Food Standards Agency
food.gov.uk

RSK ADAS Ltd
Spring Lodge, 172 Chester Road
Helsby
WA6 0AR

[redacted]

Date: 25/08/2022
Our ref: FS900232

Dear [redacted]

Supply of Systematic review of the literature on dioxin and dioxin-like PCBs

Following your tender/ proposal for the supply of Systematic review of the literature on dioxin and dioxin-like PCBs to Food Standards Agency we are pleased confirm our intention to award this contract to you.

The attached contract details ("**Order Form**"), contract conditions and the ***Annexes*** set out the terms of the contract between Food Standards Agency 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 the Conditions by signing and returning the Order Form. No other form of acknowledgement will be accepted. Please remember to include the reference number above in any future communications relating to this contract.

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

Yours faithfully,

[redacted]

[redacted]

Order Form

1. Contract Reference	FS900232	
2. Date		
3. Buyer	Food Standards Agency Clive House 70 Petty France London SW1H 9EX	
4. Supplier	RSK ADAS Ltd Spring Lodge, 172 Chester Road Helsby WA6 0AR	
5. The Contract	The Supplier shall supply the deliverables described below on the terms set out in this Order Form and the attached contract conditions ("**Conditions**") and any ***Annexes***. Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in Conditions. In the event of any conflict between this Order Form and the Conditions, this Order Form shall prevail. Please do not attach any Supplier terms and conditions to this Order Form as they will not be accepted by the Buyer and may delay conclusion of the Contract.	
6. Deliverables	**Goods**	None.

	Services	To be performed at **the Suppliers premises.** **See Annex 3 –Technical Proposal.**
7. Specification	The specification of the Deliverables is as set out in **Annex 2**.	
8. Term	The Term shall commence on **01/10/2022** and the Expiry Date shall be **31/05/2022**, unless it is otherwise extended or terminated in accordance with the terms and conditions of the Contract. 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 terms and conditions of the Contract shall apply throughout any such extended period.	
9. Charges	The Charges for the Deliverables shall be as set out in **Annex 4**.	
10. Payment	All invoices must be sent, quoting a valid purchase order number (PO Number), to: [redacted] Within 10 Working Days of receipt of your countersigned copy of this letter, we will send you a unique PO Number. You must be in receipt of a valid PO Number before submitting an invoice. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO Number item number (if applicable) and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment.	

11. Buyer Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted]
12. Address for notices	**Buyer:** Food Standards Agency FSA Commercial Foss House Peasholme Green York YO1 7PR **Supplier:** RSK ADAS Ltd Spring Lodge, 172 Chester Road Helsby WA6 0AR
13. Key Personnel	[redacted] Further details in **Annex 3 –Technical Proposal.**

14. Procedures and Policies	The Buyer may require the Supplier to ensure that any person employed in the delivery of the Deliverables has undertaken a Disclosure and Barring Service check. 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.

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

Annex 1 – Authorised Processing Template

Contract:	**FS900232**
Date:	
Description Of Authorised Processing	**Details**
Subject matter of the processing	No personal data is approved to be processed as part of this Contract.
Duration of the processing	
Nature and purposes of the processing	
Type of Personal Data	
Categories of Data Subject	

Annex 2 - Specification

A. THE SPECIFICATION

Background

Dioxins are members of a large group of substances with similar chemical structures. They are not deliberately produced but are formed during fires and most forms of combustion (e.g., fires, incinerators, automobile engines) and as trace contaminants in the synthesis of chemicals and some industrial processes. Due to their similar biological activity some members of another group of substances, the dioxin-like polychlorinated biphenyls (PCBs) are usually included in an assessment of dioxins.

Dioxins remain in the environment for a long time and accumulate, usually in the fatty tissues, of animals. Dioxins are known to cause a wide range of toxic effects in animals, some of which have been seen at very low doses. These effects may have significant consequences for human health (COT, 2001).

In 2018, the European Food Safety Authority (EFSA) re-evaluated dioxins and dioxin-like polychlorinated biphenyls (PCBs) and established a new tolerable weekly intake (TWI) of 2 pg/TEQ/kg bw, which is 7-fold lower than its previous tolerable intake.

This 7-fold reduction of the tolerable intake would entail that, from a situation in which dietary exposure for most of the UK population is below a level of concern, exposure would instead be at a potentially harmful level. This suggests that current risk management measures for dioxins and dioxin-like PCBs in food, which include regulatory limits and precautionary advice to consumers and are based on the previous tolerable intake, may be inadequate. There were also concerns that the EFSA evaluation appeared to raise questions over the common mechanistic basis for evaluation and management of this group of compounds.

Given the implications for risk management, the UK's independent Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) felt that the rationales for the choices of key studies were not sufficiently clear in the EFSA opinion, which made it difficult to evaluate the strength of the evidence (COT, 2020).

EFSA's key study was a study the COT considered to provide only a weak data set and to be inconsistent with findings in a second study. The COT furthermore considered there were inconsistencies in the animal data presented in the EFSA opinion. They had raised concerns previously in 2001, which resulted in FSA commissioned studies to address these concerns, which failed to replicate the specific findings. Overall, the COT considered the data presented in EFSA's opinion to be inconsistent with the existing body of data on dioxins and dioxin-like PCBs and knowledge on the relative sensitivity of the human compared to the rat.

These inconsistencies and concerns regarding the implications for the current risk management approach meant that the COT did not agree with the newly established tolerable intake and was unable to endorse the EFSA opinion.

The 7-fold reduction in the tolerable weekly intake appeared too conservative for the database overall and the COT considered it necessary to reconsider the evidence base and set its own tolerable intake. The COT noted that this would be consistent with their approach to the previous major re-evaluation by JECFA and the EU in 2000 (COT 2001)

To allow the Committee to undertake its own review of dioxins and dioxin-like PCBs a systematic literature review (of all relevant endpoints) is required. Given the implications, and the size of the database, it is prudent that the work is undertaken by individuals with the right knowledge and capacity.

Overall, doing this work would ensure the appropriate level of protection for the UK consumer.

The Specification

Tenders are invited to carry out a systematic literature review of dioxins and dioxin-like PCBs.

Overview

We would like to commission a systematic literature review of the database on dioxins and dioxin-like PCBs. Given the size of the database and the recommendations by the Committee on Toxicity (COT), the systematic review will be focused on a specific timeframe and number of specific endpoints/adverse effects, detailed below.

Details

Proposals submitted **must** include the following key elements:

- The proposed work should gather existing epidemiological and toxicological data in the literature (including peer-reviewed publication, grey literature and other sources) for the critical endpoint(s) of dioxins and dioxin-like PCBs, namely a) effects on the reproductive system, focussing on changes in the male reproductive system parameters and b) immunotoxicity; the review should also include existing data on the aryl hydrocarbon receptor (AhR) mechanism of dioxins and dioxin-like PCBs.
- A narrative review of the literature should also be performed to confirm other effects are less sensitive and to identify other endpoint(s) in toxicological (animal) studies which may be more relevant to other subpopulations. This section of the work should also include data to confirm whether or not the carcinogenicity observed with dioxins and dioxin-like PCBs involves direct genotoxicity.
- We anticipate this project starting in **October 2022** with the final report being submitted to the FSA in **May 2023**.
- The FSA estimates that the cost for this work to be between £45-60k. 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.
- EFSAs systematic literature review on dioxins and dioxin-like PCBs in 2018 should have selected all relevant literature for the most sensitive endpoint. Hence, the proposed systematic literature review should collate and consider literature from nine months prior to the cut-off date applied by EFSA to December 2022. However, the applicant should be flexible to possibly extend the search end date to ensure that the review is as "up to date" as possible if publication of the final report is delayed. To support the evaluation of epidemiological evidence, the proposed work would further include a systematic search for any publications on meta-analysis of data on dioxins and dioxin-like PCBs,

without any date restrictions. The candidates are advised to carry out a quick search of the literature to estimate the number of papers and include this within their proposal. A description of how the applicant proposes to identify and source grey literature should also be included.

- The quality of the data will need to be considered carefully. Hence the proposal should include a clear approach to the critical review process, including the scope, search terms/strings, databases to be searched, inclusion-exclusion criteria, a strategy for sifting/evaluating publications, key milestones and deliverable dates. The proposal should include the standard guidelines (e.g., PRISMA) the applicant will be applying to the systematic literature search. Depending on the data/publications collated, the proposed work should categorise the publications in groups with similar properties/endpoints and provide a rational for this.
- A key component of the work requires expertise in terms of interpreting the findings of the review. Therefore, the applicant(s), either individually or collectively, should have demonstratable expertise in
    - A (chemical) toxicological background, ideally with knowledge of risk assessment or chemical knowledge of dioxins or dioxin-like compounds.
    - Expertise or at least some awareness of reproductive toxicology, immunotoxicity and carcinogenicity.
    - Knowledge concerning epidemiological and animal studies, as well as mechanistic studies.
    - Carrying out critical/systematic literature reviews of relevant scientific literature to standard guidelines (e.g., PRISMA).
- Given that this list of expertise is quite extensive, the FSA strongly encourages collaborative proposals to ensure all relevant backgrounds and expertise is suitably covered to undertake the proposed work. Sub-contractors should be included in the original proposal, if applicable, or if required after work has commenced with written authorisation by the FSA. The applicant will remain liable to the FSA for the Sub-contractor's compliance.

Outcomes

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

- A full technical report addressing the relevant areas of the work. The report should include a lay summary, an executive summary, introduction (including the background and aims/objectives of the review), methodologies (including any mitigation measures to account for unforeseen problems during the work), findings, discussions, conclusions, list of evidence gaps and the references. The final report will need to be formatted in accordance with guidance from the FSA to be published on the COT's/FSA's website.
- The critical review should be both transparent and reproducible. Full details of all relevant publications included in the critical review should be provided to the FSA, i.e. the bibliographic references including relevant information (e.g. title, authors abstract). The database should be presented in a user-friendly and widely accessible format. The retrieved literature/data should be categorised into groups with similar properties/endpoints and a rational for the grouping should be provided.
- The database should include the weblinks to the relevant publications, and where possible should indicate whether these are open access or be provided in electronical format.

- Publication in open access peer reviewed literature and presentations at scientific conferences are encouraged by the FSA. However, any publication will need to be approved by the FSA prior to being submitted to the journal. It is important that the applicant(s) notify the FSA of the publication date for any papers arising from this work at the earliest opportunity.

- If appropriate, attend a future COT meeting to present the work and answer questions raised on aspects of the systematic literature search.

Collaborative applications with an appropriate management framework are encouraged to promote well-balanced, innovative proposals that offer value for money and make use of the best available research and analytical approaches.

References

COT (2001). COT statement on the tolerable daily intake for dioxins and dioxin-like polychlorinated biphenyls.

The statement can be found here

COT (2021). COT position statement on dioxins.

The statement can be found here.

EFSA (2018). Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food. EFSA Panel on the Contaminants in the Food Chain (CONTAM), EFSA Journal, 16(11): e05333

https://doi.org/10.2903/j.efsa.2018.5333

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.

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

Data security

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

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 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.

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.

Openness

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.

Annex 3 – Technical Proposal

TENDER APPLICATION FORM FOR A PROJECT WITH THE FOOD STANDARDS AGENCY	Food Standards Agency food.gov.uk

- **APPLICANTS SHOULD COMPLETE EACH PART OF THIS APPLICATION AS FULLY AND AS CLEARLY AS POSSIBLE**
- **BRIEF INSTRUCTIONS ARE GIVEN IN THE GREY BOXES AT THE START OF EACH SECTION.**
- **PLEASE SUBMIT THE APPLICATION THROUGH THE AGENCY'S ESOURCING PORTAL (BRAVO) BY THE DEADLINE SET IN THE INVITATION TO TENDER DOCUMENT.**

LEAD APPLICANT'S DETAILS				
[redacted]				
Is your organisation is a **small and medium enterprise**. (EU recommendation 2003/361/EC refers http://www.hmrc.gov.uk/manuals/cirdmanual/cird92800.htm)	~~Yes~~		**No**	

TENDER SUMMARY						
TENDER TITLE						
Systematic review of the literature on dioxins and dioxin-like polychlorinated biphenyls (PCBs)						
TENDER REFERENCE	FS900232					
PROPOSED START DATE	October 2022		**PROPOSED END DATE**		May 2023	

1: TENDER SUMMARY AND OBJECTIVES
A. TENDER SUMMARY
Please give a brief summary of the proposed work in no more than 400 words.

In light of the recently published tolerable weekly intake for dioxins and dioxin-like PCBs by EFSA, which is 7-fold lower than EFSA's previous tolerable intake, the aim of this project is to carry out a systematic literature review of dioxins and dioxin-like PCBs to allow the Committee to form an opinion on a tolerable intake to ensure the appropriate level of protection for the UK consumer.
The systematic literature review will be split into different objectives in order to select as many high-quality papers as possible, on which the Committee can base their opinion.
The project will consist of a number of objectives namely the derivation of search terms and inclusion/exclusion criteria to use to retrieve as many relevant references as possible, carrying out the literature search, data selection using inclusion/exclusion criteria/ data evaluation and finally presenting a narrative of the data. The project will focus on the male reproductive toxicity and immunotoxicity of dioxins and dioxin-like PCBs in animals and from epidemiology data, as well as aryl hydrocarbon receptor (AhR) mechanism of action to investigate differences between animal species and humans. The project will also investigate if carcinogenicity observed with dioxins and dioxin-like PCBs involves a genotoxic mechanism, confirm that other toxicological endpoints are less sensitive than male reproductive and immunotoxicity endpoints and identify if other endpoints are relevant in subpopulations based on animal toxicity studies.
The literature search will be carried out using the search terms and appropriate papers will be selected based on the inclusion/exclusion criteria, some of which will be pre-defined prior to literature searching i.e., date, and some based on the data obtained.
The toxicity data obtained will be evaluated using Klimisch, and epidemiology data evaluated using the Strengthening the reporting of observational studies in epidemiology (STROBE) Statement or Newcastle-Ottawa (Quality Assessment) Scale (NOS) to ensure data selected is of good quality.
A narrative for each selected paper will be provided and, if appropriate, the outcome will be presented to the Committee.

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

OBJECTIVES

PLEASE DETAIL HOW YOUR PROPOSED WORK CAN ASSIST THE AGENCY IN MEETING IT STATED OBJECTIVES AND POLICY NEEDS. PLEASE NUMBER THE OBJECTIVES AND ADD A SHORT DESCRIPTION. PLEASE ADD MORE LINES AS NECESSARY.

OBJECTIVE NUMBER	OBJECTIVE DESCRIPTION
1	SELECTION OF SEARCH TERMS AND INCLUSION/EXCLUSION CRITERIA
2	LITERATURE SEARCH FOR RELEVANT LITERATURE
3	DATA SELECTION USING INCLUSION/EXCLUSION CRITERIA
4	DATA EVALUATION
5	NARRATIVE OF DATA
6	DATA PRESENTATION

We will assist the FSA in achieving its objective to inform and develop policy decisions and assessing the impacts of these decisions to ensure the core statutory objective to protect public health and consumers' and other interests in relation to food. We will assist the Agency to be a fair and effective regulator employing proportionate and forward-looking regulatory approaches and achieving the policy outcome desired. We will help the FSA to ensure food is safe to consumers.

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.

APPROACH

The specification of the project is to gather epidemiological and toxicological data in the literature on the effects of dioxins and dioxin-like PCBs on the male reproductive system and immunotoxicity, as well as investigating data on the aryl hydrocarbon receptor (AhR) mechanism of dioxins and dioxin-like PCBs. To ensure that the process used for the systematic review is transparent, accurate and complete, The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA 2020) checklist will be followed which is an 'evidence-based minimum set of items for reporting in systematic reviews and meta-analyses'.

The approach proposed below outlines the steps needed to achieve the specification of the project, generated through a systematic review of the available information/data published in different sources in the public domain (e.g. scientific literature, reports from EU/national/international authorities, European Food Safety Authority (EFSA) and other EU Agencies, EU databases, and other available sources). Priority will be given to information from peer reviewed sources; however, other sources of available data (grey literature) will be taken into consideration when relevant. References will be in a format that is compatible with EndNote™. The literature search strategy (from different bibliographic database platforms, such as, but not limited to: PubMed and Scopus,) and selection criteria (inclusion/exclusion) for the review shall be based on the EFSA Systematic Review Guidance (EFSA, 2010).

Data will be extracted from selected studies and summarised in a narrative and/or tabular format as appropriate, which will outline the relevant data for each selected study.

METHODOLOGY

TASK 0: PROJECT INCEPTION

The objective of this task is to understand the FSA's expectations for the project and to agree on the specific methodology that will be used to achieve these goals. The Project inception aims to outline additional information, formalise the work plan and coordinate with partners, in addition to elaborating the potential challenges expected. It is anticipated that a kick-off meeting will be organised at the start of the project, within 2 weeks of contract signature. This meeting will provide an opportunity for the consultants and FSA to review the approach and methodology set out in this proposal.

OBJECTIVE 1: LITERATURE SEARCH FOR THE COLLATION OF RELEVANT LITERATURE

Selection of information sources

The project team has access to a number of scientific and bibliographic databases such as Scopus and PUBMED, as well as information from other sources such as IUCLID, Toxnet, e-Chem Portal.

- Scopus is the world's largest abstract and citation database, covering MEDLINE amongst other databases. It contains over 20,500 titles from 5,000 publishers worldwide. Scopus links to full-text articles and other library resources.
- PUBMED comprises >22 million citations for biomedical literature, covering biomedicine and health, life, behavioural and chemical sciences.

Although there will inevitably be duplication between the databases, the use of at least two is deemed necessary to ensure as wide a coverage of available literature as possible.

Relevant reports from national and European CE programmes or conferences not identified via database searches will be reviewed. In addition, the bibliographies of key systematic and narrative reviews will be searched for articles that meet the inclusion/exclusion criteria but not identified by search of the bibliographic databases.

Selection of search terms

As part of this technical offer, the Project Manager, Lead Experts and Information Scientist will discuss and draw-up a potential list of search terms that are appropriate to retrieve published literature relating to the objectives of this project. Search terms will be developed, based on previous literature reviews carried out by EFSA, to gather data on the topic areas outlined in the tender documents such as male reproductive toxicity, immunotoxicity and aryl hydrocarbon mechanism of action. Broad search terms will be used that are appropriate to the database being interrogated over a period of seven years, as outlined in the tender document, to capture as many publications as possible. The final selected search terms will be agreed with the FSA.

The search strategies and related information to be used for the different search databases will be presented before the inception meeting. It is proposed that these can be amended following consultation between team members and the FSA Project Manager at the project start-up meeting. In addition, sensitivity analyses will be employed to ensure that relevant articles are being captured and, if necessary, search terms will be amended. All searches will be carried out in English, and will focus initially on "Title", "Keyword", and "Abstract". Search terms can be expanded, reduced and refined in a testing and scoping procedure, if required, and depending on the number of initial hits. If only a few retrievable references are identified, the search can be expanded to cover "Any Field". All titles and abstracts retrieved from the literature search will be held in a centralised location using Endnote bibliographic software, which will be accessible to all team members.

Example of search terms related to human toxicity, based on that used by EFSA (detailed in RPA and IEH, 2018) and including terms for aryl hydrocarbon receptor and immune toxicity from 2016 to present:

(TITLE-ABS-KEY (tetrachlorodibenzodioxin OR "2,3,7,8-Tetrachlorodibenzo-p-dioxin" OR tcdd OR dioxin* OR "polychlorinated biphenyl*" OR pcb OR teq OR "total equivalen*" OR coplanar OR "aryl hydrocarbon receptor" OR pcdd OR pcdf OR "Polychlorinated dibenzofuran" OR "Polychlorinated dibenzodioxin") AND TITLE-ABS-KEY (epidemiolog* OR "cohort stud*" OR "case control stud* " OR "adverse effect*" OR "observational stud*" OR "case serie*" OR "case report*" OR "cross sectional stud*" OR urine OR serum OR plasma OR haema* OR hema* OR blood OR sperm OR semen OR hormone* OR reproduct* OR immun*) AND TITLE-ABS-KEY (human OR men OR child*)) AND (LIMIT-TO (PUBYEAR , 2023) OR LIMIT-TO (PUBYEAR , 2022) OR LIMIT-TO (PUBYEAR , 2021) OR LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016)): 3913 (3849 in English)

Example of search terms related to animal studies, based on that used by EFSA (detailed in wca environment ltd., 2018) and including terms for aryl hydrocarbon receptor and immune toxicity from 2016 to present:
(TITLE-ABS-KEY (tetrachlorodibenzodioxin OR "2,3,7,8-Tetrachlorodibenzo-p-dioxin" OR pentachlorodibenzodioxin OR hexachlorodibenzodioxin OR tcdd OR dioxin* OR "polychlorinated biphenyl*" OR "dioxin like" OR pcdf OR pecdd OR pcb OR teq OR pcdd OR pcdf OR "Polychlorinated dibenzofuran" OR "Polychlorinated dibenzodioxin" OR heptachlorodibenzofuran OR octochlorodibenzofuran OR tetrachlorobiphenyl OR hexachlorobiphenyl OR pen

tachlorobiphenyl OR hexachlorobiphenyl) AND TITLE-ABS-KEY (toxic* OR "combined effect*" OR "dose depend*" OR repro* OR immun* OR disrupt* OR "oxidative stress" OR antioxidant* OR susceptibil* OR neuro* OR dimorphi*) AND TITLE-ABS-KEY (rat* OR mice OR monkey* OR pig* OR rabbit* OR hamster* OR dog* OR cat* OR mink OR hare OR chinchilla* OR vivo OR primate*)) AND (LIMIT-TO (PUBYEAR , 2022) OR LIMIT-TO (PUBYEAR , 2021) OR LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016)) AND (LIMIT-TO (DOCTYPE , "ar") OR LIMIT-TO (DOCTYPE , "re")): 2605 (2537 in English)

Removal of duplicate records

Duplicate records will be removed by the information scientist, in terms of the same publication retrieved from different databases. Where there are multiple publications stemming from the same study, all will be retained through primary screening and the full articles will be retrieved from each publication. All will be included providing that either the outcomes or the population analysed differs. If not, the most recent, relevant publication will be used.

OBJECTIVE 2 DATA SELECTION USING INCLUSION/EXCLUSION CRITERIA

Development of eligibility criteria for study selection

Identification of eligibility criteria is crucial to the validity of the critical literature review. It is proposed that for this study, the Project Manager, Lead Experts and Information Scientist will identify generic and data-specific inclusion/exclusion criteria to be used during the literature search. Initially, generic eligibility criteria will be used such as date, language and publication type. Once the literature search has been carried out, the results will be interrogated, and data-specific inclusion/exclusion criteria will be formulated and applied to the data. Examples of data-specific and generic inclusion/exclusion criteria are presented in tables 1-3.

Primary screening on title

The titles of all references retrieved, after duplicates are removed, will initially be screened by members of the study team against the inclusion/exclusion criteria. This primary screening will remove records relating to irrelevant topic areas. In situations where it is unclear whether the record is of relevance to the study, the article will be retained for further screening. In some cases, the record may be inappropriate for inclusion for one question, but relevant for another. In such cases the article will be retained where appropriate.

Table 1. Possible Inclusion and exclusion criteria to be used during primary screening of studies in experimental animals

	Inclusion criteria	**Exclusion criteria**
Experimental animals	Rats, mice, monkeys, guinea pigs, rabbit, hamster, dog, cat, mink Immunised animals Pathogen infected animals	Other species, transgenic animals In vitro studies Human (epidemiology) studies
Study population	Any experimental animal study, all ages, male and females	None
Route of administration	Oral (feeding, gavage and drinking water studies) Inhalation studies Dermal studies Subcutaneous injection (s.c.) Intraperitoneal injection (i.p.) Intramuscular injection (i.m.)	None
Study duration	Any	None
Chemicals	Dioxins Dioxin-like PCBs	Non-dioxin-like (indicator) PCBs Mixtures with compounds other than the target PCDD/Fs and DL-PCBs (e.g. organochlorinated compounds, brominated flame retardants, etc).
Endpoint	Male reproductive toxicity and immunotoxicity Other toxicity endpoints in *in vivo* studies	Female reproductive toxicity Other toxicity endpoints in epidemiology studies Enzyme induction (e.g. CYP modulation), gene expression or-omics profiles only Co-administration of pro-carcinogens (CON A, DMBA, NKK) Protective effects of certain substances against PCDD/Fs and/or DL-PCB toxicity

		Exposure data only
Mode of action	Articles related to mode of action of carcinogenicity	Articles related to mode of action of other endpoints

Table 2: Possible data-specific inclusion/exclusion criteria to be used during primary screening of studies in human epidemiology studies

	Inclusion criteria	**Exclusion criteria**
Study design	Cross-sectional studies Cohort studies Case-control studies (retrospective and nested) Case series/Case reports	Animal studies *In vitro* studies
Study population	All populations groups, all ages, males and females Study location: all countries	None
Route of administration	Dietary, dermal, inhalation, transplacental exposure	None
Chemicals	tbc	tbc
Endpoint	Male reproductive toxicity and immunotoxicity	Female reproductive toxicity Gene expression only Drug metabolising enzyme Activity/levels only Exposure data only

Table 3: Possible generic Inclusion and exclusion criteria to be used during primary screening

Inclusion criteria	**Exclusion criteria**
Articles in English language	Articles in other languages
Articles published from Aug 2015 to present	Articles published prior to Aug 2015
Systematic reviews, reviews, meta-analyses, scientific articles, reviews, reports and letters that report re-working of data	Expert opinions, commentaries, editorials and letters to the editor PhD Theses Extended abstracts, conference proceedings

On completion of this primary screening of titles, we will present FSA with (if required):

- The total number of studies identified (after duplicates are removed);
- The total number of studies that will go forward to the primary screening on abstracts (after irrelevant titles are removed).

We will also present the initial list of publications retrieved and the list of articles after primary screening on titles in Endnote™ format. Such titles will then undergo primary screening on abstracts.

A preliminary search has been carried out using the search string above, relating to human toxicity.

A total of 3921 documents were identified. Of these, 64 results are not in the English language, leaving 3857 documents for screening. 2965 are published articles and 757 are reviews. The remaining 135 documents were editorials, commentaries etc., hence were excluded due to publication type. The remaining 3722 articles will go forward to primary screening on title.

Of these, the following papers would be selected based on title:

Ikeno, Tamiko, Chihiro Miyashita, Sonomi Nakajima, Sumitaka Kobayashi, Keiko Yamazaki, Yasuaki Saijo, Toshiko Kita et al. (2018). Effects of low-level prenatal exposure to dioxins on cognitive development in Japanese children at 42 months. Science of the total environment 618. 1423-1430.

Shi, Li Li, Mei Qin Wang, Shoji F. Nakayama, Chau-Ren Jung, Yue Hua Wang, Jing Jian Dong, Chao Chen Ma, Teruhiko Kido, Xian Liang Sun, and Hao Feng (2020). The association between dioxins and steroid hormones in general adult males: a cross-sectional study in an e-waste region of China. Environmental Science and Pollution Research 27, no. 21. 26511-26519.

S. Alarcón, J. Esteban, R. Roos, P. Heikkinen, I. Sánchez-Pérez, A. Adamsson, et al. (2021). Endocrine, metabolic and apical effects of in utero and lactational exposure to non-dioxin-like 2,2´,3,4,4´,5,5´-heptachlorobiphenyl (PCB 180): A postnatal follow-up study in rats. Reproductive Toxicology. Vol. 102. Pages 109-127.

The following papers would be excluded based on title:

M. N. Ahmed, S. N. Sinha, S. R. Vemula, P. Sivaperumal, K. Vasudev, S. Ashu, et al. (2016).
Accumulation of polychlorinated biphenyls in fish and assessment of dietary exposure: a study in Hyderabad City, India. Environmental Monitoring and Assessment. Vol. 188 Issue 2 Pages 1-11. Excluded as reports exposure data only.

C. Akemann, D. N. Meyer, K. Gurdziel and T. R. Baker (2019). Developmental dioxin exposure alters the methylome of adult male zebrafish gonads. Frontiers in Genetics 2019 Vol. 10 Issue JAN. Excluded as data are from zebrafish.

Secondary screening on abstract

Titles that pass the primary screening on title will undergo secondary screening on abstract to ensure the paper is relevant. The same data-specific inclusion/exclusion criteria as described above will be used.

For records in which it is not clear from the abstract whether the article meets the inclusion criteria, if the title is ambiguous or does not give the required information, the full text will be retrieved and reviewed for necessary information.

OBJECTIVE 3 DATA EVALUATION

Quality evaluation

Articles will be assessed for quality using appropriate tools for the different type of studies retrieved.

For toxicological studies, the ToxRTool (a tool to assess the reliability of toxicological data) will be used as the secondary screening tool. This software-based tool is based on the Klimisch categories (Klimisch et. al., 1997) and was developed within the context of a project to provide comprehensive criteria and guidance for reliably evaluating toxicological data. It aids in the transparency and harmonisation of reliability assessment. This form is in Excel format and contains guidance on how each question should be answered to aid consistency between reviewers. The tool comprises assessment criteria on the test substance, test system, study design, results and plausibility of design and data. Articles will be scored according to whether the criterion is met (1) or not (0) by using the drop-down list in the spreadsheet.

The reliability classification used to assess the quality of the study is initially based on the total number of points given which may be then revised based on the criteria given in the tool in red. Such criteria have special importance and must achieve a score of 1 in order to achieve a reliability classification of 1 (reliable without restriction) or 2 (reliable with restrictions).

Studies that are classified as 1 or 2 will be retained, from which data will be extracted. Those scoring 3 or 4 will be excluded from further analysis.

It is anticipated that any study published by an authoritative body such as ATSDR, EFSA etc will achieve a score of 1 or 2 and therefore will not go through this secondary screening stage.

For epidemiology studies, the STROBE (Strengthening the reporting of observational studies in epidemiology) Statement or Newcastle-Ottawa (Quality Assessment) Scale (NOS) will be used as the secondary screening tool to assess the quality of the papers.

The STROBE statement is a checklist of items that should be addressed in articles reporting on the three main study designs of analytical epidemiology: namely cohort, case-control, and cross-sectional studies. It consists of a checklist of 22 items that relate to the title, abstract, introduction, methods, results and discussion sections of articles. Eighteen items are common to all three study types, and four are specific to each of the three study designs. For each item either a Yes or No response is given, which will be guided by the explanations given by Vandenbroucke et al. (2007).

The NOS was proposed by Wells et al. (2009) to assess the quality of published non-randomised studies. The tool can either be used as a checklist or scale, and separate scales exist for cohort and case-control studies. It contains eight items, categorised into three dimensions, including selection, comparability and, depending on study type, outcome (cohort studies) or exposure (case-control studies).

For each item a series of response options is provided. A star system is used to allow a semi-quantitative assessment of study quality, such that the highest quality studies are awarded a maximum of one star for each item with the exception of the item related to comparability that allows the assignment of two stars. The NOS ranges between zero up to nine stars. Although details of the NOS have not been published in a peer-reviewed journal, a number of studies have shown the scale to be reliable and valid. Studies awarded seven or more stars will be considered as high-quality studies because standard criteria have not been established.

In practice, secondary screening and data abstraction from studies will be carried out in parallel.

OBJECTIVE 5 NARRATIVE OF DATA

In parallel with the secondary screening all articles will be critically reviewed by a team member and relevant data will be extracted and captured according to the PRISMA checklist.

A narrative will be provided for each study, capturing the relevant data. These include, but not limited to:

- Chemicals under investigation
- Study population and control group
- Dose groups and routes of exposure
- Toxicity endpoints
- Summary of results
- Health-based guidance values

OBJECTIVE 6 DATA PRESENTATION

If necessary, the data will be presented at a COT meeting for comments from the Committee members.

REFERENCES

EFSA, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. doi.org/10.2903/j.efsa.2010.1637

Klimisch et. al., 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regul Toxicol Pharmacol. 1997 Feb;25(1):1-5. doi: 10.1006/rtph.1996.1076.

RPA and IEH (Risk & Policy Analysts Limited and IEH Consulting Limited), 2018. Extensive literature search, selection for relevance and data extraction of studies related to the toxicity of PCDD/Fs and DL-PCBs in humans. EFSA supporting publication 2018:EN-1136. 57 pp. doi:10.2903/sp.efsa.2018.EN-1136

Vandenbroucke et al. 2007. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. Epidemiology. 2007 Nov;18(6):805-35. doi: 10.1097/EDE.0b013e3181577511.

wca environment Ltd, 2018. Extensive literature search, selection for relevance and data extraction of studies related to the toxicity of PCDD/Fs and DL-PCBs in experimental animals. EFSA supporting publication 2018: EN-1137. 68 pp. doi:10.2903/sp.efsa.2018.EN-1137

Wells et al. 2009. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses.

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 most robust, efficient and up to date practices will be used to achieve a reliable selection of relevant data.
All references retrieved from the literature search will be downloaded into the reference management system Endnote™. This software will be stored in the cloud / Google drive or similar, to allow all team members access and all simultaneous working on the same document, to avoid issues with version control.

3: THE PROJECT PLAN AND DELIVERABLES

A. THE PLAN

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

The tasks per objective are described below and summarized in table 4.

OBJECTIVE 1. SELECTION OF SEARCH TERMS AND INCLUSION/EXCLUSION CRITERIA

Task 1-1. Search terms and generic inclusion/exclusion criteria will be developed within one week of signing the contract or kick off meeting and agreed with FSA prior to carrying out the literature search.

OBJECTIVE 2. LITERATURE SEARCH FOR RELEVANT LITERATURE

Task 2-1. The literature search will be carried out using the agreed search terms and generic inclusion/exclusion criteria within two weeks once such search terms have been agreed with FSA. The references will be stored in an EndNote™ Library stored in a central location so all team members have access.

OBJECTIVE 3. DATA SELECTION USING INCLUSION/EXCLUSION CRITERIA

Task 3-1. Data will be interrogated to determine data-specific inclusion/exclusion criteria. Once determined, such criteria will be applied to the titles and abstracts of the literature within four weeks of the literature search being carried out.

OBJECTIVE 4. DATA EVALUATION

Task 4-1. Primary toxicity data will be evaluated using Klimisch scoring (ToxRTool) and epidemiology data will be assessed using STROBE or NOS within four weeks of obtaining the list of selected references.

OBJECTIVE 5. NARRATIVE OF DATA

Task 5-1. A draft final narrative report outlining data on male reproductive toxicity and immunotoxicity of dioxins and dioxin-like PCBs, AhR mechanism, sensitive effects and sensitive sub-populations will be provided to FSA within 4 months of data evaluation or 7 months from the start of the project.

Task 5-2. A final narrative report, taking into consideration comments provided by FSA, will be provided within 1 month of receiving comments or within 8 months from the start of the project.

OBJECTIVE 6. DATA PRESENTATION

Outcomes of the literature search will be presented to a COT committee meeting if/when appropriate.

Table 4: Summary of objectives, tasks and deliverables

Objective/task	**Deliverable**	**Timeline**
Objective 1 Task 1-1	Search terms and generic inclusion/exclusion criteria	Within **1 week** of the start of the contract.
Objective 2 Task 2-1	Initial list of references obtained from the literature search	Within **2 weeks** of agreeing search terms and inclusion/exclusion criteria
Objective 3 Task 3-1	List of references obtained following application of data-specific inclusion/exclusion criteria	Within **4 weeks** of carrying out the literature search
Objective 4 Task 4-1	Final list of references obtained following evaluation of data	Within **4 weeks** of applying data-specific inclusion/exclusion criteria to the initial list of references
Objective 5 Task 5-1	Draft final report	Within **4 months** of data evaluation or **7 months** from the start of the project.
Objective 5 Task 5-2	Final report	Within **1 month** of receiving comments or **8 months** from the start of the project

Objective 6	Presentation of data at COT meeting	As appropriate

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 DELIVERABLE OR MILESTONE
1	10/10/2022	SELECTION OF SEARCH TERMS AND INCLUSION/EXCLUSION CRITERIA (OBJECTIVE 1, TASK 1-1)
2	24/10/2022	LITERATURE SEARCH FOR RELEVANT LITERATURE (OBJECTIVE 2, TASK 2-1)
3	21/11/2022	DATA SELECTION USING INCLUSION/EXCLUSION CRITERIA (OBJECTIVE 3, TASK 3-1)
4	19/12/2022	DATA EVALUATION (OBJECTIVE 4, TASK 4-1)
5A	30/4/2023	NARRATIVE OF DATA – DRAFT (OBJECTIVE 5, TASK 5-1)
5B	30/5/2023	NARRATIVE OF DATA – FINAL (OBJECTIVE 5, TASK 5-2)
6	TBC	DATA PRESENTATION (OBJECTIVE 6)

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.

[redacted]

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

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

Lead Applicant	[redacted]

Named staff members, details of specialism and expertise.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Participant Organisation 1	[redacted]

Named staff members, details of specialism and expertise.

[redacted]

[redacted]

[redacted]

C. STAFF EFFORT

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

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

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.

[redacted] will have overall project organisation and management responsibility and will be the principal point of contact for FSA and will be responsible for the day-to-day management of the project. [redacted] has extensive experience of project management for government and non-government clients, including research projects and workshop coordination.

[redacted] will ensure proper technical and financial project management and quality in delivery, with due regard to agreed milestones, budgets and specifications (client expectations), so that the project aims and objectives can be met to time and to budget. As overall Project Director, she will ensure sufficient resources (staff, time and budgets) are available to meet the agreed aims and objectives of the project. Any risks or delays in achieving the milestones will be reported immediately to the client, outlining the potential impacts to the project. [redacted] will be appointed the deputy project manager and will be responsible for IEH's contribution to the project to provide support on technical coordination and project delivery. [redacted] will liaise with the nominated FSA project officer and will report regularly to the FSA nominated officer via email/ telephone and face to face meetings as appropriate or necessary. Internal peer review will be documented to ensure appropriate and consistent sign off and quality review. The final project report(s) will be prepared to ensure consistency and all contributions will be peer-reviewed and then quality assessed.

[redacted] will communicate regularly with RSK and IEH team members, respectively and have regular updates, either by email or teleconference, to communicate progress, problems or issues arising. [redacted] interact on a regular basis as they are currently working on a number of projects together. [redacted] has been working with IEH for a number of years, as the team are contracted by UK Health Security Agency to provide support to the secretariat and Committees on Toxicity, Mutagenicity and Carcinogenicity and has therefore worked with all IEH team members previously. [redacted] have also worked with some IEH members on two projects recently completed for the Environment Agency. Overall, we are confident that all team members will communicate and interact well to achieve the desired outcomes.

RSK utilises key project management skills in combination with our SHEQMS to manage communications with partners and clients. The systems in place ensure that:

- Single point of contact is identified to liaise with key members of the project team and client and to coordinate communications and documentation. This point of contact is either a company director or the assigned project manager
- all documentation issued is given a unique identifier and recorded according to company procedures
- management and report reviews occur to assess progress on projects and ensure a continuously high level of performance
- regular progress reports are issued to the client
- quality standards apply to all reports and work issued
- procedures are present to obtain routine feedback from customers on the quality of work, the manner in which it was conducted and, where necessary, any corrective actions issued. This includes a defined customer care programme.

The definition of work including milestones and deliverables for the project is defined at the kick-off meeting. Means of communication between key contacts are also identified. Update reports and meetings are then provided/held at the identified frequency throughout the lifetime of each project. In the event of external communication with third parties being required, communication requests are logged and responded to following approval by the client.

Performance monitoring and measurement are critical to ensuring all projects meet the client's expectations. Indicators and milestones to assess performance are agreed traditionally from the outset. Performance monitoring is built into RSK's project management guidelines as part of our quality assurance system. This includes internal review procedures during the project with appropriate feedback and response. Ongoing client reviews are enabled by regular update reports and meetings to review progress. This includes a summary of activities that have occurred during the reporting period, discussion of performance, identification of problems, corrective actions (where necessary) and outstanding areas of work or next steps.

A work plan is developed at the project outset. This identifies activities, duration, expected completion dates and the resources necessary to complete each activity. The resources required are broken down into both the assigned personnel who will deliver the required output and associated financial considerations. Tools such as Gantt charts provide a suitable tool with which to assess progress against agreed deliverables and budgets. RSK is highly experienced in managing large-scale, multi-disciplinary projects and the use of such project management tools.

All of ADAS offices are certified to the ISO 45001 safety and health standard as part of the company's SHEMS management system. At a project level, the project manager must conduct a risk assessment as part of the project plan and communicate the outcome of the risk assessment with the project team and client. An independent auditor audits the SHEMS system and its implementation regularly. The SHEMS management system is also certified to the environmental standard ISO 14001.

Project completion to client satisfaction
Throughout the project, weekly and monthly progress reviews will be undertaken to ensure the project is running to budget and programme. Where slippage is anticipated, additional resources will be allocated to the project to meet agreed deadlines.

Upon completion of a project, we will undertake an internal project review in accordance with our ISO 9001 QA procedures. Where lessons learnt have been identified, both positive and negative, these will be disseminated to all RSK project managers. Some project reviews have taken the form of workshops, held between ADAS staff and the client, to review the project and ensure lessons learnt are transferred across all parties involved.

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
Non-availability of staff due to holidays, sickness, etc.	**Low**	**Low**	At least two team members, and generally more, cover each area of required expertise.
Lack of scientific certainty to inform studies	**Medium**	**Medium**	The Study Team members have adequate expertise and experience to undertake this study and can identify controversial or uncertain information during the progress of the project. Any limitations of study findings due to such uncertainties will be clearly identified in our reporting. Incorporation of a study steering group will also provide peer-review.
Inclusion of low-quality literature	**Low**	**Medium**	It is possible that publications and studies of lower or ambiguous quality will be collected during the literature review, thus lowering the quality of the final deliverable. The implementation of a preliminary screening of identified studies using evaluation criteria that will be developed by the Study Team and its high expertise in the specific field will assist in reducing this risk.
Shifts in scientific knowledge during the duration of the study	**Low**	**Medium**	Given the relatively short duration of the project, it is unlikely that the state of science will change significantly while the research is in progress. The likelihood of this occurring is further reduced because the Study Team includes scientists working at the forefront of research and they will highlight any very recent or upcoming developments to ensure they are covered in the outputs to the extent possible.
Regulatory development during the duration of the study	**Low**	**Medium**	Given the relatively short duration of the project, it is unlikely that significant regulatory developments will occur. The likelihood of this occurring is further reduced because our study team regularly works in the development of the regulations and is thus familiar with the latest planned developments.
Effective management of study team	**Low**	**High**	The study team has extensive experience of working together on projects for the Committees, and other clients.
Consequences of ongoing disruption to services resulting from COVID-19	**Medium**	**Low**	We have continued to deliver on time to all our customers throughout the current COVID pandemic. Our working practices and data access are all COVID proof. We have a contingency and emergency recovery plan that can be implemented immediately. We were all home workers prior to the pandemic so changes in working arrangement had no significant impact on the team.

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 principal 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

Quality Assurance systems are fundamental to achieve a high standard of excellence. We recognise the need to ensure control procedures for this contract, particularly as there are a number of individuals involved in drafting reports. Consistency of work will be achieved by adhering to standardised protocols (and templates where possible) using a flow process which will be shared with all team members. This will consist of methodologies for literature searching, selecting data (inclusion/exclusion criteria), evaluating and reporting data. A proforma will be developed outlining how and what data should be included in different sections of the report, where possible, including what data to report from different types of study.

The quality and consistency of each report will be achieved by assigning experts to provide a technical review of the reports. Experts will be provided on toxicology and epidemiology. The draft and final document will also undergo a quality control review and the Project Manager will also provide a quality review, in accordance with our Quality Assurance management procedures.

The RSK Group (of which RSK ADAS Ltd is a part) has been certified by Det Norske Veritas (DNV) under the ISO 9001 standard since April 1997 and are currently certified to ISO 9001:2015. RSK is committed to providing its clients with quality assured services and, by doing so, ensuring that their needs are met on time, in full and to budget. DNV undertakes two periodic audits annually, with a re-registration audit once every three years.

We have established eight key performance indicators (KPIs) that are used regularly to measure business performance at all levels within the company and are captured within the ISO 9001-certified integrated safety, health, environment and quality management system (SHEQMS).

1. Health, safety and environment: performance is reviewed in terms of near misses, lost time incidents and reportable accidents. As a component of our SHEQMS this is a mandatory agenda item at each of the key project progress meetings.
2. Financial performance: we review company profitability and the performance of individual projects.
3. Quality audits: feedback from internal and external audits in order to implement improvements on a continuous basis.
4. Customer feedback: all feedback from our customers is reviewed and is passed to the employee involved. Where negative feedback is received, a formal investigation is undertaken, and lessons learned. Where necessary, changes to our management system are implemented.
5. Subcontractors: the performance of our subcontractors is assessed regularly, and unsatisfactory performance is brought to the attention of the company concerned. If the situation is not remedied, the subcontractor is removed from the RSK approved supplier's database.
6. Project performance: we track the performance of each project. A project plan is developed that establishes milestones, key deliverables, financial management targets and the approach to quality management and peer review. Performance against the project plan is the key component of project review meetings.
7. Repeat business: we seek to develop relationships with our clients and undertake repeat business on a long-term basis. Much of our work is repeat business.
8. Staff development: we recognise that motivated and able employees are central to our business. We seek to train and retain our staff and this philosophy is central to the company's vision statement (available on request). All staff undergo a staff appraisal when they join the company, which identifies their competencies and training needs. Staff appraisals are undertaken regularly (at least once per year) in which past performance is reviewed and objectives are set for the coming year. Training requirements and the benefit of previous training are reviewed.

A discussion about our performance in these key result areas takes place in management meetings (every Monday), directors' meetings (as required, but usually three or four times a year) and management review meetings (which take place at least once a year, a requirement of our SHEQMS).

We are also registered with and assessed by Achilles UVDB and Verify. Achilles is the world's leading provider of supplier management information; its UVDB (Utilities Vendor Database) registration and pre-qualification system is used by all major UK utilities to source suppliers and contractors. Verify is an extension to UVDB and is used to further qualify suppliers through an assessment of their safety, health, environment and quality (SHEQ) capabilities, thus promoting supply chain efficiencies, independent assessment and benchmarking, credibility in the marketplace and industry-specific assessments

RSK/ADAS can confirm that we, and IEH, will fully comply with the Joint Code of Practice for Research (JCoPR), which is applicable to scientific research funded by Defra, FSA, BBSRC, NERC and devolved Government administrations in the UK.

B. ETHICS

Please identify the key ethical issues for this project and how these will be managed. Please respond to any issues raised in the Specification document
Please describe the ethical issues of any involvement of people, human samples, animal research or personal data in this part. In addition, please describe the ethical review and governance arrangements that would apply to the work done.

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

There are no ethical issues in the project

C. DATA PROTECTION

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

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

Our Data Protection addresses the Integrity, security and confidentiality of data and records. The ADAS SHEQ Management System also contains a Standard Operating Procedure which covers the Security of Computer, Software and Data (SOP COMP/003). This details the measures and procedures to be followed to ensure that data is secure and confidential. It specifically covers how data should be processed to ensure compliance with the Data Protection Act.

Unless otherwise advised by our clients all information, data and records generated for project work, will be treated as strictly confidential and we will ensure measures are in place to ensure data security and confidentiality.

ADAS is registered under the Data Protection Act 1988 and processes data covered by the Act in accordance with its eight principles. Our systems and procedures are being updated to ensure compliance with GDPR.

ADAS has long experience of dealing with issues related to access to privileged or sensitive government information; this experience will be used to meet the requirements of our clients to ensure that the services we provide are not compromised

Below is a table which describes the measures we take to ensure compliance with GDPR.

Protocol	Description	Reason
Data Retention Policy	We keep a document that describes how long we are storing data and when it will be destroyed. We typically store data for 12 months. Data subjects will be informed of this date prior to their consent and will be informed of any changes.	• To comply with data minimisation • In order to honor the rights of data subjects
Data Map	We will keep a document showing what data is being collected, where it is being stored and the collection purpose. This will be regularly updated in order to be as transparent and accurate as possible. This aims to maintain records of personal data processing.	To comply with: • purpose limitation of data • storage limitation • transparency of data handling
Data Breach Protocol and Incident Records	The data breach procedure will occur in the extremely unlikely event of a data breach. In compliance with GDPR all participants will be notified within 72 hours of knowing about the breach. We also keep a document describing any data incidents. Details include why it was decided that it did not meet the standard for reporting it to the ICO or notifying individuals.	To comply with: • transparency of data handling • the law • To avoid harm to our participants or company

Right to Access Documents- Subject Access Request	Our data subjects have the right to request access to their data. This is a subject access request. In the event of a subject access request we will endeavor to provide a copy of the information in an electronic form to the participant at the earliest opportunity. This data will be specifically only about the individual who has requested the information. The Data Protection Officer will investigate any subject access requests that we receive to ensure that the individual requesting data is the data subject. This will avoid data leaks and harm to data subjects.	To comply with: • transparency of data handling • confidentiality of data subjects' identity
Right to be Forgotten	All participants have the right to withdraw consent at any time and have the right to be forgotten. We have a protocol in place to destroy the data on request. We also have a legal responsibility to compare comply with the data subject's request to be forgotten with "the public interest in the availability of the data".	To comply with: • transparency of data handling • confidentiality of data subjects • the law • ethical integrity
Storage of Data	Our data subject's data will be stored on our server which is password protected and backed up daily. This data will only be accessible to specific members of the team and only for the specific purposes outlined to the data subject. This data will then be destroyed 12 months after the project using the detailed method in the Data Retention Policy.	To comply with: • transparency of data handling • the law • ethical integrity • confidentiality of data subjects' identity • To avoid breaches

In addition to the protocols set out above we take the following measures to gain consent and ensure confidentially:

Consent

Our definition of consent is a freely given, unambiguous, informed approval from the individual data subjects for us to collect and store specific data about them for the research purposes.

We will not be transferring any data including personal data of data subjects outside of the EU, therefore the legal safeguards regarding this are not applicable.

Confidentiality

After collection our data will be uploaded onto our secure server which is regularly backed up. The data will be stored in a password protected file which can only be accessed by specific members of the project team. All names and identifying data will be removed from the data before analysis. The data will be coded and the codes along with the original identifying data will be kept securely in a different password protected file. This is done in the interests of confidentiality but also so that we are able to alter or remove data at the request of the data subject. All of our measures are in place to protect the identity, data and trust of our data subjects, data security and confidentiality is a top priority for ADAS.

Overall, RSK/ADAS can confirm that we have the human and technical resources to perform the contract to ensure compliance with the General Data Protection Regulation and to ensure the protection of the rights of data subjects.

D. SUSTAINABILITY

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

Sustainability

As a business offering environmental solutions to the majority of sectors in the UK economy, ADAS recognises that it has an environmental responsibility in all activities to ensure that sustainability and the environment are taken into consideration as it operates its business. By building, through education and mentoring, an understanding of the importance of sustainability within the company, all staff are motivated to reduce the environmental impact of our operating practice. Specific ADAS policies (available on request) include:

- Environment Policy
- Sustainable Procurement and Purchasing Policy
- Energy Management Policy
- Travel Policy
- Waste Management and Recycling Policy
- Water Management Policy.

These policies and practices will be employed in delivering this Contract insofar as they influence travel and the efficient use of resources. In particular, the use of online meetings via Teams or Zoom will limit team travel and we will use public transport for the project meetings where feasible. Electronic media will be used to communicate and report evidence and analysis, including contract deliverables, unless otherwise required by FSA.

Carbon footprint

Travel to survey sampling sites will be minimised by optimising routes between samples and by choice of location of samplers.
Measures taken to reduce the company's carbon footprint have included:

- Implementation of an agreement with a leading waste management company to manage waste streams at the main sites where waste management is a company responsibility
- Continuation of waste-paper recycling schemes
- All purchased electricity is now from renewable resources
- Purchasing 'green' stationery, including recycled copy paper
- Energy management campaign conducted at main locations
- All office printers networked
- All safety clothing now obtained from a low environmental impact source supplier
- Implementation of corporate policies covering business travel, waste management and recycling, energy management and water management
- Implementation of an ethical and sustainable procurement policy committing the company to procure from sustainable resources whenever possible
- Introduction of an improved risk assessment process aimed at ensuring that the environmental impacts of work delivered to clients are effectively assessed and that work complies with relevant environmental legislation
- Increased use of online meetings thereby reducing business travel related greenhouse gas (GHG) emissions

Energy and Water

All electricity procured by ADAS is certified 'green'. An energy efficiency campaign is also being conducted at major sites to reduce usage. All office locations are metered with smart meters now installed at main locations. Carbon Trust audits of key locations have been undertaken. An energy management system compliant with BSEN 16001 is being implemented. We are continually looking to reduce energy consumption. This is achieved in a variety of ways, including installing of low energy bulbs (LED) and ensuring all computer equipment is set up with optimum energy settings (e.g. monitors off when not in use). We recently upgraded our heating to a much more efficient system. We aim to use water as efficiently as possible by:

- use of water minimiser systems and water-saving devices
- only washing equipment when necessary for safety reasons
- using only tap water for ADAS-hosted meetings, seminars and conferences instead of bottled water.

Waste

ADAS has a contract with a major waste supplier to remove all our office waste and then to recycle and/or reuse the waste. Recycled waste, including paper pulp and remanufactured plastics, is used for a variety of purposes; any waste that can't be recycled is reused by burning it in power stations. Only a small percentage of our waste is put to landfill.

Controlling Pollution

We have a travel policy which strives to reduce business travel across all operations, promotes alternative transport options which offer reduced carbon emissions such as travel by train, bike, bus or car-share and ensures all staff travel sustainably wherever possible. We capture and report actual data relating to all modes of business travel.
Our strategic objective is to reduce GHG emissions associated with business travel measured as carbon emissions (g)/mile travelled/year for business mileage ('Grey Fleet'). Approaches include:

- reducing the need to travel for contract progress meetings where this is appropriate by encouraging the use of online meetings via Teams or Zoom
- encouraging the use of public transport over car travel
- discouraging the use of air travel where travel by train is a practical alternative
- paying an additional 5p/mile to staff that use their car with one or more passengers (other ADAS employees) on business travel
- paying a 20p/mile bicycle mileage rate and a 24p/mile motorcycle mileage rate for business travel
- using hire cars more effectively by specifying that we only hire low emission, fuel efficient models via our central purchasing contract
- actively encouraging staff to adopt low emission, high fuel efficiency vehicles for journeys where car travel remains the only practical option ('Grey Fleet').

Improving Biodiversity

ADAS carries out research in the terrestrial and aquatic environments, agriculture, and the rural economy. We specialise in translating the results of our applied research into practical tools, techniques and advice. We apply the knowledge from our services and expertise to our work on all projects and take all reasonable steps to prevent any pollution, disruption or damage to the ecology on site. This includes a rigorous risk assessment on each project which endeavours to implement any necessary measures to protect against environmental or ecological damage.

Supply chain

ADAS is committed to sourcing materials under the terms of the ADAS sustainable procurement practice, which aims to preferentially procure goods and services from suppliers who share our principles and can demonstrate a sustainable approach to their own activities. In practice this means that the environmental and sustainability credentials of items or services to be purchased are considered as part of the procurement process. This applies throughout our purchasing activities. Materials are managed according to ADAS policies, which ensures all products purchased have comprehensive labelling detailing information for safe storage, use and disposal.

Environmental certification

ADAS is committed to achieving a high level of safety, health, environmental and quality (SHEQ) performance and has therefore a documented SHEQ management system (SHEQMS), which is implemented throughout the Company. The primary aim of the SHEQMS is to ensure that safety, health, environmental and quality risks (i.e. business risks) are identified, assessed and adequately controlled. Within the company we have a SHEQ Director who holds overall responsibility for SHE and Quality management and is assisted on a day-to-day basis by the SHEQ Team. However, all Company employees have SHEQ responsibilities.

At the core of SHEQMS are our policy statements for health and safety, environmental and quality as well as an extensive range of Standard Operating Procedures prescribing internal business processes and technical methodologies.
Senior management periodically review SHEQMS to ensure the continuing suitability, adequacy and effectiveness of the system and to identify or assess opportunities for further improvement or requirement for change.
Compliance with SHEQMS ensures that client needs are identified, understood and that services and products are subsequently delivered in a professional and independent manner designed to fully meet and satisfy client expectations.
Delivery to clients is:

- Subject to risk assessment and subsequent risk management.
- Specified and agreed in formal contract agreements.
- Controlled via the use of effective project planning to meet milestones, specifications, time frames and budget.
- Project managed by appropriately trained and qualified staff, using up-to-date equipment and facilities where appropriate.
- Subject to rigorous quality control checking before release to ensure technical soundness and compliance with contractual requirements and ADAS standards.

Effective implementation of SHEQ is assessed by scheduled internal audits carried out by independent Quality Assurance staff. Critical aspects of work and that of sub-contractors and collaborators are also audited where contractually required.

RSK/ADAS Accreditations

ISO9001: 158762-2014-MSC-UKAS-GBR / **ISO14001**: 10000492677-MSC-UKAS-GBR / **ISO45001:** 10000492678-MSC-UKAS-GBR
Joint Code of Practice for Research: ADAS fully complies with this code which is applicable to scientific research funded by Defra, FSA, BBSRC, NERC and devolved Government administrations in the UK.
UVDB Achilles/Safety Management Advisory Services Worksafe Consultant/RISQS/Oreto /Constructionline - Gold & Acclaim SIPPS

E. DISSEMINATION AND EXPLOITATION

Where applicable please indicate how you intend to disseminate the results of this project, including written and verbal communication routes if appropriate. Applicants are advised to think carefully about how their research aligns with the FSA strategy,

what is the impact that their research has on public health/ consumers and decide how the results can best be communicated to the relevant and appropriate people and organisations in as cost-effective manner as possible. Please provide as much detail as possible on what will be delivered. Any costs associated with this must be documented in the Financial Template.

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

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

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

The results of this systematic literature search will be disseminated through a report, which will be provided to FSA with the ultimate aim of it being verbally presented to the COT to help make decisions that will ensure the appropriate level of protection from dioxins and dioxin-like PCBs for the UK consumer.

The report will consist of a narrative about all selected studies and summary tables, if appropriate, of the toxicity and epidemiology data. We will also provide the titles of the data received during the literature review, in Endnote™, as well as the final list of references included in the narrative report. Prior to presenting the findings to the COT, we will provide a chair's brief, briefly outlining the objective of the project, methodology used and the findings. This document will also contain a number of questions that will be posed to Committee members to help in their decision-making process.

This project largely necessitates the reporting of publicly available data, hence Intellectual Property is limited, but would be retained by FSA.

Clarification Questions and Responses

[redacted]

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[redacted]

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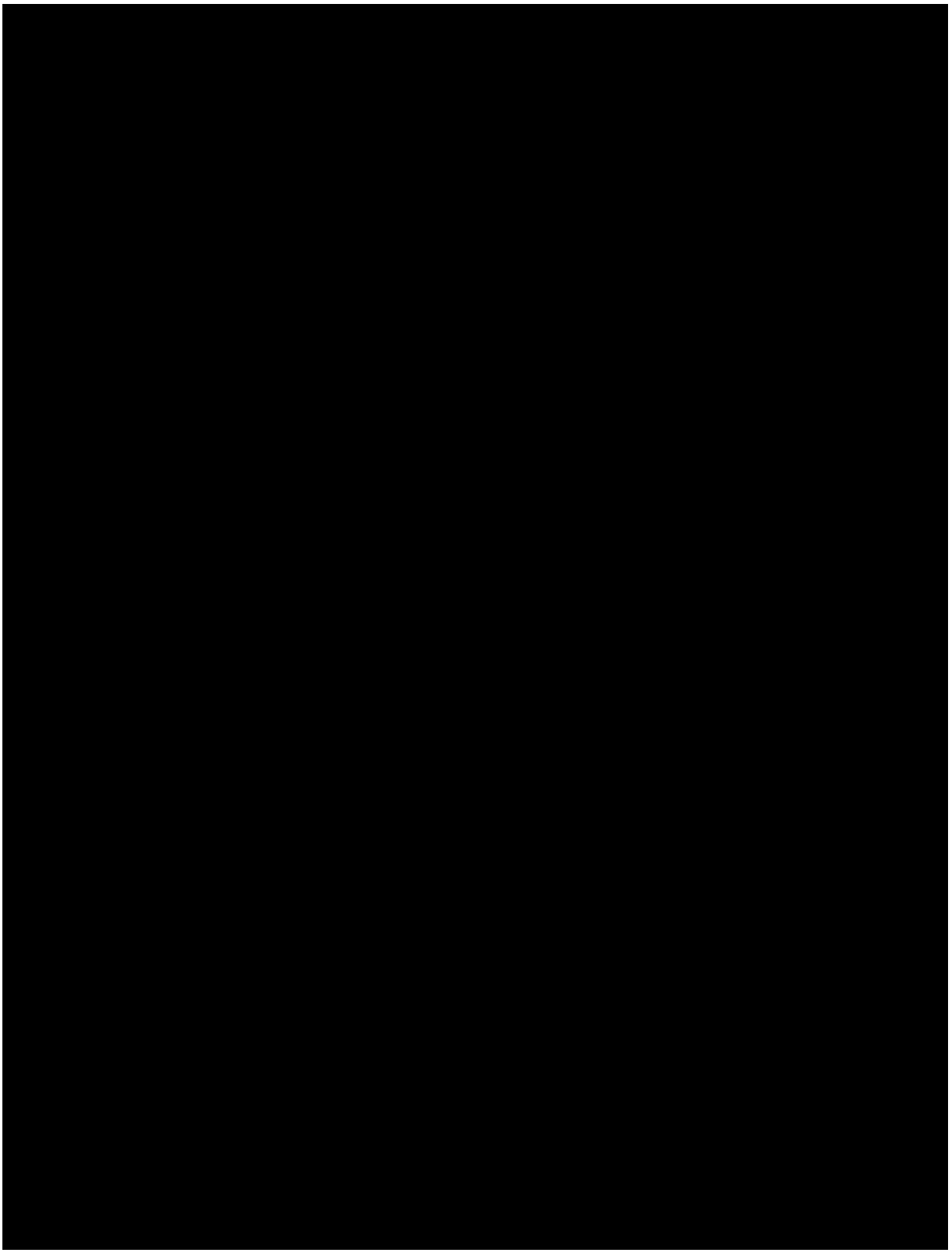
[redacted]

Annex 4 - Charges



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

Project Costs Summary (*Automatically calculated*)

[redacted]

Total Project Costs	**£ 58,018.00**

COST OR VOLUME DISCOUNTS - INNOVATION
The Food Standards Agency collaborates with our suppliers to improve efficiency and performance to save the taxpayer money. A tenderer should include in his tender the extent of any discounts or rebates offered against their normal day rates or other costs during each year of the contract. Please provide full details below:

[redacted]

Staff Costs Table

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

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

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

[redacted]

[redacted]

Overhead rate for RSK staff is 80% of staff costs.
The Day Rate is divided by 1.8 to get the Daily Rate (£/Day)
The Daily Rate is then multiplied by 0.8 to get the Daily Overhead Rate (£/Day)
The Daily Rate is then multiplied by 0.8 to get the Daily Overhead Rate (£/Day)

Consumable/Equipment Costs

[redacted]

Travel and Subsistence Costs

[redacted]

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The Pricing Schedule

Please complete a proposed schedule of payments below, **excluding VAT** to be charged by any subcontractors to the project lead
applicant. This must add up to the same value as detailed in the Summary of project costs to FSA including participating

organisations costs.

Where differing rates of VAT apply against the deliverables please provide details on separate lines.
Please link all deliverables (singly or grouped) to each payment. Please ensure that deliverable numbers are given as well as a
brief description e.g. Deliverable 01/02: interim report submitted to the FSA, monthly report, interim report, final report
Payment will be made to the Contractor, as per the schedule of payments upon satisfactory completion of the deliverables.

[redacted]

Total	**£ 58,018.00**

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Short form Terms

1. Definitions used in the Contract

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

"Central Government Body"	means 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"	means the charges for the Deliverables as specified in the Order Form;
"Confidential Information"	means 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;
"Contract"	means 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 Order Form and Annexes;
"Controller"	has the meaning given to it in the GDPR;
"Buyer"	means the person identified in the letterhead of the Order Form;
"Date of Delivery"	means that date by which the Deliverables must be delivered to the Buyer, as specified in the Order Form;
"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;
"Data Protection Legislation"	(i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the Data Protection Act 2018 to the extent that it relates to processing

	of personal data and privacy; (iii) all applicable Law about the processing of personal data and privacy;
"Data Protection Impact Assessment"	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
"Data Protection Officer"	has the meaning given to it in the GDPR;
"Data Subject"	has the meaning given to it in the GDPR;
"Data Loss Event"	any event that results, or may result, in unauthorised access to Personal Data held by the Supplier 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 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;
"Deliver"	means hand over 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 [ ]. Delivered and Delivery shall be construed accordingly;
"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"	means the date for expiry of the Contract as set out in the Order Form;
"FOIA"	means 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, occurrence, circumstance, matter or cause affecting the performance by either Party of its obligations under the Contract arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control which prevent or materially delay it from performing its obligations under the Contract 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;

"GDPR"	the General Data Protection Regulation (Regulation (EU) 2016/679);
"Goods"	means 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 Data Controller;
"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; ii) 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); iii) if an administrator or administrative receiver is appointed in respect of the whole or any part of the persons assets or business; iv) if the person makes any composition with its creditors or 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;
"Key Personnel"	means any persons specified as such in the Order Form or otherwise notified as such by the Buyer to the Supplier in writing;
"LED"	Law Enforcement Directive (Directive (EU) 2016/680);
"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;
"Order Form"	means the letter from the Buyer to the Supplier printed above these terms and 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 GDPR;

"Personal Data Breach"	has the meaning given to it in the GDPR;
"Processor"	has the meaning given to it in the GDPR;
"Purchase Order Number"	means the Buyer's unique number relating to the order for Deliverables to be supplied by the Supplier to the Buyer in accordance with the terms of the Contract;
"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"	means the services to be supplied by the Supplier to the Buyer under the Contract;
"Specification"	means 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"	means all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any sub-contractor of the Supplier engaged in the performance of the Supplier's obligations under the Contract;
"Staff Vetting Procedures"	means vetting procedures that accord with good industry practice or, where applicable, the Buyer's procedures for the vetting of personnel as provided to the Supplier from time to time;
"Subprocessor"	any third Party appointed to process Personal Data on behalf of the Supplier related to the Contract;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor engaged in the performance of the Supplier's obligations under a Contract;
"Supplier"	means the person named as Supplier in the Order Form;
"Term"	means the period from the start date of the Contract set out in the Order Form to the Expiry Date as such period may be extended in accordance with clause [ ] or terminated in accordance with the terms and conditions of the Contract;
"US-EU Privacy Shield Register"	a list of companies maintained by the United States of America Department for Commence that have self-certified their commitment to adhere to the European legislation relating to the processing of personal data to non-EU countries which is available online at: https://www.privacyshield.gov/list;

"VAT"	means value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"Workers"	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;
"Working Day"	means 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 terms and 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; and

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

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 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; (ii) to a professional standard; (iii) using reasonable skill and care; (iv) using Good Industry Practice; (v) using its own policies, processes and internal quality control measures as long as they don't conflict with the Contract; (vi) on the dates agreed; and (vii) 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 three 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 specified location during the Buyer's working hours.

(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 steps 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 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 [sub-suppliers].

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 any security requirements.

(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 shall be entitled to invoice the Buyer for the charges in the Order Form. The Supplier shall raise invoices promptly and in any event within 90 days from when the charges are due.

5.2 All Charges:

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

(b) include all costs 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 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;

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

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 33.

5.6 The Buyer may retain or set-off payment of any amount owed to it by the Supplier 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;
- (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;
- (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 seven years after the date of expiry or termination of the Contract.

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

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

7.5 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;
- (c) provide a deadline for completing the corrective action.

7.6 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

(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).

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 using Good Industry Practice

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

8.2 Where a 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 8.

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 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 in the Order Form (if any) to provide the Deliverables and shall not remove or replace any of them unless:

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

(b) the person concerned resigns, retires or dies or is on maternity 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.

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) it maintains all necessary rights, authorisations, licences and consents to perform its obligations under the Contract;
(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 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;
(b) non-payment by the Supplier of any tax or National Insurance.

9.4 If the Supplier becomes aware of a representation or warranty 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 it and its sub-licensees to both:
(a) receive and use the Deliverables;
(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 for the purpose of fulfilling its obligations under the Contract and a perpetual, royalty-free, non-exclusive licence to use any New IPRs.

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;

(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.

11. Ending the contract

11.1 The Contract takes effect on the date of or (if different) the date specified in the Order Form and ends on the earlier of the date of expiry 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(b) to 11.5(g) 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) if 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) if 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 Court of Justice of the European Union uses Article 258 of the Treaty on the Functioning of the European Union (TFEU) to declare that the Contract should not have been awarded to the Supplier because of a serious breach of the TFEU or the Regulations;

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

(b) If any of the events in 73(1) (a) to (c) of the Regulations (substantial modification, exclusion of the Supplier, procurement infringement) happen, the Buyer has the right to immediately terminate the Contract and clause 11.5(b) to 11.5(g) applies.

11.5 What happens if the Contract ends

Where the Buyer terminates the Contract under clause 11.4(a) all of the following apply:

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

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

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

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

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

(f) 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;

(g) the following clauses survive the termination of the Contract: [3.2.10, 6, 7.2, 9, 11, 14, 15, 16, 17, 18, 34, 35] and any clauses which are expressly or by implication intended to continue.

11.6 When the Supplier can end the Contract

(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) If a Supplier terminates the Contract under clause 11.6(a):

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

  (iii) clauses 11.5(d) to 11.5(g) apply.

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 24) any necessary variation required by clause 11.7, but the Supplier may not either:

  (i) reject the variation;

  (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;
(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;
(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 4.2(j), 4.2(m), 8.5, 9.3, 10.5, 13.2, 14.26(e) or 30.2(b).

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

12.6 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, use reasonable endeavours to:
(a) comply and procure that its subcontractors comply with the Supplier Code of Conduct appearing at (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779660/20190220-Supplier_Code_of_Conduct.pdf) and such other corporate social responsibility requirements as the Buyer may notify to the Supplier from time to time;
(b) support the Buyer in fulfilling its Public Sector Equality duty under S149 of the Equality Act 2010;
(c) not use nor allow its subcontractors to use modern slavery, child labour or inhumane treatment;
(d) 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 27 to 32

13.4 "Compliance Officer" the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its legal obligations;

14. Data protection

14.1 The Buyer is the Controller and the Supplier is the Processor for the purposes of the Data Protection Legislation.

14.2 The Supplier must process Personal Data and ensure that Supplier Staff process Personal Data only in accordance with this Contract.

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

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

14.5 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.

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

14.7 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 five Working Days from the date that the Buyer receives notice, or the Supplier finds out about the issue, whichever is earlier;

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

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

14.9 Only the Buyer can decide what processing of Personal Data a Supplier can do under the Contract and must specify it for the Contract using the template in Annex 1 of the Order Form (*Authorised Processing*).

14.10 The Supplier must only process Personal Data if authorised to do so in the Annex to the Order Form (*Authorised Processing*) by the Buyer. Any further written instructions relating to the processing of Personal Data are incorporated into Annex 1 of the Order Form.

14.11 The Supplier must give all reasonable assistance to the Buyer in the preparation of any Data Protection Impact Assessment before starting any processing, including:

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

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

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

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

14.12 The Supplier must notify the Buyer immediately if it thinks the Buyer's instructions breach the Data Protection Legislation.

14.13 The Supplier must put in place appropriate Protective Measures to protect against a Data Loss Event which must be approved by the Buyer.

14.14 If lawful to notify the Buyer, the Supplier must notify it if the Supplier is required to process Personal Data by Law promptly and before processing it.

14.15 The Supplier must take all reasonable steps to ensure the reliability and integrity of any Supplier Staff who have access to the Personal Data and ensure that they:
(a) are aware of and comply with the Supplier's duties under this clause 11;
(b) are subject to appropriate confidentiality undertakings with the Supplier or any Subprocessor;
(c) 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 Buyer or as otherwise allowed by the Contract;
(d) have undergone adequate training in the use, care, protection and handling of Personal Data.

14.16 The Supplier must not transfer Personal Data outside of the EU unless all of the following are true:
(a) it has obtained prior written consent of the Buyer;
(b) the Buyer has decided that there are appropriate safeguards (in accordance with Article 46 of the GDPR);
(c) the Data Subject has enforceable rights and effective legal remedies when transferred;
(d) the Supplier meets its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred;
(e) where the Supplier is not bound by Data Protection Legislation it must use its best endeavours to help the Buyer meet its own obligations under Data Protection Legislation; and
(f) the Supplier complies with the Buyer's reasonable prior instructions about the processing of the Personal Data.

14.17 The Supplier must notify the Buyer immediately if it:
(a) receives a Data Subject Access Request (or purported Data Subject Access Request);
(b) receives a request to rectify, block or erase any Personal Data;
(c) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;
(d) receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract;
(e) 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;
(f) becomes aware of a Data Loss Event.

14.18 Any requirement to notify under clause 14.17 includes the provision of further information to the Buyer in stages as details become available.

14.19 The Supplier must promptly provide the Buyer with full assistance in relation to any Party's obligations under Data Protection Legislation and any complaint, communication or request made under clause 14.17. This includes giving the Buyer:
(a) full details and copies of the complaint, communication or request;
(b) reasonably requested assistance so that it can comply with a Data Subject Access Request within the relevant timescales in the Data Protection Legislation;
(c) any Personal Data it holds in relation to a Data Subject on request;
(d) assistance that it requests following any Data Loss Event;
(e) assistance that it requests relating to a consultation with, or request from, the Information Commissioner's Office.

14.20 The Supplier must maintain full, accurate records and information to show it complies with this clause 14. This requirement does not apply where the Supplier employs fewer than 250 staff, unless either the Buyer determines that the processing:
(a) is not occasional;
(b) includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR;
(c) is likely to result in a risk to the rights and freedoms of Data Subjects.

14.21 The Supplier must appoint a Data Protection Officer responsible for observing its obligations in this Schedule and give the Buyer their contact details.

14.22 Before allowing any Subprocessor to process any Personal Data, the Supplier must:
(a) notify the Buyer in writing of the intended Subprocessor and processing;
(b) obtain the written consent of the Buyer;
(c) enter into a written contract with the Subprocessor so that this clause 14 applies to the Subprocessor;
(d) provide the Buyer with any information about the Subprocessor that the Buyer reasonably requires.

14.23 The Supplier remains fully liable for all acts or omissions of any Subprocessor.

14.24 At any time the Buyer can, with 30 Working Days notice to the Supplier, change this clause 14 to:
(a) replace it with any applicable standard clauses (between the controller and processor) or similar terms forming part of an applicable certification scheme under GDPR Article 42;
(b) ensure it complies with guidance issued by the Information Commissioner's Office.

14.25 The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office.

14.26 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;
(e) indemnifies the Buyer against any and all Losses incurred if the Supplier breaches clause 14 and any Data Protection Legislation.

15. What you must keep confidential

15.1 Each Party must:
(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;
(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 or by a court with the relevant jurisdiction if the recipient Party notifies the disclosing Party of the full circumstances, the affected Confidential Information and extent of the disclosure;
(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) 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;
(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 Staff must enter into a direct confidentiality agreement with the Buyer at its request.

15.4 The Buyer may disclose Confidential Information in any of the following cases:
(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;
(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 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 steps to ensure that Supplier Staff do not either.

16. When you can share information

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

16.2 Within the required timescales the Supplier must give the Buyer full co-operation and information needed so the Buyer can:
(a) comply with any Freedom of Information Act (FOIA) request;
(b) comply with any Environmental Information Regulations (EIR) request.

16.3 The Buyer may talk to the Supplier to help it decide whether to publish information under clause 16. However, the extent, content and format of the disclosure is the Buyer's decision, which does not need to be reasonable.

17. Invalid parts of the contract

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

18. No other terms apply

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

19. Other people's rights in a contract

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

20. Circumstances beyond your control

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

(a) provides written notice to the other Party;
(b) uses all reasonable measures practical to reduce the impact of the Force Majeure Event.

20.2 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.

20.3 Where a Party terminates under clause 20.2:
(a) each party must cover its own losses;
(b) clause 11.5(b) to 11.5(g) applies.

21. Relationships created by the contract

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

22. Giving up contract rights

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

23. Transferring responsibilities

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

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

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

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

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

23.6 If the Buyer asks the Supplier for details about Subcontractors, the Supplier must provide details of Subcontractors at all levels of the supply chain including:
(a) their name;
(b) the scope of their appointment;
(c) the duration of their appointment.

24. Changing the contract

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

25. How to communicate about the contract

25.1 All notices under the Contract must be in writing and are considered effective on the Working Day of delivery as long as they're delivered before 5:00pm on a Working Day. Otherwise the notice is effective on the next Working Day. An email is effective when sent unless an error message is received.

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

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

26. Preventing fraud, bribery and corruption

26.1 The Supplier shall not:

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

(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.

26.2 The Supplier shall take all reasonable steps (including creating, maintaining and enforcing adequate policies, procedures and records), in accordance with good industry practice, to prevent any matters referred to in clause 26.1 and any fraud by the 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.

26.3 If the Supplier or the Staff engages in conduct prohibited by clause 26.1 or commits fraud in relation to the Contract or any other contract with the Crown (including the Buyer) the Buyer may:

(a) terminate the Contract and recover from the Supplier the amount of any loss suffered by the Buyer resulting from the termination, including the cost reasonably incurred by the Buyer of making other arrangements for the supply of the Deliverables and any additional expenditure incurred by the Buyer throughout the remainder of the Contract; or

(b) recover in full from the Supplier any other loss sustained by the Buyer in consequence of any breach of this clause.

27. Equality, diversity and human rights

27.1 The Supplier must follow all applicable 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;

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

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

28. Health and safety

28.1 The Supplier must perform its obligations meeting the requirements of:
(a) all applicable law regarding health and safety;
(b) the Buyer's current health and safety policy while at the Buyer's premises, as provided to the Supplier.

28.2 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.

29. Environment

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

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

30. Tax

30.1 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.

30.2 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 Off 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;
(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 Contract Period in connection with the provision of the Deliverables by the Supplier or any of the Supplier Staff.

30.3 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 the following requirements:
(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 30.2, 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 30.2 or confirms that the Worker is not complying with those requirements;
(d) the Buyer may supply any information they receive from the Worker to HMRC for revenue collection and management.

31. Conflict of interest

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

31.2 The Supplier must promptly notify and provide details to the Buyer if a conflict of interest happens or is expected to happen.

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

32. Reporting a breach of the contract

32.1 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 26 to 31.

32.2 The Supplier must not retaliate against any of the Supplier Staff who in good faith reports a breach listed in clause 32.1.

33. Resolving disputes

33.1 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.

33.2 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 33.3 to 33.5.

33.3 Unless the Buyer refers the dispute to arbitration using clause 33.4, the Parties irrevocably agree that the courts of England and Wales have the exclusive jurisdiction to:
(a) determine the dispute;
(b) grant interim remedies;
(c) grant any other provisional or protective relief.

33.4 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.

33.5 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 33.3, 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 33.4.

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

34. Which law applies

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

APPENDIX A - VARIATION REQUEST FORM

Contract / Project Title: Contract / Project Ref No (FS /FSA No):
Full Description of Variation Request: A full justification and impact assessment including any supplementary evidence must be provided. Any supporting information should be appended to this form.
Area (s) Impacted: - Price ☐ Duration ☐ Price & Duration ☐ Scope of work ☐ Key Personnel ☐ Other ☐
Requester: Signature: Team / Organisation Date:
Supplier Contact Details Supplier Name : Contact Name : Contact Address : : Telephone No : Email Address :
FSA Use Only (Business Area) Amount Approved: Authorised By:- ☐ Cost Centre Manager ☐ Investment Board Signed : Date of Approval: **Please submit this form to** fsa.commercial@food.gov.uk

Procurement Use Only (confirm contract allows for requested variation) Variation Request No: Variation Request Approved by: Date of Approval:
On full approval of this Request for Variation, Procurement will produce a Variation Form for agreement and approval by both parties to append to the Agreement / Contract.

APPENDIX B VARIATION FORM

PROJECT TITLE:

DATE:

VARIATION No:

BETWEEN:

The Food Standards Agency (hereinafter called "the Client") & SUPPLIER (hereinafter called "the Supplier")

1. The Contract is varied as follows:

Contract x

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

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

SIGNED:

For: The Client	For: The Supplier
By:	By: . . . . .
Full Name:	Full Name: . . . . .
Position:	Title: . . . . .
Date:	Date: . . . . .