



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

Participation in a Panel of C4SL Exposure Modellers

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 offers to participate as one of a panel of Exposure Modellers in the planned C4SL project. This text should be read in conjunction with the illustrative flow chart graphic that is contained as Graphic 1 in Annex 1 of this document.

The paper seeks to provide an indication of the envisaged Exposure Modeller role together with the anticipated interfaces with the parties involved, namely the Project Steering Group (SG), the Project Manager (PM) to be appointed to manage the project and Specialist Tier 1 and Tier 2 toxicologists.

Unlike the recent call for the toxicologists' roles, there is no Expression of Interest stage for Exposure Modellers. This call is aimed at creating a Panel of up to six nominated individuals as appointees, all of whom have been judged to satisfy requisite criteria. Should submissions be received from more than six applicants who meet the criteria, members of the Panel will be chosen through a random selection process that is outlined in the paper.

Those who are interested in responding to the invitation are directed to the required information to be furnished, together with parties' confirmations of approach, in particular:

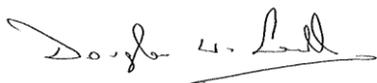
- i) For parties' and their nominated representatives' confirmation of both understanding and acceptance of the described constraints and requirements as described in the attached call document
- ii) Submissions of name(s) of nominated representative(s) to undertake the Exposure Modeller role in the project on the applicant party's behalf
- iii) Submissions of a short (1 page max) CV demonstrating the capability of those proposed to undertake the role to meet the criteria described in the attached document

Interested parties are, therefore, invited to respond to this call to myself as SAGTA Secretary, at dwlaidler@dwlenv.co.uk, by no later than close of business on 5th September 2017.

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 tender will be the responsibility of that party.

Any queries must be submitted via email, to be received by close of business on **25th August 2017**, to Doug Laidler (email: dwlaidler@dwlv.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 that reads "Doug Laidler". The signature is written in a cursive style and is underlined with a single horizontal line.

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 Applications: C4SL Exposure Modellers

1) Introduction

This enquiry is to invite applications from individuals, organisations or consortia to undertake the role of Exposure Modeller in a panel of Exposure Modellers to support the delivery of outputs relating the development of further Category 4 Screening Levels (C4SLs) for defined chemicals.

The enquiry is made on behalf of collaborative funders to the C4SL project (the Group). SAGTA is acting as coordinator and end client on behalf of the Group.

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. As a fundamental feature of the project, SAGTA is seeking to ensure this phase proceeds in a fashion that is coordinated with previous C4SL initiatives.

To date 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) and supporting Tier 2 (T2) toxicologists.
- iv) Planned the production of a number of preparatory documents to provide assistance and facilitate consistency of approach within the project as a whole. These are listed in Annex 1 and those that are available will be made available to parties who are appointed to the project.

This invitation seeks to identify (and inform) interested parties who, if found to broadly satisfy given criteria, are prepared to submit an offer to SAGTA to be appointed as Exposure Modellers.

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.

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

- i) The PM role - in acknowledgement of the expected scope of work involved.
- ii) Specialist toxicological (Tier 1 (T1)) work areas. This is in acknowledgement of the scale of specialism, professional responsibility and commitment required of those undertaking T1 appointments.

The technical development work associated with the Exposure Modeller role (literature searching, appraising and modelling) supporting outputs in this project is envisaged to be undertaken on an unpaid, voluntary basis by a range of practitioners prepared to contribute in this fashion. As such, participation will not involve any remuneration either for time spent or out of pocket expenses that may be incurred.

The final scope of work cannot be confirmed until the PM has been appointed and the scheme is further developed in detail, but is anticipated circa five days will be required from Exposure Modellers over a period of time.

Preliminary enquiries have indicated positive feedback that a number of organisations are prepared to so contribute.

The chemicals to be involved as the subjects of this Phase 2 project assessments are anticipated to number 20, but are not, as yet, specifically defined.

2) Project History, Background and Preparation

Background information relating to the C4SL Project is presented in Annex 1.

3) Project Roles

Annex 2 provides a summary of the respective roles and interfaces in the project.

4) Scope of applicants' submissions for role of Exposure Modeller

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 application for the role will be the sole responsibility of that party.

The sections below provide the criteria that must be met to be considered for an Exposure Modeller appointment. It is to be noted that it will be a condition of any confirmed appointment to undertake the role that the relevant party will, if called upon, provide SAGTA with relevant, appropriate evidence of the experience capabilities, approach and commitments to timelines etc that are contained in its application.

Applicants' submissions are to cover:

- i) *Approach to policy.* Confirmation of understanding and acceptance of the described constraints and requirements as described namely:
 - 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.
- ii) *Representation.* Name of nominated representative(s) to undertake the role on the party's behalf
- iii) *Capabilities.* Submission of a short (1 page max) CV demonstrating the capability of those proposed to undertake the role to possess:
 - A minimum of 2 years demonstrable experience/evidence in the following areas:
 - Assessing risks to humans from exposure to chemicals in the environment (preferably the soil environment).
 - Use of CLEA 1.04 and subsequent versions.
 - Collation of physical chemical data in accordance with the Environment Agency 2008 SR7 report.
 - Critically assessing literature data and other information relevant to select appropriate input parameters for use in risk assessment (preferably soil to plant concentration factors, dermal absorption factors, soil to dust transport factors).
 - Qualifications
 - Degree qualified.
 - Chartered or able to provide evidence of working towards chartership with a relevant institution.
- (iv) *Provision of continuity.* Confirmation that, in circumstances where it is found to be not reasonably possible for such named individuals to participate for the full period of the project, alternative resourcing of comparable capability and experience to those as may have been originally proposed will be provided.

- (v) *Adherence to timelines.* Confirmation to commit to project timelines as may be reasonably defined. At this point in time these remain subject to ongoing development. However, dates for a proposed 2-day Workshop (venue to be confirmed) have been provisionally assigned. These are envisaged to cover Toxicological and Exposure Modelling issues on consecutive days, and dates that have been provisionally reserved comprise either **8th and 9th November 2017** OR **28th and 29th November 2017**. Attendance at the Workshops by the nominated representatives is seen as pivotal to managing progress and quality of outputs on the project. **As such, applicants are requested to confirm that their nominated representative(s) is/are able to attend the workshop in person on either of these paired dates.**
- (vi) *Conflicts of interest.* Confirmation from parties that there is no awareness of circumstances that may give rise to possible conflicts of interest of whatever nature in carrying out the Exposure Modeller role.
- (vii) 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) Short listing process and basis of appointment assessment

The aim of this enquiry is to formally establish that your company is interested in being appointed for this work and can meet the required criteria which are described in Section 4.

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

5.1 Application assessment and notification

During the development stages of this project, more than six volunteers came forward for the exposure modelling task and SAGTA would like to take this opportunity to thank those who volunteered.

In the context of this call, should more than 6 applications be received that meet the criteria, SAGTA intends to follow the following procedure as being the most equitable in the circumstance:

- The SG will affirm those individual applicants meeting the criteria and inform SAGTA Secretary.
- On behalf of SAGTA, the SAGTA Secretary will confidentially create a master list of individuals in a random order.
- Out of a range that equates to the total number of individuals qualifying as potential Panel appointees the SG will randomly select six numbers and inform the SAGTA Secretary.
- The SAGTA Secretary will apply the numbers to the random list of qualifying applicants as a basis of identifying those to be invited to serve on the Panel.

It is envisaged notification of appointments to the Panel or otherwise will be made in September 2017.

As acknowledgement of their preparedness to participate, those qualifying applicants who are not selected as Panel appointees will be kept abreast of project developments. It is also hoped that should additional Exposure Modeller resources being required, those who have submitted offers to participate will keep their offers open.

In the event that vacancies occur due to withdrawal or the need for additional participants is identified, the above process will be repeated as the basis of identifying further invitees.

ANNEX 1 Project History, Background and Preparation

A1.1 Introduction

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

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 exposure modellers 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, toxicological criteria will be developed which will be incorporated into the 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.

A1.2 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.

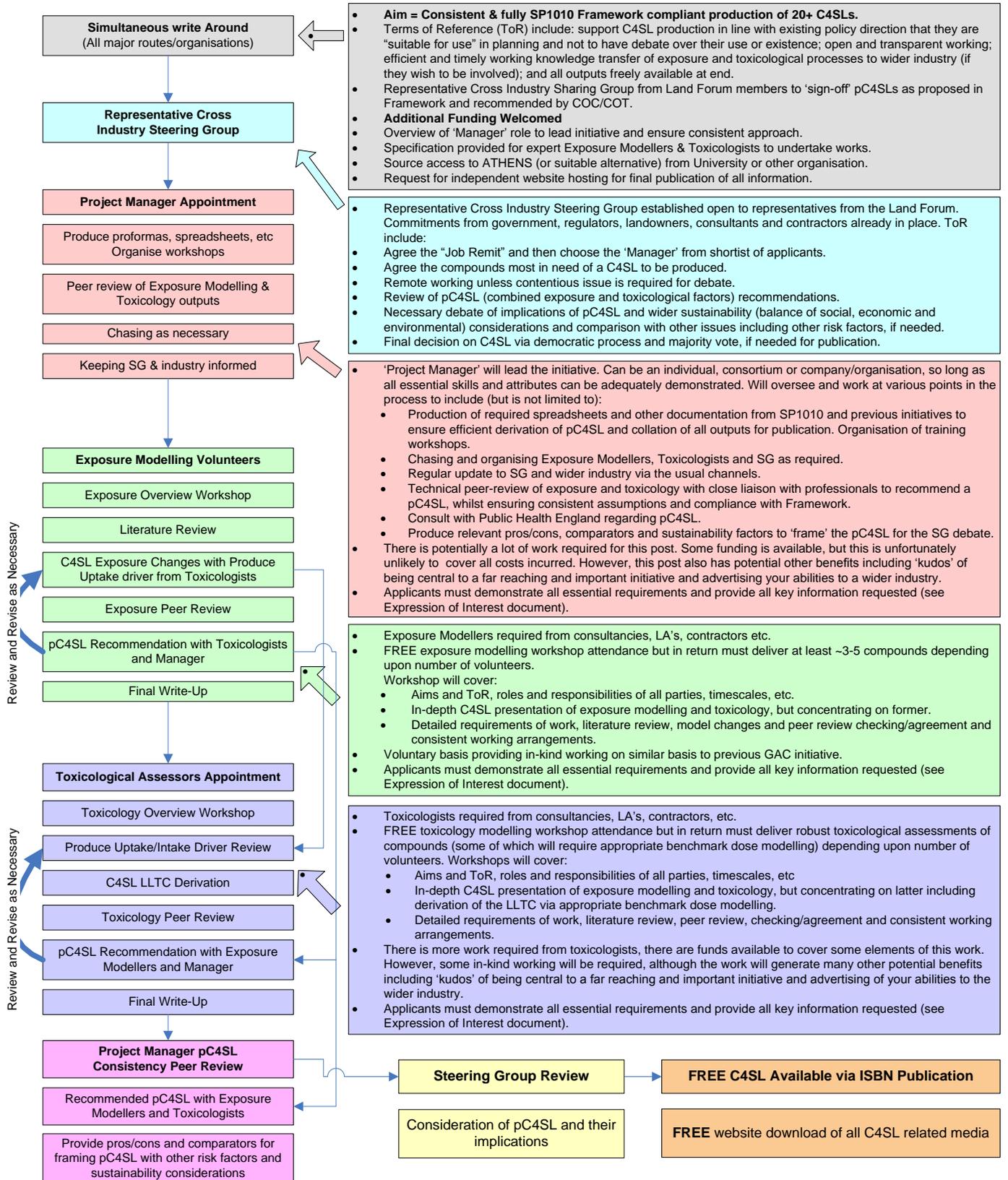
In this respect, Graphic 1 - *Proposals for C4SL Phase 2 Delivery Process* is attached.

Other titles of planned support provisions are listed below. Those documents that have been completed will be made available to parties appointed to the Panel.

- *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*

Graphic 1: Flow Chart Proposal - C4SL Phase 2 Delivery

Proposals for C4SL Phase 2 Delivery Process – July 2017 v2



ANNEX 2 Summary of the respective roles and interfaces in the project

A2.1 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 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 the assessment of the exposure modeller submissions.

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)

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.

The PM's responsibilities will centre on:

- *Management*: develop and implement a Resource Management Scheme and manage delivery of participants' outputs.
- *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.

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.

A2.3 Toxicologists

SAGTA is in the process of appointing two tiers of toxicologist:

- Specialist Tier 1 Toxicologists (T1): formally qualified and appropriately registered toxicologists. As defined above, 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): practitioners experienced in the field of contaminated land risk assessment with demonstrable depth and breadth of experience in toxicological sectors or applying toxicological principles.

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 PM and T2 practitioners.

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 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 at the *Toxicology Workshop*.
- Adherence to defined timeframes as may have been defined.