

SOLICITATION 1000166421
Provision of Scientific Expertise for Coordination and
Conduct of Human Health Risk Assessment, Scientific Peer Reviews and Consultations

Question 6

Referring to RFSO Section 1.6, Stream 2: Stream 2 of the proposed tasks and activities includes the provision of information gathering services to support human health risk assessment of novel substances (among other substances). Is there a particular novel substance or substance type being referenced? E.g. New chemicals on the market, nano materials, etc.

Response 6

The requirements could require services to support risk assessment of a range of types of chemicals, potentially including those mentioned.

Question 7

Referring to RFSO Section 1.6, Stream 3: Stream 3 of the proposed tasks and activities includes the scientific expertise services including the development of methodologies and application of new technologies such as in silico models. What defines an in silico model in this context?

Response 7

In silico models could include, but not limited to, (quantitative) structure activity models or PBPK modeling and other computational tools that could contribute to the characterization of potential health hazards of chemicals and risk assessment.

Question 8

Referring to RFSO Section 13.2, Streams 1, 2, and 3: For the Project Manager responsibilities, R3 requires "proof of dealings or working relationships with international regulatory agencies or organizations in relation to chemical risk assessment." Can Health Canada please define what they mean by "organizations"? Would private or non-profit entities be acceptable organizations in this regard?

Response 8

"Organization" is intended to include institutions with experience in human health risk assessment or related areas of work. Work performed for other entities, can be submitted; however, it must indicate how it relates to the work required under the different streams.

Question 9

Referring to RFSO Section 13.2, Stream 1: For the Human Health Risk Assessor responsibilities, R4 indicates the experiences listed should be related to HHRA conducted "according to Canadian regulatory guidance." Can Health Canada please specify which guidance documents that the respondents should use as a reference?

Response 9

This requirement refers to the principles and practices applied in Canadian regulatory risk assessment activities as reflected in published risk assessment reports. The requirement will be revised to read "...according to Canadian regulatory practices".

SOLICITATION 1000166421
Provision of Scientific Expertise for Coordination and
Conduct of Human Health Risk Assessment, Scientific Peer Reviews and Consultations

Question 10

Referring to RFSO Section 13.2, Streams 1, 2, and 3: Under “Capacity”, R10 indicates a point hinges on the availability of subcontractors to the respondent. If the respondent has sufficient expertise to address the Scope of Work within a stream and believes it can conduct all of the work in-house, is it still necessary to provide a list of subcontractors? That is, will the respondent’s proposal be penalized for not including a list of available subcontractors if it states it has sufficient means to fully execute and complete the full number of call-in projects potentially assigned in a year?

Response 10

If the respondent feels that it has sufficient resources to complete required work without the use of sub-contractors, there is no need to provide such a list. – see revised RFSO document section

Question 11

Referring to RFSO Section 9.1.1: Does the Cost Proposal need to be presented in a *Per Diem* format (per section 9.1.1, General Information for the Cost Proposal), or can it be presented as a flat rate for all deliverables?

Response 11

See revised RFSO document section.

Question 12

Could you please clarify the following phase from Stream 1: “Providing scientific consultation and/or scientific interpretation/data analysis on hazard characterization, exposure and risk assessment and risk management issues (first bullet, page 7).” Is this referring to writing chemical assessments or providing comments and analysis? Peer review was covered in the 3rd bullet of that stream.

Response 12

This activity could include either writing chemical assessments or scientific interpretation/data analysis and writing an integrated review.

Question 13

Regarding the final “bidder tendered price to perform the work from contract award to 15 Match 2016” on page 11 – how should this be calculated? Should this be the average per diem rate of the project manager and human health risk assessors? Should the per diem rate of research assistants be included (where research assistants may assist in data gathering)? Or should the per diem rates for the project manager and risk assessors be the only ones included?

Response 13

See revised RFSO section

SOLICITATION 1000166421
Provision of Scientific Expertise for Coordination and
Conduct of Human Health Risk Assessment, Scientific Peer Reviews and Consultations

Question 14

Do the mandatory requirements (M1 through M5) apply to all team members, or can the team collectively meet the requirements? For example, is it sufficient that the Project Manager and Risk Assessor have the credentials listed under M1, but not all team members do?

Response 14

See revised RFSO document

Question 15

The requirements for the Project Manager (R3) require proof of dealings or working relationships with international regulatory agencies or organizations. Does the use of “international” mean the regulatory agency itself (like the World Health Organization) or does it refer to work conducted outside applicant’s country of origin? For example, does work with the US Environmental Protection Agency or Health Canada meet this requirement?

Response 15

The requirement will be revised from “international regulatory agencies or organizations” to “international, national or provincial/state agencies or organizations”. National agencies such as Health Canada and the US Environmental Protection Agency meet this requirement.

Question 16

One of Tasks and Activities (p. 7) for Stream 2 involves review of risk assessments from international regulatory agencies. Would the U.S. EPA and ATSDR be considered international regulatory agencies in this context?

Response16

The requirement will be revised from “international regulatory agencies or organizations” to “international, national or provincial/state agencies or organizations”. National agencies such as the US Environmental Protection Agency and ATSDR meet this requirement.

Question 17

Please confirm that the Standing Offer Holder will be required to submit a firm/fixed price for each call-up issued (see Allocation of Work, p.11), based on an estimated level of effort and established hourly rates. –

Response 17

Yes see RFSO document section

SOLICITATION 1000166421
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Question 18

The text in Section 9.1.1 (Per Diem, p. 19) indicates that the proposed time rate and the estimated time requirement be provided for each labor category (including subcontractors). Please confirm that a list of hourly rates by labor category with a typical proportion of labor hours, is sufficient to meet this requirement.

Response18

Bidder must submit per diem rates within their proposal as set out in Appendix "B" Financial Table.

Question 19

Section 3.3 (pg 10) states: "Offer Holder must provide the services of the resource(s) named in the SOA to perform the work, unless the Standing Offer Holder is unable to do so for reasons beyond his/her control." Does this mean that the staffing for each call-up must include someone who is named in the proposal?

Response 19

No this has been amended. Please see section 3.3 Standing Offer Holder(s)' Obligations.

"Suppliers who are awarded a Standing Offer Agreement may however provide additional resources under the Human Health Risk Assessment prior to any resulting Call-up providing the proposed resource(s) meet the Technical evaluation criteria and the per diem rate under the Financial Table for that category set out in this RFSO".

Question 20

Requirement M1-M3 (pg 21) – Who does this refer to? Is this only for the project manager's experience, or do we need to show these requirements for each named resource?

Response 20

See amended RFSO document

Question 21

Requirement R1 for each stream (p. 22, 24, 25) relates to the *Project Manager*'s understanding of the scope of the RFSO. What is needed to show this understanding on an individual basis? Is it sufficient to show that the Project Manager played key roles in projects where the scope of the RFSO applies? Where should the general Technical Approach be included?

Response 21

See amended RFSO.

Question 22

Requirement R3 for each stream (p. 22, 24, 25) states that the project manager must have had dealings or working relationships with "international regulatory agencies or organizations." Please define international. If the individual worked with agencies based in another country (e.g., a Canadian company doing work with the U.S. EPA), would that count? Do international societies (e.g., Society of Toxicology) qualify? At what level of management is "organization" defined? For example, for a U.S. company, would work with multiple divisions within Health Canada qualify?

SOLICITATION 1000166421
Provision of Scientific Expertise for Coordination and
Conduct of Human Health Risk Assessment, Scientific Peer Reviews and Consultations

Response 22

Please see amended RFSO - note that R3 has been amended.

Yes, work with multiple divisions within Health Canada would qualify.

Question 23

Requirement R4 of Stream 1 (p. 22) asks for examples of human health risk assessments. In order to obtain the maximal points, does each listed assessment need to include each of the listed topics (hazard and exposure assessments conducted, dose-response assessment [e.g., BMD and PBPK], and risk characterization or remediation). Or can different examples focus on different topics? For example, if one example shows a hazard and dose-response assessment, and another shows exposure and risk characterization, is that sufficient?

Response 23

Please see amended RFSO document.

No, the listed assessment needs are examples only. Yes, the provided examples can focus on different topics of human health risk assessment. For example, if a company focuses solely on PBPK modeling, then PBPK modeling for a variety of chemicals and different issues for the chemicals should be highlighted.

Question 24

Requirement R4 (p. 24, 25, streams 2 and 3) - For the qualifications of the Human Health Risk Assessor, can multiple people be listed who fulfill different aspects of the named positions (e.g., separate people for hazard and exposure part of human health risk assessor)? In such cases, would the points be awarded based on the combined qualifications for that role, or some other approach?

Response 24

Yes all assessors will be rated. Yes, overall scoring will be determined based on all information submitted and the nature of the work performed by each all assessors collectively.

Question 25

How is knowledge of scientific peer review accounted for in the point ratings? This is the first item in the Stream 1 list of specifications, but we could not find any mention of such knowledge in the points-rated requirements for Stream 1.

Response 25

Knowledge of scientific peer review will be assessed as part of R4. Experience in scientific peer-review, science expertise and examples will all be taken into consideration.

Question 26

We have reports in the scientific literature (many reports prepared for the UK Environment Agency, for instance), albeit not in scientific journals. However, the majority of our work is confidential and therefore cannot be published in the scientific literature, and this is therefore a requirement that we would never be able to fulfil.

SOLICITATION 1000166421

Provision of Scientific Expertise for Coordination and

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A number of our confidential reports were commissioned by Health Canada over a period of >10 years; these would have allowed at least an equivalent, and probably a more directly relevant, means of judging our company's scientific merits.

Would you consider modifying future tender documentation, with the effect that the many reports our company has produced for Health Canada in the past (by scientists who are still in post) would at least have an equivalent status to reports published in scientific journals (which are often very poorly peer-reviewed)?

Response 26

Health Canada will sign a Non-Disclosure/Confidentiality Agreement with respect to the confidential information/documentation should this be required by your company/organisation for the submission of a proposal.

All documentation/bids must be received by Health Canada by the time and date set out under this RFSO

Health Canada will assess all information provided by all Bidders based on the information provided within their proposals as per the RFSO.

Question 27

Our organization is a UK-based Partnership and I would like to inquire whether we are eligible to submit a bid for the above tender? In particular I note that applicants require a Procurement Business Number and wondered if it is possible for a UK-based Partnership to acquire this? I did follow the link regarding this provided in the tender document but unfortunately it was broken.

Response 27

Please see amended RFSO - Link provided below:

<https://buyandsell.gc.ca/for-government>

Question 28

We were contacted regarding bidding on the Subject RFP, for which you are listed as the point of contact. Exponent has many offices, including five countries, but none in Canada. Before we start work to respond, I wanted to check in with you to see if there will be a disadvantage in not having a Canadian office.

Can you provide any advice on this?

Response 28

No there will not be a disadvantage; with the possible exception of some training, the work will be done on the contractors' premises.

Question 29

In Table A1 is their a weighting process for each personnel category and per diem rate in order to determine the overall "bidder's cost" or is it simply a sum of the five categories?

Response 29

Under Appendix "A" Financial Proposal the total dollar value will be based on the sum of the two category of resources for evaluation purposes only.

SOLICITATION 1000166421
Provision of Scientific Expertise for Coordination and
Conduct of Human Health Risk Assessment, Scientific Peer Reviews and Consultations

Question 30

Section 8.3 (page 18) of the RFSO states that the technical proposal should include a Work Plan/Project Schedule (Section 8.3.3). Could you please clarify if a hypothetical project should be used to provide this information?

Response 30

Please see amended RFSO rated criteria 1

Question 31

Are we able to list more than one person in the Project Manager category or are we limited to one Project Manager and one Back-up Project Manager?

Response 31

Please see M1 under the amended RFSO document

Question 32

Are we able to create new personnel categories in Tables A1, A3, A5 and A7 or are we limited to those listed in the tables? Specifically, do all personnel in the Human Health Risk Assessor category need to have the same per diem rate?

Response 32

A project team may contain up to 10 assessors.

Please see amended RFSO document under M1

Question 33

3.7 Call-up procedure

1. "Health Canada will enter an individual call-up [...] on the Project Authority or designate's decision, based on operational requirements, supplier availability for a complete requirement and supplier ranking"

□□□Our understanding is that a SOA may be signed with up to 5 suppliers per stream, and that the awarded contractors will be ranked based on their global score (per stream). The sentence above suggests that the supplier ranking may be of importance for the distribution of the contracts however no such information is provided in the RFSO. Could you please elaborate on this, assuming that several suppliers are awarded for a given stream. For instance:

- o Does it mean that the 1st rank will receive all the call-ups, and that only the call-ups refused by this supplier (or for which the supplier cannot provide a complete service) will be submitted to the next rank, and so on?
- o Or each supplier will be allocated an equal (or not?) part of the global budget and the call-up will be sent by starting with the first supplier, then the call-up to the second supplier, and so on?
- Or each supplier will be allocated a part of the global budget (part depending on the ranking?) and the call-up will be sent to one of the suppliers whatever its ranking?

Response 33

Please see section 3.6 Allocation of work under the amended RFSO document

SOLICITATION 1000166421
Provision of Scientific Expertise for Coordination and
Conduct of Human Health Risk Assessment, Scientific Peer Reviews and Consultations

Question 34

Should the SO holder be unable to perform the work requirement due to unavailability of resources or delivery schedule, the SO holder must notify the Project Authority in writing within four (4) hours of being contacted”

Could you please elaborate on what is meant by “being contacted”? does it mean the time when an email is sent by the project Authority?

The delay of 4 hours is extremely short considering that

o The person which receives the call-up (by email?) may not be at the office (e.g. on travel, in holidays, ill) or may not be available within 4 hours;

- An answer can be provided quickly when the call-up is provided in a non-busy period and when the workload can be estimated rapidly. However, based on our

- experience with numerous projects similar to those included in this RFSO, the decision to submit a proposal on a call-up may request more than 4 hours to allow for an estimate of the workload and an assessment of the availability of the qualified professionals and the possibility to achieve the time constraints. A period of at least 48 hours (2 business days) would be more appropriate

Response 34

Please see section 3.7 Call Up Procedures – this has been revised to 48 hours.

Question 35

8.3.3 Work Plan/Project Schedule

- Our understanding is that this section should be deleted since no specific project has to be evaluated in the technical proposal.
- If our understanding is wrong, could you please elaborate on what is actually expected for this item?

Response 35

Please see amended RFSO document under R1.

Question 36

On page 21 of the RFSO, under M1, if a staff member holds a “CIH = Certified Industrial Hygienist” or “ROH = Registered Occupational Hygienist” accreditation, but not a M.Sc, can this be considered as “scientific field relevant to human health risk assessment”

Réponse 36

CIH and ROH does not quality or meet the mandatory requirement for project manager or risk assessor.