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11th July 2017

July 2017

11912/21/9

Category 4 Screening Levels – Call for Expressions of Interest:

Participation in a Panel of C4SL Specialist Tier 1 Toxicologists

Issued by SAGTA on behalf of C4SL Funders and the Project Steering Group, the attached call paper is provided as information to interested parties to submit Expressions of Interest (EoI) to be considered for invitation to participate as one of a panel of Specialist Tier 1 Toxicologists (T1) in the planned C4SL project. This text should be read in conjunction with the illustrative flow chart graphic that comprises an Annex to ~~this~~ the call document.

This paper and the Annex documents seek to provide an indication of the envisaged T1 role together with the anticipated roles and interfaces with the parties involved, namely the Project Steering Group (SG), the Project Manager (PM) to be appointed to manage the project and supporting Tier 2 Toxicologists (T2).

For the avoidance of doubt, this notification is NOT an invitation to submit a formal application to be appointed. This call is aimed at establishing those who are interested in submitting a tender to join a panel of appointees, all of whom will have been adjudged to satisfy the requisite criteria.

By submitting information, interested parties are asked to:

i) Confirm their understanding and acceptance of the described constraints and requirements as described in the attached document
ii) Submit the name of their nominated representative(s) to undertake the role on the party's behalf
iii) Submit a one page CV demonstrating the capability of those proposed to undertake the role have the capability to meet the criteria described in the attached document
iv) Confirm their nominated representative (with contact details) to receive subsequent enquiry documentation

From those who respond and meet the criteria, the intention is then to compile a shortlist who will be subsequently issued with an invitation, updated specification and related documentation to submit their confirmed proposals for undertaking the T1 role.

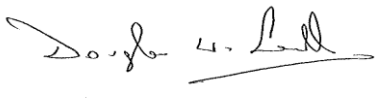
Multiple appointees to a panel are anticipated to be the outcome as a result of this call and invitation to tender from those who satisfy the criteria, subject only to an upper limit of **five** such appointments. Where more than five parties are invited to tender, those applying should note that the appointment cut-off point will be established through assessment of the comparative strengths of submissions received and as described in the accompanying call paper.

Interested parties are, therefore, invited to respond to this call by no later than close of business on 27th July 2017. Submissions are to be sent by email to SAGTA Secretary, Doug Laidler (email: dwlaidler@dwlenv.co.uk).

For the avoidance of doubt, any expenses or losses which are incurred by a party as a result of the preparation and / or submission of its EoI will be the responsibility of that party.

Any queries must be submitted via email, to be received by close of business on **20th July 2017** to Doug Laidler (email: dwlaidler@dwlenv.co.uk), copied also to the Project Steering Group Deputy Chairperson, Hannah White (email: hannah.white@nationalgrid.com).

Yours sincerely



Doug Laidler
Secretary
Enc

cc
Richard Boyle
Hannah White
Frank Evans

SAGTA - on behalf of C4SL Funders and Associated Project Steering Group

C4SLs Project Phase 2 July 2017

Call for Expressions of Interest - C4SL Panel of Specialist Tier 1 (T1) toxicologists

1) Introduction

This enquiry is to invite Expressions of Interest (EoI) from individuals, organisations or consortia to undertake the role of Specialist Tier 1 Toxicologist (T1) to participate in a panel of T1s to deliver outputs relating the development of further Category 4 Screening Levels (C4SLs) for defined chemicals. This proposed work will supplement the original efforts to produce a first tranche of C4SLs which resulted in their publication in 2014 by DEFRA and the Welsh Assembly.

The enquiry is made on behalf of collaborative funders (the Group). SAGTA is acting as coordinator and end client on behalf of the Group.

In relation to the overall concept of this C4SL project, SAGTA has:

i) Invited representatives from industry and government (memberships to be subsequently advised) to act as a Steering Group (SG) for the project. Its membership is aimed to provide a wide range of expertise and perspectives that, in combination, are considered to be representative of industry interests.

ii) Undertaken a process to appoint a Project Manager (PM) for the project

iii) Commenced a process to appoint a panel of supporting Tier 2 (T2) toxicologists

This EoI invitation seeks to identify (and inform) interested parties who, and if found to satisfy given criteria, are prepared to receive a subsequent invitation package as a basis of submitting an offer to SAGTA to be appointed as a T1 practitioner.

This call paper aims, at this stage, to inform interested parties by offering a perspective of the scope of the project and the roles of the parties with whom T1s will interact: SG, PM, Tier 2 Toxicologists (T2). It provides:

- A summary of project history and background
- A summary of:
  - The current anticipated scope of work involved to develop further C4SLs
  - The SG's current vision of how such work is to be carried out
  - The anticipated role of appointed T1s
  - The anticipated roles of:
    - SG
    - PM
    - T2
- The credentials that are to be regarded as being required of the T1s to undertake their roles.
- Process of submitting EoI and an indicative framework of the basis of how the T1s are to be selected.
- Annex 1. A flow chart illustration of the proposed C4SL Phase 2 Delivery Process

- Annex 2. Summary of the respective roles of the SG and the PM

In the context of this enquiry, it is to be made clear that:

- As matters currently stand, given the envisaged scale of work involved and the extent of overall funding that is likely to be available, a process broadly similar to that adopted in the 2010 CL:AIRE / EIC / AGS initiative for producing GACs will be undertaken.
- A total of 20 contaminants is currently planned to comprise the outputs of this project. As noted below, the chemicals to be involved as the subjects of assessments are not, as yet, specifically defined.
- In acknowledgement of the expected scope of work involved certain funds are available for payment to parties appointed to undertake the PM and T1 roles. This is outlined below.
- Much of the supporting technical development work (literature searching, appraising and modelling) is envisaged to be undertaken on an unpaid, voluntary basis by a range of practitioners prepared to contribute in this fashion.
    - Preliminary soundings has indicated that a number of organisations are prepared to so contribute. At this stage, however, the range of practitioners prepared to participate is as yet undefined.

The current position for the project is that there will be certain funds allocated to:

i) The PM role - in acknowledgement of the expected scope of work involved.
Annex 2 summarises this PM role

ii) Specialist toxicological (T1) role to which this call relates.
This is in acknowledgement of the scale of specialism, professional responsibility and commitment required of those undertaking T1 appointments.

In that the role will involve exchange and related peer review of other T1 outputs, it is envisaged a minimum number of T1s will be appointed. That said, to help consistency it is intended that there will no more than **five** T1s.

It is currently envisaged that the roles of each of the T1s in terms of allocated contaminants will be similar in scope to each other. As such, the total available funds for remuneration of T1s to cover personnel time and any and all out of pocket expenses, namely **£25,000,** exclusive of VAT will be equally divided between those appointed.

SAGTA will, however, reserve the right to adjust proportions of remuneration should it be found that appropriate to similarly adjust the number of contaminants to be allocated to T1s on basis of applicants' tender submissions. To this effect, those submitting responses to this call are invited to provide information on available resourcing etc that may be viewed as relevant for allocation of a higher proportion of contaminants.

At this stage, SAGTA is still considering the option of direct appointment of its T1s or via a process as nominated subcontractors to the PM. Respondees are asked to indicate to SAGTA any objections they may have to the latter arrangement.

2) Project History and Background

The initial C4SL project was a test exercise to develop an approved methodology for the derivation of screening values. The framework developed two streams of work

- *Exposure Modelling* - a revised approach to the CLEA model
and
- *Toxicological Modelling* - a model framework for the identification of appropriate authoritative toxicological reports in order to identify an appropriate toxicological input for the exposure modelling (the Low Level of Toxicological Concern, LLTC). However, where there is insufficient toxicological information, the use of 'tolerable' or 'minimal risk levels' or levels currently in use and widely accepted is equally appropriate and fully in line with the Framework.

Six compounds were initially considered to explore the range of exposure pathways. Outputs for that initiative comprised the following:

Defra 2014

Science and Research Projects: *Development of Category 4 Screening Levels for assessment of land affected by contamination - SP1010*

CL:AIRE 2013

Final Report : SP1010 Development of Category 4 Screening Levels Main Report
Annex : SP1010 Appendix A - Sensitivity analysis parameters
Annex : SP1010 Appendix B - Probabilistic Modelling
Annex : SP1010 Appendix C - Arsenic
Annex : SP1010 Appendix D - Benzene
Annex : SP1010 Appendix E - BaP
Annex : SP1010 Appendix F - Cadmium
Annex : SP1010 Appendix G - Chromium VI
Annex : SP1010 Appendix H - Lead
Annex : SP1010 Appendix I - Statistics Review
Information Leaflet : SP1010 Policy Companion Document
Information Leaflet : SP1010 Project Erratum - December 2014
Other: Peer Review - Professor Alan Boobis
Other: Peer Review - Robert Scofield
Other: SP1010 Stakeholder Report

Preparatory working already undertaken for this project phase is described in 3.1 below.

3) Scope of work involved in this project

3.1 Introduction

This piece of work is intended to provide expansion of the chemicals with associated C4SL numbers that will be available to industry. Currently this particular initiative is envisaged to cover approximately 20 chemicals and is planned to be the basis within which T1s would be engaged.

A key underlying principle will be that all such work is undertaken that recognises, and is compliant with, the C4SL framework that was produced in the initial C4SL project.

In accordance with the C4SL framework, there will be two key pieces of toxicological work.

- *Derivation of low risk C4SL screening numbers:* where sufficient good quality, authoritative toxicological data exists to derive a *Low Level of Toxicological Concern*
  and
- *Selection / derivation of minimal risk C4SL screening values:* using traditional toxicological approaches in line with UK policy.

The relevant toxicological output will then be used for incorporation into framework with compliant exposure modelling to derive the provisional C4SLs (pC4SL). A process will then follow for pC4SL outputs to be as approved to move forward as finalised C4SL outputs.

3.2 Preparation for this project

As preparation for this project, a number of summary documents have been produced. These are planned to provide both general assistance as well as facilitating consistency of approach to those involved in contributing to the project.

To provide initial indications of the planned provisions, the titles are listed below:

- *Proposals for C4SL Phase 2 Delivery Process*

- *Category 4 Screening Levels - Proposed Terms of Reference*
- *C4SL Steering Group Members*
- *Specification for Exposure Modellers*
- *Specification for the Derivation of a Low Level of Toxicological Concern (LLTC)*
- *Inorganic contaminant pro forma*
- *Organic contaminant pro forma*
- *Human Toxicological Data Sheet for C4SL derivation: Toxicological Evidence, HBGVs, MDIs and LLTC derivation*
- *Priority contaminants*

Copies of available information will be provided, in confidence, at tender stage.

3.2.1 The Steering Group (SG)

An integral part of the C4SL framework in moving forward was that central oversight of further C4SLs should be made. Therefore, a Steering Group (SG) has been established to oversee the production of further C4SLs. The list of participating organisations is in the process of reaffirmation.

The SG's role is outlined in Annex 2.

3.2.2 The Project Manager (PM)

SAGTA is in the process of appointing a Project Manager (PM), who will be responsible for delivering outputs of the project in general accordance with process flow chart contained in Annex 1: *Proposals for C4SL Phase 2 Delivery Process*.

The outputs will consist of baseline work carried out by the various participants on defined chemicals.

The Task titles that comprise this initiative are:

- Task 1 Exposure modelling.
- Task 2 Toxicological derivation.
- Task 3 Management of available resources.
- Task 4 Documents' finalisation and review in preparation for publication.
- Task 5 Publication.

As will be indicated in the following sections, the PM's responsibilities will comprise but be not necessarily limited to:

- *Management:* develop and implement a Resource Management Scheme and manage delivery of participants' outputs.
- *Management (provisional):* administration of appointment and activities of T1s as nominated subcontractors
- *Quality review:* ensuring outputs are consistent and accurate.
- *Submission of pC4SL:* Developing and executing working schemes to analyse, review and collate documentation in terms of completeness and accuracy as submissions of packages of provisional C4SLs (pC4SLs) documents to the SG for its review.
- *Finalisation*. Taking forward documentation to full C4SL status.
- *Dissemination*. Disseminating information to the public on progress and the position of finalised full C4SL outputs.

The role of the PM within the various tasks is set out in Annex 2.

3.3 Toxicologists

3.3.1 Overview

The role of appointed toxicologists to which this enquiry relates, is to derive a Low Level of Toxicological Concern (LLTC) for a total of approximately 20 chemicals.

Current planning is for two tiers of toxicologist to be appointed:

- Specialist Tier 1 Toxicologists (T1): formally qualified and appropriately registered toxicologists. As defined above, to enable complementary cross checking of outputs and to help maintain consistency, a minimum of 3 and a maximum of 5 T1s is planned.
- Supporting Tier 2 Toxicologists (T2): practitioners experienced in the field of contaminated land risk assessment with demonstrable depth and breadth of experience in toxicological sectors or applying toxicological principles

3.3.2 Specialist Tier 1 Toxicologist (T1)

The role of a T1 will be, in conjunction with other appointed T1s, to:

- Work with the PM and define achievable and reasonable timeframes for relevant tasks
- Support the PM to plan, organise and convene a *Toxicology Scheme Workshop* that will contribute to identifying how relevant issues will be resolved and defined within a formal *Toxicology Scheme* to be developed by the PM. Aspects to be resolved will comprise, but will be not necessarily limited to processes, and specifically including those required actions and deadlines of T1 and T2 practitioners, to:
  - Initially assess toxicological data
  - Determine whether sufficient evidence exists for an LLTC to be derived, or if a minimal risk value is to be used
  - Derive appropriate toxicological input (e.g. BMD modelling)
  - Review, check and establish consistency in reporting (including peer review)
  - Recommend LLTC for use in modelling
  - Structure reporting (including how to concisely (<5 pages) report the relevant options for the point of departure and to clearly report the chosen option(s) describing key issues consistently for each contaminant
- Fulfil the requirements of the *Toxicology Scheme* including adherence to defined timeframes and interaction with both PM and T2 practitioners

3.3.3 Supporting Tier 2 Toxicologists (T2)

For information, the role of T2 practitioners is expected to comprise:

- Fulfil the requirements of T2 practitioners as set out in the *Toxicology Scheme,* including, but not necessarily limited to:
  - Interaction with the PM and T1 toxicologists
  - Attendance and due contributions as may reasonably be expected of T2s at the *Toxicology Workshop* referred to above
  - Collation of toxicological data (in a similar manner to the former EIC GAC project)
  - Initial review of toxicological information and provide concise written document summarising all pertinent information (exact requirements to be advised by Tier 1 toxicologist)
  - Adherence to defined timeframes for T2 activity as may have been reasonably defined.

4) Scope of applicants' EOI submissions for role of T1

4.1 Overview

Applicants' responses to the following criteria will be utilized in assessing capabilities to be invited to tender:

i) Confirmation of understanding and acceptance of the described constraints and requirements ~~again~~ as described below
ii) Submission of a one page CV demonstrating the capability of those proposed to undertake the role to have the capability of to meet the criteria described below.
iii) Name of nominated representative(s) to undertake the T1 role on the applicant party's behalf
iv) Confirmation of nominated representative (with contact details) to receive subsequent enquiry documentation

4.2 T1 Criteria

4.2.1 Credentials

The required role is one that is centred upon named representatives acting in their capacity as specialists to personally verify the scope and quality of their outputs and the peer review checking procedures undertaken and conclusions formed on outputs from others.

Those applying to undertake the T1 role will be expected to provide relevant and appropriate evidence of qualities and experience and approach that are set down as being required of the representative(s) of the eventual appointee.

At this EOI stage, this will involve submitting evidence in relation to the headings listed below.

(i) *Experience*

Requirements of nominated individuals for the T1 role are as follows:

- A minimum of 10 years:
  - Demonstrable experience of assessing risks to humans from exposure to chemicals in the environment (preferably the soil environment).
  - Demonstrable evidence of experience of ability to critically assess literature data and other information relevant to select the most appropriate toxicological endpoint.
  - Demonstrable evidence of experience of ability to review opinions and assessments from different relevant authoritative bodies (which in some cases may be conflicting) to collate relevant information e.g. health based guideline values.
  - Demonstrable evidence of knowledge of the various methods for deriving points of departure for chemical risk assessment. For this purpose, evidence of experience of relevant projects comprising a summary of titles and contexts of the scheme is envisaged.
  - Experience in the use of the benchmark dose modelling approach is desirable, it will not be viewed as essential.

(ii) *Qualifications*

To act as a T1 Toxicologist, a successful nominated representative will also meet the following criteria:

- Relevant PhD, or Masters qualification in Toxicology, or equivalent qualification in the field of Toxicology.
- Note: Inclusion on the UK and European Register of Toxicologists is desirable but not essential.

4.2.2 Applicants' confirmation of approach to the project

SAGTA seeks to ensure the project proceeds with a coordinated approach that is consistent with earlier initiatives to which this project relates. To that effect, SAGTA will seek the following:

- Acceptance of, and commitment to, the DEFRA, Welsh Assembly and DCLG policies of covering both the purpose that the C4SLs can serve within the Part 2A and planning regimes and their alignment to the concept of '*suitable for use'*.
- Confirmation of full familiarity with the technical aspects of the original SP 1010 initiative.
- Confirmation to provide, where reasonably possible, such individual(s) as the applicant's proposed representative(s) that are named and described in submissions as fulfilling the level of skills, qualifications and experience to fulfil theT1 role
- Confirmation that, in circumstances where it is found to be not reasonably possible for such named individuals to participate, alternative resourcing of comparable capability and experience to those as may have been originally proposed will be provided to ensure seamless transitions
- Confirmation of no awareness of circumstances that may give rise to possible conflicts of interest of whatever nature in carrying out the T1 role
- Confirmation of no intention to retain or seek to retain any matters of copyright or IPR in relation to the issues or data associated with the development and/or completion of the initiative.

5) Other arrangements

5.1 Contract terms and conditions.

These will be notified at the time that successful applicants to this EoI are subsequently invited to make a tender submission.

5.2 Procurement timetable

At this point in time this remains subject to ongoing development, but will be advised as part of a subsequent invitation to submit. It is anticipated that the formal tender period will run over a two week period in late July/early August with formal appointment over the summer period.

5.3 Technical documents

It is envisaged that the preparatory documents that are available will themselves be made available to those who are applicants at the start of an invitation process to establish T1 appointees.

6) Short listing process and basis of tender assessment

6.1 Short listing

The aim of this enquiry is to establish that you/your company is interested in being appointed for this work.

The closing date for responses to this EoI enquiry is identified in the covering letter to this documentation.

Information at EoI stage is described in Section 4. Those who are assessed to satisfy the criteria will be short listed to receive tender documentation for the role.

6.2 Tender assessment

The subsequent application assessment stage will be subject to a comparative evaluation scheme based on a sliding scale of marking that takes into account assessors' views acting on behalf of SAGTA on applicants' capacity to meet the requirements of each criterion. This will range from:

- High level service, performance and comprehensive coverage of a criterion in question to
- Competent service, performance and acceptable coverage of criterion in question that may or may not be subject to possible omissions that are not considered to be significant.

A basis of a comparative tender assessment process of applicants, when required, will be confirmed at subsequent invitation stage, but is at present envisaged to be driven by the following weightings to be applied to an overall assessment:

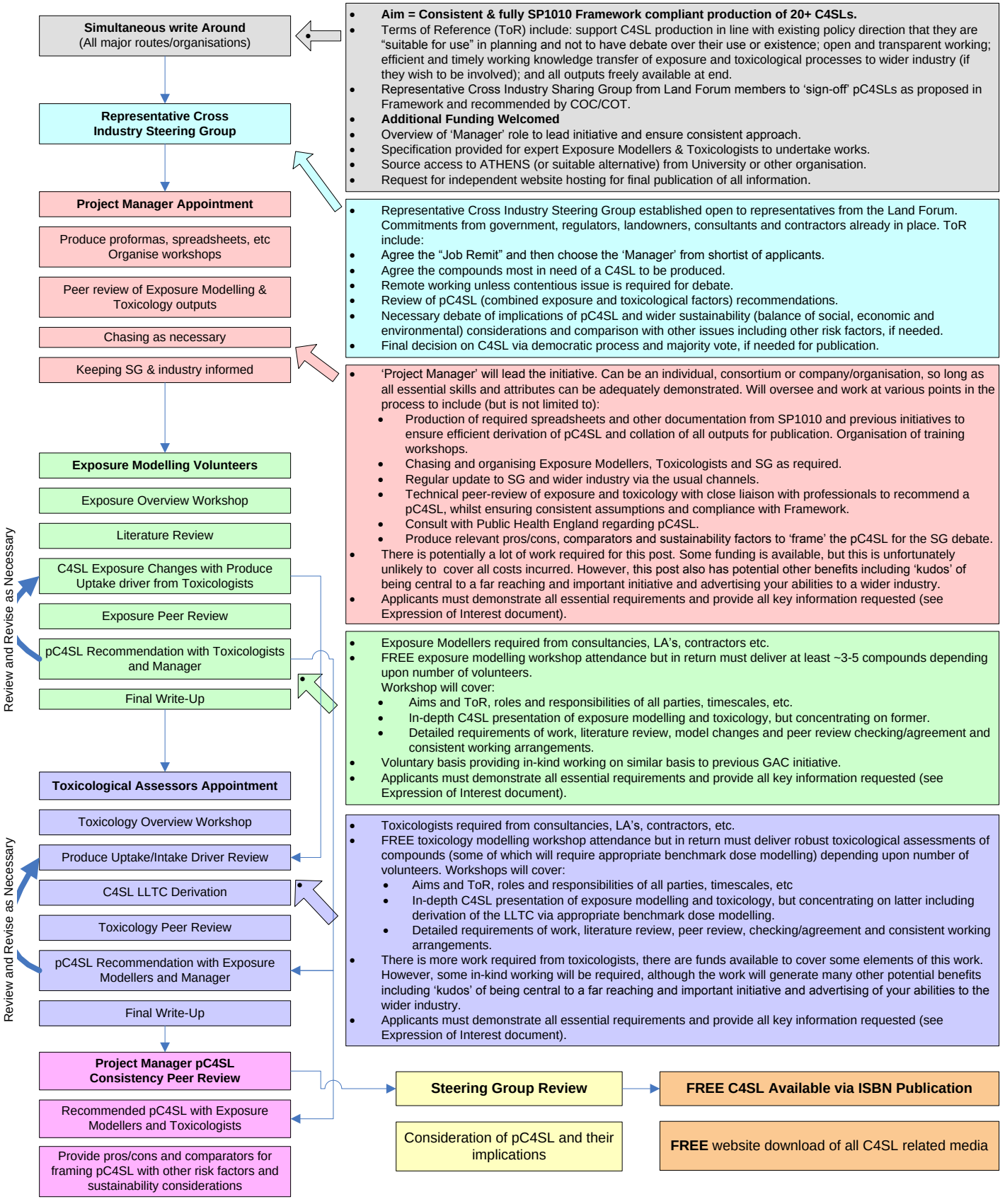
- Acceptance of the financial ceiling, technical and policy constraints - Satisfy / Default
- Full familiarity with the technical aspects of the original SP 1010 initiative - 5%
- Provision of individuals with relevant skills, qualifications and experience - 30%
- Technical capability - 30%
- Capacity / experience in providing authoritative judgement to areas of uncertainty - 25%
- Capacity for providing QA oversight of draft outputs in relation to their accuracy and consistency in relation to other elements of work - 5%
- Experience in successful communication with stakeholders - 5%

The following detailed aspects will also be sought at tender application stage:

- The organisation which is applying as a T1 appointee
- Status of the applying organisation - sole trader, partnership, private limited company, public limited company, or other
- Registered Office (if different from above)
- Address for correspondence
- Confirmation of identity of organisation's representative submitting information on its behalf
- Position of that representative within the organisation
- Details of relevant credentials of other proposed collaborating and/or subcontractor organisations that are proposed as being involved in providing any areas of T1 services and the nature of their particular role(s)
- Notification of any incidences (with details) or otherwise of any directors, partners or associates of tendering firm or subcontractor(s) if relevant, having been involved in any firm which at the time of such involvement been liquidated or entered into receivership.
- Confirmation of any directors, partners or associates who have any involvement with that organisation, subcontractor(s) or any other firms which have provided services to SAGTA, its constituent Members or other funding organisation funding the initiative.

ANNEX 1 Graphic: Flow chart proposals for C4SL Phase 2 Delivery Process

Proposals for C4SL Phase 2 Delivery Process – July 2017 v2



ANNEX 2 Summary of the respective roles and interfaces of Steering Group and Project Manager in the project

A2.1 Steering Group (SG)

The SG's membership is aimed to provide a wide range of expertise and perspectives that, in combination, it considers to be representative of industry interests.

The SG's Terms of Reference have been set out. This includes supporting the assessment of the EoI and tender submissions for the T1 and T2 roles.

The SG's activities are to be chaired by Richard Boyle of HCA. In his absence, Hannah White, representing SoBRA, SAGTA and National Grid Property, is proposed to act as his delegated deputy. The SG will also have a designated Secretariat.

The SG's role incorporates:

- Making contributions to finalise the scope of required work and support documents.
- Refining the selection of priority contaminants for consideration.
- Ensuring that a consistent approach is adopted that is in agreement with the framework and policy criteria or take necessary decisions if deviation is required for a specific compound or set of compounds under consideration.
- Receiving outputs and, within its Terms of Reference to act in consensus, defining acceptance or otherwise that outputs may proceed to full C4SL status.

A2.2 Project Manager (PM)

Project tasks and associated PM interfaces

Task 1 Exposure modelling.

Undertaken by volunteer practitioners within a framework of interfaces where the PM:

- Organises volunteers in accordance with the defined Process Delivery
- Develops a Modelling Scheme to define how the following, but not necessarily limited to, issues will be resolved:
  - The adequacy of peer-review, cross checking and verification of input parameters
  - The documenting the decisions made in the modelling together with deviations from the standard protocol
  - Reviewing and checking procedures in relation to the selected exposure modelling endpoints.
- Ensures technical modelling requirements of the C4SL regime are defined and followed

Task 2 Toxicological derivation.

As with Task 1, task to be undertaken by a group of practitioners (Tier 1 paid, Tier 2 volunteer) within a framework of interfaces where the PM:

- Organises both Tier 1 and Tier 2 Toxicologists, including arrangement of the workshop for such persons.
- Ensures the technical modelling requirements of the C4SL regime are followed by developing a *Toxicology Scheme* that will identify how, but not necessarily limited to, the following issues will be resolved:
  - *Initial assessment of toxicological data:*
  - *Derivation of appropriate toxicological input*:
  - *Review and checking procedures*
- Ensures adequacy of peer-review, cross checking and verification of and justification of input parameters.

Task 3 Management of available resources.

- Managing work packages:
- Devising a Work Programme for SG agreement incorporating, but not necessarily limited to:
  i) Defined combinations of participants in the initiative and their allocated chemicals
  ii) The setting of programme timelines
  iii) Coordination and organisation of workshops
  iv) Coordination of SG links
  v) A publication scheme
  vi) Communicating externally with industry on progress

Task 4 Documents' finalisation and review in preparation for publication

In respect of documents' finalisation for public issue, the PM's duties incorporate:

- Adjustments to format / content of proformas and templates
- Collation of related documentation supporting individual chemicals
- Via a Publication Scheme set down proposals for layouts of final documentation, including:
  - The proposed format of output concise and factual documents
  - Tranches of chemicals to be published
  - Timeline - publication of C4SLs and supporting material

Task 5 Publication

In conjunction with the SG, for the free and unrestricted public issue of full C4SL outputs including but not necessarily limited to:

- Initial briefings and associated press releases
- Identification of dissemination routes
- Finalisation and editorial polishing of final outputs
- Press releases, launch events / workshops