SHORT FORM CONTRACT FOR THE SUPPLY OF SERVICES

Yordas Limited
Lancaster Environment Centre, Lancaster University
Lancaster
Lanchashire
LA1 4YQ

[redacted]

Date: 12/12/2023
Our ref: FS900348

Following your tender/proposal for the supply of New Approach Methodologies (NAMs) to Support Regulatory Decisions for Chemical Safety to the Food Standards Agency, we are pleased confirm our intention to award this Contract to you.

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

We thank you for your co-operation to date, and look forward to forging a successful working relationship resulting in a smooth and successful Delivery of the Deliverables. Please confirm your acceptance of this Contract by signing and returning the Order Form within [7] days from the date of the Order Form. No other form of acknowledgement will be accepted. Please remember to include the reference number(s) above in any future communications relating to this Contract.

[We will then arrange for the Order Form to be countersigned which will create a binding contract between us/You should arrange for the Order Form to be countersigned which will create a binding contract between us]

Yours faithfully,

FSA Commercial

I. Order Form

1. Contract Reference	FS900348	
2. Buyer	**Food Standards Agency** Foss House, Kings Pool 1-2 Peasholme Green York YO1 7PX	
3. Supplier	**Yordas Limited** Lancaster Environment Centre, Lancaster University Lancaster Lanchashire LA1 4YQ	
4. The Contract	This Contract between the Buyer and the Supplier is for the supply of Deliverables. The Supplier shall supply the Deliverables described below on the terms set out in this Order Form and the attached contract conditions ("**Conditions**") and Annexes. Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in the Conditions. In the event of any conflict between this Order Form and the Conditions, this Order Form shall prevail.	
5. Deliverables	**Goods**	None
	Services	As set out in the Supplier's tender as set out in [Annex 4 – Supplier Tender]
6. Specification	The specification of the Deliverables is as set in [Annex 2 – Specification]	
7. Start Date	*01/12/2023*	
8. Expiry Date	*01/04/2023*	

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

15. Buyer Authorised Representative(s)	For general liaison your contact will continue to be [redacted]
16. Supplier Authorised Representative(s)	For general liaison your contact will continue to be [redacted]
17. Address for notices	**Buyer:** **Supplier:** Food Standards Agency Yordas Limited [redacted]
18. Key Staff	**Key Staff Role:** **Name:** [redacted]
19. Procedures and Policies	For the purposes of the Contract the: [The Buyer's additional sustainability requirements are: ***FSA Environmental Sustainability Strategy***].

20. Special Terms	Special Term 1 -
	[Special Term 2 -]
	[Special Term 3 -]
21. Incorporated /terms	The following documents are incorporated into the Contract. If there is any conflict, the following order of precedence applies: a) The cover letter from the Buyer to the Supplier dated 12/12/2023 (if used) b) This Order Form c) Any Special Terms (see **row 20 (Special Terms)** in this Order Form) d) Conditions e) The following Annexes in equal order of precedence: i. Annex 1 – Processing Personal Data ii. [Annex 2 – **Specification]** iii. [Annex 3 **– Charges]** iv. [Annex 4 – **Supplier Tender]**

II. Annex 1 – Processing Personal Data

A. Part A - Authorised Processing Template

Contract:	New Approach Methodologies (NAMs) to Support Regulatory Decisions for Chemical Safety
Date:	**12/12/2023**
Description of authorised processing	**Details**
Identity of Controller and Processor for each category of Personal Data	The Buyer is the Controller and the Supplier is the Processor
Subject matter of the processing	*This should be a high level, short description of what the processing is about i.e. its subject matter of the contract.*
Duration of the processing	For the duration of the Contract
Nature and purposes of the processing	*[Please be as specific as possible, but make sure that you cover all intended purposes.*
Type of Personal Data	*[Examples here include: name, address, date of birth, NI number, telephone number, pay, images, biometric data etc*
Categories of Data Subject	*[Examples include: Staff (including volunteers, agents, and temporary workers), customers/ clients, suppliers, patients, students / pupils, members of the public, users of a particular website etc]*
Plan for return and destruction of the data once the processing is complete UNLESS requirement under law to preserve that type of data	*[INSERT Describe how long the data will be retained for, how it be returned or destroyed]*
Locations at which the Supplier and/or its Subcontractors process Personal Data under this Contract	**[*Clearly* identify each location]**

Protective Measures that the Supplier and, where applicable, its Subcontractors have implemented to protect Personal Data processed under this Contract against a breach of security (insofar as that breach of security relates to data) or a Personal Data Breach	*[Please be as specific as possible]*

[Annex 2 – Specification]

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SPECIFICATION

Specification Reference
FS900348
Specification Title
New Approach Methodologies (NAMs) to Support Regulatory Decisions for Chemical Safety
Contract Duration
4 months

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

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

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

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

Tenders for FSA funded projects must be submitted through the health-family single e-Commercial System (Atamis), using the following link: https://health-family.force.com/s/Welcome. Failure to do so may result in the tender response not being processed by the system or the response being automatically disqualified during the evaluation stage of the tender process.

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THE SPECIFICATION, INCLUDING PROJECT TIMETABLE AND EVALUATION OF TENDERS

GENERAL INTRODUCTION

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

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

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This literature review being tendered links into the FSA Strategy 2022 – 2027. This strategy states that the FSA's fundamental mission is food you can trust. The FSA will continue to protect consumers by ensuring that food is safe and is what it says it is. This proposed piece of work is part of a wider programme of work and will sit in the Chemical Hazards in Food and Feed research programme. This is one of the FSAs Areas of research interest | Food Standards Agency (ARI) and sits under Research priority one: Assuring food and feed safety and standards – what is the impact of chemical hazards?

The main aim of the Chemical Hazards research programme is to support and improve the FSA's evidence base to keep the consumer safe and ensure that food is what it says it is. Research under this ARI, including surveys and other research projects, will provide FSA scientists and policymakers with current and reliable information on chemicals in food and feed.

The rapidly changing scientific landscape provides new challenges but also new opportunities for the field of regulatory science. New technologies hold the potential to improve our understanding of chemical and food safety while also reducing our reliance on animal-based methods of testing for safety. The objective of this work therefore is to collate the most up-to-date scientific evidence and data for the UK's own evaluation of the New Approach Methodologies (NAM) in the field of chemical risk assessment.

Once a literature review has been completed, the FSA and a scientific advisory committee (SAC), the Committee on Toxicology of Chemicals in Food, Consumer Products and the Environment (COT), will evaluate the data gathered and use it to inform future risk assessments and risk management and wider regulatory policy decisions and guidance. Ultimately the aim is to start to use NAMs, where appropriate, in regulatory applications as encouraged by the COT and ensure the UK is a leader in using NAMs in support of regulated product applications and as a wider science and evidence base, in order to keep UK consumers safe.

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A. THE SPECIFICATION

Background

New Approach Methodologies

New Approach Methodologies (NAMs) consist of any scientific advances or technologies, beyond traditional animal-based approaches, which may provide information that could inform chemical safety assessment and regulatory application. They include *in vitro*, *in silico* or *in chemico* (chemistry) - based methods, as well as the processes to implement them.

Whilst offering great potential, current legislation in the UK/EU has yet to adopt the widespread use of these new technologies. The biggest challenge is the current uncertainty in extrapolating NAMs results to human populations, particularly when considering factors such as metabolic interactions, complex or unknown biological pathways, interindividual sensitivity and vulnerable populations. Any modern approach to chemical risk assessment, therefore, must leverage the power of *in vitro* and *in silico* data while accounting for the complexities of moving away from animal data to support sound human health safety decisions.

Such concerns have also highlighted the need for clear guidelines and a pragmatic framework under which data from NAMs can be used to support applications in a regulatory context. In the EU, regulatory chemical risk assessment is implemented using a combination of 'hard laws' comprised of formal legal powers and regulation along with 'soft laws' such as technical guidance and formal guidelines for regulatory decision-making. The rapid development of NAMs to provide new types of toxicity data demonstrates the potential for these methods to improve our evidence-based assessments. However, unlike more traditional animal-based methods, NAMs are less standardised approaches, and deviations in the acceptance, weight and consideration of evidence may currently exist between regulators and governing bodies.

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The use of animals in chemical safety research

The FSA is committed to the development and validation of approaches to guarantee the safety of chemicals in food that do not rely on the use of animal testing. While acknowledging that scientific and regulatory systems still rely on traditional animal-based testing methods as a "gold standard" of chemical risk assessment, it is possible that equivalent, or even superior, protection of human health could be achievable through our continuing developments in understanding and technology. That is why the FSA is committed to the principles enshrined in the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) mission by pursuing all available scientific approaches to ensuring food safety while reducing the need for animals in the process.

The Specification

Tenders are invited to carry out a literature review of the New Approach Methodologies to support regulatory decision making in chemical risk assessment.

The specification must:

Firstly, we would like to commission a literature review of the most up-to-date scientific literature regarding NAMs and their use in toxicology. Secondly, we seek to understand the extent to which these technologies have been successfully integrated into modern regulatory approaches, and the degree to which they are accepted as providing confidence in the final decision-making process, both in the UK and internationally. This information will help to improve our understanding of how these new technologies are impacting our current approach to chemical risk assessment and help inform the FSA's own mission to provide the highest safety possible to UK consumers in a rapidly changing scientific landscape.

Proposals submitted must include the following key elements:

- A comprehensive review of NAMs, including a discussion of the scientific and technical basis of these technologies. There should be discussion of how

these approaches can and have been validated to provide confidence in their use in risk assessments to human health. Information should include peer-review journals, grey literature, and other sources.

- A discussion of how specific NAMs fit into the existing regulatory decision-making process. e.g., Do NAMs fill an unmet need, providing evidence where previously they had not been available? Can they be used to replace existing animal-based testing methods directly? Do NAMs act as stand-alone methods whose results can be relied upon with confidence to provide protection to human health or do they form part of a broader decision-making process. This discussion can be integrated alongside the discussion of the scientific and technical basis of the NAMs or as a separate section. Either way, it should include its own sources drawn from regulatory agency guideline and scientific bodies.
- A summary of the current guidelines if they exist for NAMs. Where NAMs have become or are becoming established and accepted methods, how have these approaches been standardised with reference to test guidelines such as OECD or accredited testing methods, such as UKAS? (It is important to note that safety decision-making using information from NAMs may ultimately be a different process to that currently applied, since NAMs are generally not direct surrogates for the output from traditional animal data). Of high interest would be an analysis of the areas of consensus and/or divergence in the current legislation, advice, or approaches between regulatory bodies as well as a discussion of areas where such guidelines are lacking and/or where guidance and interpretation are insufficient or inconsistent across international scientific bodies.
- Summarise the expert opinions of the scientific needs still present which prevent further adoption of NAMs into the regulatory process. The focus here should document the current evidence gaps that need to be addressed but also any issues at a regulatory level affecting the confidence in interpretating

NAMs data as regard decision making. Evaluate the opportunity of using NAMs within the FSA risk assessment framework.

- It would be prudent to consider chemical risk assessment in the context of consumption of food and also exposure to chemicals through other routes, including but not limited to cosmetics and personal products, household products, organic and inorganic residues, biocides and agricultural products as well as industrial chemicals.

The following should **not** be included as part of this Literature review:

- Established Ex-vivo methodology such as micronucleus studies etc which already make up a well-established area of regulatory toxicology.
- New scientific approaches which have been developed but have not yet been validated or used to support regulatory studies.

We anticipate this project starting in December 2023 with the final report being submitted to the FSA in April 2024.

- A key part of the work is the requirement carrying out a thorough literature review. Therefore, the applicant(s), either individually or collectively, should have demonstratable expertise in carrying out critical/systematic literature reviews of relevant scientific literature to standard guidelines (e.g., PRISMA).
- Whilst some expertise in the nature of the review would be an advantage, it is not a pre-requisite for application. More important is the ability to summarise opinion, and where available, the consensus of experts in the field. Therefore, applicants, should have demonstrable ability to understand expert opinion and be able to provide the basis, scientific or otherwise, upon which they formed their position.
- The review should consider literature up to as recent as the contract start date. However, some flexibility may be required to potentially extend the

search end date to allow for the review to be as up to date as possible particularly if delivery or publication of the final report is delayed for any reason.

- A clear and organised strategy to the literature review process is expected. Applicants should discuss how they intend to define the scope of the review and indicate how search method and terms, databases selection, and inclusion-exclusion criteria will be chosen to ensure an unbiased search.
- It is advisable to carry out a basic search of the existing literature to understand the quantity and sources of information available. It would be useful to provide estimates as to the number of papers and include this within the proposal. Applicants should also consider how grey literature and other sources of information will be identified and collected as part of the of the review.
- The FSA estimates that the cost for this work to be approximately £70,000 - £80,000. The onus is on the applicant(s) to provide the costings they believe are reasonable to meet the evidence gap as outlined in the specification and provide the justification of this within their research proposal. The applicant(s) should be aware that one of the key criteria that all research proposals are evaluated against is 'value for money' which is delivering the research asked for in the research requirement (including the anticipated outputs and benefits) at a competitive price.

Outcomes

It is anticipated that the following will be delivered to the FSA as part of this work:

- A full report addressing the relevant areas of the literature review which is suitable for publication on the FSA/COT website. The report should include a lay summary, an executive summary, introduction (including the background and aims/objectives of the review), methodology, findings, discussions, conclusions, list of evidence gaps, recommendations for further work,

references, and an appendices section. The final report will need to be structured and formatted in accordance with guidelines from the FSA Web Content Accessibility Guidelines. Please note that the final report should be submitted to the FSA by **1st April 2024** and will undergo an external peer-review process before it can be accepted by the FSA. A draft report should be submitted at least 4 weeks before the final report is due to allow FSA officials sufficient time to comment.

- Successful applicants will be expected to submit regular updates, either in writing or through online meetings (they will be responsible for organising and chairing meetings). They must also meet key deliverables - including an interim report, dates of which will be agreed upon in advance. The FSA reserve the right, on the basis of this report, to determine if project will continue to conclusion.
- The review should be both transparent and reproducible. A full database of all the relevant publications included in the review should be provided to the FSA. The database should be in a format suitable for publication on the FSA website e.g. in an accessible format (for example CSV or Excel).
- Publication of findings from this study in the peer reviewed open access journals and presentations at scientific conferences are encouraged by the FSA. Such material will need to be approved by the FSA prior to being submitted to the journal or presented. It is important that the researcher(s) notify the FSA of the publication date for any papers arising from this study at the earliest opportunity especially if the findings are contentious and therefore likely to generate media interest.

Risk

Please outline in your tender how you will manage your resources and anticipate and mitigate potential slippage, e.g. delays or changes in time due to other work commitments alongside this commissioned work.

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Please also outline in your tender how you will mitigate unforeseeable problems that may require modifications to the literature review and criteria applied.

Data protection

General Data Protection Regulation (GDPR)

Tenderers should also note that the EU's General Data Protection Regulation (GDPR) was introduced in the UK from the 25th of May 2018. Tenderers are therefore asked to consider what additional measures may need to be taken in order to comply with the new regulatory regime for data protection and to include in their proposals an explanation of how they intend to implement these measures.

In particular, the processor (the lead contractor) must:

- process the personal data only on the documented instructions of the Controller (the FSA).
- comply with security obligations equivalent to those imposed on the Controller (implementing a level of security for the personal data appropriate to the risk).
- ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- only appoint Sub-processors (any sub-contractors) with the Controller's prior specific or general written authorisation, and impose the same minimum terms imposed on it on the Sub-processor; and the original Processor will remain liable to the Controller for the Sub-processor's compliance. The Sub-processor must provide sufficient guarantees to implement appropriate technical and organisational measures to demonstrate compliance. In the case of general written authorisation, Processors must inform Controllers of intended changes in their Sub-processor arrangements.
- make available to the Controller all information necessary to demonstrate compliance with the obligations laid down in Article 28 GDPR and allow for and contribute to audits, including inspections, conducted by the Controller or

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another auditor mandated by the Controller - and the Processor shall immediately inform the controller if, in its opinion, an instruction infringes GDPR or other EU or member state data protection provisions.

- assist the Controller in carrying out its obligations with regard to requests by data subjects to exercise their rights under chapter III of the GDPR, noting different rights may apply depending on the specific legal basis for the processing activity (and should be clarified by the Controller up-front).
- assist the Controller in ensuring compliance with the obligations to implementing a level of security for the personal data appropriate to the risk, taking into account the nature of processing and the information available to the Processor.
- assist the Controller in ensuring compliance with the obligations to carry out Data Protection Impact Assessments, taking into account the nature of processing and the information available to the Processor; and
- notify the Controller without undue delay after becoming aware of a personal data breach.

At this moment in time, the FSA does not envisage the need to collect any personal data as part of this work.

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Quality

Please outline in your tender that you (individually or collectively) have the required scientific background and toxicological knowledge to undertake the proposed work. In support of your qualification please submit the relevant CVs.

Please also outline in your tender any relevant previous experience with systematic literature reviews and collating scientific literature.

Open and transparent

FSA has values and specific policy on being open and transparent, which also applies to the COT and therefore any relevant information applied (including this literature review) in the risk assessment will be published. Both the lead contractor and their sub-contractors must agree to this openness policy. Any potential issues with this should be highlighted within the proposals.

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B. PROCUREMENT TIMETABLE

Table 1 details an **estimated** project timetable for the project. Tenderers should however be aware that the Agency needs to acquire the evidence outlined in this ITT in a timely manner and you should justify your timings in your work plan.

TABLE 1. ESTIMATED PROJECT TIMETABLE	
EXPECTED DATE	**INVITATION TO (ITT) TENDER**
13th October	Invitation to Tender (ITT) issued by the Agency
13th October Immediately as above	ITT Clarification period opens*
27th October	ITT Clarification period closes**
13th November	Closing date for submission of ITT responses***
To commence immediately after closing date	Evaluation of ITT responses
w/c 13th November	Appraisal panel meeting held to consider clarified ITT responses
w/c 20th November	Tenderers notified of outcome of appraisal and preferred Tenderer (or Tenderers) identified
30th November	Contract awarded and signed
3rd December	Project initiation meeting takes place and project commences
31st March	Latest date for submission of final report to FSA

* If a Tenderer wishes to raise any points of clarification over the procurement process, the actual project objectives or any other query these must be raised through the health family single e-Commercial system (Atamis) by the date specified.

** Queries will not be answered after this date.

*** Submissions must be uploaded onto the health-family single e-Commercial system (Atamis) before the closing date and time.

§ These stages are optional

Further Information

For any technical queries or issues regarding the use of the health-family single eCommercial System, (Atamis) please contact the Helpdesk:

Please contact our helpdesk:
Phone: 0800 9956035
E-mail: support-health@atamis.co.uk

For any points of clarification regarding this specification or procurement procedures, please submit through the Health Family eCommercial System (Atamis).

Closing Date

Tenders should be submitted on the FSA e-Commercial system **by the date specified on the system using the tender application forms provided.**

When a Supplier clicks Submit the system will check they have completed all the Required (including Pass/Fail) Requirements, then mark all Responses as Complete and display a submission confirmation message to the supplier.

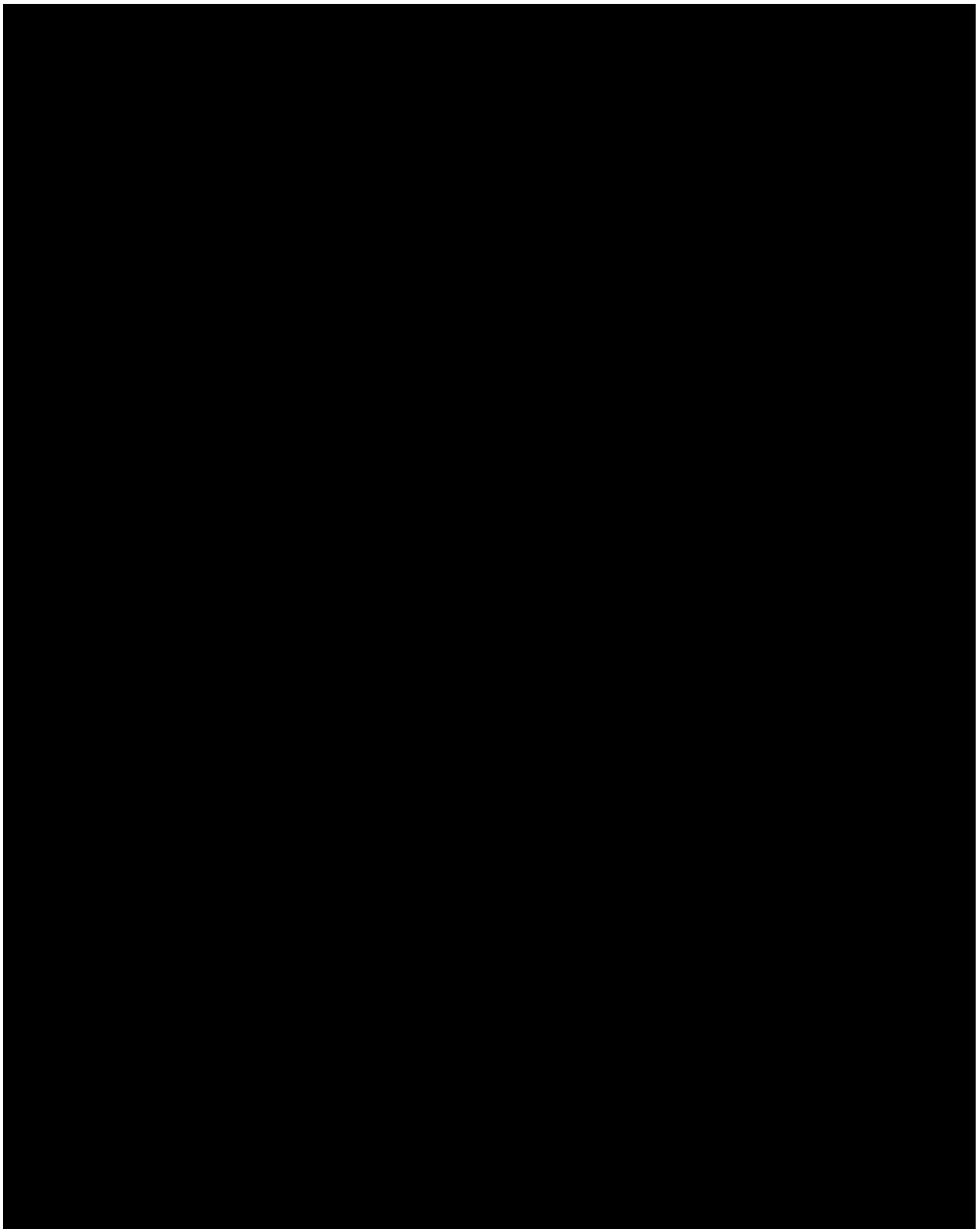
Tenders received after this time will not be considered or evaluated. Please allow sufficient time to upload your tender and all supporting evidence before the closing date.

C. EVALUATION OF TENDERS

The Tenderers Application consists of the:

- Technical envelope (80% of overall value), in which applicants should detail the approach, the work plan and their ability to undertake the work, and

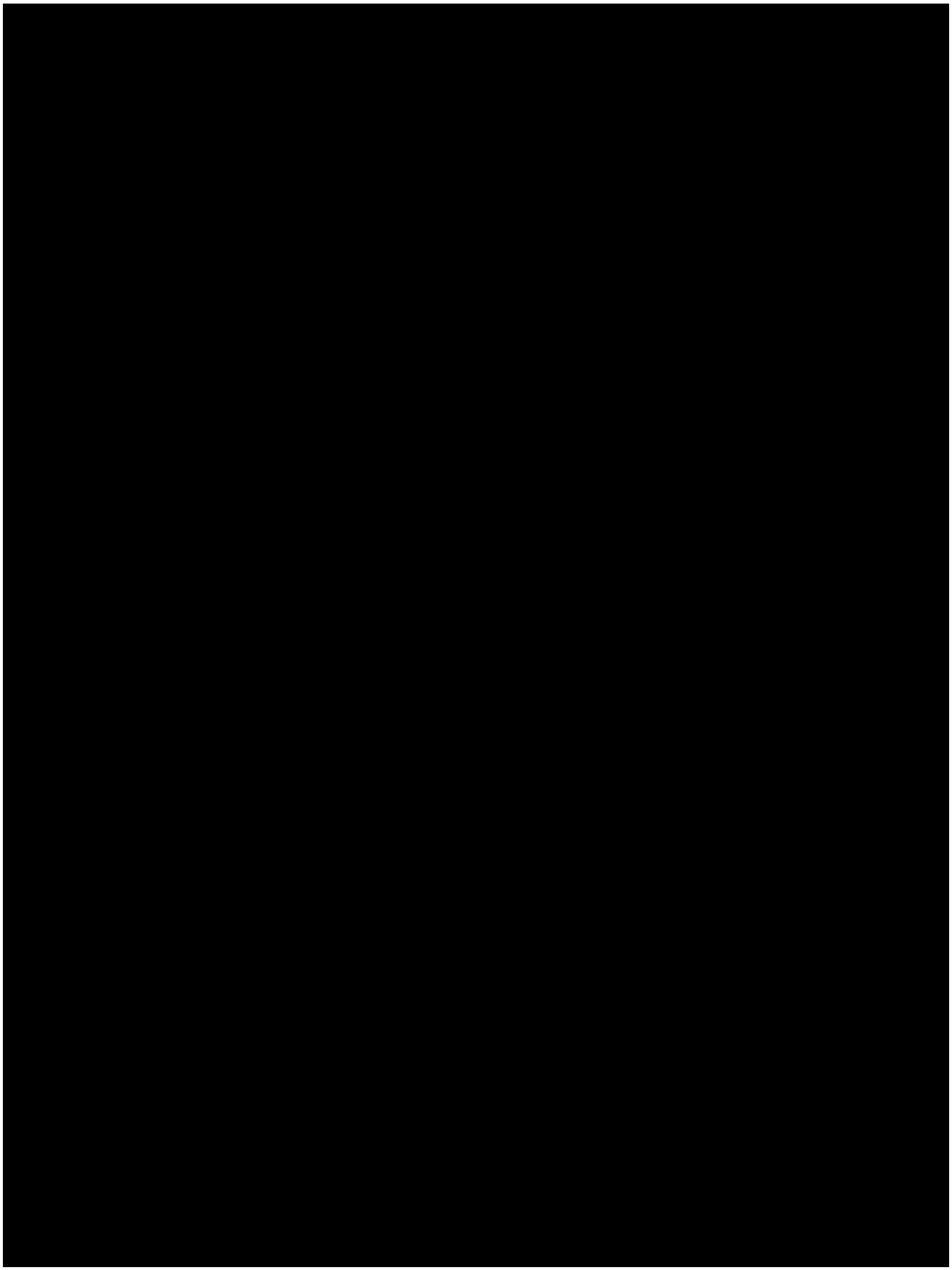
[Annex 3 – Charges]



[redacted]

Total Project Costs (excluding VAT) **	**£ 75,600.00**

[redacted]



[redacted]

Total Labour Costs	£ 75,600.00

[redacted]

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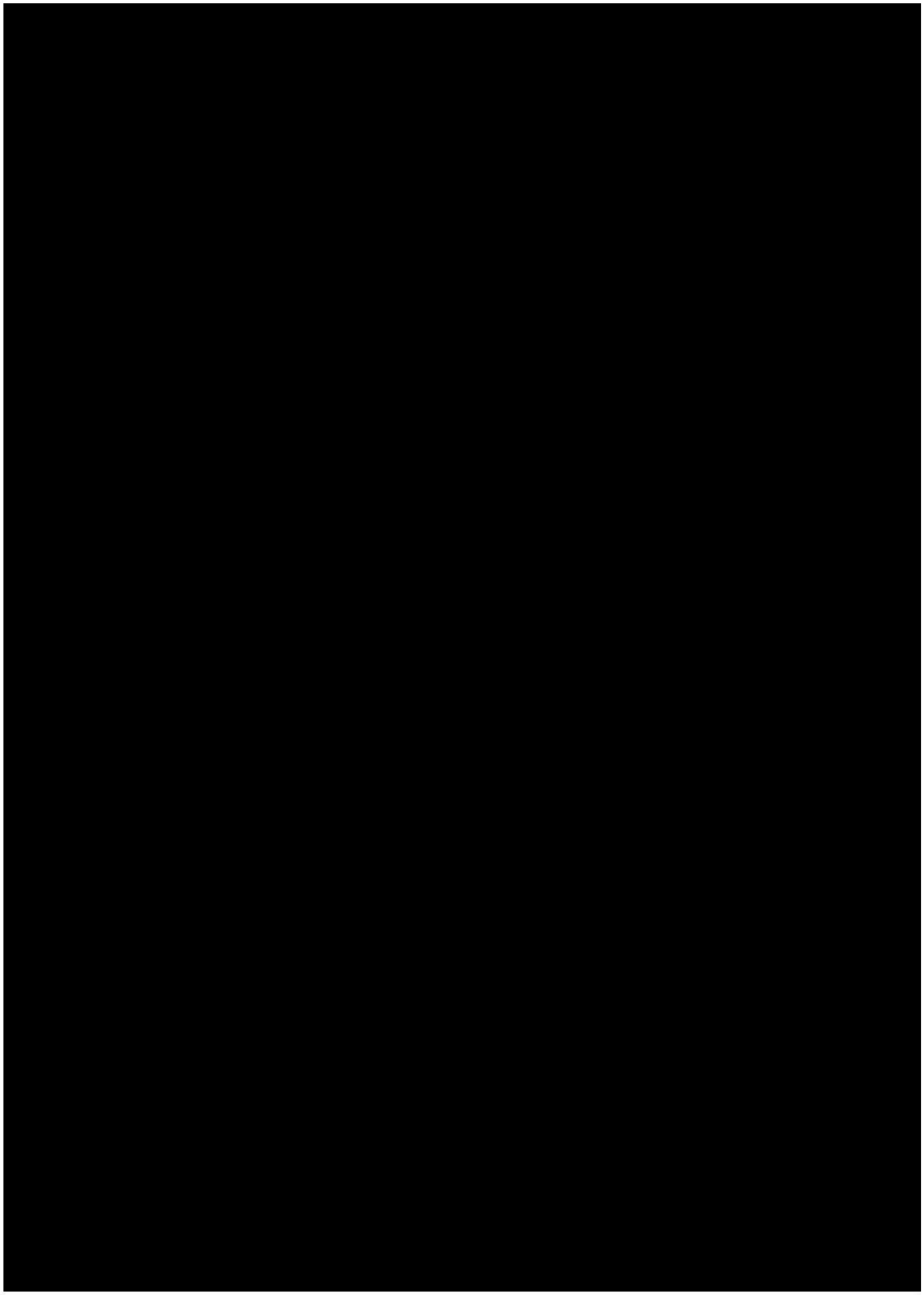

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Yordas Limited **CONFIDENTIAL**

Tender Application form for a project with the Food Standards Agency

- Applicants should complete each part of this application as fully and as clearly as possible
- Brief instructions are given in the grey boxes at the start of each section.
- Please submit the application through the Agency's health-family single e-Commercial System (Atamis) by the deadline set in the invitation to tender document.

LEAD APPLICANT'S DETAILS

[redacted]

TENDER SUMMARY

TENDER TITLE

New Approach Methodologies (NAMs) to Support Regulatory Decisions for Chemical Safety

TENDER REFERENCE	FS900348		
PROPOSED START DATE	01/12/2023	**PROPOSED END DATE**	01/04/2024

1: TENDER SUMMARY AND OBJECTIVES

A. TENDER SUMMARY

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

The current approach to toxicity testing in regulatory framework globally puts animal testing as a core requirement. However, scientific advancements have led to investments in the development, implementation, and acceptance of reliable and relevant new approach methodologies (NAMs). NAMs are increasingly being used for regulatory decision-making by agencies worldwide because of their potential to reliably and efficiently produce information that is fit for purpose while reducing animal use.

The tender proposal aims to address the current status of the development of NAM methods in toxicology to support decision-making process in chemical risk assessment. In the first phase of the project, a systematic literature search will be conducted designed to explore the NAMs used in chemical risk assessment to human health, focused on but not

[Annex 4 – Supplier Tender]

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limited to chemicals used in food, cosmetic products, household products, biocides, and industrial chemicals. The literature review will be carried out using a stepwise approach; firstly, the scope, the structure and the protocol for the literature review will be defined; secondly, a literature search will be conducted across a wide range of sources following the principles of Systematic Mapping; finally, the hits from the search will be given an initial review to both exclude irrelevant hits and categorise relevant hits for the next phase of the project.

Once the literature review is completed, the database of references collected will be scrutinised and assessed for regulatory readiness. The assessment will follow a simple semi-quantitative measure based on individual factors out of three (2 = ready for use in regulations with minimal work; 1 = includes many aspects required for regulations but some important aspects are missing; 0 = significant further work needed to be considered for regulatory use). The regulatory readiness of different types of NAM will be assessed for different categories of NAMs: In vitro studies and QSARs. The results of the literature search, rapid interviews with experts from different fields and assessment for regulatory readiness will be used in the last phase of the projects to discuss the usefulness and trust of NAMs by regulatory decision-making to identify the areas where NAMs have been successfully implemented in chemical risk assessment considering advantages and disadvantages of alternative approaches to animal testing.

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

OBJECTIVES

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

OBJECTIVE NUMBER	OBJECTIVE DESCRIPTION
O1	To collate the most up-to-date scientific evidence and data for the UK's own evaluation of the New Approach Methodologies (NAM) in the field of chemical risk assessment by looking at the types of testing developed for different purposes (regulatory, research, to assess an adverse outcome pathway), and at what stage these studies are (Task 1)
O2	To review the collated information on NAMs and categorise them to answer the FSA question (Task 2)
O3	To assess the regulatory readiness of NAMs (Task 3)
O4	To discuss and summarise the practical problem formulation of regulatory bodies in interpreting data from new approach methodologies; the usefulness and trust of NAMs; advantages and disadvantages of their implementation and gaps (Task 4)

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..

The tender proposal is concerned with the application of alternative methods to support regulatory decision-making in chemical risk assessment. New Approach Methodologies (NAMs) are increasingly used for regulatory decision-making by agencies worldwide because of their potential to reliably and efficiently produce information that is fit for purpose while reducing animal use. Although NAMs are widely researched, their acceptance in the regulatory framework is in its infancy, with 239 studies under assessment in the TSAR system by ECVAM[1].

The existing paradigm for the risk assessment of chemicals and mixtures for regulatory purposes is that animal studies provide the most credible and relevant results for application to human health or the entire environmental ecosystem. This has meant that results from in vivo studies are a requirement for many regulatory framework. However, many ethical arguments have been raised against testing on animals regarding the possible suffering to and ultimate death of the animals being used and whether testing on animals is a representative way of predicting hazards to humans health. The Cosmetics Regulation prohibits animal testing on any cosmetic product or on any ingredient of a cosmetic product whose sole use is in cosmetic products (Article 18).

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The current status of the implementation of NAM methods in toxicology and how integrated and accepted these approaches are in the regulatory framework globally need to be clarified and will be addressed by this tender.

Task 1. Literature search. Scope Structure and Methodology

Task 1 is a systematic literature search on the implementation of NAMs in chemical risk assessment to human health. The primary focus will be for chemicals used in food consumption, but chemicals used in cosmetic products, biocides, and industrial chemicals will also be included. The methodology will follow the Collins et al. approach on quick scoping reviews and rapid evidence assessment. It is worth noting that similar projects examining the applicability of NAMs to regulations have already been conducted[3456]. Other similar reviews will be identified during the initial stages of the literature search and used as primary resource for this project.

Scope:
The scope of the literature review would need to be as general as possible, as it will be the starting point to address the tender questions during the project. It will need to identify all types of NAMs designed to assess human toxicology for use with industrial chemicals and chemicals used in food, cosmetic and household products.

The issues around the scope of the search that will need to be addressed may include:

- What types of NAMs should be included in the scope of work? Should the search focus on NAMs used to generate new data from non-animal testing or assessments (i.e. in vitro methodologies), or on prediction of (eco)toxicological properties of a substance (i.e. QSARs, read-across)?
- Which apical endpoints should be addressed? Should endpoints that are currently not included in UK regulations should be addressed? For example, the identification of ED require NAMs data and this is an are that will return a large number of hits.
- Will the study focus on methods included in certain regulatory framework or will it assess all available methods which are currently not included in regulatory framework?

The scope of work will be further refined during the kick-off meeting in discussion with FSA.

Structure:
The literature search will be done across various data sources. The types and examples of data sources that will be searched are summarised in Table 1.

Table 1. Relevant sources to be used

Category	Sources	Comments
Database/ Scientific Journal	Databases: Web of Science; ScienceDirect; Scopus; PubMed. Additional search on the websites of journals whose primary goal are NAMS: e.g. ATLA (Alternatives to laboratory animals); ALTEX (Alternatives to animal experimentation)	A range of databases, publishers and scientific journals will be searched for points and opinions on the use of NAMs related human toxicology.
Research project deliverables and presentations	Research projects focused on development of NAMs, especially those identified by ECVAM or European Partnership for Alternative Approaches to Animal Testing (EPAA), e.g. In3; QSAREACH; EuroMix; EU-ToxRisk; NC3Rs	Relevant projects will be identified by examining CORDIS (Community Research and Development Information Service). Where multi-project initiatives are identified the search will be repeated for projects involved in these initiatives.
Research Institutes	The EU Joint Research Centre will be a key source, especially the parts	We will review reports, videos and articles

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	targeted towards alternative methods: ECVAM; EURL ECVAM; TSAR. Similar organisations in other regions will also be searched, e.g. National Institute for Occupational Safety and Health (NIOSH); ILAR (Institute for laboratory animal research);	
Regulatory Bodies and Agencies	OECD WPNM; Scientific Committee on Consumer Safety (SCCS); European Committee for Standardization (CEN);CIRCA-BC; CARACAL; European Chemicals Agency (ECHA); European Union Observatory for Nanomaterials (EUON); European Food Safety Authority (EFSA); US Environmental Protection Agency (EPA); Health Canada; National Institure for Health and Safety (Canada); DEFRA(UK)	Search databases of numerous regulatory bodies and agencies in OECD member states to access relevant data to review in the literature search.
NGOs and industry	NGOs and industrial bodies with a special interest in NAMs, e.g. ChemSec; People for the Ethical Treatment of Animals (PETA); Cruelty Free International; NIA (Nanotechnology Industries Association); European Partnership for Alternative Approaches to Animal Testing (EPAA)	Media releases and publications by NGOs and industrial groups will be used.

Methodology. Different approaches will be used for each type of data source as follows:

Academic journals: A search for all non *in vivo* studies would find a considerable number of different methods, beyond the scope of this project. As alternative methods can cover a range of different types of approaches (e.g. grouping, QSAR, *in silico*, *in vitro, in chemico*), we intend to perform separate searches for each method as each one has associated different key terms. These terms would be linked by the Boolean operator OR to give a wide range of hits. An example of search terms are presented in Table 2.2.

Table 2.2. Potential search terms

Alternative method	Potential search terms
In silico	Simulation; screening; modelling; *in silico*
In vitro	Mechanism; concentration - response; *in vitro;*
QSAR	QSAR; training set; applicability domain
General	New Approach Methodology; validated methods; alternative to animal testing; 3Rs; replacement technologies; Adverse Outcome Pathway; Key Event; Mode of Action; Mechanism of Action; Next Generation Risk Assessment

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Research Projects, Research Institutes, NGOs and Industry Organisations: Relevant research projects will be identified through CORDIS or similar databases and other organisations will be identified using a standard search engine such as Google. Only published reports and deliverables will be considered.
The principal focus will be on alternative methods used in chemical risk assessment.

Task 2. Literature search and data review

Once the scope of the study is set, a literature search across a wide range of sources that follows the principles of Systematic Mapping[7] will be performed. The aim of this task will be to review and categorise the hits for Task 3 from the search to both exclude irrelevant hits.
Screening the evidence should be done using a two-phased approach. The screening of search results ensures that only the most relevant findings are taken to the following stages. As with all literature searches, the initial search will generate a large number of hits, many of which will not be relevant to the project, and even those applicable to the project will be of differing quality of relevance. Therefore, the hits need to be filtered and categorised. Using **inclusion** and **exclusion criteria** to do this reduces bias but should be recorded in order to ensure transparency.

Inclusion and exclusion criteria:
The initial search is expected to identify a high number of potential hits but many of these will not be relevant to the goal of this tender. Therefore, inclusion and exclusion criteria will be defined to select only applicable search hits. Although some criteria might be applicable across all types of NAMs (e.g. validation), other will be specific to the type of NAMM. Examples of these criteria are shown in the table below.

Type of NAM	Inclusion Criteria	Exclusion criteria
In vitro study	Clearly define the AoP or Key Event it examines. Relation to a regulatory apical endpoint clearly explained.	Already well established in regulatory toxicology
QSAR	Recommended for use in regulatory guidance	No applicability domain defined.
Grouping framework	Applicability to regulatory requirements discussed	No method to describe scientific justification included

Only studies that are proposed to be or are actively being considered for a standardised protocol by one of the standardisation organisations (for NAMs) or are directly aligned with an accepted regulatory approach (for methods that use existing data) will be included. Therefore, we propose to search for alternative methods that are proposed for, or are in the process of, being validated by one of the organisations that specialise in this (e.g. ECVAM, OECD, ISO).
Many literature searches would establish a time limit for publication. However, in this project we believe the inclusion and exclusion criteria would do this task. For example, a NAM published more than ten years ago will either have been well established in the regulatory framework (an exclusion criteria) or has not been proposed for validation/rejected during validation (an exclusion criteria). We also think that any discussion on why a method has not been validated would support the goals of this tender.
As the initial search is expected to identify many potential hits, we propose using a two stage filtration process to optimise resource utilisation.

First Phase Screening/First Pass:

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Many hits will have no relevance at all to the research and would be easily identifiable from examination of report title and abstract. The first screen could be done without reference to the full article from the journal. The reviewer would judge each hit as clearly relevant, clearly not relevant or uncertain. If the evidence is found to be clearly relevant or uncertain at this first stage it would pass to the second screening phase. As uncertain hits would pass to the second screening phase any bias would be towards inclusion, so we expect this task to be done be a single reviewer. A record of the number of hits will be recorded but no record of excluded hits at this stage will be kept. Hits that pass this step will be recorded in a database that details the basic article details (e.g. author, title, journal, issue, doi). This will allow the second screening phase to be achieved more effectively. Search hits that are excluded would be examined to see if there is a common theme from which to extract a search term to specify that it is not included in any future searches.

Second Phase Screening/Second Pass:
This involves reading the abstract or first paragraph of the clearly relevant or uncertain evidence to identify those that meet the inclusion/exclusion criteria and will be used in the evidence extraction and synthesis phases. The second screen will require the full paper to be examined, and as such a pdf or other version will be stored in a file. The second screen will make a detailed examination of the full paper to judge it against the inclusion and exclusion criteria. In order to avoid bias, two researchers will perform the second screen independently, and select the hits they feel should be remain in the mapping exercise. They will annotate the database with their decision including reasoning for either inclusion or exclusion. Neither researcher will base their decision on that of the other researcher. Hits that have a unanimous verdict will be automatically included or excluded. Hits where there is dissent will be examined by a more experienced third-party to reach a final decision. This will reduce the chance of individual bias in the search.
Each researcher will categorise included hits (see below) and record this in the database.
During the search, duplicate hits will be identified and removed from the database.

We expect that there will be many hits that are linked in some way, for example two papers by the same authors, where the later paper is an extension of the original paper, perhaps by using different chemicals. Where this is clearly the case, this will be identified in the database.

Difficult to access sources
It is our experience that research project websites are poorly maintained beyond the project's lifespan, so some search hits may not be directly accessible. Where this occurs the project coordinator will be approached directly to either get the information or to identify the best person to approach.

Categorisation
The key goal of building a database of references for NAMs used in toxicology is for it to be searchable in order to find the literature directly relevant for the questions posed by FSA, some of which are specified in the tender specifications. To facilitate this the search hits will be categorised according to the key aspects of their content such as: type of method (e.g. in silico; in chemico; in vivo); apical event addressed (e.g. mutagenicity (gene mutation); chronic toxicity (lungs) etc); Adverse Outcome Pathway (e.g. chronic inflammation of lung leading to tumour formation); Key Event (e.g. ROS production). These categories would be high-level, so key words related to the category would be included in the database.

Reference Management System
The use of a reference management system allows us to collectively manage a collection of publications for the purposes of searching, storing and writing research papers. There are several systems that can be used to achieve this purpose. Yordas uses Paperpile, within the Google suite. This reference management system allows us to add citations and bibliographies to documents in a simple and collaborative manner, and syncs with a set of folders and subfolders where the references are stored. Yordas is familiar with other systems, such as EndNote and Mendeley, which can also be used for this project as needed. The preferred reference management system can be discussed and agreed upon with the FSA

during the Kick-off meeting. Yordas will be able to grant FSA access to the chosen reference management system, as needed.

Risk Management: A description of the risk management approach and mitigation measures for risks specific to the completion of a literature search are described in the appropriate section 6 of this form.

Task 3. Regulatory readiness of NAMs

The objective of Task 3 is to assess the regulatory readiness of NAMs based on the date extracted during the literature review. Using the systematic map described above, a database of identified NAMs will be kept. It is expected that some NAMs will have multiple hits associated with it as the method is optimised or the method is used with a new type of substance which should be easily identified by the categorisation used in the database. This database of NAMs for toxicology will link back to the literature relevant to it but will also allow an ongoing regulatory readiness assessment of each NAM. This assessment would be an overview of the regulatory readiness addressing factors such as applicability domain identified; quality of protocol available; proof of repeatability; demonstrable link to in vivo results demonstrated. It would enable the rapid identification of relevant studies from which to start an assessment. It would also be open for Fera to access so they can identify topics around which there is a lot of research activity or where more activity needs to be encouraged. The learning points from the European Partnership for Alternative Approaches to Animal Testing (EPAA) Deep Dive Workshop would be used as one of the guiding principles to establishing this assessment[8] .
This will be a semi-quantitative measure that will score individual factors out of three (2 = ready for use in regulations with minimal work; 1 = includes many aspects required for regulations but some important aspects are missing; 0 = significant further work needed to be considered for regulatory use). An average score will then be used to calculate an overall regulatory readiness score. This approach will be used to allow comparison of different types of NAMs which will probably have a different number of relevant factors under assessment.
This approach will also demonstrate the areas of the NAM that would need further work before it was ready for use in the regulatory arena. An example of this is given below.
Scoring criteria: Parameter fully addressed = 2; Parameter addressed incompletely = 1; Parameter not addressed = 0

Method	Method protocol published	Negative and positive controls identified	Data acceptance criteria detailed	Clear definition of negative and positive results	Regulatory readiness score
A	0	1	2	1	**4**
B	2	2	1	2	**7**

The overall score would be used to reach a conclusion on the regulatory readiness of each identified method. For example: 0 - 2: Much work needed before consideration for standardisation; 3 - 6: Basic structures in place but some work needed; 7 - 8: Ready to be considered for standardisation or regulatory use. In our example Method A would need further work to be proposed for use in regulations but Method B could be proposed (this might mean considering validation in the case of a NAM or receiving regulatory acceptance for modelling or use of existing data). The timelines for validation of NAMs methods will also be considered in this analysis as well as the impact of the length of the validation process across different regulations.

The regulatory readiness of different types of NAMs would will be assessed for the following categories of NAMs:

In vitro studies: The regulatory preparedness of an individual *in vitro* study would include the following assessments.

1. Is a harmonised or standardised protocol available. Although an OECD or ISO test guideline would be ideal, a protocol established across a range of experimentalists as can be found in a number of EU projects may be acceptable for screening purposes?

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2. Is the Molecular Initiator Event (MIE) that the study examines part of an accepted AOP towards an apical event relevant to regulations?
3. Is the applicability domain for the study clearly understood (e.g. if the study was developed for metal oxides, should it be used to examine carbon allotropes?)?
4. Does the study give a qualitative or quantitative result?
5. How many NAMs studies are needed to replace an in vivi study?
6. What areas would need to be improved to accelerate acceptance of NAMs, if any?

QSARs: The regulatory readiness assessment would be based on the principles of QSAR validation as stated by the OECD.[9]

1. a defined endpoint
2. an unambiguous algorithm
3. a defined domain of applicability
4. appropriate measures of goodness–of–fit, robustness and predictivity
5. a mechanistic interpretation

The result of this would be included in the regulatory readiness assessment of the individual NAM based on the result of the literature review.

Task 4. Understanding the usefulness and trust in NAMs for the regulatory decision making process

In addition to the literature review Yordas propose to carry out rapid interviews with key stakeholders from governments, research and industry to deepen the analysis around the implementation of NAMs. We will seek to interview up to 10 stakeholders, Yordas will aim to identify participants from each stakeholder group with a balance of stakeholder representation and geographical distribution. The final interview list will be agreed with FSA. This will be supplemented by a list of those expressing their willingness for an interview.
This final task (Task 4) takes the results of the literature review and interviews during the stakeholder engagement to identify NAMs that are used in the regulatory decision-making process in different regions and address potential shortcomings.

The final discussion will include:

- A comparison between regulatory jurisdictions (e.g. US, EU, Japan, Canada) regarding the approaches to use.
- A summary of the apical endpoints with a list of in vivo studies and validated NAMs used to fulfil them. A comparison of costs and timelines required to reach validation of the endpoint will be discussed.
- A summary of the different views about NAMs from different stakeholder groups interviewed and highlight similarities and differences each group. Trends will be discussed if applicable.

After analysing the answer to these questions, we would then identify a number of different steps to improve the usefulness and trust of NAMs in chemical risk assessment for chemicals used in food consumption. Other chemicals such as biocides, agrochemicals, cosmetic products and industrial chemicals will also be considered where appropriate. In identifying the steps needed to overcome the challenges to implement NAMs in regulatory decision-making will include:

1. Are current NAMs compatible with the approaches used in human health chemical risk assessment?
2. In which area of the chemical risk assessment NAMs can be more useful and trustful?
3. Is more guidance needed from regulators and scientific community on cases where NAMs can be accepted for decision-making processes.

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[1] https://tsar.jrc.ec.europa.eu/
[2] Collins, A., Coughlin, D., Miller, J., & Kirk, S. (2015). The Production of Quick Scoping Reviews and Rapid Evidence Assessments: A How to Guide" as this is better aligned with the needs of this relatively quick turn around project.
[3] Ball, N., Bars, R., Botham, P.A. *et al.* A framework for chemical safety assessment incorporating new approach methodologies within REACH. *Arch Toxicol* **96**, 743–766 (2022). https://doi.org/10.1007/s00204-021-03215-9
[4] Westmoreland C, Bender H, Doe J, Jacobs M, Kass G, Madia F, Mahony C, Manou I, Maxwell G, Prieto P, Roggeband R, Sobanski T, Schütte K, Worth A, Zvonar Z, Cronin M (2022). Use of New Approach Methodologies (NAMs) in regulatory decisions for chemical

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safety: Report from an EPAA Deep Dive Workshop, Regulatory Toxicology and Pharmacology, 135, 105261. https://doi.org/10.1016/j.yrtph.2022.105261

[5] https://euon.echa.europa.eu/view-article/-/journal_content/title/latest-euon-study-identifies-models-and-tools-for-computational-safety-assessment-of-nanomaterials

[6] Escher, SE, Partosch, F, Konzok, S, Jennings, P, Luijten, M, Kienhuis, A, de Leeuw, V, Reuss, R, Lindemann, K-M, Hougaard Bennekou, S, 2022. Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment. 19(6): 153 pp. doi:10.2903/sp.efsa.2022.EN-7341

[7] Collins, A., Coughlin, D., Miller, J., & Kirk, S. (2015). The Production of Quick Scoping Reviews and Rapid Evidence Assessments: A How to Guide" as this is better aligned with the needs of this relatively quick turn around project.

[8] Westmoreland C, Bender H, Doe J, Jacobs M, Kass G, Madia F, Mahony C, Manou I, Maxwell G, Prieto P, Roggeband R, Sobanski T, Schütte K, Worth A, Zvonar Z, Cronin M (2022). Use of New Approach Methodologies (NAMs) in regulatory decisions for chemical safety: Report from an EPAA Deep Dive Workshop, Regulatory Toxicology and Pharmacology, 135, 105261. https://doi.org/10.1016/j.yrtph.2022.105261

[9] https://www.oecd.org/chemicalsafety/risk-assessment/37849783.pdf

B. INNOVATION

Please provide details of any aspect of the proposed work which are considered innovative in design and/or application? E.g. Introduction of new or significant improved products, services, methods, processes, markets and forms of organization .

The developments of new in vitro methods or the refinement of existing ones is crucial to continue to move towards regulatory requirements free from vertebrate testing. Consumers are now opting for products having cruelty-free and vegan labels increasing the the investments of the industry in non animal testing. This will certainly reduce testing costs for the industry, improving our knowledge of toxicity of chemicals by developing novel approaches to investigate toxicity.

Typically, facilities that engage in animal testing not only dispose of animals, but also dispose of potentially dangerous chemicals, food waste and a variety of supplies used during the testing process. Animal research facilities require total fresh air exchanges for ventilation, using large volumes of air, resulting in a high consumption of energy and carbon emissions. Additionally, animal testing also heavily impacts water and air quality. Therefore, reducing animal testing will have a huge impact on environment and sustainability.

The ambitious objectives of all regulatory frameworks in EU, UK and North America are to increase the amount of information available on potentially hazardous chemicals while at the same time making the best use of innovative non-animal methods. Those include in vitro testing, computer modelling and organ-chip devices. Despite the efforts and drives to move towards a world free from animal testing, regulations globally still require a full battery of animal testing when registering substances. The main aim of this tender proposal is to identify the most up-to-date scientific literature regarding NAMs and their use in toxicology and seek to understand the extent to which these technologies have been successfully integrated into modern regulatory approaches in the UK and internationally. Although there is not much innovation in the scope of this project because similar reviews have already been conducted in other jurisdictions, the results of this project will certainly highlight the most up to date gaps in the use of NAMs for regulatory assessment and the work require to fill them.

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.

A project timeline has been included in the Gantt chart below. This Gantt chart includes the key project management and Task deliverables and the overall timeline for each task. Over the course of the project, Yordas will monitor the progress of each task and work package on this Gantt chart. An updated Gantt chart will be submitted monthly to FSA as a part of the monthly progress report.
The plan is to execute the project in 4 project tasks:

Task 1 Literature search. Scope, Structure and Methodology
Task 2 Literature search and Data review
Task 3 Regulatory readiness of NAMs
Task 4 Understanding the usefulness and trust of NAMs for the regulatory decision-making process

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Given the time constraints of this project, the execution of some tasks will need to overlap to ensure successful delivery. Tasks that can start at the same time of others have been identified. For example, some of the activities of Task 2 can already start while Task 1 is concluded. Similarly, Task 3 and 4 can already start while Task 2 is concluded.

B. Deliverables

Please outline the proposed project milestones and deliverables. Please provide a timetable of key dates or significant events for the project (for example fieldwork dates, dates for provision of research materials, draft and final reporting). Deliverables must be linked to the objectives.
For larger or more complex projects please insert as many deliverables /milestones as required.
Each deliverable should be:

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

Please insert additional rows to the table below as required.

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

Deliverable number or MILESTONE IN ORDER OF EXPECTED ACHIEVEMENT	Target Date	TITLE of Deliverableor milestone
1	01/12/2023	Contract Award
2	03/12/2023	Project Kick-off and Project commences
3	15/01/2024	Project progress meeting
4	01/02/2024	intermediate Literature search spreadsheet sent to fsa
5	15/02/2024	Project Progress Meeting
6	15/02/2024	Final literature search spreadsheet
7	01/03/2024	Project progress meeting
8	15/03/2024	Intermediate report
9	31/03/2024	Final output and project conclusion

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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

A Study on the Role of the Robust Study Summary in Hazard Assessment with Practical Suggestions on the Improvement of the OECD Harmonised Templates Concept – ECHA/2021/46
Dates: 2021- Dec 2022
Customer: ECHA
Value: €169,000
Country: EU
Description
This ongoing project aims to study the role of robust study summary (RSS) in hazard assessment and improve the OECD Harmonised Templates (OHT) concept. For work package 1 of the project, the expert team at Yordas completed a systematic literature search on applications and reporting of toxicity studies in RSS across legislation. Yordas developed a list of key search terminology and are using databases and academic websites for the search. The findings of this literature search were assessed to investigate whether there is a link between factors that may impact perceived quality and its use in hazard assessment by a registrant. Yordas also has a team of experts who led the stakeholder engagement activities such as developing a survey and conducting interviews with the aim of understanding stakeholder relationships and experiences with RSS in hazard assessment, and ways in which improvements can be made. The stakeholder engagement report has been published by ECHA and is available here: https://echa.europa.eu/documents/10162/17069/study_rss_hazard_assessment_surveys_en.pdf/b2656b6f-7d45-b2e8-f35d-1aa0ef146584?t=1650882479519
Work package 2 focuses on the authoring of over 100 RSSs by Yordas scientists on key endpoints such as repeated-dose toxicity, reproduction toxicity and genotoxicity. These expertly written RSSs are critically compared with those submitted by REACH registrants to identify similarities, discrepancies and analyse the causes of these observations. Work package 3 will analyse the results collected throughout the project to make practical suggestions and improve the usefulness of the OHT concept and the role of RSS in hazard assessment.

Proposal for non-animal based methodology for replacing acute inhalation toxicity endpoint under EU-REACH
Dates: 2021-ongoing
Customer: Confidential
Value: Not applicable
Country: EU
Description
As part of an EU-REACH update to 10-100 tonnage band, a data gap analysis outlined the testing requirements for several endpoints, including acute inhalation toxicity. As our product is used as the raw material for fragrances or flavours and the fragrance is widely used in cosmetics, we wanted to avoid animal testing. To achieve this goal, we evaluated all other possible alternative methods including QSAR predictions, read across assessment, and development of in-vitro weight of evidence-based approaches.
Read across to a structurally similar substance was not viable because the data matrix for the potential source and target substances revealed significant differences in their toxicological profiles. A trend analysis prediction using the OECD QSAR toolbox failed to produce a reliable prediction of acute inhalation toxicity due to a limited range of substances with available experimental data.
We identified a possible in-vitro method to address the acute inhalation toxicity endpoint. The proposed experiment would use EpiAirway (upper respiratory) and EpiAlveolar (lower respiratory) tissues in separate experiments. The test item would be incubated on the tissue for 24 hours at 10 different concentrations (to allow for BMD modelling) using 6

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tissue replicates per condition. The endpoints for this study would have been pathology, H&E stain, LDH release, and Resazurin metabolism. A similar approach had been recently proposed to the US EPA's Office of Pesticide Programs (OPP) by a crop manufacturer for the purpose of refining inhalation risk assessment of the pesticide chlorothalonil. The approach proposed to the US EPA only simulated the upper respiratory system (MucilAir™ using human nasal tissue) so we felt that our method, which included both upper and lower respiratory tract tissues, was much more robust for the purposes of hazard assessment. Unfortunately, since the method was not validated it could be used to fulfil the REACH requirements for acute inhalation. There is an ongoing discussion with the competent authority to initiate the validation of the method and hence its use in a REACH registration.

Monitoring of regulatory and scientific studies in the automotive sector
Dates: 2020-Present
Customer: Confidential Client
Value: 120,000 GBP
Country: Global
Description
Yordas has been contracted by a global industry association in the automotive sector to support the monitoring of regulatory and scientific studies. The project aims to anticipate, identify, analyse and address the potential human health and environmental impacts associated with the use of chemicals through the life cycle of tyres.
The project's main objective was to develop a database of information regarding tyre materials and chemicals to support scientific and science communication work long term. Yordas undertook a data gathering and analysis task to monitor the regulatory and scientific studies related to materials and chemicals used by the tyre industry by performing a systematic literature search across scientific databases and media articles. The specific focus was on the toxicity of chemicals used for tyre manufacturing or release during their use or end-of-life processing and disposal. The project was defined into two phases.
During the project's first phase, Yordas identified and assessed over 300 legislations, nearly 300 research papers, and over 100 media articles directly related to chemical toxicity and environmental impact. These findings are essential for understanding legislators', scientists', and media views on the toxicity of chemicals used in tyres. The first phase provided insight into the evolution of the knowledge related to tyre chemicals toxicity, environmental and health impacts such as endocrine disruptors and carcinogenicity. Yordas also produced a list of priority hazardous substances relevant to the tyre industry, based on an analysis of substance lists provided by tyre manufacturers and trade associations.
As well as the indexed database of findings and priority substances, Yordas delivered a written report highlighting data gaps and providing suggestions for future research. Current research analysed the interaction between legislation, research and media, and gave an insight into how media reports can contribute to legislation development, such as regulation of 6PPD chemicals. Yordas used a systematic review approach to generate a list of relevant research publications, and a global monitoring approach to identify a list of legislations that can impact the use of chemicals in tyre manufacturing, recycling or reuse. Further, automatic and targeted media searches were used to identify the most recent articles that communicated issues directly related to tyre toxicity and its health and environmental impacts.
In the second phase of the project, Yordas will continue its regular monitoring to maintain the database. This will allow the collection of findings as they are published. Metadata contains anywhere between 20 to 40 categories for each finding - regulation, research, media. Metadata categories will allow easy database searching by date, author, geographical area or chemical and efficient post-processing and extraction of relevant information for future research, as metadata contain summaries and relevance assessment and the link to the source file.
The database will be used by tyre manufacturers and trade associations to help them to maintain regulatory compliance, be alerted when chemicals are identified as hazardous, anticipate regulatory changes to these chemicals and understand media perception of the tyre industry. This knowledge will help to drive changes in the use of chemicals to reduce the impact of known hazardous chemicals on human health and the environment, identify new potentially hazardous chemicals and phase out or phase down chemicals where hazards are identified.

[redacted]

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[redacted]

B. Named Staff Members and Details of their Specialism and expertise

[redacted]

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

[redacted]

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[redacted]

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

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

C. STAFF EFFORT

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

Name and Role of Person where known/ Role of person to be recruited	Working hours per staff member on this project
[redacted]	

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Total staff effort	980

5: PROJECT MANAGEMENT

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

To ensure that project management processes are adequately implemented throughout the project, Yordas will implement our internal project management procedures. This includes key principles to ensure efficient interactions between project team members, such as distinctly defined roles and responsibilities. The organisational structure allows clear lines of communication as it efficiently organises the project team. Continuous improvement processes will be implemented to ensure continuous evaluation of activities so only the highest quality is delivered. Delegation of authority to the technical leads establishes operational efficiency as tasks are undertaken where the role's scope and authority are suitably matched.

Communication Management

Clear and effective communication is crucial for the success of this contract. It is the responsibility of the project management team to facilitate communication within the team and with FSA. To ensure the project team is informed and aligned, Yordas will hold regular internal video calls to discuss progress, issues, resource capacity and next steps. Updates resulting from these calls will be communicated to FSA via monthly progress reports.

Short progress video calls will also be scheduled with FSA on a needs basis to discuss any project-related issues, proposed solutions, and their potential implications. A final project closing meeting will be held between Yordas and FSA to discuss outcomes and hand off the final deliverables.

Team Organisation

The project team has been structured to ensure operational efficiency and clarity of communication channels to encourage collaboration and efficient communication between team members. An overview of the project team is provided in the figure 1 below. A short biography of the team members is provided in Section B and CVs may be found in the attached bid package. Our Project Management Team comprises a Project Director, [redacted] and a Project Manager, [redacted] who will be the key day-to-day contact with FSA and the project team [redacted] are responsible for coordination and communication between the team and FSA. In case of unavailability of the Project Manager, the Science Lead will provide continuity to the project by assuming the interim Project Manager role. The Project Manager will approve deliverables, ensuring that the team members have checked quality.

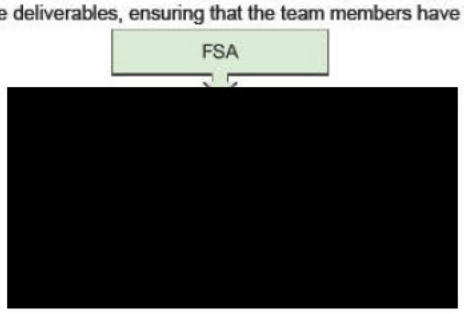

Figure 1 Project Organisational Structure

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The Project Director, [redacted] will ensure that the project's progress is monitored and controlled. The project management team will also be responsible for implementing quality management procedures and overseeing the review process to monitor the quality of deliverables diligently.

The technical team comprises a balanced number of individuals with expertise in mammalian toxicology, study monitoring and study design, Microsoft Suite, Adobe Acrobat and systematic literature searches. The technical team will communicate directly with the Project Manager regularly. Together, the expert team has the skills and complementary expertise to advise and support across multiple project areas. Therefore, in the absence of a team member, there will be continued support in all areas. Furthermore, Yordas has a staff of over 100. In the event that one or more team members become unavailable, we can immediately replace them and continue with the task execution. Where suitable, junior staff members will support the team leads, and their work will be overseen, managed and quality checked by the team leads with greater expertise in that area.

6. RISK MANAGEMENT

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

Identified risk	Likelihood of risk (high, medium, low)	Impact of Risk (high, medium, low)	Risk management strategy
Availability of data: insufficient data availability	Low	Medium	The team will use different approaches to gather data that are tailored to the type of data to maximise the chances of finding as much information as possible. Furthermore, a number of data sources will be utilised to ensure we can find all relevant information.
Availability of data: Inconsistent or contradictory data from literature search, database review	Medium	Medium	We will quality assure the data and cross-reference the data we receive based on the data review. We will give those who complete the survey the option to share their contact details so we can follow up for further information if needed. We will transparently set out inconsistencies using our experience and make a judgement on the balance of evidence.
Availability of data: Publications could be behind a paywall	Low	Low	Yordas has access to several online libraries and will gain access to the full-text articles through new subscriptions if they are not accessible within the existing ones.
Resources: Unavailability of specific experts to carry out the task	Low	High	Alternative resources have been identified and can be used if necessary. Several experts have been assigned to the project team, and together, they have conducted many literature reviews. Furthermore, Yordas has a staff of over 100. In the event that one or more team members become unavailable, we can immediately replace them and continue with the task execution.
Quality: High volume of comments and changes requested during report review	Medium	Low	Yordas will closely communicate with FSA the results of each work package, present the next steps and request that FSA agree upon the structure of the interim and final reports. Therefore, the volume of comments and requested changes will be minimised as FSA is being kept informed of

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			the results presented and the structure of each deliverable.
Quality: The deliverable quality does not meet the requirements of FSA	Low	Medium	We have allocated an experienced management team with dedicated quality assurance managers and a project-specific quality management plan. We have assigned the quality assurance manager role to the technical leads, and deliverables will be required to be reviewed and signed off by senior team members.
Schedule: Delay in delivery of project deliverables	Low	Medium	We will outline a formal procedure for ensuring timely deliveries in the Quality Management Plan, this includes adding additional resources and being transparent with FSA by immediately informing them of any delays. Project progress will also be frequently monitored through the use of project management tools, such as Gantt charts and dashboards.

7. Quality Management

A. QUALITY MANAGEMENT

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

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

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

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

The project management structure is designed to ensure that individuals with the most relevant expertise and decision-making capacity are involved in multiple areas of the project to maintain continuity. Yordas adheres to an integrated management system (IMS) certified to the ISO 9001 (quality), 14001 (environmental management), and 27001 (information security) standards, and all project activities will follow Yordas's IMS procedures. Upon award of a contract, monthly project internal reviews by the Project Management Team will assess technical, financial, and schedule progress against the project plan and risk register. Yordas' internal Project Quality Management Procedure will ensure the technical leads quality check and assure project deliverables. The Project Team will establish and share with FSA a project-specific quality management plan, responsibility (RASCI) matrix and Gantt chart for the project team to follow. Yordas also uses a multi-stage quality assurance checking system, which requires at least two senior experts to sign off on all documentation (e.g., reports, presentations) to ensure suitability, validity, and accuracy. Copies of Yordas's ISO certificates can be provided upon request.

B. DATA PROTECTION

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Please identify any specific data protection issues for this project and how these will be managed. Please respond to any specific issues raised in the Specification document.
Please note that the successful Applicant will be expected to comply with the Data Protection Act (DPA) 2018 and ensure that any information collected, processed and transferred on behalf of the FSA, will be held and transferred securely.

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

Yordas and therefore this project conforms to ISO 27001, for which Yordas holds accreditation. Furthermore, Yordas adheres to an Information Security Policy which is available upon request. We are committed to maintaining and improving information security procedures including the Data Protection Act (DPA) 2018 and GDPR to uphold the availability, integrity and confidentiality (AIC) of all informational assets, however stored.

The project team recognises the importance of risk management activities such as data classification, storage, handling and access rights. The following approaches will be taken:

- Technology: Yordas uses technology to safeguard data privacy, and protect against security breaches and data loss. Yordas implements hardware and software authentication, firewalls, user behaviour analytics, data encryption, intrusion detection, device authentication and secure cloud storage tools to safeguard information availability, integrity, and confidentiality.
- Conformance: Yordas recognise the importance of data confidentiality and commit to managing information responsibly in line with all applicable UK, EU and International data protection laws including DPA 2018, GDPR and Non-disclosure Agreements.
- Transparency: Yordas shall always be transparent regarding the use and management of the information shared as part of this project.

We will archive all information in dedicated folders and files on a secured server, with access limited to the members of the project involved in the work. Furthermore, Yordas's Chief Information Office, [redacted]s available for questions on data management and protection at any time.

The protection of confidential information is fully integrated into Yordas' everyday business activities and as such we have developed several strategies for managing CBI information, including signing separate third party non-disclosure agreements. It is worth noting that we frequently work for law firms under the context of attorney-client privileged information; thus, careful handling of sensitive documentation is a fundamental part of our culture. We also work successfully with several Trade Associations on longstanding and ongoing projects that require us to handle competitively sensitive information and ensure that this is not exchanged between Member Companies.
Furthermore, this policy is supported through various procedures, including our User Account and Access Control Procedure.

C. SUSTAINABILITY

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

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Yordas Group is committed to making a positive environmental contribution and supporting our clients in addressing sustainable development challenges. We believe that sustainability is fundamentally a drive to do better: environmentally, socially, and economically. We recognise that our success and the success of our clients is increasingly dependent on the integration of sustainability principles in our activities. We are dedicated to delivering this project through:

- Effective leadership: We demonstrate active, visible and effective leadership aimed at inspiring our peers and the next generation to apply sustainability principles in their everyday activities. We engage with our employees and build collaborative business relationships to embed best practices into our business decisions. We will work very closely with FSA, employing our leadership in this area.
- Innovative and sustainable solutions: We are committed to working closely with FSA to introduce innovative business solutions that meet sustainability objectives and are grounded with sound technical knowledge and scientific evidence. Yordas also aspires to work with clients, partners and suppliers who are committed to continuous improvement of their environmental and sustainability performance.
- Risks and opportunities management: We are committed to minimising our environmental impact and maximising social benefits. We manage our risks and opportunities by setting organisational objectives, monitoring our progress and taking actions to improve our performance. For this project, we will minimise the environmental impact through video calls.
- Continuous improvement: We are working to create a culture of environmental and social responsibility where we continuously improve our business practices. We are committed to improving our environmental performance and to avoid or reduce negative impacts from our activities. We strive for excellence and innovation and we encourage communication of progress with our stakeholders and FSA.
- Equality, Diversity and Inclusion: Our employees are our most important asset. At Yordas, we aim to drive equality, embrace diversity and cultivate inclusion that also shows in the staff working on this project. We encourage a workplace that's equal, diverse, and inclusive that not only can increase employee morale but also our business reputation. The collective sum of the individual differences, life experiences, unique capabilities and skills that our employees invest in their work greatly contributes to our corporate culture and achievements.

ISO 14001 Environmental and Sustainability Policy

We encourage behaviour and initiatives that will protect and improve the environment, while fostering the creation of economic and social benefits.

As a privately-owned company, we strive to build strong and meaningful relationships with our colleagues, clients, partners and society, while delivering sustainable solutions that support our clients' visions and objectives.

We implement our principles by:

- Raising awareness of this Policy, both internally and externally;
- Fulfilling all applicable environmental compliance obligations;
- Integrating environmental considerations into everyday purchasing decisions;
- Using resources efficiently to reduce consumption and waste;
- Reducing carbon intensive travel where possible, through flexible work arrangements, use of technology for remote conferences, and by encouraging use of sustainable transport systems;
- Managing risks associated with chemical use, storage and disposal;
- Ensuring activities are adequately resourced and systematically managed following the PDCA (Plan, Do, Check, Act) framework

D. DISSEMINATION AND EXPLOITATION

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

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

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

[Supplier Tender – Clarification Responses]

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Food Standards Agency

Lancaster, 11 December 2023

Dear FSA Commercial Team,

TENDER REFERENCE: FS900348
TENDER TITLE: New Approach Methodologies (NAMs) to Support Regulatory Decisions for Chemical Safety

Thank you very much for your notification letter dated 7 December 2023.

We are pleased to provide our answers to your clarification questions.

1. Does the applicant understand that the purpose is for chemicals found in food as opposed to those used in food. This is important as the team would want to consider chemicals such as contaminants and additives.

We are aware that chemicals found in food are potentially of greatest concern because they are not intentionally added so the dose cannot be accurately predicted. These are often referred to as contaminants and may come from a variety of sources (production, packaging, transport, cooking). Examples of such chemicals maybe residual pesticides and biocides, processing contaminants such as PAHs, substances from the environment particularly PBTs and vPvBs (of key concern currently are PFASs), and toxins produced by the food due to spoilage or simply those occur naturally (e.g. THC, alkaloids).
Could you please confirm that this project does not cover biological entities such as prions, viruses etc as the expertise required to assess the risk of these entities is quite different to that for chemicals?

2. 2. A key concern is whether this is sufficiently human focussed. The panel wonders if the focus might be too much on the eco-tox side. Will there be enough in-house support to deliver on this front?

The named people on this project have demonstrable expertise in human toxicology and extensive experience with all types of regulatory testing, including higher-tier toxicological testing such as OECD 414, 408, and 443 for the purpose of substance evaluation under REACH. In addition, in the last 10 years, our toxicologists have developed considerable

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experience and expertise in utilizing alternative approaches to testing for regulatory submission of human toxicology endpoints.

3. "Assessment of regulatory readiness will be open to FERA". There was confusion about this. Did the applicant mean FSA instead of FERA?

Apologies for the confusion, yes, we meant FSA.

Please do not hesitate to contact us if you have any further questions. We look forward to hearing from you.

Yours sincerely,

[redacted]

10. Intellectual Property Rights (IPRs)

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

(a) receive and use the Deliverables; and

(b) use the New IPR.

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

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

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

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

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

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

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

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

If the Supplier cannot obtain for the Buyer a licence in respect of any Third Party IPR, for whatever reason, the Supplier shall:

(a) notify the Buyer in writing; and

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

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

10.9 Subject to clause 10.11, the Supplier agrees that the Buyer may at its sole discretion publish under Open Licence all or part of the New IPR Items and the Supplier warrants that the New IPR Items are suitable for release under Open Licence.

10.10 The Supplier will supply any or all New IPR Items in a format suitable for publication under Open Licence ("**the Open Licence Publication Material**") within 30 days of written request from the Buyer ("**Buyer Open Licence Request**").

10.11 The Supplier may within 15 days of a Buyer Open Licence Request under clause 10.10 request in writing that the Buyer excludes all or part of:

(a) the New IPR; or

(b) Supplier Existing IPR or Third Party IPR that would otherwise be included in the Open Licence Publication Material supplied to the Buyer pursuant to clause 10.10

from Open Licence publication.

10.12 Any decision to approve any such request from the Supplier pursuant to clause 10.11 shall be at the Buyer's sole discretion, not to be unreasonably withheld, delayed or conditioned.

10.13 Subject to clause 12, the Buyer will not be liable in the event that any Supplier Existing IPR or Third Party IPR is included in the Open Licence Publication Material published by the Buyer.

III. Short form Terms ("Conditions")

1. Definitions used in the Contract

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

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

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

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

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

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

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

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

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

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

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

2. Understanding the Contract

In the Contract, unless the context otherwise requires:

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

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

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

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

2.5 the singular includes the plural and vice versa;

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

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

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

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

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

3. How the Contract works

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

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

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

4. What needs to be delivered

4.1 All Deliverables

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

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

4.2 Goods clauses

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

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

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

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

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

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

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

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

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

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

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

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

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

4.3 **Services clauses**

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

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

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

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

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

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

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

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

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

5. Pricing and payments

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

5.2 All Charges:

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

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

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

5.4 A Supplier invoice is only valid if it:

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

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

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

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

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

6. The Buyer's obligations to the Supplier

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

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

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

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

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

6.2 Clause 6.1 only applies if the Supplier:

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

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

(c) mitigated the impact of the Buyer Cause.

7. Record keeping and reporting

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

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

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

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

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

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

(a) tell the Buyer and give reasons;

(b) propose corrective action; and

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

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

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

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

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

8. Supplier Staff

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

(a) be appropriately trained and qualified;

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

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

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

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

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

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

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

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

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

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

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

9. Rights and protection

9.1 The Supplier warrants and represents that:

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

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

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

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

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

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

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

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

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

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

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

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

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

10. Intellectual Property Rights (IPRs)

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

(a) receive and use the Deliverables; and

(b) use the New IPR.

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

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

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

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

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

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

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

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

(a) notify the Buyer in writing; and

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

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

11. Ending the contract

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

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

11.3 **Ending the Contract without a reason**

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

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

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

(i) there's a Supplier Insolvency Event;

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

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

(iv) there's a change of control (within the meaning of section 450 of the Corporation Tax Act 2010) of the Supplier which isn't pre-approved by the Buyer in writing;

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

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

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

(b) The Buyer also has the right to terminate the Contract in accordance with clauses 7.7(b), 21.3, 29.4(b), 34.3 and Paragraph 8 of *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* (if used).

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

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

(a) Where the Buyer terminates the Contract under clause 11.4(a), 7.7(b), 29.4(b), or Paragraph 8 of *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* (if used), all of the following apply:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11.7 **Partially ending and suspending the Contract**

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

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

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

(i) reject the variation; or

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

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

12. How much you can be held responsible for

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

12.2 No Party is liable to the other for:

(a) any indirect losses; and/or

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

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

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

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

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

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

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

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

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

13. Obeying the Law

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

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

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

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

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

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

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

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

14. Data Protection

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

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

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

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

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

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

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

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

14.7 The Supplier:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with UK GDPR Article 46 or section 75 of the DPA 2018) as determined by the Controller which

could include relevant parties entering into the International Data Transfer Agreement (the "**IDTA**"), or International Data Transfer Agreement Addendum to the European Commission's SCCs (the "**Addendum**"), as published by the Information Commissioner's Office from time to time as well as any additional measures determined by the Controller;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(vi) becomes aware of a Data Loss Event.

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

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

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

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

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

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

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

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

(i) is not occasional;

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

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

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

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

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

(ii) obtain the written consent of the Controller;

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

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

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

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

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

14.10 **Joint Controllers of Personal Data**

In the event that the Parties are Joint Controllers in respect of Personal Data under the Contract, the Parties shall implement paragraphs that are necessary to comply with UK GDPR Article 26 based on the terms set out in *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*.

14.11 **Independent Controllers of Personal Data**

In the event that the Parties are Independent Controllers in respect of Personal Data under the Contract, the terms set out in Part C – *Independent Controllers* of Annex 1 – *Processing Personal Data* shall apply to this Contract.

15. What you must keep confidential

15.1 Each Party must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) where requested by Parliament; and

(e) under clauses 5.7 and 16.

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

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

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

16. When you can share information

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

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

(a) comply with any FOIA request;

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

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

16.3 To the extent that it is allowed and practical to do so, the Buyer will use reasonable endeavours to notify the Supplier of a Request For Information and may talk to the Supplier to help it decide whether to publish information under clause 16. However,

the extent, content and format of the disclosure is the Buyer's decision in its absolute discretion.

17. Insurance

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

18. Invalid parts of the contract

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

19. No other terms apply

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

20. Other people's rights in the contract

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

21. Circumstances beyond your control

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

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

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

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

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

21.4 Where a Party terminates under clause 21.3:

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

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

22. Relationships created by the contract

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

23. Giving up contract rights

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

24. Transferring responsibilities

24.1 The Supplier cannot assign, novate or in any other way dispose of the Contract or any part of it without the Buyer's written consent.

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

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

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

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

25. Supply Chain

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

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

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

(c) the proposed Subcontractor employs unfit persons.

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

(a) their name;

(b) the scope of their appointment; and

(c) the duration of their appointment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26. Changing the contract

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

27. How to communicate about the contract

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

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

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

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

28. Dealing with claims

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

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

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

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

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

28.2 The Supplier must:

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

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

29. Preventing fraud, bribery and corruption

29.1 The Supplier shall not:

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

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

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

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

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

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

(b) immediately terminate the Contract.

30. Equality, diversity and human rights

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

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

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

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

31. Health and safety

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

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

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

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

32. Environment and sustainability

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

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

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

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

33. Tax

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

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

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

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

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

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

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

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

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

34. Conflict of interest

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

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

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

35. Reporting a breach of the contract

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

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

36. Further Assurances

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

37. Resolving disputes

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

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

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

(a) determine the dispute;

(b) grant interim remedies; and

(c) grant any other provisional or protective relief.

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

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

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

38. Which law applies

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