

Date: 05/06/2024

For the attention of [REDACTED]
wca environment Ltd

Dear [REDACTED]

Ref: ENV6005704R-2

Project Title: Use of mammalian toxicity data to derive an ED PNEC for environmental protection

I am pleased to inform you that the Environment hereby accepts your tender in respect of the above call off contract from the Environmental risk assessment services framework (ERAS2), framework reference 29581. The contract shall be carried out in accordance with the attached Project Form dated 25/04/2025 and your response dated 24/05/2024

The costs for this contract will be reimbursed at the rates set out in the Project Form for completed tasks.

The contract shall commence on 10/06/2024 and shall conclude on 22/11/2024.

A copy of the final Project Form is attached, please sign and return the form by email to the undersigned to confirm receipt and accept the contract offer.

We will issue a Purchase Order number within 2 weeks of the contract being signed. We will require you to quote this number, together with Contract Reference ENV6005704R-2 on all invoices for this project to ensure timely payment. Invoices should be sent to:

SSCL
Environment Agency
PO Box 797
Newport
Gwent
NP10 8FZ

Electronic invoices should be submitted to: APinvoices-ENV-U@gov.sscl.com

Invoices not containing the correct Purchase Order number will mean we are unable to process them and they will be returned to you.

Please liaise with the project manager, [REDACTED] (phone: [REDACTED] 85, email: [REDACTED]ment-agency.gov.uk) regarding the commencement of this contract.

The contract will be governed by the Environmental risk assessment services framework (ERAS2), framework reference 29581 Terms and Conditions as contained and agreed in the Framework Agreement, including GDPR Schedule and Prior Rights Schedule.

Yours sincerely,

[REDACTED]
Project Manager

Phone: [REDACTED] 885

Email: [REDACTED]ncy.gov.uk

Aqua House,
20 Lionel Street,
Birmingham,
B3 1AQ

29581 - ENVIRONMENTAL RISK ASSESSMENT SERVICES FRAMEWORK (ERAS2) - PROJECT FORM			
Part 1 – to be completed by Environment Agency Project Manager			
Project title: Use of mammalian toxicity data to derive an ED PNEC for environmental protection			
Bravo project ref (if applicable): Not applicable			
Date: 25 th April 2024			
Contracting Authority (Environment Agency; Natural England; Defra etc)	Environment Agency		
Environment Agency Project Manager:	<div>██████████</div> <div>[Technical Lead: ██████████]</div>	Phone number:	<div>██████████</div> <div>[Technical Lead: ██████████54]</div>
Budget holder:	██████████	Cost code:	ENV6005704R-2
Procurement Contact (if over £50k):	n/a	Email:	<div>██████████ _gov.uk</div> <div>(cc: ██████████ _agency.gov.uk)</div>
Project Start Date		June 2024	
Project Completion Date		November 2024	
For any projects over £10k, full competition is required (i.e. all suppliers on the Lot invited to quote). Please tick		Direct Award	<input type="checkbox"/>
		Mini-comp	<input checked="" type="checkbox"/> X (Lot 2)
Proposal return date: (no less than 10 working days from current date)		24 May 2024	

Notes	Any extensions, or amendments to existing orders need to be discussed with the contract manager first and the table in section 6 completed to authorise the change to the contractor.
	A Prior Rights Schedule to record data being shared between parties and a GDPR Schedule (if personal data is being handled as part of the project) must be completed with the successful contractor at contract start up and updated throughout the project and held as part of the contract record.

Evaluation criteria: (for work over £10k project managers need to prepare and complete an evaluation model on receipt of tender submissions – see guidance notes). Please note price and quality weightings are fixed (although you may alter the quality sub-criteria weightings).		
Consultants: Failure to meet the minimum score threshold stated will result in the bid being removed from the process with no further evaluation regardless of other quality or price scores.		
Price	Weighting	40%
Quality	Weighting	60%
Quality Sub-Criteria Weightings:		
Approach & Methodology (minimum score threshold 4 will apply (if applicable))		40%
Proposed Staff (inc CV's) minimum score threshold 4 will apply (if applicable)		30%

Project Management (including project plan) <i>minimum score threshold 4 will apply (if applicable)</i>	30%
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Specification (Details to be provided by the Environment Agency project manager. **Note** – the contractor's proposal will be limited to 3 pages (excluding pen portraits and costs) unless otherwise indicated in your specification. **Please also detail the Contractor's required Limitation of Liability.**

Please detail the Contractor's required Limitation of Liability. If no sum is stated, the Contract Price for the Services performed or to be performed under the Contract or five million pounds whichever is the greater will apply.

1. Description of work required – overall purpose & scope

Background

In 2023-24, the Chemicals Assessment Unit (CAU) completed a project with a contractor titled *A review of options to assess the "sufficiency" of environmental endocrine disruptor databases for regulatory purposes*. The aim of the work was to support CAU in assessing current Applications for Authorisation (AfAs) received under UK REACH, as well as for future restriction work. The output is also relevant to Defra's forthcoming Chemical Strategy where assessing endocrine disruption (ED) is an important element. The work focussed on assessing environmental ED for chemicals concluded to be Substances of Very High Concern (SVHC) based on fish data. Environmental ED has also been concluded based on effects observed in laboratory mammalian studies, for example the recent European Union (EU) conclusion for PDDP¹. If this substance or others were accepted as an ED under UK REACH, an environmental PNEC may be required during the submission and review of AfAs or to establish the level of risk for a restriction. Due to this, we need to explore how the PNEC approach proposed in the 2023-24 report could be applied to this situation.

Detailed requirements

The contractor shall prepare a standalone report considering how an environmental PNEC can be derived where environmental ED has been concluded based on mammalian ED effects. This shall include:

- A focus on the key level 4 and 5 studies used to conclude on mammalian ED for human health as described in OECD Guidance Document 150, but also considering mechanistic data from lower level studies where these provide supporting information. This shall take account of the difference in assessment approach between human health (individual level protection) and environment (population level protection).
- An explanation of how these studies can be used to derive a secondary poisoning PNEC to protect predatory wildlife (aquatic, including marine, and terrestrial) from ED effects, together with consideration of the relevant assessment factor(s). As there would not be a log Kow threshold for secondary poisoning in these circumstances, the report should also consider how predatory wildlife would be protected for water exposure of the ED substance (for example consumption of river water) within the approach.
- A section discussing the applicability of the approach suggested to ensure protection against possible ED effects in birds.
- Examples assessing the proposed approach using PDDP, 4-MBC², bis(2-ethylhexyl) phthalate³ and 4,4'-sulphonyldiphenol³ (these are all human health ED SVHCs in the EU). The contractor should also suggest two additional suitable substances.
- There is existing guidance (e.g. for Water Framework Directive) for the calculation of water concentration thresholds based on biota effects. The report should also discuss how these would be derived using the ED approach in the report. Where a substance has both fish and mammalian ED data, this would allow comparison of the two PNECs to determine which is lower for REACH risk management purposes.
- A review of the relevance of the following papers Choi *et al.*, 2024 (<https://doi.org/10.1007/s00204-024-03748-9>), Borgert *et al.*, 2024 (<https://doi.org/10.1007/s00204-024-03723-4>), and Brescia, 2020 (<https://doi.org/10.1080/10408444.2020.1740973>).

The approach proposed by the contractor should not assume that every human health ED SVHC would be an environmental ED SVHC. Instead, it needs to take account of the previous UK position under EU REACH for assessing the relevance of mammalian ED effects to the environment, which was a *mammalian reproductive effect with a plausible ED mechanism leading to a CLP classification, combined with indications of intrinsic*

¹ <https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e185f788ad>. Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/or combinations thereof

² (±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one covering any of the individual isomers and/or combinations thereof

³ Please exclude the fish data, and only focus on mammalian information, for the purposes of testing the approach

*potential for food chain contamination (i.e. persistence and/or a high level of bioaccumulation)*⁴. Persistence and bioaccumulation were assessed based on the Globally Harmonised System of Classification and Labelling of Chemicals⁵ hazard criteria: lack of ready biodegradation, and a measured BCF exceeding 500.

Deliverables

The output will be a report covering the detailed requirements above. This should be prepared using the Environment Agency standard report template and must be fully referenced for transparency. The report is to be submitted digitally to the project manager as a Microsoft Office® 2013 (or earlier) file. Other formats may be used where appropriate in agreement with the project manager. Where legally possible and relevant, provide copies of any supporting information in digital format, or relevant links were not.

All written reports and the presentation should be suitably quality assured, and your tender should clearly state how QA will be carried out for both the draft and final reports. This includes, but is not limited to, how typographical errors, formatting, editorial consistency, and the coherence of argumentation will be ensured before submission to the project manager. Accurate bibliographies referencing supporting information will be required.

Receivables

- EA Report produced in 2023-24
- EA report template

Timetable

Submit a draft written report to the Environment Agency for review no later than 11th October 2024. Following an EA commenting period of three weeks, the contractor shall provide a final version of the report by 22nd November 2024.

Administrative procedures

The contractor shall arrange two main project meetings: the first at project start up (within 2 weeks of contract award), and the second within 3 weeks of submission of the draft report, to discuss Environment Agency comments. These meetings will be held virtually using MS Teams. The contractor shall provide minutes of these meetings and list of actions by email to the project manager for agreement within two working days of the meeting. In addition, three progress meetings will be held at monthly intervals following the start up meeting virtually using MS Teams, for a minimum of 30 minutes (these may be stood down if deemed unnecessary by agreement with Environment Agency project manager). A brief written update (template to be provided by EA), and will also be required monthly.

If artificial intelligence (AI) is proposed to be used to produce any part of the report or perform any tasks contributing to the project, this shall be made clear in your tender, together with any relevant quality assurance. This shall also be communicated and agreed in advance with the project manager.

Invoicing will be for the amount agreed at the start of project, in arrears once the work is completed. The draft invoices should be agreed with the project manager before submission to Environment Agency Finance. The contractor will submit the invoice for payment within two weeks of it being agreed with the project manager.

A purchase order will be issued to the successful supplier as the contract award.

The contractor is responsible for obtaining all journal articles where needed.

Quotation

The fixed price quote should be based on an estimate of the number of hours needed for each named member of staff (which should be provided separately and in total), along with any reasonably foreseen non-staff related costs as relevant. Payment will only be made for actual hours and costs incurred.

Any potential conflict of interest (e.g. because of contractual involvement with actual or potential stakeholders) must be clearly declared.

2. Required skills / experience from the Framework contractor

The work will require a good understanding of mammalian endocrine disruption testing and evaluation (including associated regulatory guidance and test methods), as well as the regulatory approaches for secondary poisoning assessment and Water Framework Directive approaches for environmental quality standards for low solubility substances. Some knowledge of SVHC identification and consequences under REACH would be

⁴ <https://echa.europa.eu/documents/10162/0c80cbbd-998f-b415-f9be-9e3ced41f333>

⁵ <https://unece.org/transport/standards/transport/dangerous-goods/ghs-rev9-2021>

useful. The contractor will need to be able to summarise information, and present analysis and reasoning, in a concise and clear way in the report.

3. Proposed programme of work and payment table (Detailing specific tasks, deliverables & completion date where appropriate). Payment schedule should detail the % amount that will be paid after delivery of each task

Task no.	Task and deliverable	Completion date	Payment schedule
1	Acceptance of the Draft report by EA (based on quality, not delivery)	11/10/24	70%
2	Acceptance of the Final report addressing EA comments (based on quality, not delivery)	22/11/24	30%

**29581 - ENVIRONMENTAL RISK ASSESSMENT SERVICES FRAMEWORK (ERAS2)
TASK QUOTATION SHEET**

Part 2 – to be completed by Framework Consultant Project Manager

Framework Consultancy name		wca environment Ltd	
Consultant Project Manager name		[REDACTED]	
Consultant project manager phone number:	[REDACTED]	Consultant project manager e-mail address:	[REDACTED]onsulting.com

Part 2 - Consultant Proposal (details to be provided by the Contractor)

(to include methodology, work programme, staff details (including relevant pen portraits) Limit to 3 sides of A4, excluding pen portraits and costs (unless otherwise indicated in Environment Agency project client's specification))

1. Approach & Methodology

wca have previously drafted a report for the EA deriving Predicted No Effect Concentrations (PNECs) for fish for substances that are endocrine disruptors (EDs) via estrogen, androgen or steroidogenesis (EAS) pathways (wca 2024). The outcomes from this initial project can be used to derive threshold values for ED substances which are SVHC based on data for fish. The EA now need an approach for deriving threshold values where the SVHC conclusion is based on data for mammals. wca are experienced at conducting ED assessments for both the environment and human health and interpreting data relevant for ED. For this project we would follow a similar approach to deriving threshold values for fish in that both mechanistic and adverse effect data would be used for the evaluation. For an environmental assessment adverse effect data from mammals at the population level would be used for deriving PNECs (effects on fecundity, fertility, and development), but the effects would be put into context by considering relevant mechanistic data (i.e. biomarker endpoints for the ED of concern). This project also focuses on EAS modalities due to the availability of data for putting any derived PNEC into context.

Two approaches will be used to derive threshold values, firstly a precautionary secondary poisoning PNEC aimed at protecting predatory wildlife, and secondly the PNEC converted to an equivalent water concentration. The PNEC converted to a water concentration would need to be protective for aquatic vertebrates based on the expected endocrine mechanism. Case studies will be used to demonstrate the acceptability of such PNECs for use with ED substances, where the concern for secondary poisoning is not driven by bioaccumulation but by ED mediated specific toxicity. The case study substances will be PDDP (estrogen receptor (ER) agonist), 4-MBC (disrupts thyroid hormone production and is an ER-agonist), bis(2-ethylhexyl) phthalate (DEHP, ER agonist) and 4,4'-sulphonyldiphenol (ER agonist). Two additional substances are chosen which both of which are confirmed ED in non-target mammals, both acting as aromatase inhibitors (prothioconazole⁶ and triflurosulfuron⁷). These substances have recent regulatory reviews which can be used as the basis for the mammalian toxicology assessment as well as different amounts of fish for comparative purposes, with a PNEC already derived for propiconazole in the fish ED PNEC report (wca 2024).

To cover the scope outlined in a-f of the request for proposal, the following tasks are proposed.

Task 1: Data gathering: The following substance information is considered relevant for the assessment.

- *In vitro* data indicating potency for the endocrine mechanism of concern
- *In vivo* mammalian toxicology and ecotoxicology data from studies relevant for assessment of ED (i.e. OECD Conceptual framework [CF] Level 3 mechanistic studies and Level 4/5 data for adverse effects, OECD 2018)
- Bioaccumulation information, including bioconcentration factors (BCF) from standard laboratory fish tests, bioaccumulation factors, and biomagnification factors, or data such as an octanol:water partition co-efficient that can be used to estimate a BCF value.

The starting point for the evaluation will be the relevant ECHA support documents for SVHC (i.e. for PDDP (2021), 4-MBC (2021), bis(2-ethylhexyl) phthalate (2014) and 4,4'-sulphonyldiphenol (2022), for propiconazole a

⁶ <https://echa.europa.eu/ed-assessment/-/dislist/details/0b0236e1842681a4>

⁷ <https://www.efsa.europa.eu/en/efsajournal/pub/7303>

Risk Assessment Report (RAR) (2023)⁸ and for triflurosulfuron an ED assessment (Appendix E) and RAR⁹. The ECHA dissemination portal will also be checked in case of updates since these regulatory documents were published. The reliability score used in the SVHC document, RAR or the ECHA portal will be used for the assessment without an independent review of the data. Standard already regulatory accepted No Observed Effect Levels (NOELs) will be used where available and appropriate.

Specific literature searches will be conducted to identify new studies published in the open literature since the finalisation of the SVHC reviews. Only data relevant for the assessment (e.g. a study which is expected to affect the Point of Departure (PoD) for mammals or a No Observed Effect Concentration (NOEC) from a relevant fish study will be considered further.

Task 2: Data extraction: The available mammalian toxicology and ecotoxicology datasets for the case study substances would be reviewed. A reliability assessment would be conducted for any relevant studies identified in the published literature using standardised methodologies (i.e. ToxRTTool¹⁰ for mammalian toxicology data or Criteria for reporting and evaluating ecotoxicity data (CRED)¹¹ for ecotoxicology studies). For this project, we estimate the need to reliably assess 8 studies. For the mammalian toxicology dataset PoDs based on NOELs would be identified based on population relevant endpoints and for endpoint based on mechanistic effects for the relevant ED mechanism. Relevant studies for a secondary poisoning PNEC would be exposure via the oral/dietary route. We will also consider the dataset on which the PoD is based. The available guidance suggests that the chronic study on which a secondary poisoning PNEC is based should be ≥90 days but shorter studies can be used by applying additional assessment factors (AF). The sensitivity of different study designs for evaluating ED effects in mammals will be a consideration for discussion as part of the review where certain studies covering developmental and reproductive endpoints might be expected to be more sensitive. For example, for fish, a multigeneration study covering both developmental and reproductive endpoints was generally most sensitive for demonstrating ED effects for substances acting via EAS modalities (wca 2024). If any chronic ecotoxicology data in fish and/or birds is available, the lowest NOECs, based on population relevant and biomarker endpoints, will be identified.

Where appropriate the data will be normalised to account for the different energy densities of different food sources. This then enables the dose to be expressed as a critical concentration in food, which is used as the PNEC for secondary poisoning in wildlife. Relatively high levels of accumulation of substances in low energy density food sources could potentially lead to a greater risk of bioaccumulation in some consumers.

Task 3: PNEC derivation: Using the PoD values for mammals PNECs would be derived for secondary poisoning and an extrapolation made to a surface water PNEC. A comparison will be made between the PNECs derived using population relevant and mechanistic data, to inform on the possible need for additional AF to account for the ED mechanism. If CF Level 3-5, fish data is available an aquatic PNEC will be derived following the approach developed in a previous project (wca 2024). This result would be used in combination with endocrine activity data to consider the acceptability of a surface water PNEC derived using data from mammals. The PNEC for secondary poisoning is set as a concentration in food, and this means that it can be compared directly to concentrations in whole fish or invertebrates, or even a food basket.

The PNEC for secondary poisoning will then be extrapolated to determine acceptable environmental concentrations in soil or water for several possible predatory species covering both terrestrial and aquatic food-chains (see below for examples).

Soil – grass – rabbit – predator (e.g. fox)

Soil – worm – bird – predatory bird (e.g. peregrine falcon)

Soil – grass – insect - bird – predatory bird (eg. Buzzard)

Water – invertebrate – small fish – bird (e.g. kingfisher)

Water – invertebrate – small fish – large fish - predator (e.g. heron, otter, or osprey)

The possibility of additional exposure occurring through drinking contaminated water will also be considered as a possible source of exposure to evaluate the importance of this as a potential exposure route for wildlife. A critical concentration in soil or water that is expected to be protective of top predators will be extrapolated for each of the identified food chains and substances. From these a critical concentration will be derived for both soil and water that is expected to be protective of all predatory species. Although longer food-chains represent the worst case for hydrophobic substances with very low water solubility it is possible that the kinds of substances assessed in this project may not all have sufficiently similar behaviour to identify the worst case food chain based on typical persistent organic pollutants.

⁸ <https://echa.europa.eu/documents/10162/4fcccb93-3dc3-fcbd-2f44-a077f48efe9e>

⁹ <https://www.efsa.europa.eu/en/consultations/call/public-consultation-active-substance-triflurosulfuron-0>

¹⁰ <https://eurl-ecvam.jrc.ec.europa.eu/about-ecvam/archive-publications/toxrttool>

¹¹ Moermond et al. (2016), CRED: Criteria for reporting and evaluating ecotoxicity data. Environ Toxicol Chem. 35(5):1297-309. doi: 10.1002/etc.3259. Epub 2016 Mar 18. PMID: 26399705.

Task 4: Data interpretation: The PNECs derived using mammalian data will be discussed based on the following:

- Whether the PoD for PNEC derivation was based on a sufficiently sensitive study design.
- Whether a secondary poisoning PNEC which incorporates bioaccumulation aspects will be sufficiently protective for an ED substance with low potential for bioaccumulation.
- Whether there needs to be additional AF applied to derive a PNEC based on the mammalian toxicology dataset (e.g. whether multigeneration study is available).
- Whether a surface water PNEC derived using extrapolation from mammalian toxicology is expected to be more, or less protective compared on a PNEC derived for fish.
- Whether any proposed approach to deriving a PNEC is expected to be relevant and protective for birds,
- Whether the approach may differ depending on the endocrine mechanism of action,
- The need for additional AF to ensure that PNECs extrapolated from mammalian toxicology data are sufficiently protective.

In addition, we will discuss potency thresholds and if and how these could be used to justify the approach or the need for additional AF. This would include consideration of whether PNECs derived using population relevant endpoints for mammals would be protective of evidence for endocrine activity *in vivo* (e.g. effects on hormone levels or gonad weights).

The output from this project will be a report in the EA template containing an overview of the available data for each case study substance, detailing the approach taken to deriving PNECs, and a synthesis of the information. The report will include recommendations for derivation of PNECs to protect non-target organisms Including the application of AF) in the scenario where data is only available for mammals.

2. Project Management (inc Project plan)

It is the policy of wca to provide our clients with monthly email updates on project progress against milestones and budgets. We will also contact you at any significant points in the project to ensure that you can adjust the direction of the project if this is necessary to meet your needs. We will keep a log of any changes to the project that we agree with you and will inform you promptly if such alterations require a change to delivery dates or budgets. wca Quality Assurance, Quality Control and Project Management processes are managed through comprehensive Quality Management Systems (QMS), which are certified to ISO 9001:2015 standard. Also, we are certified to ISO 14001:2015 standard for our environmental performance and make a continuous effort to minimise our impact on the environment.

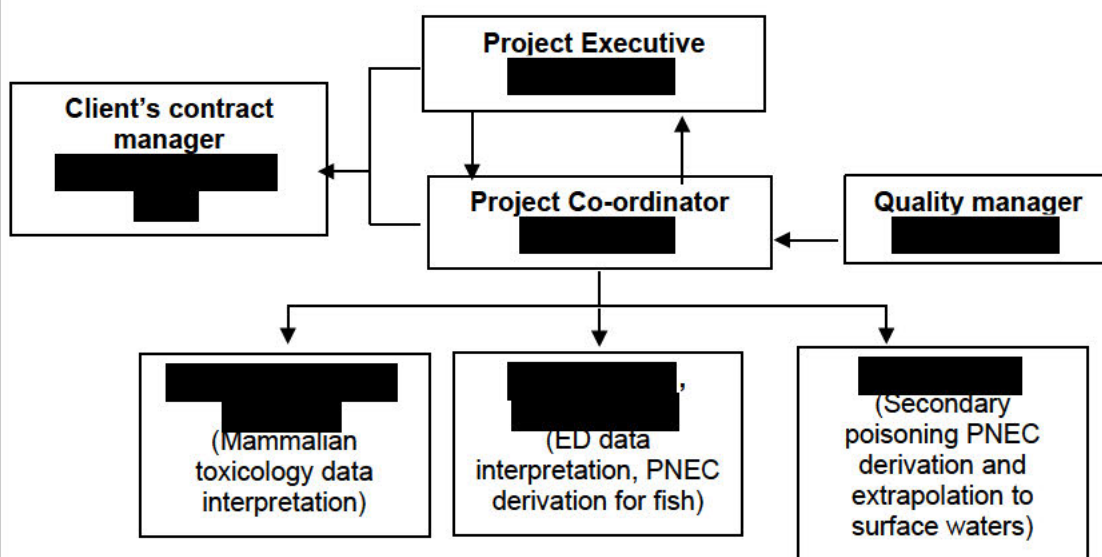
We operate our projects within the QMS, which is reviewed internally at least once a year and is externally audited annually. This certification of the QMS, awarded through external third-party inspection and audit, demonstrates that all wca services and products are maintained at a consistently high quality through the implementation and application of internal protocols and procedures, detailed record-keeping and iterative improvement and risk mitigation practices. We operate a shadowing project management procedure, where at least two members of the project team for wca are included in all communications. For this project, the co-ordinator will be [REDACTED], who has worked with the Agency on other ED related projects. An organisation chart of wca staff that would undertake this project is shown in Section 3.

A plan of the project timings is given below. The timings assume a project start mid-June 2024.

Task	Month									
	June		July		Aug		Sept		Oct	Nov
Meetings	KO								Final	
Task 1 (data gathering)										
Task 2 (data extraction)										
Task 3 (PNEC derivation)										
Task 4 (data interpretation)										
Draft									11 th Oct	
EA consolidated comments										
Revision of report										
Final report										22 nd Nov

3. Proposed Staff who will do the work and briefly state previous relevant experience

Organisation chart:



The Project Manager, responsible for day-to-day project management) will be [REDACTED], she will have project oversight and input on environmental PNECs for ED based on a previously project deriving ED PNECs for fish. The Project Executive and Quality Manager, will be [REDACTED]. [REDACTED] is a toxicologist with experience of evaluating mammalian toxicology data for ED and PoD assessments, he will derive relevant NOELs, for PNEC derivation supported by [REDACTED]. [REDACTED] will provide additional technical insights relating to ED effects observed in non-target organisms other than mammals (birds, fish and amphibia). [REDACTED] is experienced at Environmental Quality Standard Derivation including deriving PNECs for secondary poisoning. [REDACTED] and [REDACTED] were the main authors of the original wca data sufficiency report.

[REDACTED] specialises in the ED effects of chemicals. She has contributed to multiple ED assessments for substances under a range of regulations (e.g. REACH, plant protection products, biocides, pharmaceuticals) including assessments which align to the ECHA/EFSA guidance for identification of an ED (ECHA/EFSA 2018). She has also worked with the EA on ED data reviews for azoles, camphors, parabens and complex phenols.

[REDACTED] is an applied ecotoxicologist specialising in the undertaking and monitoring of aquatic studies required to support datasets for ED evaluations and in the assessment of potential EDs. She has worked on azole substances in her previous roles at a pharmaceutical company (designing bespoke aquatic tests) and an agrochemical company (conducting environmental risk assessments to support the registration of active ingredients and products in EU submissions).

[REDACTED] is an ecotoxicologist with over 30 years of experience in applied ecotoxicological research and project management. [REDACTED] has extensive expertise in the assessment of ecotoxicological data (including ED effects data) and derivation of PNECs using deterministic and probabilistic methods under a wide range of different chemical regulations and national/ regional approaches.

[REDACTED] is a European and UK registered mammalian/human health toxicologist with considerable experience in the conduct and interpretation of regulatory mammalian toxicology programs supporting the chemical, agrochemical, pharmaceutical, cosmetics and medical device sectors. He has contributed to many ED assessments for substances under a range of regulations, including REACH, PPP and BPR, in accordance with ECHA/EFSA 2018 guidance.

[REDACTED] is a European and UK registered toxicologist with experience in a number of ED weight of evidence assessments and toxicological risk assessments. She has extensive experience in literature and data searching, as well as interpretation of mammalian toxicology data. Additionally, she has experience in the use of mammalian toxicology Quantitative Structure Activity Relationship (QSAR) and structure activity relationship (SAR) models to assist with hazard assessments, chemical registrations and endocrine disruption assessments.

[REDACTED], PhD is a Principal Scientist at wca environment and an environmental chemist with over 20 years of experience in environmental consultancy, environmental regulation, and academia. He has been closely involved with the development and implementation of Environmental Quality Standards, and his main areas of expertise are in the assessment of environmental fate, behaviour, bioavailability and effects of chemicals; and the assessment of persistent, bioaccumulative and toxic (PBT) substances. [REDACTED] has previously worked for the

Scottish Environment Protection Agency as a principal chemicals assessment scientist, and the Environment Agency in previous chemical registration systems (NONS and ESR). [REDACTED] worked as a post-doctoral researcher at Durham University, and has a Ph.D. in Aquatic Chemistry, and a B.Sc. in Environmental Chemistry.

No conflict of interest is expected based on conduct of this work. wca are not currently working for other clients on any of the case study substances in any capacity nor have we worked on these substances in the last 5 years. There is no plan to use AI as part of this project.

4. Proposal cost

Please use day rates, including any applicable discounts, as agreed under the framework contract.

Please use day rates, including any applicable discounts, as agreed under the framework contract.

Task No.	Consultant name	Framework grade	Day rate	No. of Days or part thereof	Cost
1	[REDACTED]	Director Senior consultant Toxicologist	[REDACTED]	[REDACTED]	[REDACTED]
2	[REDACTED]	Director Toxicologist Senior consultant	[REDACTED]	[REDACTED]	[REDACTED]
3	[REDACTED]	Director Toxicologist Principal Consultant Principal Consultant	[REDACTED]	[REDACTED]	[REDACTED]
4	[REDACTED]	Director Toxicologist Principal Consultant Director	[REDACTED]	[REDACTED]	[REDACTED]
Total staff costs					£[REDACTED]
Expenses (please detail type ie travel, accommodation etc)		Purchase of scientific literature charged at cost [REDACTED]			[REDACTED]
Total overall cost					£30,493

5.-Terms & Conditions

Note to contractor – All call off contracts under the ERAS2 Framework are subject to the terms and conditions issued with the framework, including the Prior Rights Schedule and GDPR Schedule completed at award of the call-off contract.

Notes

You must have a purchase order number from the EA project manager before you start any work in connection with this proposal.

Contractor Project Manager:

[REDACTED]

Signature :

[REDACTED]

Date:

6th June 2024

6. Proposal Acceptance

Notes

All agreed post submission amendments to scope, proposal, timetable or costs must be updated prior to accepting the proposal.

A Bravo ECM reference should be obtained from Commercial if the project has been issued by Bravo and quoted on your purchase order.

Authorisation	Name	Signature	Date
Contract Project Manager			04/06/24
Authorised Contracting Authority Signature			04/06/24
DgC Authorised Signature (if required)			
Bravo ECM Ref (if applicable)			

7. Change Control

All amendments to scope, timetable or costs must be submitted to and approved by the PM Prior to implementing the change.

[illegible]