 and ISO/IEC27002 in accordance with Paragraph **Error! Reference source not found.**;

3.4.4 document the security incident management processes and incident response plans;

3.4.5 document the vulnerability management policy including processes for identification of system vulnerabilities and assessment of the potential impact on the Deliverables of any new threat, vulnerability or exploitation technique of which the Supplier becomes aware, prioritisation of security patches, testing of security patches, application of security patches, a process for Buyer approvals of exceptions, and the reporting and audit mechanism detailing the efficacy of the patching policy; and

3.4.6 be certified by (or by a person with the direct delegated authority of) a Supplier's main board representative, being the "Chief Security Officer", "Chief Information Officer", "Chief Technical Officer" or "Chief Financial Officer" (or equivalent as agreed in writing by the Buyer in advance of issue of the relevant Security Management Plan).

3.5 Subject to Paragraph 2 the references to Standards, guidance and policies contained or set out in Paragraph 3.4 shall be deemed to be references to such items as developed and updated and to any successor to or replacement for such standards, guidance and policies, as notified to the Supplier from time to time.

3.6 In the event that the Supplier becomes aware of any inconsistency in the provisions of the standards, guidance and policies set out in Paragraph 3.4, the Supplier shall immediately notify the Buyer Representative of such inconsistency and the Buyer Representative shall, as soon as practicable, notify the Supplier as to which provision the Supplier shall comply with.

3.7 If the bespoke ISMS submitted to the Buyer pursuant to Paragraph 3.3.1 is Approved by the Buyer, it shall be adopted by the Supplier immediately and thereafter operated and maintained in accordance with this Schedule. If the ISMS is not Approved by the Buyer, the Supplier shall amend it within ten (10) Working Days of a notice of non-approval from the Buyer and re-submit it to the Buyer for Approval. The Parties shall use all reasonable endeavours to ensure that the Approval process takes as little time as possible and in any event no longer than fifteen (15) Working Days from the date of the first submission of the ISMS to the Buyer. If the Buyer does not Approve the ISMS following its resubmission, the matter shall be resolved in accordance with the Dispute Resolution Procedure. No Approval to be given by the Buyer pursuant to this Paragraph 3 may be unreasonably withheld or delayed. However any failure to approve the ISMS on the grounds that it does not comply with any of the requirements set out in Paragraphs 3.4 to 3.6 shall be deemed to be reasonable.

3.8 Approval by the Buyer of the ISMS pursuant to Paragraph 3.7 or of any change to the ISMS shall not relieve the Supplier of its obligations under this Schedule.

4. Security Management Plan

4.1 Within twenty (20) Working Days after the Start Date, the Supplier shall prepare and submit to the Buyer for Approval in accordance with Paragraph **Error! R eference source not found.** fully developed, complete and up-to-date Security Management Plan which shall comply with the requirements of Paragraph 4.2.

4.2 The Security Management Plan shall:

4.2.1 be based on the initial Security Management Plan set out in Annex 2 (Security Management Plan);

4.2.2 comply with the Baseline Security Requirements and, where specified by the Buyer in accordance with paragraph 3.4.3 d, the Security Policy;

4.2.3 identify the necessary delegated organisational roles defined for those responsible for ensuring this Schedule is complied with by the Supplier;

4.2.4 detail the process for managing any security risks from Subcontractors and third parties authorised by the Buyer with access to the Goods and/or Services, processes associated with the delivery of the Goods and/or Services, the Buyer Premises, the Sites, the Supplier System, the Buyer System (to the extent that it is under the control of the Supplier) and any ICT, Information and data (including the Buyer's Confidential Information and the Government Data) and any system that

could directly or indirectly have an impact on that information, data and/or the Deliverables;

4.2.5 unless otherwise specified by the Buyer in writing, be developed to protect all aspects of the Deliverables and all processes associated with the delivery of the Deliverables, including the Buyer Premises, the Sites, the Supplier System, the Buyer System (to the extent that it is under the control of the Supplier) and any ICT, Information and data (including the Buyer's Confidential Information and the Government Data) to the extent used by the Buyer or the Supplier in connection with this Contract or in connection with any system that could directly or indirectly have an impact on that Information, data and/or the Deliverables;

4.2.6 set out the security measures to be implemented and maintained by the Supplier in relation to all aspects of the Deliverables and all processes associated with the delivery of the Deliverables and at all times comply with and specify security measures and procedures which are sufficient to ensure that the Deliverables comply with the provisions of this Schedule (including the requirements set out in Paragraph 3.4);

4.2.7 demonstrate that the Supplier's approach to delivery of the Deliverables has minimised the Buyer and Supplier effort required to comply with this Schedule through consideration of available, appropriate and practicable pan-government accredited services (for example, 'platform as a service' offering from the G-Cloud catalogue);

4.2.8 set out the plans for transitioning all security arrangements and responsibilities from those in place at the Start Date to those incorporated in the ISMS within the timeframe agreed between the Parties;

4.2.9 set out the scope of the Buyer System that is under the control of the Supplier;

4.2.10 be structured in accordance with ISO/IEC27001 and ISO/IEC27002, cross-referencing if necessary to other Schedules which cover specific areas included within those standards; and

4.2.11 be written in plain English in language which is readily comprehensible to the staff of the Supplier and the Buyer engaged in the Deliverables and shall reference only documents which are in the possession of the Parties or whose location is otherwise specified in this Schedule.

4.3 If the Security Management Plan submitted to the Buyer pursuant to Paragraph 4.1 is Approved by the Buyer, it shall be adopted by the Supplier immediately and thereafter operated and maintained in accordance with this Schedule. If the Security Management Plan is not approved by the Buyer, the Supplier shall amend it within ten (10) Working Days of a notice of non-approval from the Buyer and re-submit it to the Buyer for Approval. The Parties shall use all reasonable endeavours to ensure that the Approval process takes as little time as possible and in any event no longer than fifteen (15) Working Days from the date of the first submission to the Buyer of the Security Management Plan. If the Buyer does not Approve the Security Management Plan following its resubmission, the

matter shall be resolved in accordance with the Dispute Resolution Procedure. No Approval to be given by the Buyer pursuant to this Paragraph may be unreasonably withheld or delayed. However any failure to approve the Security Management Plan on the grounds that it does not comply with the requirements set out in Paragraph 4.2 shall be deemed to be reasonable.

4.4 Approval by the Buyer of the Security Management Plan pursuant to Paragraph 4.3 or of any change or amendment to the Security Management Plan shall not relieve the Supplier of its obligations under this Schedule.

5. Amendment of the ISMS and Security Management Plan

5.1 The ISMS and Security Management Plan shall be fully reviewed and updated by the Supplier and at least annually to reflect:

5.1.1 emerging changes in Good Industry Practice;

5.1.2 any change or proposed change to the Supplier System, the Deliverables and/or associated processes;

5.1.3 any new perceived or changed security threats;

5.1.4 where required in accordance with paragraph 3.4.3 d, any changes to the Security Policy;

5.1.5 any new perceived or changed security threats; and

5.1.6 any reasonable change in requirement requested by the Buyer.

5.2 The Supplier shall provide the Buyer with the results of such reviews as soon as reasonably practicable after their completion and amend the ISMS and Security Management Plan at no additional cost to the Buyer. The results of the review shall include, without limitation:

5.2.1 suggested improvements to the effectiveness of the ISMS;

5.2.2 updates to the risk assessments;

5.2.3 proposed modifications to the procedures and controls that affect information security to respond to events that may impact on the ISMS; and

5.2.4 suggested improvements in measuring the effectiveness of controls.

5.3 Subject to Paragraph 5.4, any change which the Supplier proposes to make to the ISMS or Security Management Plan (as a result of a review carried out pursuant to Paragraph 5.1, a Buyer request, a change to Annex nnex **1** (Security) or otherwise) shall be subject to the Variation Procedure and shall not be implemented until Approved in writing by the Buyer.

5.4 The Buyer may, acting reasonably, Approve and require changes or amendments to the ISMS or Security Management Plan to be implemented on timescales faster than set out in the Variation Procedure but, without prejudice to their effectiveness, all such changes and amendments shall thereafter be subject to the Variation Procedure for the purposes of formalising and documenting the relevant change or amendment.

6. Security Testing

6.1 The Supplier shall conduct Security Tests from time to time (and at least annually across the scope of the ISMS) and additionally after any change or amendment to the ISMS (including security incident management processes and incident response plans) or the Security Management Plan. Security Tests shall be designed and implemented by the Supplier so as to minimise the impact on the delivery of the Deliverables and the date, timing, content and conduct of such Security Tests shall be agreed in advance with the Buyer. Subject to compliance by the Supplier with the foregoing requirements, if any Security Tests adversely affect the Supplier's ability to deliver the Deliverables so as to meet the KPIs, the Supplier shall be granted relief against any resultant under-performance for the period of the Security Tests.

6.2 The Buyer shall be entitled to send a representative to witness the conduct of the Security Tests. The Supplier shall provide the Buyer with the results of such Security Tests (in a form approved by the Buyer in advance) as soon as practicable after completion of each Security Test.

6.3 Without prejudice to any other right of audit or access granted to the Buyer pursuant to this Contract, the Buyer and/or its authorised representatives shall be entitled, at any time upon giving reasonable notice to the Supplier, to carry out such tests (including penetration tests) as it may deem necessary in relation to the ISMS and the Supplier's compliance with the ISMS and the Security Management Plan. The Buyer may notify the Supplier of the results of such tests after completion of each such test. If any such Buyer's test adversely affects the Supplier's ability to deliver the Deliverables so as to meet the KPIs, the Supplier shall be granted relief against any resultant under-performance for the period of the Buyer's test.

6.4 Where any Security Test carried out pursuant to Paragraphs 6.2 or 6.3 reveals any actual or potential Breach of Security or weaknesses (including un-patched vulnerabilities, poor configuration and/or incorrect system management), the Supplier shall promptly notify the Buyer of any changes to the ISMS and to the Security Management Plan (and the implementation thereof) which the Supplier proposes to make in order to correct such failure or weakness. Subject to the Buyer's prior written Approval, the Supplier shall implement such changes to the ISMS and the Security Management Plan and repeat the relevant Security Tests in accordance with the timetable agreed with the Buyer or, otherwise, as soon as reasonably possible. For the avoidance of doubt, where the change to the ISMS or Security Management Plan is to address a non-compliance with the Security Policy or security requirements (as set out in Annex 1 (Baseline Security Requirements) to this Schedule) or the requirements of this Schedule, the change to the ISMS or Security Management Plan shall be at no cost to the Buyer.

6.5 If any repeat Security Test carried out pursuant to Paragraph 6.4 reveals an actual or potential Breach of Security exploiting the same root cause failure, such circumstance shall constitute a material Default of this Contract.

7. Complying with the ISMS

7.1 The Buyer shall be entitled to carry out such security audits as it may reasonably deem necessary in order to ensure that the ISMS maintains compliance with the principles and practices of ISO 27001 and/or the Security Policy where such compliance is required in accordance with paragraph 3.4.3 d.

7.2 If, on the basis of evidence provided by such security audits, it is the Buyer's reasonable opinion that compliance with the principles and practices of ISO/IEC 27001 and/or, where relevant, the Security Policy are not being achieved by the Supplier, then the Buyer shall notify the Supplier of the same and give the Supplier a reasonable time (having regard to the extent and criticality of any non-compliance and any other relevant circumstances) to implement and remedy. If the Supplier does not become compliant within the required time then the Buyer shall have the right to obtain an independent audit against these standards in whole or in part.

7.3 If, as a result of any such independent audit as described in Paragraph the Supplier is found to be non-compliant with the principles and practices of ISO/IEC 27001 and/or, where relevant, the Security Policy then the Supplier shall, at its own expense, undertake those actions required in order to achieve the necessary compliance and shall reimburse in full the costs incurred by the Buyer in obtaining such audit.

8. Security Breach

8.1 Either Party shall notify the other in accordance with the agreed security incident management process as defined by the ISMS upon becoming aware of any breach of security or any potential or attempted Breach of Security.

8.2 Without prejudice to the security incident management process, upon becoming aware of any of the circumstances referred to in Paragraph 8.1, the Supplier shall:

8.2.1 immediately take all reasonable steps (which shall include any action or changes reasonably required by the Buyer) necessary to:

(a) minimise the extent of actual or potential harm caused by any Breach of Security;

(b) remedy such Breach of Security or any potential or attempted Breach of Security in order to protect the integrity of the Buyer Property and/or Buyer Assets and/or ISMS to the extent that this is within the Supplier's control;

(c) apply a tested mitigation against any such Breach of Security or attempted Breach of Security and provided that reasonable testing has been undertaken by the Supplier, if the mitigation adversely affects the Supplier's ability to provide the Deliverables so as to meet the relevant Service Levels the Supplier shall be granted relief against any resultant under-performance for such period as the Buyer, acting reasonably, may specify by written notice to the Supplier;

(d) prevent a further Breach of Security or any potential or attempted Breach of Security in the future exploiting the same root cause failure; and

(e) supply any requested data to the Buyer (or the Computer Emergency Response Team for UK Government ("GovCertUK")) on the Buyer's request within two (2) Working Days and without charge (where such requests are reasonably related to a possible incident or compromise); and

(f) as soon as reasonably practicable provide to the Buyer full details (using the reporting mechanism defined by the ISMS) of the Breach of Security or attempted Breach of Security, including a root cause analysis where required by the Buyer.

8.3 In the event that any action is taken in response to a Breach of Security or potential or attempted Breach of Security that demonstrates non-compliance of the ISMS with the Security Policy (where relevant) or the requirements of this Schedule, then any required change to the ISMS shall be at no cost to the Buyer.

9. Vulnerabilities and fixing them

9.1 The Buyer and the Supplier acknowledge that from time to time vulnerabilities in the ICT Environment will be discovered which unless mitigated will present an unacceptable risk to the Buyer's information.

9.2 The severity of threat vulnerabilities for COTS Software shall be categorised by the Supplier as 'Critical', 'Important' and 'Other' by aligning these categories to the vulnerability scoring according to the agreed method in the ISMS and using the appropriate vulnerability scoring systems including:

9.2.1 the 'National Vulnerability Database' 'Vulnerability Severity Ratings': 'High', 'Medium' and 'Low' respectively (these in turn are aligned to CVSS scores as set out by NIST http://nvd.nist.gov/cvss.cfm); and

9.2.2 Microsoft's 'Security Bulletin Severity Rating System' ratings 'Critical', 'Important', and the two remaining levels ('Moderate' and 'Low') respectively.

9.3 The Supplier shall procure the application of security patches to vulnerabilities within a maximum period from the public release of such patches with those vulnerabilities categorised as 'Critical' within 14 days of release, 'Important' within 30 days of release and all 'Other' within 60 Working Days of release, except where:

9.3.1 the Supplier can demonstrate that a vulnerability is not exploitable within the context of any Service (e.g. because it resides in a software component which is not running in the service) provided vulnerabilities which the Supplier asserts cannot be exploited within the context of a Service must be remedied by the Supplier within the above timescales if the vulnerability becomes exploitable within the context of the Service;

9.3.2 the application of a ‘Critical’ or ‘Important’ security patch adversely affects the Supplier’s ability to deliver the Services in which case the Supplier shall be granted an extension to such timescales of 5 days, provided the Supplier had followed and continues to follow the security patch test plan agreed with the Buyer; or

9.3.3 the Buyer agrees a different maximum period after a case-by-case consultation with the Supplier under the processes defined in the ISMS.

9.4 The Specification and Implementation Plan (if applicable) shall include provisions for major version upgrades of all COTS Software to be upgraded within 6 Months of the release of the latest version, such that it is no more than one major version level below the latest release (normally codified as running software no older than the ‘n-1 version’) throughout the Term unless:

9.4.1 where upgrading such COTS Software reduces the level of mitigations for known threats, vulnerabilities or exploitation techniques, provided always that such upgrade is made within 12 Months of release of the latest version; or

9.4.2 is agreed with the Buyer in writing.

9.5 The Supplier shall:

9.5.1 implement a mechanism for receiving, analysing and acting upon threat information supplied by GovCertUK, or any other competent Central Government Body;

9.5.2 ensure that the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier) is monitored to facilitate the detection of anomalous behaviour that would be indicative of system compromise;

9.5.3 ensure it is knowledgeable about the latest trends in threat, vulnerability and exploitation that are relevant to the ICT Environment by actively monitoring the threat landscape during the Contract Period;

9.5.4 pro-actively scan the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier) for vulnerable components and address discovered vulnerabilities through the processes described in the ISMS as developed under Paragraph 3.4.5;

9.5.5 from the date specified in the Security Management Plan provide a report to the Buyer within five (5) Working Days of the end of each Month detailing both patched and outstanding vulnerabilities in the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier) and any elapsed time between the public release date of patches and either time of application or for outstanding vulnerabilities the time of issue of such report;

9.5.6 propose interim mitigation measures to vulnerabilities in the ICT Environment known to be exploitable where a security patch is not immediately available;

9.5.7 remove or disable any extraneous interfaces, services or capabilities that are not needed for the provision of the Services (in order to reduce the attack surface of the ICT Environment); and

9.5.8 inform the Buyer when it becomes aware of any new threat, vulnerability or exploitation technique that has the potential to affect the security of the ICT Environment and provide initial indications of possible mitigations.

9.6 If the Supplier is unlikely to be able to mitigate the vulnerability within the timescales under this Paragraph 9, the Supplier shall immediately notify the Buyer.

9.7 A failure to comply with Paragraph 9.3 shall constitute a Default, and the Supplier shall comply with the Rectification Plan Process.

Part B – Annex 1:

Baseline security requirements

10. Handling Classified information

10.1 The Supplier shall not handle Buyer information classified SECRET or TOP SECRET except if there is a specific requirement and in this case prior to receipt of such information the Supplier shall seek additional specific guidance from the Buyer.

11. End user devices

11.1 When Government Data resides on a mobile, removable or physically uncontrolled device it must be stored encrypted using a product or system component which has been formally assured through a recognised certification process of the National Cyber Security Centre ("NCSC") to at least Foundation Grade, for example, under the NCSC Commercial Product Assurance scheme ("CPA").

11.2 Devices used to access or manage Government Data and services must be under the management authority of Buyer or Supplier and have a minimum set of security policy configuration enforced. These devices must be placed into a 'known good' state prior to being provisioned into the management authority of the Buyer. Unless otherwise agreed with the Buyer in writing, all Supplier devices are expected to meet the set of security requirements set out in the End User Devices Security Guidance (https://www.ncsc.gov.uk/guidance/end-user-device-security). Where the guidance highlights shortcomings in a particular platform the Supplier may wish to use, then these should be discussed with the Buyer and a joint decision shall be taken on whether the residual risks are acceptable. Where the Supplier wishes to deviate from the NCSC guidance, then this should be agreed in writing on a case by case basis with the Buyer.

12. Data Processing, Storage, Management and Destruction

12.1 The Supplier and Buyer recognise the need for the Buyer's information to be safeguarded under the UK Data Protection regime or a similar regime. To that end, the Supplier must be able to state to the Buyer the physical locations in which data may be stored, processed and managed from, and what legal and regulatory frameworks Government Data will be subject to at all times.

12.2 The Supplier shall agree any change in location of data storage, processing and administration with the Buyer in accordance with Clause 14 (Data protection).

12.3 The Supplier shall:

12.3.1 provide the Buyer with all Government Data on demand in an agreed open format;

12.3.2 have documented processes to guarantee availability of Government Data in the event of the Supplier ceasing to trade;

12.3.3 securely destroy all media that has held Government Data at the end of life of that media in line with Good Industry Practice; and

12.3.4 securely erase any or all Government Data held by the Supplier when requested to do so by the Buyer.

13. Ensuring secure communications

13.1 The Buyer requires that any Government Data transmitted over any public network (including the Internet, mobile networks or un-protected enterprise network) or to a mobile device must be encrypted using a product or system component which has been formally assured through a certification process recognised by NCSC, to at least Foundation Grade, for example, under CPA.

13.2 The Buyer requires that the configuration and use of all networking equipment to provide the Services, including those that are located in secure physical locations, are at least compliant with Good Industry Practice.

14. Security by design

14.1 The Supplier shall apply the 'principle of least privilege' (the practice of limiting systems, processes and user access to the minimum possible level) to the design and configuration of IT systems which will process or store Government Data.

14.2 When designing and configuring the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier) the Supplier shall follow Good Industry Practice and seek guidance from recognised security professionals with the appropriate skills and/or a NCSC certification (https://www.ncsc.gov.uk/section/products-services/ncsc-certification) for all bespoke or complex components of the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier).

15. Security of Supplier Staff

15.1 Supplier Staff shall be subject to pre-employment checks that include, as a minimum: identity and right to work.

15.2 The Supplier shall agree on a case by case basis Supplier Staff roles which require specific government clearances (such as 'SC') including system administrators with privileged access to IT systems which store or process Government Data.

15.3 The Supplier shall prevent Supplier Staff who are unable to obtain the required security clearances from accessing systems which store, process, or are used to manage Government Data except where agreed with the Buyer in writing.

15.4 All Supplier Staff that have the ability to access Government Data or systems holding Government Data shall undergo regular training on secure information management principles. Unless otherwise agreed with the Buyer in writing, this training must be undertaken annually.

15.5 Where the Supplier or Subcontractors grants increased ICT privileges or access rights to Supplier Staff, those Supplier Staff shall be granted only those permissions necessary for them to carry out their duties. When staff no longer need elevated privileges or leave the organisation, their access rights shall be revoked within one (1) Working Day.

16. Restricting and monitoring access

16.1 The Supplier shall operate an access control regime to ensure all users and administrators of the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier) are uniquely identified and authenticated when accessing or administering the Services. Applying the 'principle of least privilege', users and administrators shall be allowed access only to those parts of the ICT Environment that they require. The Supplier shall retain an audit record of accesses.

17. Audit

17.1 The Supplier shall collect audit records which relate to security events in the systems or that would support the analysis of potential and actual compromises. In order to facilitate effective monitoring and forensic readiness such Supplier audit records should (as a minimum) include:

17.1.1 Logs to facilitate the identification of the specific asset which makes every outbound request external to the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier). To the extent the design of the Deliverables allows such logs shall include those from DHCP servers, HTTP/HTTPS proxy servers, firewalls and routers.

17.1.2 Security events generated in the ICT Environment (to the extent that the ICT Environment is within the control of the Supplier) and shall include: privileged account log-on and log-off events, the start and termination of remote access sessions, security alerts from desktops and server operating systems and security alerts from third party security software.

17.2 The Supplier and the Buyer shall work together to establish any additional audit and monitoring requirements for the ICT Environment.

17.3 The Supplier shall retain audit records collected in compliance with this Paragraph 17 for a period of at least 6 Months.

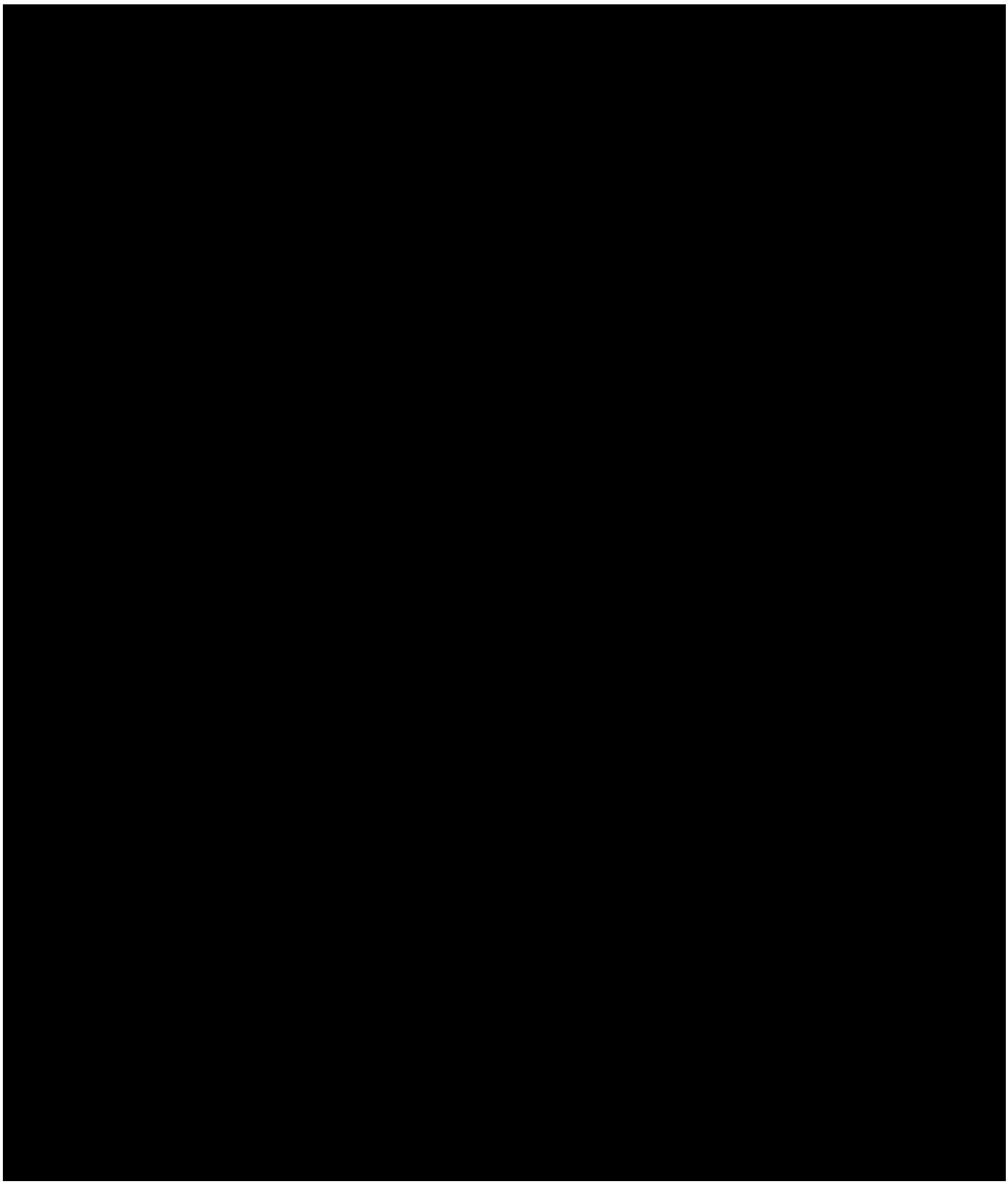
Part B – Annex 2 - Security Management Plan

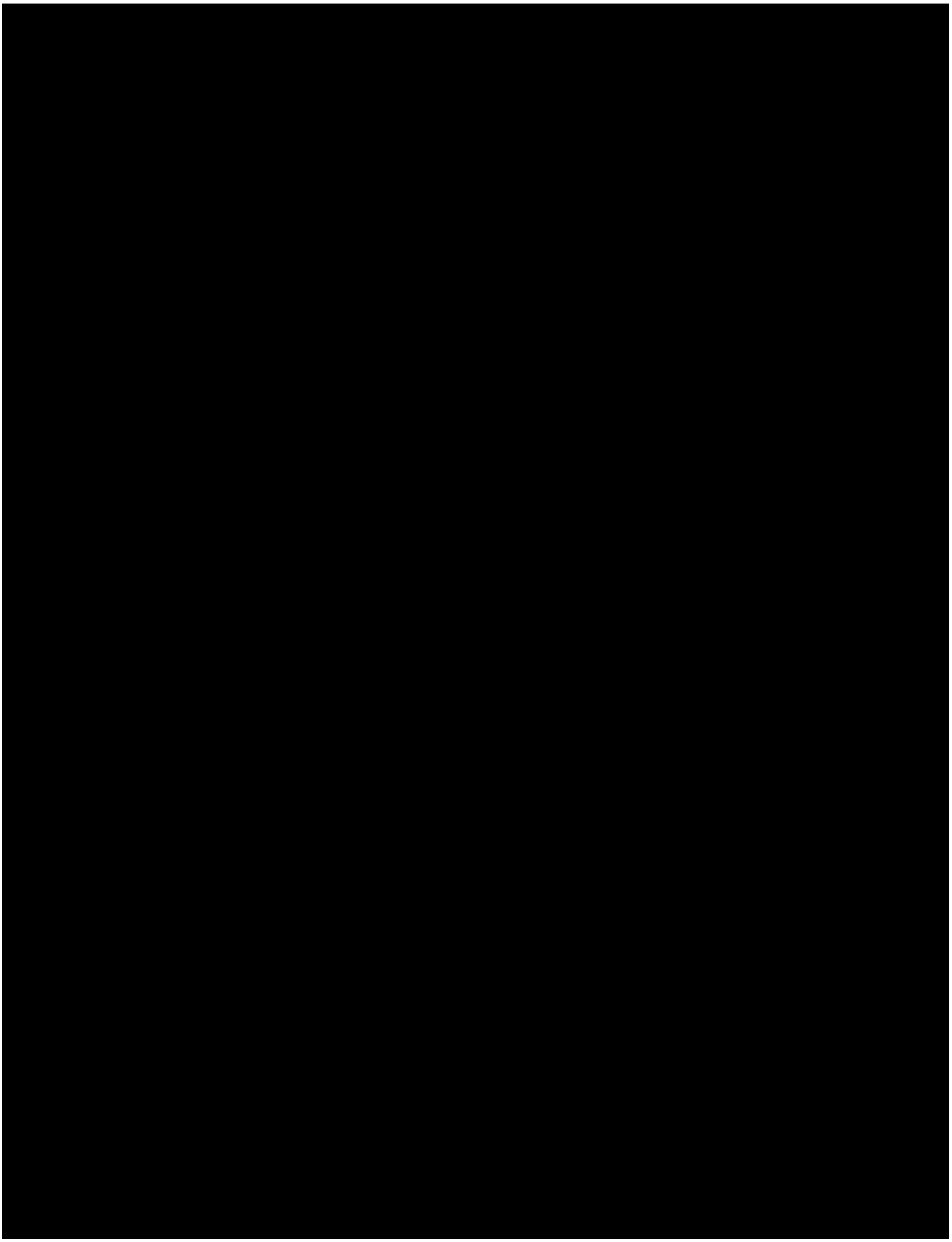
The initial Security management plan outlined by LGC in their "IT and Cyber Arrangements" document and its corresponding email below covering backups, data transfer and portal access provide reasonable assurances to the operation of LGC's security in accordance with the information provided in the tender. This included operating security in accordance with principles and practices of ISO27001 as required under section 4 of the contract. LGC's Security Plan (s0002) as referred to therein, associated policies and procedures should be updated in accordance with the principles of the standard and in accordance with provisions of this contract.

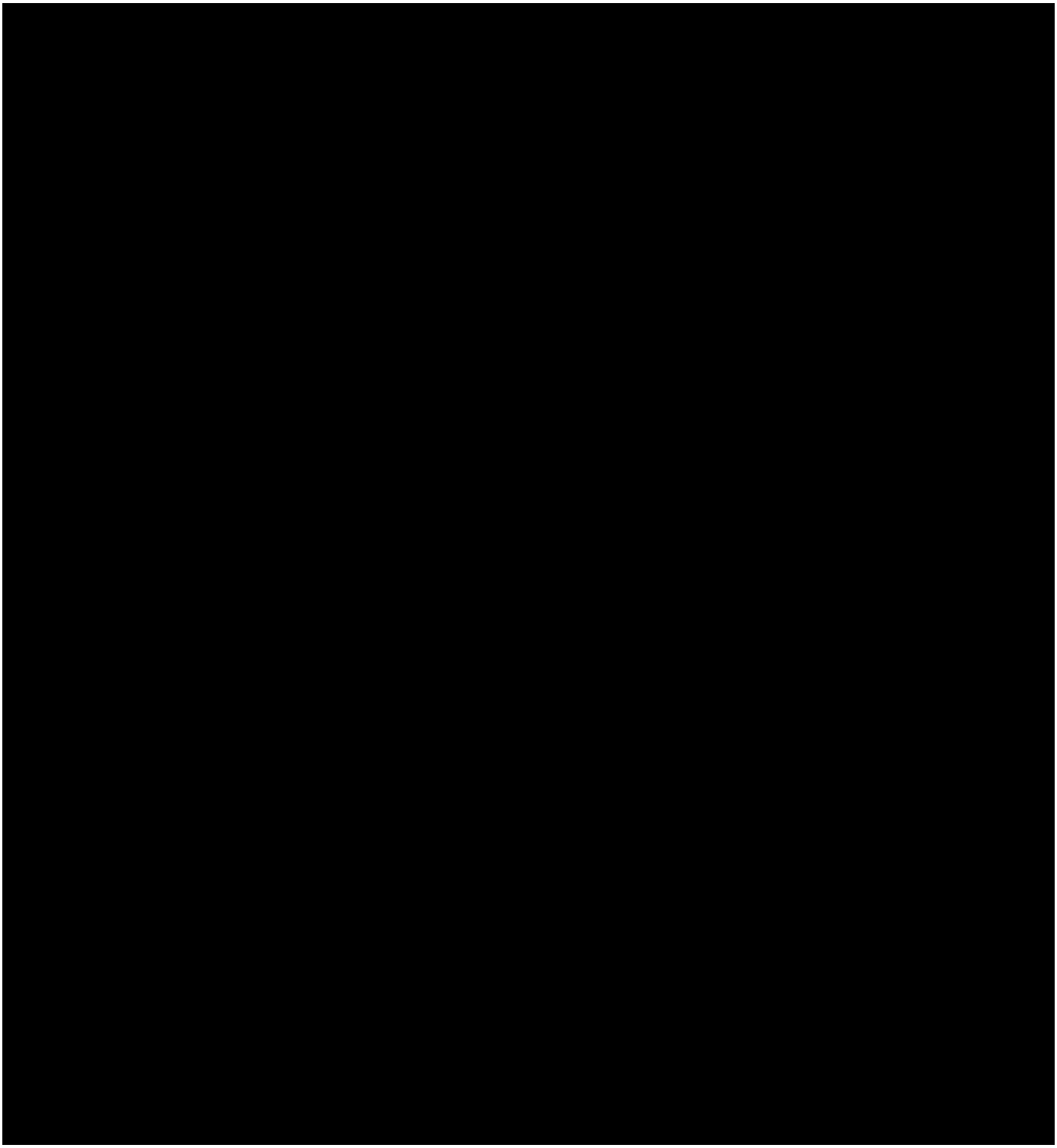
LGC IT Cyber Arrangements and answers (below in red) to specific IT-related questions.

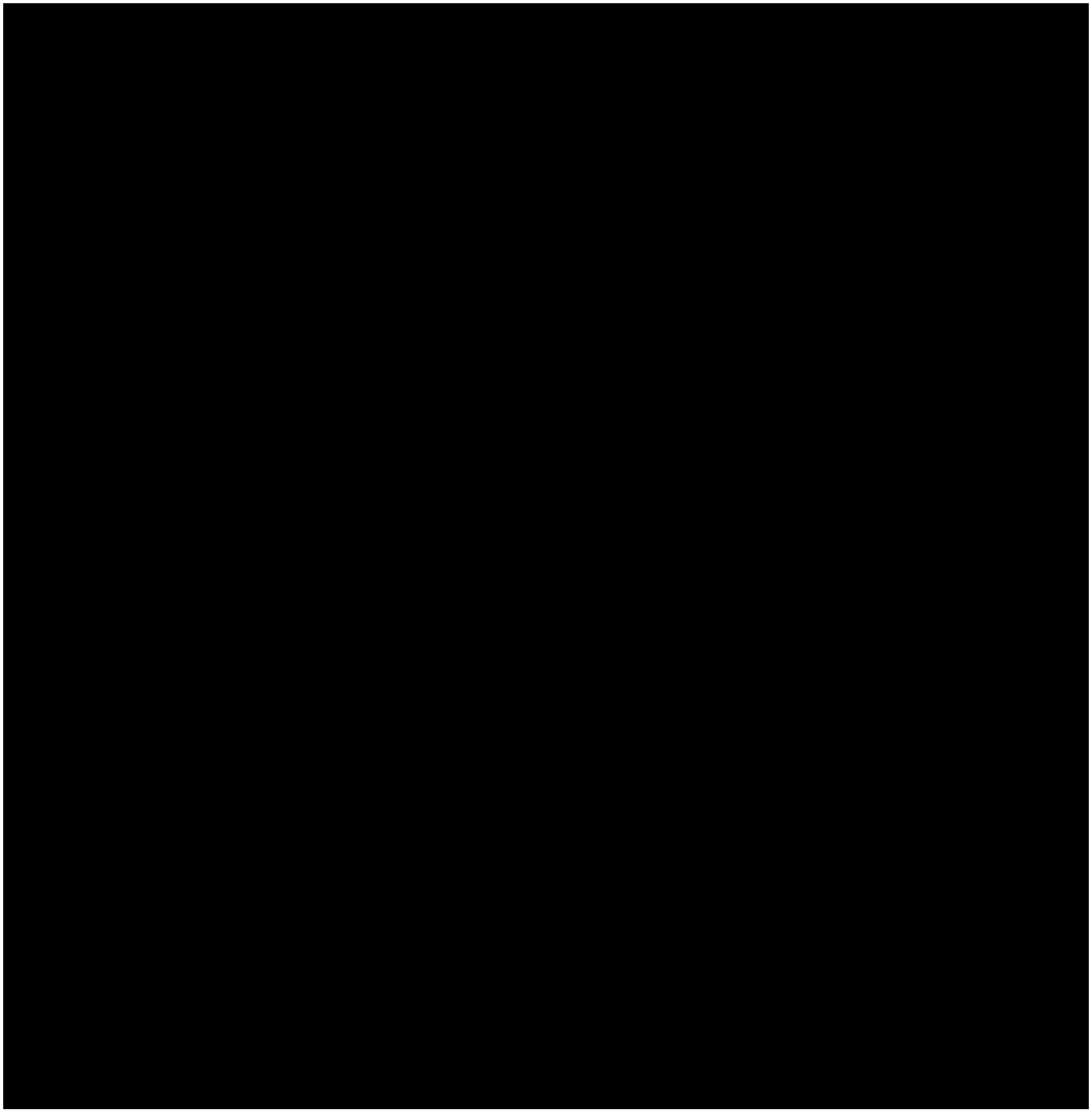
In addition to the information in the IT Cyber Arrangement document, it is anticipated that the data collected on stand-alone PCs will be backed up to SharePoint Online at the conclusion of each experimental run and in accordance with the Removable Media policy detailed in the IT Cyber Arrangement document.

LGC's IT and Cyber Arrangements









Schedule 20 (Processing Data)

Status of the Controller

1. 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 a Contract dictates the status of each party under the DPA. 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 a Contract and shall specify in Annex 1 *(Processing Personal Data)* which scenario they think shall apply in each situation.

Where one Party is Controller and the other Party its Processor

2. Where a Party is a Processor, the only Processing that it is authorised to do is listed in Annex 1 *(Processing Personal Data*) by the Controller.

3. The Processor shall notify the Controller immediately if it considers that any of the Controller's instructions infringe the Data Protection Legislation.

4. The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Controller, include:

(a) a systematic description of the envisaged Processing and the purpose of the Processing;

(b) an assessment of the necessity and proportionality of the Processing in relation to the Services;

(c) an assessment of the risks to the rights and freedoms of Data Subjects; and

(d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

5. The Processor shall, in relation to any Personal Data Processed in connection with its obligations under the Contract:

(a) Process that Personal Data only in accordance with Annex 1 *(Processing Personal Data*), unless the Processor is required to do otherwise by Law. If it is

so required the Processor shall notify the Controller before Processing the Personal Data unless prohibited by Law;

(b) ensure that it has in place Protective Measures, including in the case of the Supplier the measures set out in Clause 14.3 of the Core Terms, which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:

(i) nature of the data to be protected;

(ii) harm that might result from a Personal Data Breach;

(iii) state of technological development; and

(iv) cost of implementing any measures;

(c) ensure that :

(i) the Processor Personnel do not Process Personal Data except in accordance with the Contract (and in particular Annex 1 *(Processing Personal Data*));

(ii) it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:

(A) are aware of and comply with the Processor's duties under this Schedule 20, Clauses 14 (*Data protection*), 15 (*What you must keep confidential*) and 16 (*When you can share information*);

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

(C) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Controller or as otherwise permitted by the Contract; and

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

(d) not transfer Personal Data outside of the EU or the United Kingdom unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:

(i) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with UK GDPR Article 46 or LED Article 37) as determined by the Controller;

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

(iii) the Processor complies with its obligations under the Data Protection Legislation 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; and

(e) at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the Contract unless the Processor is required by Law to retain the Personal Data.

6. Subject to paragraph 7 of this Schedule 20, the Processor shall notify the Controller immediately if in relation to it Processing Personal Data under or in connection with the Contract it:

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

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

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

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

(e) receives a request from any third Party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or

(f) becomes aware of a Personal Data Breach.

7. The Processor's obligation to notify under paragraph 6 of this Schedule 20 shall include the provision of further information to the Controller, as details become available.

8. Taking into account the nature of the Processing, the Processor shall provide the Controller with assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under paragraph 6 of this Schedule 20 (and insofar as possible within the timescales reasonably required by the Controller) including by immediately providing:

(a) the Controller with full details and copies of the complaint, communication or request;

(b) such assistance as is reasonably requested by the Controller to enable it to comply with a Data Subject Access Request within the relevant timescales set out in the Data Protection Legislation;

(c) the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;

(d) assistance as requested by the Controller following any Personal Data Breach; and/or

(e) assistance as requested by the Controller with respect to any request from the Information Commissioner's Office, or any consultation by the Controller with the Information Commissioner's Office.

9. The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this Schedule 20. This requirement does not apply where the Processor employs fewer than 250 staff, unless:

(a) the Controller determines that the Processing is not occasional;

(b) the Controller determines the Processing 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

(c) the Controller determines that the Processing is likely to result in a risk to the rights and freedoms of Data Subjects.

10. The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller's designated auditor.

11. The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.

12. Before allowing any Subprocessor to Process any Personal Data related to the Contract, the Processor must:

(a) notify the Controller in writing of the intended Subprocessor and Processing;

(b) obtain the written consent of the Controller;

(c) enter into a written agreement with the Subprocessor which give effect to the terms set out in this Schedule 20 such that they apply to the Subprocessor; and

(d) provide the Controller with such information regarding the Subprocessor as the Controller may reasonably require.

13. The Processor shall remain fully liable for all acts or omissions of any of its Subprocessors.

14. The Buyer may, at any time on not less than 30 Working Days' notice, revise this Schedule 20 by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to the Contract).

15. The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Buyer may on not less than 30 Working Days' notice to the Supplier amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner's Office.

Where the Parties are Joint Controllers of Personal Data

16. 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 Annex 2 to this Schedule 20 (*Processing Data*).

Independent Controllers of Personal Data

17. With respect to Personal Data provided by one Party to another Party for which each Party acts as Controller but which is not under the Joint Control of the Parties, each Party undertakes to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Controller.

18. Each Party shall Process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.

19. Where a Party has provided Personal Data to the other Party in accordance with paragraph 7 of this Schedule 20 above, the recipient of the Personal Data will provide all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.

20. The Parties shall be responsible for their own compliance with Articles 13 and 14 of the UK GDPR in respect of the Processing of Personal Data for the purposes of the Contract.

21. The Parties shall only provide Personal Data to each other:

(a) to the extent necessary to perform their respective obligations under the Contract;

(b) in compliance with the Data Protection Legislation (including by ensuring all required data privacy information has been given to affected Data Subjects to meet the requirements of Articles 13 and 14 of the UK GDPR); and

(c) where it has recorded it in Annex 1 *(Processing Personal Data).*

22. Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its Processing of Personal Data as Independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the UK GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the UK GDPR.

23. A Party Processing Personal Data for the purposes of the Contract shall maintain a record of its Processing activities in accordance with Article 30 UK GDPR and shall make the record available to the other Party upon reasonable request.

24. Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to the Contract **("Request Recipient")**:

(a) the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or

(b) where the request or correspondence is directed to the other Party and/or relates to that other Party's Processing of the Personal Data, the Request Recipient will:

(i) promptly, and in any event within five (5) Working Days of receipt of the request or correspondence, inform the other Party that it has received the same and shall forward such request or correspondence to the other Party; and

(ii) provide any information and/or assistance as reasonably requested by the other Party to help it respond to the request or correspondence in the timeframes specified by Data Protection Legislation.

25. Each Party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other Party pursuant to the Contract and shall:

(a) do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Personal Data Breach;

(b) implement any measures necessary to restore the security of any compromised Personal Data;

(c) work with the other Party to make any required notifications to the Information Commissioner's Office and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and

(d) not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.

26. Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under the Contract as specified in Annex 1 *(Processing Personal Data).*

27. Personal Data shall not be retained or processed for longer than is necessary to perform each Party's respective obligations under the Contract which is specified in Annex 1 *(Processing Personal Data)*.

28. Notwithstanding the general application of paragraphs 2 to 15 of this Schedule 20 to Personal Data, where the Supplier is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with paragraphs16 to 27 of this Schedule 20.

Annex 1 - Processing Personal Data

This Annex shall be completed by the Controller, who may take account of the view of the Processors, however the final decision as to the content of this Annex shall be with the Buyer at its absolute discretion.

1.1 The contact details of the Buyer's Data Protection Officer are: InformationManagement@food.gov.uk

1.2 The contact details of the Supplier's Data Protection Officer are:

Name: Clear Comm

Address: ClearComm, Devonshire House, 60 Goswell Road, London, EC1M 7AD

Email address: [redacted]

Telephone number: [redacted]

1.3 The Processor shall comply with any further written instructions with respect to Processing by the Controller.

1.4 Any such further instructions shall be incorporated into this Annex.

Description	Details

Identity of Controller for each Category of Personal Data	The Parties acknowledge that in accordance with paragraph 2 to paragraph 15 and for the purposes of the Data Protection Legislation, the Buyer is the Controller and the Supplier is the Processor of the following Personal Data:
	• Contact details received by LGC as required for analytical work requested by FSA for GMO testing and animal feed additives method assessments specifically:
	  ○ GMO applicant's contact details (individuals name, business address and business contact details e.g. phone number, email)
	  ○ Animal Feed Additives applicant's contact details (individuals name, business address business contact details e.g. phone number, email)
	• Personal data processed by LGC in connection with services provided to FSA to support regulatory testing and the work of the FSA, specifically:
	  ○ Business contact details (individuals name, business address business contact details e.g. phone number, email for FSA employees and stakeholders.

Duration of the Processing	As specified contractually, data must be retained for the duration of the contract (01 Apr 2021 to 31 Mar 2026 – with possible break clause after 3 years at 31 Mar 2024). All personal data should be kept until all contracted work has been completed and disposed of at the request of the FSA. Electronic data is retained indefinitely on LGC's secure email server unless otherwise stated.
Nature and purposes of the Processing	This is a requirement by the UK Food Standards Agency on regulated GMO and Feed Additive products. The benefit will be that the UK will be able to undertake its own scientific assessment of applications to support the risk assessment. Business cases have been approved. https://www.food.gov.uk/business-guidance/regulated-products/genetically-modified-organisms-guidance https://www.food.gov.uk/business-guidance/regulated-products/feed-additives-guidance • FSA will receive applications from external parties via the Regulated Products Portal • FSA will send applicant's contact details and method information to LGC via a joint, secure portal base system • LGC will use the applicant's contact details to contact the applicant directly via email • Personal data will be held for the duration of the contract (5 years with a breakpoint point after 3 years) and until all contracted work is completed and disposed of at the request of the FSA. Storage, retrieval and destruction of data made available to LGC by FSA or the applicant in connection with regulatory and testing activities.

	Personal details in relation to methods required for the analysis in the laboratory/application review are shared electronically by the FSA using a joint, secure portal base system. Emails and associated attachments may be kept and retained on LGC's secure server unless otherwise stated.
Type of Personal Data	• GMO applicant's business contact details (name, address, phone number, email) • Animal Feed Additives applicant's business contact details (name, address, phone number, email) • FSA employees and stakeholders business contact details (name, address, phone number, email)
Categories of Data Subject	FSA clients that have applied to get their products approved, the applicants are usually Food Business owners
Plan for return and destruction of the data once the Processing is complete UNLESS requirement under Union or Member State law to preserve that type of data	On completion of processing the data under this contract (and any associated IPR as governed by clause 9) should be securely transferred to the FSA in a suitable format, and as required by the FSA. The FSA expect LGC only to continue to hold data in accordance with its instructions and delete data where it is no longer required. All personal data will be retained for the duration of the contract and until all contracted work is completed, or until a request is received on behalf of the FSA for destruction. Emails and associated attachments may be kept and retained indefinitely on LGC's secure server unless otherwise stated.

Annex 2 - Joint Controller Agreement

1. Joint Controller Status and Allocation of Responsibilities

1.1 With respect to Personal Data under Joint Control of the Parties, the Parties envisage that they shall each be a Data Controller in respect of that Personal Data in accordance with the terms of this Annex 2 (Joint Controller Agreement) in replacement of paragraphs 2-15 of Schedule 20 (Where one Party is Controller and the other Party is Processor) and paragraphs 7-27 of Schedule 20 (Independent Controllers of Personal Data). Accordingly, the Parties each undertake to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Data Controllers.

1.2 The Parties agree that the [Supplier/Buyer]:

(a) is the exclusive point of contact for Data Subjects and is responsible for all steps necessary to comply with the UK GDPR regarding the exercise by Data Subjects of their rights under the UK GDPR;

(b) shall direct Data Subjects to its Data Protection Officer or suitable alternative in connection with the exercise of their rights as Data Subjects and for any enquiries concerning their Personal Data or privacy;

(c) is solely responsible for the Parties' compliance with all duties to provide information to Data Subjects under Articles 13 and 14 of the UK GDPR;

(d) is responsible for obtaining the informed consent of Data Subjects, in accordance with the UK GDPR, for Processing in connection with the Services where consent is the relevant legal basis for that Processing; and

(e) shall make available to Data Subjects the essence of this Annex (and notify them of any changes to it) concerning the allocation of responsibilities as Joint Controller and its role as exclusive point of contact, the Parties having used their best endeavours to agree the terms of that essence. This must be outlined in the [Supplier's/Buyer's] privacy policy (which must be readily available by hyperlink or otherwise on all of its public facing services and marketing).

1.3 Notwithstanding the terms of clause 1.2, the Parties acknowledge that a Data Subject has the right to exercise their legal rights under the Data Protection Legislation as against the relevant Party as Controller.

2. Undertakings of both Parties

2.1 The Supplier and the Buyer each undertake that they shall:

(a) report to the other Party every [x] months on:

(i) the volume of Data Subject Access Request (or purported Data Subject Access Requests) from Data Subjects (or third parties on their behalf);

(ii) the volume of requests from Data Subjects (or third parties on their behalf) to rectify, block or erase any Personal Data;

(iii) any other requests, complaints or communications from Data Subjects (or third parties on their behalf) relating to the other Party's obligations under applicable Data Protection Legislation;

(iv) any communications from the Information Commissioner or any other regulatory authority in connection with Personal Data; and

(v) any requests from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law,

that it has received in relation to the subject matter of the Contract during that period;

(b) notify each other immediately if it receives any request, complaint or communication made as referred to in clauses 2.1(a)(i) to (v);

(c) provide the other Party with full cooperation and assistance in relation to any request, complaint or communication made as referred to in clauses 2.1(a)(iii) to (v) to enable the other Party to comply with the relevant timescales set out in the Data Protection Legislation;

(d) not disclose or transfer the Personal Data to any third party unless necessary for the provision of the Services and, for any disclosure or transfer of Personal Data to any third party, save where such disclosure or transfer is specifically authorised under the Contract or is required by Law). For the avoidance of doubt, the third party to which Personal Data is transferred must be subject to equivalent obligations which are no less onerous than those set out in this Annex;

(e) request from the Data Subject only the minimum information necessary to provide the Services and treat such extracted information as Confidential Information;

(f) ensure that at all times it has in place appropriate Protective Measures to guard against unauthorised or unlawful Processing of the Personal Data and/or accidental loss, destruction or damage to the Personal Data and unauthorised or unlawful disclosure of or access to the Personal Data;

(g) take all reasonable steps to ensure the reliability and integrity of any of its Personnel who have access to the Personal Data and ensure that its Personnel:

(i) are aware of and comply with their duties under this Annex 2 (Joint Controller Agreement) and those in respect of Confidential Information

(ii) are informed of the confidential nature of the Personal Data, are subject to appropriate obligations of confidentiality and do not publish, disclose or divulge any of the Personal Data to any third party where the that Party would not be permitted to do so;

(iii) have undergone adequate training in the use, care, protection and handling of personal data as required by the applicable Data Protection Legislation;

(h) ensure that it has in place Protective Measures as appropriate to protect against a Personal Data Breach having taken account of the:

(i) nature of the data to be protected;

(i) harm that might result from a Personal Data Breach;

(iii) state of technological development; and

(iv) cost of implementing any measures;

(i) ensure that it has the capability (whether technological or otherwise), to the extent required by Data Protection Legislation, to provide or correct or delete at the request of a Data Subject all the Personal Data relating to that Data Subject that the Supplier holds; and

(i) ensure that it notifies the other Party as soon as it becomes aware of a Personal Data Breach.

2.2 Each Joint Controller shall use its reasonable endeavours to assist the other Controller to comply with any obligations under applicable Data Protection Legislation and shall not perform its obligations under this Annex in such a way as to cause the other Joint Controller to breach any of its obligations under applicable Data Protection Legislation to the extent it is aware, or ought reasonably to have been aware, that the same would be a breach of such obligations

3**. Data Protection Breach**

3.1 Without prejudice to Clause 3.2, each Party shall notify the other Party promptly and without undue delay, and in any event within 48 hours, upon becoming aware of any

Personal Data Breach or circumstances that are likely to give rise to a Personal Data Breach, providing the Buyer and its advisors with:

(a) sufficient information and in a timescale which allows the other Party to meet any obligations to report a Personal Data Breach under the Data Protection Legislation;

(b) all reasonable assistance, including:

(i) co-operation with the other Party and the Information Commissioner investigating the Personal Data Breach and its cause, containing and recovering the compromised Personal Data and compliance with the applicable guidance;

(ii) co-operation with the other Party including taking such reasonable steps as are directed by the Buyer to assist in the investigation, mitigation and remediation of a Personal Data Breach;

(iii) co-ordination with the other Party regarding the management of public relations and public statements relating to the Personal Data Breach; and/or

(iv) providing the other Party and to the extent instructed by the other Party to do so, and/or the Information Commissioner investigating the Personal Data Breach, with complete information relating to the Personal Data Breach, including, without limitation, the information set out in clause 3.2.

3.2 Each Party shall take all steps to restore, re-constitute and/or reconstruct any Personal Data where it has lost, damaged, destroyed, altered or corrupted as a result of a Personal Data Breach as it was that Party's own data at its own cost with all possible speed and shall provide the other Party with all reasonable assistance in respect of any such Personal Data Breach, including providing the other Party, as soon as possible and within 48 hours of the Personal Data Breach relating to the Personal Data Breach, in particular:

(a) the nature of the Personal Data Breach;

(b) the nature of Personal Data affected;

(c) the categories and number of Data Subjects concerned;

(d) the name and contact details of the Supplier's Data Protection Officer or other relevant contact from whom more information may be obtained;

(e) measures taken or proposed to be taken to address the Personal Data Breach; and

(f) describe the likely consequences of the Personal Data Breach.

4**. Audit**

4.1 The Supplier shall permit:

(a) the Buyer, or a third-party auditor acting under the Buyer's direction, to conduct, at the Buyer's cost, data privacy and security audits, assessments and inspections concerning the Supplier's data security and privacy procedures relating to Personal Data, its compliance with this Annex 2 and the Data Protection Legislation; and/or

(b) the Buyer, or a third-party auditor acting under the Buyer's direction, access to premises at which the Personal Data is accessible or at which it is able to inspect any relevant records, including the record maintained under Article 30 of the UK GDPR by the Supplier so far as relevant to the Contract, and procedures, including premises under the control of any third party appointed by the Supplier to assist in the provision of the Services.

4.2 The Buyer may, in its sole discretion, require the Supplier to provide evidence of the Supplier's compliance with clause 4.1 in lieu of conducting such an audit, assessment or inspection.

5. Impact Assessments

5.1 The Parties shall:

(a) provide all reasonable assistance to each other to prepare any Data Protection Impact Assessment as may be required (including provision of detailed information and assessments in relation to Processing operations, risks and measures); and

(b) maintain full and complete records of all Processing carried out in respect of the Personal Data in connection with the Contract, in accordance with the terms of Article 30 of the UK GDPR.

6. ICO Guidance

The Parties agree to take account of any guidance issued by the Information Commissioner and/or any relevant Central Government Body. The Buyer may on not less than thirty (30) Working Days' notice to the Supplier amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner and/or any relevant Central Government Body.

7. Liabilities for Data Protection Breach

7.1 If financial penalties are imposed by the Information Commissioner on either the Buyer or the Supplier for a Personal Data Breach ("**Financial Penalties**") then the following shall occur:

(a) if in the view of the Information Commissioner, the Buyer is responsible for the Personal Data Breach, in that it is caused as a result of the actions or inaction of the Buyer, its employees, agents, contractors (other than the Supplier) or systems and procedures controlled by the Buyer, then the Buyer shall be responsible for the payment of such Financial Penalties. In this case, the Buyer will conduct an internal audit and engage at its reasonable cost when necessary, an independent third party to conduct an audit of any such Personal Data Breach. The Supplier shall provide to the Buyer and its third party investigators and auditors, on request and at the Supplier's reasonable cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach;

(b) if in the view of the Information Commissioner, the Supplier is responsible for the Personal Data Breach, in that it is not a Personal Data Breach that the Buyer is responsible for, then the Supplier shall be responsible for the payment of these Financial Penalties. The Supplier will provide to the Buyer and its auditors, on request and at the Supplier's sole cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach; or

(c) if no view as to responsibility is expressed by the Information Commissioner, then the Buyer and the Supplier shall work together to investigate the relevant Personal Data Breach and allocate responsibility for any Financial Penalties as outlined above, or by agreement to split any financial penalties equally if no responsibility for the Personal Data Breach can be apportioned. In the event that the Parties do not agree such apportionment then such Dispute shall be referred to the Dispute Resolution Procedure set out in Clause 34 of the Core Terms (*Resolving disputes*).

7.2 If either the Buyer or the Supplier is the defendant in a legal claim brought before a court of competent jurisdiction ("**Court**") by a third party in respect of a Personal Data Breach, then unless the Parties otherwise agree, the Party that is determined by the final decision of the court to be responsible for the Personal Data Breach shall be liable for the losses arising from such Personal Data Breach. Where both Parties are liable, the liability will be apportioned between the Parties in accordance with the decision of the Court.

7.3 In respect of any losses, cost claims or expenses incurred by either Party as a result of a Personal Data Breach (the "**Claim Losses**"):

(a) if the Buyer is responsible for the relevant Personal Data Breach, then the Buyer shall be responsible for the Claim Losses;

(b) if the Supplier is responsible for the relevant Personal Data Breach, then the Supplier shall be responsible for the Claim Losses: and

(c) if responsibility for the relevant Personal Data Breach is unclear, then the Buyer and the Supplier shall be responsible for the Claim Losses equally.

7.4 Nothing in either clause 7.2 or clause 7.3 shall preclude the Buyer and the Supplier reaching any other agreement, including by way of compromise with a third party complainant or claimant, as to the apportionment of financial responsibility for any Claim Losses as a result of a Personal Data Breach, having regard to all the circumstances of the Personal Data Breach and the legal and financial obligations of the Buyer.

8. Termination

If the Supplier is in material Default under any of its obligations under this Annex 2 (*Joint Controller Agreement*), the Buyer shall be entitled to terminate the Contract by issuing a Termination Notice to the Supplier in accordance with Clause 10 of the Core Terms (*Ending the contract*).

9. Sub-Processing

10.1 In respect of any Processing of Personal Data performed by a third party on behalf of a Party, that Party shall:

(a) carry out adequate due diligence on such third party to ensure that it is capable of providing the level of protection for the Personal Data as is required by the Contract, and provide evidence of such due diligence to the other Party where reasonably requested; and

(b) ensure that a suitable agreement is in place with the third party as required under applicable Data Protection Legislation.

10. Data Retention

The Parties agree to erase Personal Data from any computers, storage devices and storage media that are to be retained as soon as practicable after it has ceased to be necessary for them to retain such Personal Data under applicable Data Protection Legislation and their privacy policy (save to the extent (and for the limited period) that such information needs to be retained by the Party for statutory compliance purposes or as otherwise required by the Contract), and taking all further actions as may be necessary to ensure its compliance with Data Protection Legislation and its privacy policy.

Schedule 21 (Variation Form)

This form is to be used in order to change a contract in accordance with Clause 24 of the Core Terms (Changing the Contract)

Contract Details		
This variation is between:	**[**Buyer**]** (**"the Buyer"**) And **[insert** name of Supplier**]** (**"the Supplier"**)	
Contract name:	**[insert** name of contract to be changed] **("the Contract")**	
Contract reference number:	**[insert** contract reference number]	
Details of Proposed Variation		
Variation initiated by:	**[delete** as applicable: Buyer/Supplier]	
Variation number:	**[insert** variation number]	
Date variation is raised:	**[insert** date]	
Proposed variation		
Reason for the variation:	**[insert** reason]	
An Impact Assessment shall be provided within:	**[insert** number] days	
Impact of Variation		
Likely impact of the proposed variation:	**[Supplier to insert** assessment of impact]	
Outcome of Variation		
Contract variation:	This Contract detailed above is varied as follows: • **[Buyer to insert** original Clauses or Paragraphs to be varied and the changed clause]	
Financial variation:	Original Contract Value:	£ **[insert** amount]
	Additional cost due to variation:	£ **[insert** amount]
	New Contract value:	£ **[insert** amount]

1. This Variation must be agreed and signed by both Parties to the Contract and shall only be effective from the date it is signed by the Buyer

2. Words and expressions in this Variation shall have the meanings given to them in the Contract.

3. The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

Signed by an authorised signatory for and on behalf of the Buyer

Signature .....

Date .....

Name (in Capitals) .....

Address .....

.....

Signed by an authorised signatory to sign for and on behalf of the Supplier

Signature .....

Date .....

Name (in Capitals) .....

Address .....

Schedule 22 (Insurance Requirements)

1. The insurance you need to have

1.1 The Supplier shall take out and maintain or procure the taking out and maintenance of the insurances as set out in the Annex to this Schedule and any other insurances as may be required by applicable Law (together the "**Insurances**"). The Supplier shall ensure that each of the Insurances is effective no later than

the Start Date in respect of those Insurances set out in the Annex to this Schedule and those required by applicable Law; and

1.2 The Insurances shall be:

1.2.1 maintained in accordance with Good Industry Practice;

1.2.2 (so far as is reasonably practicable) on terms no less favourable than those generally available to a prudent contractor in respect of risks insured in the international insurance market from time to time;

1.2.3 taken out and maintained with insurers of good financial standing and good repute in the international insurance market; and

1.2.4 maintained for at least six (6) years after the End Date.

1.3 The Supplier shall ensure that the public and products liability policy contain an indemnity to principals clause under which the Buyer shall be indemnified in respect of claims made against the Buyer in respect of death or bodily injury or third party property damage arising out of or in connection with the Deliverables and for which the Supplier is legally liable.

2. How to manage the insurance

2.1 Without limiting the other provisions of this Contract, the Supplier shall:

2.1.1 take or procure the taking of all reasonable risk management and risk control measures in relation to Deliverables as it would be reasonable to expect of a prudent contractor acting in accordance with Good Industry Practice, including the investigation and reports of relevant claims to insurers;

2.1.2 promptly notify the insurers in writing of any relevant material fact under any Insurances of which the Supplier is or becomes aware; and

2.1.3 hold all policies in respect of the Insurances and cause any insurance broker effecting the Insurances to hold any insurance slips and other evidence of placing cover representing any of the Insurances to which it is a party.

3. What happens if you aren't insured

3.1 The Supplier shall not take any action or fail to take any action or (insofar as is reasonably within its power) permit anything to occur in relation to it which would entitle any insurer to refuse to pay any claim under any of the Insurances.

3.2 Where the Supplier has failed to purchase or maintain any of the Insurances in full force and effect, the Buyer may elect (but shall not be obliged) following written notice to the Supplier to purchase the relevant Insurances and recover the reasonable premium and other reasonable costs incurred in connection therewith as a debt due from the Supplier.

4. Evidence of insurance you must provide

4.1 The Supplier shall upon the Start Date and within 15 Working Days after the renewal of each of the Insurances, provide evidence, in a form satisfactory to the Buyer, that the Insurances are in force and effect and meet in full the requirements of this Schedule.

5. Making sure you are insured to the required amount

5.1 The Supplier shall ensure that any Insurances which are stated to have a minimum limit "in the aggregate" are maintained at all times for the minimum limit of indemnity specified in this Contract and if any claims are made which do not relate to this Contract then the Supplier shall notify the Buyer and provide details of its proposed solution for maintaining the minimum limit of indemnity.

6. Cancelled Insurance

6.1 The Supplier shall notify the Buyer in writing at least five (5) Working Days prior to the cancellation, suspension, termination or non-renewal of any of the Insurances.

6.2 The Supplier shall ensure that nothing is done which would entitle the relevant insurer to cancel, rescind or suspend any insurance or cover, or to treat any insurance, cover or claim as voided in whole or part. The Supplier shall use all reasonable endeavours to notify the Buyer (subject to third party confidentiality obligations) as soon as practicable when it becomes aware of any relevant fact, circumstance or matter which has caused, or is reasonably likely to provide grounds to, the relevant insurer to give notice to cancel, rescind, suspend or void any insurance, or any cover or claim under any insurance in whole or in part.

7. Insurance claims

7.1 The Supplier shall promptly notify to insurers any matter arising from, or in relation to, the Deliverables, or the Contract for which it may be entitled to claim under any of the Insurances. In the event that the Buyer receives a claim relating to or arising out of the Contract or the Deliverables, the Supplier shall co-operate

with the Buyer and assist it in dealing with such claims including without limitation providing information and documentation in a timely manner.

7.2 Except where the Buyer is the claimant party, the Supplier shall give the Buyer notice within twenty (20) Working Days after any insurance claim in excess of 10% of the sum required to be insured pursuant to Paragraph 5.1 relating to or arising out of the provision of the Deliverables or this Contract on any of the Insurances or which, but for the application of the applicable policy excess, would be made on any of the Insurances and (if required by the Buyer) full details of the incident giving rise to the claim.

7.3 Where any Insurance requires payment of a premium, the Supplier shall be liable for and shall promptly pay such premium.

7.4 Where any Insurance is subject to an excess or deductible below which the indemnity from insurers is excluded, the Supplier shall be liable for such excess or deductible. The Supplier shall not be entitled to recover from the Buyer any sum paid by way of excess or deductible under the Insurances whether under the terms of this Contract or otherwise.

ANNEX: REQUIRED INSURANCES

1. The Supplier shall hold the following insurance cover from the Start Date in accordance with this Schedule:

1.1 professional indemnity insurance with cover (for a single event or a series of related events and in the aggregate) of not less than two million pounds (£2,000,000);

1.2 public liability insurance with cover (for a single event or a series of related events and in the aggregate)] of not less than two million pounds (£2,000,000); and

1.3 employers' liability insurance with cover (for a single event or a series of related events and in the aggregate) of not less than 2 million pounds (£2,000,000).

Schedule 27 (Key Subcontractors)

1. Restrictions on certain subcontractors

1.1 The Supplier is entitled to sub-contract its obligations under the Contract to the Key Subcontractors set out in the Award Form.

1.2 Where during the Contract Period the Supplier wishes to enter into a new Key Sub-contract or replace a Key Subcontractor, it must obtain the prior written consent of the Buyer and the Supplier shall, at the time of requesting such consent, provide the Buyer with the information detailed in Paragraph 1.4. The decision of the Buyer to consent or not will not be unreasonably withheld or delayed. Where the Buyer consents to the appointment of a new Key Subcontractor then they will be added to Key Subcontractor section of the Award Form. The Buyer may reasonably withhold their consent to the appointment of a Key Subcontractor if it considers that:

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

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

1.2.3 the proposed Key Subcontractor employs unfit persons.

1.3 The Supplier shall provide the Buyer with the following information in respect of the proposed Key Subcontractor:

1.3.1 the proposed Key Subcontractor's name, registered office and company registration number;

1.3.2 the scope/description of any Deliverables to be provided by the proposed Key Subcontractor;

1.3.3 where the proposed Key Subcontractor is an Affiliate of the Supplier, evidence that demonstrates to the reasonable satisfaction of the Buyer that the proposed Key Sub-Contract has been agreed on "arm's-length" terms;

1.3.4 the Key Sub-Contract price expressed as a percentage of the total projected Charges over the Contract Period; and

1.3.5 (where applicable) Credit Rating Threshold (as defined in Schedule 24 (Financial Distress)) of the Key Subcontractor.

1.4 If requested by the Buyer, within ten (10) Working Days of receipt of the information provided by the Supplier pursuant to Paragraph 1.3, the Supplier shall also provide:

1.4.1 a copy of the proposed Key Sub-Contract; and

1.4.2 any further information reasonably requested by the Buyer.

1.5 The Supplier shall ensure that each new or replacement Key Sub-Contract shall include:

1.5.1 provisions which will enable the Supplier to discharge its obligations under the Contract;

1.5.2 a right under CRTPA for the Buyer to enforce any provisions under the Key Sub-Contract which confer a benefit upon the Buyer;

1.5.3 a provision enabling the Buyer to enforce the Key Sub-Contract as if it were the Supplier;

1.5.4 a provision enabling the Supplier to assign, novate or otherwise transfer any of its rights and/or obligations under the Key Sub-Contract to the Buyer;

1.5.5 obligations no less onerous on the Key Subcontractor than those imposed on the Supplier under the Contract in respect of:

(a) the data protection requirements set out in Clause 14 (Data protection);

(b) the FOIA and other access request requirements set out in Clause 16 (When you can share information);

(c) the obligation not to embarrass the Buyer or otherwise bring the Buyer into disrepute;

(d) the keeping of records in respect of the goods and/or services being provided under the Key Sub-Contract, including the maintenance of Open Book Data; and

(e) the conduct of audits set out in Clause 6 (Record keeping and reporting);

1.5.6 provisions enabling the Supplier to terminate the Key Sub-Contract on notice on terms no more onerous on the Supplier than those imposed on the Buyer under Clauses 10.4 (When the Buyer can end this contract) and 10.5 (What happens if the contract ends) of this Contract; and

1.5.7 a provision restricting the ability of the Key Subcontractor to sub-contract all or any part of the provision of the Deliverables provided to the Supplier under the Key Sub-Contract without first seeking the written consent of the Buyer.

Annex 1

Special Term 1 - Amendments to the Agreement

Both Parties agree to make the following amendments to the Agreement:

Clause	Clause Detail (as currently drafted)	Agreed Amendment
Definitions (Schedule 1)	***“"IPR Claim"*** *any claim of infringement or alleged infringement (including the defence of such infringement or alleged infringement) of any IPR, used to provide the Deliverables or otherwise provided and/or licensed by the Supplier (or to which the Supplier has provided access) to the Buyer in the fulfilment of its obligations under the Contract;”*	The Parties agree to amend this definition to read as follows: “*any claim of infringement or alleged infringement (including the defence of such infringement or alleged infringement) of any IPR used by the Supplier to provide the Deliverables or otherwise provided and/or licensed by the Supplier (or to which the Supplier has provided access) to the Buyer in the fulfilment of its obligations under the Contract**.** For the avoidance of doubt, an “IPR Claim” shall not include any Third Party IPR supplied by, or transferred from, the Buyer.*
3.3.2	*“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 of the Buyer or third party suppliers.”*	The Parties agree to amend this clause to read as follows: *“The Supplier must co-operate with the Buyer and third party sub-contractors appointed by the Supplier on all aspects connected with the Delivery of the Services and ensure that Supplier Staff comply with any reasonable instructions of the Buyer or such third party sub-contractors. The Supplier may co-operate with third party sub-contractors appointed by the Buyer. Notwithstanding the foregoing, the Supplier shall be under no obligation to disclose the Supplier’s Confidential Information or transfer any Existing IPR to any third party sub-contractors appointed hereunder.*”

4.10 (Core Terms)	*"The Supplier has no right of set-off, counterclaim, discount or abatement unless they're ordered to do so by a court."*	The Parties agree to amend this clause to read as follows: *"The Supplier has no right of counterclaim, discount or abatement unless they're ordered to do so by a court. The Supplier may retain or set-off payment of any amount owed to it by the Buyer if notice, reasons and relevant evidence are provided to the Buyer. "*
8.5 (Core Terms)	*"The Buyer can terminate the Contract for breach of any warranty or indemnity where they are entitled to do so."*	The Parties agree to amend this clause to read as follows: "*The Buyer can terminate the Contract for any material breach of any warranty or indemnity on immediate written notice*."
9.1 (Core Terms"	*"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 it to both:* • *receive and use the Deliverables* • *make use of the deliverables provided by a Replacement Supplier"*	The Parties agree to amend this clause to read as follows: *"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 the Supplier's Existing IPR to enable it to both for the purpose of this Contract:* • *receive and use the Deliverables* • *make use of the deliverables provided by a Replacement Supplier* *The Supplier agrees and acknowledges that the Buyer will need to (and therefore has the necessary rights to) host and access the methods and the reports provided under this Contract on its internal systems but also to communicate the methods to certain third parties for validation requirements and also publish the reports openly on the Buyer's website for transparency."*
9.2 (Core Terms)	*"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 New IPRs for the purpose of fulfilling its*	The Parties agree to amend this clause to read as follows: *"Excluding any Know-How and any improvements or modifications made to the Supplier's existing processes in connection with the Services which forms the Existing IPR, any New IPR created under*

	obligations during the Contract Period."	*the Contract is owned by the Buyer. The Buyer gives the Supplier a licence to use any Existing IPRs and New IPRs for the purpose of fulfilling its obligations during the Contract Period.* *For the avoidance of doubt, it is agreed and acknowledged by the Parties that the UK compendium of validated methods for GMO control tests are New IPRs and owned by the Buyer."*
10.8.1 (Core Terms)	*"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."*	The Parties agree to amend this clause to read as follows: *"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 at a reasonable cost*."
11.1	*"Each Party's total aggregate liability in each Contract Year under the Contract (whether in tort, contract or otherwise) is no more than the greater of £5 million or 150% of the Estimated Yearly Charges unless specified in the Award Form."*	The Parties agree to amend this clause to read as follows: *"Each Party's total aggregate liability in each Contract Year under the Contract (whether in tort, contract or otherwise) is no more than the greater of two million Pounds Sterling (£2,000,000) or 150% of the Estimated Yearly Charges, unless specified in the Award Form." Okay FSA approved*
11.2 (Core Terms)	*"No Party is liable to the other for:* • *any indirect Losses* • *Loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect)"*	The Parties agree to amend this clause to read as follows: *"No Party is liable to the other for:* • *any indirect or consequential Losses;* • *Loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect); and* • *Loss of anticipated savings."*
14.3 (Core Terms)	"*The Supplier must make accessible back-ups of all Government Data, stored in an agreed off-site location and*	The Parties agree to amend this clause to read as follows: *"The Supplier must make accessible back-ups of all Government Data, stored in an agreed secondary off-*

	send the Buyer copies every 6 Months."	*site location and make copies available to send to the Buyer at agreed intervals of six months."*
25 (Core Terms)	*Notices*	The Parties agree for the following to be incorporated into clause 24 as clause 24.4: "*24.4 Notices to the Supplier must be sent to the address in the Award Form addressed for the attention of General Counsel, with a copy to be sent by email to legal@lgcgroup.com.*"
Section 1.4 of Schedule 1 (Definitions)	Definition of Force Majeure: *"[Force Majeure Event] means any event, circumstance, matter or cause affecting the performance by either the Buyer or the Supplier of its obligations arising from: acts, events, omissions, happenings or non-happenings beyond the reasonable control of the Affected Party which prevent or materially delay the Affected Party from performing its obligations under a Contract; riots, civil commotion, war or armed conflict, acts of terrorism, nuclear, biological or chemical warfare; acts of a Crown Body, local government or regulatory bodies; fire, flood or any disaster; or an industrial dispute affecting a third party for which a substitute third party is not reasonably available but excluding: 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; any event, occurrence, circumstance, matter or cause which is attributable to the wilful act, neglect or failure to*	The Parties agree to amend this clause to read as follows: *"[Force Majeure Event] means any event, circumstance, matter or cause affecting the performance by either the Buyer or the Supplier of its obligations including, without limitation, any event, circumstance matter or cause arising from: acts, events, omissions, happenings or non-happenings beyond the reasonable control of the Affected Party which prevent or materially delay the Affected Party from performing its obligations under a Contract; pandemics or epidemics, riots, civil commotion, war or armed conflict, acts of terrorism, nuclear, biological or chemical warfare; acts of a Crown Body, local government or regulatory bodies; fire, flood or any disaster; or an industrial dispute affecting a third party for which a substitute third party is not reasonably available but excluding: 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; 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 any failure of delay caused by a lack of funds."*

	take reasonable precautions against it by the Party concerned; and any failure of delay caused by a lack of funds."	