# Tender for Toxicology and Epidemiology Review Service ITT Ref LSRS352 / Project C308768 Attachment Two – Statement of Requirements

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# 1. PURPOSE

1.1. Procurement of services to prepare comprehensive toxicological and/or epidemiological reviews to support the assessment of human health risks of chemicals in the environment for three independent Government advisory committees.

# 2. BACKGROUND TO THE CONTRACTING authority

2.1. The UK Health Security Agency (UKHSA) is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological, and nuclear incidents, and other health threats. We provide intellectual, scientific, and operational leadership at national and local level, as well as on the global stage, to make the nation's health secure.

# 3. **DEFINITIONS**

Expression or Acronym	Definition
COC	Committee on Carcinogenicity of Chemicals in Food, Consumer Products, and the Environment
СОМ	Committee on Mutagenicity of Chemicals in Food, Consumer Products, and the Environment
СОТ	Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment
UKHSA	UK Health Security Agency

# 4. BACKGROUND AND SCOPE OF REQUIREMENT

- 4.1. UK Health Security Agency (UKHSA), also referred to as the 'Authority' is looking to appoint a provider to enable preparation of comprehensive toxicological and/or epidemiological reviews for several independent UK expert committees supported by the UKHSA Toxicology Department.
- 4.2. These are: the Committee on Mutagenicity of Chemicals in Food, Consumer Products, and the Environment (COM), the Committee on Carcinogenicity of Chemicals in Food, Consumer Products, and the Environment (COC), the Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT), and their working groups.
- 4.3. The preparation and presentation of comprehensive reviews will comprise the identification and critical appraisal of extensive published literature on health risks (from toxicology and/or epidemiology studies) and/or, less commonly, of unpublished submissions on laboratory and other studies from industry. The areas covered by this service will include environmental chemicals in air, soil, water and from waste processes, chemicals in consumer products and at times pesticides

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and veterinary residues. In addition, the Supplier should ideally also be able to support the Committees discussing general principles and new approaches to chemical risk assessment.

- 4.4. UKHSA Committee Secretariats undertake the commissioning of individual reviews. Their role includes identifying the issues on which a Committee view is needed by Government, specifying the requirements in terms of the scope of the review and ensuring the formal paper delivered by the Supplier meets the specification.
- 4.5. The reviews will need to be completed within deadlines specified by the Committee Secretariats, to enable finalised papers to be sent out to Committee/Working Group Members two (2) weeks before the meeting. These deadlines will be agreed in advance with the Supplier, facilitated through regular liaison meetings between the Supplier and UKHSA.

# 5. THE REQUIREMENT

- 5.1. Delivery requirement summary
  - 5.1.1. It is anticipated that upon receipt of a request for a topic review from the UKHSA Secretariat, the Supplier will:
    - develop appropriate literature searches to identify the available evidence,
    - obtain the included evidence papers in a manner such that they can be shared with the Secretariat and Committee/Working Group where necessary,
    - critically review the available evidence and summarise it for the Committee/Working Group, in the form of a discussion paper, or for more developed topics as draft Committee statements/reports or guidance,
    - attend the Committee/Working Group meetings and verbally present the paper, and address questions from committee members on the prepared reviews.
    - draft minutes of the items presented, and
    - develop Committee statements, guidance or reports based on the reviews undertaken and subsequent Committee discussion.

# 5.2. Budget

Based on the request, the Authority and the Supplier will discuss the size and urgency of each project to be delivered under the topic and agree the timescales and scope, this will provide a forecast of the budget required to undertake the work.

### 5.3. Contract

The duration of this contract will be for an initial 3-year term with the option to extend for an additional 3 years (+2+1). Extensions will be dependent on contract performance and internal budget approval. The duration of the contract shall be no longer than 6 years or until the maximum value of £1.9m excluding VAT is consumed.

# 6. KEY DELIVERABLES AND SERVICE LEVELS

6.1. Initially the following Contract key deliverables and service levels are expected to apply:

For each paper to be delivered to a Committee or Working Group (a project):

Key Deliverables	Description	Service Level Delivery Date	
Draft Committee or Working Group paper	Full draft Committee or Working Group paper for UKHSA review in Committee style and structure	4 weeks before meeting	
Final Committee or Working Group paper	Finalised version of the Committee or Working Group paper addressing UKHSA comments	3 weeks before meeting	
Preparation of briefing for Committee or Working Group Chair	Short summary of the request for the Committee or Working Group for discussion in the briefing for the Chair	2 weeks before meeting	
Committee or Working Group meeting	Attendance and presentation of the paper at the Chair's briefing and main Committee or Working Group meeting.	On date of meeting	
Preparation of minutes following discussion	Provision of draft minutes for the item in Committee style and structure for addition to the full meeting minutes.	1 week after meeting	

# 7. CONTRACT MANAGEMENT AND REPORTING

7.1. Below are the proposed reporting and contract management expectations

Milestone/Deliverable	Description	Timeframe or Delivery Date	
Summary of activity	Position update for all active projects by email	Monthly	

Annual report	Report of all topics and projects addressed in previous contract year	Annually
Project meetings	Discuss Project delivery progress, in relation to allocated work	As required
Contract meetings	Supplier account manager liaison meetings with UKHSA to discuss workplan and contract aspects	As required, at least quarterly

- 7.2. The supplier is required to allocate an Account Manager who will be responsible for managing the contract on the supplier's side.
- 7.3. Contract meetings will focus on reviewing the quality of work, delivery on time and in full and provide an opportunity for two-way feedback to support the continuous improvement of the contract deliveries.

# 8. VOLUMES

### **PROJECTS**

- 8.1. It is envisaged that UKHSA will commission a variety of reviews, with differing amounts of underpinning evidence, and sometimes on specific substances whilst others will be on general principles or new approaches to testing and risk assessment. Data-rich reviews may contain over 75 references for assessment, moderate reviews around 40-50 references, while the smaller mini and generic reviews will have fewer references to review or may focus on key evidence, e.g., 10-20 references.
- 8.2. The demand for and profile of the reviews can fluctuate across the year and between years depending on Committee requirements and the subjects being considered. Lead times will be agreed depending on the urgency and the quantity of resources to be reviewed. Normally lead times are discussed and allow for projects to be planned, if an issue is urgent the supplier will be informed, and appropriate adjustments made to recognise the additional resource required to meet the need. However, even for short notice requirements there should always be a minimum of 1 months' notice.
- 8.3. The expectation is that all projects, require the verbal presentation of finalised papers to the relevant Committee and/or its associated Working Group
- 8.4. It is envisaged that UKHSA will commission a variety of reviews.
- 8.5. Below is the profile of the topics and underlying projects that have been commissioned since September 2020.

		Projects				
	No. of Topics	Mini	Generic	Moderate	Data Rich	
СОТ	7	21	11	4	5	
coc	9	14				
СОМ	14	27	2	2		
Joint Topics	11	17				

**To note:** A project is a paper delivered to a Committee or Working Group, and multiple papers/projects are likely to be required for full consideration of a topic by the Committee/Working Group

On average the annual demand has been 15 mini projects, 3 generic projects, 2 moderate projects and 2 data-rich projects, however the profile of projects and overall demand is likely to fluctuate and vary between years.

Historically there have been no short notice requirements, where additional resource has been required to meet timeframes. Historical demand that has required additional resource have been more in relation to the size of the project to meet an agreed timeframe.

- 8.6. Review project timescale expectations:
  - Mini projects up to a week's work and review,
  - Generic projects around 2 weeks work and review.
  - Moderate projects 3-4 weeks work and review
  - Data rich projects over a month's work and review.

### **MEETINGS**

- 8.7. On average, the COT meets 6 or 7 times a year; the COC and COM each meet 3 times per year, or the equivalent as shorter meetings. There may also be Working Groups of these Committees; these are established on an ad-hoc basis, for example where a topic for consideration by the parent Committee requires more time for consideration than is available in the main Committee so a smaller group of Members form a Working Group. Since September 2020 under the preceding contract, three working groups have been supported with reviews in the same manner as the parent Committee for which a total of 9 further half-day meetings were attended by the supplier.
- 8.8. Historically approximately 50% of meetings have been held face-to-face, primarily in London or UKHSA Chilton and occasionally elsewhere in the UK, whilst the remaining 50% have been held virtually. The Supplier will be expected to provide the technical expertise to support the presentation and relevant personnel to attend the meeting.

# 9. **CONTINUOUS IMPROVEMENT**

- 9.1. The Supplier is expected to share where relevant feedback from UKHSA on the prepared papers such that all staff working under this Contract is aware of it, in particular with respect to quality, positions, or phrasings from the Committee in question, or expectations with respect to style.
- 9.2. The Supplier is expected to have a suitable representative in attendance at Committee meetings where they are presenting a paper, to bring learnings from across the meeting back to the Supplier.
- 9.3. Changes to the way in which the service is to be delivered must be brought to the Authority's attention and agreed prior to any changes being implemented. This includes the replacement of key personnel to ensure appropriate experience and qualifications are maintained

# 10. SOCIAL VALUE AND SUSTAINABILITY

10.1. For the purpose of the contract the supplier shall perform the service in accordance with the Authority's environmental policy



- 10.2. Social Value and sustainability requirements will be evaluated as part of this procurement, in accordance with PPN 06/20
- 10.3. Tenders will be asked to provide details of how they plan to create social value over the life of this contract. For further information about social value please refer to PPN06/20 Taking account of Social Value in the Award of Central Government Contracts (publishing service.gov.uk)
- 10.4. The invitation to tender documentation (ITT) will provide further details and the marking scheme that will be used to score Social Value responses

# 11. QUALITY

- 11.1. The Supplier is expected to provide objective reporting of the available evidence base in a clear and transparent manner, such that the Committees can undertake its evaluation in accordance with the <u>Code of Practice for Scientific Advisory Committees</u>. The reviews provided should be of sufficient standard for publication, as Committee and Working Group discussion papers are usually published on Committee websites and are written to a similar level as scientific peer reviewed paper.
- 11.2. The Authority will provide appropriate templates for Committee/Working Group papers to ensure accessibility requirements are met. The Supplier is expected to familiarise itself with the style of Committee discussion papers, minutes, and statements to ensure prepared materials are suitable for use by the Committees.

- 11.3. The Authority will review the draft Committee/Working Group papers provided by the Supplier to consider, determine, and safeguard whether the reviews are of the standard the Committees/Working Groups are accustomed to. The Supplier is expected to have a quality review or internal sign off process prior to delivery of reviews to the Authority, and a mechanism in place to rectify potential issues where the quality of the prepared reviews is deemed unsatisfactory or delayed such that the agreed deadline is not met.
- 11.4. UKHSA strongly feel that this is a service where the quality of the staff assigned can have a significant impact on the level of performance of the contract. As part of the tender process, the Supplier is asked to provide CVs of the people supporting the contract which will be considered as part of the evaluation process. UKHSA should be consulted in advance of anyone not outlined in the tender undertaking work to support the contract.
- 11.5. The Supplier should have appropriate document management processes in place, along with business continuity plans to reduce impacts on UKHSA and the Committees.

# 12. **PRICE**

- 12.1. The maximum value of the contract will be £1.9 m ex VAT over the maximum potential term of 6 years (3+2+1). This has been estimated based on previous years draw-down and expected budgetary request for next financial year (24-25). However, bidders are asked to note that this contract does not offer any committed spend and all proposed spend is subject to annual internal budgetary approval.
- 12.2. Bid Prices for a sample annual requirement and Rates, excluding VAT, are to be submitted using the commercial envelope in the Atamis e-procurement system. Bid Prices submitted should not exceed the current maximum annual budget of £315,000.
- 12.3. A separate attachment has been provided for potential suppliers to submit a bid price and rate card references as Attachment Five Commercial Response, with instructions on how to complete this document provided in Attachment 1 Invitation to Tender.
- 12.4. Whilst indicative pricing will be submitted for the Bid Price, the Agency anticipates the cost of individual reviews will be driven by the size, and occasionally the urgency, of the project, to be agreed between the Supplier and the Authority at the beginning of each project review on a case-by-case basis.

# 13. STAFF AND CUSTOMER SERVICE

- 13.1. The Supplier shall provide a sufficient level of resource throughout the duration of the Contract in order to consistently deliver a quality service, noting that demand for reviews fluctuates across the year and between Committees.
- 13.2. The Supplier's staff assigned to the Contract shall have the relevant qualifications and experience to deliver the Contract to the required standard. The service

provider should use appropriately trained or competent staff to undertake the reviews.

- 13.3. The Supplier shall ensure that staff understand the Authority's vision and objectives for its work with the Committees and who will provide excellent customer service to the Authority and Committees throughout the duration of the Contract.
- 13.4. The Supplier will be expected to have a plan in place to manage staffing changes relating to the Contract, and detailed arrangements should a key or pivotal staff member become unavailable. The Authority will expect to review the CV and experience of any new members of the Supplier's team before they work on this Contract.

# 14. SECURITY AND CONFIDENTIALITY REQUIREMENTS

- 14.1. The Authority may on occasion request the Supplier undertake work on topics or materials which are not in the public domain. Similarly, in attending Committee meetings, the Supplier may become aware of confidential information or know-how from the Authority or other Crown bodies. The Supplier is expected to keep such information confidential and only pass this on to those persons necessary to perform the duties of this Contract.
- 14.2. The Supplier and its staff are expected to declare any interests in the topics for which reviews are requested by the Authority so an appropriate judgement can be made whether these would be a conflict of interest in undertaking the work requested. Interests include but are not limited to where relevant staff members have, directly or indirectly, a financial, economic or other personal interest which might be perceived to compromise their impartiality and independence in the context of the work requested, and the Authority recommends declaring interests so they are recorded, even if they are deemed to not be a conflict.

# 15. PAYMENT AND INVOICING

In line with Government policy, guidance and legislation the Authority recognises that delayed payment can adversely affect businesses especially smaller concerns therefore the Authority has an SME Action Plan as part of our five year <a href="Commercial Strategy">Commercial Strategy</a> for health security.

- 15.1. Therefore, the Authority proposes that staged payments would be an equitable payment profile, the proposal is therefore to allow the Supplier to invoice for 70% of costs incurred on a monthly basis with each months retained 30% becoming due following satisfactory delivery and sign off by the Authority of the written review.
- 15.2. The cost of individual reviews will be driven by the size, and occasionally urgency, of the project. The cost, and any specific payment profile, of individual reviews will be agreed by the Supplier and the Authority at the beginning of each project review on a case-by-case basis. The standard payment profile for a project is anticipated to be based on 70% of the costs incurred, including working time, to be paid on a monthly basis in arrears, with the final 30% of all costs for the project to be paid

following satisfactory delivery of all five deliverables for each project (outlined above) and sign off by the Authority of the written review.

- 15.2.1 For meeting attendance, this should be a separate line within the monthly invoices. UKHSA will pay a standard attendance fee per person attending the meeting based on the Suppliers day rate. In addition, travel expenses will be paid for travel undertaken in line with UKHSA's staff travel policy, capped at £300.00 for a return journey.
- 15.3. The Supplier shall issue invoices monthly in arrears. The Authority shall pay the Supplier within thirty (30) Working Days of receipt of a Valid Invoice, submitted in accordance with this paragraph.
- 15.4. Before payment can be considered, each invoice must include a detailed elemental breakdown of work undertaken and the associated costs.
- 15.5. Invoices should be submitted to: payable@ukhsa.gov.uk
- 15.6. No invoice will be accepted without a valid Purchase Order reference.

# 16. Location

- 16.1. The Supplier is expected to interact with the Authority regularly, with online meetings being hosted by the Authority on Microsoft Teams.
- 16.2. Committee and Working Group meetings are held either face-to-face, usually in London or UKHSA Chilton, or virtually hosted on Microsoft Teams.