



SAGTA Secretary
Douglas Laidler
c / o GRM
1 Bedford Row
Holborn
London
WC1R 4BZ

Tel 07742 723507

Email dwlaidler@dwlenv.co.uk

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Category 4 Screening Levels – Call for Expressions of Interest: Participation in a Panel of C4SL Supporting Tier 2 Toxicologists

Issued by SAGTA on behalf of C4SL Funders and the Project Steering Group, the attached 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 Supporting Tier 2 Toxicologists (T2) in the planned C4SL project. This text should be read in conjunction with the illustrative flow chart graphic that comprises an Annex to the call document.

This paper and the Annex documents seek to provide an indication of the envisaged T2 role together with the anticipated roles and interfaces with the parties involved, namely the Project Steering Group (SG) and the Project Manager (PM) to be appointed to manage the project and specialist Tier 1 (T1) toxicologists.

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 joining 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 its understanding and acceptance of the described constraints and requirements again 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 T2 role.

Multiple appointees to a T2 panel are anticipated to be the outcome as a result of this call.

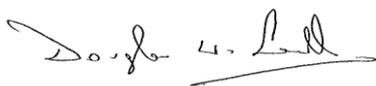
Appointments will be sought from those who satisfy the criteria, subject only to an upper limit that will be defined at subsequent enquiry stage.

Interested parties are, therefore, invited to respond to this call by no later than close of business on 4th August 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 **31st 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

A handwritten signature in black ink, appearing to read 'Doug Laidler', with a horizontal line underneath the name.

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 Supporting Tier 2 (T2) toxicologists

1) Introduction

This enquiry is to invite Expressions of Interest (EoI) from individuals, organisations or consortia to undertake the role of Supporting Tier 2 Toxicologist (T2) to participate in a panel of T2s 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 the process of establishing a panel of specialist Tier 1 (T1) toxicologists

This EoI invitation seeks to identify (and inform) interested parties who, if found to broadly 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 T2 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 T2s will interact: SG, PM, Tier 1 Toxicologists. 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 T2s
 - The anticipated roles of:
 - SG
 - PM
 - T1
- The credentials that are to be regarded as being required of the T2s to undertake their roles.
- Process of submitting EoI and an indicative framework of the basis of how the T2s 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 but this will apply to the parties appointed to undertake:
 - The PM role - in acknowledgement of the expected scope of work involved. Annex 2 summarises this PM role
 - Specialist toxicological (T1) work areas. This is in acknowledgement of the scale of specialism, professional responsibility and commitment required of those undertaking T1 appointments. Section 3.3.2 summarises the T1 role
- In respect of this invitation to submit an EOI, the invitation relates to parties who are prepared to contribute to the outcome of this project by undertaking technical development work of literature searching, appraising and modelling to support the outputs on an unpaid, voluntary basis.

For the avoidance of doubt, an appointment to participate in a T2 role will not involve any remuneration either for time spent or out of pocket expenses that may be incurred.

No upper ceiling of T2 participants is currently envisaged. SAGTA, however, reserves the right to limit the number of T2s and, if this is the case, will apply a comparative assessment of submitted criteria at appointment assessment stage as is described in Section 6.

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 T2s 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 submission to appoint 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 subsequent 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

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 maximum of 3-5 T1s is planned. This role is to derive a Low Level of Toxicological Concern (LLTC) for approximately **20** chemicals
- Supporting Tier 2 Toxicologists (T2) – to which this EOI relates: 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 Tier 2 toxicologists (T2)

The role of T2 practitioners is 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
 - 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)
 - Attendance and due contributions as may reasonably be expected of T2s at the *Toxicology Workshop* referred to above
 - Adherence to defined timeframes for T2 activity as may have been reasonably defined.

4) Scope of applicants' EOI submissions for role of T2

4.1 Overview

Applicants' responses to the following criteria will be utilized in assessing capabilities to be invited to participate as a T2 practitioner:

- i) Confirmation of understanding and acceptance of the described constraints and requirements as described below
- ii) Name of nominated representative(s) to undertake the T2 role on the applicant party's behalf
- iii) Submission of a one page CV demonstrating the capability of those proposed to undertake the role to have the capability described below
- iv) Confirmation of nominated representative (with contact details) to receive subsequent enquiry documentation

4.2 T2 Criteria

4.2.1 Credentials

Individuals applying to undertake the T2 role will be expected to provide relevant and appropriate evidence of qualities and experience and approach that are seen as required of the appointee.

(i) Experience

- A minimum of 6 years in at least 3 of the following areas:
 - 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.

(ii) Qualifications

- To act as a T2 Toxicologist, a successful nominated representative will also meet the following qualification criteria:
 - Degree qualified, preferably chartered with a relevant institution

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 the 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 the T2 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 T2 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 Basis of appointment

These will be notified at the time that those applicants to this EoI who are subsequently invited to make a submission in relation to an appointment as a T2.

5.2 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 a formal period for submitters to compile proposals will run over a two week period in August/September with issue of formal appointments as T2 practitioners confirmed within the following month.

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 T2 appointees.

6) Short listing process and basis of appointment assessment

6.1 Short listing

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

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

Information at Eol stage is described in the preamble to Section 4.

6.2 Application assessment

Subject to applicants satisfactorily confirming their capabilities to meet all the described criteria at Eol stage, should it be found to be necessary to place a ceiling to limit the numbers of T2 participants the subsequent application assessment stage will be subject to a comparative evaluation scheme of applicants' submissions based on a sliding scale of marking that takes into account assessors' views 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 assessment process of applicants, should it be required, will be confirmed at subsequent invitation stage. However this 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 | - 10% |
| - Provision of individuals with relevant skills, qualifications and experience | - 30% |
| - Technical capability | - 30% |
| - Capacity / experience in providing authoritative judgement to areas of uncertainty | - 25% |
| - Experience of delivering accurate work within a defined timeframe | - 5% |

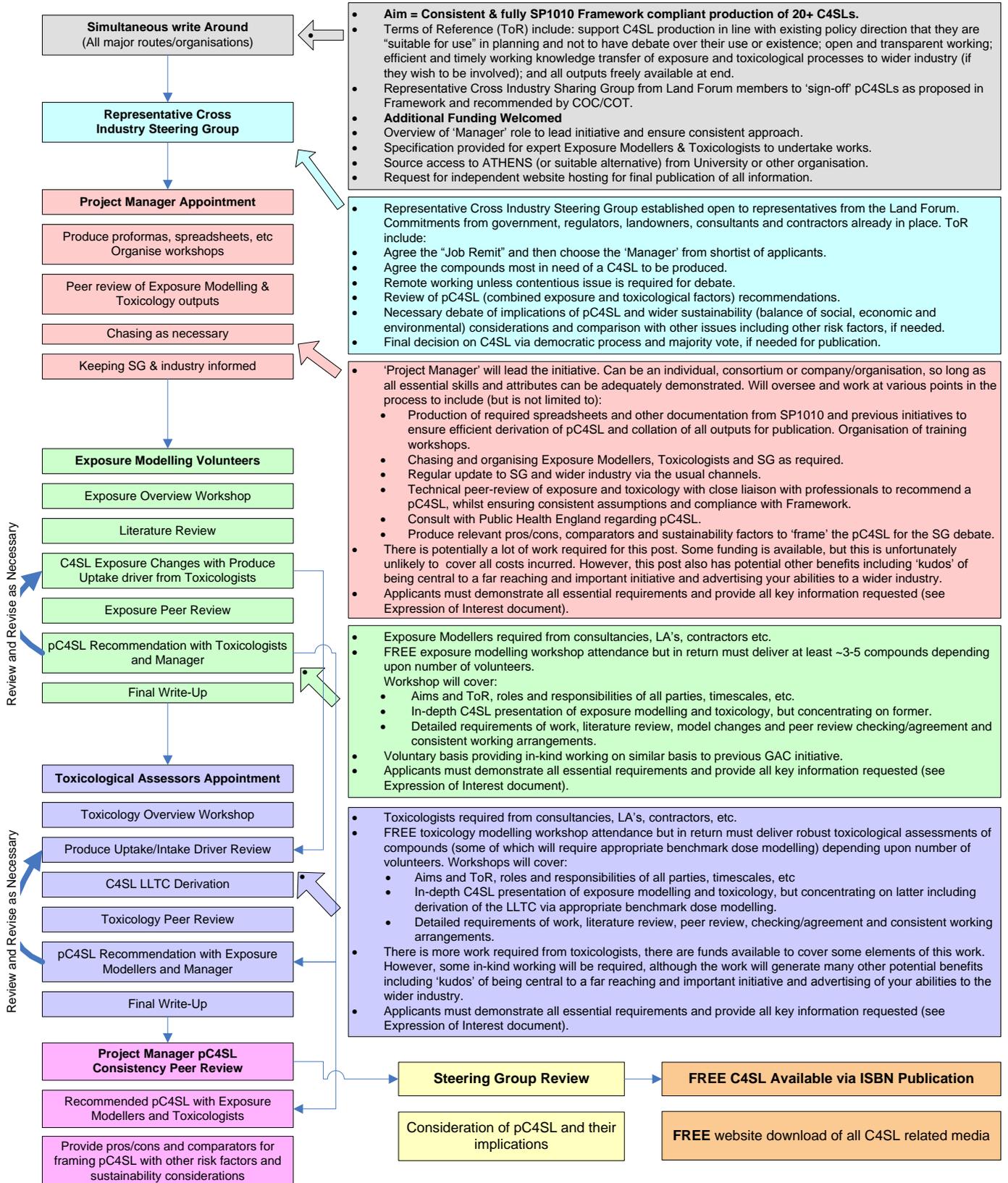
The following detailed aspects will also be sought at the subsequent application stage:

- The organisation which is applying as a T2 panel 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 organisations that are proposed as being involved in providing any areas of the T2 functions 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 and application submissions for the T1 and T2 roles respectively.

The SG's activities are to be chaired by Richard Boyle of HCA. In his absence, Hannah White, representing SAGTA, SoBRA 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 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 T1 and T2 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 be limited to:
 - Defined combinations of participants in the initiative and their allocated chemicals
 - The setting of programme timelines
 - Coordination and organisation of workshops
 - Coordination of SG links
 - A publication scheme
 - 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