Food Standards Agency
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# Award Form

Mid-tier Contract
Project Version: v1.0
Model Version: v1.0

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

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| **1.** | **Buyer** | Food Standards Agency (the Buyer)<br>Its offices are on:<br><br>Clive House<br>70 Petty France<br>London, SW1H 9EX |
| **2.** | **Supplier** | Name: LGC<br>Address: Queens Road, Teddington, TW11 0LY<br>Registration number: 2991879<br>SID4GOV ID: NA |
| **3.** | **Contract** | This Contract between the Buyer and the Supplier is for the supply of Deliverables.<br><br>This opportunity is advertised in the Contract Notice in the Official Journal of the European Union reference 2021/S 000-000424 (OJEU Contract Notice). |
| **4.** | **Contract Reference** | **FS616029** – National Reference Laboratory for Genetically Modified Organisms in Food and Feed |
| **5.** | **Deliverables** | See Schedule 2 (Specification) for further details. |
| **6.** | **Start Date** | 1st April 2021 |
| **7.** | **End Date** | 31st March 2025 (with a review point break clause at 2 Years |
| **8.** | **Extension Period** | Review point break clause at 2 years 31st March 2023. |
| **9.** | **Incorporated Terms**<br><br>(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:<br><br>1. This Award Form<br>2. Any Special Terms (see **Section 10 Special Terms** in this Award Form)<br>3. Core Terms (version 1.0) |

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| | | 4. Schedule 1 (Definitions)<br>5. Schedule 20 (Processing Data)<br>6. The following Schedules (in equal order of precedence):<br>● Schedule 2 (Specification)<br>● Schedule 3 (Charges)<br>● Schedule 4 (Tender)<br>● Schedule 5 (Commercially Sensitive Information)<br>● Schedule 13 (Contract Management)<br>● Schedule 16 (Security)<br>● Schedule 20 (Processing Data)<br>● Schedule 21 (Variation Form)<br>● Schedule 22 (Insurance Requirements)<br>● 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]<br><br>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.<br><br>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 |

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| | | may lead to a delay in payment.<br><br>If you have a query regarding an outstanding payment please contact our Accounts Payable section either by email to<br><br>[Insert email address] or by telephone [Insert telephone number] between 09:00-17:00 Monday to Friday. |
| **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 £1 **million** |
| **18.** | **Supplier Contract Manager** | [redacted] |
| **19.** | **Key Subcontractors** | **Key Subcontractor 1**<br>Name (Registered name if registered) [**insert** name]<br>Registration number (if registered) [**insert** number]<br>Role of Subcontractor [**insert** role]<br>**[Guidance:** copy above lines as needed] |
| **20.** | **Buyer Authorised Representative** | Bhavna Parmar<br><br>Senior Methods and Lab Policy Advisor<br><br>[redacted] |

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

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## 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 andthat 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 dayscontinuously.

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

# Schedule 2 (Specification)

| ***Specification Reference*** |
|---|
| FS616029 |
| ***Specification Title*** |
| *National Reference Laboratory for Genetically Modified Organisms in Food and Feed* |
| ***Contract Duration*** |
| *1 April 2021 - 31 March 2025* (subject to a break clause after two years) |

This specification, which forms part of the Invitation to Tender (ITT), comprises 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 PROCESS FOR EVALUATION OF TENDERS

## GENERAL INTRODUCTION

The Food Standards Agency (FSA) is a non-ministerial government department governed by a Board appointed to act in the public interest, with the task of protecting consumers in relation to food. We work across England, Wales and Northern Ireland and collaborate closely with colleagues in Food Standards Scotland (FSS).

The National Reference Laboratories (NRLs) are a critical part of our national infrastructure for delivering a safe and authentic food system. The role of NRLs is to provide scientific advice and support to Official Laboratories (OLs) for food and feed safety official control testing.

The FSA is committed to openness and transparency of our evidence and its use, and equality of treatment to all suppliers. For NRLs, the FSA/FSS approves annual reports of work programmes for publication by NRLs on their own dedicated websites.

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. Underpinning data should also be published in an open, accessible, and re-usable format, such that the data can be made available to future researchers and the maximum benefit is derived from it. The Agency has established the key principles for release of underpinning data that will be applied to all new science and evidence-gathering projects which we would expect Contractors to comply with[1]. Further details regarding applying for research funding can be found on the FSA website[2].

## A.THE SPECIFICATION

The FSA and FSS are respectively designated as the Competent Authority (CA) for Official Feed and Food Controls within their area of responsibility. The UK has a legal obligation to appoint NRLs. NRLs provide advice and support to food and feed enforcement laboratories and CAs to ensure a harmonised approach to food and feed enforcement. NRLs are responsible for setting standards for routine procedures and

[1] http://www.food.gov.uk/about-us/data-and-policies/underpinning-data

[2] https://www.food.gov.uk/about-us/applying-for-research-funding

reliable testing methods in the regulated areas of feed and food. This delivers consumer protection and effective, risk-based and proportionate regulation and enforcement.

NRLs will play an important role following EU Transition as they will incorporate some of the activities previously performed by their lab counterparts in the EU (the European Reference Labs), including sharing and developing new and emerging disease intelligence, methodologies, reference materials and training. Following EU transition, NRLs will continue to play a pivotal role in the UK enforcement process.

This project is to re-procure the contract for the UK National Reference Laboratory for Genetically Modified Organism (GMO) in food and feed from the 1st April 2021 for four years (incorporating a two year break point for review in 2023). The FSA will confirm if they wish to proceed with the break point by variation to the contract, confirming intentions and any changes to the requirement.

The Agency may only designate laboratories as an NRL if they are accredited in accordance with: -

- EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories";EN ISO/IEC 17011:2017 “Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies”.

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

The scope of the accreditation must cover the following:

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

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

## Scope of Services to be Provided

### NRL GMO Services

- The appointed laboratory will carry out the provision of services for the UK National Reference Laboratory for GMOs. The NRL GMO will provide support to the UK official control laboratories for GMO control and will be required to identify and participate as an independent expert at international GMO meetings and networks to build expertise and knowledge in the area.
- The NRL will liaise with and, as and when required, provide advice to the FSA appointed laboratory responsible for the scientific assessment and validation of detection methods for GMOs in food and feed as part of the UK GMO authorisation of regulated products procedure.

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

(a) co-operate internationally in their area of competence, including collaborating and participating inter-laboratory comparative tests organised by international laboratories (where appropriate);

(b) co-ordinate, for their area of competence, the activities of OLs responsible for the analysis of official controls samples to ensure the verification of compliance with feed and food law;

(c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

(d) ensure the dissemination of any information required by the CA;

(e) provide scientific and technical assistance to the CA, especially for the implementation of Multi Annual National Control Plans;

(f) participate in relevant national and international networks, workshops and training courses and, where necessary, conduct training courses for the staff of OLs;

(g) upon request by the appropriate authority, actively assist in relevant foodborne incident and outbreak situations, should be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations and in cases of non-compliance of consignments, by carrying out confirmatory analysis;

(h) carry out research, evaluation and development of new and existing methods for the analysis of UK regulated and officially monitored foods and feed and emerging new risks to UK food safety;

(i) provide advice and expertise on standardisation of methods at CEN and ISO;

(j) obtain and maintain accreditation for official reference and other relevant regulatory methods for food and feed within the NRL area of competence;

(k) be responsible for carrying out other specific duties as required by the CA, where appropriate and by prior agreement;

The laboratory will be required, but not limited to:

(a) be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as NRLs;

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

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

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

(e) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents and secure access to any reference materials required in order to fulfil their responsibilities and support the relevant OLs;

(f) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and where appropriate, assist the CA in food incidents by carrying out diagnosis and/or testing of samples, when necessary;

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

(h) maintain a list of the accreditation for the relevant OLs;

(i) liaise with other CA-appointed NRLs (as and when required);

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

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

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

**1. Secretariat services**

(a) disseminating relevant information/advice to the OLs, CA, when required, and other relevant laboratories in a timely and effective manner;

(b) co-ordinating the activities of OLs and other relevant laboratories in food and feed below;

(c) creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation;

(d) providing regular updates to the CA on NRL activities, and up-to-date information on UK OLs and other relevant laboratories to the CA as requested;

(e) creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OLs, information on methods of analyses, Standard Operating Procedures (SOPs), latest developments and other background information.

**2. Advice and representation within the UK and internationally**

(a) provide details of analytical methods including reference methods to OLs and co-ordinate application of these methods through proficiency testing (see 4c);

(b) provide impartial expert advice as requested to the CA, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment;

(c) represent the UK at relevant international meetings, networks and working groups, consulting the CA on objectives and requirements before each meeting and providing the CA with an internal report of the meeting within 10 working days of each meeting;

(d) participate in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledge;

(e) provide advice to the CA, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in consultation with the CA that facilitate and promote their application in the UK within the policy aims of the CA;

(f) keep abreast of and advise the CA, OLs and other relevant laboratories of research and development for the sampling, testing and detection of GMOs;

(g) identify and inform the CA, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommending action to address them;

(h) provide technical assistance to the CA in cases of contested results of analyses;

(i) where appropriate, partake and/or keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area.

**3. Production of standard operating procedures, codes of practice,**

**guidance documents and databases**

(a) contribute to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLs and other relevant laboratories, as requested by the CA.

(b) where required, develop a database to store relevant information in relation to GMO official control testing, e.g. GMO methods, SOPs, codes and guidance

**4. Compliance assessment via audits, ring trials and provision of reference materials**

(a) ensure consistency and quality of testing approaches applied by UK OLs and other relevant laboratories, including advising on corrective action following adverse reports on OLs from UKAS;

(b) source and provide suitable reference materials and testing kits to OLs;

(c) plan and coordinate GMO proficiency testing for UK OLs and other relevant laboratories as appropriate (taking into account the number of relevant laboratories), analysing and evaluating the outcome, informing the CA and OLs of the results and advising on appropriate follow-up action;

(d) co-ordinate the participation of UK OLs and other relevant laboratories in international method validation studies and other initiatives, informing the CA and OLs of the results and advising on further action;

(e) where relevant, participate in proficiency tests and method validation studies organised by international organisations, informing the CA of the results and implementing any corrective measures required;

(f) co-ordinate training exercises for OLs and other relevant laboratories to promote best laboratory practice in respect of GMO analysis.

(g) Provide OLs with advanced notification of proficiency testing rounds to enable OLs to implement such activities in a timely manner.

**5. Co-ordination within the UK of international initiatives**

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

**6. Liaison and support work on GMO food/feed authorisation**

(a) liaise with the FSA appointed laboratory on GMO food/feed authorisation process and applications.

(b) where necessary, provide support/advice to the FSA appointed laboratory for GMO authorisation on the validation of methods of analyses, reference materials.

**7. Communication of results and data use**

(a) the Contractor shall ensure that the CA receives regular updates of any developments related to the core functions of the NRL;

(b) the Contractor shall notify the CA immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual work programme;

(c) the Contractor shall notify the CA immediately by email of any unusual occurrences resulting from any of the core functions of the NRL;

(d) The Contractor shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the CA by 31st March each year. Annual reports will be approved by the CA prior to publication by NRLs on NRL dedicated websites. If requested by the CA, the Contractor may also need to provide interim reports during the annual work programme;

(e) any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the CA;

(f) the use of the data for presentations and/or papers will not be permitted unless written permission has been sought and given by the CA;

(g) the Contractor will maintain records. Retention periods will be agreed and defined in the contract and if necessary the contractor will assist with transfer of archived reference material; (h) in other work related to the core functions of the NRL, the specified deadlines agreed between the CA and the Contractor should be met;

(i) if necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the CA. This will include assisting with transfer of archived reference materials;

(j) provide an internal report of meetings with other organisations within 10 working days of the meeting.

(k) the Contractor will engage in quarterly dialogues with the CA to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the CA may also be organised to ensure any potential or evolving issues are flagged and work is kept on track;

(l) the Contractor will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results;

(m) the Contractor will review NRL finances regularly and communicate spending, including a break-down of costs, with the CA on a monthly basis.

**Tender Application Form**

The Tender Application Form[3] requests the supplier to complete information under the following headings -

- Project summary
- Description of approach/scope of work
- The project plan and deliverables
- Participating Organisations and sub-contractors

[3] https://food.bravosolution.co.uk/web/login.html.

- Project and staff management
- Risk management
- Quality management
- Social Values

**Cost**

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

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

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

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

# 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<br>£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<br>Up to £130 per night in London |
| Subsistence | Up to a maximum of £21 for a 24-hour period |

# Annex 1: Rates and Prices

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

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

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

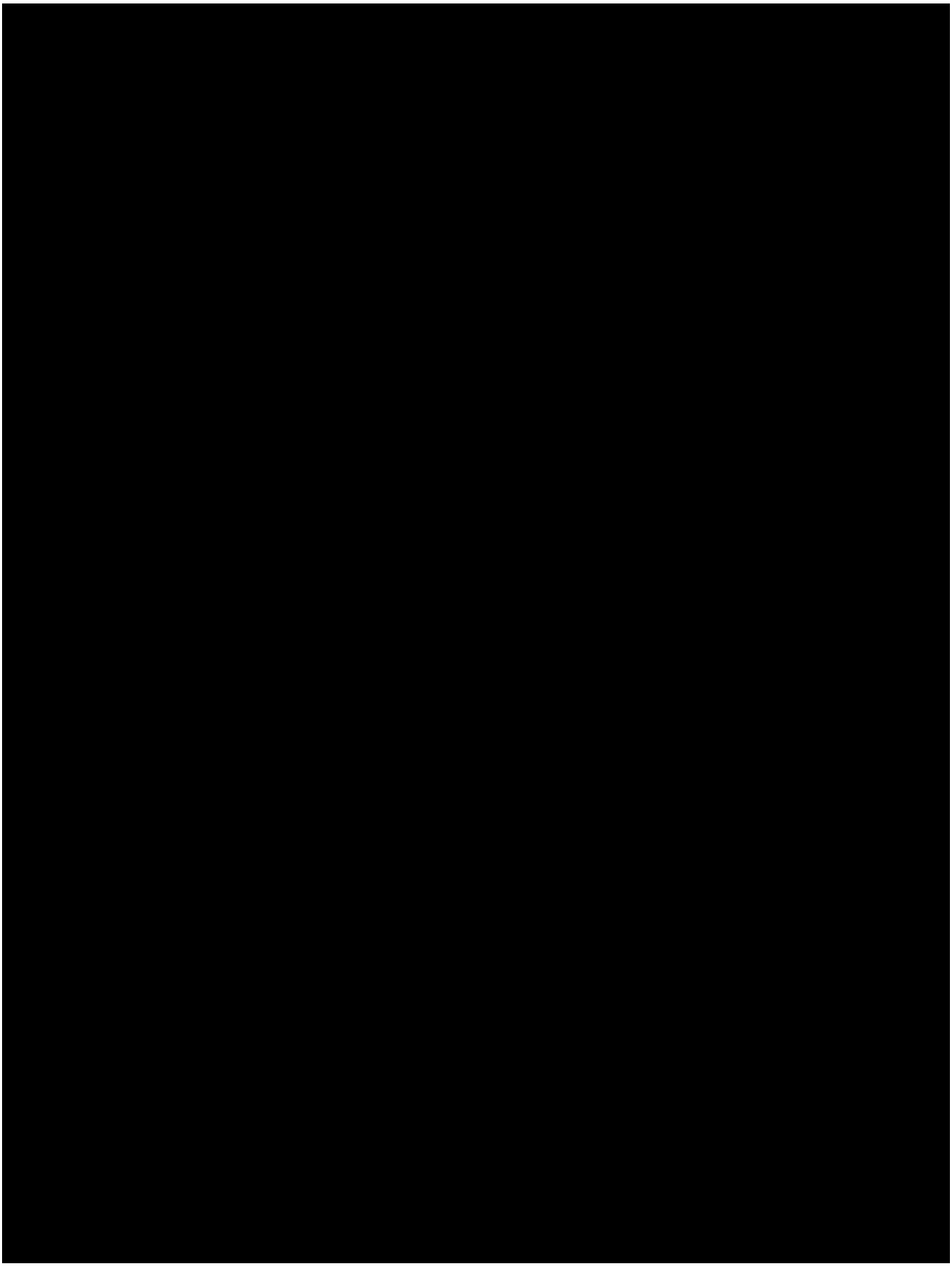
Some boxes have **blue** text and this indicates that the value is calculated automatically

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

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

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

This form should be completed by the project lead applicant and must include the collated costs for all participating organisations applying for the project work



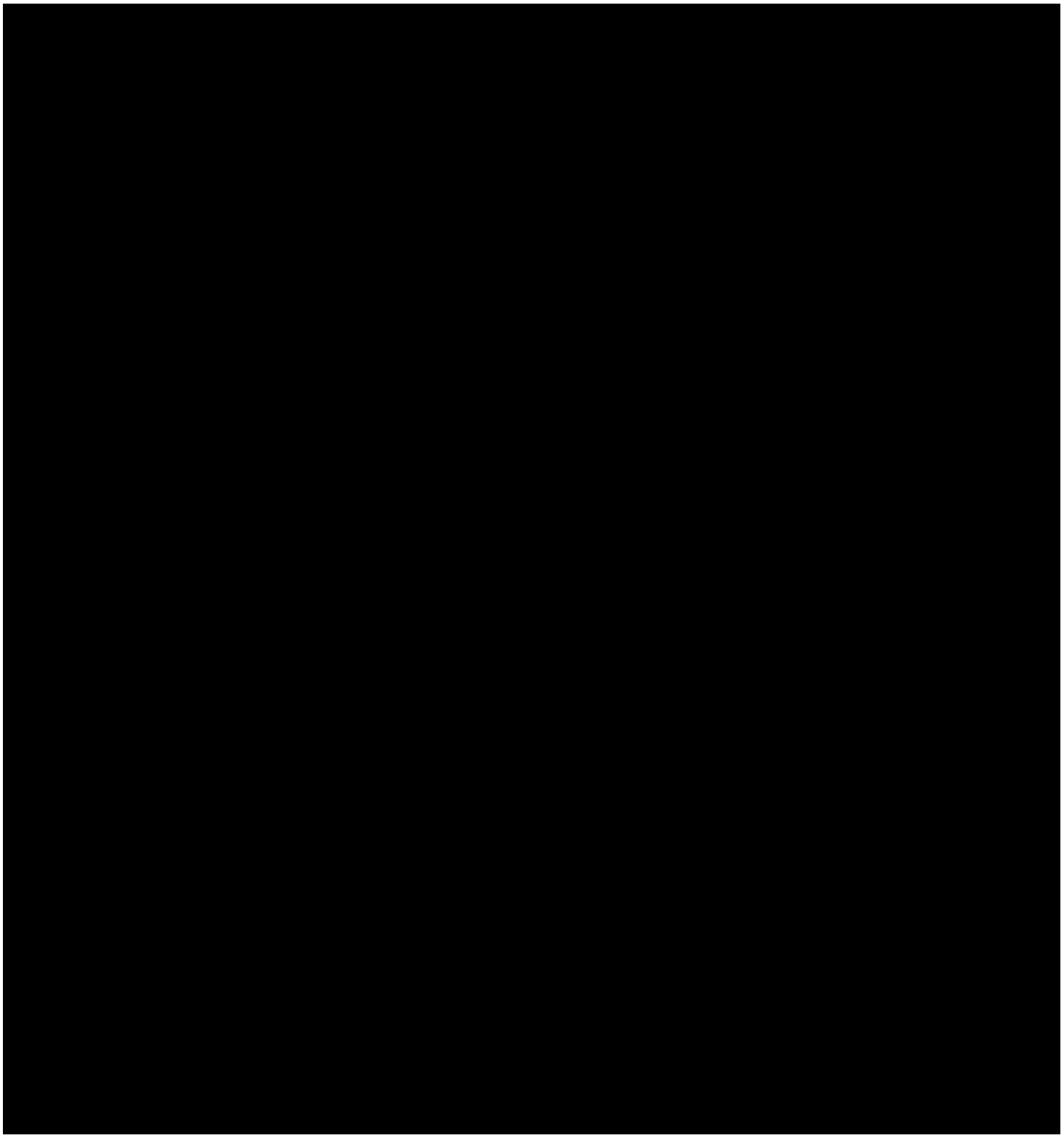
** The total cost figure should be the same as the total cost shown in table 4
** The total cost figure should be the same as the total cost shown below and in the Schedule of payments tab.

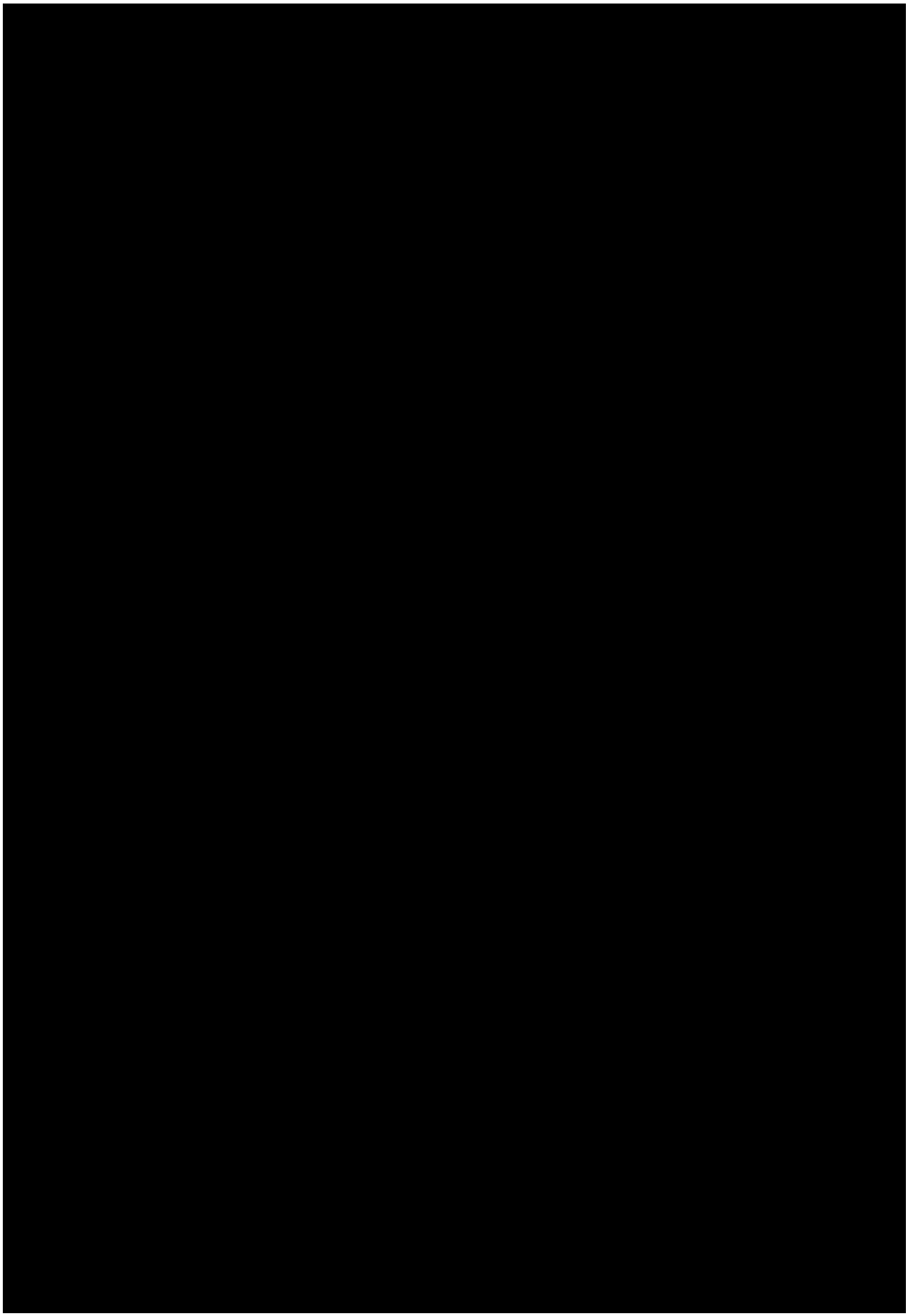
| **Project Costs Summary (*Automatically calculated*)** |
|---|

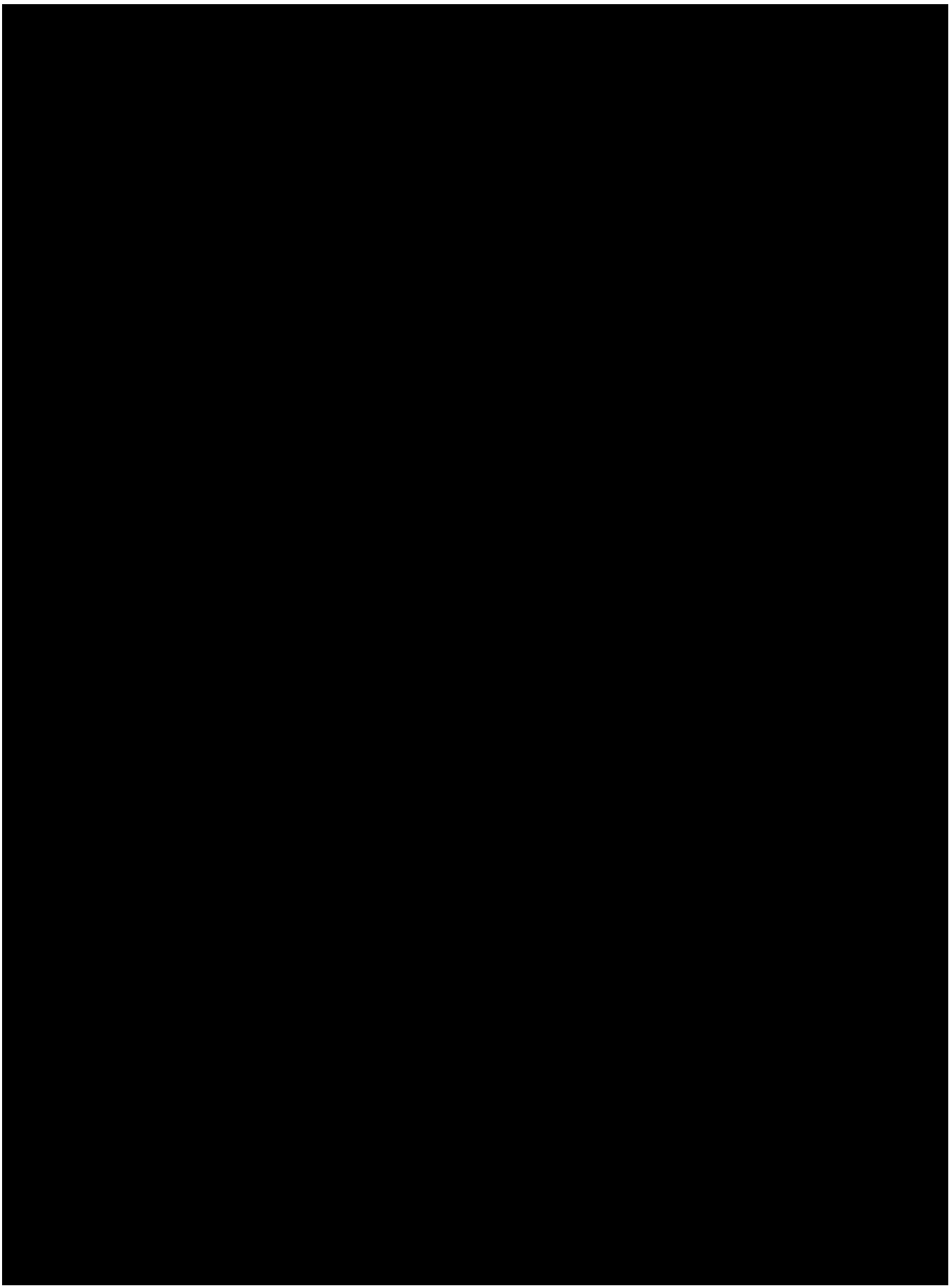
[redacted]

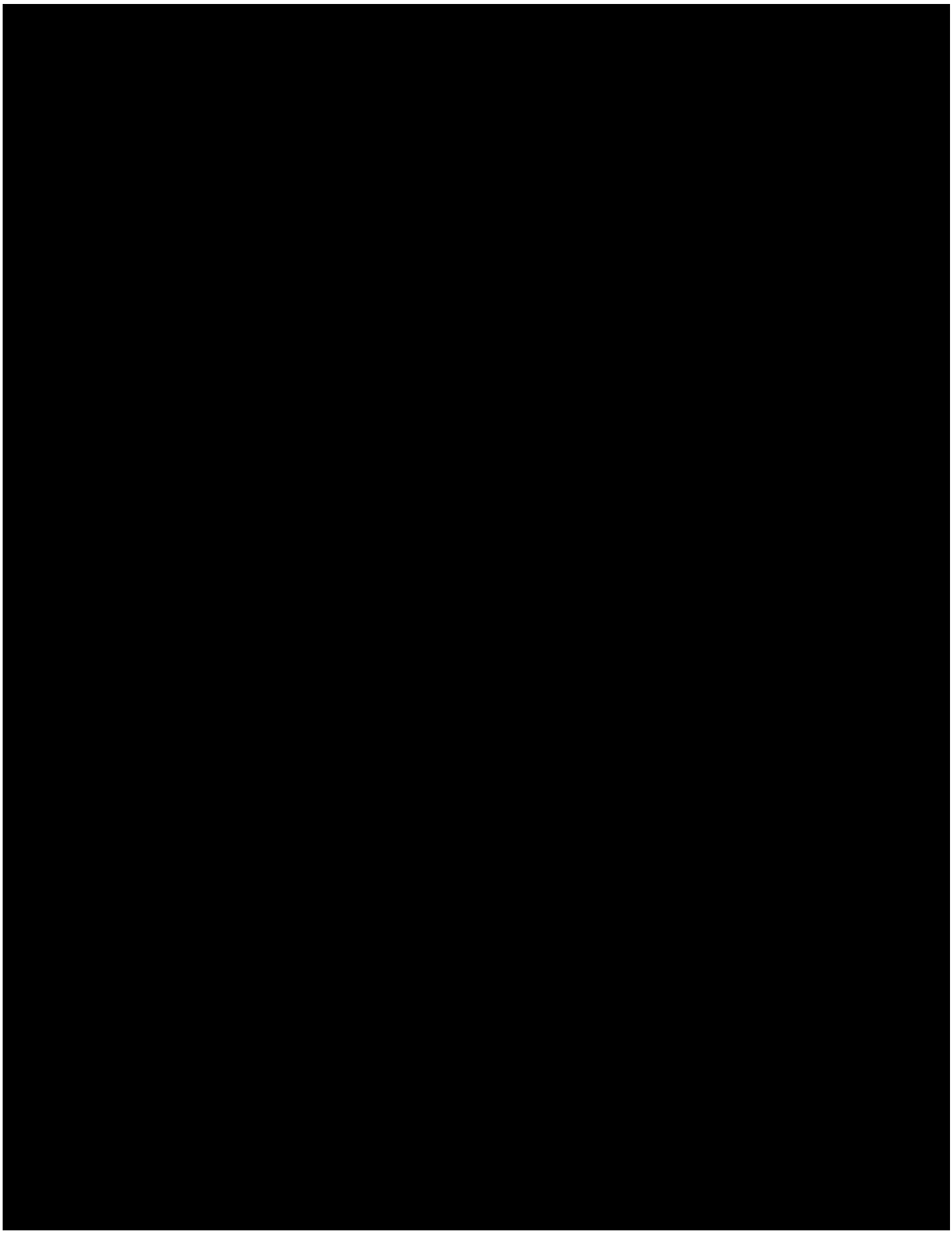
| | |
|---|---|
| **Total Project Costs** | **£ 533,941.76** |

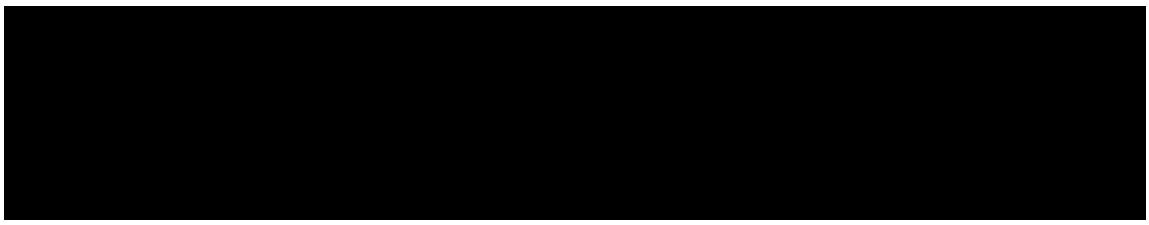
[redacted]











# Schedule 4 (Tender Application and Clarifications)

## Tender Application form for a project with the Food Standards Agency

Food Standards Agency
food.gov.uk

- 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]

**TENDER SUMMARY**

| | | | |
|---|---|---|---|
| **TENDER TITLE** | | | |
| **National Reference Laboratory for Genetically Modified Organisms in Food and Feed** | | | |
| **TENDER REFERENCE** | **FS616029** | | |
| **PROPOSED START** | 01/04/2021 | **PROPOSED END** | 31/03/2025 |

**1: TENDER SUMMARY AND OBJECTIVES**

**A. TENDER SUMMARY**

Pleasegive a brief summaryof the proposedwork in nomore than 400 words.

The National Reference Laboratories (NRLs) are a critical part of our national infrastructure for delivering a safe and authentic food system. The role of NRLs is to provide scientific advice and support to Official Laboratories (Ol s) for food and feed safety official control testing and to help towards ensuring a harmonisedapproach to food and feed enforcement. UK based NRLs play a pivotal role following the completion of EU Transition as they incorporatesome of the activities previously performed by the European Reference Labs, including sharing and developing new and emerging intelligence, methodologies, reference materials and training.
The NRL GMO will provide support to the UK official control laboratories for GMO control and will be required to identify and participate as an independent expert at international GMO meetings and networks to build expertise and knowledge in the area.

LGC propose to continue to bring the following key-benefits and added value aspects to their continued role as NRL for GMOs in food and feed, based on the following qualifying criteria for provision of the NRL services listed in the tender specifications:

**Secretariat Services:**

- Pre-established communication channels with the FSA and all OCLs, augmented through the position of the Association of Public Analysts Training Officer at LGC;
- Provision and maintenance of NRL GMO webpages.

**Advice and representation with the UK and internationally:**

- Dr, Malcolm Burns (LGC) has been recognised as an international expert in GMO analysis by the European Commission, facilitating continued attendance at ENGL (European Network of GMO Laboratories) working groups, meetings, workshops and training activities;
- Twenty one ENGL and EU NRL labs have written to Dr. Burns to express an interest in continuing GMO based activities irrespective of the ramifications of the UK/EU trade deal on UK involvement in EU science, such is the impact of the current UK GMO NRL (LGC);
- Continuous and consistent attendance at all 31 EURL and ENGL plenary meetings and all 16 NRL workshops;
- Dr. Burns (LGC) is the nominated UK ENGL Steering Committee meeting representative;
- Responded with advice and guidance to over 334 individual enquiries from stakeholders (inclusive of FSA, OCLs, EURL and UK stakeholders) since the inception of the UK NRL function in 2009;
- Expert advice complimented through LGC's National Measurement Laboratory for chemical and bio-chemical measurements status, and synergy with practical expertise for GMO analysis provided via the Government Chemist function;
- Access and membership on a number of international networks aimed at harmonising GMO analysis and setting best measurement practice advice.

**Provision of guidance and SOPs:**

- The only UK representative to participate in all current ENGL Working Groups;
- Bespoke access and participation in topical GMO working groups on dPCR, DNA extraction, NGS, gene editing and genetically modified microbes;
- Provision of guidance notes and UK authorship on published EURL and EC Guidance Documents;
- Provision of general training courses on GMO related activities for all controls labs;
- Example key publications: EU guidance on measurement uncertainty testing for GMO testing labs (3rd edition, 2020)

**Compliance assessment:**

- LGC possesses ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis (a mandatory requirement for NRLs under 2017/625);
- The Food and Veterinary Office official audit for UK compliance with EU legislation on GM regulations (in 2014) reported that the NRL met all of the requirements of Article 33 of Regulation (EC) No 882/2004 (now replaced by 2017/625);
- Experience and participation in all 21 EURL Comparative Tests (as per 2017/625) generating 67 successful Z-scores (all meeting quality criterion <[2]);
- Participation in method validation trials; 37 rounds of GeMMA Proficiency Test rounds (combined with the EURL Comparative Tests to generate full PT round compliance with 95 Z-scores across 58 individual PT rounds); participation in CCQM international metrology key comparisons involving GMOs;
- Awareness of UK OCL GMO analytical capability through frequent face-to-face visits, monitoring of capability, training courses and distribution of questionnaires;
- LGC has ISO/IEC 17025:2017 accreditation for digital PCR, further future proofing the area as dPCR is increasingly being seen as a fit for purpose method for GMO analysis;
- Access to 25+ cross-trained staff at LGC as well as a recently refurbished and fully operational laboratory set-up for GMO analysis.

**Coordination within the UK of international activities:**

- All UK OCLs known personally and frequent communication augmented through APA Training Officer;
- On-site OCL visits have been conducted and be-spoke GMO training courses (DNA extraction, PCR assay design, DNA sequencing, and real-time PCR), on-site visits and provision of advice to all UK OCLs, inclusive of testing for Chinese GM rice;
- Laboratory tours and best-measurement practice advice on laboratory layout / instrumentation provided to OCLs;
- Maintain dedicated laboratory facility for GMO control materials, including electronic registration and monitoring of storage in accordance with ISO 9001:2015.

Communication of results and data use:

- Implemented a Confidentiality Disclosure Agreement with OCLs to allow provision and safekeeping of all EURL and international meeting reports.

LGC was appointed the GMO NRL position in 2009, receiving consistent and positive feedback from OCLs, the FSA, the EURL and other UK stakeholders. This proposal allows LGC to bring together a wealth of expertise, technical knowledge and hands-on functionality to continue to deliver continued and consistent coverage of the UK NRL position for GMOs in feed and food, to time, quality and budget, in the face of EU exit.

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

### OBJECTIVES

Please detail how your proposed work can assist the agency in meeting 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 | **SECRETARIAT SERVICES** |
| 2 | **ADVICE AND REPRESENTATION WITHIN THE UK AND INTERNATIONALLY** |
| 3 | **PRODUCTION OF STANDARD OPERATING PROCEDURES, CODES OF PRACTICE,** GUIDANCE DOCUMENTS AND **DATABASES** |
| 4 | COMPLIANCE ASSESSMENT VIA AUDITS, RING TRIALS AND PROVISION OF **REFERENCE** MATERIALS |
| 5 | **COORDINATION WITHIN THE UK OF INTERNATIONAL INITIATIVES** |
| 6 | **LIAISON AND SUPPORT WORK ON GMO FOOD/FEED AUTHORISATION** |
| 7 | **COMMUNICATION OF RESULTS AND DATA USE** |

## 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 is the Competent Authority for the purpose of retained Regulation (EU) 2017/625 on Official Feed and Food Controls in the UK. The UK has a legal obligation (through adopting the Official Food and Feed Controls Regulations 2009) to appoint NRLs.
The work of the National Reference Laboratories (NRLs) is guided by the programme of the respective EU Reference Laboratories (EURLs). NRLs are designated for the corresponding EURL work areas and post EU exit, it is anticipated the engagement with the EURL may continue on a Third Country basis, on invitation by the EURL. Core functions and duties of the appointed NRLs are based on Article 101 of the retained EC Regulation 2017/625.

The main functions and duties of the NRLs are to provide scientific and technical assistance to the Official Feed and Food Control Laboratories (OLs) and the Competent Authority (CA) and, where appropriate, liaise and cooperate with relevant international organisations. Other planned activities include:

- Participating in workshops and training courses organised by the EURL (where possible) or other relevant organisations;
- Evaluation and development of new methods;
- Participating in inter-laboratory comparison organised by the EURL (where possible) or other relevant organisations;
- Providing advice and expertise on standardisation of methods at CEN and ISO.

A laboratory appointed as a National Reference Laboratory should comply with the Competent Authority's requirements based on Article 101 and other relevant articles on laboratories in Regulation (EC) 2017/625, for its specific areas of responsibility. The Competent Authority may only designate laboratories as an NRL if they possess accreditation to EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories", in compliance with EN ISO/IEC 17011:2004 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

LGC has accumulated extensive experience in delivering the statutory functions mentioned above which has equipped it with the skills necessary to continue to serve as the NRL for Genetically Modified Organisms (GMOs) in food and feed post EU transition, a position which it has retained since 2009. LGC has extensive internationally recognised quality management systems and fully conforms with the requested accreditation for EN ISO/IEC 17025:2017 in accordance with EN ISO/IEC 17011:2004.

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

Issues surrounding GMO analysis continue to evolve and develop in complexity, not only due to the ever increasing number of GMO varieties now in existence (particularly unauthorised varieties in the EU), but also due to the types of organisms now being genetically modified. Whilst there are a number of validated protocols available for identification of EU authorised GMOs, these no longer allow good coverage for all GMO varieties. The number of GMOs for food and feed use approved in the EU has increased dramatically over recent years. At the time of this tender application, there are 82 GMO events approved for placing on the market in the EU, 17 of which were authorised for use since 2019 and a further 4 are undergoing renewal for authorisation[4]. The situation is further compounded by the occurrence of unauthorised GM events, including GM papaya (approved for use in China), GM Basmati rice, and Genetically Modified Microorganisms (e.g. *Bacillus subtilis* for Vit B2 production), which have all appeared in recent RASFF's. The FDA has also approved GM AquaAdvantage® Salmon for use in the USA, which is likely to be the first GM animal to be in the food chain. The effort to maintain and update a large portfolio of methods and all related procedures is high and can only remain sustainable if smart and efficient solutions are found.
Furthermore, a recent ruling made by the European Court of Justice [5] stated that products of new (plant) breeding technologies and products of synthetic biology (i.e. gene edited products) should fall under pre-existing EU legislation for GMOs. Equally well, the issue of Genetically Modified Microorganisms (GMM) is likely to gather increased focus for the future. GMM are used in food fermentation products to produce food enzymes to increase the productivity of the resultant food, but the presence of GMM in any food product is considered non-compliant with the retained EU legislation. Both products of gene editing and GMM pose significant analytical challenges, as methods for their detection have not been approved or harmonised. In this era of GMOs produced through modern technologies, it is imperative that the UK remains at the forefront of the science through international collaboration with its partners via such means as expert meetings, training, workshops and working groups.
Following the end of the UK transition period from the EU on the 1st January 2021, the UK now has a duty of care to set and implement its own legislation for control purposes. The default position was to incorporate the pre-existing EU regulations into UK legislation on day one of the closure of the EU transition period. This "retained" legislation will hold the UK in good stead regarding controls in the short term, but these are unprecedented times which holds an element of uncertainty for the future direction of travel for UK GMO authorisations, controls and trade.

The ever evolving and dynamic environment with respect to GMO analysis, fueled in part by the increasing number of GM varieties and associated legislation, means that there is a direct requirement for an appropriately qualified laboratory to continue to act as a UK National Reference Laboratory for GMOs in food and feed, in order to continue to provide advice and technical assistance to the Competent Authority (FSA) as well as disseminate best measurement practice guidance and information to UK Official Control Laboratories.
LGC was appointed the NRL for GMOs in 2009 and has helped better equip OCLs for the ever evolving GMO analytical landscape, but more needs to be done in this area and continued and consistent support and advice needs to be given. The legislation and revised guidance for GMOs (e.g. for testing for Chinese GM rice varieties (EU Regulation 2011/884)) is evidence of this fact, where LGC was able to use the combined expertise of the NRL and Government Chemist functions to complement each other in providing best-measurement practice advice to OCLs as well as successfully resolving twelve samples for the potential presence of Chinese GM rice taken formally as part of the UK referee function. The provision of such a position will continue to ensure that the UK remains in a strategic position to rapidly respond to new and emerging GMO analytical issues within Europe and beyond.

LGC's exclusive placement as the only UK laboratory to consistently attend 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 current position as the UK National Reference Laboratory (NRL) for GMOs in food and feed under retained Regulation 2017/625, provide bespoke and unsurpassed UK skill sets in support of this proposal. 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; housing of

[4] *European Commission Community register of GM food and feed*

[5] *European Parliament Briefing (May 2018) on New plant-breeding techniques and applicability of GM rules. European Parliamentary Research Service, PE 582.018*

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 by the European Commission; ISO/IEC 17025:2017 accreditation for all GMO related activities inclusive of DNA extraction, quantitative real-time PCR (qPCR) and dPCR, supported through successful 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, provide a unique and solid foundation to continue to provide the GMO National Reference Laboratory services, now and in the future.

Other unique benefits that LGC affords to the **GMO NRL** position

LGCis uniquely positioned to deliver this project. Having acted as the UK National Reference Laboratory **(NRL) for GMOs** in **food and feed** since the establishment of the position in 2009, LGC has excellent relations with all UK based Official Control Laboratories, remaining aware of the technological capabilities of these and being in constant communication with these. 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 becoming more involved in GMO analysis and training with LGC going forward.

In terms of **external quality assessment exercises** associated with GMO activities, LGC has successfully participated in 58 of these since 2000, being a mixture of both EURL Comparative Tests and GeMMA proficiency test rounds. In all 58 proficiency test rounds, LGC has received satisfactory (z<[2)) scores based on all 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, LGC regularly participates in international metrology studies as part of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM).
The mission of the CCQM includes responsibility for developing, improving and documenting the equivalence of national standards (certified reference materials and reference methods) for chemical and biological measurements, to establish global comparability of measurement results through promoting traceability to the international system of units (SI) and other internationally agreed references, and to contribute to the establishment of a globally recognized system of national measurement standards, methods and facilities for chemical and biological measurements. Five 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 above and beyond any other UK laboratory, 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. In relation to this and the currently uncertain impact on UK science as a result of EU exit, 21 ENGL and NRL laboratories have written personally to Dr. Malcolm Burns (LGC) to express their firm support in wishing to continue GMO related activities with the current UK NRL, irrespective of the final outcome of UK inclusion in official EURL activities. These expert laboratories represent 12 countries from Slovakia, Czech Republic, Netherlands, Poland, Austria, Italy, Slovenia, Sweden, Germany, Denmark, Luxembourg and Belgium.

[redacted]

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 meets 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.

Based on current knowledge of the GMO area, it is the current expectation that a number of future GMO related detection methods proposed by applicants will be based on digital PCR (dPCR). Being aware that digital PCR (dPCR) applications for GMO authorisations are becoming increasingly more common in the future, LGC has already participated in the **first two EU dPCR GMO authorisations** based on the ENGL Minimum Performance Requirements (MPR) guidance document (2015) 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 new EU Working Group set to provide published guidance on the minimum performance requirements for dPCR and detection of products of gene editing GM animals, due to provide guidance in this topical area in the near future.
Equally well, **genetically modified microbes (GMM)** and **products of gene editing (GE)** are beginning to gain additional traction as evidenced by recent RASFFs, 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 in 2019) fully equipped with all modern pieces of equipment including a range of qPCR and dPCR machines, manual and automated DNA extraction instruments and techniques, all of which are instrumental in developing and maintaining analytical capabilities for GMO detection and quantitation. Our 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 GMO analytical requirements as part of this proposal.
As part of the current GMO NRL position for **storage of control materials**, LGC houses multiple dedicated secure walk-in cold room facilities, 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 intra- and inter-laboratory trials), will be used to help ensure reference and control samples are continually kept safely and appropriately.

**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**

**Scope of Services and duties to be provided to the FSA based on the NRL GMO Functions (as stipulated on page 5 of Tender Specification FS616029)**

**a) Co-operate internationally in their area of competence, including collaborating and participating in inter-laboratory comparative tests organised by international laboratories (where appropriate);**

Wherever feasible, LGC will continue to work with the EURL for GMOs in food and feed as it has done so since its appointment as UK NRL for GMOs in food and feed in 2009. Examples of the key contributions that LGC has made are given below:

LGC has supported the ENGL (European Network of GMO Laboratories) since its inauguration in Brussels on December 4th 2002. ENGL is an fundamental part of the GMO analytical forum, and is underpinned by EU Regulation 1981/2006 as an integral part in assisting the EURL in terms of method validation as part of the authorisation procedure for GMOs in the EU. LGC has provided continuous and consistent attendance and has participated in all 31 ENGL plenary meetings (the only UK laboratory to do so). Where feasible, LGC proposes to continue NRL attendance at such meetings in order to support UK policy on GMOs based on best available scientific knowledge. In recognition of LGC's input and impact at ENGL related meetings, and following consultation with the FSA and ENGL laboratories in the UK, Dr. Malcolm Burns (LGC) was nominated as the UK representative on ENGL Steering

Committee meetings in November 2015. LGC has also attended all 16 NRL workshops (National Reference Laboratories appointed under EU Regulation 2017/625) which have been organised by the EU-RL.
LGC has provided meeting and workshop reports to the FSA within the 10 working days deadline for all meetings attended under the NRL position, as stipulated for this tender. Furthermore, LGC has taken steps to ensure effective dissemination of ENGL matters to relevant UK OCLS whilst still maintaining the appropriate confidentiality associated with ENGL meetings. This has been facilitated by LGC constructing and implementing a Confidentiality Disclosure Agreement for UK OCLs on behalf of ENGL to ensure that proprietary information discussed at ENGL is not circulated beyond UK OCLs.
With respect to international comparative tests as interpreted by the EU Reference Laboratory for GMOs in food and feed (EURL GMFF), and pursuant to EC Regulation 2017/625, the EURL GMFF has the obligation to organise testing rounds and to ensure an appropriate follow-up of the results obtained. These consist of international based proficiency test schemes. The EURL Comparative Tests are interpreted by the EURL as the most objective evaluation that a laboratory is fit for purpose as a NRL (appointed under 2017/625), and they consider it mandatory for NRLs to participate in them. LGC has ISO/IEC 17025:2017 flexible scope for accreditation for GMO analysis as appointed by UKAS. To date, 21 NRL Comparative Tests have been organised. LGC has successfully participated in all of these, quantitatively analysing 42 different samples for the presence of 29 different GMO events and receiving 67 Z-scores in total across the 21 test rounds. All of these Z-scores have been <[2], which is the key quality criterion for showing the fitness for purpose of a laboratory as part of any external quality assessment exercise. The effectiveness of LGC's expertise and proficiency in the determination of GMOs is highlighted by the 5$^{th}$ EU-RL Comparative Test in which more than 58% of the 32 participating laboratories received an unsatisfactory Z-score for one of the tests.

The EURL and ENGL frequently organise Working Groups whose function is to help address current and future GMO analytical issues that are of immediate importance and are of high priority. LGC has been a member of a number of these including "Measurement Uncertainty Estimates for GMO laboratories", "Method verification for GMO testing laboratories", "Method selection and validation", "ENGL Working Group on Digital PCR" and "ENGL Procedures". Currently, **LGC is the only UK laboratory to participate in ENGL working groups**, and is a member of all of these working groups addressing DNA extraction, next generation sequencing, detecting products of gene editing, detection of genetically modified microorganisms, detection of GM animals, and the revision of the minimum performance requirements document. These Working Groups have resulted in a number of publications, of which

LGC is a named author ([6],[7],[8],[9]). It is recommended that LGC continue to participate in future working groups to help ensure that the relevant UK 'reference' methods are generated and are considered as fit for purpose.

LGC's core input into these scientific working groups has been acknowledged to such an extent that the European Commission wrote to Dr. Burns in January 2021, acknowledging him 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/UK for future UK interaction with EU scientific activities. 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.

In December 2020, the European Commission has informed all EURLs that official UK laboratories cannot participate in EURL activities as of 1st January 2021. The uncertainties revolving around this are yet to dissipate despite a trade deal now being agreed between the EU and the UK. However, this tender application encompasses a unique position held by Dr. Burns at LGC and the European Network of GMO Laboratories (ENGL). The ENGL is referred to in the legislation as helping advice the EURL in its duties for GMO controls, and as such is independent of the EURL and governed by an ENGL consortium agreement. As part of the agreement and in certain circumstances, ENGL internal procedures allow recognized independent scientific experts to continue to participate in ENGL activities, inclusive of workshops, training, meetings and working groups. Dr. Burns is an active member of all current ENGL working groups, being an official Task Leader with respect to some of the initiatives, encompassing leading small task groups associated with the provision of specific scientific guidance. This is inclusive of working groups on digital PCR, DNA extraction, Next Generation Sequencing, gene editing, genetically modified microbes, and the revised minimum performance requirements guidance) and Dr. Burns has already been granted special status and asked to continue in this stead for the future. No other UK laboratory is part of these working groups or has been awarded such special status. This unique situation afforded by this tender will continue to provide guaranteed information exchange with

[6] JRC Scientific and Technical Reports (2011) "Verification of analytical methods for GMO testing when implementing interlaboratory validated methods" Guidance document from the European Network of GMO laboratories (ENGL) Prepared by the ENGL working group on "Method Verification". ISBN 978-92-79-19925-7 doi: 10.2788/88038 http://gmo-crl.jrc.ec.europa.eu/doc/ENGL%20MV%20WG%20Report%20July%202011.pdf

[7] Trapmann, S., Burns, M., Corbisier, P., Gatto, F., Robouch, P., Sowa, S., and Emons, H., (2020) "Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition" European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565S

[8] Pecoraro S., Berben G., Burns M., Corbisier P., De Giacomo M., De Loose M., Dagand E., Dobnik D., Eriksson R., Holst-Jensen A., Kagkli D. M., Kreysa J., Lievens A., Mäde D., Mazzara M., Paternò A., Peterseil V., Savini C., Sovová T., Sowa S., Spilsberg B. *Overview and recommendations for the application of digital PCR.* EUR 29673 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-00180-5, doi:10.2760/192883, JRC 115736

[9] European Network of GMO Laboratories (ENGL) "Detection of food and feed plant products obtained by new mutagenesis techniques" 26 March 2019 (JRC16289)

international partners as well as providing insight into new GMO technologies and guidance, as part of the NRL tender.

Page 4 of Project Specifications document FS616029 states that the NRL GMO will provide support to the UK official control laboratories for GMO control and will be required to identify and participate as an independent expert at international GMO meetings and networks to build expertise and knowledge in the area. **The qualification of Dr. Burns as an acknowledged scientific expert to continue to attend and contribute to these EC/ENGL Working Groups has since be reaffirmed by the ENGL on 13th January 2021.**

Furthermore, a number of EU based ENGL labs and NRLs (2017/625) has written to Dr. Burns, expressing their desire and support to continue to interact on the international front for all GMO (and food authenticity) related matters, expressing their loss at this key UK based member. These continued collaborative opportunities and information exchange and potential for involvement in independent EU based GMO initiatives are not impacted upon by the trade agreement between the EU and the UK. In total, 21 ENGL and NRL laboratories have written to Dr. Burns to express their firm support in continuing GMO related activities, representing laboratories in Slovakia, Czech Republic, Netherlands, Poland, Austria, Italy, Slovenia, Sweden, Germany, Denmark, Luxembourg and Belgium.
In addition, Dr. Burns and LGC as the current NRL for GMOs, are well known to and part of other selected international networks aimed at developing best measurement practice guidance for GMO analysis, This includes, but is not limited to:

- Plant Ed COST Action - This European Cooperation in Science and Technology (COST) Action brings together expertise from a range of disciplines to evaluate plant genome editing techniques and their resulting products from various perspectives. The findings help serve to design roadmaps for directing and facilitating applications of genome editing in plant research and breeding, which in turn help setting R&D priorities and stimulate further cross-national and cross-disciplinary collaborations;
- The N8 Research Partnership (AgriFood) – LGC contributes towards GMO related activities as part the collaboration of the eight most research intensive Universities in the North of England: Durham, Lancaster, Leeds, Liverpool, Manchester, Newcastle, Sheffield and York. GMOs and gene editing;
- Network of GMO Testing Laboratories (NGTL) of India – LGC is in contact with the Head of the Indian Council of Agricultural Research (ICAR) at the National Bureau of Plant Genetic Resources in India. The ICAR are involved in the management and promotion of the sustainable use of plant genetic and genomic resources for crop species, and carry out related research. Additionally the ICAR are involved in coordination and capacity building in plant genetic resource management and policy setting and provide molecular profiling of crop varieties and GM detection strategies in India;
- LGC has strong links with the GMO networks in the African region – these include the Southern African Network for GM Detection Laboratories (SANGL) consisting of 13 countries, and the Western Africa Network of GM Laboratories (WANGL) consisting of 16 countries.

**Continued interactions with international partners**
Page 4 of the Tender Specification FS616029 explicitly states that “The NRL GMO will . . .be required to identify and participate as an independent expert at international GMO meetings and networks to build expertise and knowledge in the area.” 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 augmented through LGC acting as the nominated UK representative on the ENGL Steering Committee (SC), which 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 scientific interaction still not be formally agreed post the UK/EU trade deal.

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. An example of one of the latest collaborative efforts resulted in the publication of the "*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, which LGC is an author on.

Furthermore, LGC has participated in the first ever international metrology key-comparison trial involving DNA and quantification of GMOs (Consultative Committee for Amount of Substance – Metrology in Chemistry [CCQM] K86) using plasmid and genomic calibrants. Z-scores for this trial were also all less than a magnitude of two. This key-comparison was as a result of participation in the international CCQM-P60 pilot study based on the quantitation of Genetically Modified (GM) material. This study showed that the accuracy of the estimated GM content of samples could be adversely affected by the choice of the DNA extraction procedure used to prepare the target template. Following on from this pilot study, Key Comparison CCQM-K86 was designed to test if the relative quantity of two genomic DNA fragments present in a biological sample could be accurately determined using real-time PCR, based on GM material as a model system. In parallel with this an additional CCQM-P113.1 pilot study was conducted to see if relative quantitation could also be achieved using digital PCR. Results of both CCQM-P60 and CCQM-K86 have been published in the peer reviewed literature (with LGC included as an author).

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.

**b) Co-ordinate, for their area of competence, the activities of OLs responsible for the analysis of official controls samples to ensure the verification of compliance with feed and food law;**

LGC has formerly discussed with the FSA the terms of reference with respect to "co-ordinate official laboratories" as part of the previous two GMO NRL appointments. For the avoidance of doubt, it was agreed and stated by both parties that this co-ordination was restricted to activities associated with the dissemination of information relating to the sampling and analysis of GMOs.

LGC started discussions with UK OCLs in 2009 regarding their capabilities for sampling and analysis of GMOs in feed and food. At that time and by their own admission, the majority of OCLs were ill equipped to undertake sampling and analysis of GMOs in feed and food and requested assistance from the UK NRL. In providing this much needed assistance, LGC was the first NRL to instigate laboratory visits to OCLs. To date, LGC has conducted multiple site visits to UK OCLs: Hampshire, Worcestershire, Kent, Somerset, and Edinburgh and thus is well versed in the capabilities of the UK OCLs. At each visit, Dr Malcolm Burns presented an overview of NRL activities and then devoted the rest of the visit to help the OCLs with their individual queries and concerns. The OCLs have been very appreciative of the opportunity to get a day of UK NRL time at their laboratory and have given LGC very positive feedback. It is proposed that LGC will continue to undertake such visits on a case by case basis as advised by the FSA.

In addition to the site visits, LGC takes OCL enquiries via telephone / E-mail. Throughout the duration of the position since 2009, the GMO NRL function at LGC has received and provide responses to **over 334 enquiries** regarding technical support and advice in relation to GMO sampling and analysis. Approximately half of these enquiries were from the FSA, one quarter from OCLs, and one quarter from other stakeholders (including the EURL and UK based ENGL laboratories). A summary of advice given and information disseminated is provided in Appendix 1. It is proposed that LGC will continue to take enquiries to assist OCLs as required.
LGC has close links with all of the UK OCLs and important stakeholders associated with GMO analysis, and will continue to provide updates and forward information from the EU-RL regarding recommendations for testing.

LGC has received feedback from PAs that although they value a dedicated web presence for NRL activities that they can interrogate at their leisure, they often don't have sufficient time to browse complex websites. To address this issue and make the activities of the NRL accessible to all in a succinct manner, it is proposed that the NRL newsletter continue to be issued to all OCLs and placed on the NRL webpage. Information on the following areas will be regularly summarised:

- Legislation updates
- Emerging issues
- Food and Feed recalls
- Information from EU-RL
- Advice given (anonymised)
- Meetings
- Work programmes
- Laboratory visits

Appendix 2 provides an example of the NRL webpages currently hosted on the LGC website.
The NRL webpages can be accessed through the LGC website, or directly at:
https://www.lgcgroup.com/what-we-do/national-laboratory-and-government-roles/national-laboratory-roles/national-reference-laboratories/
Appendix 3 provides an example of the NRL newsletter that is published and circulated to all OCLs.

Paul Hancock, Head of the Office of the Government Chemist and Referee Analyst, is the duly appointed Association of Public Analyst (APA) Training Officer and is responsible for organising training tailored to the needs of the APA. NRL representatives have frequent discussions with Paul and feed into the APA Training Committee (TC) of which Paul is a member, to elicit the APA's needs in relation to this NRL function. It is proposed that NRL updates continue to be given at two APA TC meetings a year. In addition, two APA TC members attend the six monthly meetings held at FSA headquarters to input their requirements into the NRL work programme.

**c) Where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;**

LGC's policy with respect to conducting comparative tests / studies / trials as the NRL has been on a 'need only' basis i.e.:

1. An existing PT scheme does not exist;
2. A measurement issue exists;
3. An interpretative issue exists;
4. An emerging issue has arisen.

The cost to the NRL function of running a PT scheme is likely to be in the order of £60k to £70k but will be dependent upon the availability of reference materials, samples, reagents and the complexity of the PT round in question. We propose that each PT round be discussed and agreed with the FSA prior to execution of these. As NRL funds are limited, it is LGC's belief that these should not be used unnecessarily on conducting comparative tests in areas where appropriate commercial PTs already exist. Where such schemes exist, OCLs are required to demonstrate competence via regular participation as part of their ISO/IEC 17025:2017 accreditation and quality management systems.
As part of its mandate for compliance with EU Regulation 2017/625, the EURL for GMOs in food and feed regularly organises two GMO comparative tests per year. These comparative tests provide an excellent measure of laboratory performance as part of a laboratory's external quality assessment exercise. Prior to the completion of the EU transition period, the EURL comparative tests were free to take part in by any UK OL, and LGC was always very supportive of UK OCL participation in such exercises and encouraged OCLs to do so, allowing much better use of valuable but restricted FSA funds. Unfortunately, all UK ENGL laboratories were notified on 18th December 2020 that the EC had advised that official participation of UK labs to all activities of the EURL will cease as of 1st January 2021. This situation is very fluid and has the potential to be reviewed depending on the outcome and impact of the trade deal agreed between the UK and EU.
Further options include both LGC and Fera who are provide regular proficiency test programmes. Fera provide the GeMMA proficiency test programme associated with GMO analysis. LGC Standards operate across 120 countries worldwide, as an authorised distributor and producer of reference materials accredited to ISO/IEC 17034;2016. LGC Standards supports a portfolio of 300,000+ reference materials and analytical standards. As the UK's designated institute for chemical and bio-measurement, LGC use 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 provide proficiency testing schemes accredited to ISO/IEC 17043:2010 which are used by more than 13,000 participant labs worldwide.
The NRL actively encourage all analytical laboratories to participate in these as part of a recognised external quality assessment exercise.

LGC does recognise that there are instances where commercial PTs do not exist for a particular target analyte. In such instances these will be examined on a case by case basis in discussion with the FSA, and with prior-agreement from the FSA these can be costed up individually and a review of current NRL funds made to examine the feasibility of running such PT schemes.

**d) Ensure the dissemination of any information required by the CA;**

A summary of advice given and information disseminated is provided in Appendix 1. In addition, Appendix 2 provides an example of the current NRL webpages illustrating the current content and functionality, and Appendix 3 provides an example of the NRL newsletter currently in circulation.
In terms of publication of GMO related advice and peer reviewed papers, the NRL contributes towards this on a regular basis. LGC and the NRL function has provided in excess of 35 articles, peer reviewed papers and EU/UK guidance notes related to GMOs. One of the latest relevant publications was the EC's third edition of the "*Guidance document on Measurement Uncertainty for GMO Testing Laboratories*"[10]. This pivotal publication demonstrates LGC's commitment and good relationship to continue working closely with the European Commission for setting best practice guidance for GMO sampling and analysis. Appendix 4 provides further examples of some of these publications.

As part of the current NRL position, Dr Malcolm Burns (LGC) is in constant contact with the FSA project officers regarding the NRL function, and advice and updates are regularly provided over the phone, via E-mails and by face-to-face meetings as the situation dictates. LGC is also available for provision of advice on GMO analysis to all OCLs by E-mail and phone. Furthermore, NRL summary reports on all ENGL plenary meetings that the UK NRL attends are supplied to all OCLs and the NRL is fully contactable in order to provide additional details on each meeting as is necessary. Full meeting reports for the ENGL plenary and NRL annual meetings have been provided to the FSA. In addition, bi-annual review meetings are held with the FSA where the NRL work programme is reviewed and discussed.

**e) Provide scientific and technical assistance to the CA, especially for the implementation of Multi Annual National Control Plans;**

During the last twelve years of execution of the GMO NRL position, there have been no requests received from the FSA to help assist the Competent Authority to implement coordinated control plans in relation to GMOs (e.g. National coordinated risk-based food and feed sampling programme 2012-13: Unauthorised GM events as referred to in Regulation (EU) 619/2011 Article 2). However, LGC remains ready to help assist the FSA with respect to coordinated control plans, and will cost these up in discussions with the FSA on a case-by-case basis. Such control plans would also require consultation with UK OCLs who currently have real-time PCR capability. The NRL would render scientific and technical assistance to the FSA in terms of advice on experimental design, number of replicates, implementation of randomisation, blinding of samples, instrument comparisons, and to help towards organising the control plan. If this activity is not called upon then the funds will be diverted to help augment other NRL activities that are considered a priority in relation to the current work programme, in agreement with the FSA.

The European Commission Food and Veterinary Office (FVO), responsible for ensuring that EC legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced, audited the UK during September 2014 in relation to the UK's compliance with the relevant EU legislation on GMO regulations. The FVO team concluded that a comprehensive authorisation and control system of GMO field trials was in place, and also reported that the NRL (LGC) was using methods and evaluating results in line with the relevant EU legislation. In their audit report, the FVO concluded that the NRL was adequately staffed and equipped to perform GMO analysis and procedures were in place to monitor the competence of official control laboratories. Following their visit to the NRL, the FVO audit team reported that the NRL met all of the requirements of Article 33 of Regulation (EC) No 882/2004 (now replaced with 2017/625) and the relevant international standards.
The official FVO audit report for the UK's implementation of a system of official controls for GMOs commented that not all OCL's were implementing EU Regulation 619/2011 for the low level presence of unauthorised GMOs in feed. The FSA response included ensuring that all OCLs were aware that accredited, quantitative event-specific methods are necessary to fully implement the regulation. Both the FSA and LGC have been working hard together in order to seek a harmonised way that 619/2011 can be implemented through provision of the appropriate guidance.

[10] Trapmann, S., Burns, M., Corbisier, P., Gatto, F., Robouch, P., Sowa, S., and Emons, H., (2020) "Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition" European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565S

**f) Participate in relevant national and international networks, workshops and training courses and, where necessary, conduct training courses for the staff of OLs;**

LGC, as the NRL for GMOs in food and feed, is currently part of a number of international networks inclusive of the European Network of GMO Laboratories (attendance at the workshops of which Dr. Burns has been confirmed as an independent scientific expert), as well as the Plant Ed COST Action, input into the N8 Research Partnership (AgriFood), the Network of GMO Testing Laboratories (NGTL) of India, the Southern African Network for GM Detection Laboratories (SANGL), and the Western Africa Network of GM Laboratories (WANGL).
LGC is a member of the majority of past and all present ENGL Working Groups, including "Measurement Uncertainty Estimates for GMO laboratories", "Method verification for GMO testing laboratories", "Method selection and validation", "ENGL Working Group on Digital PCR" and "ENGL Procedures". Currently, LGC is the only UK laboratory to participate in ENGL working groups, and is a member of all of these working groups addressing DNA extraction, Next Generation Sequencing, detecting products of gene editing, detection of genetically modified microorganisms, detection of GM animals, and the revision of the minimum performance requirements document (MPR2). These Working Groups have resulted in a number of publications, of which LGC is a named author ([11],[12],[13],[14]). It is recommended that LGC continue to participate in all future working groups to help ensure relevant horizon scanning and access to up to date information and strategies.

Following on directly from OCL feedback and after seeking agreement from the FSA, LGC has run a number of bespoke training courses for Public Analysts. An example of a two day training course for GMO analysis using real-time PCR is given below, which consisted of a tailored series of presentations, practical laboratory work, data interpretation and question and answer exercises Training courses were held for delegates from Edinburgh and Tayside Scientific Services (Figure 1).

**Figure 1. Example itinerary from the Real-time PCR analysis of GMOs training course run by LGC as the NRL**

[11] JRC Scientific and Technical Reports (2011) "Verification of analytical methods for GMO testing when implementing interlaboratory validated methods" Guidance document from the European Network of GMO laboratories (ENGL) Prepared by the ENGL working group on "Method Verification". ISBN 978-92-79-19925-7 doi: 10.2788/88038 http://gmo-crl.jrc.ec.europa.eu/doc/ENGL%20MV%20WG%20Report%20July%202011.pdf

[12] Trapmann, S., Burns, M., Corbisier, P., Gatto, F., Robouch, P., Sowa, S., and Emons, H., (2020) "Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition" European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565S

[13] Pecoraro S., Berben G., Burns M., Corbisier P., De Giacomo M., De Loose M., Dagand E., Dobnik D., Eriksson R., Holst-Jensen A., Kagkli D. M., Kreysa J., Lievens A., Mäde D., Mazzara M., Paternò A., Peterseil V., Savini C., Sovová T., Sowa S., Spilsberg B. *Overview and recommendations for the application of digital PCR.* EUR 29673 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-00180-5, doi:10.2760/192883, JRC 115736

[14] European Network of GMO Laboratories (ENGL) "Detection of food and feed plant products obtained by new mutagenesis techniques" 26 March 2019 (JRC16289)

Extremely positive feedbackfor these courses was sent to LGC and the FSA from the participants, including "/ *found the course very informative and very* easy *to understand, which* was *quite a refreshing changefrom previous*courses *I have attended at other companies". "The course provided a very useful, relevant insight in to what should be recorded and implemented for the real-time PCR and* as *a beginner in this field I found* LGC's *course* was *ideal for what I* was *looking for."*
LGC proposes to continue to hold more of these training exercises for Public Analyst laboratories in the future as part of the NRL role. Further to the official GMO analysis training courses designed and held at LGC above, LGC has also hosted one day training visits from Hampshire Scientific Services including presentations on DNA, real-time PCR and a tour of lab facilities, in direct response to a request for assistance in GMO analyses.

With respect to knowledge and expertise in best practice for laboratory design and advice on laboratory instrumentation, LGC has provided in-depth advice and conducted be-spokelaboratory tours and site visits for Public Analysts regarding draft molecular-biology laboratory plans in order to minimise contamination and maximize efficiency. LGC has regularly arranged visits from OCL's to tour the recently refurbished National Measurement Laboratory (NML) facility and to provide adviceon what real-time PCR instruments were available.

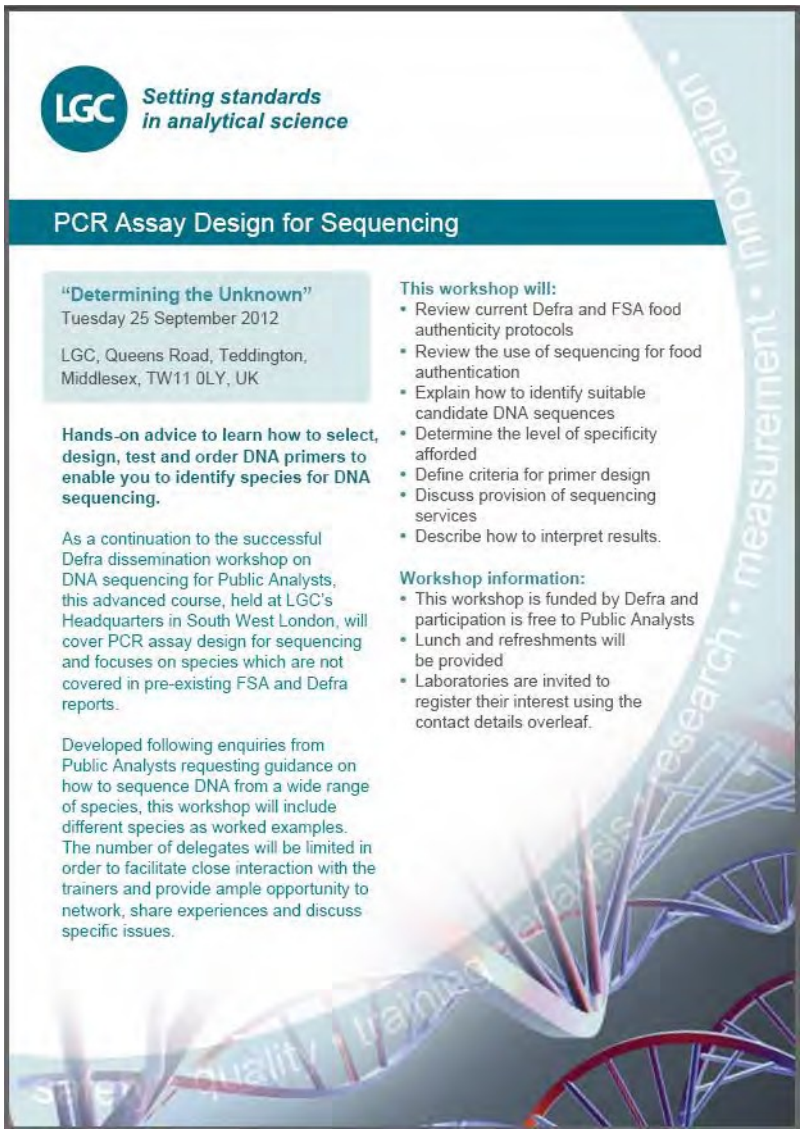
LGC also has direct hands-on experience of designing and running large training courses. LGC has further demonstrated its expertise and continued support in relation to analytical issues typically encountered by PAs by running regular training courses and providing e-seminars as part of combined GC/FSA/Defra/FSS funding, on a variety of GMO and nucleic acid related subjects, as shown in Table 1 below:

| Trainin /dissemination event | Format | Year |
|---|---|---|
| Defra DNA sequencing training course | Worksho | 2011 |
| PCR Assay Design for Sequencing | Worksho | 2012 |
| The use of real-time PCR for meat species identification and the determination of asta adulteration | Workshop | 2013 |
| Interactive worksho for detection of Chinese GM rice | Worksho | 2014 |
| DNA extraction approaches to supportfood labelling enforcement | Workshop | 2014 |
| The application of real-time PCR for food authenticity testin inclusive of the uantitation of **E** uine DNA | Workshop | 2015 |
| An introduction to designing quantitative PCR assays | e-seminar | 2018 |

| | | |
|---|---|---|
| An introduction to the digital polymerase chain reaction | e-seminar | 2018 |
| An introduction to quantitative PCR assay optimisation | e-seminar | 2019 |
| Using service providers to undertake next generation sequencing analysis | e-seminar | 2019 |
| DNA melting curve analysis | e-seminar | 2019 |
| Fish speciation inclusive of the Labelfish project | e-seminar | 2020 |
| An introduction to quantitative PCR assay validation | e-seminar | 2020 |
| Food allergens risk assessment, Part 1 | e-seminar | Approved for upload 2021 |
| An introduction to GMO detection | e-seminar | Approved for upload 2021 |

**Table 1. Table to illustrates the different training courses and e-seminars organised by LGC to help disseminate best measurement practice in the field of real-time PCR, nucleic acid research and GMO analysis**

**Figure 2. Example OCL training courses and course content provided by LGC.**




The subject of DNA extraction is a fundamental upstream process prior to conducting analysis of GMOs, which is instrumental in providing purified DNA that can be analysed with confidence. Equally well, PCR and real-time PCR provide the foundations for conducting routine GMO analyses, and DNA sequencing is also becoming more common for unequivocal identification of the actual GM variety. All of the above training courses, developed and ran by members of LGC's NRL and NML teams, have provided a firm infrastructure for OCLs to help develop and maintain their core molecular biology skill set for GMO analysis.

LGC proposes holding one bespoke training exercise/ scientific study for Public Analyst laboratories per year, with prior approval from the FSA. The subject matter will be agreed with the OCLs and FSA on an annual basis. If this activity is not required in any one year, then, in consultation with the FSA, the associated funds will be reallocated to another core service.

In relation to continual development and learning for GMO related expertise, LGC has attended, contributed and provided presentations for the following workshops and training courses, largely organised by the EURL and the ENGL:

| Workshop title | Year |
|---|---|
| GMO quantification: proper calibration and estimation of measurement uncertaintv | 2013 (Belgium) |
| diaital PCR trainina workshoo | 2014 ItaM |
| New technoloaies: diaital PCR and NGS | 2015 {Slovenia) |
| ENGL procedures | 2016 (Italy) |
| Practical aoolications of diaital PCR | 2017 (Slovenia) |
| GMO Screenina workshop | 2018 (Beloium) |
| dPCR accreditation for GMO analysis | 2019 (Belgium) |
| Workshop for measurement uncertainty evaluation for laboratories involved in testino for GMOs | 2020 (Belgium) virtual event |

All UK OCLs were contacted to make them aware of the publication and the dissemination of advice from LGC as part of the above workshops and training courses.

Additionally, in June 2017, Malcom Burns helped develop, organise, co-chair, present and deliver a DNA extraction workshopwith the EU Reference Laboratory (EURL) for GMOs in feed and food. This three-day EURULGC workshop was held at the Joint Research Centre (JRC) in Ispra (Italy) in June, and was attended by over 30 experts representing 19 EU member states and other countries as far afield as Mexico, Ecuador and Brazil.
The workshop was designed to capitalise upon the shared knowledge and collective expertise and experiences of scientists working in the topical area of extracting DNA from challenging matrices. As well as co-chairing sessions on the other days, Malcolm chaired the interactive session on the second day. Feedbackfrom the workshopincluded how positive the interactive session was led by LGC using an innovative new format. The workshop has resulted in a guidance document being written, detailing issues commonly encountered when extracting DNA from food and feed samples, as well as associated potential solutions for these issues. This guidance document will be made available as an aid to providing best measurement practice advice in the area.

**Agenda of the DNA extraction workshop organised by the EURL and LGC, and the participants representing over 20 different countries**.

**g) Upon request by the appropriate authority, actively assist in relevant foodborne incident and outbreak situations, should be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations and in cases of non-compliance of consignments, by carrying out confirmatory analysis;**

For any emergency situation regarding GMO analysis, LGC has direct access to the necessary laboratory based analytical equipment to help the CA in resolving these. An example of LGC's capability, competency and experience in responding to emergency situations was demonstrated during the 2013 EU/UK horse-meat crisis. In response to this, LGC worked closely with the FSA and Defra to develop, optimise and fully validate a real-time PCR method for the relative quantitation of horse DNA in raw meat peat products. This method was based on exactly the same approach and rationale used for development of methods for GMO detection and quantitation, providing further evidence of LGC expertise in this area. The method is now being considered for international standardisation through the relevant CEN committee.
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.
Furthermore, LGC is a recognised expert in providing leading analytical advice on experimental design, estimation of measurement uncertainty, method validation and design and organisation on intra- and inter- laboratory trials, as qualified by the number of commercial training courses it offers on these subjects and peer reviewed publications on these. All of this knowledge, held collectively under one roof, will be brought to bear via the NRL function to help the CA in relation to resolving any GMO emergency situations.

Regarding confirmatory analysis on non-compliant consignments of food/feed in the UK, this route is currently governed by the UK Referee function at LGC as part of the Government Chemist role. This role, underpinned by several Acts of UK Parliament, empowers the Government Chemist role to act as an independent and impartial referee analyst when there is a dispute between a Food Business Operator (FBO) and an enforcement laboratory (e.g. UK OCL) over the nature or provenance of a sample (usually food).
The Government Chemist role was originally created to help in the protection of the public from fraud, malpractice and harm. In 1875, the laboratory was appointed as "referee analyst", a role linked to the Sale of Food and Drugs Act of that year. The role continues to this day, fulfilling statutory and advisory functions, which are funded by the Department for Business, Energy and Industrial Strategy (BEIS). The Government Chemist uses up-to-date and authoritative measurement procedures coupled with experienced interpretative skills to act as a fair and independent arbiter to resolve disputes. In doing so we protect consumers, provide a route of technical appeal for businesses and contribute to regulatory enforcement in sectors where chemical and bio-measurements are important.
LGC therefore has unparalleled knowledge and experience of running this in the UK and is thus very well prepared to assist the FSA in relation to this. Indeed, one the most common types of referee cases submitted to the Government Chemist are samples where a dispute has arisen regarding the possible presence of Chinese GM rice. LGC has successfully resolved disputes over twelve samples regarding this, so is well versed in complex GMO analyses as well as how to handle and resolve such disputes.

Cases will be dealt with on an individual basis when referred to the NRL by the appropriate authority. LGC will discuss with the FSA the most appropriate course of action and where the NRL can provide the most value added assistance, prior to the commencement of any work as part of contributing to resolving emergency situations. This is particularly so should LGC be asked to carry out confirmatory analysis as a result of potential non-compliance findings, a role currently governed by the UK referee analyst function as part of the Government Chemist position.

**h) Carry out research, evaluation and development of new and existing methods for the analysis of UK regulated and officially monitored foods and feed and emerging new risks to UK food safety;**

LGC has a track record of carrying out research, development, optimisation and method validation for a range of molecular biology based analytical methods, inclusive of meat speciation/quantitation and also GMO detection.
LGC regularly participates in method validation trials organised by the EURL GMFF, hence is well versed in the procedure for generating objective evidence for the fitness for purpose of a GMO analytical method based on the assessment of relevant performance characteristics. LGC possesses ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis, following the published ENGL guidance document "*Verification of analytical methods for GMO testing when implementing interlaboratory validated methods*" (2017) in relation to incorporating new GMO methods within the scope of accreditation. Additionally, LGC contributed towards the development of the published ENGL guidance document "*Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing*" (2015) and is part of the new EC method verification working group who will publish the "*Definition of*

*minimum performance requirements for analytical methods of GMO testing – Part 2*" (2021), aimed providing at best measurement practice guidance for the detection of gene edited products, detection of GM animals and the use of dPCR.
This is further augmented through LGC's participation and performance in GMO related proficiency test (PT) schemes. In total, LGC has participated in 58 PT rounds associated with GMO analysis (21 EURL Comparative Tests and 37 GeMMA PT rounds), analysing 95 separate GM events and receiving the best possible Z-scores in every case (Z<[2]). This provides further evidence of LGC's capability to correctly use and evaluate methods for GMO analysis.
With respect to capacity to develop and validate methods, LGC's extensive laboratory set-up, which operates to ISO 9001 certification, has been referred to in (g) above. Briefly, laboratory capability and capacity is maintained within the National Measurement Laboratory (NML) facility on-site at Teddington, which is a recently refurbished laboratory facility (opened in 2019) fully equipped with all modern pieces of equipment including a range of qPCR and dPCR machines, manual and automated DNA extraction instruments and techniques, all of which are instrumental in developing and maintaining analytical capabilities' for GMO detection and quantitation. 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 GMO analytical requirements as part of this proposal.
LGC also boasts an extensive publication list regarding research, development and validation of methods for detection of GMOs [15] [16] [17] [18] [19]
Additionally, LGC has in-depth knowledge and experience of developing analytical methods from the ground up for consideration as international standards. This has been demonstrated with the real-time PCR method for the relative

[15] European Network of GMO Laboratories (ENGL) "Detection of food and feed plant products obtained by new mutagenesis techniques" 26 March 2019 (JRC16289)

[16] Timothy Wilkes, Gavin Nixon and Malcolm Burns (2016) "Recent Developments in DNA-based Screening Approaches for Detection of GMO's" Journal of Association of Public Analysts (Online) 2016, Volume 44, pages 40-50.

[17] Eloise Busby and Malcolm Burns (2014) "A Simple DNA-Based Screening Approach for the Detection of Crop Species in Processed Food Materials" Journal of the Association of Public Analysts 2014 (42): 035-060
http://www.apajournal.org.uk/2014_0034-0060.pdf

[18] Malcolm Burns, Gavin Nixon, Michael Walker, Eloise Busby (2013) "Development of an in-house Plasmid Control for Cauliflower Mosaic Virus (CaMV) for the Detection of Genetically Modified (GM) Chinese Rice Lines" Journal of the Association of Public Analysts (Online) 2013 (41) 45-52

http://www.apajournal.org.uk./html/japa_vol_41_pg45-52.html

[19] Trapmann, S., Burns, M., Corbisier, P., Gatto, F., Robouch, P., Sowa, S., and Emons, H., (2020) "Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition" European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565

quantitation of horse DNA in raw meat peat products. This was in response to the 2013 UK/EU horse meat scandal, where LGC fully developed, optimised, and validated a novel method for quantitation of horse DNA through a series of Defra and FSA funded projects. This method was based on exactly the same approach and rationale used for development of methods for GMO detection and quantitation, providing further evidence of LGC expertise in this area. The method I snow being considered for international standardisation through the relevant CEN committee [20] [21] [22].

**i) Provide advice and expertise on standardisation of methods at CEN and ISO;**

LGC staff are highly experienced at serving on national and international committees, inputting into, and influencing, the development of new legislation, standards and policy to ensure that measurement issues are considered adequately. A list of committees that Government Chemist staff serve on is available on the GC website (inclusive of the CEN Food Authenticity Coordination Group (FACG) and CEN TC 460 – Food Authenticity Technical Committee): ( https://www.gov.uk/government/organisations/government-chemist/about/membership ).

Many of our staff are considered leading experts in their field and are often invited to contribute to international standardisation efforts, for example, at the end of last year, when the UK was notified that its experts could no longer participate in European Commission expert committees, Dr Malcolm Burns was invited by the European Network of GMO Laboratories (ENGL), in recognition of his expertise and contributions to date, to continue to participate as an individual expert. Selvarani Elahi has been part of the UK delegation for the Codex Committee on Methods of Analysis and Sampling (CCMAS) for over ten years. In 2020, FSA and Defra put in place arrangements for LGC to support the standardisation of two UK methods (developed by LGC): determination of horse DNA in beef and detection of previously frozen chicken by determining the HADH content, by the European standardisation committee, CEN.
Also in 2020, two LGC staff were appointed as Eurachem Chair and Eurachem Secretariat. Eurachem is a network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices.
As a National Measurement Laboratory, LGC represents UK interests for its designation of chemical and biological measuremenst as part of the global network of national metrology institutes that make up the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA). The CIPM MRA provides the framework through which National Institutes demonstrate the international equivalence of their Calibration and Measurement Capabilities (CMCs), so that a global infrastructure of equivalence is in place. In real terms this ensures that the results of a medicines testing lab in the UK is the same as that in Korea or the USA. The CIPM MRA requires that three fundamental elements are in place in order for the NML's CMCs to be approved:
1. The NML must participate in reviewed and approved scientific comparisons (known as Key Comparisons)

[20] Burns M, Nixon C, Cowen S, Wilkes T., "International Collaborative Trial of a Real-time PCR Approach for the Relative Quantitation of Horse DNA". Food Nutr OA. 2018 Dec;1(3):113. 10.31021/fnoa.20181113

[21] Arulandhu AJ, Staats M, Hagelaar R, Voorhuijzen MM, Prins TW, Scholtens I, Costessi A, Duijsings D, Rechenmann F, Gaspar FB, Barreto Crespo MT, Holst-Jensen A, Birck M, Burns M, Haynes E, Hochegger R, Klingl A, Lundberg L, Natale C, Niekamp H, Perri E, Barbante A, Rosec JP, Seyfarth R, Sovová T, Van Moorleghem C, van Ruth S, Peelen T, Kok E., (2017) "Development and validation of a multi-locus DNA metabarcoding method to identify endangered species in complex samples" GigaScience, 6, 2017: 1-18. DOI: 10.1093/gigascience/gix080

[22] Gavin J Nixon, Timothy M Wilkes and Malcolm J Burns (2015) "Development of a real-time PCR approach for the relative quantitation of horse DNA" Analytical Methods (2015) 7, 8590-8596. DOI: 10.1039/c5ay01867f

2. The NML must operate a quality management system in accordance with ISO/IEC 17025 and ISO 17034 (for producing or assigning values to reference materials)
3. The NML's CMCs must undergo international peer-review by EURAMET (the Regional Metrology Organisation for Europe) and CCQM (the CIPM's inter-regional committee responsible for the field of chemical and biological metrology). NML staff are active participants in CCQM Working Groups e.g. Chairperson for the Working Group on Nucleic Acid Analysis) and frequently lead CCQM inter-laboratory comparisons.

**j) Obtain and maintain accreditation for official reference and other relevant regulatory methods for food and feed within the NRL area of competence;**

Page 3 of the Tender Specifications document FS616029 explicitly states that the Agency may only designate laboratories as an NRL if they are accredited with EN ISO/IEC 17025:2017 on the "General requirements for the competence of testing and calibration laboratories"; in accordance with EN ISO/IEC 17011:2017 on "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies".
The specifications state that the applicant is required to operate in accordance with the standard EN ISO/IEC 17025 and be accredited in accordance with that standard by a national accreditation body operating in accordance with retained Regulation (EC) No 765/2008.

The scope of the accreditation must cover the following:

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

LGC possesses and maintains ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis, and was one of the first laboratories in the UK to acquire this. The scope of accreditation includes all operational aspects associated with GMO analysis, inclusive of DNA extraction, DNA quantitation, real-time PCR operation, data analysis, data interpretation, expression of results with associated measurement uncertainty estimates, and the reporting of results.
As LGC possess ISO/IEC 17025:2017 flexible scope of accreditation, this helps facilitate the scope of accreditation to include modified versions of the methods as the need arises. 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. This accreditation was awarded in 2014 and fully complies with, and is based on, the European Commission published guidance on flexible scope of accreditation for GMO analysis[23], which LGC helped contribute towards.
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 analytical function as part of the NRL role.

As part of a recognise Quality Management System under ISO/IEC 17025:2017 accreditation, LGC regularly participates in External Quality Management exercises via recognised proficiency test rounds.
Representing the NRL for GMOs in the UK since 2009, LGC has participated in all EURL Comparative Tests organised by the EURL for GMOs in Food and Feed. The NRL Comparative Tests consist of international based proficiency test schemes and are stated by the EURL as representing the most objective test to qualify that a laboratory is fit for purpose as an NRL (2017/625).
At the time of this application, 21 EURL Comparative Tests have been organised and completed by the EURL. LGC has demonstrated complete compliance with EU Regulation 2017/625 through participation in all 21 of these EURL Comparative Tests, producing 67 test sample results for the presence of 29 different GMO events, and has provided evidence of all results being fit for purpose as they are compliant with quality criteria ([Z]<2) as well as competency to extract DNA from a range of different food matrices. In total 67 Z-scores have been received by LGC, all of which have been less than a magnitude of 2, which is the key quality criterion for showing the fitness for purpose of a laboratory as part of any external quality assessment exercise. This is of particular note, for example, as for one of the tests in the 5th EURL Comparative Test, more than 58% of the 32 participating laboratories received an unsatisfactory Z-score.

[23] European Commission, JRC Scientific and Policy reports (2013) "European technical guidance document for the flex ble scope accreditation of laboratories quantifying GMOs", ISBN 978-92-79-26176-3. doi:10.2787/67611

As further qualification of its fitness for purpose as for 2017/625, LGC regularly participates in other external quality assessment exercises including the FAPAS and GeMMA (Genetically Modified Material Analysis Scheme) Proficiency Tests. LGC has actively supported and participated in the GeMMA PT scheme since its inception in the year 2000. To date, LGC has participated in over 37 rounds of the GeMMA PT scheme, analysing over 55 samples from a range of food matrices including flour, milk powder; snack foods, biscuits, canned meats, soya, pate, animal feed, cake, etc. In all cases Z scores received were less than a magnitude of two, providing evidence of LGC's applicability at producing accurate GMO results.
Whilst LGC has never received a Z-score greater than a magnitude of two for any GMO related analyses, it is aware of the corrective actions that need to be followed if such a case arises, as dictated by ISO/IEC 17025:2017 and the UKAS policy on corrective actions.

**k) Be responsible for carrying out other specific duties as required by the CA, where appropriate and by prior agreement;**
A crucial service that has been requested by the FSA is the maintenance of an archive of positive and negative reference materials needed for control purposes in the UK.
In terms of storage of control materials, LGC houses multiple dedicated secure walk-in cold rooms, 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 are 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 Building Management System (BMS) temperature monitoring system and recorded by our in-house building services system.
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
Control materials are available for distribution to UK OCLs on request.
LGC provides an unrivalled knowledge of available control and reference materials. This is supported through continuous attendance at all ENGL meetings where updates on new control materials and reference materials are announced, and further reinforced through awareness of new GM Certified Reference Materials (CRMs) as LGC is an authorised distributor of such materials. Evidence of this in-house knowledge is provided through advice and guidance that LGC has given to OCLs for provision of reference materials (Appendix 1).

As part of the UK authorisation process for GMOs, the FSA and the UK laboratory appointed for technical authorisation of methods may ask the NRL for assistance in testing and validating the methods of detection for GMOs. LGC has regularly participated in the previous EU GMO authorisation process through inter-laboratory trials in order to qualify a method as fit for purpose and thus has extensive experience in this area.

Following discussion and agreement between LGC and the FSA, LGC will carry out other specific duties as required but only on approval from the FSA. Costs for these additional specific duties will be agreed with the FSA on a case by case basis.

**How this project fulfils the laboratory requirements listed as part of the specification (page 5 of FS616029 specification)**

**a) Be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as NRLs**

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.

The Government Chemist role at LGC was originally created to help in the protection of the public from fraud, malpractice and harm. In 1875, the laboratory was appointed as "referee analyst", a role linked to the Sale of Food and Drugs Act of that year. The GC role has two main functions. The GC's statutory function comprises science based duties prescribed in several acts of Parliament, covering public protection, safety and health, value for money, and consumer choice. This "referee analyst" function resolves disputes between regulators and businesses. The second function is an advisory one, providing consultancy, help and support in matters related to the analytical science implications for policy, standards and regulations.

BEIS has put into place arrangements to ensure that the Government Chemist Programme is delivered competently, and that scientific standards, impartiality, transparency and integrity are maintained. The Government Chemist Programme Expert Group (GCPEG) provides independent scrutiny, overseeing the delivery, planning and quality of the programme and offering advice to BEIS regarding future priorities and strategic direction of the programme. Furthermore, the GC has in place a set of working instructions to support this (GCF-WI-003 – Government Chemist Function – Avoidance and Management of Conflicts of Interest), which can be viewed upon request. These working instructions are fully compliant with LGC's published quality and compliance documents as well as its Supplier Code of Conduct, which can be freely viewed at https://www.lgcgroup.com/about-us/quality-and-compliance/ and https://www.lgcgroup.com/media/1301/lgc-supplier-code-of-conduct.pdf .

Hence, impartiality is maintained between the NRL and GC functions to ensure there are no conflicts of interest. Indeed, the housing of the GC and GMO NRL functions under "one roof" at LGC is extremely beneficial. The function of the NRL is governed by the FSA and the relevant UK legislation of 2017/625 to provide impartial advice to the member state Competent Authority and OCLs for all matters related to GMO analysis. This role provides the horizon scanning and intelligence gathering, but not necessarily a large scope for any laboratory based competency building. On the other hand, the GC aspect is defined by several UK Acts of Parliament, the partial function of which is focused on maintaining and demonstrating laboratory based capability building. This partnership allows direct action based on intelligence gathering and GC funds are used for practical competency and capability building in the laboratory environment, such that the GC can efficiently deliver its referee case function on analytical results. An excellent example of this is demonstrated through the successful resolution of over 12 samples referred to the Government Chemist function for referee analysis regarding disputes over the presence of Chinese GM rice. Intelligence gathering via the GMO NRL function has positioned LGC at the forefront of knowledge surrounding the scope and application of the methods for Chinese GM rice testing as referred to in the appropriate legislation. This has allowed the GC function to act on this intelligence led evidence in demonstrating laboratory based capability for testing for Chinese GM rice which has contributed towards the successful resolution of these referee cases, demonstrating excellent synergy and value for money between the NRL and GC functions, providing efficient support and analysis for UK controls.

**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” (2020) 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 and secure access to any reference materials required in order to fulfil their responsibilities and support the relevant OLs;**

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.

In terms of storage of control materials, LGC houses multiple dedicated secure walk-in cold room, 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.

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
Control materials are available for distribution to UK OCLs on request.
LGC provides an unrivalled knowledge of available control and reference materials. This is supported through continuous attendance at all ENGL meetings where updates on new control materials and reference materials are announced, and further reinforced through awareness of new GM Certified Reference Materials (CRMs) as LGC is an authorised distributor of such materials. Evidence of this in-house knowledge is provided through advice and guidance that LGC has given to OCLs for provision of reference materials (Appendix 1).
As part of past operations of the GMO National Reference Laboratory function at LGC, the NRL has provided access by OCLs to EURL control materials (provided by the EURL) for official UK control. It is proposed that this function and service provision is still maintained as part of this NRL position.

**f) Be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and where appropriate, assist the competent authority in food incidents by carrying out diagnosis and/or testing of samples, when necessary**
As a responsible company, LGC has extensive an Extensive Business Continuity and Disaster Recovery (BCDR) procedure, which has been formalised as a policy, a copy of which can be viewed upon request. Ownership of BCDR plans sits with individual teams and divisional management. This BCDR policy details the approaches to take to ensure that the health and safety of LGC employees are prioritised, to minimise the impact to the customer and to the business in the event of a critical incident, and to return to a normal operational business condition in the most efficient and effective manner possible following that incident.

In terms of having access to the relevant laboratory based equipment during an emergency situation, LGC houses the National Measurement Laboratory (NML) facility on-site at Teddington, which is a recently refurbished laboratory facility (opened in 2019) fully equipped with all modern pieces of equipment including a range of qPCR and dPCR machines, manual and automated DNA extraction instruments and techniques, all of which are instrumental in developing and maintaining analytical capabilities' for GMO detection and quantitation. 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 GMO analytical requirements as part of this proposal.
Furthermore, 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.
The GMO facility at LGC operates to ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis, ensuring the upmost confidence can be afforded in analytical test results provided as part of this service. Should a GMO emergency situation arise, LGC stands ready to help assist the FSA in terms of provision of appropriate support, advice, methods and (where available) control samples for use in emergency situations.

LGC has good expertise and experience for continued operational delivery to the highest quality standards whilst under "emergency conditions". This has been demonstrated when LGC supported the FSA and Defra in a number of projects, testing initiatives, method development and provision of advice during the 2013 EU/UK horse-meat issue. More recently, LGC has continued to provide operational excellence throughout the COVID-19 pandemic, putting into place new risk assessments, working instructions and protocols as part of a recognised quality management system, in line with government guidance and law, to ensure staff can continue to work safely in a laboratory environment through the pandemic (e.g. designation as key workers).

**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. Should additional biosecurity measures need to be developed in the future as part of any GMO activities delivered under the GMO NRL position, 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) Maintain a list of the accreditation for the relevant OLs**

The manager of the current GMO NRL position, Dr. Malcolm Burns, is well known by all of the UK Official Control Laboratories and is on first name basis with all of the Public Analysts. Throughout the 12-year period of the GMO NRL position, LGC has built up an excellent working relationship with all Official Control Laboratories. LGC has good knowledge of UK OCL capability for GMO sampling and analysis and individual ISO/IEC 17025:2017 accreditation, which has been marinated as part of regular contact with the OCLs, answering queries with respect to GMO analysis (please see Appendix 1 for examples), face to face visits and meetings, and deployment of a regular questionnaire.

As part of the current tender response, it is proposed to continue to maintain these close relations with all UK based OCLs to help maintain up to date information on UK based accreditation relevant for GMO sampling and analysis.

**i) Liaise with other CA-appointed NRLs (as and when required)**

LGC has a good track record of liaising and communicating with other CA appointed NRLs across a range of diverse scientific areas. An example of this was given at the Defra/FSA Food and Feed NRLs Workshop on the 26th November 2018, as well as LGC attending the first ever FSA NRL annual meeting back on the 5th October 2010. LGC also regularly liaises with other NRLs through various networking events at other FSA, Defra and LGC workshops (e.g. FSA Post Transition Period EU-GB imports workshop, September 2020).

To further add value to this point, LGC is the only UK based laboratory to having been present at all ENGL plenary meetings since the establishment of the ENGL in 2002, consistently so by the same staff member. Hence, all of the heads of the 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).

**j) Have experience of, and be able to operate in accordance with, the relevant sampling and analysis legislation, including maintaining specific UK Accreditation Service (UKAS) accreditation (or equivalent) for the relevant analytes, and satisfactory performance in proficiency test schemes**

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.

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. Five 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. These include recognised international measurement claims in quantifying GMOs in maize and soya plant tissue samples, crop seeds in general, and purified buffer solutions containing plasmids with GM inserts.

**k) Be familiar with the enforcement system in operation in the UK**
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.

**Explanation of how the project advances knowledge in the area and provides the information indicated by the Specification Requirement document FS616029**

For the past twelve years, the provision of the GMO NRL function at LGC has been fundamental in helping the UK official control network understand and deal with GM related issues. Control materials archived at LGC as part of the

NRL function have been sent to Official Control Laboratories for use in compliance testing. Since the award of the original GMO NRL contract to LGC through open competitive tender in 2009, LGC has also responded to over 334 enquiries from a diverse range of stakeholders, including the FSA, Public Analysts, Official Control Laboratories and UK industry, providing advice and guidance on a range of subjects inclusive of new and emerging GMOs, application of new EU legislation (e.g. EU Regulation 619/2011 on low level presence of unauthorized GMOs; Chinese GM rice testing in support of Commission Implementing Decision 2011/884), GM pollen in honey, gene editing, GM animals, genetically modified microbes, provision of best practice guidance for OCLs, visits with OCLs, and also by providing bespoke hands-on training on site for GMO testing for OCLs. Compared to previous NRL contracts the duration and complexity of these enquires has significantly increased, mainly due to the intricacy of the enquiries related to EU exit and the uncertainty and impact upon UK science and control capability (please see Appendix 1).
Regular attendance at all ENGL plenary meetings and EC workshops, coupled with the responsibilities and delivery of the above NRL tasks, has meant that the most current methods and approaches for GMO analysis are made available to stakeholders within the UK, and that the UK's capability for GMO analytical issues continues to remain fit for purpose.
Delivery of the NRL function for GMOs in food and feed via execution of the duties specified in retained EU Regulation 2017/625 ensures that the UK complies with European legislation and provides the infrastructure for further refinement and development in the UK. Reappointing LGC as the UK NRL for GMOs in feed and food will ensure that continuous coverage for the capability of UK OCLs can be maintained to cover both fundamental and emerging issues related to GMO analysis, and that such coverage is consistent.

The housing of the Government Chemist and the NML for chemical and bioanalytical measurement in the same organisation as the NRL function is of enormous benefit as they all provide separate but synergistic roles. LGC gains invaluable insight into new / difficult areas of analysis in the execution of the Government Chemist, NRL and NML functions that it puts to good use by proactively sharing best practice with all stakeholders including UK OCLs.

**Explanation of how the proposed objectives will meet FSA policy needs**

Delivery of the proposed objectives will help fulfill three strategic outcomes named in the Food Standard Agency's Strategic plan 2015-2020 in relation to GMOs: fit for purpose analysis of food samples resulting in correct labelling and "Food we can trust"; correct analysis and labelling of foods facilitating informed decisions to be made regarding consumer choice, helping ensure food is "what it says it is"; and the proposed scope of work in relation to the NRL objectives will help ensure the UK has access to reliable and cost effective approaches for food analysis.

The issue of GMOs still continues to increase in importance in the UK in line with the completion of EU transition as well as because of recent developments in gene edited products and genetically modified microorganisms, with many consumers choosing to avoid foods containing them. Thus, to protect consumer choice, it is imperative that products are correctly labeled. In order for this to be possible, robust methods of analysis are required and the competence of expert laboratories must be maintained to provide confidence in the results generated. Since its original appointment as the UK NRL for GMOs in 2009, LGC has helped contribute significantly in both these areas. Reappointing LGC as the UK NRL-GMFF for the next contractual period will allow the FSA to be confident that this important duty is in safe, capable hands and coverage is both consistently and continually maintained.

**Innovation**

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 and Head of the GMO unit 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 the impact upon official UK attendance at EC meetings still not be guaranteed as part of the EU/UK trade deal. Indeed, Dr. Burns' appointment as an independent scientific expert recognised in the area of GMO analysis has been confirmed by the European Commission and he has already attended five ENGL working group meetings post the EU transition/implementation period of 1st January 2021. This provides this tender with unequalled knowledge and continued access to EU/EC intelligence and guidance on GMO analysis post the EU transition phase.

LGC has ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis using real-time PCR. 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.

Based on in-depth knowledge of the GMO area and relevant analytical methods, it is the current expectation that the majority of methods for detection of GMOs in the UK and UK based applications for GMO authorisation will be based on qPCR approaches for the immediate future. 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 helping future proof the UK in terms of access to and provision of guidance for appropriate technologies for GMO detection.
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.

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 PT rounds which may be required as part of the NRL position.

LGC has participated successfully in 58 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 58 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, LGC regularly participates in international metrology studies as part of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM). The mission of the CCQM includes responsibility for developing, improving and documenting the equivalence of national standards (certified reference materials and reference methods) for chemical and biological measurements, to establish global comparability of measurement results through promoting traceability to the 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. Five 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.

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 active participation on all of these EC Working Groups for the future has been confirmed via Dr. Burns invited attendance at these as a recognised international expert, irrespective of the final outcome of the EU/UK trade deal and its impact upon official UK inclusion in EU scientific matters.

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.

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 sit 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 methods and acceptance criteria for detection of such targets, and the NRL will work with the FSA in order to best accommodate these for the future.

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 relevant control and reference samples are kept safely and appropriately.

Within the Health, Science and Innovation Division, LGC regularly invests funds for capital expenditure of analytical instrumentation, to ensure that the Research and Development remains at the cutting edge of the science, and staff have access to the most appropriate, new and innovative analytical technologies. In the current financial year, the CAPEX budget amounted to £830k, facilitating purchase of the latest innovative technologies for GMO analysis, including real-time PCR instrumentation (Applied Biosystems QuantStudio 7 Flex), and Next Generation Sequencers (Illumina MiSeq, Oxford Nanopore MinION, etc.).
This innovative approach to the delivery of the NRL functions is augmented through LGC's unique position as the National Measurement Laboratory for chemical and bio-chemical measurements and also housing the Government chemist function to help safe-guard the quality of public science in relation to food analysis.

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)
  B.

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.

## 3: THE PROJECT PLAN AND DELIVERABLES

### A. THE PLAN

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

The duties of NRLs according to retained Regulation (EC) 2017/625 have been grouped together into the core functions as per the FSA's original invitation to tender FS616029.

| | **Objective 01 - infrastructure development** |
|---|---|
| **Task/Sub-task** | **Description** |
| **1.a** | Disseminating relevant information/advice to the OLs, CA, when required, and other relevant laboratories in a timely and effective manner |
| 1.b | Co-ordinating the activities of OLs and other relevant laboratories in food and feed below |
| 1.c | Creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation |
| 1.d | Providing regular updates to the CA on **NRL** activities, and up-to-date information on UK OLs and other relevant laboratories to the CA as reauested |
| 1.e | Creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and suooort to OLs, information on methods of |

| | |
|---|---|
| | **analyses, Standard Operating Procedures (SOPs), latest developments and other background information** |

C.
D.

## Core function 1 - Secretariat services

**Task 1.a - Disseminating relevant information/advice to the OLs, CA, when required, and other relevant laboratories in a timely and effective manner**

LGC is in regular and constant contact with the FSA in relation to all matters concerned with GMO controls. Recent example topics in 2021 have included detection of gene edited products, controls for genetically modified microorganisms, and the impact of EU exit on GMO controls in the UK. Communication is facilitated by regular E-mail, phone and online video/tele-conferencing facilities.

LGC also maintains close contact with all UK OCLs and UK based ENGL laboratories, maintaining updated distribution lists for these purposes. Following approval from the FSA, these distribution lists are used to cascade relevant GMO information in a timely and efficient manner to the relevant laboratories (e.g. emergency issues on GMOs, reports from relevant meetings, etc.).

As part of the current tender response, it is proposed that these levels of effective communication be maintained through the NRL contract.

The NRL also maintains webpages dedicated towards the GMO NRL activities (an example of these are provided in Appendix 2). These webpages house relevant information such as the GMO NRL annual reports as well as relevant newsletters.

LGC has also received feedback from OCLs that although they value a dedicated web presence for NRL activities that they can interrogate at their leisure, they often don't have sufficient time to browse websites. To address this issue and make the activities of the NRL accessible to all in a succinct manner, it is proposed that the regular NRL newsletter be issued to all OCLs and placed on the NRL webpage. An example of the NRL newsletter has been provided in Appendix 3.

Information accessible via the NRL webpages includes topics covering legislation updates, emerging issues, food and feed recalls, information from the EURL, advice given (anonymised), meetings, work programmes and laboratory visits.

**Task 1.b - Co-ordinating the activities of OLs and other relevant laboratories in food and feed below**

LGC has discussed with the FSA the terms of reference with respect to "co-ordinate official laboratories" as part of all previous NRL contracts. For the avoidance of doubt, it was agreed and stated by both parties that this "co-ordination" was understood to be restricted to activities associated with the dissemination of information relating to the sampling and analysis of GMOs. It is therefore envisaged that this task will continue to be completely covered under Task 4.a below.

**Task 1.c - Creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation**

Paul Hancock, Head of the Office of the Government Chemist and Referee Analyst at LGC, is the official Association of Public Analysts (APA) Training Officer and is responsible for organising training tailored to the needs of the APA. NRL representatives have frequent discussions with Paul and feed into the regular APA Training Committee (TC) of which Paul is a member, to elicit the APA's needs in relation to this NRL function. It is proposed to continue to provide NRL updates at the two APA TC meetings a year.

In addition, two APA TC members attend the six monthly meetings held at FSA headquarters to input their requirements into the NRL work programme, and this pre-existing method of communication will be capitalised upon in order to disseminate and gather appropriate information and feedback.

LGC maintains close contact with all UK OCLs and UK based ENGL laboratories, maintaining updated distribution lists for these purposes. All heads of the OCLs and the Public Analysts themselves are known personally by Dr. Burns at LGC. Additionally. Heads of all EU National Reference Laboratories are known by Dr. Burns and have expressed an aim to continue with relevant scientific discussions and collaborations with LGC, irrespective of the final outcome of the UK/EU trade agreement. Furthermore, Dr. Burns is a member of a number of other GMO related groups and networks, inclusive of networks both in the UK (N8 AgriFood) and internationally (African and Indian GMO control networks, Plant Ed COST action, etc.).

The NRL remains easily available to contact and respond to queries via phone, video/tele-conferencing and E-mail. It is proposed that this effective two-way channel of communication be maintained as part of the new contract.

At the wider international level, LGC is known as an international life sciences company. Our 3,800 employees include internationally-recognised scientists who are experts in their field, and LGC operates out of 17 countries worldwide and is extensively accredited to quality standards such as GMP, GLP, ISO 13485, ISO 17034, ISO 17043, ISO/IEC 17025 and ISO 9001. Specifically in relation to GMOs, Dr. Malcolm Burns is an internationally recognised

expert, having published 35 peer reviewed scientific papers and guidancedocuments associated with GMO analysis and international harmonisation (Appendix 4). In line with this credibility at the international level, Dr. Burns has attended in excess of 200 meetings, workshops and working groups associated with GMO analysis, many as an invited speaker.

Task 1.d - Providing regular updates to the CA on NRL activities, and up-to-date information on UK OLs and other relevant laboratories to the CA as requested

As per the current NRL contract, it is alsoproposed that the LGC project leader (Dr Burns) continues to be in constant contact with the FSA project officers by phone, E-mails, video/tele-conferencing and by face-to-face meetings as the situation dictates. LGC is also available for provision of advice on GMO analysis to all OCLs by the same means. Furthermore, summaries on all ENGL plenary meetings that the UK NRL attends are supplied to all OCLs and the NRL will be fully contactable in order to provide additional details on each meeting as is necessary. The EURL now routinely provides full meeting reports associated with the ENGL and NRL meetings a few days after the meetings are held, and these will be forwarded on to the FSA and OCLs immediately they are available.

The NRL is in constant contact with the OCLs and maintains up to date information on their capability, capacity and relevant accreditation/certification to conduct GMO analyses.

In addition, it is proposedthat regular NRL review meetings be held with the FSA where the NRL work programme will be reviewed and discussed.

Task 1.e - Creati on and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OLs, information on methods of analyses, Standard Operating Procedures **(SOPs),** latest developments and other background information

As LGC has already developed the NRL webpages as part of the current and previous GMO NRL contracts, this represents cost-svaing opportunities for the FSA in that new webpages do not need to be created. The dedicated NRL webpages will be maintained and regularly updated to continue to house the GMO NRL function. The updated NRL webpages are currently held at: https://www.lgcgroup.com/services/regulatory-support/naibnal-reference laboratoies/#WGOGIJvjcu and an example is given in Appendix 2.

**Core function 2 - Advice and representation within the UK and internationally**

| | **Core function 2 - Advice and representation within the UK and internationally** |
|---|---|
| **Task/Sub-task** | **Description** |
| **2.a** | **Provide details of analytical methods** including **reference methods** to **OLs and** co-**ordinate** application **of these methods** throuah **proficiency testina (see Task 4.c)** |
| **2.b** | Provide impartial expert advice as requested to the CA, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment |
| 2.c | Represent the UK at relevant international meetings, networks and working groups, consulting the CA on objectives and requirements before each meeting and providing the CA with an internal report of the meetina within 10 workina davs of each meetina |
| 2.d | Participate in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledae |
| 2.e | Provide advice to the CA, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in consultation with the CA that facilitate and promote their application in the UK within the policy aims of the CA |
| 2.f | Keep abreast of and advise the CA, OLs and other relevant laboratories of research and development for the samplina, testina and detection of GMOs |
| 2.g | Identify and inform the CA, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommendingaction to address them |
| 2.h | Provide technical assistance to the CA in cases of contested results of analvses |
| 2.i | Where appropriate , partake and/or keep abreast of standardisation activities (e.g. **CEN,** ISO, etc.) relevant to the work area |

**Task 2.a - Provide details of analytical methods including reference methods to OLs and co-ordinate application of these methods through proficiency testing (see 4c)**

Following the end of the UK transition period away from the EU, the default status for most legislation was for the UK to adopt the tried and tested EU regulations, inclusive of the legislation pertaining to GMOs. This "retained" legislation specifically refers to methods for GMO detection and quantitation which have been validated by the EURL as part of the EU authorisation process.
LGC is well versed in the use of all of the standardised EU analytical methods for the detection and quantitation of GMOs, having ISO 17025 flexible scope of accreditation to accommodate these methods and also being a regular participant on the EURL method validation trials. LGC also has copies of all of the EURL validated methods which can be distributed to OCLs upon request, although it is expected that these methods will remain freely accessible in the public domain on the EURL website for all stakeholders to view (the UK inclusive). The methods can currently be accessed at the following web address: https://gmo-crl.jrc.ec.europa.eu/gmomethods/

Having close connections with all of the UK official control network, LGC is well versed in providing advice on the application of the EU methods for GMO detection, as evidenced by the advice provided to OCLs on a regular basis (please see Appendix 1). Whilst it is the responsibility of the participating laboratory to ensure it applied the relevant analytical method for the detection of the correct target analytes as part of any proficiency test scheme according to their own internal quality management system, LGC remains happy to provide the necessary assistance to advise on which methods to implement for any given test. Furthermore, the FSA authorisation position (FS430418), which is currently undergoing the project tender process, has set out provisions for both the FSA and the laboratory appointed to be responsible for authorisations in Great Britain, to provide access to databases of methods for newly authorised GMOs, which must be available to all OCLs.
In terms of relevant certified reference materials for use in the methods for detection of EU authorised GMOs, all of these are available for commercial purchase from the JRC (Geel) and AOCS (in America), based on their shared mandate. Similar to before, LGC is happy to provide assistance in an advisory capacity on where and how to source these reference materials.

**Task 2.b - Provide impartial expert advice as requested to the CA, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment**
LGC will continue to advise the FSA, UK OCLs and other relevant laboratories as required. In cases, where the advice is relevant to all OCLs, it is proposed that it will be anonymised and placed in the NRL annual report.
As part of the current GMO NRL position, LGC provided individual pieces of advice and guidance in response to 334 requests received from the FSA, UK OCLs and other stakeholders (UK based ENGL labs, the EURL, Defra, etc.). On average, this equates to 28 separate pieces of expert advice per year across the 12 years of the GMO NRL position in the UK, where the number of requests has dramatically increased in recent years. Appendix 1 provides examples of the advice provided as part of the NRL position. It is envisaged that at least this level of support will still be required for the future running of the NRL function, particularly given that the UK is post the EU transition/implementation period.

**Task 2.c - Represent the UK at relevant international meetings, networks and working groups, consulting the CA on objectives and requirements before each meeting and providing the CA with an internal report of the meeting within 10 working days of each meeting**
Based on previously experience, it is the NRL's expectation that at least two international meetings will be held per year, for example through attendance at EURL or other equivalent international meetings. In the case of the EURL, official minutes to these meetings are now routinely provided on the EURL website, and in order to keep costs down and to avoid repetition, these EURL full meeting minutes will be forwarded by the NRL to the FSA as soon as they are made available.
Dr. Burns (LGC) is also a member of all current ENGL working groups, addressing current and topical aspects associated with GMO controls, inclusive of setting guidance for the use of digital PCR, Next Generation Sequencing, and the detection of genetically modified microbes, GM animals and products of gene editing. Dr. Burns is the only UK based member to provide continuous and consistent attendance at all ENGL based meetings, as well as all technical working groups. In recognition of this, **Dr. Burns has been acknowledged as an independent international scientific expert in GMO analysis by the ENGL, thus facilitating continued input and participation in ENGL working groups post the EU transition period**, irrespective of when the outcome of the UK/EU trade agreement has been made clearer in terms of how the UK will officially interact with the EU on a longer term scientific basis. The result of these Working Groups ultimately culminates in the publication of EC guidance documents associated with GMO control. The UK's input and attendance at these working groups via Dr. Burns will allow the UK to maintain being kept abreast of topical GMO control issues, allows the UK to horizon scan for potential issues and react accordingly, promotes exchange of best measurement practice guidance with other NRLs, permits networking with like-minded scientists; and facilitates in helping the UK influence science and policy in a positive fashion.

In order to continue to remain abreast of GMO initiatives within the EU, help influence science and policy, network with appropriate like-minded scientists, horizon scan for emerging GMO issues, and help the UK remain pro-active

and continue to establish a presence internationally, a variation to contract to the current NRL position was issued by the FSA to provide additional funds for such pro-active involvement. This has already benefited the UK GMO science, control and policy areas through intelligence gathering on topical issues inclusive of GMO authorisations, gene editing, genetically modified microorganisms and best measurement practice guidance on GMO minimum performance criteria.
As part of this this tender response, it is proposed that this increased UK presence at relevant GMO international meetings and workshops continues to be maintained, generating much needed added-value to the role on information gathering in lieu of the withdrawal of access to EURL services. These Additional activities are required to continue to position the UK as strongly as possible for advice/readiness for GMO control as a result of the EU interim/transition period, and will help mitigate loss of access to EURL services and will ensure full NRL functionality is maintained.

As part of the current GMO NRL variation to contract, this further added value attendance was facilitated through additional funds to augment those provided and envisaged in the original NRL contract. In order to continue to provide these added value benefits to the UK GMO NRL position, it is proposed to take into account the additional staff effort required to maintain this as part of the tender bid.

The NRL will provide a meeting summary report to the FSA for all relevant meetings attended, within the 10 working days of attending that meeting.

**Task 2.d - Participate in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledge**
The activities associated with this Task are covered by Task 2.c above. LGC also has good contact with, or is a member of, a number of other networks and organisation involved in elaborating on GMO controls, inclusive of the Plant Ed COST Action, the N8 Research Partnership (AgriFood), the Network of GMO Testing Laboratories (NGTL) of India, and the Southern African Network for GM Detection Laboratories (SANGL) and the Western Africa Network of GM Laboratories (WANGL). In addition, as a recognised National Measurement Laboratory which regularly participates in CCQM (Consultative Committee for Amount of Substance – Metrology in Chemistry) activities, LGC has excellent communication channels with National Measurement Institutes situated in other countries (e.g. the NMI in Australia). These channels will be used to help provide further links with other appropriate national organisations involved in GMO analysis.

**Task 2.e - Provide advice to the CA, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in consultation with the CA that facilitate and promote their application in the UK within the policy aims of the CA**
Advice will be provided to the FSA, OCLs and other relevant laboratories on best scientific practice in testing for Official Controls. Activities will be carried out, in consultation with the FSA, which facilitate and promote their application in the UK within the policy aims of the FSA.
As part of the GMO NRL position, LGC has provided over 334 separate pieces of expert advice. This advice is broken down to advice given to the FSA (162 pieces of advice), UK OCLs (76 pieces of advice) and other stakeholders such as UK based ENGL labs, the EURL, Defra, etc. (96 pieces of advice). This ranged from providing advice provided and disseminated by the EURL GMFF, advice based on official representation in the UK and EU, production of SOPs and other published official guidance, advising of proficiency test results with the FSA, advice on the use of GMO control/reference materials, communication of results, method validation studies and general scientific best measurement practice advice for GMO analysis. Appendix 1 provides examples of these.

**Task 2.f - Keep abreast of and advise the CA, OLs and other relevant laboratories of research and development for the sampling, testing and detection of GMOs**
LGC will use all channels available to it for keeping abreast of GMO analytical issues, inclusive of attendance at related ENGL meetings and workshops, legislation updates, emerging issues, Food and Feed recalls, information from the EURL, advice given (anonymised), relevant international meetings, work programmes, laboratory visits, the RASFF, additional networks and orgainsations (e.g. the Plant Ed COST action) and changes to new and existing legislation.

**Task 2.g - Identify and inform the CA, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommending action to address them**
LGC will keep abreast of emerging analytical issues or developments in relation to sampling, detection, identification and quantitation of GMOs and how this may impact on Official Control and testing methods. This is afforded through multiple channels inclusive of

- the ENGL;

- international meetings, workshops, working groups and training;
- new legislation;
- RASFFs;
- and horizon-scanning initiatives from the GVC and NML functions.

This information will be disseminated to the FSA, OCLs and other relevant laboratories.

**Task 2.h - Provide technical assistance to the CA in cases of contested results of analyses**

LGC houses the UK Referee function (part of the UK Government Chemist role). Underpinned by several Acts of UK Parliament, this role imbues the Government Chemist to act as an independent referee analyst when there is a dispute between a Food Business Operator (FBO) and an enforcement laboratory (e.g. UK OCL) over the nature or provenance of a sample (usually food) that has been taken formally.

The Government Chemist role was originally created to help in the protection of the public from fraud, malpractice and harm. In 1875, the laboratory was appointed as “referee analyst”, a role linked to the Sale of Food and Drugs Act of that year. The role continues to this day, fulfilling statutory and advisory functions, which are funded by the Department for Business, Energy and Industrial Strategy (BEIS). The Government Chemist uses up-to-date and authoritative measurement procedures coupled with experienced interpretative skills to act as a fair and independent arbiter to resolve disputes. In doing so we protect consumers, provide a route of technical appeal for businesses and contribute to regulatory enforcement in sectors where chemical and bio-measurements are important.

Should any formal samples be taken and referred to LGC for analysis, the procedure and deployment of advice for this is governed by the UK Government Chemist function, and it is envisaged that no additional cost will be attributed to this through the NRL role. Indeed, one the most common types of referee cases submitted to the Government Chemist are formal samples where a dispute has arisen regarding the possible presence of Chinese GM rice. LGC has successfully resolved disputes for over twelve samples regarding this, so is well versed in complex GMO analyses as well as how to handle and resolve such contested results.

If the contested results associated with an analyses do not constitute as arising from a formal sample according to UK law, then best measurement practices advice afforded through the NRL function will be used to provide technical assistance to the FSA in resolving such issues.

In the event that formal samples are referred directly to the NRL by the FSA, it is proposed that each sample be treated on a case by case basis and prior agreement will be sought between the FSA and LGC on how best to proceed, whilst still supporting FSA policy and UK legislation.

**Task 2.i - Where appropriate, partake and/or keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area**

LGC staff are highly experienced at serving on national and international committees, inputting into, and influencing, the development of new legislation, standards and policy to ensure that measurement issues are considered adequately. A list of committees that Government Chemist staff serve on is available on the GC website (inclusive of the CEN Food Authenticity Coordination Group (FACG) and CEN TC 460 – Food Authenticity Technical Committee): ( https://www.gov.uk/government/organisations/government-chemist/about/membership ).

As part of the current NRL tender response, LGC proposes to continue to attend and input into the relevant standardisation activities.

Many of our staff are considered leading experts in their field and are often invited to contribute to international standardisation efforts, for example, at the end of last year, when the UK was notified that its experts could no longer participate in European Commission expert committees, Dr Malcolm Burns was invited by the European Network of GMO Laboratories (ENGL), in recognition of his expertise and contributions to date, to continue to participate as an individual expert. Selvarani Elahi has been part of the UK delegation for the Codex Committee on Methods of Analysis and Sampling (CCMAS) for over ten years. In 2020, FSA and Defra put in place arrangements for LGC to support the standardisation of two UK methods (developed by LGC): determination of horse DNA in beef and detection of previously frozen chicken by determining the HADH content, by the European standardisation committee, CEN.

Also in 2020, two LGC staff were appointed as Eurachem Chair and Eurachem Secretariat. Eurachem is a network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices.

As a National Measurement Laboratory, LGC represents UK interests for its designation of chemical and biological measuremenst as part of the global network of national metrology institutes that make up the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA). The CIPM MRA provides the framework through which National Institutes demonstrate the international equivalence of their Calibration and Measurement Capabilities (CMCs), so that a global infrastructure of equivalence is in place. In real terms this ensures that the results of a medicines testing lab in the UK is the same as that in Korea or the USA. The CIPM MRA requires that three fundamental elements are in place in order for the NML’s CMCs to be approved:

1. The NML must participate in reviewed and approved scientific comparisons (known as Key Comparisons)

2. The NML must operate a quality management system in accordance with ISO/IEC 17025 and ISO 17034 (for producing or assigning values to reference materials)
3. The NML's CMCs must undergo international peer-review by EURAMET (the Regional Metrology Organisation for Europe) and CCQM (the CIPM's inter-regional committee responsible for the field of chemical and biological metrology). NML staff are active participants in CCQM Working Groups e.g. Chairperson for the Working Group on Nucleic Acid Analysis) and frequently lead CCQM inter-laboratory comparisons.

## Core function 3 - Production of standard operating procedures, codes of practice, guidance documents and databases

| | Core function 3 - Production of standard operating procedures, codes of practice, guidance documents and databases |
|---|---|
| **Task/Sub-task** | Description |
| 3.a | Contribute to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLs and other relevant laboratories, as reQuested bv the CA |
| 3.b | **E.** Where required, develop a database to store relevant information in relation to GMO official control testing, e.g. GMO methods, **SOPs,** codes and guidance |

Task 3.a - Contribute to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLs and other relevant laboratories, as requested by the CA
LGC will continue to contribute to the development and publication of Standard Operating Procedures, codes of practice and guidancedocuments for use by OCLs and other relevant laboratories, as requested by the FSA.

**F.** Task 3.b - Where required, develop a database to store relevant information in relation to **GMO** official control testing, e.g. GMO methods, **SOPs,** codes and guidance
Project specifications state that, where required, the contractor should have the capacity and capability to develop a database to store relevant information in relation to GMO official control testing (e.g. GMO methods, SOPs, codes and guidance).
It is proposed to develop such a database (hereafter referred to as a Compendium) with the relevant compiled information all in one place. 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 databaseas part of this project.
This Compendium will be actively curated and maintained, housing the relevant methods, SOPs codes and guidance, listed according to GMO event. In addition, it is proposed that the Compendium also list the relevant control and reference materials (as applicable) associated with each GMO event.

LGC has demonstrable expertise and in-depth knowledge of providing such Compendiums in a secure manner, as illustrated by the list of FSA and Detra validated methods and research projects associated with food analysis, as housed on the Food Authenticity Network website (http://www.foodauthenticity.uk/methods). A proto-type example of the user-interfaceon the Compendium is provided below. Whilst the pertinent information is in direct relation to the FSA (FS430418) "GMO Food and Feed Authorisation GB" tender bid, the principal remains the same and, should LGC be awarded both tenders, it would make perfect logistical sense to combine the NRL and GMO authorisations databases together as it will list relevant information on a GM event by event basis. This would provide cost saving opportunities for the FSA with one combined compendium of information.
The screen shot below is a simple mock-up of an area within a SharePoint site that shows a list (Figure 3) containing direct links to validated methods housed within a document library(Figure 4).


**Figure 3: Screen sho t of a Sh are Point list hou sing a comp end ium of va lid ated m eth ods**

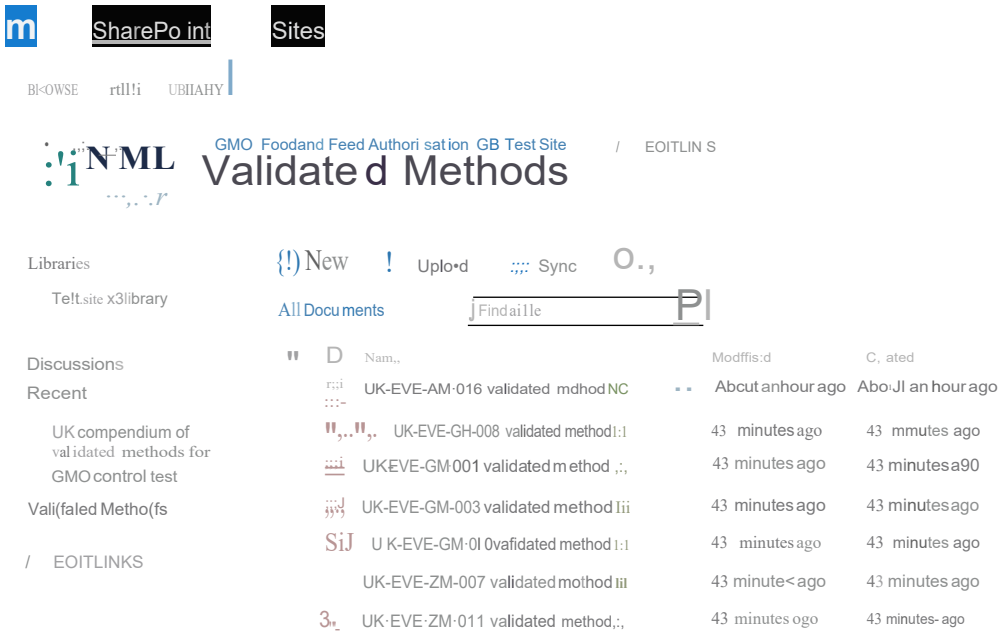



**Figure 4: Scr ee n sho t of a Sh ar ePo in t Lib r a ry co n taining pd f ve rsi o n s of t h e va lid ate d m e th o d s th at a r e link ed to the co m pend ium.**

Depe ndin g up o n th e e xact 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 above shows a simple mock-up of an area within Nextcloud demonstrating a home page interface with associated folders.

As part of the response to tender reference FS430418 "GMO Food and Feed Authorisation GB", LGC proposed to develop the above "compendium" to house all of the relevant information pertaining to GMO authorisations. Should LGC be awarded the positions for the NRL and the GMO authorisation roles, the further development of this compendium to also house relevant information pertaining to the GMO NRL function would be a relatively simple

matter. Hence, should LGC be awarded the NRL and GMO authorisations contract, the total cost of NRL contract will be reduced by up to **£5,000** for the four-year period where both contacts are in operation, to reflectthe cost-saving opportunities for housing synergistic activities for both functions under the one roof.

**Core objective 4 - Compliance assessment via audits, ring trials and provision of reference materials**

| | **Core objective 4 - Compliance assessment via audits, ring trials and provision of reference materials** |
|---|---|
| **Task/Sub-task** | **Description** |
| **4.a** | **Ensure consistency and quality of testing approaches applied by UK OLs and other relevant laboratories, including advising on corrective action following adverse reoorts on OLs from UKAS** |
| **4.b** | **Source and provide suitable reference materials and testing kits to OLs** |
| **4.c** | **Plan and coordinate GMO proficiency testing for UK OLs and other relevant laboratories as appropriate (taking into account the number of relevant laboratories),** analysing and evaluating the outcome, informing the CA and OLs of the results and advising on aooropriate follow-up action |
| 4.d | Co-ordinate the participation of UK OLs and other relevant laboratories in internati onal method validation studies and other initiati ves, inf orming the CA and OLs of the results and advisinQ o n further action |
| 4.e | Where relevant, parti cipate in pr oficiency tests and method validation studies organised by international organisations, informing the CA of the results and implementing any corrective measures required |
| 4.f | Co-ordinate training exercises for OLs and other relevant laboratories to promote best laboratorv practice in respect of GMO anal vsis |
| 4.g | Provide OLs with advanced notification of proficiency testing rounds to enable OLs to implement such activities in a timelv manner |

Task 4.a - Ensure co nsisten cy and qualit y of testing appr oaches applied by UK OLs and other relevant laboratories, including advising on corrective action following adverse reports on OLs from UKAS
LGC is aware and monitors UK GMO analysis capability, being in frequent contact with all OCLs. This is augmented through the formulation, distribution, and collation of information via a questionnaire to PAs. LGC maintains an up to date list of those OCLs that have real-time PCR equipment and capability, and those that have ISO accreditation for GMO analysis. An updated questionnaire will be sent to PAs to gather information on accreditation status and performance in proficiency testing scheme rounds. Assistance will be offered to OCLs to help them deal with corrective actions following adverse UKAS audit observations and / or proficiency test Z scores.
LGC will ensure the consistency and quality of testing approaches applied by UK OCLs and other relevant laboratories by way of the questionnaire to gather information on accreditation status and performancein proficiency testing scheme rounds including corrective actions taken to address adverse reports from PT rounds, UKAS etc. This information will be summarisedby LGC and made available to the FSA in confidence.

**Task 4.b - Source and provide suitablereference materials and testing kits to OLs**
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 Americaand 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 own internal 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.
It is proposed that this provision of advice will continue as part of the NRL function, providing value for money for the FSA in not having to develop, source or otherwise validate these commercial available reference materials. In a similar vein, it is proposed that the NRL continues to provide advice to OCLs in relation to best measurement practice guidance for GMO testing, inclusive of advice on relevant reagents and instrumentation needed for GMO analysis. Requests to source and provide advice on testing kits will be treated on a case-by-casebasis, as the retained EU legislation dictates the use of event specific methods for GMO detection and quantitation, and the validity of any GMO kits must be made in relation to the legislation. Nevertheless, LGC remains happy to provide consultancy to the FSA and OCLs on the efficacy of using such kits. Indeed, the NRL proposes to engage further with the FSA in discussion regarding the development and implementation of a harmonised GMO screening approach for implementation in the UK, reducing the need for the use of commercially available kits but also

promoting standardisation within the UK for GMO sampling and analysis (to be treated outside the current tender proposition).

**The cost of purchase and delivery of all commercially available certified reference materials and kits will be borne by the laboratory requesting these.**

As part of past operations of the GMO National Reference Laboratory function at LGC, the NRL has provided access by OCLs to EURL control materials (provided by the EURL) for official UK control. It is proposed that this function and service provision is still maintained as part of this NRL position.
In terms of storage of control materials, LGC houses multiple dedicated secure walk-in cold room, 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.
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.

Whilst part of the EU, the UK NRL benefited from the service provided by the EURL which helped develop and validate GMO control materials for use for control purposes. A suite of these GMO control materials were provided to each EU NRL, inclusive of the UK NRL. **It is proposed that the UK NRL continue to house such control materials, which can be distributed in a limited form to UK OCLs for control purposes on request.** However, the availability of these control materials will be limited as no new control materials will be provided by the EURL, and it is beyond the remit of the current NRL tender to develop and validate UK based control materials. As part of this tender response, it is proposed that the laboratory responsible for the technical aspect of the GMO authorisation procedure be responsible for managing any control materials as part of the authorisation procedure, and discussions be held with the FSA in order to determine the value proposition of producing and providing more of these for UK controls. The NRL would be happy to provide advice as part of these discussions in order to agree on an appropriate way forward for producing/housing GMO control materials to best support FSA and UK policy in this area.

**Task 4.c - Plan and coordinate GMO proficiency testing for UK OLs and other relevant laboratories as appropriate (taking into account the number of relevant laboratories), analysing and evaluating the outcome, informing the CA and OLs of the results and advising on appropriate follow-up action**
LGC encourages OCLs to participate in accredited and pre-existing proficiency test schemes where possible e.g. GeMMA (Genetically Modified Material Analysis Scheme) or LGC Standards based ones. If the FSA wish the NRL to plan additional proficiency tests above and beyond those already commercially available, then it would be envisaged that the NRL could plan one or two such testing schemes over the four year period. Costs for organising and running any additional proficiency testing rounds will be discussed and agreed with the FSA on a case by case basis, and hence are not included as part of the current tender on the basis that alternative GMO PT schemes of sufficient quality are already available, thus making better use of limited NRL funds.

Task 4.d - Co-ordinate the participation of UK OLs and other relevant laboratories in international method validation studies and other initiatives, informing the CA and OLs of the results and advising on further action

Based on previous experience, all OCLswere free to participatein EURL method validation trialsproviding that they fulfill the requirements of 1981/2006 and were nominated by the Member State Laboratory as a member of the European Network of GMO Laboratories (ENGL).In a similar vein, OCLparticipation in EURL led collaborative tests (proficiency tests) were also free of charge. Whilst the immediate future for continued participation of UK based laboratories in these EURL led activities is currently uncertain, it is the long term aspiration that such activities will recommence again in the future, once the EU/UK trade deal has been further ratified in terms of its impact upon continued UK and EU scientific interactions, exchange and collaborative work.

LGC remains happy to co-ordinate the participation of UK OCLs and other relevant laboratories in relevant EURUi nternational method validation studies and other initiatives, based on informing the FSA and OCLs of the availability of these studies, appraising the results and advising on further action as is necessary.

Task 4.e - Where relevant, participate in proficiency tests and method validation studies organised by international organisations, informing the CA of the results and implementing any corrective measures required

LGCwill seek to participate in relevant proficiency tests organised by accredited providers informing the FSA of the results and implementing any corrective measures required. In the immediate future, this will be facilitated through inclusion in such PT programmes as afforded by the GeMMA and LGC proficiency test rounds, but LGC will also strive to recommence inclusion in the EURL led comparative tests when formal approval has been given for continued UK and EU scientific collaborations and interactions as part of the EU/UK trade agreement.

LGC's participation and performance in GMO related proficiency test (PT) schemes is unrivalled within the UK. In total , LGC has successfully participated in 58 **PT** rounds associated with GMO analysis , comprising all 21 EURL Comparative Tests delivered to date as well as 37 GeMMA PT rounds, analysing 95 separate GM events and receiving the best possible Z-scores in every case (Z<(2)). Nonetheless, as LGC has ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis and has ISO 17043 for reference material production and organisation of proficiency test rounds, it is well versed in the relevant corrective actions to take as part of a recognised quality management system, should unsatisfactory Z-scores occur through proficiency test round participation.

Task 4.f - Co-ordinate training exercises for OLs and other relevant laboratories to promote best laboratory practice in respect of GMO analysis

LGC has previously run two bespoke GMO analysis training courses for OCLs, consisting of a three day event incorporating theoretical and practical training elements, as well as question and answer sessions. Furthermore, LGC is well versed in holding all-inclusive training courses, open to all OCLs, at LGC utilising conference rooms and IT training facilities, and has run six such courses over the last duration of the NRL positions with respect to best practice PCR design and use of molecular biology approaches.

LGC proposes to hold one bespoke training exercise/ scientific study for UK OCLs within the duration of the contract to promote best laboratory practice in the sampling and analysis of GMOs. Alternatively, LGC will take steps to identify appropriate on-line training activities for OCLs to participate in, or otherwise take steps to provide bespoke advice and support to OCLs as the situation demands. Such an approach could be taken for example, should underlying conditions dictate that such face to face training not be appropriate due to COVID-19 restrictions. If such training courses are not required by the FSA during the contractual period then the available funds from this task will be diverted onto other tasks following consultation and prior-agreement with the FSA.

Task 4.g - Provide OLs with advanced notification of proficiency testing rounds to enable OLs to implement such activities in a timely manner

As part of its own ISO/IEC 17025:2017 flexible scope of accreditation for GMO analysis, LGC regularly participates in relevant GMO related proficiency test rounds (e.g. EURL Comparative Tests, GeMMA and LGC proficiency test programmes). Furthermore, Dr. Burns at LGC has been acknowledged as an independent international scientific expert in relation to GMO analysis, having close contacts through a number of GMO networks inclusive of ENGL, Plant Ed COST action group, and Indian and African GMO networks. This unique international involvement and exposure allows LGC to be kept abreast of relevant national and internationally led GMO proficiency test rounds and schemes. Advice will be provided to OCLs as to the relevant proficiency test rounds which they can participate in to demonstrate competency for GMO analysis.

## G. Core function 5 - Co-ordination within the UK of international initiatives

H.

| Core function 5 - Co-ordination within the UK of international initiatives |
|---|

| Task/Sub-task | Description |
|---|---|
| 5.a | **Where appropriate, co-ordinate the recommendations of international organisations related to the standardisation of testinQ methods** |

I.

**Task 5.a - Where appropriate, co-ordinatethe recommendations of international organisations related to the standardisation of testing methods**

It is estimated that this activity would entail use of appropriate communication and monitoring media inclusive of e-mails, video and teleconferencing facilities and face-to-face meetings. Dr. Burns' input into such standardisation activities with international organisations has resulted in a number of published guidance documents[24],[25]. LGC is the only UK based laboratory to participate in all current ENGL scientific working groups aimed at provided best measurement practice guidance in GMO analyses (inclusive of digital PCR, next generation sequencing, detection of products of gene editing, detection of genetically modified microorganisms and detection of GM animals.). Furthermore, Dr. Burns' unique status as a recognised independent international expert in GMO analysis by the EU will help facilitate NRL attendance, input and dissemination of recommendations to the UK control network from all of these working group initiatives for the future.

The publication of any recommendation from an international organisation in relation to the standardisation of GMO analytical testing methods will be brought to the attention of the FSA immediately. Following consultation and agreement with the FSA, the NRL will continue to distribute relevant links/references to these recommendations amongst the UK official control network.

Core function 6 - Liaison and support work on GMO food /feed authorisation

| | Core function 6 - Liaison andsupport work on GMO food/feed authorisation |
|---|---|
| Task/Sub-task | Description |
| 6.a | Liaise with theFSA appointed laboratory on GMO food /feed authorisation process and applications |
| 6.b | Where necessary, provide support/advice to the FSA appointed laboratory for GMO authorisation on the validation of methods of analvses, reference materials |

Task 6.a - Liaise with the FSA appointed laboratory on GMO food /feed authorisation process and applications

LGC will put in place mechanisms to be available for and to consult with the FSA appointed laboratory responsible for technical GMO authorisation, to best support FSA and UK policy in this area.

Task 6.b - Where necessary, provide support/advice to the FSA appointed laboratory for GMO authorisation on the validation of methods of analyses, reference materials

LGC will put in place mechanisms to provide support and advice, where necessary, to the FSA appointed laboratory responsible for technical GMO authorisation, to best support FSA and UK policy in this area. Indeed, LGC's exclusive placement for continued scientific interaction with the EU on all GMO related matters inclusive of discussions on methods of analyses and availability of reference materials means that it is in a unique position to do so.

[24] Trapmann, S., Burns, M., Corbisier, P., Gatto, F., Robouch, P., Sowa, S., and Emons, H., (2020) "Guidance document on Measurement Uncertainty for GMO Testing Laboratories - 3rd edition" European Commission, ISBN 978-92-76-19432-3, ISSN 1831-9424, doi:10.2760/738565S

[25] Pecoraro S., Berben G., Burns M., Corbisier P., De Giacomo M., De Loose M., Dagand E., Dobnik D., Eriksson R., Holst-Jensen A., Kagkli D. M., Kreysa J., Lievens A., Made D., Mazzara M., Paterno A., Peterseil V., Savini C., Sovova T., Sowa S., Spilsberg B. *Overview and recommendations for the application of digital PCR.* EUR 29673 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-00180-5, doi:10.2760/192883, JRC 115736

LGC declares an interest in the GMO authorisation position, and has provided a response to the FSA (FS430418) "GMO Food and Feed Authorisation GB" tender bid. Should LGC be awardedboth tenders, exchange of information and flow of communicationsbetweenthe NRL and GMO authorisation functions will be naturally facilitated through housing of both functions under the one roof at LGC, providing cost saving opportunities for the FSA.

Should LGC be awarded the NRL and GMO authorisations contract, the total cost of NRL contract will be reduced by up to £4,000 for the four yearperiod for Task6.a and6.b where both contacts are in operation, to reflectthe cost-saving opportunities for housingsynergistic activities for both functionsunderthe one roof.

## Core function 7 - Communication of results and data use

| | Core function 7 - Communication of results and data use |
|---|---|
| **Task/Sub-task** | Description |
| 7.a | The Contractor shallensure that the CA receives regularupdates of any developments related to the core functions of the NRL |
| 7.b | The Contractor shall notify the CA immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual work programme |
| 7.c | The Contracto r shall notify the CA immediately by email of any unusual occurrences resultinq from anv of the core functions of the NRL |
| 7.d | The Contractor shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the CA by 31st March each year. Annual reports will be approved by the CA prior to publication by **NRLs** on **NRL** dedicated websites. If requestedby the CA, the Contractor may also need to provide interim reports durinq the annual work proqramme |
| 7.e | Any results or reports arising from the work of the NRL will not be communicated to anv external oarties without the written oermission of the CA |
| 7.f | The use of the data for presentations and/or papers will not be permitted unless written oermission has been sought and given by the CA |
| 7.g | The Contractor will maintain records. Retention periods will be agreed and defined in the contract and if necessary the contractor will assist with transfer of archived reference material |
| 7.h | In other work related to the core functions of the **NRL,** the specified deadlines agreed between the CA and the Contractor should be met |
| 7.i | If necessary, at the end of the Contract all information and data gained from, and required for, **NRL** function over the course of the Contract will be handed over to the CA. This will include assistinq with transfer of archived reference materials |
| 7.j | Provide aninternal report of meetings with other organisations within10 working days of the meetinq |
| 7.k | The Contracto r will engage in quarterly dialogues with the CA to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the CA may also be organised to ensure any potential or evolvinq issues are flaaaed and work is kept on track |
| 7.1 | The Contractor will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates, enforcement, training and other relevant information issues and to discuss **PT** proqrammes and results |
| 7.m | The Contractor will review **NRL** finances regularly and communicate spending, includinq a break-down of costs, with the CA on a monthlv basis |

Task 7.a -The Contracto r shall ensure that the CA receives regular updates of any developments relatedto the core functions of the NRL
LGC will be in constant contact with the FSA regarding developments associated with the core functions of the NRL throughout the entire year, mediated mainly by phone, video and tele conferencingfacilities and E-mail discussions.

Task 7.b - The Contractor shall notify the CA immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual **work** programme
LGC will notify the FSA immediately by email of any deviations which may affect the specifications and timing of the annual workprogramme.

**Task 7.c - The Contractor shall notify the CA immediately by email of any unusual occurrences resulting from any of the core functions of the NRL**
LGC shall notify the FSA immediately by email of any unusual occurrences resulting from any of the core functions of the NRL.

**Task 7.d - The Contractor shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the CA by 31st March each year. Annual reports will be approved by the CA prior to publication by NRLs on NRL dedicated websites. If requested by the CA, the Contractor may also need to provide interim reports during the annual work programme**
LGC will continue to provide an NRL annual report detailing all relevant NRL activities for the financial year. Following approval by the FSA, the annual report will be uploaded to the NRL webpages alongside previous annual reports, and will be made freely accessible to stakeholders.
Where deemed necessary and as requested by the FSA, LGC can provide interim reports during the annual work programme. It is assumed that the regular NRL and FSA liaison meetings, coupled with the routine and frequent channels of communication detailed in Tasks 7.a, 7.k and 7.m will provide the necessary information to keep the competent authority fully updated on relevant NRL activities. However, should there be a requirement to provide interim reports as part of the reporting procedure, the frequency and scope of these will be agreed with the FSA and costed as appropriate.

**Task 7.e - Any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the CA**
LGC will not communicate any results or reports arising from the work of the NRL to any external parties without the written permission of the FSA.

**Task 7.f - The use of the data for presentations and/or papers will not be permitted unless written permission has been sought and given by the CA**
LGC will seek written permission the FSA before the data arising from the work of the NRL is used for external presentations and / or papers.

**Task 7.g - The Contractor will maintain records. Retention periods will be agreed and defined in the contract and if necessary the contractor will assist with transfer of archived reference material**
In accordance with the requirements and accreditation to ISO/IEC 17025:2017, LGC keeps all records for a minimum of six years as standard. LGC will assist in the transfer of any relevant archived control materials at the end of the contract period at the cost of the recipient.

**Task 7.h - In other work related to the core functions of the NRL, the specified deadlines agreed between the CA and the Contractor should be met**
LGC will use its best endeavours to deliver work related to the core functions of the NRL within agreed deadlines following discussions and confirmation between the NRL and the FSA.

**Task 7.i - If necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the CA. This will include assisting with transfer of archived reference materials**
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.

If necessary, at the end of the contract, LGC will ensure that all information and data gained from and required for the delivery of the NRL function is transferred to the FSA or appropriate laboratory, at the cost of the recipient.
As per Task 7.g, the NRL will assist in the transfer of any relevant archived control materials at the end of the contract at the cost of the recipient.

**Task 7.j - Provide an internal report of meetings with other organisations within 10 working days of the meeting**
The NRL will use its best endeavours to provide internal summary reports to the FSA of appropriate meetings held with external organisations, within 10 working days.

**Task 7.k - The Contractor will engage in quarterly dialogues with the CA to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the CA may also be organised to ensure any potential or evolving issues are flagged and work is kept on track**
Both formal and informal quarterly and monthly catch-ups can be managed and organised as appropriate. Based on past experiences with the GMO NRL position, an excellent route of communication and dialogue between the NRL and the FSA has been maintained through regular informal catch-ups and dialogue facilitated through face to face meetings, phone, E-mail and video/tele-conferencing facilities. This will be further augmented through Tasks 7.a to 7.c inclusive, where the NRL will be providing regular updates to the CA as well as ensuring they are aware of any deviations or unusual occurrences which will impact upon the delivery of the NRL function and work plan.

**Task 7.l - The Contractor will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results**
LGC maintains close links with all OCLs via phone, e-mail, face to face meetings and video/tele-conferencing facilities, providing regular advice and updates as part of the NRL function (please see Appendix 1 for examples). It is proposed that this form of communication be maintained as part of the contract tender.
Additionally, Paul Hancock, Head of the Office of the Government Chemist and Referee Analyst, is the duly appointed Association of Public Analyst (APA) Training Officer and is responsible for organising training tailored to the needs of the APA. NRL representatives regularly discuss with Paul OCL training requirements and feed into or present NRL updates at the regular APA Training Committee (TC) meetings. As part of the current contract, it is proposed that NRL updates continue to be given at two APA TC meetings a year.
The Contractor will keep the NRL website up to date on developments, relevant information (especially to the OCLs) and the work of the NRL. This will be facilitated through the NRL webpages which can be accessed from the LGC general website or directly via the following link:
https://www.lgcgroup.com/services/regulatory-support/national-reference-laboratories/#.WG0C-IJvjcu
The webpages will be maintained and relevant information updated to include links through to the most recent NRL annual reports and newsletters, as per Task 1.e described above. An example of the webpage is included in Appendix 2.

**Task 7.m - The Contractor will review NRL finances regularly and communicate spending, including a break-down of costs, with the CA on a monthly basis**
Based on experiences with the GMO NRL position, an excellent route of communication and dialogue between the NRL and the FSA has been maintained through regular informal catch-ups and dialogue facilitated through face to face meetings, phone, E-mail and video/tele-conferencing facilities. This will be further augmented through Tasks 7.a to 7.c inclusive, where the NRL will be providing regular updates to the CA as well as ensuring they are aware of any deviations or unusual occurrences which will impact upon the delivery of the NRL function and work plan.
Because of this, it is proposed that a comprehensive approach be maintained through the formal involvement of an LGC Key Account Manager, who will assist the GMO NRL project manager for commercial and contractual matters.
It is suggested that the frequency and detailed needs of the spending review with the FSA be discussed and agreed with the duly appointed FSA project officer at the initial NRL project kick-off meeting, in order to make most efficient use of NRL funds for this activity. Experience through running the GMO NRL function for the last 12 years would suggest that the regular updates and meetings with the CA as already governed by previous tasks (Tasks 7.a, 7.b, 7.c, 7.d, 7.g and 7.k) would be more than sufficient to provide an effective reporting structure, and that these be used as the benchmark for agreeing the need for additional meetings in line with providing the best value for money to the FSA as part of the NRL function.

Gantt chart to show activities carried out on a monthly basis for the 2021-2022 financial year. These activities will be repeated on a yearly basis for the duration of the project. Please note that the Core Objectives and Tasks are labeled in line with the above sections.

| Core function | Task | Brief Description | Month 1 Apr | 2 May | 3 Jun | 4 Jul | 5 Aug | 6 Sep | 7 Oct | 8 Nov | 9 Dec | 10 Jan | 11 Feb | 12 Mar |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | **Secretariat services** | | | | | | | | | | | | |
| | 1a | Dissemination | | | | | | | | | | | | |
| | 1.b | Covered by Task 4.a | | | | | | | | | | | | |
| | 1.c | OCL communication | | | | | | | | | | | | |
| | 1.d | Regular updates | | | | | | | | | | | | |
| | 1.e | Update GMO NRL Weboaaes | | | | | | | | | | | | |
| **2** | | **Advice and Reoresentation** | | | | | | | | | | | | |
| | 2.a | Reference methods | | | | | | | | | | | | |
| | 2.b | Provision of advice | | | | | | | | | | | | |
| | 2.c | International meetings | | | | | | | | | | | | |
| | 2.d | International activities | | | | | | | | | | | | |
| | 2.e | Covered by Core function 1 | | | | | | | | | | | | |
| | 2J | Covered by Task 1.d | | | | | | | | | | | | |
| | 2.g | Covered by Task 1.4 | | | | | | | | | | | | |
| | 2.h | Technical assistance | | | | | | | | | | | | |
| | 2.i | Standardisation activities | | | | | | | | | | | | |
| 3 | | **Provisionof guidance** | | | | | | | | | | | | |
| | 3.a | Guidance /SOPS | | | | | | | | | | | | |
| | 3.b | Database | | | | | | | | | | | | |
| **4** | | Compliance **assessment** | | | | | | | | | | | | |
| | 4.a | Monitor quality | | | | | | | | | | | | |
| | 4.b | Reference material advice | | | | | | | | | | | | |
| | 4.c | Coordinate PT indusion | | | | | | | | | | | | |
| | 4.d | OCL coordination | | | | | | | | | | | | |
| | 4.e | PT participation | | | | | | | | | | | | |
| | 4.f | Training exercises | | | | | | | | | | | | |
| | 4.g | PT horizon scanning | | | | | | | | | | | | |
| **5** | | **Internationalinitiatives** | | | | | | | | | | | | |
| | 5.a | International guidance | | | | | | | | | | | | |
| **6** | | **GMO authoirsation SUDDOrt** | | | | | | | | | | | | |
| | 6.a | Liaise with GMO authorisation lab | | | | | | | | | | | | |
| | 6.b | Advice and support to GMO authorisation lab | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7 | | **Communication of results** | | | | | | | | | | | | | |
| | 7.a | Regular updates | | | | | | | | | | | | | |
| | 7.b-7.c | Functionupdates | | | | | | | | | | | | | |
| | 7.d | Annual report | | | | | | | | | | | | | |
| | 7.e-7.i | Functionupdates | | | | | | | | | | | | | |
| | 7.k | Quarterly meetings t•it r= uiredl | | | | | | | | | | | | | |
| | 7.1 | OCL Networkmeetings | | | | | | | | | | | | | |
| | 7.m | Financial updates | | | | | | | | | | | | | |

## B. DELIVERABLES

Please outline the proposed proje ct mi lestones and deliverab les. Pleas e pro vid e a tim etab le of key dates or significant events for the project (for example fieldwork dates, dates for provision of research materials, draft and final reporting). Deliverables must be linked to the objectives.
For larger or more complex projects please insert as many deliverables /milestones as required.
Each deliverable should be:

i. no more 100 characters in length
ii. self-explanatory
iii. cross referenced with objective numbers i.e. deliverables for Objective 1 O1/ 0 1 , O1/02 O bje ctive 2 02/0 1 , 02/02 etc

Please insert additional rows to the table below as required.

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

**Please note: Deliverable numbers are labeled** in **accordance with the Core Functions and Task numbers described** in **the previous sections to aid cross referencing. The Deliverables shown below will also apply** to YEAR 2 (2021 - 2022), and as appropriate to YEAR 3 (2022 - 2023) and **YEAR** 4 (2023 - 2024) as per any contract extensions.

| DELIVERABLE NUMBER OR MILESTONE IN ORDER OF EXPECTED | TARGET DATE | TITLE OF DELIVERABLE OR MILESTONE |
|---|---|---|
| **1.A** | **CONTINUOUS** | **DISSEMINATION ACTIVITIES** |
| **1.B** | **COVERED BY DELIVERABLE4.A** | COVERED BY DELIVERABLE 4.A |
| 1.C | CONTINUOUS | OCL COMMUNICATION |
| 1.0 | **ASANO WHEN REQUIRED** | **PROVIDE REGULAR UPDATES** TO **THE FSA** |
| **1.E** | **UPDATE GMO NRL WEBPAGE FOUR TIMES A YEAR** | **UPDATE GMO NRL WEBPAGE** |
| **2.A** | **CONTINUOUS** | **REFERENCE METHOD ADVICE** |

| | | |
|---|---|---|
| **2.B** | **CONTINUOUS** | **ANALYTICAL METROLOGY ADVICE** |
| **2.C** | **THROUGHOUT THE YEAR** | **INTERNATIONAL REPRESENTATION** |
| **2.D** | **THREE TIMES A YEAR** | **ATTENDANCE AT INTERNATIONAL LED MEETINGS** |
| **2.E** | **AS AND WHEN REQUIRED** | **COVERED BY CORE FUNCTION 1** |
| **2.F** | **COVERED BY DELIVERABLE 1.D** | **COVERED BY DELIVERABLE 1.D** |
| **2.G** | **COVERED BY DELIVERABLE 1.D** | **COVERED BY DELIVERABLE 1.D** |
| **2.H** | **AS AND WHEN REQUIRED** | **PROVIDE TECHNICAL ASSISTANCE** |
| **2.I** | **CONTINUOUS** | **STANDARDISATION ACTIVITIES** |
| **3.A** | **CONTINUOUS** | **PROVISION OF GUIDANCE / SOPS** |
| **3.B** | **AS AND WHEN REQUIRED** | **DATABASE DEVELOPMENT (IF REQUIRED)** |
| **4.A** | **CONTINUOUS** | **MONITOR QUALITY** |
| **4.B** | **CONTINUOUS** | **REFERENCE MATERIAL ADVICE** |
| **4.C** | **AS AND WHEN REQUIRED** | **COORDINATE PT ROUND INCLUSION** |
| **4.D** | **AS AND WHEN REQUIRED** | **UK LAB VALIDATION PARTICIPATION** |
| **4.E** | **TWICE YEARLY, USUALLY MARCH AND AUGUST** | **PT PARTICIPATION** |
| **4.F** | **AS AND WHEN REQUIRED** | **TRAINING EXERCISES** |
| **4.G** | **CONTINUOUS** | **PT HORIZON SCANNING** |
| **5.A** | **AS AND WHEN REQUIRED** | **INTERNATIONAL STANDARDISATION** |
| **6.A** | **EVERY QUARTER** | **GMO AUTHORISATION LIAISON** |
| **6.B** | **EVERY QUARTER** | **ADVICE AND SUPPORT TO GMO AUTHORISATION LAB** |
| **7.A – 7.C** | **CONTINUOUS INFORMATION EXCHANGE** | **REGULAR UPDATES GIVEN TO THE FSA REGARDING THE NRL FUNCTION** |

| | | |
|---|---|---|
| **7.D** | **TO COVER THE CONTRACTUAL YEAR** | **ANNUAL REPORT** |
| **7.E-7.F** | **AS AND WHEN REQUIRED** | **GMO NRL FUNCTION UPDATES TO THE FSA** |
| **7.K** | **EVERY QUARTER** | **QUARTERLY MEETINGS (IF REQUIRED)** |
| **7.L** | **TWICE YEARLY** | **OCL NETWORK MEETINGS** |
| **7.M** | **EVERY QUARTER** | **FINANCIAL UPDATES, IF REQUIRED** |
| | | |
| | | |

## 4: ORGANISATIONAL EXPERIENCE, EXPERTISE and STAFF EFFORT

### A. PARTICIPATING ORGANISATIONS ' PAST PERFORMANCE

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

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

J.

[redacted]

[redacted]

[redacted]

[redacted]

**Additional LGC Experience**

LGC is already very experienced in delivering services as NRL for the following areas:

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

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.

LGC has shown continuous and consistent attendance at EU-RL organised workshops and meetings, including ENGL, and all NRL (2017/625) and 1981/2006 meetings. Through attendance at these meetings LGC has maintained an up-to-date awareness of the most applicable analytical strategies to apply for GMO detection, identification and quantitation. Examples of this include LGC's participation in the validation of the original ENGL 96 well-screening and LGC's awareness and practical demonstration of compliance in using the Maede *et al*., protocol for detection of the original Bt63 Chinese rice. LGC then disseminated the knowledge regarding these to OCLs, as well as procuring and delivering the screening plates and Bt63 control materials to OCLs that requested them. LGC has firsthand experience, and arguably the most extensive expertise and knowledge, of the practical implementation of the SYBR®Green screening approach for the detection of Chinese GM rice varieties, in support of EC Regulation 2011/884. The expertise in the NRL function is fully supported and augmented via LGC acting as the UK referee laboratory for four Chinese GM rice referee cases in 2012, and a further one in 2014. In all cases the NRL and GC functions have been mutually complimentary and have augmented each other in terms of provision of expert advice and guidance: for the Chinese GM rice issue (EU Commission Implementing Decision 2011/884) the NRL position has provided the knowledge regarding the legislation and guidance on the approved approaches for analysis, whilst the GC function has provided advice regarding the hands-on and practical application of the techniques required for analysis and the associated experience from experimental application. The resultant combined advice and experience, uniquely facilitated through the collective knowledge of the NRL and GC functions, has been disseminated to the benefit of stakeholders within the UK associated with GM analyses.

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 also has a fully up to date and working laboratory equipped with the latest instruments used in GMO detection including an Applied Biosystems QuantStudio 7 Flex and ABI 7900 HT Sequence detection system,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), 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. Quality procedures and practices underpin all work conducted. Update on refurbishment and new instrumentation.

The technical facility is not only supported by a core of five staff available to work on the NRL function but also backed up by a team of 25 molecular biologists who form the Molecular and Cell Biology Team within the Science and Innovation Division at LGC, and 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 24 years research experience in house specialising in the development of sensitive and specific analytical procedures and boasts a combined CV comprising in excess of 300 publications representing research in a variety of different sectors. This ensures that the NRL 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 five cases of Official Control for Chinese GM rice from 2012 to 2014.

LGC provides a range of consultancy and research services in support of Government policy. These include statutory functions such as the Government Chemist Function. The post of UK Government Chemist (GC) has existed within LGC since the 1870s. Under the provisions of many Acts of Parliament, but significantly the Food Safety Act 1990 and the Agriculture Act 1970, the Government Chemist acts as an independent referee in cases of dispute between enforcement authorities and industry.

It is vital therefore that the Government Chemist's findings are scientifically sound and that the court is convinced of their accuracy. This is achieved through the BEIS funded Government Chemist Programme assuring the technical

position of the Government Chemist, maintaining awareness of trends in regulatory enforcement, maintaining awareness of advances in analytical science in relation to food/agricultural law enforcement, and dissemination of best scientific practice to all stakeholders to assist in the anticipation and prevention of disputes.

The Government Chemist's Programme requires that the Government Chemist and LGC:

- Maintain appropriate scientific expertise and resources;
- Perform appropriate research, intelligence gathering and foresight activities;
- Act as a centre of dissemination of information to 'industry' and enforcement authorities;
- Advise Government on measurement issues and policies;
- Maintain demonstrable independence in relation to the Statutory Functions.

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

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

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

**Additional activities at LGC that will benefit the NRL function**

**Programme and Commercial team**

The Programme and Contract Management Team is part of the NML and is office-based providing programme, contract and commercial management to support to LGC's national roles as a National Measurement Laboratory and the Government Chemist.

The team is composed of very experienced programme and project managers, commercial service managers (measurements, training and consultancy) and continuous improvement manager. The team manages large Government programmes (>£10m per year) i.e. monitoring cost/progress, reporting and invoicing using our ERM system. The team also deals with more than 100 commercial projects per year, facilitating all the steps i.e. initial discussion, quotation, delivery, reporting and invoicing for the NML products and services.

The delivery of the GMO authorization process will be supported by this team.

**Key account Management team**

LGC's National Laboratories operate a dedicated Key Account Management Team responsible for managing government contracts and relationships. LGC proposes that this contract would benefit from Selvarani Elahi supporting Malcom Burns in a Key Account Manager capacity. Selvarani, Deputy Government Chemist (and recipient of an MBE for her services to food measurement science) would act as the primary point of contact for commercial or contractual matters. This would include contract onboarding, the management of commercial reviews, contract variations, as well as performance reporting and route of escalation for issues arising. Selvarani would also continue to ensure excellent communication between the FSA and teams with LGC, ensuring the Agency is briefed on novel technologies, pilots and innovation taking place across the wider organisation that may be of interest.

**Reference Material Production team**

The NML Reference Materials team supports the measurement community through the provision of high-order, primary reference materials. These materials are certified under ISO 17034 accreditation, using primary methods of analysis that are validated by comparison with other worldwide National Measurement Institutes/Designated Institutes. These materials consist of pure organic compounds to be used for calibration as well as a wide range of complex matrix materials for validation or development of analytical techniques across numerous sectors.

**Statistical capability**

LGC has a specialist professional Statistics and Chemometrics Group that takes the lead in many European and Worldwide standardisation bodies. Scientifically, it is led by Dr Steve Ellison, an acknowledged international expert on the application of statistics to analytical data.

Steve is an active member of the Royal Society of Chemistry's Statistics sub-committee of the Analytical Methods Committee and is a senior member of several ISO, CEN and BSI committees involving applications of statistics to analytical science. He has managed technical projects, including National Measurement Laboratory projects, for over ten years at LGC. Recent work includes statistical software validation, method validation, confidence in identification and analytical statistics, with a particular interest in uncertainty estimation and traceability for chemistry.

Thus LGC has the statistical capability for data analysis if required by the FSA.

LGC Trainin g
LGC has been providing first-rate training courses for analytical scientists worldwide for over 20 year. Our long history and role as the UK's National Measurement Laboratory for chemical and biomeasurement means that we have a wide range of expertise in analytical techniques such as chromatography, mass spectrometry and hyphenated techniques. We offer both live face-to-face (COVID-19 restrictions allowing) and virtual courses, as well as web based eLearning modules. Our courses cover topics such as quality systems, statistics, method validation and measurement uncertainty. We offer a scheduled programme of courses, as well as delivering training at customer sites (both in-person and virtually). Examples of our training material can be downloaded from the training resource centre https:/lwww.lgcgroup.com/measurement-services/training-and-consultancy/our-training-courses/

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

Other Netw orkin g with Labo rato ries and Research Groups
The Food Authenticity Network (FAN; http://www.foodauthenticity.uk/) is led by LGC and is funded using a public - private partnership approach, including the FSA.

FAN can help to build a more resilient food supply chain as it gathers information on food authenticity testing, food fraud mitigation and food supply chain integrity, in a structured manner and disseminates it via its open access website. This enables best practice information to be shared for the benefit of all stakeholders, helping to raise standards worldwide. FAN also ensures that stakeholders have access to a resilient network of laboratories providing fit for purpose testing to check for food authenticity so that ultimately, consumers can have greater confidence in the food they buy.

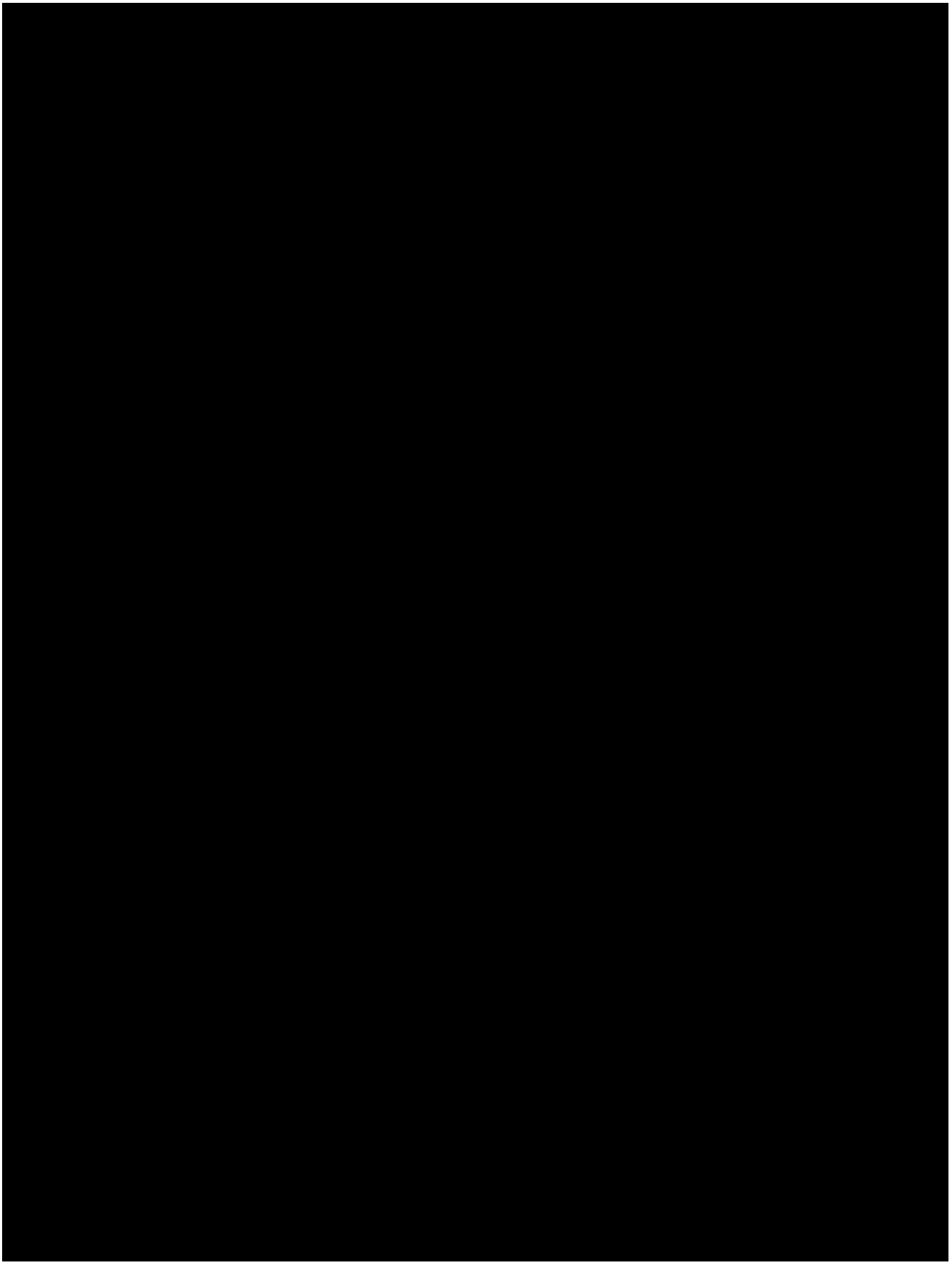
It is important for FAN to be run impartially and independently and LGC has demonstrated its ability to do this successfully in the past 4 years.

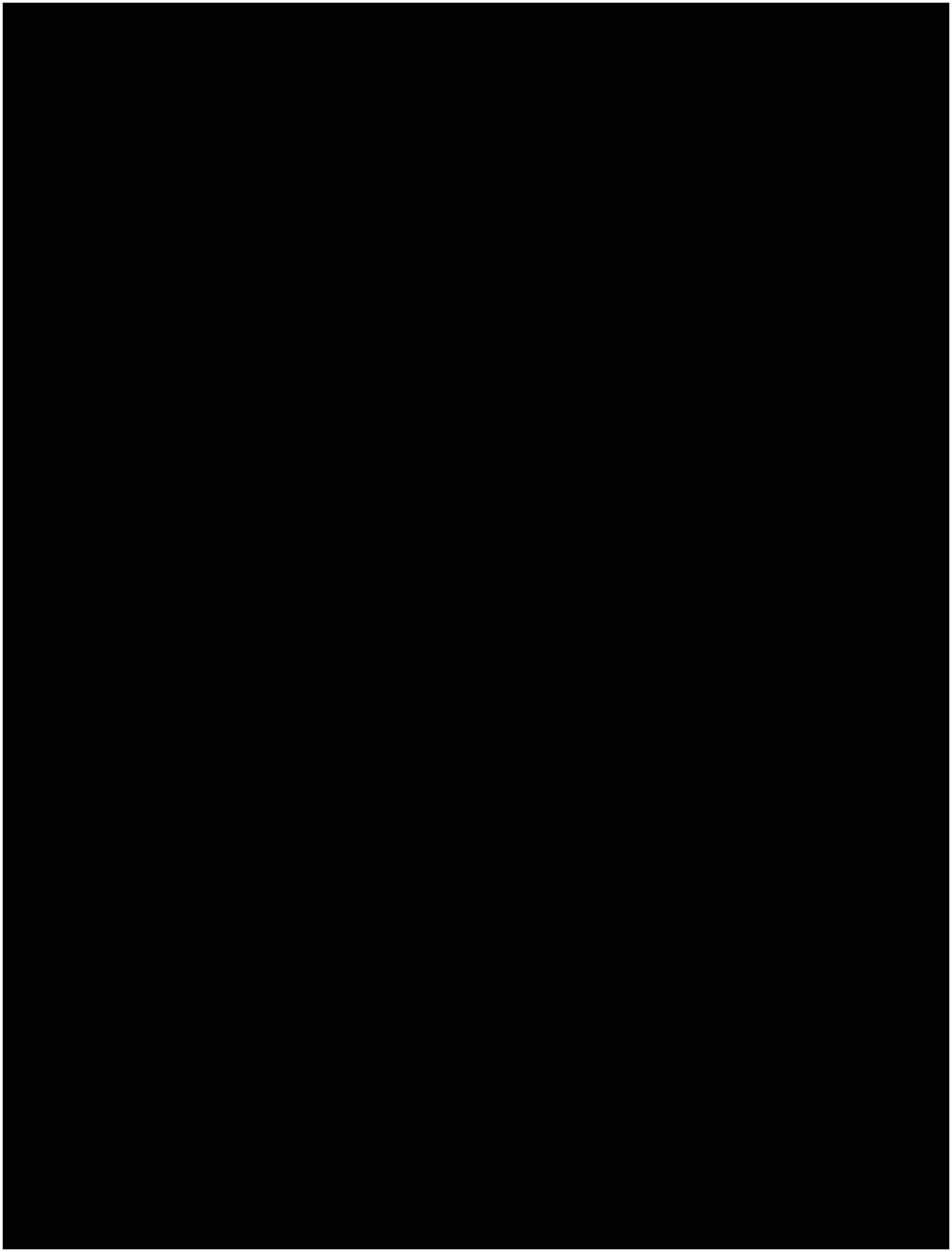
LGC staff have a long track record of attending and providing technical support to national and international committees dealing with sampling and analytical issues. We also have comprehensive contacts with chemists and analysts in industry, academia and the public sector through LGC's role as the NML for chemical and bio-measurement. A key aspect of the role is providing a link between industry and academia, to keep up to date with research, and to drive its application to UK industry. The GMO authorisation function will have the benefit of the supportand expertise of LGC's highly respected capability, numerous experts and our staff s comprehensive contacts in industry and academia.

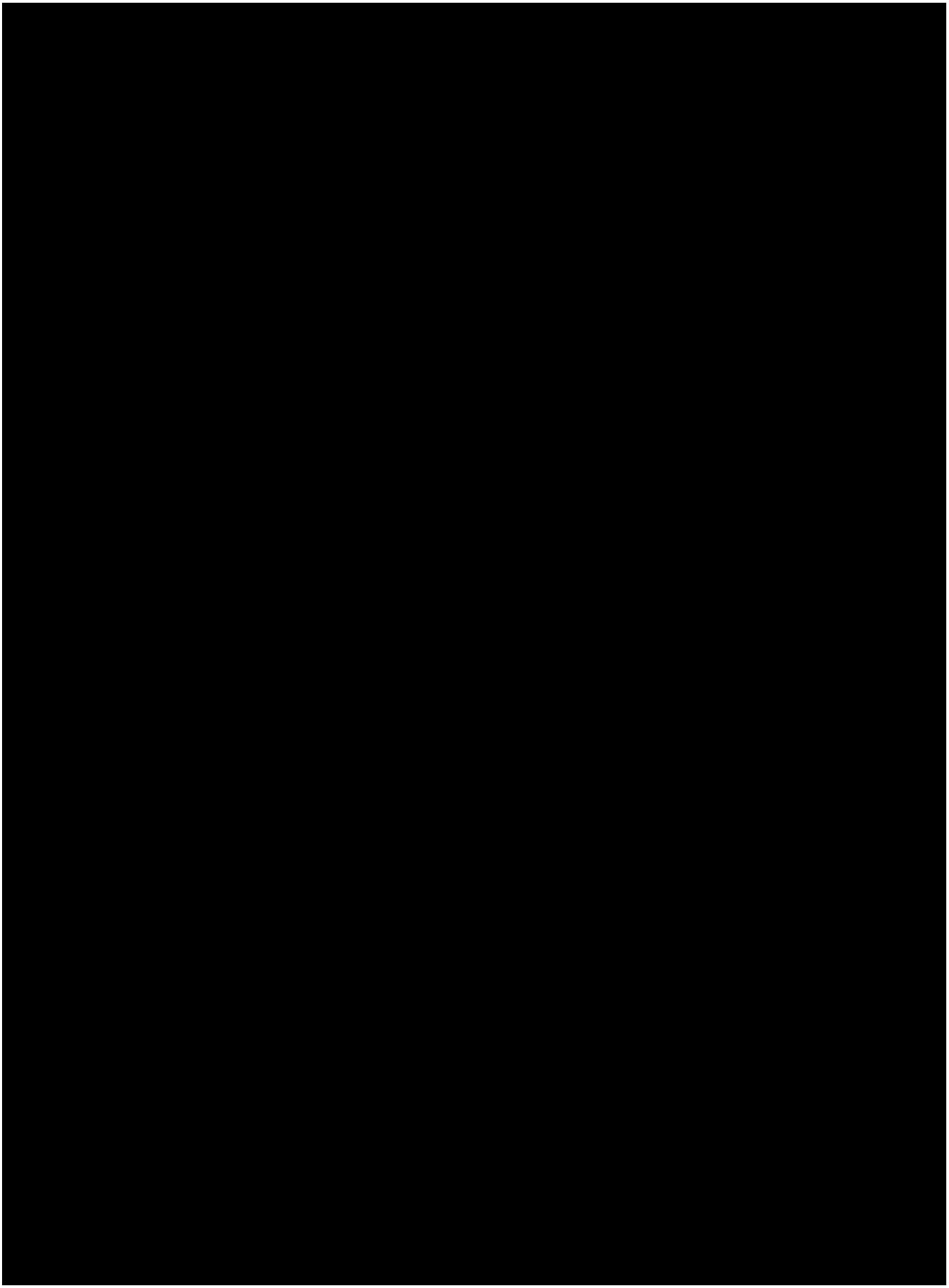
## B. NAMED STAFF MEMBERS AND DETAILS OF THEIR SPECIALISM AND EXPERTISE

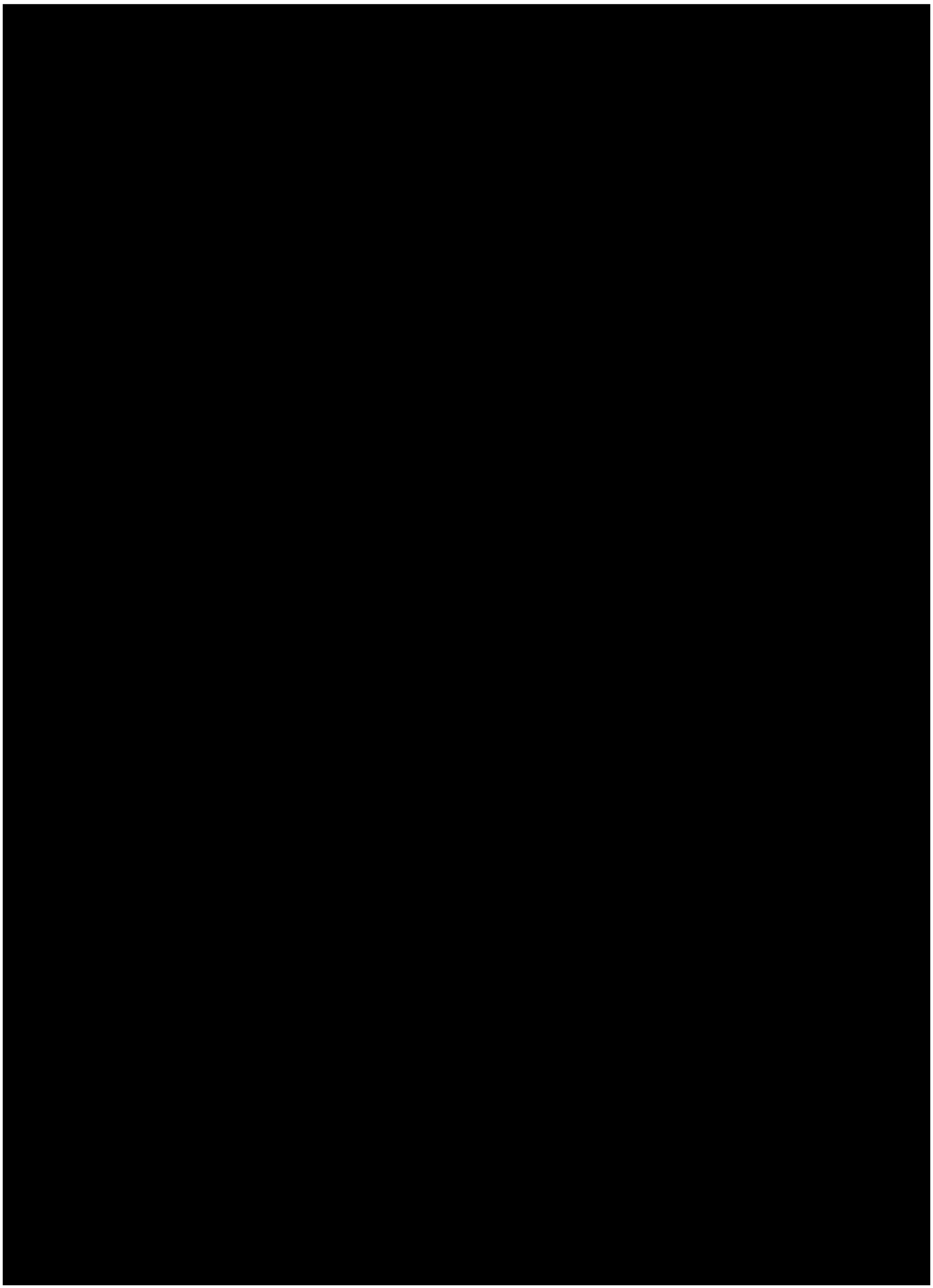
For each participating organisation on the project team please list:- the names and grades of all staff who will work on the project together with details of their specialism and expertise, their role in the project and details of up to 4 of their most recent, relevant published peer reviewed papers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

Lead Applicant LGC Ltd.
Na med staff members, details of spec ialism and expertise.









[redacted]

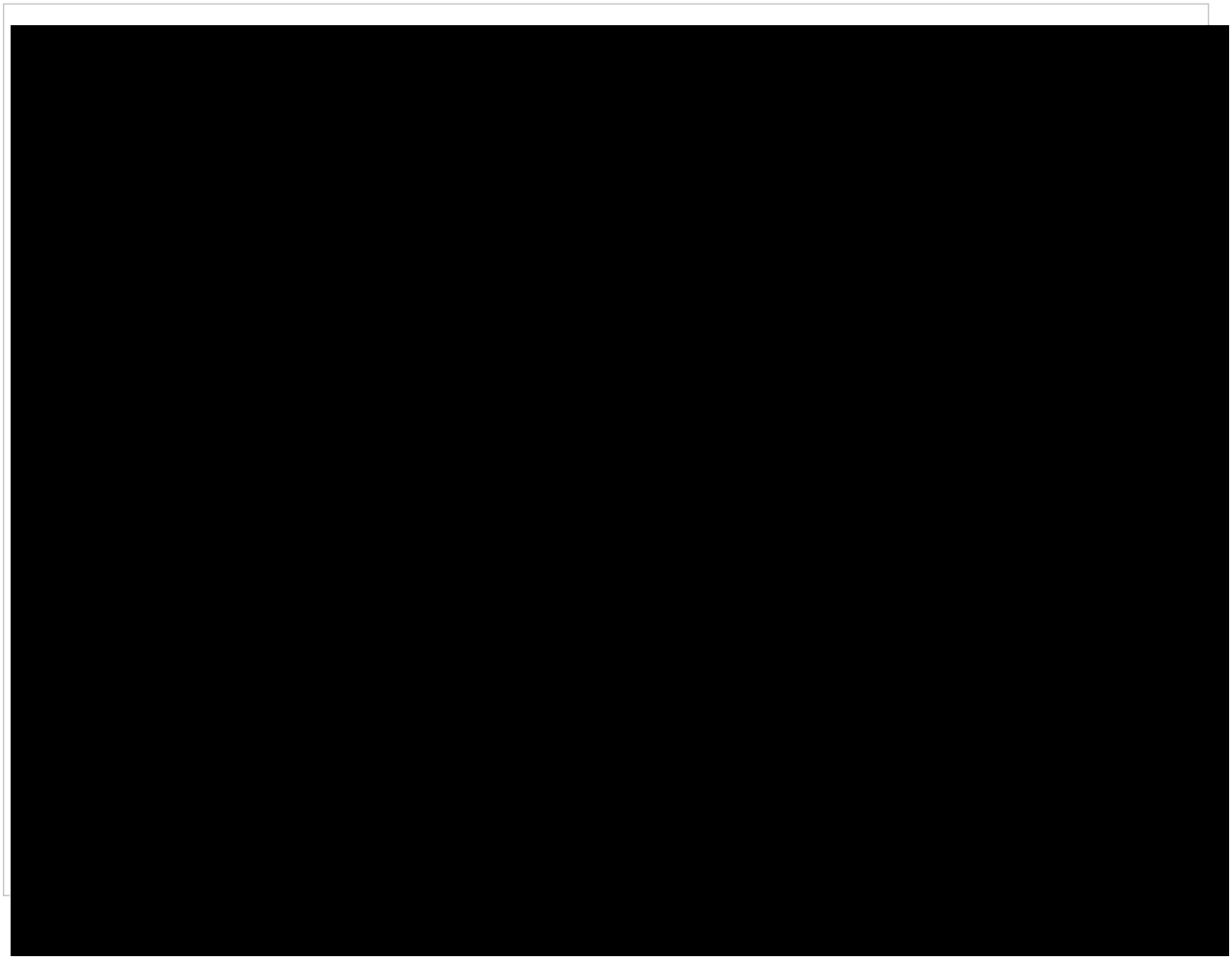
## C. STAFF EFFORT

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

## 5: PROJECT MANAGEMENT

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

[redacted]



## 6. RISK MANAGEMENT

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

| Identified risk | Likelihood of risk (high, medium, low) | Impact of **Risk** (high, medium, low) | **Risk** management strateg y |
|---|---|---|---|
| Insufficient capacity due to COVID-19 absences | low | medium | 1. LGC Teddington operating under stringent COVID secure measures i.e. minimal presence onsite, Teddington COVID tracker, one way system in building, enhanced cleaning regime, sanitisation stations throughout building.<br>2. Staff provided with laptops and secure 2-step log in (including independent user verification stage) so able and encouraged to work from home, minimising footfall on site.<br>3. LGC encouraging staff to adhere to national self-isolation/quarantining requirements. LGC has introduced a global policy allowing employees to request up to 1O d a y s p a id em erge n cy lea v e to d ea l wi th excep tio n al, unp la nn e d e m e r ge n cy s itu at i o n s th at ar i se o u t of CO VID - 1 9 .<br>4 . A ll staff are cross trained so that we have multiple staff qualified to operate an instrument at anv one time. |
| Unable to readily source instrument parts, kit and consumables due to delays at ports caused by EU-Exit transition | low | medium | 1. LGC Procurement managing relationship with Suppliers and back-ups secured for key items.<br>2. Additional stock levels purchased to reduce impact of temporary delays.<br>3. Stringent stock management and controlled issuina of suoolies bv LGC Stores Team. |
| Loss of control materials | low | medium | Temperature controlled cold room storage facility is electronically monitored routinely to ensure environment is correct. Stock will be split between different storage facilities and relevant DNA extract aliquots. |
| Personnel | low | medium | 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. |
| Laboratory equipment malfunction | low | medium | 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. |
| NRL webpage failure | low | low | In the unlikely event that the NRL webpages are unavailable for a period of time, this would not compromise the ability of the NRL to communicate with the FSA and UK OCLs as other mechanisms (telephone, telecon. E-mail, NRL newsletter, tele/video-conferencing) are regularly used. |

## Risk Management

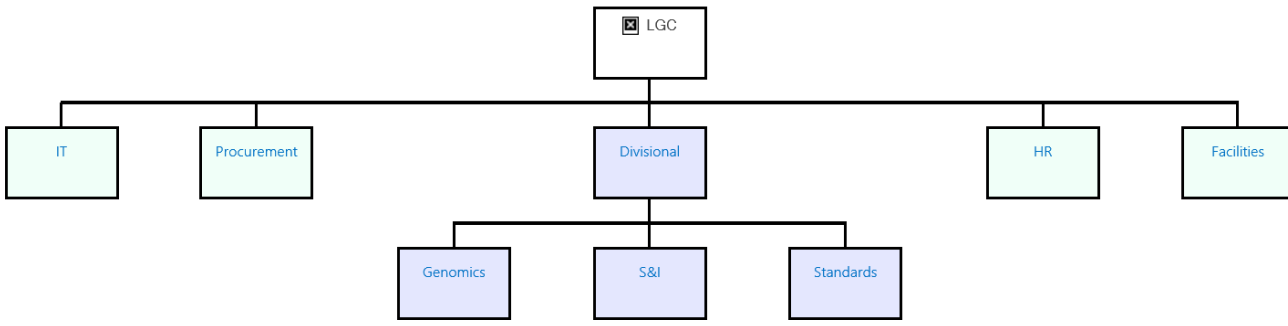



**Figure 6:** Risk management at LGC (schematic)

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

- Managing  Risk Management - version 1.1
- LGC Risk Management Process (based on ISO31000:2009 Risk Management Process)
- LGC Security Management System Policy and Arrangements
- LGC DPL Policy: Dealing with Denied Persons, Politically Exposed Persons and other sanctions lists.
- Anti-corruption and Anti-Bribery Policy*
- Risk register for NL
- Business Continuity Disaster Recovery plan (BCDR) for Molecular and Cell Biology team
- Sub-contracting process
- LGC group ISMS 2001 – Data Privacy and processing Policy 2020*

Documents marked * are included as supplementary documents to this tender. Others are available on request.

LGC's risk management infrastructure and implementation is managed by two key appointments; the Senior Information Risk Owner and the Group Head of Security. They are supported by a Risk Steering Committee, which has representation from key functions across LGC. LGC's National Laboratories Teams are experienced in the management of risk for government Customers and stakeholders, and have enhanced their risk monitoring and mitigation activities during 2020 to account for the challenges posed by the COVID-19 pandemic and EU Exit transition. Below is an example of a LGC Government Customer's Risk Register (reviewed and updated fortnightly in consultation with the Customer):

## 7. QUALITY MANAGEMENT

### A. QUALITY MANAGEMENT

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

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

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

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

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

- **ISO/IEC** 17025:2017 fl exible scope of accreditation for GMO analysis **(UKAS)**
  This was awarded in 2014, where LGC was one of the first UK laboratories to be accredited for ISO 17025 flexible scope of GMO analysis, and ensures that LGC is fully compliant with the criteria to be awarded the NRL positon according to EU Regulation 882/2004. This accreditation fully complies with, and is based on, the European Commission published guidance on flexible scope of accreditation for GMO analysis[26], which LGC helped contribute towards.
- **BS EN ISO 9001:2015 (BS5750 Part 1)**
  Granted March 1994, all Laboratory activities are covered, i.e. bothscientific and support activities, e.g. customer relations and financial services.
- **ISO17034:2016**
  Granted in 2006 (ISO Guide 34) for the general requirements for the competence of Reference Materials producers
- **Additional UK Accreditation Service, UKAS**
  Granted April & November 1984 (testing & calibration respectively), LGC was one of the first laboratories to achieve this foremost assurance of analytical quality and reliability, and now has one of the most extensive scopes of accreditation to the requirements of ISO/IEC 17025:2015 of any laboratory in Europe.
  - LGC is also accredited by UKAS for the provision of proficiency testing (PT) schemes to ISO Guide 1743:20101, and for the production of Certified Reference Materials (CRMs) to ISO/IEC 17025:2015 in combination with ISO 17034:2016, being in the first tranche of accredited organisations for both these activities.
  - LGC has ISO17025 accreditation to provide statements of opinions and interpretation in relation to referee analyst. This accreditation covers the interpretation of analytical data derived from prescribed methods of analysis and the expression of opinions with regard to product compliance with the relevant legislation.

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

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

[26] European Commission, JRC Scientific and Policy reports(2013) "Europeantechnical guidancedocument for the flex ble scope accreditation of laboratories quantifying GMOs", ISBN 978-92-79-26176-3. doi 10.2787/67611

- All of LGC's operations comply with the requirements of ISO 9001:2015;
- Recognition of LGC as the Government's Referee Analyst and cited explicitly in Acts of Parliament;
- Management of, and participation in, proficiency testing schemes, such as Aquacheck, CONTEST, FAPAS, Toytest, Quartz, Aims, DAPS, BAPS, UKNEQAS, UKFSLG, CTS, EUPTS and Asia
- Production, and use, of certified reference materials (CRMs) for traceability and calibration;
- A continuous improvement cycle to all aspects of service, including technical, commercial and customer relations;
- Regular internal audits to ensure that the highest standards of quality are maintained.

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

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

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

LGC also serves as the UK National Reference Laboratory in a range of key areas:
- Genetically modified organisms (GMOs) in food and feed
- Added water in poultry
- Feed Additives – Authorisation
- Feed Additives – Control

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

**LGC fully complies with the Joint Code of Practice for Research (JCoPR).**

**<u>Quality Information Related to GMOs</u>**

- LGC has flexible scope ISO/IEC 17025:2005 accreditation for quantitative testing of genetically modified organisms in food and feed, thus meeting the requirements to act on behalf of the FSA for the method validation aspect of GMO authorisations, as stipulated in the tender specifications. As part of this accreditation, the guidance in the EURL Guidance document "*Minimum Performance Requirements for Analytical Methods of GMO testing*" (2015) is cited and used throughout.
- LGC is fully aware of and has implemented the official EU-RL/ENGL guidance document "European technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs" as best measurement practice guidelines for ISO 17025 in this area.
- Following the Food and Veterinary Office official audit of UK compliance with EU legislation for GMOs in 2014, the FVO audit team reported that the NRL (LGC) met all of the requirements of Article 33 of Regulation (EC) No 882/2004 (now replaced by 2017/625) and the relevant international standards for GMO analysis.
- LGC maintains a fully traceable track-record and demonstrable experience in key ISO 17025 and 2017/625 criteria including method validation, uncertainty of measurement, traceability of measurement results, participation in external quality assessment schemes, and testing/calibration of methods.
- LGC is fully compliant with UK regulations with respect to GMO analysis.
- In terms of quality criteria associated with fitness for purpose of an analytical laboratory associated with GMO testing, LGC always applies the EU-RL validated event-specific tests for GMO quantitation where available. All

of these validated protocols have LODs/LOQs listed as part of the qualifying criteria. Additionally, LGC also uses the EU-RL Guidance document "*Minimum Performance Requirements for Analytical Methods of GMO testing*" (2015) that specifies the minimum quality criteria a laboratory has to meet to ensure that a GMO analytical test is performing fit for purpose in the laboratory's hands. Such criteria include r-squared and PCR efficiencies of calibration curves being >0.98 and 100% ± 10% respectively. The precision estimates must also be $RSD_r$ less than or equal to 25%. As part of its own Quality Procedures, LGC ensures that it is operating within the specifications listed in this guidance document. As LGC has a wealth of data associated with all GMO analytical tests, these have not been provided as Appendices but can be provided or inspected upon request.

- In terms of quality criteria associated with fitness for purpose of an analytical laboratory associated with the GMO analysis in food and feed, LGC applies internationally recognised approaches for:
    - Establishment of LODs/LOQs
    - Method validation
    - Establishing measurement uncertainty
    - Organising collaborative trials
    - Organising proficiency testing schemes.

**LGC's Performance in Comparative / Proficiency Testing Schemes**

Representing the NRL for GMOs in the UK since 2009, LGC has participated in all EU-RL Comparative Tests organised by the EU-RL for GMOs in Food and Feed. The NRL Comparative Tests consist of international based proficiency test schemes and are stated by the EU-RL as representing the most objective test to qualify that a laboratory is fit for purpose as an NRL (2017/625) or nrl (1829/2011).

At the time of this application 20 EU-RL Comparative Tests have been organised and completed by the EU-RL. LGC has demonstrated complete compliance with EU Regulation 2017/625 through participation in all 20 of these EU-RL Comparative Tests, producing over 66 test sample results for the presence of 29 different GMO events, and has provided evidence of all results being fit for purpose as they are compliant with quality criteria ([Z]<2) as well as competency to extract DNA from a range of different food matrices. In total 66 Z-scores have been received by LGC, all of which have been less than a magnitude of 2, which is the key quality criterion for showing the fitness for purpose of a laboratory as part of any external quality assessment exercise. This is of particular note, for example, as for one of the tests in the 5$^{th}$ EU-RL Comparative Test, more than 58% of the 32 participating laboratories received an unsatisfactory Z-score. It is envisaged that mandatory NRL participation in the EU-RL organised Comparative Tests will continue at a frequency of two per year. The EU-RL have stated that these will continue to increase in complexity in terms of number and nature of GM events being tested for, as well as the nature of the sample matrix being extracted from. We believe LGC is uniquely positioned to meet these new challenges as demonstrated by its proven track record of good Z-scores.

As further qualification of its fitness for purpose as for 2017/625, LGC regularly participates in other external quality assessment exercises including the FAPAS and GeMMA (Genetically Modified Material Analysis Scheme) Proficiency Tests. LGC has actively supported and participated in the GeMMA PT scheme since its inception in the year 2000. To date, LGC has participated in over 37 rounds of the GeMMA PT scheme, analysing over 55 samples from a range of food matrices including flour, milk powder; snack foods, biscuits, canned meats, soya, pate, animal feed, cake, etc. In all cases Z scores received were less than a magnitude of two, providing evidence of LGC's applicability at producing accurate GMO results.

Furthermore, LGC has participated in the first ever international metrology key-comparison trial involving DNA and quantification of GMOs (Consultative Committee for Amount of Substance – Metrology in Chemistry [CCQM] KC-86) using plasmid and genomic calibrants. Z-scores for this trial were also all less than a magnitude of two. This key-comparison was as a result of participation in the international CCQM-P60 pilot study based on the quantitation of Genetically Modified (GM) material. This study showed that the accuracy of the estimated GM content of samples could be adversely affected by the choice of the DNA extraction procedure used to prepare the target template. Following on from this pilot study, Key Comparison CCQM-KC86 was designed to test if the relative quantity of two genomic DNA fragments present in a biological sample could be accurately determined using real-time PCR, based on GM material as a model system. In parallel with this an additional CCQM-P113.1 pilot study was conducted to see if relative quantitation could also be achieved using digital PCR. Results of both CCQM-P60 and CCQM-K86 have been published in the peer reviewed literature (with LGC included as an author).

Whilst LGC has never received a Z-score greater than a magnitude of two for any GMO related analyses, it is aware of the corrective actions that need to be followed if such a case arises, as dictated by ISO/IEC 17025 and the UKAS policy on corrective actions.

LGC has a system for managing incidents; all incidents, including unsatisfactory performance (Z score >[3]) in proficiency testing rounds, are logged onto the LGC ERM database (LGC database in which all safety, health,

environment, quality & security incidents are recorded and interrogated by management for learning points). Investigation of the incident is conducted in consultation with the LGC Quality Manager and a report covering root cause analysis, conclusions and corrective actions is produced. Samples are reanalysed if required. Any learning points are shared across the company facilitated by the LGC Group Quality manager.

**Measurement uncertainty**

LGC is a member of the EU-RL working group on measurement uncertainty estimation, and is a named author on the 2020 peer reviewed EC published guidance entitled "Guidance document on measurement uncertainty for GMO testing laboratories - 3rd edition". This guidance document applies the measurement uncertainty principles outlined in the GUM and ISO 17025 to a GMO analytical background, and is consistently used for the estimation of measurement uncertainty associated with results for all NRL Comparative Tests. The relative measurement uncertainty (expressed on a mass per mass basis) in and around the legislative limit for all of LGC's reported results was always less than 25%, which greatly surpasses the key quality criteria of RSD, <25% as defined in the ENGL Guidance documents *"Verification of analytical methods for GMO testing when implementing interlaboratory validated methods"* and *"Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing"*. As LGC has a wealth of data associated with all GMO analytical tests, these have not been provided as Appendices but can be provided or inspected upon request.

## B. ETHICS

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

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

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

LGC has a central bio-ethics committee to provide consistent and formal advice to staff on the compliance of all work undertaken with respect to the Human Tissue Act the in the UK, the committee also advises LGC staff on other ethical issues if required. We do not currently foresee any ethical issues arising from this project, which is mainly an advisory role in line with Commission Regulation (EC) 2017/625.

## C. DATA PROTECTION

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

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

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

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

LGC operates a policy of performing suitability checks on new staff to ensure their eligibility for appointment. This includes checks to ensure suitability, integrity and experience and the methods employed are:

- Character references
- Health declaration form, supplemented as required by examination/referral to occupational health service
- Nationality, birth certificate, passport and other relevant certificates such as marriage, alien etc.
- Education and professional attainment - relevant certificates of qualification

In certain cases, LGC staff involved in particularly sensitive activities are cleared to Security Check (SC) or Developed Vetting (DV) level as appropriate. It is recognised that for the delivery of this contract, background checks on new staff will need to be implemented.

Job descriptions exist for each category of role and there is a clear differentiation between the job responsibilities, the skills required to carry out the role, and the purpose of the specific role. Access to sensitive data is managed according to the individual's role and authorisation level.
It is also recognized that access to mobile devices might be prohibited for staff delivering unless encrypted devices are used.

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

Control of documents including (but not limited to) Standard Operating Procedures, Work Instructions, Experimental Data, and reports will be undertaken in accordance HS&I quality procedure 'QM QI 001', a copy of which can be provided upon request. Documents under ISO 9001, 17025, and 17034 will created, issued, and controlled in accordance with the requirements of the management systems in operation.

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

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

**GOPR** and data privacy
LGC has a Data Privacy & Processing Policy which is fully compliant with the EU General Data Protection Regulation (EU 2016/679). This policy describes LGC's obligations and its own employee's responsibilities with regard to the protection of Personal Data held and processed in the course of LGC's business. It outlines responsibilities for handling and safeguarding Personal Data and it also identifies those who have specific duties in respect of Personal Data and privacy protection.
A copy of this policy can be viewed upon request.

**LGC Cata processing policy**
Details of LGC's Data processing policy has been provided as supplementary information.

**GMOs**
Furthermore, LGC has taken steps to ensure effective dissemination of ENGL matters to relevant UK OCLS whilst still maintaining the appropriate confidentiality associated with ENGL meetings. This has been facilitated by LGC constructing and implementing a Confidentiality Disclosure Agreement for UK OCLs on behalf of ENGL to ensure that proprietary information discussed at ENGL is not circulated beyond UK OCLs.

## D. SUSTAINABILITY

The Food Standards Agency is committed to improving sustainability in the management of operations. Please state what (if any) environmental certification you hold or briefly describe your current Environmental Management System (EMS)

Summaries of LGC's Environmental and Sustainability policies are included below. The full policies have been submitted as supporting documents to this tender.

**LGC Sustainability Policy**

LGC is committed to a policy of sustainable development that meets the needs of the present, without compromising the ability of future generation to meet their own needs. LGC has set specific goals and targets for sustainability. LGC recognises that its activities have the potential for both positive and negative impacts upon the environmen t at local, national and global levels. LGC acknowledges the importance of delivering a sustainable service that will contribute to an increase in the quality of life and of the environment. To deliver our goals and strategies LGC will: Communicate LGC's Sustainability Policy and strategy to staff and stakeholders and raise awareness of their sustainability responsibilities and the requirement to commit to environmental improvements; Set continuous improvement targets by which LGC's performance can be measured, demonstrated and reported to LGC's Board; Identify opportunities and take action where practicable to improve the sustainability of LGC's activities, products and operations; Reduce waste created and where possible reuse and recycle before responsible disposal of surplus materials; Comply fully and where possible exceed standards set in relevant UK, EU and international regulatory requirements and agreements; Deliver a travel plan to implement measures to encourage walking, cycling, the use of public transport and a car share scheme as the principle means for commuting to LGC sites; Provide the right level of advice, awareness and competency to staff and to our contractors' employees; Work with our suppliers to ensure that goods and services procured by LGC are sourced in a sustainable manner. LGC recognises that is has an important part to play in society in the way that it carries out its business. Much of our work is aimed at improving the quality of life within society. LGC has a significant role in the analytical chemistry community as well as having an effect on the safety of society. In order for LGC to behave in a socially responsible manner, it is vital that staff are aware of LGC's current activities and take an active part in developing LGC's sustainability activities. The importance of being able to deliver a reliable and continuous service to customers is guided and governed by LGC's ESG Policy (please see attachments).

## E. DISSEMINATION AND EXPLOITATION (Science Projects Only)

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

The applicant should describe plans for the dissemination of the results for the project team as a whole and for individual participants. Details should include anticipated numbers of publications in refereed journals, articles in trade journals etc., presentations or demonstrations to the scientific community, trade organisations and internal reports or publications. Plans to make any information and/or reports available on the internet with the FSA's permission are also useful, however, this does not remove the requirement for Tenderers to think how best to target the output to relevant groups.
If a final report is part of the requirement, please make sure, as part of the executive summary, that aims and results are clear to the general audience and that the impact of the research on public health/consumers and it's alignment to FSA priorities is clearly stated.

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

Please indicate whether any Intellectual Property (IP) may be generated by this project and how this could be exploited. Please be aware the FSA retains all rights to the intellectual property generated by any contract and where appropriate may exploit the IP generated for the benefit of public health.
In this part Applicants should demonstrate the credibility of the partnership for exploitation of the results and explain the partnership's policy in respect of securing patents or granting licenses for the technology (if applicable). It should deal with any possible agreements between the partners to extend their co-operation in the exploitation phase and with relevant agreements with companies, in particular users, external to the partnership

It is anticipated that key audiences will include Government and Regulatory bodies e.g. FSA and Defra, their associated working groups (including the AMWG); Enforcement agencies and Public Analysts and Official Control Laboratories; Industry, food retailers, food manufacturers and consumer bodies etc., who have a key interest in food labelling and food traceability.

The results of the project will be disseminated in multiple ways to maximise communication of the dissemination events to a range of stakeholders. Every effort will be made to publish results and guidance from the NRL following agreement and approval with the FSA.

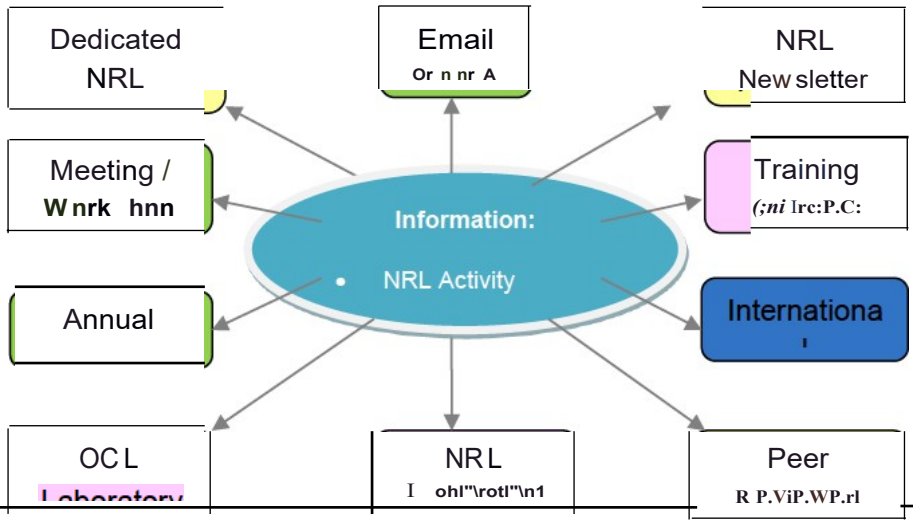
Example routes of dissemination will include:

- Dedicated **NRL** webpages - this will be one of the main sources of dissemination, as detailed in the invitation to tender. As well as copies of the NRL newsletter and annual reports, the NRL webpages will house links through to updated information on GMOs as well as contact points for the NRL;
- **A NRL** newslett er - this will be produced and distributed to all Official Control Labs and to the Competent Authority. Information will include legislation updates, emergingissues, food and feed recalls, information from the EU-RL, advice provided (anonymised), meetings, work programmes, and laboratory visits. Back copies of the newsletter will be accessible via the NRL webpages;
- **An NRL** annual report - providing details of all of the activities that the NRL has been engaged in on an annual basis;
- **FSA/NRL** liaison meetin gs - regular progress meetings will be held with the FSA as detailed in this tender so that delivery of the NRL functions can be monitored;
- Regular contact with the FSA - as facilitated by regular telephone, video/tele-conferencing, and E-mail dialogue as the need arises;
- **Visits with OCLs** - these will be arranged with OCLs as the need arises and with prior consultation with the FSA;
- **Training courses** - bespoke training courses associated with GMO analysis can be arrangedby LGC for OCLs (either virtually or on-iste), by prior agreement with the FSA;
- **International representation and meeting attendance** - a two way channel of communication between the NRL and international stakeholders will continue to be maintained via these regular meetings;
- **Publication of guidance notes** - The NRL will continue to input into standardisation and harmonization activities (e.g. CEN and ENGL Working Groups). Any official EU guidance notes regarding GMO analysis will be forwarded by the NRL to the FSA and OCLs when the NRL is aware of the publication of these. Regarding preparing its own Guidance Notes on GMOs, LGC has a strong record for publishing these in peer-reviewed journals[27].

Figure 7 shows the primary methods of dissemination that LGC intends to use to disseminate information relevant to NRL activities. Other possible dissemination activities include publication of appropriate GMO protocols, guidance notes, Knowledge Transfer events, presentations, posters, abstracts, meetings and collaborative trial of methods.

Where ever possible, information will be placed on the dedicated NRL webpages and in relevant cases, with the permission of the FSA, peer reviewed publications will be sought.
As the contract tender is in relation to fulfilling duties associated with a National Reference Laboratory under retained EU legislation 2017/625, there is no anticipated generation of IP associated with this project.

Figure 7: Example routes for dissemination of information to be used by LGC




[27] Timothy Wilkes, Gavin Nixon and Malcolm Burns (2016) "Recent Developments in DNA-based Screening Approaches for Detection of GMO's" Journal of Association of Public Analysts (Online) 2016, Volume 44, pages 40-50.

## 8. SOCIAL VALUE

K.

Social value has a lasting impact on individuals, communities and the environment. Government has a huge opportunity and responsibility to maximise benefits effectively and comprehensively through its commercial activity. To be effective it is essential that the FSA consider social value at all stages of the procurement life cycle. In order to do this, we are applying the Government Commercial Functions social value model PPN 06/20 Procurement Policy Note - Taking account of social value in the award of government contracts.

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

L.

**A. TACKLING ECONOMIC INEQUALITY** - Provide evidence of how you will support innovation and disruptive technologies throughout the supply chain to deliver lower cost and/or higher quality goods and services.

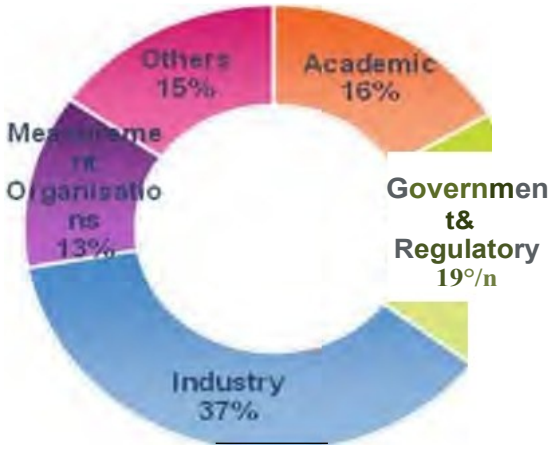
A model response should include activities that demonstrate and describe the tenderer's existing or planned:

M.

- Understanding of opportunities to drive innovation and greater use of disruptive technologies, green technologies, efficiency and quality to deliver lower cost and/or higher quality goods and services.
- Creation of a design and tendering environment that is conducive to tenders that offer innovation and disruptive technologies. Illustrative examples: outcomes-based specifications enabling alternative approaches to be offered; codesign with users and communities; approaches that invite innovative approaches to be proposed and developed; activities that promote collaboration to access new technologies/green technologies and/or approaches.
- Measures to ensure the development of scalable and future-proofed new methods to modernise delivery and increase productivity.

As the designated institute for chemical and Bio-measurements (funded by BEIS), we develop and formulate our research programme on a 3-year cycle. For this, we maintain close stakeholder relationship (~850 stakeholders across multiple sectors of which we collaborate directly with more than 25%) that enables us to adapt and consider new approaches and technologies.

The figure below shows our stakeholder engagement (2020)




Our research programme aligns with the UK strategic goals and across our research teams, we address a complex set of cross-sector issues to help solve complex global challenges, developing reference methods and materials, setting standards, providing advice and informing legislation. Our fundamental measurement research in advanced therapeutics, diagnostics and safety and security underpins some of the biggest challenges of our time, including cancer, anti-microbial resistance, climate change and food safety.

Our scientists attend several technical conferences in the field of Environment and food security that enable them to keep up to date with new technologies. They are also part of numerous technical committees, including Detra Nanomaterials Environment, Health Industry Group and ISO committee on Nanotechnology.We have collaborated with Energy companies to better understand novel technologies(e.g. fuel cells) and sources of energy (e.g. bio-fuels). For example, our cutting edge measurement technologies in inorganic analysis (laser ablation-ICP-MS) allowed multi-elements solid state characterisation of cell layers that is key for quality assurance, performance and stability.

For further evidence of innovative approaches delivered as part of this NRL tender, please see the "Innovation" section on page 25

**B. FIGHTING CLIMATE CHANGE -** Influence staff, suppliers, customers and communities through the delivery of the contract to support environmental protection and improvement.

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

- Understanding of how to influence staff, suppliers, customers, communities and /or any other appropriate stakeholders through the delivery of the contract to support environmental protection and improvement.
- Activities to reconnect people with the environment and increase awareness of ways to protect and enhance it.

Illustrative examples:

- Engagement to raise awareness of the benefits of the environmental opportunities identified.
- Co-design/creation. Working collaboratively to devise and deliver solutions to support environmental objectives.
- Training and education. Influencing behaviour to reduce waste and use resources more efficiently in the performance of the contract.
- Partnering/collaborating in engaging with the community in relation to the performance of the contract, to support environmental objectives.
- Volunteering

**LGC Environmental Policy**

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

LGC helps its customers respect the environment and reduce waste by providing accurate measurement and quality control systems. We also work to reduce the impact of our own activities have on the environment, including energy consumption and waste production. LGC's commitment to maintaining and enhancing the environment is captured and governed by the following policies and systems: the LGC Environmental Policy; LGC's Sustainability Policy and Group EP2005 Sustainable Procurement; CRC reporting; and management systems certified to ISO 14001. The Group Head of Environment, in conjunction with the Environment Adviser, Environment Manager, and the Environmental Management Steering Group, is responsible for setting the environmental strategy and monitoring environmental compliance and performance.

**N.**

## Clarifications

## Dated 19th March 2021

1. The Plan does not specifically provide details on how the NRL will enable official laboratories access to external PT programmes for GMOs.

Traditionally, laboratory participation in PT rounds is at the expense of that laboratory, as a recognised way of maintaining accreditation and demonstrable evidence of External Quality Assessment exercises.

Page 10 of the tender response refers to the pre-existing FAPAS (GeMMA) Proficiency Test Programme for GMOs, which is a well-regarded and well-established programme

underpinned with the relevant accreditation to support effective PT work. These GMO PT rounds continue to be open to all participants, and details of the PT programme are available on the FAPAS website.

The NRL has advised, and would continue to advise, OL's that this option should be considered in the initial instances, as it represents a cost-effective and accessible route for external quality assessment exercises.

Task 4c (page 36 of the tender) again acknowledges the pre-existing GeMMA PT programme and indicates that, as necessary and with prior agreement with the FSA, additional bespoke PT rounds could be negotiated by the NRL with the organiser of the PT programme, to further support the NRL function.

An alternative, but additional, cost-option to enable OL participation in GMO PT rounds could be for the FSA to consider a financial contribution towards OL's costs in such participation (similar to specific FSA ring-trials and PT rounds). The NRL would be happy to assist in implementing any such decision.

In the absence of the above, the NRL will continue to actively encourage OL's participation in any relevant GMO-related proficiency test schemes, as part of recognised external quality assessment exercises.

As detailed on page 37 of the tender, the NRL will also continue to be an active participant of a number of international networks associated with GMOs. This intelligence gathering, coupled with the knowledge of the FAPAS PT programme, will be used to provide advanced notification to OL's of appropriate GMO PT rounds in which they can partake, thus enabling their effective participation.

### 2. More detail on risk mitigation is required for absences/loss of main project lead in terms of accessing ENGL and EURL GMFF.

Official UK participation and access to ENGL and EURL GMFF will be determined by the ongoing negotiations between the UK and EU. In the meantime, the currently negotiated (informal) arrangement for participation has been based on acceptance of the experience of the nominated UK individual (the proposed main project lead).

Any short-term absence would most likely not affect any current arrangement. It could reasonably also be assumed that a similar situation could be negotiated for any replacement of the main project lead in the event of their loss.

Strategies put in place to mitigate staff absence/loss under previous NRL contracts will be continued. These include cross-training, succession planning, and recruitment. Further to the situation arising as a result of the pandemic, the ability to offer continued working from home on a needs be basis has been established and tested effectively.

Where the case for recruitment was required, the wider LGC Group offers potential access to experienced candidates and is well positioned to access the market to be able to recruit high calibre scientists. We are a global leader in the life sciences sector, and recently ranked 25$^{th}$ in The Sunday Times PwC Top Track 250, an index of the UK's leading mid-market growth companies. Temporary access to experienced individuals would be sought through LGC's wider internal network of scientists and/or currently contracted consultants.

Were LGC to also be awarded the GMO authorisation role, delivery of that contract would necessitate recruitment on larger scale. This would provide further risk mitigation for the NRL position due to increased staffing levels within the team.

3. More clarification required on the indirect costs of £96k. Financial template mentions contract management, administration, key account management, contingency, margin.

The indirect costs highlighted in the financial template cover a variety of activities which support the core technical delivery of this contract. These include, but are not limited to:

- Key account management – covers the involvement of the NML Key Account Management team to support the relationship between the FSA and LGC. Activities include contract negotiation, contract on-boarding, management of commercial reviews, performance setting and reporting, and serving as route of escalation for any issues arising (see p. 47 of the tender submission for further details).
- Contract Management – Covers activities associated with routine management of the contract (e.g. legal and contract set-up and any associated variations and collation of financial reporting information). This function will be delivered primarily by the NML Programme and Contract Management Team (see p. 47 of the tender submission for further details).
- Administration – Covers internal activities such as invoicing, progress monitoring and routine maintenance of the GMO NRL webpage. Again, this will be delivered primarily by the NML Programme and Contract Management Team.
- Contingency – An element of contingency was used in the costing approach for this tender, and was highlighted in the Financial Template for transparency. This will allow LGC, subject to consultation and agreement with the FSA, to respond to emerging challenges or issues which may not have been foreseen at the outset of the contract and cannot be passed on to any third party.
- Margin – An element of profit margin, was included within the contingency costing approach for this tender, and was highlighted in the Financial Template for transparency. Inclusion of this element ensures commercial sustainability for LGC to continue to carry out the important NRL role.

4. Considering both contracts for the NRL GMO and Ref lab for GMO authorisation, could LGC provide indication of cost savings envisaged.

As stated in the tender response, if both contracts were awarded to LGC, we anticipate the following cost savings due to synergies between the two contracts.

- [redacted]
  - [redacted]
- [redacted]

[redacted]

## Dated 22nd April 2021

| Objective | Communication of results and data use | LGC comment | FSA requirement | Cost saving due to new/clarified FSA requirements |
|---|---|---|---|---|
| 6(d) | The Contractor shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the CA by 31st March each year. Annual reports will be approved by the CA prior to publication by NRLs on NRL dedicated websites. If requested by the CA, the Contractor may also need to provide interim reports during the annual work programme; | Interim reports: new activity | Annual reports as per previous contract.<br>Reports of ENGL/EURL meetings as per previous contract.<br>Interim reports not required on regular basis. | 33% |
| 6(j) | Provide an internal report of meetings with other organisations within 10 working days of the meeting. | Potential increased scope of activity in line with additional meeting attendance due to lack of access to EURL activities | ENGL and EURL meeting reports as per previous contract.<br>Any reports from international meetings will be new activity. | Costs have been kept to a minimum for this and were underestimated in previous NRL contracts. |
| 6(k) | The Contractor will engage in quarterly dialogues with the CA to review contract management | New activity | (i) Quarterly meetings with a record of meeting (progress review, contract and actions | 50% |

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| | requirements and update on progress against work programme. Informal monthly check-ins with the CA may also be organised to ensure any potential or evolving issues are flagged and work is kept on track; | | – see Quarterly meeting template). This will replace current ad-hoc meetings (4 per year).<br>(ii) Monthly activity logs (see template). These are simple logs of NRL monthly activity against core function delivery). Also provides chance for NRL to flag any concerns rather than waiting for quarterly meetings. | |
| 6(l) | The Contractor will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results; the Contractor will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results; | New activity | Annual OCL/NRL meeting to discuss NRL activities, PTs, methods. This was carried out informally on an ad-hoc basis in the past. Annual meeting will provide chance to disseminate information, update OCLs on methods, training, PTs etc. and for OCLs to flag any issues. Happy to discuss further. | Costs have been kept to a minimum for this and were underestimated in previous NRL contracts. |
| 6(m) | The Contractor will review NRL finances regularly and communicate spending, including a break-down of costs, with the CA on a monthly basis. | New activity | Quarterly invoice should be copied to project manager and should be accompanied by a breakdown of the activities covered. | 50% |

# 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] |