## RETURN BIDS TO: RETOURNER LES SOUMISSIONS À:

Health Canada / Santé Canada 200, Eglantine Driveway Tunney's Pasture Ottawa Ontario K1A 0K9 Attn: Darlene Fisher Email: Darlene.Fisher2@canada.ca

# REQUEST FOR PROPOSAL DEMANDE DE PROPOSITION

#### Proposal To: Health Canada

We hereby offer to sell to Her Majesty the Queen in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods, services, and construction listed herein and on any attached sheets at the price(s) set out thereof.

#### Proposition à: Santé Canada

Nous offrons par la présente de vendre à Sa Majesté la Reine du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens, services et construction énumérés ici sur toute feuille ci-annexées, au(x) prix indiqué(s).

## Instructions : See Herein Instructions: Voir aux présentes

## Issuing Office – Bureau de distribution

Health Canada / Santé Canada 200, Eglantine Driveway Tunney's Pasture Ottawa Ontario K1A 0K9

## Title – Sujet In vitro toxicity testing of vaping liquids and vaping liquid ingredients Solicitation No. – N° de l'invitation Date 1000203303 September 19, 2018 Solicitation Closes at – L'invitation Time Zone prend fin à **Fuseau horaire** EDT 2:00 PM on / le - October 9, 2018 F.O.B. - F.A.B. Plant-Usine: Destination: Other-Autre: Address Enquiries to: - Adresser toutes questions à : Name: Darlene Fisher Email: Darlene.Fisher2@canada.ca Telephone - téléphone : 613-941-2125 Destination – of Goods, Services, and Construction: Destination – des biens, services et construction : See Herein – Voir ici Delivery required - Livraison exigée See Herein – Voir ici Vendor/firm Name and address Raison sociale et adresse du fournisseur/de l'entrepreneur Facsimile No. – N° de télécopieur : Telephone No. – N° de téléphone : Name and title of person authorized to sign on behalf of Vendor/firm Nom et titre de la personne autorisée à signer au nom du fournisseur/de l'entrepreneur (type or print)/ (taper ou écrire en caractères d'imprimerie)

Signature

Date

Canada

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## PART 1 - GENERAL INFORMATION

#### 1.1 Introduction

The bid solicitation is divided into seven parts plus attachments and annexes, as follows:

- Part 1 General Information: provides a general description of the requirement;
- Part 2 Bidder Instructions: provides the instructions, clauses and conditions applicable to the bid solicitation;
- Part 3 Bid Preparation Instructions: provides Bidders with instructions on how to prepare their bid;
- Part 4 Evaluation Procedures and Basis of Selection: indicates how the evaluation will be conducted, the evaluation criteria that must be addressed in the bid, and the basis of selection;
- Part 5 Certifications and Additional Information: includes the certifications and additional information to be provided;
- Part 6 Security, Financial and Other Requirements: includes specific requirements that must be addressed by Bidders; and
- Part 7 Resulting Contract Clauses: includes the clauses and conditions that will apply to any resulting contract.

The Annexes include the Statement of Work, the Basis of Payment, Security Requirements, the Security Requirements Checklist, the Task Authorization Form and any other annexes.

#### 1.2 Summary

Health Canada requires the services of a Contractor to conduct *in vitro* toxicity testing of identified chemicals and vaping liquid samples in support of research activities at the Tobacco Control Directorate (TCD) on an "as and when requested basis" using a Task Authorization (TA) process. A minimum of one (1) Project Manager and one (1) Laboratory Technician are required. Work is to be completed at the Contractor's place of business.

The period of the contract is from date of Contract Award (estimated November 1, 2018) to March 31, 2020 with two (2) irrevocable one(1)-year option periods.

There are no security requirements associated with this requirement.

This requirement is not subject to trade agreements.

#### 1.3 Debriefings

Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

## PART 2 - BIDDER INSTRUCTIONS

### 2.1 Standard Instructions, Clauses and Conditions

All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the <u>Standard Acquisition Clauses and Conditions Manual</u> (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.

The <u>2003</u> (2018-05-22) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

Subsection 5.4 of <u>2003</u>, Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: 60 days Insert: one-hundred and twenty (120) calendar days

#### 2.2 Submission of Bids

Bids must be submitted to Darlene Fisher by the date and time indicated on page 1 of the Request for Proposal, through one of the methods below:

A. Via E-mail

Emailed bids must be submitted only to <u>Darlene.fisher2@canada.ca</u> by the date, time and place indicated on page 1 of the Request for Proposal.

The RFP Reference Number and the title of the Requirement must be in the subject line of your email and your Bid should be structured in accordance to Part 3 – Bid Preparation Instructions.

If the Bid is **greater than 20mb** then the bid submission must be directed to the Bid Receiving Unit at the address below.

B. Via Bid Receiving Unit

Any bid not submitted via e-mail as above must be delivered to the following address:

Health Canada Bid Receiving Unit Federal Records Centre Building, 161 Goldenrod Driveway (Loading Dock), Ottawa, Ontario K1A 0K9 Attention: Darlene Fisher RFP Reference Number: 1000203303 Hours of Operation: 07h30 to 16h30 Monday to Friday

The RFP Reference Number and the name of the RFP Authority must be marked on all documents, binders and respective envelopes.

Due to the nature of the Request for Proposal, transmission of offers by facsimile will not be accepted.

## 2.3 Former Public Servant

Contracts awarded to former public servants (FPS) in receipt of a pension or of a lump sum payment must bear the closest public scrutiny, and reflect fairness in the spending of public funds. In order to comply with Treasury Board policies and directives on contracts awarded to FPS, offerors must provide the information required below before the issuance of a standing offer. If the answer to the questions and, as applicable the information required have not been received by the time the evaluation of offers is completed, Canada will inform the Offeror of a time frame within which to provide the information. Failure to comply with Canada's request and meet the requirement within the prescribed time frame will render the offer non-responsive.

Definitions

For the purposes of this clause,

"former public servant" is any former member of a department as defined in the Financial Administration Act R.S., 1985, c. F-11, a former member of the Canadian Armed Forces or a former member of the Royal Canadian Mounted Police. A former public servant may be:

- a. an individual;
- b. an individual who has incorporated;
- c. a partnership made of former public servants; or
- d. a sole proprietorship or entity where the affected individual has a controlling or major interest in the entity.

"lump sum payment period" means the period measured in weeks of salary, for which payment has been made to facilitate the transition to retirement or to other employment as a result of the implementation of various programs to reduce the size of the Public Service. The lump sum payment period does not include the period of severance pay, which is measured in a like manner.

"pension" means a pension or annual allowance paid under the Public Service Superannuation Act (PSSA), R.S., 1985, c. P-36, and any increases paid pursuant to the Supplementary Retirement Benefits Act, R.S., 1985, c. S-24 as it affects the PSSA. It does not include pensions payable pursuant to the Canadian Forces Superannuation Act, R.S., 1985, c. C-17, the Defence Services Pension Continuation Act, 1970, c. D-3, the Royal Canadian Mounted Police Pension Continuation Act , 1970, c. R-10, and the Royal Canadian Mounted Police Superannuation Act, R.S., 1985, c. R-11, the Members of Parliament Retiring Allowances Act, R.S. 1985, c. M-5, and that portion of pension payable to the Canada Pension Plan Act, R.S., 1985, c. C-8.

Former Public Servant in Receipt of a Pension

As per the above definitions, is the Offeror a FPS in receipt of a pension? YES INO I

If so, the Offeror must provide the following information, for all FPS in receipt of a pension, as applicable:

- a. name of former public servant;
- b. date of termination of employment or retirement from the Public Service.

By providing this information, Offerors agree that the successful Offeror's status, with respect to being a former public servant in receipt of a pension, will be reported on departmental websites as part of the published proactive disclosure reports in accordance with Contracting Policy Notice: 2012-2 and the Guidelines on the Proactive Disclosure of Contracts.

Work Force Adjustment Directive

Is the Offeror a FPS who received a lump sum payment pursuant to the terms of the Work Force Adjustment Directive? YES \_\_ NO \_\_

If so, the Offeror must provide the following information:

- a. name of former public servant;
- b. conditions of the lump sum payment incentive;
- c. date of termination of employment;
- d. amount of lump sum payment;
- e. rate of pay on which lump sum payment is based;
- f. period of lump sum payment including start date, end date and number of weeks;
- g. number and amount (professional fees) of other contracts subject to the restrictions of a work force adjustment program.

For all contracts awarded during the lump sum payment period, the total amount of fees that may be paid to a FPS who received a lump sum payment is \$5,000, including Applicable Taxes.

#### 2.4 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than ten (10) calendar days before the bid closing date. Enquiries received after that time may not be answered.

Bidders should reference as accurately as possible the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated and the enquiry can be answered to all Bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

#### 2.5 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

### 2.6 Basis for Canada's Ownership of Intellectual Property

Health Canada has determined that any intellectual property rights arising from the performance of the Work under the resulting contract will belong to Canada, for the following reasons, as set out in the <u>Policy</u> <u>on Title to Intellectual Property Arising Under Crown Procurement Contracts</u>: the main purpose of the Contract, or of the deliverables contracted for, is to generate knowledge and information for public dissemination.

## **PART 3 - BID PREPARATION INSTRUCTIONS**

## 3.1 Bid Preparation Instructions

Canada requests that Bidders provide their offer in separate sections as follows (Bidders choose A or B as their submission method):

A. For electronic bid submissions via e-mail:

Section I:	Technical Bid (one (1) electronic copy submitted via e-mail)
Section II:	Financial Bid (one (1) electronic copy submitted via e-mail)
Section III:	Certifications (one (1) electronic copy submitted via e-mail)

B. For hard-copy submissions to Bid Receiving Unit:

Section I:	Technical Bid (four (4) hard-copies and one (1) soft copy via CD)
Section II:	Financial Bid (one (1) hard-copy and one (1) soft copy via CD)
Section III:	Certifications (one (1) hard-copy and one (1) soft copy via CD)

If there is a discrepancy between the wording of the soft copy and the hard copy, the wording of the hard copy will have priority over the wording of the soft copy.

Prices must appear in the financial offer only. No prices must be indicated in any other section of the offer.

Canada requests that bidders follow the format instructions described below in the preparation of hard copy of their bid:

(a) use 8.5 x 11 inch (216 mm x 279 mm) paper;

(b) use a numbering system that corresponds to the bid solicitation.

In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary steps to incorporate environmental considerations into the procurement process <u>Policy</u> <u>on Green Procurement</u> (https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32573). To assist Canada in reaching its objectives, bidders should:

- 1) use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and containing minimum 30% recycled content; and
- use an environmentally-preferable format including black and white printing instead of colour printing, printing double sided/duplex, using staples or clips instead of cerlox, duotangs or binders.

## Section I: Technical Bid

In their technical bid, Bidders should demonstrate their understanding of the requirements contained in the bid solicitation and explain how they will meet these requirements. Bidders should demonstrate their capability and describe their approach in a thorough, concise and clear manner for carrying out the work.

The technical bid should address clearly and in sufficient depth the points that are subject to the evaluation criteria against which the bid will be evaluated. Simply repeating the statement contained in the bid solicitation is not sufficient. In order to facilitate the evaluation of the bid, Canada requests that Bidders address and present topics in the order of the evaluation criteria under the same headings. To

avoid duplication, Bidders may refer to different sections of their bids by identifying the specific paragraph and page number where the subject topic has already been addressed.

## Section II: Financial Bid

**3.1.1** Bidders must submit their financial bid in accordance with the Pricing Schedule detailed in Annex "B".

## 3.1.2 Exchange Rate Fluctuation

C3011T(2013-11-06), Exchange Rate Fluctuation

## Section III: Certifications

Bidders must submit the certifications and additional information required under Part 5.

## PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

#### 4.1 Evaluation Procedures

- (a) Bids will be assessed in accordance with the entire requirement of the bid solicitation including the technical and financial evaluation criteria.
- (b) An evaluation team composed of representatives of Canada will evaluate the bids.

## 4.1.1 Technical Evaluation

## 4.1.1.1 Mandatory Technical Criteria

Refer to Appendix 1 to Part 4.

## 4.1.1.2 Point Rated Technical Criteria

Refer to Appendix 1 to Part 4.

## 4.1.2 Financial Evaluation

## 4.1.2.1 Mandatory Financial Criteria

SACC Manual Clause A0220T (2014-06-26), Evaluation of Price

### 4.2 Basis of Selection

#### 4.2.1 Lowest Price per Point

SACC Manual Clause A0035T, Basis of Selection – Lowest Price Per Point

- 1. To be declared responsive, a bid must:
  - a. comply with all the requirements of the bid solicitation;
  - b. meet all mandatory technical evaluation criteria; and
  - c. obtain the required minimum of 21 points overall for the technical evaluation criteria which are subject to point rating. The rating is performed on a scale of 42 points.
- 2. Bids not meeting (a) or (b) or (c) will be declared non-responsive. Neither the responsive bid that receives the highest number of points nor the one that proposed the lowest price will necessarily be accepted. The responsive bid with the lowest evaluated price per point will be recommended for award of a contract.

## APPENDIX 1 TO PART 4 – TECHNICAL EVALUATION CRITERIA

## 1. Mandatory Technical Criteria

At bid closing time, the Bidder must comply with the following mandatory technical criteria and provide the necessary documentation to support compliance. Any bid which fails to meet the following mandatory technical criteria will be declared non-responsive. Each criterion should be addressed separately.

ltem	Description	Compliant (Yes/No)	Reference to Bidder's Proposal (page #)
	The Bidder must submit a project team including a minimum of:	Yes	
	<ul> <li>One (1) Project Manager/Lead; and</li> <li>One (1) Laboratory Technician</li> </ul>	No	
	Bidders must include within their Technical Offer a detailed résumé for EACH proposed resource which must include a detailed, chronological listing of:		
M-1	<ul> <li>his/her technical experience and capability as a Project Manager/Lead or Laboratory Technician; and</li> <li>his/her education and professional attainments and academic credentials.</li> </ul>		
	In addition, for every resource proposed by the Bidder who is not an employee of the firm, the actual resource must certify that they are aware that they are being proposed as part of the Bid and state their relationship with the firm.		
	The Bidder's proposed project team from M-1 must submit five (5) projects of similar scope, size and complexity* where the work was completed within the last eight (8) years from date of bid closing.	Yes	
M-2	*This includes projects testing at least 10 or more chemicals/compounds using at least 5 different <i>in vitro</i> toxicity assays in at least 2 different cell types.		
	The experience of either project team member will suffice for this criterion, although if both team members worked on		

ltem	Description	Compliant (Yes/No)	Reference to Bidder's Proposal (page #)
	a project, it will only be counted once.		
	For each project, the Bidder must submit all of the following details:		
	<ul> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail)</li> </ul>		
M-3	The Bidder's Project Manager/Lead and the Laboratory Technician from M-1 must each have a minimum of sixty (60) months' experience in <i>in vitro</i> toxicity assessment, including experience related to cell-based assays. In order to demonstrate experience, the Bidder must submit projects with all of the following details: • a summary describing the project, including but not	Yes	
	<ul> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail)</li> </ul>		
	The Bidder's proposed Project Manager/Lead and Laboratory Technician from M-1 must demonstrate experience with the development of robust <i>in vitro</i> protocols for toxicity assessment. This experience must include activities that employed a range of human and mammalian cell lines (including cells of the respiratory tract and lungs).	Yes	
M-4	<ul> <li>In order to demonstrate experience, the Bidder must submit projects with all of the following details:</li> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail)</li> </ul>		
	The experience of either project team member will suffice		

ltem	Description	Compliant (Yes/No)	Reference to Bidder's Proposal (page #)
	for this criterion.		
M-5	The Bidder's proposed Project Manager/Lead from M-1 must have a Canadian graduate degree (Master's level or Doctorate) or a recognized Canadian equivalent. And,	Yes	
	The Bidder's proposed laboratory technician from M-1 must have a Canadian undergraduate degree in Science (Bachelors level) or a recognized Canadian equivalent. To demonstrate compliance, the Bidder must provide a copy of their degree with the bid.		
M-6	<ul> <li>Work Plan and Methodological Approach</li> <li>The Bidder must provide a written Work Plan and Methodological Approach to undertake the work identified in the Statement of Work at Annex 'A'.</li> <li>The Work Plan must show: <ul> <li>A logical and detailed organization of the tasks to be completed for the project as per the SOW including all methods and experimental details;</li> <li>Estimated timelines for completion of apph task;</li> </ul> </li> </ul>	Yes	
	<ul> <li>Estimated timelines for completion of each task;</li> <li>Where applicable, provide details on team composition, the responsibilities of the team members and the expected effort per task;</li> <li>The Methodological Approach must be provided in sufficient detail to allow for a complete understanding of the approach to the work undertaken by the Senior or Lead Resource and should identify the advantages and disadvantages of the proposed Methodological Approach.</li> </ul>		

## 2. Point Rated Technical Criteria

Each Technical Proposal which meets all the Mandatory Requirements will be evaluated and scored in accordance with the point rated technical evaluation criteria provided below.

The Bidder must meet a minimum of 21 points overall to be responsive.

ltem	Description	Max Points Available	Reference to Bidder's Proposal (page #)
PR-1	Experience of Bidder:	5	()
	The Bidder must demonstrate experience with the <i>in vitro</i> toxicity testing of vaping (electronic cigarette) liquids in cell-based assays.		
	The experience of either project team member will suffice for this criterion, although if both team members worked on a project, it will only be counted once.		
	<b>Points Breakdown:</b> One (1) point for each of the <i>in vitro</i> studies conducted using vaping liquids to a maximum of five (5) points; To demonstrate experience, the Bidder must submit projects with all of the following details:		
	<ul> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail)</li> </ul>		
PR-2	Experience of Project Manager/Lead:	5	
	The Bidder's proposed Project Manager/Lead from M-1 must demonstrate experience with the <i>in vitro</i> assays described in the Statement of Work including cytotoxicity and genotoxicity assays and cell-based assays measuring oxidative stress, inflammation and <i>in vitro</i> cardiovascular function.		
	<b>Points Breakdown:</b> One (1) point for each of the number of assays for which the Senior Lead has experience to a maximum of five (5) points. To demonstrate experience, the Bidder must submit projects with all of the following details:		
	<ul> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail), number of assays, etc.</li> </ul>		
PR-3	Experience of Bidder:	10	
	The Bidder must demonstrate experience with quantifying		

lterre	Description	Max Points Available	Reference to
ltem	Description		Bidder's Proposal (page #)
	multiple proteins/markers in cell lysates and culture media including via ELISA or multi-plex methodology.		
	The experience of either project team member will suffice for this criterion, although if both team members worked on a project, it will only be counted once.		
	<b>Points Breakdown:</b> One (1) point for each of the number of projects completed in the last 5 years that involved projects that used ELISA or multi-plex methods to quantify proteins in the cell lysates or culture media to a maximum of ten (10) points; To demonstrate experience, the Bidder must submit projects with all of the following details:		
	a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail), number of assays, etc.		
PR-4	<b>Experience of Bidder:</b> The Bidder must demonstrate experience designing and conducting cell-based <i>in vitro</i> assays assessing chemical toxicity including dose-responses and IC <sub>50</sub> determination.	5	
	The experience of either project team member will suffice for this criterion, although if both team members worked on a project, it will only be counted once.		
	<b>Points Breakdown:</b> One (1) point for each of the different assays performed to a maximum of five (5) points; To demonstrate experience, the Bidder must submit projects with all of the following details:		
	<ul> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and a mail) number of account ato</li> </ul>		
PR-5	number and e-mail), number of assays, etc. Experience of Bidder:	5	
	The Bidder must demonstrate experience conducting cell- based <i>in vitro</i> toxicity assays using a variety of cell types (human, mammalian, cell lines, primary cells) including cell		

ltem	Description	Max Points Available	Reference to Bidder's
			Proposal (page #)
	types related to the respiratory tract or lungs.		
	The experience of either project team member will suffice for this criterion, although if both team members worked on a project, it will only be counted once.		
	<b>Points Breakdown:</b> One (1) point for each of the different cell types used in previous studies to a maximum of five (5) points; To demonstrate experience, the Bidder must submit projects with all of the following details:		
	<ul> <li>a summary describing the project, including but not limited to: who the work was conducted for, the duration of the project (start and end dates), the project lead name and contact information (phone number and e-mail), number of assays, etc.</li> </ul>		
PR-6	Work Plan	4	
	The proposed Work Plan from M-4 will be assessed and scored as follows:		
	A score of four (4) points will be assigned if the Work Plan is Excellent – provide realistic details and explanations of work phase definitions, activities, and deliverables. Includes details on number of staff hours required to complete each task for a block of 50 chemicals and describes feasible arrangements to run more samples or more tasks simultaneously. The knowledge, experience or approach demonstrated must ensure highly effective performance on this aspect of the work. Addresses and exceeds as outlined in the Statement of Work.		
	A score of three (3) points will be assigned if the Bidder's response to this criterion addresses the requirement well. The knowledge, experience or approach demonstrated must ensure more than adequate performance on this aspect of the work. Addresses all elements as outlined in the Statement of Work, including number of staff hours required to complete each tasks for a block of 50 chemicals.		
	A score of two (2) points will be assigned if the Bidder's response satisfactorily addresses this criterion. The knowledge, experience or approach demonstrated must meet the minimum needed for adequate performance on this aspect of the work. Addresses most elements as outlined in		

		Max Points Available	Reference to
Item	Description		Bidder's Proposal (page #)
	the Statement of Work.		
	A score of one (1) point will be assigned if the Bidder's response minimally addresses the criterion. The knowledge, experience or approach demonstrated is insufficient for the effective performance of the work. Addresses few elements as outlined in the Statement of Work.		
	A score of zero (0) points will be assigned if the Bidder does not address the criterion. Does not address any elements as outlined in the Statement of Work.		
PR-7	Methodological Approach	8	
	The proposed Methodological Approach from M-4 will be assessed and scored as follows:		
	Eight (8) points		
	<ul> <li>Addresses and exceeds as outlined in the Statement of Work.</li> </ul>		
	A score of eight (8) points will be assigned if the methodological approach is Excellent and fully shows:		
	<ul> <li>a. Understanding of the project objectives;</li> <li>b. Understanding of what is included from the scope of the research and what; literature sources that may be referenced;</li> <li>c. Proposed analytical strategies; and</li> <li>d. Strategies to mitigate possible project challenges.</li> </ul>		
	<ul> <li>Addresses all elements as outlined in the Statement of Work.</li> </ul>		
	A score of four (6) points will be assigned if the methodological approach addresses the following criteria well:		
	<ul> <li>a. Understanding of the project objectives;</li> <li>b. Understanding of what is included from the scope of the research and what; literature sources that may be referenced;</li> <li>c. Proposed analytical strategies; and</li> <li>d. Strategies to mitigate possible project challenges.</li> </ul>		
	<ul> <li>Addresses most elements as outlined in the Statement of Work.</li> </ul>		

ltem	Description	Max Points Available	Reference to Bidder's Proposal (page #)
	A score of four (4) points will be assigned if the methodological approach satisfactorily addresses the following criteria:		
	<ul> <li>a. Understanding of the project objectives;</li> <li>b. Understanding of what is included from the scope of the research and what; literature sources that may be referenced;</li> <li>c. Proposed analytical strategies; and</li> <li>d. Strategies to mitigate possible project challenges.</li> </ul>		
	<ul> <li>Addresses some elements as outlined in the Statement of Work.</li> </ul>		
	A score of two (2) points will be assigned if the methodological approach minimally addresses the following criteria:		
	<ul> <li>a. Understanding of the project objectives;</li> <li>b. Understanding of what is included from the scope of the research and what; literature sources that may be referenced;</li> <li>c. Proposed analytical strategies; and</li> <li>d. Strategies to mitigate possible project challenges.</li> </ul>		
	A score of zero (0) points will be assigned if the Bidder does not address the criterion. Does not address any elements as outlined in the Statement of Work.		
	Maximum available points: 42		
	Minimum Pass Mark: 21		
	Bidders Score:		

## PART 5 – CERTIFICATIONS AND ADDITIONAL INFORMATION

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue, whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

## 5.1 Certifications Required with the Bid

Bidders must submit the following duly completed certifications as part of their bid.

## 5.1.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the Integrity declaration form available on the <u>Forms for the Integrity Regime</u> website (http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html), to be given further consideration in the procurement process.

## 5.2 Certifications Precedent to Contract Award and Additional Information

The certifications and additional information listed below should be submitted with the bid but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame specified will render the bid non-responsive.

#### 5.2.1 Integrity Provisions – Required Documentation

In accordance with the section titled Information to be provided when bidding, contracting or entering into a real procurement agreement of the <u>Ineligibility and Suspension Policy</u> (http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

## 5.2.2 Additional Certifications Precedent to Contract Award

#### 5.2.2.1 Former Public Servant

Contracts awarded to former public servants (FPS) in receipt of a pension or of a lump sum payment must bear the closest public scrutiny, and reflect fairness in the spending of public funds. In order to comply with Treasury Board policies and directives on contracts awarded to FPSs, bidders must provide the information required below before contract award. If the answer to the questions and, as applicable the information required have not been received by the time the evaluation of bids is completed, Canada will inform the Bidder of a time frame within which to provide the information. Failure to comply with Canada's request and meet the requirement within the prescribed time frame will render the bid non-responsive.

### Definitions

For the purposes of this clause,"former public servant" is any former member of a department as defined in the *Financial Administration Act*, R.S., 1985, c. F-11, a former member of the Canadian Armed Forces or a former member of the Royal Canadian Mounted Police. A former public servant may be:

- a. an individual;
- b. an individual who has incorporated;
- c. a partnership made of former public servants; or
- d. a sole proprietorship or entity where the affected individual has a controlling or major interest in the entity.

"lump sum payment period" means the period measured in weeks of salary, for which payment has been made to facilitate the transition to retirement or to other employment as a result of the implementation of various programs to reduce the size of the Public Service. The lump sum payment period does not include the period of severance pay, which is measured in a like manner.

"pension" means a pension or annual allowance paid under the <u>Public Service Superannuation</u> <u>Act</u> (PSSA), R.S., 1985, c. P-36, and any increases paid pursuant to the <u>Supplementary</u> <u>Retirement Benefits Act</u>, R.S., 1985, c. S-24 as it affects the PSSA. It does not include pensions payable pursuant to the <u>Canadian Forces Superannuation Act</u>, R.S., 1985, c. C-17, the <u>Defence</u> <u>Services Pension Continuation Act</u>, 1970, c. D-3, the <u>Royal Canadian Mounted Police Pension</u> <u>Continuation Act</u>, 1970, c. R-10, and the <u>Royal Canadian Mounted Police Superannuation Act</u>, R.S., 1985, c. R-11, the <u>Members of Parliament Retiring Allowances Act</u>, R.S., 1985, c. M-5, and that portion of pension payable to the <u>Canada Pension Plan Act</u>, R.S., 1985, c. C-8.

#### Former Public Servant in Receipt of a Pension

As per the above definitions, is the Bidder a FPS in receipt of a pension? Yes () No ()

If so, the Bidder must provide the following information, for all FPSs in receipt of a pension, as applicable:

- a. name of former public servant;
- b. date of termination of employment or retirement from the Public Service.

By providing this information, Bidders agree that the successful Bidder's status, with respect to being a former public servant in receipt of a pension, will be reported on departmental websites as part of the published proactive disclosure reports in accordance with <u>Contracting Policy</u> <u>Notice: 2012-2</u> and the <u>Guidelines on the Proactive Disclosure of Contracts</u>.

#### Work Force Adjustment Directive

Is the Bidder a FPS who received a lump sum payment pursuant to the terms of the Work Force Adjustment Directive? **Yes** () **No** ()

If so, the Bidder must provide the following information:

- a. name of former public servant;
- b. conditions of the lump sum payment incentive;
  - c. date of termination of employment;
  - d. amount of lump sum payment;
  - e. rate of pay on which lump sum payment is based;
  - f. period of lump sum payment including start date, end date and number of weeks;
  - g. number and amount (professional fees) of other contracts subject to the restrictions of a work force adjustment program.

For all contracts awarded during the lump sum payment period, the total amount of fees that may be paid to a FPS who received a lump sum payment is \$5,000, including Applicable Taxes.

#### 5.2.3.2 Status and Availability of Resources

The Bidder certifies that, should it be awarded a contract as a result of the bid solicitation, every individual proposed in its bid will be available to perform the Work as required by Canada's representatives and at the time specified in the bid solicitation or agreed to with Canada's representatives. If for reasons beyond its control, the Bidder is unable to provide the services of an individual named in its bid, the Bidder may propose a substitute with similar qualifications and experience. The Bidder must advise the Contracting Authority of the reason for the substitution and provide the name, qualifications and experience of the proposed replacement. For the purposes of this clause, only the following reasons will be considered as beyond the control of the Bidder: death, sickness, maternity and parental leave, retirement, resignation, dismissal for cause or termination of an agreement for default.

If the Bidder has proposed any individual who is not an employee of the Bidder, the Bidder certifies that it has the permission from that individual to propose his/her services in relation to the Work to be performed and to submit his/her résumé to Canada. The Bidder must, upon request from the Contracting Authority, provide a written confirmation, signed by the individual, of the permission given to the Bidder and of his/her availability. Failure to comply with the request may result in the bid being declared non-responsive.

#### 5.2.3.3 Education and Experience

The Bidder certifies that all the information provided in the résumés and supporting material submitted with its bid, particularly the information pertaining to education, achievements, experience and work history, has been verified by the Bidder to be true and accurate. Furthermore, the Bidder warrants that every individual proposed by the Bidder for the requirement is capable of performing the Work described in the resulting contract.

## PART 6 - SECURITY AND OTHER REQUIREMENTS

## 6.1 Security Requirements

There is no security requirement associated with this requirement.

#### 6.2 Insurance Requirements

The Contractor is responsible for deciding if insurance coverage is necessary to fulfill its obligation under the Contract and to ensure compliance with any applicable law. Any insurance acquired or maintained by the Contractor is at its own expense and for its own benefit and protection. It does not release the Contractor from or reduce its liability under the Contract.

## PART 7 - RESULTING CONTRACT CLAUSES

The following clauses and conditions apply to and form part of any contract resulting from the bid solicitation.

## 7.1 Statement of Work

The Contractor must perform the Work in accordance with the Statement of Work at Annex "A".

## 7.1.1 Task Authorization

The Work or a portion of the Work to be performed under the Contract will be on an "as and when requested basis" using a Task Authorization (TA). The Work described in the TA must be in accordance with the scope of the Contract.

## 7.1.1.1 Task Authorization Process

- 1. The Project Authority will provide the Contractor with a description of the task using the Task Authorization Form specified in Annex C.
- The Task Authorization (TA) will contain the details of the activities to be performed, a description
  of the deliverables, and a schedule indicating completion dates for the major activities or
  submission dates for the deliverables. The TA will also include the applicable basis(bases) and
  methods of payment as specified in the Contract.
- 3. The Contractor must provide the Project Authority, within 5 calendar days of its receipt, the proposed total estimated cost for performing the task and a breakdown of that cost, established in accordance with the Basis of Payment specified in the Contract.
- 4. The Contractor must not commence work until a TA authorized by the Contracting Authority has been received by the Contractor. The Contractor acknowledges that any work performed before a TA has been received will be done at the Contractor's own risk.

## 7.1.1.2 Task Authorization Limit

The Project Authority may authorize individual task authorizations up to a limit of \$250,000.00, Applicable Taxes included, inclusive of any revisions.

Any task authorization to be issued in excess of that limit must be authorized by the Contracting Authority before issuance.

#### 7.1.1.3 Minimum Work Guarantee - All the Work - Task Authorizations

1. In this clause,

"Maximum Contract Value" means the amount specified in the "Limitation of Expenditure" clause set out in the Contract; and

"Minimum Contract Value" means 5% percent of the Maximum Contract Value.

2. Canada's obligation under the Contract is to request Work in the amount of the Minimum Contract Value or, at Canada's option, to pay the Contractor at the end of the Contract in accordance with paragraph 3. In consideration of such obligation, the Contractor agrees to stand in readiness

throughout the Contract period to perform the Work described in the Contract. Canada's maximum liability for work performed under the Contract must not exceed the Maximum Contract Value, unless an increase is authorized in writing by the Contracting Authority.

- 3. In the event that Canada does not request work in the amount of the Minimum Contract Value during the period of the Contract, Canada must pay the Contractor the difference between the Minimum Contract Value and the total cost of the Work requested.
- 4. Canada will have no obligation to the Contractor under this clause if Canada terminates the Contract in whole or in part for default.

## 7.1.1.4 Periodic Usage Reports - Contracts with Task Authorizations

The Contractor must compile and maintain records on its provision of services to the federal government under authorized Task Authorizations issued under the Contract.

The Contractor must provide this data in accordance with the reporting requirements detailed below. If some data is not available, the reason must be indicated. If services are not provided during a given period, the Contractor must still provide a "nil" report.

The data must be submitted on a quarterly basis to the Contracting Authority.

The quarterly periods are defined as follows:

1st quarter: April 1 to June 30;

2nd quarter: July 1 to September 30;

3rd quarter: October 1 to December 31; and

4th quarter: January 1 to March 31.

The data must be submitted to the Contracting Authority no later than 20 calendar days after the end of the reporting period.

#### **Reporting Requirement- Details**

A detailed and current record of all authorized tasks must be kept for each contract with a task authorization process. This record must contain:

#### For each authorized task:

- i. the authorized task number or task revision number(s);
- ii. a title or a brief description of each authorized task;
- iii. the total estimated cost specified in the authorized Task Authorization (TA) of each task, exclusive of Applicable Taxes;
- iv. the total amount, exclusive of Applicable Taxes, expended to date against each authorized task;
- v. the start and completion date for each authorized task; and
- vi. the active status of each authorized task, as applicable.

## For all authorized tasks:

- i. the amount (exclusive of Applicable Taxes) specified in the contract (as last amended, as applicable) as Canada's total liability to the contractor for all authorized TAs; and
- ii. the total amount, exclusive of Applicable Taxes, expended to date against all authorized TAs.

#### 7.2 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in the <u>Standard</u> <u>Acquisition Clauses and Conditions Manual</u> (https://buyandsell.gc.ca/policy-and-guidelines/standardacquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

## 7.2.1 General Conditions

2035 (2018-06-21), General Conditions - Higher Complexity - Services, apply to and form part of the Contract.

#### 7.2.2 Supplemental General Conditions

<u>4007</u> (2010-08-16) Canada to Own Intellectual Property Rights in Foreground Information, apply to and form part of the Contract.

#### 7.3 Security Requirements

**7.3.1** There is no security requirement applicable to the Contract.

#### 7.4 Term of Contract

#### 7.4.1 Period of the Contract

The period of the Contract is from date of Contract to March 31, 2020.

#### 7.4.2 Option to Extend the Contract

The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to two (2) additional one (1)-year period(s) under the same conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable provisions as set out in the Basis of Payment.

Canada may exercise this option at any time by sending a written notice to the Contractor at least fifteen (15) calendar days before the expiry date of the Contract. The option may only be exercised by the Contracting Authority, and will be evidenced for administrative purposes only, through a contract amendment.

#### 7.5 Authorities

#### 7.5.1 Contracting Authority

The Contracting Authority for the Contract is:

Name: Darlene Fisher Title: Senior Procurement & Contracting Officer Health Canada Directorate: MAMD Address: 200 Eglantine Driveway, Ottawa ON K1A 0K9

Telephone: 613-941-2125 E-mail address: <u>Darlene.Fisher2@canada.ca</u>

The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

## 7.5.2 Project Authority

The Project Authority for the Contract is:

To be inserted at Contract Award

Name:	
Title:	
Organization:	
Address:	

Telephone:			
Facsimile:		·	
E-mail addre	ess:_		

(Insert or delete as applicable)

In its absence, the Project Authority is:

	_

 Telephone:
 \_\_\_\_\_

 Facsimile:
 \_\_\_\_\_\_

 E-mail address:
 \_\_\_\_\_\_

The Project Authority is the representative of the department or agency for whom the Work is being carried out under the Contract and is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Project Authority; however, the Project Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

#### 7.5.3 Contractor's Representative

To be inserted at Contract Award

## 7.6 **Proactive Disclosure of Contracts with Former Public Servants**

By providing information on its status, with respect to being a former public servant in receipt of a <u>Public</u> <u>Service Superannuation Act</u> (PSSA) pension, the Contractor has agreed that this information will be reported on departmental websites as part of the published proactive disclosure reports, in accordance with <u>Contracting Policy Notice: 2012-2</u> of the Treasury Board Secretariat of Canada.

## 7.7 Payment

## 7.7.1 Basis of Payment

The Contractor will be paid for the Work specified in the authorized task authorization, in accordance with the Basis of payment at Annex "B".

Canada's liability to the Contractor under the authorized task authorization must not exceed the limitation of expenditure specified in the authorized task authorization. Custom duties are included and Applicable Taxes are extra.

No increase in the liability of Canada or in the price of the Work specified in the authorized task authorization resulting from any design changes, modifications or interpretations of the Work will be authorized or paid to the Contractor unless these design changes, modifications or interpretations have been authorized, in writing, by the Contracting Authority before their incorporation into the Work.

#### 7.7.2 Limitation of Expenditure - Cumulative Total of all Task Authorizations

- 1. Canada's total liability to the Contractor under the Contract for all authorized Task Authorizations (TAs), inclusive of any revisions, must not exceed the sum of \$ \_\_\_\_\_ (to be inserted at Contract Award). Customs duties are included and Applicable Taxes are extra.
- 2. No increase in the total liability of Canada will be authorized or paid to the Contractor unless an increase has been approved, in writing, by the Contracting Authority.
- 3. The Contractor must notify the Contracting Authority in writing as to the adequacy of this sum:
  - a. when it is 75 percent committed, or
  - b. four (4) months before the contract expiry date, or
  - c. as soon as the Contractor considers that the sum is inadequate for the completion of the Work required in all authorized TAs, inclusive of any revisions, whichever comes first.
- 4. If the notification is for inadequate contract funds, the Contractor must provide to the Contracting Authority, a written estimate for the additional funds required. Provision of such information by the Contractor does not increase Canada's liability.

#### 7.7.3 Method of Payment

Canada will pay the Contractor on a monthly basis for work performed during the month covered by the invoice in accordance with the payment provisions of the Contract if:

- a. an accurate and complete invoice and any other documents required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
- b. all such documents have been verified by Canada;
- c. the Work performed has been accepted by Canada.

## 7.7.4 Taxes – Foreign-Based Contractor

<u>C2000C</u> (2007-11-30) Taxes – Foreign-Based Contractor, apply to and form part of the Contract.

## 7.7.5 T1204 - Direct Request by Customer Department

<u>A9117C</u> (2007-11-30) T1204 - Direct Request by Customer Department, apply to and form part of the Contract.

#### 7.8 Invoicing Instructions

1. The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.

Each invoice must be supported by:

- a. a copy of time sheets to support the time claimed;
- b. a copy of the release document and any other documents as specified in the Contract;
- c. a copy of the invoices, receipts, vouchers for all direct expenses, and all travel and living expenses;
- d. a copy of the monthly progress report.
- 2. Invoices must be distributed as follows:
  - a. One (1) copy must be forwarded to the following email address(es) for certification and payment.
     <u>hc.p2p.east.invoices-factures.est.sc@canada.ca</u>

## 7.9 Certifications and Additional Information

#### 7.9.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

#### 7.10 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

## 7.11 **Priority of Documents**

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

- (a) the Articles of Agreement;
- (b) the supplemental general conditions <u>4007</u> (2010-08-16) Canada to Own Intellectual Property Rights in Foreground Information;
- (c) the general conditions 2035 (2018-06-21) Higher Complexity Services;
- (d) Annex A, Statement of Work;
- (e) Annex B, Basis of Payment;
- (f) the signed Task Authorizations (including all of its annexes, if any) (*if applicable*);
- (g) the Contractor's bid dated \_\_\_\_\_, (insert date of bid) (If the bid was clarified or amended, insert at the time of contract award:", as clarified on \_\_\_\_\_" or ", as amended on \_\_\_\_\_" and insert date(s) of clarification(s) or amendment(s)).

## 7.12 Foreign Nationals (Canadian Contractor OR Foreign Contractor)

SACC Manual clause <u>A2000C</u> (2006-06-16) Foreign Nationals (Canadian Contractor)

## OR

SACC Manual clause <u>A2001C</u> (2006-06-16) Foreign Nationals (Foreign Contractor)

## 7.13 Insurance

SACC Manual clause G1005C (2016-01-28) Insurance

## ANNEX "A"

## STATEMENT OF WORK

#### 1. Scope

## 1.1. Title

In vitro toxicity testing of vaping liquids and vaping liquid ingredients

## 1.2. Introduction

With an estimated 45,000 deaths attributable to smoking in Canada in 2012, leading to nearly 600,000 potential years of life lost for premature mortality, tobacco use remains the leading preventable cause of disease and premature death in Canada. Health Canada is responsible for helping Canadians protect, maintain, and improve their health, while respecting individual choices and circumstances.

The renewal of Canada's Tobacco Strategy provides an opportunity to chart a new course in tobacco control and further protect Canadians from the devastating impacts of tobacco use. At the same time, the emergence of alternative products, such as vaping products<sup>1</sup> and heated tobacco products, is shifting the tobacco and nicotine use landscape in a manner that may have significant implications for public health in Canada. In order for public health to benefit from the opportunity these alternative products represent while minimizing harm there is a need to bridge critical scientific knowledge gaps related to their use.

The Tobacco Control Directorate (TCD) has developed a research program which includes studies comparing acute and short-term health effects of alternative products compared to cigarettes. Health Canada lacks the capacity to perform a large battery of in vitro toxicity tests in a short period of time at scale. As such, TCD is seeking the services of a Contractor for the undertaking of laboratory studies to investigate the in vitro toxicity of chemicals found in vaping products.

## **1.3.** Objective of the Requirement

The main objective of the requirement is to conduct *in vitro* toxicity testing of identified chemicals and vaping liquid samples. The data and results provided by the Contractor will be evaluated by Health Canada for appropriate methodology, data accuracy, appropriate quality assurance/quality control (QA/QC) measurements employed and reporting standards according to Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practices (GLP) guidelines.

<sup>&</sup>lt;sup>1</sup> Vaping products are also known as electronic cigarettes, e-cigarettes, vaping, and electronic nicotine delivery system (ENDS). Vaping products are varied in design but tend to include a battery, heating element, reservoir, and mouthpiece. The heating element is used to produce a vapour from vape-liquid (e-liquid) that come in a variety of flavours and may or may not contain nicotine. Vaping products come in many forms including basic disposable devices and refillable kits using a cartridge or tank system.

The objective of the Work is to provide Health Canada, TCD with *in vitro* toxicity testing of vaping liquids and ingredients (referred to as test chemicals or testing materials for the purpose of this document) with select tasks as determined by the Health Canada Scientific and Technical Authority to be provided on an "as and when requested basis" using a Task Authorization (TA).

## **1.4.** Background and Specific Scope of the Requirement

The Office of Research and Surveillance (ORS) in the Tobacco Control Directorate is interested in obtaining information relating to the toxicity of chemicals identified in vaping liquids by generating data on the *in vitro* toxicity in four main categories: cytotoxicity, genotoxicity, oxidative stress/inflammation and *in vitro* cardiovascular toxicity. The *in vitro* toxicity tests include cell-based assays for cytotoxicity, genotoxicity, oxidative stress/inflammation and cardiovascular function as indicated in the task-based table below. Most of the assays must be completed using commercial assay kits when available. Alternative assays to those listed below may be considered at the discretion of the Health Canada Scientific and Technical Authority providing the contractor demonstrates sufficient rationale and benefit to an alternative assay.

The list of chemical substances, vaping liquids and vehicle controls will be provided by the Health Canada Scientific and Technical Authority at Contract Award. Not all chemical substances, vaping liquids and vehicle controls will be identified at Contract Award; therefore they will be released in batches of about 50 following Contract Award. The Contractor will be required to complete *in vitro* toxicity testing of all chemical substances listed and provided by Health Canada by March 2021.

The Contractor shall conduct *in vitro* toxicity testing of chemicals and provide the results to the Health Canada Scientific and Technical Authority in the form of a report for each task as determined by the Health Canada Scientific and Technical Authority to be provided on an "as and when requested basis" using a Task Authorization (TA). In each report the Contractor will provide evidence that the method used has been validated and that the data are supported by appropriate quality assurance procedures. The start and completion times for each task will be subject to the specific requirements of the project as determined exclusively by Health Canada.

## 2. Requirements

## 2.1. Tasks, Activities, Deliverables and Milestones

## Tasks or Activities:

The Contractor must undertake the following tasks and produce the following deliverables according to the identified schedule on an "<u>as and when requested basis</u>" using a Task Authorization (TA):

Tasks will be requested on a per needs basis. In general, blocks of 50 chemicals / vaping liquids will be requested at a time, with order and number of tasks specified in response to HC data needs.

## 1. TASKS

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment

conditions and cost of chemicals / vaping liquids (including shipping costs).

Task #1 – In vitro cytotoxicity testing of vaping liquids and ingredients using the 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) cytotoxicity assay. The Contractor must conduct in vitro toxicity testing of vaping liquids and ingredients to assess cytotoxicity using a commercially available MTT assay. Assays must be carried out over multiple doses (at least twelve dilutions with 10000 µM being the highest concentration for the individual ingredients (10000, 1000, 100, 10, 1, 0.1, 0.01, 0.001, 0.0001, 0.00001, 0.000001 and 0 µM) and 1/10, 1/25, 1/50, 1/100, 1/250, 1/500, 1/1000, 1/5000, 1/10000, 1/50000, 1/100000 dilutions of the vaping liquids or as determined by the Health Canada Scientific and Technical Authority. Appropriate positive and negative controls for cytotoxicity must also be included. The vehicle/solvent and PBS will serve as the negative controls. The assay should be determined following 24 hours of exposure to the vaping liquids and/or vaping liquid ingredient chemicals. The assays must be conducted triplicate wells and each assay must be repeated independently 3 times. Cytotoxicity testing must include all cell lines used to complete the tasks listed in this SOW. At a minimum the assays must be conducted in the A549 human alveolar cell line (task 2b, 3 ac), BEAS-2B human bronchial epithelial cell line (task 3 a-c), a human coronary arterial endothelial or vascular endothelial cell line (task 3c, 4 a-b), human monocytes (task 4a), TK6 human lymphoblastoid cell line (task 2a) and the Bhas 42 cell line (task 2c). The results of cytotoxicity testing will be used to optimize chemical concentrations and exposure times for all subsequent tasks listed in the SOW. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (Dimethyl sulfoxide (DMSO) or a reference vaping liquid containing a specific propylene glycol/vegetable glycerin (PG/VG) composition).

Prior to completing the MTT assay, the contractor must verify that chemicals are completely soluble in the solvent and report all chemicals and concentrations that are not completely soluble in the appropriate vehicle. Those chemicals and concentrations that are not completely soluble should not be used. In addition, any chemicals and/or chemical concentrations that significantly affect the pH of the cell culture media to such an extent that, in the expert opinion of the contractor may affect the results of the assay must be reported.

Storage, use, maintenance and care of all reagents and cells must be performed according to the supplier, manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated and authenticated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required.

Task #2A – In vitro genotoxicity testing of vaping liquids and ingredients using the Organization for Economic Co-operation and Development (OECD) In vitro mammalian cell gene mutation tests using the thymidine kinase gene Guideline 490. The Contractor must conduct *in vitro* toxicity testing of vaping liquids and ingredients to assess genotoxicity using the mammalian gene mutation assay according to OECD guideline 490. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical authority based on the

cytotoxicity assays carried out in **Task #1**). Appropriate positive and negative controls must also be included. The assays must be conducted in triplicate wells. The assays must also be conducted in the appropriate TK6 human lymphoblastoid cell line. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition).

Storage, use, maintenance and care of all reagents and cells must be performed according to OECD guidelines, the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required..

Task #2B – *In vitro* genotoxicity testing of vaping liquids and ingredients using the OECD *In vitro* mammalian micronucleus test. The Contractor must conduct *in vitro* toxicity testing of vaping liquids and ingredients to assess genotoxicity using the *in vitro* mammalian cell micronucleus test according to OECD guideline 487 including all reporting requirements. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the cytotoxicity assays carried out in **Task #1**). Appropriate positive and negative controls must also be included. The assays must be conducted in triplicate wells. The assays must also be conducted in the A549 human alveolar cell line or a cell line to be determined by the Health Canada Scientific and Technical Authority. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition). Metabolic activation should be used depending on the cell line used in the assay.

Storage, use, maintenance and care of all reagents and cells must be performed according to OECD guidelines, the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required..

Task #2C – In vitro genotoxicity testing of vaping liquids and ingredients using the *in vitro* Bhas cell transformation assay according to OECD guidelines. The Contractor must conduct *in vitro* toxicity testing of vaping liquids and ingredients to assess genotoxicity using the *in vitro* Bhas cell transformation assay according to OECD guidance Document on the *in vitro* has cell transformation assay Series on Testing and Assessment No 231. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the

cytotoxicity assays carried out in **Task #1**). Appropriate positive and negative controls must also be included. The assays must be conducted in triplicate wells. The assays must also be conducted in the Bhas 42 cell line. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition).

Storage, use, maintenance and care of all reagents and cells must be performed according to OECD guidelines, the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required..

Task #3A – *In vitro* oxidative stress/inflammation assay testing of vaping liquids and ingredients using a commercially available *in vitro* oxidative stress glutathione:glutathione disulfide (GSH:GSSG) assay. The Contractor must conduct *in vitro* toxicity testing of vaping liquids and ingredients to assess oxidative stress using a commercial GSH:GSSG assay according to the manufacturer's instruction. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the cytotoxicity assays carried out in **Task #1**). Appropriate positive and negative controls must also be included. The assay must be conducted following 24 hours of exposure to the vaping liquids and/or vaping liquid ingredient chemicals. The assays must be conducted in triplicate wells and each assay must be repeated independently 3 times. The assays must also be conducted in the A549 human alveolar cell line and the BEAS-2B human bronchial epithelial cell line or as determined by the Health Canada Scientific and Technical Authority. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority.

Storage, use, maintenance and care of all reagents and cells must be performed according to OECD guidelines, the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required.

Task #3B – In vitro oxidative stress/inflammation assay testing of vaping liquids and ingredients using a commercially available in vitro oxidative stress reactive oxygen species (ROS) assay. The Contractor must conduct in vitro toxicity testing of vaping liquids and ingredients to assess oxidative stress using a commercial ROS assay according to the manufacturer's instruction. Assays must be carried out over

multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the cytotoxicity assays carried out in **Task #1**). Appropriate positive and negative controls must also be included. The assay must be conducted following 24 hours of exposure to the vaping liquids and/or vaping liquid ingredient chemicals. The assays must be conducted in triplicate wells and each assay must be repeated independently 3 times. The assays must also be conducted in the A549 human alveolar cell line and the BEAS-2B human bronchial epithelial cell line or as determined by the Health Canada Scientific and Technical Authority. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition).

Storage, use, maintenance and care of all reagents and cells must be performed according to OECD guidelines, the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1 the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required.

Task #3C – Cell-based in vitro testing of vaping liquids and ingredients using commercially available multi-plex protein kits to quantify protein markers of in vitro oxidative stress, inflammation and cardiovascular toxicity. The Contractor must conduct in vitro toxicity testing of vaping liquids and ingredients to assess oxidative stress and inflammation markers using a commercial multi-plex protein assay according to the manufacturer's instructions. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the cytotoxicity assays carried out in Task #1). Appropriate positive (i.e. LPS at 1 µg/ml) and negative controls must also be included. The proteins to be quantified in the cell culture supernatants following exposure to the vaping liquids and/or ingredients for 24 and 48 hours. The assays must be conducted in triplicate wells and each assay must be repeated independently 3 times. The assays must also be conducted in the A549 human alveolar cell line and the BEAS-2B human bronchial epithelial cell line and in a relevant human coronary artery or vascular endothelial cell line used in Task #4A and 4B or as determined by the Health Canada Scientific and Technical Authority. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition). A commercially available protein assay for all wells must also be performed to quantify total cell protein content per well. The proteins to be quantified in the cell culture supernatants will be determined by the Health Canada Scientific and Technical Authority and must include:

- Interleukin (IL)-10
- Lactate dehydrogenase (LDH)
- Elastase
- Collagenase
- Granulocyte-macrophage colony-stimulating factor (GM-CSF)
- IL-12p70
- Matrix metalloproteinase (MMP)-9

- MMP-1
- CXCL-9
- CXCL-10
- Interferon (IFN)-γ
- IL-1α
- IL-2
- Tumour necrosis factor (TNF)- $\alpha$
- IL-4
- Monocyte chemoattractant protein (MCP)-1
- Vascular endothelial growth factor (VEGF)- $\alpha$
- IL-6
- IL-8
- Transforming growth factor (TGF)-β
- IL-1
- Plasminogen activator inhibitor (PAI)-1,
- Soluble vascular cell adhesion molecule (VCAM)-1
- soluble cell adhesion molecule (sICAM)-1

Storage, use, maintenance and care of all reagents and cells must be performed according to the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required.

Task #4A – *In vitro* cardiovascular toxicity assay testing of vaping liquids and ingredients using a commercially-available monocyte endothelial adhesion assay. The Contractor must conduct *in vitro* toxicity testing of vaping liquids and ingredients to assess *in vitro* cardiovascular toxicity using a commercially available monocyte adhesion assay. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the cytotoxicity assays carried out in **Task #1**). Appropriate positive and negative controls must also be included. The assays must be conducted in triplicate wells and each assay must be repeated independently 3 times. The assays must also be conducted in cardiovascular disease-relevant cell lines (human monocytes (i.e.THP-1 cells) and either human coronary artery endothelial cell line or human vascular endothelial cell line) to be determined by the Health Canada Scientific and Technical Authority. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition). The endothelial cells will be treated with vaping liquid or vaping liquid ingredients for 24 hours (or as recommended by the assay supplier) followed by monocyte adhesion quantification according to the manufacturer's instructions.

Storage, use, maintenance and care of all reagents and cells must be performed according to the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada

Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

Before commencing this task, in addition to the task deliverables outlined in Section 2.1.1, the contractor must submit a detailed project plan including all methods, controls, parameters, treatment conditions and cost of chemicals / vaping liquids (including shipping costs) if additional chemicals are required.

Task #4B – *In vitro* cardiovascular toxicity assay testing of vaping liquids and ingredients using a commercially available monocyte/leukocyte trans-endothelial cell migration assay. The Contractor must conduct *in vitro* toxicity testing of vaping liquids and ingredients to assess *in vitro* cardiovascular toxicity using a commercially available trans-endothelial migration assay. Assays must be carried out over multiple doses (specific concentrations will be determined at a later date by the Health Canada Scientific and Technical Authority based on the cytotoxicity assays carried out in Task #1). Appropriate positive and negative controls must also be included. The assays must be conducted in triplicate wells and each assay must be repeated independently 3 times. The assays must also be conducted in a relevant human coronary artery or vascular endothelial cell line with appropriate human leukocyte cell line to be approved and determined by the Health Canada Scientific and Technical Authority. The vehicle for vaping liquid dilutions will also be determined by the Health Canada Scientific and Technical will also be determined by the Health Canada Scientific and Technical Authority (DMSO or a reference vaping liquid containing a specific PG/VG composition). Endothelial cells will be treated with vaping liquid or vaping liquid ingredients for 24 hours (or as recommended by the assay supplier) and trans-migration will be quantified according to the manufacturer's instructions.

Storage, use, maintenance and care of all reagents and cells must be performed according to the supplier or manufacturer's instructions and specifications and/or as determined by the Health Canada Scientific and Technical Authority. All other laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated according to OECD GLP guidelines.

A final report for each task as described in section 2.1.8 must be completed after consulting with the Health Canada Scientific and Technical Authority. In the event of unforeseen methodological problems or delays in carrying out the work, the Contractor will consult with the Project Authority to determine modified dates for completion of the work. Please refer to section 2.6 for more details on any changes in the scope of work.

At the beginning of each task, the Contractor shall provide Health Canada with information on the assays to be conducted – i.e., its standard operating protocols for *in vitro* toxicity testing, including a method description, well/plate maps as well as a detailed plan and schedule for completion of the assays.

The Health Canada Scientific and Technical Authority will provide the list of chemicals to be tested during the first fiscal year at the time the contract is awarded. The estimated total number of different

chemicals to be processed through all tasks by March 2021 will be approximately 250 but may be more or less as determined by the Health Canada Scientific and Technical Authority.

The Contractor shall be responsible for procuring the testing materials including but not limited to testing kits, cell culture supplies and other laboratory supplies and equipment required for completion of the assays listed in the contract and as specified in the SOW.

The Contractor shall perform *in vitro* toxicity testing and send the results to Health Canada within the timeline specified in the task authorization; the Contractor shall continue to do so for the duration of the contract, as required by each task authorization.

**2.1.1 FOR EACH TASK AUTHORIZATION**, the Contractor must perform the tasks and studies specified in the approved Task Authorization. The Contractor must perform these tasks in accordance with Section 1 Scope and must provide the following deliverables, unless otherwise specified in the Task Authorization: Task Kick-off Meeting, Task Draft and Final Project Plan, Task Status Report(s), Task Draft Report and Task Final Report.

For all deliverables included in a Task Authorization, the Contractor must deliver each deliverable to the Health Canada Scientific and Technical Authority by its delivery date specified in the Task Authorization.

# 2.1.2 Task Kick-off Meeting

The Contractor must participate in a Task Kick-off Meeting to discuss the Task Draft Project Plan for Optional Analysis and acquire initial review from the Health Canada Scientific and Technical Authority, or to review the Task Authorization prior to the start of the tasks. The Task Kick-off Meeting will take place by teleconference as stipulated in the Task Authorization.

# 2.1.3 Task Project Plan

The Contractor must provide a detailed Task Project Plan including estimated completion dates for each step of the Work as stipulated in the Task Authorization.

# 2.1.4 Task Draft Project Plan

The Contractor must provide a Task Draft Project Plan to the Health Canada Scientific and Technical Authority, as stipulated in the Task Authorization, for acceptance and review by the Health Canada Scientific and Technical Authority. The Task Draft Project Plan must include, but is not limited to, the following items:

- A schedule with all steps of the Work from beginning to end of the Task Authorization;
- A detailed study plan, schedule and methodology; including plate map diagrams and description of treatment conditions in each well.

- A description of all data analysis requested from the Health Canada Scientific and Technical Authority and if applicable, any suggestion from the Contractor on these questions to improve the analysis; and,
- Detailed description and schedule of study parameters and all endpoints to be measured.
- Detailed description of all procedures and analytical methods.

# 2.1.5 Task Final Project Plan

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The Contractor must provide a Task Final Project Plan that includes the same elements as the Task Draft Project Plan incorporating all revisions requested by the Health Canada Scientific and Technical Authority. The Contractor must provide the Task Final Project Plan for review and approval by the Health Canada Scientific and Technical Authority, within 10 working days of receipt of the Health Canada Scientific and Technical Authority's final comments on the Task Draft Project Plan.

The Contractor must receive approval of the Task Final Project Plan from the Health Canada Scientific and Technical Authority prior to the commencement of any Work conducted under the Task Authorization.

Any changes to the Task Final Project Plan during the performance of the Work conducted under Optional Analysis must be approved by the Health Canada Scientific and Technical Authority, either through verbal or written communication to the Contractor, prior to implementation.

# 2.1.6 Task Status Report

At the Health Canada Scientific and Technical Authority's request, the Contractor must provide a written Task Status Report as a status update on a monthly basis and to raise any issues related to the Work specified in the Task Authorization. The Task Status Report must address the following:

- Overall project status;
- Timelines (according to approved Task Final Project Plan);
- Task Authorization progress;
- Situation (problems or anomalies);
- Identification of any changes to the approved Task Final Project Plan;
- Preliminary results (upon availability); and,
- Any other relevant issues.

# 2.1.7 Task Draft Report

The Contractor must provide a Task Draft Report to the Health Canada Scientific and Technical Authority, as stipulated in the Task Authorization, for acceptance and review by the Health Canada Scientific and Technical Authority. The Contractor must provide one electronic copy of the draft report to the Health Canada Scientific and Technical Authority which must contain all the study findings including the detailed methodology, test procedures, experimental parameters, visual microscopic observations, results, graphs, tables and expert interpretation of findings including statistical analysis. For all relevant genotoxicity assays, the project report must be in accordance with appropriate OCED test guidelines.

All reports must include raw data from each independent assay in addition to tabulated and summarized results. Statistical analyses must also be conducted to determine statistical significance of differences between the different treatment groups.

# 2.1.8 Task Final Report

The Contractor must provide a Task Final Report that includes the same elements as the Task Draft Report incorporating all revisions requested by the Health Canada Scientific and Technical Authority. The Contractor must provide the Task Final Report at least 10 working days prior to the Task Authorization completion date, for review and approval by the Health Canada Scientific and Technical Authority. Authority.

### 2.2. Specification and Standards

N/A

# 2.3. Technical, Operational and Organizational Environment

The Contractor must ensure that all of the deliverables are compatible with the technical specifications set out by the Health Canada Scientific and Technical Authority at the time the deliverables are completed/achieved.

Refer to sections 1.2 and 1.4 regarding how the work will fit within other initiatives and who will be the ultimate end user of the requirement.

# 2.4. Method and Source of Acceptance

The Health Canada Scientific and Technical Authority will review all project deliverables (draft reports, final report) for quality, performance of required tasks, and format, and will indicate in writing to the Contractor within 15 working days whether a specific deliverable has been accepted, and will identify any required changes to the deliverable. The Contractor will have 15 working days to revise the deliverable unless both parties agree to an alternative deadline. At that point, the Health Canada Scientific and Technical Authority will re-review the deliverable and determine if it is acceptable or requires revision (at no cost to Health Canada).

#### 2.5. Reporting Requirements

The Contractor shall deliver the services using the methods agreed upon, in the format requested, and within the timelines established in this contract. The Contractor shall submit one (1) electronic copy of each deliverable (i.e., draft project reports, and final reports and raw data) to the Health Canada Scientific and Technical Authority. The Contractor shall submit periodic progress/status reports, with

each report outlining the accomplishments for the given period, any open issues, and upcoming milestones. Refer to Section 2.1 for associated details on reporting requirements.

### 2.6. Project Management Control Procedures

The Health Canada Scientific and Technical Authority shall monitor the progress of the work, ensure that the work will be brought in on time, on budget, and is of acceptable quality. The Contractor shall ensure that all deployed personnel are qualified and trained to fulfil their responsibilities in the conduct and management of this project. In addition, the Contractor shall ensure that all its assigned personnel are operating at all times in accordance with all applicable legislation, regulations, and codes as well as requirements specified by the Research Ethics Board if required.

See also the details outlined in sections 2.4, 2.5 and 3.1.

# 2.7. Ownership of Intellectual Property

Intellectual property and ownership of the data/results generated will remain with the Government of Canada. The justification for Canada retaining IP ownership is due to the fact that the main purpose of the contract is to generated knowledge and information for subsequent publication and/or public dissemination.

Section 6.4 of the Treasury Board Policy on *Title to Intellectual Property Arising Under Crown Procurement Contracts* stipulates that the Crown may retain copyright:

6.4 where the main purpose of the Crown Procurement Contract, or of the deliverables contracted for, is:

6.4.1 to generate knowledge and information for public dissemination.

# 3. Additional Information (Other Terms and Conditions of the SOW)

#### 3.1. Authorities

Departmental representative: The Departmental Representative (or delegated representative) is the Health Canada Project Authority and is responsible for the management of this Contract. Any changes to the Contract must be authorized in writing by the Departmental Representative. The Contractor is not to perform work in excess of or outside the scope of this contract that are based on verbal or written requests or instructions from any government personnel other than the Health Canada Project Authority.

To be announced at time of contract award.

The Health Canada Scientific and Technical Authority (or delegated representative) is responsible for all matters concerning the scientific/technical content of the work under the contract. Any proposed changes to the scope of the work are to be discussed with the Health Canada Scientific and Technical

Authority, but any resulting changes can only be confirmed by a Contract Amendment issued by the aforementioned Departmental Representative.

To be announced at time of contract award.

The person who will handle invoicing and administrative questions will be:

To be announced at time of contract award.

### **3.2.** Health Canada's Obligations

Health Canada shall:

- a) Health Canada's representatives will establish a clear statement of tasks, activities, deliverables and milestones.
- b) Health Canada's representatives will communicate with the contractor as required to review the testing protocol, verify details for completeness and to assess progress.
- c) Provide guidance on how to report study results, including the early results reporting protocol (if applicable)
- d) Provide comments on draft reports and final reports to the Contractor within fifteen (15) working days.

### **3.3.** Contractor's Obligations

The Contractor shall:

- a) Purchase the chemicals to be tested (direct cost will be reimbursed based on invoicing), assays, cells and all reagents required to complete the tasks in the SOW
- b) Unless otherwise specified, the Contractor shall supply its own equipment and software for the performance of the work.
- c) The Contractor shall provide the services described in this contract in accordance with the specific delivery requirements described herein, which may include samples reception (under certain time and temperature conditions), sample preparation, and special sample and data destruction procedures.
- d) The Contractor shall provide all the personnel required for carrying out the work outlined in this contract, and shall conduct its activities in accordance with the current occupational health and safety guidelines applicable in its laboratory.
- e) The Contractor shall store the study samples/chemicals until final approval of the results by Health Canada.

Refer also to section 2.1 through 2.8 for other obligations of the Contractor.

# 3.4. Location of Work, Work Site and Delivery Point

The work outlined in this contract will be conducted at the Contractor's site or normal place of business, with the submission of deliverables to Health Canada's facilities as specified herein. Due to existing workload and deadlines, all personnel assigned to this contract must be ready to work in close and

frequent contact with the Health Canada Scientific and Technical Authority and other departmental personnel as needed.

The specifications outlined in this contract will be interpreted and governed by the laws of the Province of Ontario unless otherwise specified.

# 3.5. Language of Work

It is expected that any status or progress reports and any correspondence either in writing or by telephone with the Health Canada Scientific and Technical Authority will be in English.

# **3.6.** Special Requirements and Security Requirements

The contractor will not be permitted to access any Health Canada premises without escort at all times.

In addition, the contractor will not be permitted to access any Health Canada resources, infrastructure or protected information at any time. Unscreened contractors must be escorted by an employee or Commissionaire at all times when visiting Government of Canada facilities.

# 3.7. Use, Storage and Retention of Information

Information which is to be used in the development of the contracted product, as reference material or otherwise made available to the contractor must be unclassified material and considered to be releasable to the public by HC/PHAC and/or The Government of Canada.

No Protected or Classified information is to be made available to the contractor, used in the production of the contracted product, or produced as a result of this contract.

# **3.8.** Insurance Requirements

It shall be the sole responsibility of the Contractor to determine whether specific insurance coverage is required for its own protection or to fulfil its obligations under this Contract and to ensure compliance with required federal, provincial or municipal laws, by-laws, and regulations. Any such insurance shall be provided and maintained by the Contractor at the Contractor's own expense. If applicable, the Contractor will ensure that sub-contracted organizations have all work-related insurance in place, including coverage if employees of the sub-contracted organizations are going to operate or ride in a vehicle for the purposes of their contribution to the work outlined in this Contract.

# 3.9. Travel and Living

Not applicable.

# 4. Project Schedule

# 4.1. Expected Start and Completion Dates

The services of the Contractor will be required for a period of approximately 17 months commencing on or about November 1st, 2018, with the option of renewal for two (2) one (1)-year options (fiscal years 2020-2021 and 2021-2022) to be exercised at Health Canada's discretion. The expected completion date of this project is the 31<sup>st</sup> of March, 2020.

### Milestones and Deliverables:

The Contractor shall submit to the Health Canada Scientific and Technical Authority all deliverables as specified in this contract. The deliverables may include, but are not necessarily limited to, a description of the method(s), study results, periodic debriefings, progress or status reports, and documented QA/QC results. Deliverables shall be provided in Microsoft Word document for draft and final project reports, and quantitative data should be presented in Microsoft Excel format, both via secured electronic data transfer. All deliverables and milestones are outlined in Section 2 of the SOW.

# 5. Required Resources or Types of Roles to be Performed

5.1. The Contractor shall provide sufficient resources to complete the tasks, activities, and milestones identified in section 2.1. The work outlined requires the services of a team of skilled research professionals who possess the specific expertise needed to carry out the work.

Category	Estimated Quantity	Brief Role Description
Project Manager/Lead	Minimum of 1.*	Oversee project management,
		design study, draft methods,
		ensure laboratory technicians
		are aware of and comply with
		OECD GLP guidelines, assign
		tasks to laboratory personnel,
		analyze data, check data quality,
		draft reports, assure tasks are
		properly completed,
Laboratory Technician	Minimum of 1.*	Complete all laboratory work in
		compliance with OECD GLP
		guidelines, help design studies
		and methodology, help analyze
		data, help draft reports

\*Throughout the contract, the Contractor must be able to provide the above resource requirements as a minimum. Resource quantities may fluctuate up or down depending on operational requirements. It is the responsibility of the Contractor to source the right amount of resources to fulfill the obligations of the Contract. All resources must first meet the establish evaluation criteria for their respective category prior to conducting work under a Task Authorization.

# 6. Applicable Documents and Glossary

# 6.1. Applicable Documents

OECD GLP guideline: OECD Principles of Good Laboratory Practice (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 1, ENV/MC/CHEM(98)17, or subsequent revisions)

#### OECD GUIDELINE FOR THE TESTING OF CHEMICALS (29 July 2016)

490: In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene

487: In Vitro Mammalian Cell Micronucleus Test

OECD GUIDANCE DOCUMENT ON THE IN VITRO BHAS 42 CELL TRANSFORMATION ASSAY. Series on testing and assessment number 231 (20 July 2017)

# 6.2. Relevant Terms, Acronyms and Glossaries

Not applicable.

#### ANNEX "B"

#### **BASIS OF PAYMENT**

The Bidder must complete this pricing schedule and include it in its financial bid. As a minimum, the Bidder must respond to this pricing schedule by inserting in its financial bid for each of the periods specified below its quoted all-inclusive firm price for each of the milestones(tasks) identified and its quoted direct and subcontracted expenses.

#### Volumetric Data

The inclusion of volumetric data in this document does not represent a commitment by Canada that Canada's future usage of the services described in the bid solicitation will be consistent with this data.

#### **Direct Expenses**

All expenses, general and administrative, normally incurred in providing the services (i.e. project office space [including Contractor's hardware and software]; word processing; non-project specific reports, photocopying, courier and telephone charges; local travel and the like) are to be included in the prices for professional services identified herein, and will not be permitted as direct expenses under the Contract.

Direct expenses include any expenses directly incurred by the Contractor during the performance of the Work or for the purpose of the project, relating to the purchase of Test Chemicals / Testing Materials and Related Shipping Costs, equipment, supplies, or other required items.

Direct expenses will be charged at net cost with a (TBD at contract award)% mark-up.

#### **Subcontracting**

Subcontracted items include any expenses incurred during the performance of the Work or for the purpose of the project for which a separate contract exists between the Contractor and the person or firm providing the goods / services. Subcontracted items may include, but are not limited to, the following: the venue, audio/video equipment rental, simultaneous interpretation equipment rental, commercial transportation, hospitality, facilitators, note takers, translation services, travel and living for event participants, on-site printing, signage, etc.

All subcontracted requirements will be provided at net cost with a *(TBD at contract award)*% mark-up. Invoices from the Contractor to Canada must be accompanied by copies of invoices from the subcontractors. Invoices from second-tier subcontractors (the subcontractors of the Contractor's subcontractors) are not required under the Contract. For each subcontracted service over \$25,000 (taxes included) the Contractor will obtain competitive bids from no fewer than three outside suppliers. The Contractor must provide to the Contracting Authority and the Project Authority, the names of the suppliers who submitted bids, the total amount of each bid obtained, the selection criteria and results.

### Instructions

The bid must include a breakdown of costs and timelines for 50 chemicals processed through each task separately for each contract period including options. Base bid costs on 12 dilutions (plus positive and negative controls) for Task 1 and 6 dilutions (plus positive and negative control) for Tasks 2a, 2b, 2c, 3a, 3b, 3c, 4a and 4b. Incorporate materials, personnel and overhead costs including administrative costs associated with purchasing materials to be tested (50 chemicals / vaping liquids) but excluding the cost of individual testing materials (chemical or vaping liquid) as these costs will be reimbursed based on pre-authorized prices.

### A. Initial Contract Period

### 1. Table 1 "A1" – Task #1

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#1	50 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x	\$
	5 cell types x 3 wells per run x 3 separate runs	
	Sub-Total A1 (excluding taxes)	\$

# 2. Table 2 "A2" – Task #2A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A2 (excluding taxes)	\$

#### 3. Table 3 "A3" – Task #2B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A3 (excluding taxes)	\$

### 4. Table 4 "A4" – Task #2C

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2C	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A4 (excluding taxes)	\$

#### 5. Table 5 "A5" – Task #3A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A5 (excluding taxes)	\$

#### 6. Table 6 "A6" – Task #3B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A6 (excluding taxes)	\$

# 7. Table 7 "A7" – Task #3C

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3C	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A7 (excluding taxes)	\$

# 8. Table 8 "A8" – Task #4A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#4A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total A8 (excluding taxes)	\$

# 9. Table 9 "A9" – Task #4B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#4B	50 Chemicals / Vaping liquids at 8 samples (6	\$
	concentrations + negative and positive controls) x	
	specified number of cell types x 3 wells per run x	
	specified number of runs (1 or 3)	
	Sub-Total A9 (excluding taxes)	\$

# **10.**Table **10** "A**10**" – Direct & Subcontracted Expenses Mark-up% (*if applicable and requires Health Canada pre-authorization*):

The Bidder must insert its Direct & Subcontracted Expenses Mark-up% in the table below.

The cost of test chemicals / testing materials and their related shipping costs will be reimbursed at net cost plus the mark-up percentage proposed below.

ltem	Description	Total Estimated Direct and Subcontracted Expenses
1	Direct & Subcontracted Expenses Mark-up% (applicable to the resulting contract)	% (in format 0.00%
2	Total Direct & Subcontracted Expenses (for evaluation purposes only)	\$10,000.00
Sub-To item 2	tal A10 (excluding taxes) – item 1 multiplied by item 2 then added to :	\$

#### B. Option Year 1

#### 1. Table 1 "B1" – Task #1

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#1	50 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x 5 cell types x 3 wells per run x 3 separate runs	\$
	Sub-Total B1 (excluding taxes)	\$

### 2. Table 2 "B2" – Task #2A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total B2 (excluding taxes)	\$

### 3. Table 3 "B3" – Task #2B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total B3 (excluding taxes)	\$

#### 4. Table 4 "B4" – Task #2C

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2C	50 Chemicals / Vaping liquids at 8 samples (6	\$
	concentrations + negative and positive controls) x	

specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	
Sub-Total B4 (excluding taxes)	\$

#### 5. Table 5 "B5" – Task #3A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total B5 (excluding taxes)	\$

#### 6. Table 6 "B6" – Task #3B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total B6 (excluding taxes)	\$

#### 7. Table 7 "B7" – Task #3C

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3C	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total B7 (excluding taxes)	\$

### 8. Table 8 "B8" – Task #4A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#4A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total B8 (excluding taxes)	\$

# 9. Table 9 "B9" – Task #4B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#4B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$

Sub-Total B9 (excluding taxes)	\$

# **10.Table 10 "B10" – Direct & Subcontracted Expenses Mark-up% (***if applicable and requires Health Canada pre-authorization):*

The Bidder must insert its Direct & Subcontracted Expenses Mark-up% in the table below.

The cost of test chemicals / testing materials and their related shipping costs will be reimbursed at net cost plus the mark-up percentage proposed below.

ltem	Description	Total Estimated Direct and Subcontracted Expenses
1	Direct & Subcontracted Expenses Mark-up% (applicable to the resulting contract)	% (in format 0.00%
2	Total Direct & Subcontracted Expenses (for evaluation purposes only)	\$10,000.00
Sub-To item 2	tal B10 (excluding taxes) – item 1 multiplied by item 2 then added to :	\$

# C. Option Year 2

#### 1. Table 1 "C1" – Task #1

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#1	50 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x 5 cell types x 3 wells per run x 3 separate runs	\$
	Sub-Total C1 (excluding taxes)	\$

#### 2. Table 2 "C2" – Task #2A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C2 (excluding taxes)	\$

### 3. Table 3 "C3" – Task #2B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C3 (excluding taxes)	\$

#### 4. Table 4 "C4" – Task #2C

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#2C	50 Chemicals / Vaping liquids at 8 samples (6	\$
	concentrations + negative and positive controls) x	
	specified number of cell types x 3 wells per run x	

specified number of runs (1 or 3)	
Sub-Total C4 (excluding taxes)	\$

#### 5. Table 5 "C5" – Task #3A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C5 (excluding taxes)	\$

### 6. Table 6 "C6" – Task #3B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C6 (excluding taxes)	\$

# 7. Table 7 "C7" – Task #3C

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#3C	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C7 (excluding taxes)	\$

### 8. Table 8 "C8" – Task #4A

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

The proposed firm lot price must include all professional services, materials, fees, indirect costs. Cost of test chemicals must be charged separately as per Table 10.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#4A	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C8 (excluding taxes)	\$

#### 9. Table 9 "C9" – Task #4B

The Bidder must insert its All Inclusive Firm Lot Price in the table below.

Task	Lot Size (Number of Chemical Types)	All Inclusive Firm Lot Price
#4B	50 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x specified number of cell types x 3 wells per run x specified number of runs (1 or 3)	\$
	Sub-Total C9 (excluding taxes)	\$

# **10.**Table **10** "C10" – Direct & Subcontracted Expenses Mark-up% (*if applicable and requires Health Canada pre-authorization*):

The Bidder must insert its Direct & Subcontracted Expenses Mark-up% in the table below.

The cost of test chemicals / testing materials and their related shipping costs will be reimbursed at net cost plus the mark-up percentage proposed below.

Item	Description	Total Estimated Direct and Subcontracted Expenses
1	Direct & Subcontracted Expenses Mark-up% (applicable to the resulting contract)	% (in format 0.00%
2	Total Direct & Subcontracted Expenses (for evaluation purposes only)	\$10,000.00
Sub-To item 2	otal C10 (excluding taxes) – item 1 multiplied by item 2 then added to :	\$

# D. Total Bid Price for Evaluation Calculation

The Total Bid Price for Evaluation is calculated for evaluation purposes and will also form the Basis of Payment for the resulting Contract.

Total Bid Price for Evaluation = Sum of Sub-Totals A1, A2, A3, A4, A5, A6, A7, A8, A9, B1, B2, B3, B4, B5, B6, B7, B8, B9, C1, C2, C3, C4, C5, C6, C7, C8, and C9.

The total value of any contract resulting from this RFP shall not exceed the sum of \$250,000.00 in the first year, and \$250,000.00 in each of the two (2) one-year option periods should they be exercised for a total cumulative value of \$750,000.00, taxes extra. This amount includes all professional services, direct and subcontracted expenses, and all other expenses.

# D.1 Bidder's Total Bid Price for Evaluation

The Bidder must insert its Total Bid Price for Evaluation below.

Bidder's Total Bid Price for Evaluation	\$
Applicable Taxes	\$

### ANNEX "C"

# TASK AUTHORIZATION FORM

# The following is provided as an example.

Contract Number	Enter the resu	Iting contract number.	
Task Authorization (TA) Number	Instructions to the TA Authority: Enter the number here.		
Contractor's Name and Address			
Instructions to the TA Authority: Enter the name and addres	s here.		
,			
Total Estimated Cost of Task (Applicable Taxes extra	) before any	S Instructions to the TA	
revisions:		Authority: Enter the amount here.	
TA Revisions Previously Authorized			
Instructions to the TA Authority: the information for the prev	viously authorized	revisions must be presented in ascending order of	
assigned revision numbers (the first revision must be identif authorized, enter \$0.00. Add rows, as needed	fied as No. 1, the se	econd as No. 2, etc ). If no increase or decrease was	
TA Revision Number: Instructions to	Authorized Inc	rease or Decrease (Applicable Taxes extra)	
the TA Authority: Enter the number here, as applicable.		Instructions to the TA Authority: Enter the amount	
the TA Automy. Enter the number here, as applicable.	here, as applicab		
TA Revision Number: Instructions to		rease or Decrease (Applicable Taxes extra)	
the TA Authority: Enter the number here, as applicable.		Instructions to the TA Authority: Enter the amount	
	here, as applicab		
TA Revision Number: Instructions to		rease or Decrease (Applicable Taxes extra)	
the TA Authority: Enter the number here, as applicable.		Instructions to the TA Authority: Enter the amount	
	here, as applicable.		
TA Revision Number: Instructions to	.  \$ Instructions to the TA Authority: Enter the amount		
the TA Authority: Enter the number here, as applicable.			
	here, as applicable. Authorized Increase or Decrease (Applicable Taxes extra)		
TA Revision Number: Instructions to the TA Authority: Enter the number here, as applicable.		Instructions to the TA Authority: Enter the amount	
the TA Authority. Enter the number here, as applicable.	Φ here, as applicab		
New TA Revision	nere, as applicat		
Instructions to the TA Authority: the first revision must be in is authorized, enter \$0.00.	dentified as No. 1, 1	the second as No. 2, etc. If no increase or decrease	
TA Revision Number: Instructions to			
the TA Authority: Enter the number here, as applicable.	Instructions to the TA Authority: Enter the amount		
	here, as applicab		
I OTAL ESTIMATED COST OF LASK (Applicable Laxes extra	extra) after \$ Instructions to the TA Authority: Enter		
this revision:	the amo	ount here, as applicable.	
Contract Security Requirements (as applicable)			
This task includes security requirements. Check the ap	plicable boxes.		
No No			
Vac. Defer to the Security Deguirements Checkling	ist (SRCL) annex	k of the Contract.	
Yes. Refer to the Security Requirements Checkli	(===) =====		
<b>Remarks:</b> Enter the remarks, if any, or enter : "N/A".	(====)====		

# **Required Work**

Instructions to the TA Authority: The content of sections A, B, C and D below must be in accordance with the Contract. To view

the instructions for Section A, click on the hyperlink.

SECTION A – Task Description of the Work Required Instructions for Section A

**SECTION B – Applicable Basis of Payment** Instructions for Section B

SECTION C - Cost Breakdown of Task Instructions for Section C

SECTION D- Applicable Method of Payment Instructions for Section D

#### Authorization - Authorization

By signing this TA, the Project Authority or the PWGSC Contracting Authority or both, as applicable, certify (ies) that the content of this TA is in accordance with the Contract.

En apposant sa signature sur cette AT, le chargé de projet ou l'autorité contractante de TPSGC ou, s'il y a lieu, les deux atteste(nt) que le contenu de cette AT respecte les conditions du contrat.

Date

Date \_\_\_\_\_

Name of Project Authority - Nom du chargé de projet \_\_\_\_\_

Signature \_\_\_\_\_

Name of PWGSC Contracting Authority -Nom de l'autorité contractante de TPSGC \_\_\_\_\_

Signature \_\_\_\_\_

Contractor's Signature - Signature de l'entrepreneur

Name and title of individual authorized to sign for the Contractor

Nom et titre de la personne autorisée à signer		
Signature	Date	_

Instructions to the TA Authority for SECTION A -Task Description of the Work required

In the case of a new task, the following information must be included directly in Section A or in an attachment applicable to Section A:

- a) details of the activities to be performed;
- b) description of the deliverables to be submitted; and
- c) completion dates for the major activities and/or submission dates for the deliverables.

In the case of a revision to a previously authorized task, the following information must be included directly in Section A or in an attachment applicable to Section A (as applicable):

- a) reason (s) for revising the task;
- b) details of the revised activities to be performed;
- c) description of the revised deliverables to be submitted; and

d) revised completion dates for the major activities and/or revised submission dates for the deliverables (or revised deliverables, as applicable).

# Instructions to the Contracting Authority for SECTION B - Applicable Basis of Payment

*I* fonly one TA basis of payment clause is inserted in the resulting contract, in Section B, enter the following:

For the Firm Unit Price TA clause, insert the following for each firm unit price included in the clause:

□ " Firm Unit Price of \$\_\_\_\_\_ensure to insert here the same amount as indicated in the clause per \_\_\_\_\_ complete by inserting the same text as included in the clause requested in Section A above"

For the Firm Lot Price TA clause, insert the following:

□ " Firm Lot Price of \$\_\_\_\_\_ Instructions to the TA Authority: insert the amount."

For the TA subject to a limitation of expenditure clause, insert the following:

"Limitation of Expenditure of \$\_\_\_\_\_Instructions to the TA Authority: insert the amount."

If more than one TA basis of payment clause is inserted in the resulting contract, in Section B, insert one check box for each one; and insert instructions as per the example below to the TA Authority for completing section B.

**EXAMPLE 1** - Commercial professional services (consultation) - Firm Lot Price TA clause (for professional fees) and TA subject to a limitation of expenditure clause (for authorized travel and living expenses):

Instructions to the TA Authority: when completing the TA form to authorize a task or, as applicable, revise a previously authorized task, check each applicable box below and insert the associated amount.

□ Firm Lot Price of \$\_\_\_\_\_\_ for the professional fees identified in Section C below

Limitation of Expenditure of \$\_\_\_\_\_ for the authorized travel and living expenses identified in Section C below"

**EXAMPLE 2** - Commercial professional services (training)- Firm unit price TA clause containing 3 distinct firm unit prices (one, for workshop delivery / two, for cancellation of previously requested workshop delivery (ies)); plus TA subject to a limitation of expenditure clause (for professional fees only for required workshop material updating Work); plus TA subject to a limitation of expenditure (for authorized travel and living expenses to be incurred when travel is required and requested to deliver a requested workshop):

Instructions to the TA Authority: when completing the TA form to authorize a task or, as applicable, revise a previously authorized task, check each applicable box below and insert the associated amount.

Firm Unit Price of \$\_\_\_\_\_ the amount that the contracting authority would insert here would be the same as indicated in the Firm Unit Price TA clause of the resulting contract) per 3 hour workshop delivery requested in Section A above

Limitation of Expenditure of \$\_\_\_\_\_ for the authorized travel and living expenses identified in Section C below for the travel requirements identified in Section A above

Limitation of Expenditure of \$\_\_\_\_\_ for the professional fees identified in Section C below for the required workshop material updating Work requested in Section A above

Firm Unit Price of \$\_\_\_\_\_the amount the contracting authority would insert here would be the same as indicated in the Firm Unit Price TA clause of the resulting contract) per previously requested 3 hour workshop delivery cancelled by Canada in Section A above without advance notice of seven business days

Firm Unit Price of \$\_\_\_\_\_\_ the amount the contracting authority would insert here would be the same as indicated in the Firm Unit Price TA clause of the resulting contract per previously requested 3 hour workshop delivery cancelled by Canada in Section A above with advance notice of seven business days"

# Instructions to the Contracting Authority for SECTION C- Cost Breakdown of Task.

When firm lot price and (or) limitation of expenditure is (are) inserted in Section B as the applicable basis or bases of payment for a TA or revision to a previously authorized TA, in Section C, insert the corresponding cost elements as they appear in the resulting contract Annex B, Basis of Payment. For example 1 included in the instructions above for Section B, the text of Section C could be as follows (text in purple are instructions for the contractor and TA Authority:

**1.0 Professional Fees** Instructions to the TA Authority: for each applicable category, insert the name and the number of days.

Category	Name	All Inclusive Fixed Daily Rate	Level of Effort (Estimated number of days required to perform the Work)
Senior Consultant		\$600.00	
Junior Consultant		\$340.00	

Total Estimated Cost of Professional Fees: \$\_\_\_\_\_ Instructions to the TA Authority: insert the amount.

#### 2.0 Authorized travel and living expenses

\_\_\_\_\_ Instructions to the TA Authority: insert the details of the authorized travel plan.

Total Estimated Cost of Authorized travel and living: \$\_\_\_\_\_ Instructions to the TA Authority: insert the amount.

# Instructions to the Contracting Authority for SECTION D – Applicable Method of Payment

If only one resulting contract TA basis of payment is inserted in Section B, insert in Section D the corresponding TA method of payment appearing in the resulting contract (i.e., monthly payments or progress payments or milestone payments or single payment). If the applicable method of payment is milestone payments, also insert in Section D the applicable schedule of milestones.

Example (the Firm Lot Price basis of payment is inserted in Section B):

Milestone Payments - The schedule of milestones for which payments will be made in accordance with the Contract is as follows:

MILESTONE	ACTIVITY(IES) TO BE PERFORMED / DELIVERABLE(S) TO SUBMIT	COMPLETION /DELIVERY DATE	FIRM AMOUNT
1	Instructions to TA Authority: specify.	Instructions to TA Authority: specify.	\$ Instructions to TA Authority: insert the amount.
2	Instructions to TA Authority: specify.	Instructions to TA Authority: specify.	\$ Instructions to TA Authority: insert the amount.

If more than one resulting contract TA basis of payment is inserted in Section B, for each one insert in Section D the corresponding TA method of payment appearing in the resulting contract (i.e., monthly payments or progress payments or milestone payments or single payment). If the applicable method of payment is milestone payments, also insert in Section D the applicable schedule of milestones.

Example (the Firm Lot Price basis of payment (for professional fees) and the Limitation of Expenditure basis of payment (for authorized travel and living expenses) are inserted in Section B):

"Instructions to TA Authority: when completing the TA form to authorize a task or, as applicable, revise a previously authorized task, check the applicable box (boxes) below and make sure a completed and acceptable schedule of milestones forms part of the authorized TA (as applicable).

☐ Milestone Payments for professional fees only

□ Schedule of Milestone:

The schedule of milestones for which payments will be made in accordance with the Contract is as follows:

MILESTONE	ACTIVITY(IES) TO BE PERFORMED / DELIVERABLE(S) TO SUBMIT	COMPLETION /DELIVERY DATE	FIRM AMOUNT
1	(Specify)	(Specify)	<pre>\$ (enter the applicable amount)</pre>
2	(Specify)	(Specify)	<pre>\$(enter the applicable amount)</pre>

□ Monthly payments for authorized travel and living expenses only