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 cell-based toxicity testing of vaping and heated tobacco devices.

Essais de toxicité cellulaire in vitro sur des dispositifs de vapotage et de tabac chauffé.

Solicitation No. – N° de l'invitation	**Date**
1000203303A	December 21, 2018 Le 21 decembre 2018
Solicitation Closes at – L'invitation prend fin à 2:00 *PM* **on / le – January 30, 2019**	**Time Zone** **Fuseau horaire** EDT

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 : 613-941-2073

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

TABLE OF CONTENTS

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

This Request for Proposal (RFP) is split into two (2) streams. **Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients; and, Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions.** Work for each stream will be performed on an "as and when requested basis" using a Task Authorization (TA) process.

Bidders must submit separate bids if bidding on both streams.

Multiple contracts may be awarded in each Stream in order to meet requirements. For Stream 1, the Bidder must bid on Task A and at least one (1) Optional Task (B, C, D, E or F) and be compliant with all mandatory requirements in the RFP in order to be awarded a contract. For Stream 2, the Bidder must bid on Task 1 & 2 and be compliant with all mandatory requirements in the RFP in order to be awarded a contract.

The services of the Contractor will be required for a period of approximately 12 months commencing on or about April 1st, 2019. The expected completion date of this project is the 31st of March, 2020. The Contract will be set up with the option of annual renewal up to a maximum of three (3) one (1) year renewals (option year 1: April 2020-March 2021; option year 2: April 2021-March 2022; option year 3: April 2022-March 2023) to be exercised at Health Canada's discretion. Should option year(s) be exercised, the expected completion date for option year one is the 31st of March, 2021; option year two is the 31st of March, 2022; and option year three is the 31st of March, 2023.

There are no security requirements associated with this requirement.

The requirement is subject to the provisions of the World Trade Organization Agreement on Government Procurement (WTO-AGP), the North American Free Trade Agreement (NAFTA), the Canada-European

Union Comprehensive Economic and Trade Agreement (CETA), and the Canadian Free Trade Agreement (CFTA)

Stream 1: In vitro testing of vaping liquids and vaping liquid ingredients

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.

Stream 2: In vitro air-liquid-interface testing of alternative product emissions

Health Canada requires the services of a Contractor to conduct *in vitro* toxicity testing of emission from conventional or alternative devices at the air-liquid interface (ALI) 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.

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 Standard Acquisition Clauses and Conditions Manual (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 2003 (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 2003, 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 Darlene.fisher2@canada.ca 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: 1000203303A (Select: Stream 1 or Stream 2)
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 ☐ NO ☐

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 *Policy on Title to Intellectual Property Arising Under Crown Procurement Contracts*: 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 Policy on Green Procurement (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

2) 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

Only the Bidders who have met the mandatory criteria shall be considered for further evaluation.

In the respective Stream, Bidders will be selected and ranked per Task (Stream 1 – Tasks B, C, D, E, F; Stream 2 – Tasks 3, 4, 5, 6) using the following selection methodology.

Up to 3 compliant Bidders per task may be awarded a contract as a result of this RFP. Bidders who rank outside of the top 3 will not be issued a contract for that task. Health Canada may combine tasks into 1 contract per compliant Bidder.

4.2.1 Highest Combined Rating of Technical Merit and Price

SACC Manual Clause A0027T, Basis of Selection – Highest Combined Rating of Technical Merit and Price

1. To be declared responsive, a bid must:
    a. comply with all the requirements of the bid solicitation; and
    b. meet all mandatory technical evaluation criteria.
2. Bids not meeting (a) or (b) will be declared non-responsive.

3. The selection will be based on the highest responsive combined rating of technical merit and price. The ratio will be 70% for the technical merit and 30% for the price.
4. To establish the technical merit score, the overall technical score for each responsive bid will be determined as follows: total number of points obtained / maximum number of points available multiplied by the ratio of 70%.
5. To establish the pricing score, each responsive bid will be prorated against the lowest evaluated price and the ratio of 30%.
6. For each responsive bid, the technical merit score and the pricing score will be added to determine its combined rating.
7. The responsive bid(s) will be recommended for award of a contract and ranked based on their combined rating of technical merit and price from highest to lowest.

The table below illustrates an example where all three bids are responsive and the selection of the contractor is determined by a 70/30 ratio of technical merit and price, respectively. The total available points equals 112 and the lowest evaluated price is $35,000 (35).

Basis of Selection - Highest Combined Rating Technical Merit (70%) and Price (30%) – Ranked Highest to Lowest

		Bidder 1	**Bidder 2**	**Bidder 3**
Overall Technical Score		100/112	89/112	92/112
Bid Evaluated Price		$45,000.00	$40,000.00	$35,000.00
Calculations	**Technical Merit Score**	100/112 x 70 = 62.5	89/112 x 70 = 55.63	92/112 x 70 = 57.5
	Pricing Score	35/45 x 30 = 23.33	35/40 x 30 = 26.25	35/35 x 30 = 30
Combined Rating		85.83	81.88	87.5
Overall Rating		2nd	3rd	1st

APPENDIX 1 TO PART 4 – TECHNICAL EVALUATION CRITERIA

This appendix contains the mandatory and point-rated evaluation criteria for both Stream 1 and Stream 2.

NOTE: Although many of the Mandatory and Points Rated Criteria are identical for Stream 1 and Stream 2, there are differences in M-4, PR-5, PR-8 and PR-9.

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients

1. Mandatory Technical Criteria Stream 1

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.

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Compliant (Yes/No)**	**Reference to Bidder's Proposal (page #)**
M-1	The Bidder must submit a project team including a minimum of: • One (1) Project Manager/Lead; and • One (1) Laboratory Technician Bidders must include within their Technical Offer a detailed résumé for EACH proposed resource which must include a detailed, chronological listing of: • his/her technical experience and capability as a Project Manager/Lead or Laboratory Technician; and • his/her education and professional attainments and academic credentials. • Project Manager/Lead must have a Canadian graduate degree (Master's level or Doctorate) or a recognized Canadian equivalent* • The Bidder's proposed laboratory technician must have a Canadian undergraduate degree in Science (Bachelors level) or a recognized Canadian equivalent*. 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. *proof of equivalence must be provided prior to Contract award. Visit www.cicic.ca for a list of organizations that provide equivalency assessments.	☐ Yes ☐ No	
M-2	The Bidder's Project Manager/Lead and the Laboratory Technician from M-1 must have a combined minimum of sixty (60) months' experience in *in vitro* assessment, including experience related to cell-based assays. In order to demonstrate experience, the Bidder must submit projects	☐ Yes ☐ No	

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Compliant (Yes/No)**	**Reference to Bidder's Proposal (page #)**
	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).		
M-3	**Work Plan and Methodological Approach** The Bidder must provide a written Work Plan and Methodological Approach to undertake the work identified in the Statement of Work (SOW) at Annex 'A' for all Tasks they are bidding on. The Work Plan must show: • A logical and detailed organization of tasks to be completed for the project as per the SOW including all methods and experimental details; • Estimated timelines for completion of each task; • Where applicable, provide details on team composition, responsibilities of team members and expected effort per task; The Methodological Approach must be provided in sufficient detail to allow for a complete understanding of the approach to the work undertaken and should identify the advantages and disadvantages of the proposed Methodological Approach. To be successful, at minimum a bidder must be compliant for Task A and one Optional Task (B-F). Only Tasks a bidder is compliant for will be awarded.	**Mandatory:** **Task A** ☐ Yes ☐ No **Optional:** **Task B** ☐ Yes ☐ No **Task C** ☐ Yes ☐ No **Task D** ☐ Yes ☐ No **Task E** ☐ Yes ☐ No **Task F** ☐ Yes ☐ No	
M-4	The Bidder's proposed project team from M-1 must submit three (3) similar* projects where the work was completed within the last eight (8) years from date of bid closing. * This includes projects testing at least 5 or more chemicals/compounds using at least 2 different in vitro toxicity assays in at least 2 different cell types, for all three (3) projects. * One project must include development of robust in vitro protocol(s) for toxicity assessment. 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. For each project, the Bidder must submit 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	☐ Yes ☐ No	

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Compliant (Yes/No)**	**Reference to Bidder's Proposal (page #)**
	end dates), the project lead name and contact information (phone number and e-mail)		
M-5	The Bidder, sub-contractor(s) and laborator(y/ies) must not have undertaken work related to the manufacturing, importation, processing, promotion, advertising or marketing of tobacco products for the purposes of sale within the past five (5) years measured back from the date of bid closing. To demonstrate compliance, the Bidder must provide a letter signed by the Bidder's Authorized Representative certifying that the Bidder, sub-contractor(s) and laborator(y/ies) have not undertaken work related to the manufacturing, importation, processing, sale, promotion, advertising or marketing of tobacco products within the past five (5) years measured back from the date of bid closing.	☐ Yes ☐ No	

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.

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
PR-1	**Experience of Project Manager/Lead:** The Bidder's proposed Project Manager/Lead from M-1 must demonstrate experience with the *in vitro* assays described in the Statement of Work such as cytotoxicity and genotoxicity assays and cell-based assays measuring oxidative stress and inflammation. a. One (1) point for each different assay for which the Senior Lead has experience to a maximum of five (5) points. b. One (1) point for each twelve (12) month period of experience with in vitro toxicity assays to a maximum of five (5) 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.	**10**	
PR-2	**Experience of Laboratory Technician:** The Bidder's proposed Laboratory Technician from M-1 must demonstrate experience with the *in vitro* assays described in the Statement of Work such as cytotoxicity and genotoxicity assays and cell-based assays measuring oxidative stress and inflammation. a. One (1) point for each of the number of assays for which the Laboratory Technician has experience to a maximum of five (5) points. b. One (1) point for each twelve (12) month period of experience with in vitro toxicity assays to a maximum of five (5) 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.	**10**	
PR-3	**Work Plan** The Work Plan from M-3 will be assessed and scored as follows: a. A score of four (4) points will be assigned if the Work Plan is Excellent – provides realistic details and explanations, activities and deliverables. Includes details on number of staff hours required to complete each task and describes feasible arrangements to run more samples or more tasks simultaneously. The knowledge, experience or approach demonstrated must ensure highly effective performance.	**4**	

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
	Addresses and exceeds all elements as outlined in the SOW, including number of staff hours required to complete each task. b. 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. Addresses all elements as outlined in the SOW, including number of staff hours required to complete each task. c. 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. Addresses most elements as outlined in the SOW. d. 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 SOW. e. 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 SOW.		
PR-4	**Methodological Approach** The proposed Methodological Approach from M-3 will be assessed based on SOW and the following: a. Understanding of the project objectives; b. Understanding of what is included from the scope of the research and what literature sources that may be referenced; c. Proposed analytical strategies; and d. Strategies to mitigate possible project challenges. Points Breakdown: i. A score of eight (8) points will be assigned if the methodological approach is Excellent, addresses and exceeds SOW and a-d (above). ii. A score of six (6) points will be assigned if the methodological approach addresses the SOW and a-d (above). iii. A score of four (4) points will be assigned if the methodological approach satisfactorily addresses the SOW and a-d (above). iv. A score of two (2) points will be assigned if the methodological approach minimally addresses the SOW and a-d (above).	**8**	

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
	v. 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 SOW.		
PR-5	**Ability of Bidder to complete Optional Tasks** The Bidder must provide a description of method(s) and/or validation data for assays described in Tasks B – F. Points per task will be awarded only if the Bidder is bidding on that specific task. a. 2 points per in vitro cytotoxic assay (**Task B**), 6 points maximum. b. 3 points per group of 4 in vitro protein markers of oxidative stress or inflammation (**Task C**), 9 points maximum. c. 2 points per in vitro oxidative stress assay (**Task D**), 6 points maximum. d. Two (2) points per in vitro cardiovascular toxicity assay (**Task E**), up to a maximum of 4 points. e. 2 points each for the OECD thymidine kinase gene Guideline 490, the OECD In vitro mammalian cell micronucleus test Guideline 487, and the OECD BHas cell transformation assay (No. 231) (**Task F**), 6 points maximum.	**31**	
PR-6	**Ability of Bidder to Operate under OECD GLP Guidelines** The Bidder must provide a description of procedures in place to follow OECD GLP Guidelines for work directly involved in in vitro studies. a. 2 points for each protocol in place for calibration or maintenance of equipment, cell exposure or steps in cell culture or in vitro toxicity assays (8 points maximum) b. 4 points for GLP certification for the laboratory and procedures that would be used for completion of a Task identified in SOW (12 points maximum).	**20**	
PR-7	**Experience of Bidder:** The Bidder must demonstrate experience with quantifying 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. a. One (1) point for each project completed in the last 5 years that involved ELISA or multi-plex methods to quantify proteins in the cell lysates or culture media to a maximum of five (5) 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	**5**	

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
	the project (start and end dates), the project lead name and contact information (phone number and e-mail), number of assays, etc.		
PR-8	**Experience of Bidder:** The Bidder must demonstrate experience with the in vitro toxicity testing of vaping liquid and/or vaping liquid ingredients 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. a. One (1) point for each of the different assays performed to a maximum of five (5) points; b. One (1) point for each cell type(s) relevant to the SOW used (human, mammalian, cell lines, primary cells) including cell types related to the respiratory tract or lungs to a maximum of five (5) 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.	**10**	
PR-9	**Experience of Bidder:** The Bidder must demonstrate experience with the in vitro toxicity testing of vaping liquid and/or vaping liquid ingredients in cell-based assays in the **Bidders Laborator(y/ies)**. a. Two (2) points for each assay validated in Bidders laborator(y/ies) (8 points maximum). b. Two (2) points for each project using vaping liquids or vaping liquid ingredients in cell based assays in the Bidders Laborator(y/ies) (6 points maximum). 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/devices, etc.	**14**	
	Maximum Available Points: 112 **Bidders Score:**		

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions

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.

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Compliant (Yes/No)**	**Reference to Bidder's Proposal (page #)**
M-6	The Bidder must submit a project team including a minimum of: • One (1) Project Manager/Lead; and • One (1) Laboratory Technician Bidders must include within their Technical Offer a detailed résumé for EACH proposed resource which must include a detailed, chronological listing of: • his/her technical experience and capability as a Project Manager/Lead or Laboratory Technician; and • his/her education and professional attainments and academic credentials. • Project Manager/Lead must have a Canadian graduate degree (Master's level or Doctorate) or a recognized Canadian equivalent* • The Bidder's proposed laboratory technician must have a Canadian undergraduate degree in Science (Bachelors level) or a recognized Canadian equivalent*. 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. *proof of equivalence must be provided prior to Contract award. Visit www.cicic.ca for a list of organizations that provide equivalency assessments.	☐ Yes ☐ No	
M-7	The Bidder's Project Manager/Lead and the Laboratory Technician from M-1 must have a combined minimum of sixty (60) months' experience in *in vitro* 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 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).	☐ Yes ☐ No	
M-8	**Work Plan and Methodological Approach** The Bidder must provide a written Work Plan and Methodological Approach to undertake the work identified in the Statement of Work (SOW) at Annex 'A' for all Tasks they are	**Mandatory: Task 1 & 2** ☐ Yes ☐ No	

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Compliant (Yes/No)**	**Reference to Bidder's Proposal (page #)**
	bidding on. The Work Plan must show: • A logical and detailed organization of tasks to be completed for the project as per the SOW including all methods and experimental details; • Estimated timelines for completion of each task; • Where applicable, provide details on team composition, responsibilities of team members and expected effort per task; The Methodological Approach must be provided in sufficient detail to allow for a complete understanding of the approach to the work undertaken and should identify the advantages and disadvantages of the proposed Methodological Approach. To be successful, at minimum a bidder must be compliant for Task 1 and 2. Only Tasks a bidder is compliant for will be awarded.	**Optional:** **Task 3** ☐ Yes ☐ No **Task 4** ☐ Yes ☐ No **Task 5** ☐ Yes ☐ No **Task 6** ☐ Yes ☐ No	
M-9	The Bidder's proposed project team from M-1 must submit two (2) similar* projects where the work was completed within the last eight (8) years from date of bid closing. * This includes projects testing at least 2 or more test devices/ conditions (cigarettes and/or alternative devices) using at least 2 different in vitro endpoints or at least 2 different cell types for both (2) projects. * One project must include cigarette or alternative product emission generation machines for exposure using an air-liquid-interface system. 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. For each project, the Bidder must submit 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)		
M-10	The Bidder, sub-contractor(s) and laborator(y/ies) must not have undertaken work related to the manufacturing, importation, processing, promotion, advertising or marketing of tobacco products for the purposes of sale within the past five (5) years measured back from the date of bid closing. To demonstrate compliance, the Bidder must provide a letter signed by the Bidder's Authorized Representative certifying that the Bidder, sub-contractor(s) and laborator(y/ies) have not	☐ Yes ☐ No	

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Compliant (Yes/No)**	**Reference to Bidder's Proposal (page #)**
	undertaken work related to the manufacturing, importation, processing, sale, promotion, advertising or marketing of tobacco products within the past five (5) years measured back from the date of bid closing.		

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.

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
PR-10	**Experience of Project Manager/Lead:** The Bidder's proposed Project Manager/Lead from M-1 must demonstrate experience with the *in vitro* assays described in the Statement of Work such as cytotoxicity and genotoxicity assays and cell-based assays measuring oxidative stress and inflammation. a. One (1) point for each different assay for which the Project Manager/Lead has experience to a maximum of five (5) points. b. One (1) point for each twelve (12) month period of experience with in vitro toxicity assays to a maximum of five (5) 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.	**10**	
PR-11	**Experience of Laboratory Technician:** The Bidder's proposed Laboratory Technician from M-1 must demonstrate experience with the *in vitro* assays described in the Statement of Work such as cytotoxicity and genotoxicity assays and cell-based assays measuring oxidative stress and inflammation. a. One (1) point for each of the number of assays for which the Laboratory Technician has experience to a maximum of five (5) points.	**10**	

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
	b. One (1) point for each twelve (12) month period of experience with in vitro toxicity assays to a maximum of five (5) 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-12	**Work Plan** The proposed Work Plan from M-3 will be assessed and scored as follows: a. A score of four (4) points will be assigned if the Work Plan is Excellent – provides realistic details and explanations activities and deliverables. Includes details on number of staff hours required to complete each task and describes feasible arrangements to run more samples or more tasks simultaneously. The knowledge, experience or approach demonstrated must ensure highly effective performance. Addresses and exceeds all elements as outlined in the SOW, including number of staff hours required to complete each task. b. 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. Addresses all elements as outlined in the SOW, including number of staff hours required to complete each task. c. 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. Addresses most elements as outlined in the SOW. d. 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 SOW. e. 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 SOW.	**4**	
PR-13	**Methodological Approach** The proposed Methodological Approach from M-3 will be	**8**	

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
	assessed based on SOW and the following: a. Understanding of the project objectives; b. Understanding of what is included from the scope of the research and what; literature sources that may be referenced; c. Proposed analytical strategies; and d. Strategies to mitigate possible project challenges. Points Breakdown: i. A score of eight (8) points will be assigned if the methodological approach is Excellent, addresses and exceeds SOW and a-d (above). ii. A score of six (6) points will be assigned if the methodological approach addresses the SOW and a-d (above). iii. A score of four (4) points will be assigned if the methodological approach satisfactorily addresses the SOW and a-d (above). iv. A score of two (2) points will be assigned if the methodological approach minimally addresses the SOW and a-d (above). v. 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 SOW.		
PR-14	**Ability of Bidder to complete Optional Tasks** The Bidder must demonstrate description of method(s) or validation data for assays described in Tasks 3 – 6. Points per task will be awarded only if the Bidder is bidding on that specific task. a. 2 points per in vitro cytotoxic assay (Task B / 3), 6 points maximum. b. 3 points per group of 4 in vitro protein markers of oxidative stress or inflammation (Task C / 4), 9 points maximum. c. 2 points per in vitro oxidative stress assay (Task D / 5), 6 points maximum. d. 2 points each for the OECD thymidine kinase gene Guideline 490 and the OECD In vitro mammalian cell micronucleus test Guideline 487 (Task F / 6), 4 points maximum.	**25**	
PR-15	**Ability of Bidder to Operate under OECD GLP Guidelines** The Bidder must demonstrate description of procedures in place to follow OECD GLP Guidelines for work directly involved in in vitro studies.	**20**	

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
	a. 2 points for each protocol in place for calibration or maintenance of equipment, cell exposure or steps in cell culture or in vitro toxicity assays (8 points maximum) b. 4 points for GLP certification for the laboratory and procedures that would be used for completion of a Task identified in SOW (12 points maximum).		
PR-16	**Experience of Bidder:** The Bidder must demonstrate experience with quantifying 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. a. One (1) point for each project completed in the last 5 years that involved ELISA or multi-plex methods to quantify proteins in the cell lysates or culture media to a maximum of five (5) 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.	**5**	
PR-17	**Experience of Bidder:** The Bidder must demonstrate experience with the in vitro toxicity testing of cigarette or alternative device emissions 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. a. One (1) point for each of the different assays performed to a maximum of five (5) points. b. One (1) point for each cell types relevant to the SOW used (human, mammalian, cell lines, primary cells) including cell types related to the respiratory tract or lungs to a maximum of five (5) 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.	**10**	

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions			
Item	**Description**	**Max Points Available**	**Reference to Bidder's Proposal (page #)**
PR-18	**Experience of Bidder:** The Bidder must demonstrate experience using aerosol exposure systems at the air-liquid-interface (ALI) in a cell-based system in the **Bidders Laborator**(y/ies). a. One (1) point for each project(s) using tobacco or alternative device emissions generation and ALI exposure system in Bidders laborator(y/ies) (4 points maximum). b. Data showing characterization of the emission generating and cell exposure system by quantifying **total particulate matter** (TPM) in emissions from tobacco or alternative products. 2 points per location within system (for example at device mouthpiece or near cell exposure) (6 points maximum). c. Data showing characterization of the emission generating and cell exposure system by quantifying **nicotine** in emissions from tobacco or alternative products. 2 points per location within system (for example at the device mouthpiece or near the point of cell exposure) (6 points maximum). d. Data showing characterization of dilution protocol (using clean air) for cell exposure system from tobacco or alternative products using TPM and/or nicotine. Four (4) points for data showing three levels of emissions and clean air control. 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/devices, etc.	**20**	
	Maximum Available Points: 112 **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 Forms for the Integrity Regime 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 Ineligibility and Suspension Policy *(*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 *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 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 Contracting Policy Notice: 2012-2 and the Guidelines on the Proactive Disclosure of Contracts.

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. TAs will be issued to the top ranked Contractors in each Task. First (1st) ranked Contractor will be issued a TA except when unable to fulfill multiple TA requirements in the same period. Health Canada also may issue a TA to any ranked Contractor to fulfill requirements and use minimum work guarantees. Contractor ranking will be in the resulting contract Statement of Work.
2. The Project Authority will provide the Contractor with a description of the task using the Task Authorization Form specified in Annex C.
3. 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.
4. The Contractor must provide the Project Authority, within 5 calendar days upon request, 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. The Contractor must advise the Project Authority within this timeframe if they are unable to perform the work within the timeline provided.
5. The Contractor must not commence work until a TA authorized by the Project Authority or Designated Approval 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 and expense.

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

Note to the Bidder: The minimum work guarantee will be the combined minimum contract value for all of the tasks they will be awarded.

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 Standard Acquisition Clauses and Conditions Manual (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-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

4007 (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 April 1, 2019 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 three (3) 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: 613-941-2073
E-mail address: Darlene.Fisher2@canada.ca

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 address: _____

(Insert or delete as applicable)

In its absence, the Project Authority is:

Name: _____
Title: _____
Organization: _____
Address: _____

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 *Public Service Superannuation Act* (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 Contracting Policy Notice: 2012-2 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

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

7.7.5 T1204 - Direct Request by Customer Department

A9117C (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.
   hc.p2p.east.invoices-factures.est.sc@canada.ca

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 4007 (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 A2000C *(2006-06-16)* Foreign Nationals (Canadian Contractor)

OR

SACC Manual clause A2001C *(2006-06-16)* Foreign Nationals (Foreign Contractor)

7.13 Insurance

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

ANNEX "A"

STATEMENT OF WORK

1. TITLE

In vitro cell-based toxicity testing of vaping and heated tobacco devices.

2. SCOPE

2.1. 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 (HC) is responsible for helping Canadians protect, maintain, and improve their health, while respecting individual choices and circumstances. To achieve this goal, Health Canada takes into account available high-quality scientific data to inform its work.

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[1], such as vaping products 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 to maximize the potential these alternative products represent, while minimizing harm, there is a need to bridge critical scientific knowledge gaps related to their use.

The tobacco industry recently introduced heated tobacco products and is promoting these new products as less harmful than cigarettes. However, there has been little independent research conducted on heated tobacco products and the health effects of switching from smoking cigarettes to an alternative product is presently uncharacterized. Information on the long term health consequences of alternative products is an essential element needed to determine with sufficient confidence where vaping products and heated tobacco products fall on a health risk continuum.

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

2.2. Objectives of the Requirement

The main objective of the requirement is to generate data on the in vitro toxicity of different alternative devices and conventional cigarette emissions in support of research activities at TCD. The data and results provided by the Contractor(s) will be evaluated by Health Canada for appropriate methodology, data accuracy, appropriate quality assurance/quality control (QA/QC) procedures, and reporting standards consistent with the Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practices (GLP) guidelines; however, GLP certification is not an essential requirement.

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[1] For the purposes of this document *alternative products* include *vaping* and *heated tobacco products*.

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.

Heated tobacco products contain tobacco and a heating element. They are also referred to as heat not burn and tobacco heating products.

There are two streams in this requirement. Stream 1 will investigate the in vitro toxicity of vaping products and chemicals found in vaping products by spiking cell culture media. Stream 2 will compare the in vitro toxicity of emissions from conventional or alternative devices at the air-liquid interface (ALI). For stream 2 the contractor must first characterize and demonstrate the use of cell exposure system(s) that generate(s) emissions from different alternative devices according to puff profiles as outlined in this SOW and then perform a series of in vitro toxicity tests to compare the relative toxicity of emissions from these devices.

2.3. 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 by generating data on the *in vitro* toxicity in four main categories: cytotoxicity, genotoxicity, oxidative stress/inflammation and *in vitro* cardiovascular toxicity. This requirement may be filled by one or more contractors depending on the capacity of bidders. Separate bids are required for each of the two streams.

The Contractor shall conduct in vitro toxicity testing as described in this SOW and to provide a report for each task 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 data are supported by appropriate QA/QC procedures. The start and completion times for each task will be subject to specific requirements of the project as determined by Health Canada. Some tasks listed below can be done in the same cell culture well; therefore, the contractor may be required for efficiency purposes to assess multiple endpoints simultaneously as determined by the HC Scientific and Technical Authority.

Task Authorization (TA) Issuance Procedure

TAs will be issued to the top ranked Contractors in each Task. First (1^{st}) ranked Contractor will be issued a TA except when unable to fulfill multiple TA requirements in the same period. Health Canada also may issue a TA to any ranked Contractor to fulfill requirements and use minimum work guarantees.

Contractor Ranking Per Task:

(Only ranking of Tasks the Bidder is compliant on to be inserted at Contract Award)

2.3.1. Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients

TCD is interested in obtaining information relating to the toxicity of chemicals identified in vaping liquids by generating data from in vitro toxicity tests including cell-based assays for cytotoxicity, genotoxicity, oxidative stress/inflammation and cardiovascular function as indicated in the task-based table below (section 3.1.1). This requirement may be filled by one or more contractors depending on the capacity of bidders.

The Contractor will be required to produce and provide the HC Scientific and Technical Authority with frozen cell lysates/pellets and cell culture supernatants from cells exposed as described in this SOW for analysis by Health Canada. In addition, if a Contractor has the capacity, in vitro toxicity testing of the emissions from different devices should include cell-based assays for cytotoxicity, genotoxicity and/or measures of oxidative stress/inflammation as indicated in the task-based table below. The assays must be completed using commercial assay kits or consistent with OECD guidelines (described below) when available and using relevant well characterized human cell lines from the respiratory tract or lungs as specified by the HC Technical Authority.

The list of chemical substances, vaping liquids and vehicle controls will be provided by the HC Scientific and Technical Authority through TA process in batches of 25 chemicals at a time. The Contractor will be required to complete in vitro toxicity testing of all chemical substances listed and provided by Health Canada.

2.3.2. Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions

TCD is interested in obtaining information relating to the toxicity of emissions produced from different alternative products compared with conventional cigarette by generating data from in vitro toxicity tests including cell-based assays for cytotoxicity, genotoxicity, oxidative stress/inflammation and cardiovascular function as indicated in the task-based table below (section 3.1.2). This requirement may be filled by one or more contractors depending on the capacity of bidders.

Emission generation must be performed using a commercially available or fully characterized emission generating machine according to puff profiles such as the Health Canada Intense smoking regimen and/or ISO 3308 (method to be used will be specified in Task Authorization process). Chemical characterization of the emissions must be determined at the mouthpiece of the device and/or near the point of cell exposure. Cell culture exposure to the emissions must be performed at the air-liquid interface in a commercially available or fully characterized exposure module under conditions appropriate for the in vitro cell model used and capable of administering multiple different doses/dilutions. The Contractor will be required to produce and provide the HC Scientific and Technical Authority with frozen cell lysates/pellets and cell culture supernatants from cells exposed as described in this SOW for analysis by Health Canada. In addition, if a Contractor has the capacity, in vitro toxicity testing of the emissions from different devices should include cell-based assays for cytotoxicity, genotoxicity and/or measures of oxidative stress/inflammation as indicated in the task-based table below. The assays must be completed using commercial assay kits or consistent with OECD guidelines (as per Section 6.1) when available and using relevant well characterized human cell lines from the respiratory tract or lungs as specified by the HC Technical Authority.

The specific list of alternative devices as well as conventional cigarettes to be tested will be provided by the HC Scientific and Technical Authority during Task Authorization process. The devices and cigarettes to be tested will likely have different mouthpiece shapes and sizes, button activation functions, settings and battery requirements that must be adapted to work with the contractor's emission generating devices. A clean air control (filtered air) must also be included in all in vitro toxicity testing assays. The HC Scientific and Technical Authority will determine the vaping liquids to be used with the vaping product devices.

3. REQUIREMENTS

3.1. Tasks, Activities, Deliverables and/or Milestones

Tasks or Activities:

The Contractor must undertake the tasks described in Section 3.1.1 (Stream 1) or 3.1.2 (Stream 2) and produce the deliverables on an "as and when requested basis" using a Task Authorization (TA). Tasks will be requested based on TCD data needs. The same Task may be requested multiple times using different devices/doses/dilutions/exposure times. The Task Authorization will include the list of devices or chemicals to be tested. Tasks need to follow appropriate manufacturer guidelines and/or be consistent with the appropriate OECD guideline(s) (Task F / 6).

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. A Task Project Plan and a Task Final Report should be completed for each task as described in Section 3.1.3, after consultation with the HC 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.

The Contractor shall be responsible for procuring all testing materials. Alternative devices, cigarettes and vaping liquids/e-liquids have not been identified in this SOW, therefore costs of procurement should not be included in the bid. All remaining costs should be included in the bid including, but not limited to, testing kits, cell culture supplies, laboratory supplies, personnel, and overhead.

This requirement may be filled by one or more contractors depending on the capacity of bidders. Separate bids are required for each of the two streams.

3.1.1. Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients

Unless otherwise stated, the following parameters/experimental design will apply to each TA:

- 25 chemicals / vaping liquids
- 24 hour exposure
- Dilutions will be achieved using Dimethyl sulfoxide (DMSO) for chemicals and DMSO or a reference vaping liquid containing a specific propylene glycol/vegetable glycerin (PG/VG) composition for vaping liquids as specified in the TA.
- Dilutions:
    - 12 dilutions per chemical for cell lysate/supernatant and cytotoxicity (Chemicals: 10000, 1000, 100, 10, 1, 0.1, 0.01, 0.001, 0.0001, 0.00001, 0.000001 and 0 µM; and vaping liquids: 1/10, 1/25, 1/50, 1/100, 1/250, 1/500, 1/1000, 1/5000, 1/10000, 1/50000, 1/100000)
    - 6 dilutions for all other tasks (to be determined following task 1)
- 3 wells per exposure condition per plate
- 3 replications of exposure on separate days
- human lung/respiratory tract cell line(s)
- store samples until Task Final Report (Section 3.1.3.5) approval by HC as per Section 4.2

The contractor must verify that chemicals are completely soluble in the solvent. Any chemicals and concentrations that are not completely soluble in the appropriate vehicle must be reported and should not be used. Any chemicals and 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. Any chemicals that interfere with assay detection methods must be noted and appropriate steps must be taken to mitigate effects on the assay (for example chromophores, autofluorescence or luminescence).

The bidder must identify in their bid which cell lines they can work with; such as A549 human alveolar cell line (task A, B, C, D, F), BEAS-2B human bronchial epithelial cell line (task A, B, C, D), a human coronary arterial endothelial or vascular endothelial cell line (task B, E), human monocytes (task B, E), TK6 human lymphoblastoid cell line (task B, F) and the Bhas 42 cell line (task B, F).

Storage, use, maintenance and care of all reagents and cells must be performed according to the supplier/ manufacturer's instructions and specifications. All laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated. Contractors should be aware of OECD GLP guidelines; however, certification is not an essential requirement. All cell culture work must be conducted under sterile conditions to prevent microbial contamination of the cells/cell culture media. Mycoplasma contamination should be routinely reported and verified.

A Task Project Plan (as per Section 3.1.3.2) must be submitted and approved prior to starting work on any Task.

MANDATORY TASKS **Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients**
Task A – Frozen cell lysates/pellets and cell culture supernatants. The Contractor will provide the HC Scientific and Technical Authority with frozen cell lysates/pellets and cell culture supernatants following 24 hour in vitro exposure to chemicals and vaping liquids at the 12 specified concentrations for analysis by Health Canada. The cell culture wells must be rinsed with PBS and immediately frozen (-80°C) either on the plates, as a pellet or as cell lysate.

OPTIONAL TASKS (a minimum of one optional task is required for any bid for Stream 1)
Task B – *In vitro* cytotoxicity testing. The Contractor must conduct *in vitro* toxicity testing of 12 concentrations of vaping liquids and ingredients to assess cytotoxicity in all cell lines using one commercially available cytotoxicity assay (for example neutral red uptake assay, lactate dehydrogenase (LDH) release, the 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay, resazurin) following 24 hours of exposure. The Contractor must include the following additional details in the Project Plan; appropriate positive and negative cytotoxicity controls.
Task C – Quantification of *In vitro* protein markers of oxidative stress and inflammation in cell culture supernatants. The Contractor must conduct *in vitro* toxicity testing of 6 concentrations of vaping liquids and ingredients to assess oxidative stress and inflammation markers in cell culture supernatants of at least one human lung/respiratory tract cell line using a commercial multi-plex protein assay or ELISA according to the manufacturer's instructions. Twenty-four (24) or 48 hours post-exposure, the proteins shall be quantified in the cell culture. The Contractor must include the following additional details in the Project Plan; appropriate positive (e.g. LPS at 1 µg/ml) and negative controls; protein assay that will be used to quantify total cell protein content; a list of protein markers of oxidative stress and inflammation such as Interleukin(s), Lactase dehydrogenase, and cell adhesion molecules (protein markers of interest listed in Section 6.3).
Task D – *In vitro* oxidative stress assay testing using commercially available assay(s). The Contractor must conduct *in vitro* toxicity testing of at least one human lung/respiratory tract cell line using 6 concentrations of vaping liquids and ingredients to assess oxidative stress using a commercial assay according to the manufacturer's instruction (for example glutathione:glutathione disulfide (GSH:GSSG), reactive oxygen species (ROS)) following 24 hours of exposure time. The Contractor must include the following additional details in the Project Plan; appropriate positive and negative controls.
Task E – *In vitro* cardiovascular toxicity assay testing using commercially-available assay(s). The Contractor must conduct *in vitro* toxicity testing of 6 concentrations of vaping liquids and ingredients to assess *in vitro* cardiovascular toxicity using a commercially available assay(s) according to manufacturer's instructions (for example monocyte adhesion assay, monocyte/leukocyte trans-endothelial cell migration assay) following 24 hour exposure (or as recommended by manufacturer's instructions). The Contractor must include the following additional details in the Project Plan; appropriate positive and negative controls; identification of the relevant human coronary artery or vascular endothelial cell line and appropriate human leukocyte or monocyte cell line.
Task F – *In vitro* genotoxicity testing using the Organization for Economic Co-operation and Development (OECD) *In vitro* mammalian cell gene mutation tests using the thymidine kinase gene Guideline 490 and/or the OECD *In vitro* mammalian cell micronucleus test Guideline 487 and/or OECD *in vitro* Bhas cell transformation assay guidance Document Series on Testing and Assessment No 231. The Contractor must conduct *in vitro* toxicity testing of 6 concentrations of vaping liquids and ingredients to assess genotoxicity using TK6 human lymphoblastoid cell line (Guideline 490), A549 human alveolar cell line (Guideline 487), and/or Bhas 42 cell line (Series on Testing and Assessment No 231). The Contractor must include the following additional details in the Project Plan; appropriate positive and negative genotoxicity controls; post-exposure lag time; metabolic activation.

3.1.2. Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions

Unless otherwise stated, the following parameters/experimental design will apply to each TA:

- 4 alternative devices, plus 2 controls (clean air and conventional cigarette)
- 4 hour maximum exposure duration
- 3 doses/dilutions per device
- 3 wells per exposure condition per plate
- 3 replications of exposure on separate days
- human lung/respiratory tract cell line(s)
- store samples until Task Final Report (Section 3.1.3.5) approval by HC as per Section 4.2

The bidder must identify in the bid which cell lines they can work with; such as A549 human alveolar cell line (task 2, 3, 4, 5, 6), BEAS-2B human bronchial epithelial cell line (task 2, 3, 4, 5), and the TK6 human lymphoblastoid cell line (task 3, 6).

Different doses/dilutions at the ALI can be achieved by diluting emissions with clean air or using different exposure times. The contractor must ensure that condensation of the emissions, in particular from alternative products, is minimized and may require a heated emissions path. Humidity levels of the emissions must be controlled and be suitable for viable cell culture conditions. Cross-contamination of emissions from different devices requires separate dedicated emission generating systems, cell exposure device and/or syringe pumps for each device type or demonstration of effective cleaning.

Exposure to emissions from different devices must be based on similar duration and number of puffs (or nicotine /TPM concentration) or as determined by the HC Scientific and Technical Authority. Smoking device parameters, puff profile parameters (equivalent to Health Canada Intense smoking regimen parameters for cigarette emissions or ISO3308), target doses/dilutions of emissions and exposure durations will be identified by Health Canada Technical Authority in consultation with the Contractor.

Storage, use, maintenance and care of all reagents and cells must be performed according to the supplier, manufacturer's instructions and specifications. All laboratory equipment, cell lines, testing devices and reagents used must be properly maintained and regularly calibrated. Contractors should be aware of OECD GLP guidelines; however, certification is not an essential requirement. All cell culture work must be conducted under sterile conditions to prevent microbial contamination of the cells/cell culture media. Mycoplasma contamination should be routinely reported and verified.

A Task Project Plan (as per Section 3.1.3.2) must be submitted and approved prior to starting work on any Task. Task #1 must be completed and accepted prior to performing any other task.

MANDATORY TASKS
Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions

Task #1 – Design, set-up and characterization of an emission generating and cell exposure system at the air-liquid interface (ALI). The Project plan for Task 1 must include a detailed (a) schematic / design of the emission generating and exposure system, (b) smoking/puff regimen for each device, and (c) design and characterization of dose/dilution methods. The Contractor must provide methods for consistent test atmosphere generation, characterization and precise delivery of diluted mainstream conventional cigarette and alternative product emissions for up to 4 hours at a time for in vitro exposure studies in cell-based models at the ALI. The contractor must provide a detailed plan on requested dilutions/doses and exposure times and how these will be achieved and characterized. This exposure system must be used in all subsequent Tasks.

Characterization of the emission generation and exposure system to ensure intra- and inter-day stability of doses/dilutions for each test device type (cigarette, vaping product, heated tobacco

product, and clean air) must be based on measurements from a minimum of 3 separate days, at the beginning and end of a 4 hour emission generation session for each device type. Characterization of the emission generating system must quantify total particulate matter and nicotine at the device mouthpiece and/or near the point of cell exposure. In addition, characterization of the emission generating system must be done for each tobacco or alternative product device (and clean air control) in triplicate.

Task #2 – Frozen cell lysates/pellets and cell culture supernatants. The Contractor will provide the HC Scientific and Technical Authority with frozen cell lysates/pellets and cell culture supernatants following in vitro exposure to emissions from different alternative devices, conventional cigarette emissions and clean air for DNA/RNA/protein analysis by Health Canada. The HC Scientific and Technical Authority will identify 1) the lag time between exposure and collection of cell lysates/pellet and cell culture supernatants (for example 24 hours) and 2) preparation method of the cell lysates/pellets (following removal of the supernatant, the cell culture wells must be rinsed with PBS and immediately frozen (-80°C) either on the plates, as a pellet or as cell lysate).

OPTIONAL TASKS

Task #3 – *In vitro* cytotoxicity testing. The Contractor must conduct *in vitro* toxicity testing using emissions from different alternative devices, conventional cigarette emissions and clean air to assess cytotoxicity of all cell lines using one commercially available cytotoxicity assay (for example neutral red uptake assay, lactate dehydrogenase (LDH) release, the 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay, resazurin). The Contractor must include the following additional details in the Project Plan; appropriate positive and negative cytotoxicity controls, post-exposure lag time (for example 24 hours or as recommended by the assay manufacturer).

Task #4 – Quantification of *In vitro* protein markers of oxidative stress and inflammation in cell culture supernatants. The Contractor must conduct *in vitro* toxicity testing using emissions from different alternative devices, conventional cigarette emissions and clean air to assess oxidative stress and inflammation markers in cell culture supernatants of at least one human lung/respiratory tract cell line using a commercial multi-plex protein assay or ELISA according to the manufacturer's instructions. Twenty-four (24) hours post-exposure, the proteins shall be quantified in the cell culture. The Contractor must include the following additional details in the Project Plan; appropriate positive (e.g. LPS at 1 µg/ml) and negative controls; protein assay that will be used to quantify total cell protein content; a list of protein markers of oxidative stress and inflammation such as Interleukin(s), Lactase dehydrogenase, and cell adhesion molecules (additional protein markers of interest listed in 6.3).

Task #5 – *In vitro* oxidative stress assay testing using a commercially available *in vitro* oxidative stress assay(s). The Contractor must conduct *in vitro* toxicity testing using emissions from different alternative devices, conventional cigarette emissions and clean air to assess oxidative stress of at least one human lung/respiratory tract cell line using a commercial assay according to the manufacturer's instruction (for example glutathione:glutathione disulfide (GSH:GSSG), reactive oxygen species (ROS)). The Contractor must include the following additional details in the Project Plan; appropriate positive and negative controls, post-exposure lag time (for example 24 hours or as recommended by the assay manufacturer).

Task #6 – *In vitro* genotoxicity testing using the Organization for Economic Co-operation and Development (OECD) *In vitro* mammalian cell gene mutation tests using the thymidine kinase gene Guideline 490 and/or the OECD *In vitro* mammalian cell micronucleus test Guideline 487. The Contractor must conduct *in vitro* toxicity testing using emissions from different alternative devices, conventional cigarette emissions and clean air to assess genotoxicity using TK6 human lymphoblastoid cell line (guideline 490) and/or A549 human alveolar cell line (guideline 487). The Contractor must include the following additional details in the Project Plan; appropriate positive and negative genotoxicity controls and post-exposure lag time; metabolic activation.

3.1.3. 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 2 Scope and must provide the following deliverables, unless otherwise specified in the Task Authorization: Task Draft Project Plan, Task Kick-off Meeting, Task 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 HC Scientific and Technical Authority by its delivery date specified in the Task Authorization.

3.1.3.1. Task Kick-off Meeting

The Contractor must provide a Task Draft Project Plan (Section 3.1.3.2.1) based on the draft Task Authorization prior to the Task Kick-off meeting. The Contractor must participate in a Task Kick-off Meeting to discuss the Task Draft Project Plan, acquire initial review from the HC Scientific and Technical Authority, and to review the draft Task Authorization prior to start of any tasks. The Task Kick-off Meeting will take place by teleconference as stipulated in Task Authorization. Following the Task Kick-off Meeting, a Final Task Authorization will be provided by HC.

Alternative assays to those listed above may be considered at the discretion of the HC Scientific and Technical Authority providing the contractor demonstrates sufficient rationale and benefit to an alternative assay in the Task Draft Project Plan. Any alternative method must be identified prior to and discussed during the task kick-off meeting and included in the written Final Task Authorization.

3.1.3.2. Task Project Plan

Before commencing any task the Contractor must obtain approval for their Task Project Plan.

3.1.3.2.1. Task Draft Project Plan

Before commencing any task the contractor must provide a Task Draft Project Plan for acceptance and review by the HC 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;
- Estimated completion date.
- A detailed study plan, schedule and methodology; including plate map diagrams and description of treatment conditions in each well. Any modifications to assay instructions from manufacturer must be identified and approved by the HC Scientific and Technical Authority.
- Identification of all positive and negative controls when applicable (for example positive and negative controls for the cytotoxicity assay)
- cell line(s) (for example A549 human alveolar cell line, BEAS-2B human bronchial epithelial cell line, TK6 human lymphoblastoid cell line)

- A description of all research questions and data analysis requested from the HC Scientific and Technical Authority and if applicable, any suggestion from the Contractor on these questions to improve the analysis;
- Detailed description and schedule of study parameters and all endpoints to be measured.
- Detailed description of all procedures and analytical methods.
- Identification of what degree OECD GLP guidelines are being followed.

3.1.3.2.2. Task Final Project Plan

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 HC Scientific and Technical Authority. The Contractor must provide the Task Final Project Plan for review and approval by the HC Scientific and Technical Authority, within 10 working days of receipt of the HC 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 HC 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 HC Scientific and Technical Authority, either through verbal or written communication to the Contractor, prior to implementation.

3.1.3.3. Task Status Report

At the HC 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.

3.1.3.4. Task Draft Report

The Contractor must provide a Task Draft Report to the HC Scientific and Technical Authority, as stipulated in the Task Authorization, for acceptance and review by the HC Scientific and Technical Authority. The Contractor must provide one electronic copy of the draft report to the HC Scientific and Technical Authority which must contain all the study findings including the detailed methodology, test procedures, experimental parameters, visual microscopic observations (any major exposure based changes must be highlighted), 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 OECD test guidelines.

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

3.1.3.5. 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 HC Scientific and Technical Authority. The Contractor must provide the Task Final Report at least 15 working days prior to the Task Authorization completion date, for review and approval by the HC Scientific and Technical Authority.

3.2. Specifications and Standards

Refer to Section 3.1

3.3. Technical, Operational and Organizational Environment

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

Refer to sections 2.1 and 2.3 regarding how the work will fit within other initiatives and who will be the ultimate end user of the requirement.

3.4. Method and Source of Acceptance

The HC 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 HC Scientific and Technical Authority will re-review the deliverable and determine if it is acceptable or requires revision (at no cost to Health Canada).

3.5. 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 HC 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 3.1 for associated details on reporting requirements.

3.6. Project Management Control Procedures

The HC Scientific and Technical Authority shall monitor the progress of the work, ensure that the Contract 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.

See also the details outlined in sections 3.4 and 3.5.

4. ADDITIONAL INFORMATION (Other Terms and Conditions of the SOW)

4.1. Health Canada's Obligations

Health Canada shall:

- Health Canada's representatives will establish a clear statement of tasks, activities, deliverables and milestones.
- Health Canada's representatives will communicate with the contractor as required to review the testing protocol, verify details for completeness and to assess progress.
- HC will provide shipping instructions for Task A (Stream 1) / 2 (Stream 2).
- Provide guidance on how to report study results, including the early results reporting protocol (if applicable).
- Provide comments on draft reports and final reports to the Contractor within fifteen (15) working days.

4.2. Contractor's Obligations

The Contractor shall:

- Unless otherwise specified, the Contractor must use its own equipment and software for the performance of this Statement of Work.
- The Contractor shall purchase the chemicals to be tested, assays, cells and all reagents required to complete the tasks in the SOW.
- 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.
- 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.
- The Contractor shall ship samples as requested by HC (Task A (Stream 1) / 2 (Stream 2).
- The Contractor shall store the study samples/chemicals until final approval of the results by Health Canada.

Refer also to Section 3.1 through 3.6 for other obligations of the Contractor.

4.3. 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 readily available to work in frequent contact with the HC 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.

4.4. Language of Work

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

4.5. Travel and Living

Not Applicable

5. PROJECT SCHEDULE

5.1. Schedule and Estimated Level of Effort (Work Breakdown Structure)

The services of the Contractor will be required for a period of approximately 12 months commencing on or about April 1st, 2019. The expected completion date of this project is the 31st of March, 2020. The Contract will be set up with the option of annual renewal up to a maximum of three (3) one (1) year renewals (option year 1: April 2020-March 2021; option year 2: April 2021-March 2022; option year 3: April 2022-March 2023) to be exercised at Health Canada's discretion. Should option year(s) be exercised, the expected completion date for option year one is the 31st of March, 2021; option year two is the 31st of March, 2022; and option year three is the 31st of March, 2023.

The Contractor shall submit to the HC 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 and progress or status reports. 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 are outlined in Section 3 of the SOW.

The Contractor shall provide sufficient resources to complete the tasks, activities, and milestones identified in Section 3.1. 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, assign tasks to laboratory personnel, analyze data, draft reports, assure tasks are properly completed,
Laboratory Technicians	Minimum of 1	Complete all laboratory work, 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.

6. APPLICABLE DOCUMENTS AND GLOSSARY

6.1. Applicable Documents

Task descriptions in Section 3.1 refer to the following Guidelines:

ISO 3308:2012 – Routine analytical cigarette-smoking machine https://www.iso.org/standard/60404.html

OECD Principles of Good Laboratory Practice (GLP): (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
https://www.oecd-ilibrary.org/environment/test-no-490-in-vitro-mammalian-cell-gene-mutation-tests-using-the-thymidine-kinase-gene_9789264264908-en
https://www.oecd-ilibrary.org/environment/essai-n-490-essai-in-vitro-de-mutation-genique-sur-cellules-de-mammiferes-utilisant-le-gene-de-la-thymidine-kinase_9789264264915-fr

487: In Vitro Mammalian Cell Micronucleus Test
https://www.oecd-ilibrary.org/environment/test-no-487-in-vitro-mammalian-cell-micronucleus-test_9789264264861-en
https://www.oecd-ilibrary.org/environment/essai-n-487-essai-in-vitro-de-micronoyaux-sur-cellules-de-mammiferes_9789264264878-fr

OECD GUIDANCE DOCUMENT ON THE IN VITRO BHAS 42 CELL TRANSFORMATION ASSAY. Series on testing and assessment number 231 (20 July 2017)
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2016)1&doclanguage=en

6.2. Relevant Terms, Acronyms and Glossaries

ALI – air liquid interface
DMSO – dimethyl sylfoxide
ELISA – Enzyme-linked immunosorbent assay
ENDS – electronic nicotine delivery system
GLP – Good Laboratory Practice
GSH: GSSG – glutathione:glutathione disulfide
HC – Health Canada
ISO – International Organization for Standardization
LDH – lactate dehydrogenase
MTT – 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide
OECD – Organisation for Economic Co-operation and Development
ORS – Office of Research and Surveillance
PG – propylene glycol
QA/QC – quality assurance / quality control
ROS – reactive oxygen species
SOW – statement of work
TA – Task Authorization
TCD – Tobacco Control Directorate
TPM – total particulate matter
VG – vegetable glycerine

6.3. PROTEIN MARKERS OF INTEREST

Please note this is not a comprehensive list of protein markers, additional markers will be considered.

- Collagenase
- CXCL-9, CXCL-10
- Elastase
- Granulocyte-macrophage colony-stimulating factor (GM-CSF)
- Interferon (IFN)-γ
- Interleukin (IL)-1, IL-1α, IL-2, IL-4, IL-6, IL-8, IL-10, IL-12p70
- Lactate dehydrogenase (LDH)
- Matrix metalloproteinase (MMP)-1, MMP-9
- Monocyte chemoattractant protein (MCP)-1
- Plasminogen activator inhibitor (PAI)-1Transforming growth factor (TGF)-β
- soluble cell adhesion molecule (sICAM)-1
- Soluble vascular cell adhesion molecule (VCAM)-1
- Tumour necrosis factor (TNF)-α
- Vascular endothelial growth factor (VEGF)-α

ANNEX "B"

BASIS OF PAYMENT

The Bidder must complete either pricing schedule at Appendix 1 to Annex B or Appendix 2 to Annex B 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.

Appendix 1 to Annex B – Basis of Payment

Stream 1: *In vitro* testing of vaping liquids and vaping liquid ingredients

Instructions

The bid must include a breakdown of costs and timelines for 25 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 A/B and 6 dilutions (plus positive and negative control) for Tasks C, D, E, and F. Incorporate materials, personnel and overhead costs including administrative costs associated with purchasing materials to be tested (25 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 A

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
A	25 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A1 (excluding taxes)	$_____

2. Table 2 "A2" – Task B

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
B	25 Chemicals / Vaping liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A2 (excluding taxes)	$_____

3. Table 3 "A3" – Task C

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
C	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A3 (excluding taxes)	$_____

4. Table 4 "A4" – Task D

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
D	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A4 (excluding taxes)	$_____

5. Table 5 "A5" – Task E

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
E	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A5 (excluding taxes)	$_____

6. Table 6 "A6" – Task F

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
F	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x	$ _____

	1 cell type x 3 wells per run x 3 separate runs	
	Sub-Total A6 (excluding taxes)	$_____

7. Table 7 "A7" – 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-Total A7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

B. Option Year 1

1. Table 1 "B1" – Task A

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
A	25 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B1 (excluding taxes)	$_____

2. Table 2 "B2" – Task B

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
B	25 Chemicals / Vaping liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B2 (excluding taxes)	$_____

3. Table 3 "B3" – Task C

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
C	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B3 (excluding taxes)	$_____

4. Table 4 "B4" – Task D

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
D	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell types x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B4 (excluding taxes)	$_____

5. Table 5 "B5" – Task E

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
E	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B5 (excluding taxes)	$_____

6. Table 6 "B6" – Task F

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
F	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B6 (excluding taxes)	$_____

7. Table 7 "B7" – 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-Total B7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

C. Option Year 2

1. Table 1 "C1" – Task A

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
A	25 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C1 (excluding taxes)	$_____

2. Table 2 "C2" – Task B

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
B	25 Chemicals / Vaping liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C2 (excluding taxes)	$_____

3. Table 3 "C3" – Task C

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
C	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C3 (excluding taxes)	$_____

4. Table 4 "C4" – Task D

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
D	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C4 (excluding taxes)	$_____

5. Table 5 "C5" – Task E

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
E	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell types x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C5 (excluding taxes)	$_____

6. Table 6 "C6" – Task F

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
F	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C6 (excluding taxes)	$_____

7. Table 7 "C7" – 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-Total C7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

D. Option Year 3

1. Table 1 "D1" – Task A

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

A	25 Chemicals / Vaping Liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D1 (excluding taxes)	$_____

2. Table 2 "D2" – Task B

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
B	25 Chemicals / Vaping liquids at 14 samples (12 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D2 (excluding taxes)	$_____

3. Table 3 "D3" – Task C

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
C	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D3 (excluding taxes)	$_____

4. Table 4 "D4" – Task D

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
D	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell types x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D4 (excluding taxes)	$_____

5. Table 5 "D5" – Task E

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
E	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D5 (excluding taxes)	$_____

6. Table 6 "D6" – Task F

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
F	25 Chemicals / Vaping liquids at 8 samples (6 concentrations + negative and positive controls) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D6 (excluding taxes)	$_____

7. Table 7 "D7" – 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-Total D7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

E. Total Bid Price for Evaluation Per Task Calculation

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

Task A Total Bid Price for Evaluation = Sum of Sub-Totals A1, B1, C1, and D1

Task B Total Bid Price for Evaluation = Sum of Sub-Totals A2, B2, C2, and D2

Task C Total Bid Price for Evaluation = Sum of Sub-Totals A3, B3, C3, and D3

Task D Total Bid Price for Evaluation = Sum of Sub-Totals A4, B4, C4, and D4

Task E Total Bid Price for Evaluation = Sum of Sub-Totals A5, B5, C5, and D5

Task F Total Bid Price for Evaluation = Sum of Sub-Totals A6, B6, C6, and D6

The total value of all contracts resulting from both Streams shall not exceed the sum of $440,000.00 in the first year, and $440,000.00 in each of the three (3) one-year option periods should they be exercised for a total cumulative value of $1,760,000.00, taxes extra. This amount includes all professional services, direct and subcontracted expenses, and all other expenses.

E.1Bidder's Total Bid Price for Evaluation (Stream 1)

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

Bidder's Task A Total Bid Price for Evaluation (Mandatory)	$

And at least one (1) optional Task below:	
Bidder's Task B Total Bid Price for Evaluation	$
Bidder's Task C Total Bid Price for Evaluation	$
Bidder's Task D Total Bid Price for Evaluation	$
Bidder's Task E Total Bid Price for Evaluation	$
Bidder's Task F Total Bid Price for Evaluation	$
Applicable Taxes	$

Appendix 2 to Annex B – Basis of Payment

Stream 2: *In vitro* air-liquid-interface testing of alternative product emissions

Instructions

The bid must include a breakdown of costs and timelines for 4 alternative devices and 2 controls (clean air and cigarette) through each task separately for each contract period including options. Base bid costs on 3 dilutions . Incorporate materials, personnel and overhead costs including administrative costs associated with purchasing materials to be tested (4 alternative devices and consumables, cigarettes) but excluding the cost of individual testing materials 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	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A1 (excluding taxes)	$_____

2. Table 2 "A2" – Task #2

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
#2	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A2 (excluding taxes)	$_____

3. Table 3 "A3" – Task #3

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
#3	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A3 (excluding taxes)	$_____

4. Table 4 "A4" – Task #4

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
#4	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A4 (excluding taxes)	$_____

5. Table 5 "A5" – Task #5

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
#5	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A5 (excluding taxes)	$_____

6. Table 6 "A6" – Task #6

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
#6	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total A6 (excluding taxes)	$_____

7. Table 7 "A7" – 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-Total A7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

B. Option Year 1

1. Table 1 "B1" – 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	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____

	Sub-Total B1 (excluding taxes)	$_____

2. Table 2 "B2" – Task #2

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**
#2	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B2 (excluding taxes)	$_____

3. Table 3 "B3" – Task #3

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**
#3	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B3 (excluding taxes)	$_____

4. Table 4 "B4" – Task #4

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
#4	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B4 (excluding taxes)	$_____

5. Table 5 "B5" – Task #5

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
#5	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B5 (excluding taxes)	$_____

6. Table 6 "B6" – Task #6

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
#6	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total B6 (excluding taxes)	$_____

7. Table 7 "B7" – 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-Total B7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

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	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C1 (excluding taxes)	$_____

2. Table 2 "C2" – Task #2

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
#2	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C2 (excluding taxes)	$_____

3. Table 3 "C3" – Task #3

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
#3	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C3 (excluding taxes)	$_____

4. Table 4 "C4" – Task #4

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
#4	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C4 (excluding taxes)	$_____

5. Table 5 "C5" – Task #5

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
#5	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C5 (excluding taxes)	$_____

6. Table 6 "C6" – Task #6

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
#6	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total C6 (excluding taxes)	$_____

7. Table 7 "C7" – 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-Total C7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

D. Option Year 3

1. Table 1 "D1" – 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	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D1 (excluding taxes)	$_____

2. Table 2 "D2" – Task #2

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
#2	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D2 (excluding taxes)	$_____

3. Table 3 "D3" – Task #3

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
#3	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D3 (excluding taxes)	$_____

4. Table 4 "D4" – Task #4

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
#4	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D4 (excluding taxes)	$_____

5. Table 5 "D5" – Task #5

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
#5	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean	$ _____

	air) x 1 cell type x 3 wells per run x 3 separate runs	
	Sub-Total D5 (excluding taxes)	$_____

6. Table 6 "D6" – Task #6

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
#6	6 test materials (4 alternative devices, cigarettes and clean air control) x 3 dilutions (except clean air) x 1 cell type x 3 wells per run x 3 separate runs	$ _____
	Sub-Total D6 (excluding taxes)	$_____

7. Table 7 "D7" – 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-Total D7 (excluding taxes) – item 1 multiplied by item 2 then added to item 2 :		$

E. Total Bid Price for Evaluation Per Task Calculation

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

Task 1 Total Bid Price for Evaluation = Sum of Sub-Totals A1, B1, C1, and D1

Task 2 Total Bid Price for Evaluation = Sum of Sub-Totals A2, B2, C2, and D2

Task 3 Total Bid Price for Evaluation = Sum of Sub-Totals A3, B3, C3, and D3

Task 4 Total Bid Price for Evaluation = Sum of Sub-Totals A4, B4, C4, and D4

Task 5 Total Bid Price for Evaluation = Sum of Sub-Totals A5, B5, C5, and D5

Task 6 Total Bid Price for Evaluation = Sum of Sub-Totals A6, B6, C6, and D6

The total value of all contracts resulting from both Streams shall not exceed the sum of $440,000.00 in the first year, and $440,000.00 in each of the three (3) one-year option periods should they be exercised for a total cumulative value of $1,760,000.00, taxes extra. This amount includes all professional services, direct and subcontracted expenses, and all other expenses.

E.1Bidder's Total Bid Price for Evaluation (Stream 2)

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

Bidder's Task 1 Total Bid Price for Evaluation (Mandatory)	$
Bidder's Task 2 Total Bid Price for Evaluation (Mandatory)	$
Bidder's Task 3 Total Bid Price for Evaluation	$
Bidder's Task 4 Total Bid Price for Evaluation	$
Bidder's Task 5 Total Bid Price for Evaluation	$
Bidder's Task 6 Total Bid Price for Evaluation	$
Applicable Taxes	$

ANNEX “C”

TASK AUTHORIZATION FORM

The following is provided as an example.

Contract Number	Enter the resulting 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 address here.		
Total Estimated Cost of Task (Applicable Taxes extra) before any revisions:	$____________ Instructions to the TA Authority: Enter the amount here.	
TA Revisions Previously Authorized		
Instructions to the TA Authority: the information for the previously authorized revisions must be presented in ascending order of assigned revision numbers (the first revision must be identified as No. 1, the second as No. 2, etc). If no increase or decrease was authorized, enter $0.00. Add rows, as needed		
TA Revision Number: ___________ Instructions to the TA Authority: Enter the number here, as applicable.	Authorized Increase or Decrease (Applicable Taxes extra) $____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
TA Revision Number: ___________ Instructions to the TA Authority: Enter the number here, as applicable.	Authorized Increase or Decrease (Applicable Taxes extra) $____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
TA Revision Number: ___________ Instructions to the TA Authority: Enter the number here, as applicable.	Authorized Increase or Decrease (Applicable Taxes extra) $____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
TA Revision Number: ___________ Instructions to the TA Authority: Enter the number here, as applicable.	Authorized Increase or Decrease (Applicable Taxes extra) $____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
TA Revision Number: ___________ Instructions to the TA Authority: Enter the number here, as applicable.	Authorized Increase or Decrease (Applicable Taxes extra) $____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
New TA Revision		
Instructions to the TA Authority: the first revision must be identified as No. 1, the second as No. 2, etc. If no increase or decrease is authorized, enter $0.00.		
TA Revision Number: ___________ Instructions to the TA Authority: Enter the number here, as applicable.	Authorized Increase or Decrease (Applicable Taxes extra) $____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
Total Estimated Cost of Task (Applicable Taxes extra) after this revision:	$_____________ Instructions to the TA Authority: Enter the amount here, as applicable.	
Contract Security Requirements (as applicable)		
This task includes security requirements. Check the applicable boxes. ☐ No ☐ Yes. Refer to the Security Requirements Checklist (SRCL) annex of the Contract. Remarks: 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.

Name of Project Authority - Nom du chargé de projet _____

Signature _____ Date _____

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

Signature _____ Date _____

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 au nom de l'entrepreneur

_____

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

☞ If only 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)	$_____ (enter the applicable amount)
2	(Specify)	(Specify)	$_____(enter the applicable amount)

☐ Monthly payments for authorized travel and living expenses only