



A.1 ELECTRONIC BID SUBMISSION

Attention: [Robert Merrick](mailto:Robert.Merrick@hc-sc.gc.ca)
[Materiel & Assets](mailto:Robert.Merrick@hc-sc.gc.ca)
[Management Division](mailto:Robert.Merrick@hc-sc.gc.ca)
 E-mail: Robert.Merrick@hc-sc.gc.ca

Request for Proposals (RFP)

for

The Performance of the Work described in Appendix 1, Annex A – Statement of Work

A2. RFP AUTHORITY

The Authority for this RFP is:

Robert Merrick
 Contracting Officer
 Materiel & Assets Management Division
 Chief Financial Officer Branch
 Ottawa, Ontario

Telephone: 613-404-6575
 E-mail: Robert.Merrick@hc-sc.gc.ca

THIS CONTRACT DOES NOT CONTAIN A SECURITY REQUIREMENT

<p>A3. TITLE Dermal Absorption Testing of Existing and New Priority Chemicals under the Chemicals Management Plan</p>	
<p>A4. BID CLOSING DATE July 05, 2016</p>	
<p>A5. SOLICITATION NUMBER 1000180299</p>	<p>A6. ISSUE DATE June 06, 2016</p>
<p>A7. ENQUIRIES All enquiries must be submitted in writing to the designated RFP Authority identified in A2 by no later than seven (7) calendar days prior to the Closing Date in order to allow sufficient time to provide a response.</p>	
<p>A8. APPLICABLE LAWS In accordance with GI15, any resulting contract must be interpreted and governed, and the relations between the Parties determined, by the laws in force in the Province of Ontario, Canada.</p>	
<p>A9. BID SOLICITATION DOCUMENTS The RFP is divided into six (6) parts as follows:</p> <ol style="list-style-type: none"> 1. Section I – Bid Submission Requirements 2. Section II – Bid Evaluation Procedures and Evaluation Criteria 3. Section III – Financial Bid 4. Section IV – General Instructions 5. Section V – Certifications 6. Appendix 1 – Resulting Contract Clauses <ul style="list-style-type: none"> Annex A – Statement of Work Annex B – Basis of Payment Annex C – Security Requirements 	
<p>A10. BID DELIVERY Bids must be received by no later than 14:00 (2 p.m) on July 5, 2016 (Eastern Daylight Savings time) at the bid receiving address indicated in A1. Bids received after the closing date and time (referred to as the “Closing Date”) will be considered non-responsive.</p>	
<p>A11. BID VALIDITY Bids will remain valid for a period of ninety (90) calendar days following the Closing Date.</p>	
<p>A12. BID CONTENT Bids must be structured in the following manner:</p> <ol style="list-style-type: none"> 1. One (1) electronic copy of a Covering Letter, signed by an authorized representative of the Bidder; 2. One (1) electronic copy of the Technical Bid; 3. One (1) electronic copy of the Certifications – Section V and, 4. One (1) electronic copy of Financial Bid – Section III contained in separate attachment <p>Please refer to Section 1 – Bid Submission Requirement, point 1.2 for further instructions.</p>	
<p>A13. INTELLECTUAL PROPERTY The Contractor Will Own Intellectual Property Rights as per Appendix 1.</p>	

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SECTION I – BID SUBMISSION REQUIREMENTS

1.1 REQUIRED INFORMATION

This section outlines the information Bidders are required to submit. To be declared responsive, a bid must:

- a. comply with all the requirements of the RFP;
- b. meet all the mandatory technical evaluation criteria;

Bids not meeting (a) or (b) will be declared non-responsive. An evaluation team comprised of representatives of Canada will evaluate the bids.

1.2 SUBMISSION OF THE BID

You are invited to submit electronic copies by e-mail in either official language (English or French) of both the Technical and Cost Proposals. The RFP Reference Number and the name of the Requirement must be in the subject line of your email and your proposal must be structured in accordance to section A12 – Bid Content on the cover page.

No price or cost information should appear in any other section of the bid. Failure to provide the Financial Bid in a separate attachment will render a bid non-responsive.

If the email including attachments is **larger than 20mb**, you may wish to try and submit your bid in separate emails to not exceed Health Canada's server limitation.

OR

You may submit your bid by hand on a USB stick or CD to the address below and send an email to the RFP Authority (found on page 1) stating it has been sent by courier. You **must** send an email to the RFP Authority to ensure your bid will be included for this requirement. The RFP Reference Number and the name of the RFP Authority must be marked on all documents, binders and respective envelopes. If you should choose to submit hard copies, your proposal must be structured in the following manner:

- one (1) Covering Letter, signed by an authorized representative of your firm;
- three (3) copies of the Technical Bid;
- one (1) copy of Certifications (Section V) and;
- one (1) copy of the Financial Bid (Section III), contained in a separate sealed envelope. No price or cost information should appear in any other section of the bid. Failure to provide the Financial Bid in a separate envelope will render a bid non-responsive.

At the following address:

Health Canada Bid Receiving Unit
161 Goldenrod Driveway, Tunney's Pasture
Loading dock of building #18,
Ottawa, ON, Canada
K1A 0K9

- 1.2.1** Bidders who submit a bid in response to this RFP agree to be bound by the instructions, clauses and conditions of the RFP and accept the terms and conditions of the resulting contract (see Appendix 1).
- 1.2.2** It is the Bidder's responsibility to obtain, if necessary, clarification of the requirements contained in the RFP and to prepare its bid in accordance with the instructions contained in the RFP. Enquiries must be submitted in writing to the Authority identified in A2 (RFP Authority) and in accordance with section A7 (Enquiries).
- 1.2.3** The RFP documents contain all the requirements relating to the bid solicitation. Any other information or documentation provided to or obtained by a Bidder from any other source is not relevant and not part of this RFP. Bidders should not assume that practices used under previous RFPs or contracts will continue, unless they are identified in the RFP. Bidders should also not assume that their existing capabilities meet the requirements of the RFP simply because they have met previous requirements.

1.3 GREENING GOVERNMENT OPERATIONS

The Government of Canada has directed federal departments and agencies to take the necessary steps to acquire products and services that have a lower impact on the environment than those traditionally acquired. The environmental impact assessment of a product and/or service considers the whole life cycle of the product and/or service. Health Canada and the Public Health Agency of Canada procurements will be including more demanding environmental criteria to encourage product/service suppliers to improve their operations to reduce any possible negative impact on the environment.

1.3.1 Canada requests that Bidders follow the format instructions described below in the preparation of their bid:

- a. use 8.5 x 11 inch (216 mm x 279 mm) paper for hardcopy submissions;
- b. use a numbering system that corresponds to the RFP.

In order to promote environmental considerations, bidders are further encouraged to:

- 1) use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and/or 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.

1.4 SET-ASIDE FOR COMPREHENSIVE LAND CLAIMS AGREEMENT(S) BENEFICIARIES

This RFP is not being set aside to Comprehensive Land Claims Agreement(s) Beneficiaries.

1.5 SET-ASIDE UNDER THE FEDERAL GOVERNMENT'S PROCUREMENT STRATEGY FOR ABORIGINAL BUSINESS (PSAB)

This RFP is not being set aside under the federal government's Procurement Strategy for Aboriginal Business (PSAB)

1.6 DIRECT DEPOSIT PAYMENTS

Health Canada has adopted electronic direct deposit as the method for paying invoices. Suppliers are asked to register for electronic direct deposit and to provide their account information upon request. For help with online registration, send an email to: DD@hc-sc.gc.ca.

1.7 SECURITY REQUIREMENTS

This RFP does not contain a Security Requirement.

1.8 REQUIREMENT VALUE

Health Canada hopes to award a one-year contract with one (1) additional option year.

SECTION II – BID EVALUATION PROCEDURES AND EVALUATION CRITERIA

2.1 BID EVALUATION PROCEDURES

- 2.1.1** The Technical Bid will first be evaluated against the mandatory technical criteria of the RFP. If the bid meets all the mandatory criteria, and the RFP contains point-rated criteria, the evaluation committee will then evaluate the point-rated technical criteria. If the mandatory technical criteria are not met, the point-rated technical criteria will not be evaluated and the bid will be given no further consideration.
- 2.1.2** Only technical bids that meet the mandatory technical criteria will be further evaluated on the basis of the Bidder's Financial Bid.

2.1.3 Supplier Selection Method

Highest combined rating of technical merit and price

For each responsive bid, the technical merit score and the pricing score will be added to determine its total combined score. The responsive bid with the highest combined rating of technical merit and price will be recommended for award of a contract. If two (2) or more responsive bids have the same combined total score, the responsive bid with the lowest evaluated price will be recommended for contract award.

To determine the overall score obtained by a bidder, the following weighting will be used to establish the technical and financial score:

Technical Score = 80%

Cost Score = 20%

Technical Score (80%)

Technical Score = $[R1/20] \times 20\% + [(R2 + R3)/100] \times 50\% + [R4/20] \times 10\%$

Cost Score (20%)

Since Health Canada has yet to decide whether the testing will be done with **one, two or four doses**, Bidders will be required to provide **three (3) firm lot prices** for their services: one firm lot price if Health Canada (HC) chooses one dose; one if HC chooses two doses; and one if HC chooses four doses. The three (3) firm lot prices will be added together and divided by three, with the lowest average firm lot price scoring the full amount of points available, while the other bidders' average firm lot prices will be given a pro-rated score based on the following formula:

$$\text{Cost Score} = \frac{\text{Lowest Bid}}{\text{Bidder's Cost}} \times 20\%$$

Total Score

$$\text{Total Score} = \text{Technical Score} + \text{Cost Score}$$

NOTE: Bids for which the total evaluated bid price is 150% greater than the lowest price of all responsive bids received will automatically receive a score of “0” points” for the financial score.

The following is an example that illustrates how this calculation would be made. The dollar figures shown are for the purposes of this example only; they do not suggest a desired price.

	Bid 1	Bid 2	Bid 3	Bid 4
Total evaluated price of each responsive bid	\$100,000.00	\$120,000.00	\$140,000.00	\$250,000.00

In the example above, bid 4 would receive “0 points” for its financial score as it exceeds the lowest priced bid by 150% ($\$100,000 \times 150\% = \$150,000.00$).

2.2 EVALUATION CRITERIA

The evaluation of the following criteria is based on a “rules of evidence” approach in that the evaluation committee can only conduct its evaluation based on the contents of the Bidder’s bid. The onus is on the Bidder to ensure that its bid is complete, clear, and provides sufficient detail for the evaluation committee to evaluate the bid. Simply repeating or copying a statement contained in the RFP is not sufficient.

To facilitate the evaluation of the bid, Canada also 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 paragraphs and page numbers where the subject topic has already been addressed.

2.2.1 Mandatory Criteria

The bid must meet the mandatory criteria set out below. The Bidder must provide the necessary documentation to support compliance. Bids which fail to meet the mandatory criteria will be declared non-responsive. Mandatory criteria are evaluated on a simple pass or fail basis. This will be evaluated as either a “Yes” or a “No.”

ATTENTION BIDDERS:			
Write beside each of the criterion the relevant page number(s) from your bid which addresses the requirement identified in the criteria.			
#	Mandatory Technical Criteria	Met (Yes/No)	Cross-Reference to bid (indicate page #)
MT1	<p><u>Good Laboratory Practice (GLP) Compliance</u> The bidder is required to be GLP compliant as recognized by the respective national GLP compliance monitoring authority. Attention Bidders: The technical proposal must include a copy of the relevant documentation or GLP compliance statement from the respective national GLP compliance monitoring authority. A list of national monitoring authorities: http://www.oecd.org/chemicalsafety/testing/linkstonationalwebsitesongoodlaboratorypractice.htm</p>		
MT2	<p><u>Performance, reliability and reproducibility</u> The bidder is required to demonstrate the performance, reliability and reproducibility of the test methodology in the performing laboratory. This can be demonstrated by showing the historical results for reference substances such as caffeine, benzoic acid or testosterone assessed at regular intervals as specified in the OECD TG 428 and providing documents to demonstrate participation in inter-laboratory comparison or proficiency-testing programs.</p>		
MT3	<p><u>Ability to acquire and handle radiolabelled chemicals for testing</u> The bidder is required to demonstrate the ability to acquire and handle radiolabelled chemicals for testing. The technical proposal must include appropriate documentation such as proof of appropriate licences and permits acquired to handle the radioactive materials, quotations from a vendor capable of synthesising radiolabelled chemicals for the chemicals 1-4 listed under the section 1.4 of statement of work.</p>		

MT4	<p><u>Ready access to human skin and Research Ethics Board approval</u></p> <p>The bidder is required to demonstrate the ready access to human skin. The bidder is required to submit a document to demonstrate that they have acquired the necessary approvals from their Research Ethics Board (REB) committee to conduct testing on human skin.</p>		
MT5	<p><u>Experience with testing human skin integrity</u></p> <p>The bidder is required to demonstrate experience with appropriate methodology to test the skin integrity as specified within SCCS 2010.</p>		
MT6	<p><u>Recent Dermal Absorption Testing Experience</u></p> <p>The bidder must demonstrate recent (within last 2 years) experience performing in vitro dermal absorption testing using human skin. The proposal must include appropriate description of projects conducted within last 2 years as well as references (maximum of 1000 words).</p> <p>References should include at least the person's name, title, telephone number and/or e-mail.</p>		

2.2.2 Point-rated Technical Criteria

In addition to meeting the Mandatory Criteria, the Bidder must also address the Point-Rated Criteria identified below.

Technical Merit – Method of Evaluation

The following point-rated requirements will be assessed:

- R1. Human In Vitro Dermal Absorption Testing Experience
- R2. Quality of Method
- R3. Demonstrated Ability to test chemical mixtures and non-radiolabelled chemicals
- R4. Quality of Documentation

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria			
		Points Allocated for Criteria	Score
	Page #		
R1. <u>Human In Vitro Dermal Absorption Testing Experience</u>			
The bidder must demonstrate the number of years of experience performing in vitro dermal absorption testing using human skin. The proposal must include a brief description of successfully completed projects of similar scope, size and complexity as well as references. (up to 10 pages) 2 points will be awarded for each unique project per year conducted in the last 10 years up to a maximum of 20 points..			
1	In vitro	20	
Maximum Total Points		20	

R2. <u>Quality of Method</u>					
The bidder should submit 3 representative examples of recent work conducted in the performing laboratory to demonstrate the quality of the existing method. The overall methodology will be judged against requirements within OECD TG 428 and SCCS 2010. The examples should include demonstration of adequate solubility in receptor fluid and ability to quantify the unabsorbed volatilised dose.					
Each report will be evaluated according to the following criteria (to a maximum of 20 points each for a total of 60 points).					
R2 - Method of Evaluation					
Points	Rating	Accuracy (Laboratory Recovery)	Precision (Coefficient of Variation)	Participation in Inter-laboratory Comparison Program	Documented Reporting Limit
20	Excellent	80-120 %	≤ 15 %	Yes	Yes
15	Good	80-120 %	≤ 15 %	No	Yes
10	Fair	70-130 %	> 15 % - < 33 %	No	Yes
5	Poor	≥60-≤140 %	33 %	No	Yes
0	Insufficient	<60 % or >140 %	> 33 %	No	Yes

R3. Demonstrated Ability to test chemical mixtures and non-radiolabelled chemicals

Some chemicals require special methodological considerations, where the existing methods cannot be applied (for example, chemical mixtures or substances which cannot be radiolabelled). The bidder should demonstrate previous experience in methods that are used in the performing laboratory to test chemical mixtures and chemical substances that cannot be radiolabelled.

The supporting documentation should include:

- a published reference method or an internal report of a method that has been used by the laboratory;
- details of the method validation;

Each methodology will be evaluated according to the criteria specified below (to a maximum of 20 points each for a total of 40 points).

R3 - Method of Evaluation					
Points	Rating	Accuracy (Laboratory Recovery)	Precision (Coefficient of Variation)	Participation in Inter-laboratory Comparison Program	Documented Reporting Limit
20	Excellent	80-120 %	≤ 15 %	Yes	Yes
15	Good	80-120 %	≤ 15 %	No	Yes
10	Fair	70-130 %	> 15 % - < 33 %	No	Yes
5	Poor	≥60-≤140 %	33 %	No	Yes
0	Insufficient	<60 % or >140 %	> 33 %	No	Yes

Quality of Documentation

Criteria		
R4. <u>Quality of Documentation</u>		
This criterion evaluates the quality of documentation for the RFP proposal in its entirety and will be evaluated based on comprehensiveness, organization, and clarity. Maximum of 10 points will be allocated as shown in the sample grid.		
Maximum Total Points		10
Excellent 10 Points	Proposal is thorough and comprehensive, describing in detail how the requirements of the RFP will be met. Proposal is ordered/structured in a logical, easy-to-follow format. Information is presented in a clear and concise manner.	
Good 7-9	The proposal is missing a few documents or all components of the proposal are not ordered or structured clearly.	
Satisfactory 4-6	The proposal addresses the criterion satisfactorily but the documentation is not comprehensive and/or is difficult to follow.	
Minimal	The proposal is missing many documents or is not organised and is hard to follow.	

1-3	
Poor 0 point	The proposal does not meet the criteria.

SECTION III – FINANCIAL BID

Health Canada hopes to award a one-year contract with one (1) additional option year.

Firm Lot Price

The Bidder must provide a firm all-inclusive lot price, inclusive of any overhead and profit, and costs such as travel, equipment, rentals, subcontractors, FOB destination charges, Canadian customs, duties and excise taxes.

The total amount of Goods and Services Tax (GST) or Harmonized Sales Tax (HST) must be shown separately, if applicable.

- 3.0.1** Bidders must provide their Financial Bid in accordance with the tables referenced at Section 3.2 – Pricing Schedule. All payments will be made in accordance with the proposed Basis of Payment (Appendix 1, Annex B) of the Resulting Contract Clauses.
- 3.0.2** Exchange rate fluctuation protection is not offered.
- 3.0.3** Since Health Canada has yet to decide whether the study will be done with **one, two or four doses**, Bidders will be required to provide **three (3) firm lot prices** for their services: one firm lot price if Health Canada (HC) chooses one dose; one if HC chooses two doses; and one if HC chooses four doses. See Section 3.2, Pricing Schedule.

3.1. Price Breakdown

In their financial bids, bidders should provide a price breakdown for **each firm lot price** quoted in response to the pricing schedule detailed in Section 3.2 – Pricing Schedule. The Financial Bid should address each of the following, if applicable:

- 3.1.1** Estimated Cost of Professional Fees
- a.** For each individual or labour category, bidders should provide: a) the estimated cost of professional fees; and b) the cost basis (comprised of the quoted all inclusive fixed hourly or daily rate; and the estimated corresponding number of working hours or days. Bidders should specify the number of hours included in a working day, exclusive of meal breaks.
 - b.** The quoted all inclusive fixed time rate must include the total estimated cost of any travel and living expenses that may need to be incurred by the individual or labour category for the Work described Annex “A”, Statement of Work.
 - c.** Under any resulting contract, Canada will not accept the travel and living expenses that may need to be incurred by the contractor for any relocation of resources required to satisfy its contractual obligations.

3.1.2 Estimated Cost of Incidental Goods

Bidders should: 1) identify each incidental good to be purchased; and 2) provide the estimated cost and the cost basis for each one.

3.1.3 Estimated Cost of Materials and Supplies

Bidders should: 1) identify each category of materials and supplies to be purchased; and 2) provide for each one, the estimated cost and the cost basis. Materials and supplies are items which will be consumed during the performance of any resulting contract.

3.1.4 Estimated Cost of Travel and Living Expenses

Not applicable.

3.1.5 Estimated Cost of Subcontracts

Bidders should: 1) identify any proposed subcontractors; and 2) provide a price breakdown

3.1.6 Estimated Cost of Other Direct Charges

Bidders should: 1) identify the categories of other direct charges anticipated (such as long distance communications and rental); and 2) provide the estimated cost and the cost basis for each one.

3.1.7 Applicable Taxes

In the price breakdown, the Applicable Taxes are to be shown separately.

3.2 Pricing Schedule

The Bidder must complete the following pricing schedules and include them in its financial bid.

Bidders are asked to provide three (3) quotes, based on one, two or four doses. Health Canada will decide on the number of doses to be used in the study prior to contract award.

NOTE: Please read note following last table describing OECD 428 and SCCS 2010 requirements for in vitro human dermal absorption study.

Table 1: In vitro human dermal absorption testing (OECD study¹) - One Dose

The following table represents the bidder's cost proposal if Health Canada elects to have the study performed using **only ONE dose**.

Chemicals that can be radiolabelled		Cost of Study – for radiolabelled chemicals	Cost of acquiring bare chemicals and radiolabelling	Total/chemical	
		One dose			
1 Benzenesulfonic acid, dodecyl-, compd. with 2-propanamine (1:1) - (CAS#26264-05-1)	8 replicates				Fiscal Year 2016-17 Total Cost
2. Acetic acid, propyl ester - (CAS#109-60-4)	8 replicates				
3. 2-Ethyl-1-hexanol - (CAS#104-76-7)	8 replicates				
4. N,N-Dimethylhexadecylamine - (CAS RN 112-69-6)	8 replicates				
FY 2016-17 Sub-total					

OPTION YEAR (FY 2017-18)

Chemicals requiring special considerations		One dose	Cost of acquiring bare chemicals and radiolabelling – if applicable	Total/chemical	
5. Trixylenyl phosphate - (CAS RN 25155-23-1)	8 replicates				Fiscal Year 2017-18 Total Cost
6. Isopropylated triphenyl phosphate - (CAS RN 68937-41-7)	8 replicates				
FY2017-18 Sub-total					

TOTAL CONTRACT VALUE – ONE DOSE (Original contract plus first Option Year)	
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Table 2: In vitro human dermal absorption testing (OECD study¹) - Two Doses

The following table represents the bidder's cost proposal if Health Canada elects to have the study performed using **TWO** doses.

Chemicals that can be radiolabelled		Cost of Study – for radiolabelled chemicals	Cost of acquiring bare chemicals and radiolabelling	Total/chemical
		Two doses		
1 Benzenesulfonic acid, dodecyl-, compd. with 2-propanamine (1:1) - (CAS#26264-05-1)	8 replicates			
2. Acetic acid, propyl ester - (CAS#109-60-4)	8 replicates			
3. 2-Ethyl-1-hexanol - (CAS#104-76-7)	8 replicates			
4. N,N-Dimethylhexadecylamine - (CAS RN 112-69-6)	8 replicates			
FY 2016-17 Sub-total				

Fiscal Year 2016-17 Total Cost

OPTION YEAR (FY 2017-18)

Chemicals requiring special considerations		Two doses	Cost of acquiring bare chemicals and radiolabelling – if applicable	Total/chemical
5. Trixylenyl phosphate - (CAS RN 25155-23-1)	8 replicates			
6. Isopropylated triphenyl phosphate - (CAS RN 68937-41-7)	8 replicates			
FY 2017-18 Sub-total				

Fiscal Year 2017-18 Total Cost

TOTAL CONTRACT VALUE – TWO DOSES (Original contract plus first Option Year)
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Table 3: In vitro human dermal absorption testing (OECD study¹) - Four Doses

The following table represents the bidder's cost proposal if Health Canada elects to have the study performed using **FOUR** doses.

Chemicals that can be radiolabelled		Cost of Study – for radiolabelled chemicals	Cost of acquiring bare chemicals and radiolabelling	Total/chemical
		Four doses		
1 Benzenesulfonic acid, dodecyl-, compd. with 2-propanamine (1:1) - (CAS#26264-05-1)	8 replicates			
2. Acetic acid, propyl ester - (CAS#109-60-4)	8 replicates			
3. 2-Ethyl-1-hexanol - (CAS#104-76-7)	8 replicates			
4. N,N-Dimethylhexadecylamine - (CAS RN 112-69-6)	8 replicates			
FY 2016-17 Sub-total				

Fiscal Year 2016-17 Total Cost

OPTION YEAR (FY 2017-18)

Chemicals requiring special considerations		Four doses	Cost of acquiring bare chemicals and radiolabelling – if applicable	Total/chemical
5. Trixylenyl phosphate - (CAS RN 25155-23-1)	8 replicates			
6. Isopropylated triphenyl phosphate - (CAS RN 68937-41-7)	8 replicates			
FY 2017-18 Sub-total				

Fiscal Year 2017-18 Total Cost

TOTAL CONTRACT VALUE – FOUR DOSES (Original contract plus first Option Year)

¹ **OECD Study:** Mass balance study according to OECD 428 and SCCS 2010 requirements - viable barrier-integrity-assessed, split-thickness human skin using eight (8) evaluable samples originating from one (1) to four (4) donors (SCCS 2010); absorption assessed over a period

of 72 hours, with receptor fluid fractions collected hourly from 0 to 6 hours and at regular intervals (e.g., every 2 hours) from 6 hours onwards. Measure substance permeated through skin layers into receptor medium as well as absorbed in skin layers and on the skin surface. The following data will be reported for each experimental condition: amount of applied dose remained on skin surface, absorbed into stratum corneum, epidermis/dermis layer, and collected in receptor medium.

SECTION IV – GENERAL INSTRUCTIONS

	INTERPRETATION		
	In this RFP:		cannot transfer this responsibility to Canada. Canada will not assume responsibility for bids that are directed to an address other than the one stipulated in A1.
0.1	“Bidder” means the person or entity (or, in the case of a joint venture, the persons or entities) submitting a bid to perform a contract for goods, services or both.	5.3	Late bids: Bids received after the closing date and Time specified in A10 will be deemed non-responsive and will not be considered for contract award.
0.2	“Her Majesty”, the “Minister” or “Canada” means Her Majesty the Queen in right of Canada, as represented by the Minister of Health, acting through Health Canada (referred to herein as the “Minister”).		
	G11 RESPONSIVENESS	G16 RIGHTS OF CANADA	
1.1	For a bid to be considered responsive, it must comply with all of the requirements of this RFP identified as mandatory. Mandatory Requirements are also expressed by using imperative verbs such as “shall”, “will” and “must”.	6.1	Canada reserves the right:
		6.2	during bid evaluation, to submit questions to or conduct interviews with Bidders, at Bidders’ cost, upon forty eight (48) hours’ notice, to seek clarification or to verify any or all information provided by the Bidder with respect to this RFP;
		6.3	to reject all bids received in response to this RFP;
		6.4	to accept any bid, in whole or in part, without prior negotiation;
		6.5	to cancel and/or re-issue this RFP at any time;
		6.6	to award one or more contracts, if applicable;
		6.7	to not accept any deviations from the stated terms and conditions;
		6.8	to incorporate all, or any portion of the Statement of Work, Request for Proposals and the successful bid in any resulting contract; and
			to not contract at all.
	G12 ENQUIRIES – BID SOLICITATION STAGE	G17 INCAPACITY TO CONTRACT WITH GOVERNMENT	
2.1	All enquiries or issues concerning this RFP must be submitted in writing to the RFP Authority identified in A2 as early as possible within the bid solicitation period. Enquiries and issues must be received within the timeframe described in A7 to allow sufficient time to provide a response. Enquiries received after that time may not be answered prior to the closing date.	7.1	By submitting a bid, the Bidder declares that the Bidder has not been convicted of an offence under the following provisions of the <i>Criminal Code</i> :
2.2	To ensure consistency and quality of information provided to Bidders, the RFP Authority will give notice, in the same manner as this RFP, of any additional information in response to significant enquiries received without revealing the sources of the enquiries.		– Section 121, Frauds upon the Government;
2.3	All enquiries and other communications with government officials throughout the solicitation period shall be directed ONLY to the RFP Authority named herein. Non-compliance with this condition during the bid solicitation period will (for that reason alone) result in bid disqualification.		– Section 124, Selling or Purchasing Office; or
			– Section 418, Selling Defective Stores to Her Majesty, other than an offence for which a pardon has been granted.
		7.2	Canada may reject a bid where the Bidder, including the Bidder’s officers, agents and employees, has been convicted of an offence referred to in clause 7.1. Where Canada intends to reject a proposal pursuant to this provision, the RFP Authority will so inform the Bidder and provide the Bidder ten (10) calendar days within which to make representations, prior to making a final decision on the bid rejection.
	G13 BIDDER’S SUGGESTED IMPROVEMENTS DURING BID SOLICITATION PERIOD	G18 INCURRING OF COSTS	
3.1	Should any Bidder consider that the specifications or Statement of Work contained in this RFP can be improved technically or technologically, the Bidder is invited to make suggestions, in writing, to the RFP Authority named herein. The Bidder must clearly outline the suggested improvements as well as the reason for the suggestion. Suggestions which do not restrict the level of competition nor favour a particular Bidder will be given consideration provided they are received by the RFP Authority within the timeframe described in article A7 to allow sufficient time to provide a response. Canada reserves the right to accept or reject any or all suggestions.	8.1	No costs incurred before receipt of a signed contract or specified written authorization from the RFP Authority can be charged to any resulting contract. In addition, the Contractor is not to perform Work in excess of or outside the scope of any resulting contract based on verbal or written requests or instructions from any government personnel other than the Contracting Authority. The Bidder’s attention is drawn to the fact that the Contracting Authority is the only authority which can commit Canada to the expenditure of the funds for this requirement.
	G14 BID PREPARATION COSTS	G19 BIDDERS ARE NOT TO PROMOTE THEIR INTEREST IN THE PROJECT	
4.1	The costs, including travel incurred by the Bidder in the preparation of its bid, or of any resulting contract, will be the sole responsibility of the Bidder and will not be reimbursed by Canada.	9.1	Bidders must not make any public comment, respond to questions in a public forum or carry out any activities to publicly promote or advertise their interest in this project.
	G15 BID DELIVERY	G110 PROPERTY OF CANADA	
5.1	Bids or amendments thereto, will only be accepted by the RFP Authority if they are received at the address indicated in A1, on or before the closing date and time specified in A10.	10.1	Bids received on or before the stipulated RFP closing date and time will become the property of Canada and may not
5.2	Responsibility for bid delivery: the Bidder has the sole responsibility for the timely receipt of a bid by Canada and		

- be returned. All bids will be treated as confidential, subject to the provisions of the *Access to Information Act* (R.S. 1985, c. A-1) and the *Access to Information Act* (R.S. 1985, c. A-1) and *Privacy Act* (R.S., 1985, c. P-21).
- GI11 PRICE JUSTIFICATION**
In the event that the Bidder's bid is the sole responsive bid received, the Bidder must provide, on the RFP Authority's request, one or more of the following price justifications:
- 11.1 a current published price list indicating the percentage discount available to Canada; or
- 11.2 copies of paid invoices for like quality and quantity of the goods, services or both sold to other customers; or
- 11.3 a price breakdown showing the cost of direct labour, direct materials, purchased items, engineering and plant overheads, general and administrative overhead, transportation, profit, etc.; or
- 11.4 price or rate certification; or
- 11.5 any other supporting documentation as requested by the RFP Authority
- GI12 ANNOUNCEMENT OF SUCCESSFUL BIDDER**
- 12.1 If this RFP was advertised on the "Buyandsell.gc.ca" tendering service, the name of the successful Bidder will be announced on Buyandsell.gc.ca upon contract award and sign off.
- 12.2 If this RFP was not advertised on "Buyandsell.gc.ca," Canada will communicate to all Bidders the name and address of the successful Bidder as well as the total dollar value and award date for the contract only after contract sign-off.
- GI13 APPLICABLE LAWS**
- 13.1 Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario, Canada. The Bidder may propose a change to the applicable laws in his/her bid. If no change is made, it acknowledges that the applicable laws specified in this RFP are acceptable to the bidder.
- GI14 CONTINGENCY FEE**
- 14.1 The Bidder declares that the Bidder has not, directly or indirectly, paid or agreed to pay, and will not, directly or indirectly pay, a Contingency Fee to any individual for the solicitation, negotiation or obtaining of the contract if the payment of the fee would require the individual to file a return under section 5 of the *Lobbying Act*, R.S.C., 1985, c. 44 (4th Supp.). In this section, "Contingency Fee" means any payment or other compensation that is contingent upon or is calculated upon the basis of a degree of success in soliciting or obtaining a government contract or negotiating the whole or part of its terms.
- GI15 CONFLICT OF INTEREST – UNFAIR ADVANTAGE**
- 15.1 In order to protect the integrity of the procurement process, Bidders are advised that Canada may reject a bid in the following circumstances:
- (a) if the Bidder, any of its subcontractors, any of their respective employees or former employees was involved in any manner in the preparation of the bid solicitation or in any situation of conflict of interest or appearance of conflict of interest; or
- (b) if the Bidder, any of its subcontractors, any of their respective employees or former employees had access to information related to the bid solicitation that was not available to other Bidders and that would, in Canada's opinion, give or appear to give the Bidder an unfair advantage.
- 15.2 The experience acquired by a Bidder who is providing or has provided the goods and services described in the RFP (or similar goods or services) will not, in itself, be considered by Canada as conferring an unfair advantage or creating a conflict of interest. This Bidder remains however subject to the criteria established above.
- 15.3 Where Canada intends to reject a bid under this section, the RFP Authority will inform the Bidder and provide the Bidder an opportunity to make representations before making a final decision. Bidders who are in doubt about a particular situation should contact the Contracting Authority before the bid Closing Date.
- 15.4 By submitting a bid, the Bidder represents that it does not consider itself to be in conflict of interest nor to have an unfair advantage. The Bidder acknowledges that it is within Canada's sole discretion to determine whether a conflict of interest, unfair advantage or an appearance of conflict of interest or unfair advantage exists.
- GI16 CONDUCT OF EVALUATION**
- 16.1 In conducting its evaluation of the bids, Canada may, but will have no obligation to, do the following:
- (a) seek clarification or verification from Bidders regarding any or all information provided by them with respect to the bid solicitation;
- (b) contact any or all references supplied by Bidders to verify and validate any information submitted by them;
- (c) request, before award of any contract, specific information with respect to Bidders' legal status;
- (d) conduct a survey of Bidders' facilities and examine their technical, managerial, and financial capabilities to determine if they are adequate to meet the requirements of the bid solicitation;
- (e) correct any error in the extended pricing of bids by using unit pricing and any error in quantities in bids to reflect the quantities stated in the bid solicitation; in the case of error in the extension of prices, the unit price will govern;
- (f) verify any information provided by Bidders through independent research, use of any government resources or by contacting third parties; and
- (g) interview, at the sole costs of Bidders, any Bidder and any or all of the resources proposed by Bidders to fulfill the requirement of the bid solicitation.
- 16.2 Bidders will have the number of days specified in the request by the RFP Authority to comply with any request related to any of the above items. Failure to comply with the request may result in the bid being declared non-responsive.
- GI17 BIDDER DEBRIEFINGS**
- 17.1 Should you require additional information or a debriefing regarding your bid, please contact the RFP authority identified in A2 within 15 calendar days of notification of results. The debriefing may be in writing, by telephone or in person. Debriefings provide bidders an opportunity to understand where their bids may need to be improved in response to future solicitations. After the debriefing, and if needed, you will be provided with information on other dispute resolution options available to you such as the Office of the Procurement Ombudsman (OPO) or other appropriate recourses. For more information on the Office of the Procurement Ombudsman go to: <http://opo-boa.gc.ca>

SECTION V – CERTIFICATIONS

The following information must be submitted along with a signed covering letter, the Technical Bid, Financial Bid (Section III) as well as the Certifications (Section V).

5.1 LEGAL NAME AND BIDDER'S INFORMATION

(print clearly)

Bidder's Legal Name

Bidder's Complete Address

Bidder's Phone number

(_____) _____

Bidder's Authorized Representative

Bidder's Authorized Representative Phone number

(_____) _____

Bidder's Authorized Representative e-mail

5.2 CERTIFICATIONS

Bidders must provide the required certifications at bid submission. Canada may declare a bid non-responsive if the required certifications are not part of the bid content.

Compliance with the certifications bidders provide to Canada is subject to verification by Canada during the bid evaluation period (before and after awarding of a contract). The RFP Authority will have the right to ask for additional information to verify Bidders' compliance with the certifications before award of a contract. The bid will be declared non-responsive if any certification made by the Bidder is untrue, whether made knowingly or unknowingly. Failure to comply with the certifications or to comply with the request of the RFP Authority for additional information will also render the Bid non-responsive.

5.3 CERTIFICATION OF EDUCATION, EXPERIENCE AND QUALIFICATIONS

The Bidder certifies that all statements made with respect to education and experience are true and that any person proposed by the Bidder to perform the Work or part of the Work is either an employee of the Bidder or under a written agreement to provide services to the Bidder.

Canada reserves the right to verify the above certification and to declare the bid non-responsive for any of the following reasons:

- an unverifiable or untrue statement; or
- unavailability of any person proposed whose statement of education and experience Canada has relied upon to evaluate the Bid and award the contract.

5.4 CERTIFICATION OF AVAILABILITY AND STATUS OF PERSONNEL

5.4.1 Availability of Personnel and Facility

The Bidder certifies that, should it be authorized to provide services under any Contract resulting from this RFP, the persons and facility proposed in its bid will be available to commence performance of the Work within a reasonable time from Contract award and will remain available to perform the Work in relation to the fulfilment of this requirement.

5.4.2 Status of Personnel

If, in the fulfilment of this requirement, the Bidder has proposed any person who is not an employee of the Bidder, the Bidder hereby certifies that it has written permission from such person (or the employer of such person) to propose the services of such person in relation to the Work to be performed and to submit such person's résumé to the RFP Authority.

During the evaluation of its bid, the Bidder must upon the request of the RFP Authority provide a copy of such written permission, in relation to any or all resources proposed. The Bidder agrees that failure to comply with such a request may lead to disqualification of the Bidder's bid from further consideration.

5.5 FORMER PUBLIC SERVANT CERTIFICATION

Contracts awarded to former public servants (FPS) in receipt of a pension or of a lump sum payment must be able to bear the closest public scrutiny, and reflect fairness in the spending of public funds. To comply with Treasury Board policies and directives on contracts with FPS, bidders must provide the information required below.

5.5.1 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.

5.5.2 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 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, 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](#).

5.5.3 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.

5.6 JOINT VENTURE/PARTNERSHIP

A joint venture is not considered a "person" for registration purposes, whereas a partnership is. Therefore, a partnership can have a Procurement Business Number (PBN); a joint venture cannot. A joint venture is limited in scope; a partnership is generally an ongoing business relationship that exists between persons carrying on common business.

A joint venture is an arrangement where two or more persons (participants) work together in a limited and defined business undertaking. Ordinarily, all participants of the joint venture contribute assets, share risks, and have mutual liability.

The Bidder certified that its bid is submitted to Canada as a: *(please choose one)*

- Sole proprietorship ()
- A corporation ()
- Partnership ()
- A joint venture ()

* In the case of a Joint Venture, the Bidder must provide the following details as part of its bid:

- a. the name of each member of the joint venture;
- b. the name of the representative of the joint venture, i.e. the member chosen by the other members to act on their behalf, if applicable;
- c. the name of the joint venture, if applicable.

5.7 INTEGRITY PROVISIONS – LIST OF NAMES

Bidders who are incorporated, including those bidding as a joint venture, must provide a complete list of names of all individuals who are currently directors of the Bidder.

Bidders bidding as sole proprietorship, as well as those bidding as a joint venture, must provide the name of the owner(s).

Bidders bidding as societies, firms or partnerships do not need to provide lists of names.

5.8 FEDERAL CONTRACTOR'S PROGRAM FOR EMPLOYMENT EQUITY CERTIFICATION

5.8.1 The Federal Contractors Program (FCP) ensures that contractors who do business with the Government of Canada achieve and maintain a workforce that is representative of the Canadian workforce. The Program applies to non-federally regulated contractors that:

- have a combined workforce in Canada of 100 or more permanent full-time, permanent part-time and/or temporary employees having worked 12 weeks or more; and
- received an initial federal government goods and services contract, a standing offer, or a supply arrangement valued at \$1 million or more (including applicable taxes).

The Federal Contractors Program was established in 1986 to further the goal of achieving workplace equity for designated groups experiencing discrimination in the Canadian labour market. These groups are:

- women;
- Aboriginal peoples;
- persons with disabilities; and

- members of visible minorities.

Effective June 27, 2013 a redesigned FCP will be in effect which includes:

- an increase in the contract threshold from \$200,000 to \$1 million to support the Government's commitment to reduce regulatory red tape burden for small- to medium-sized employers;
- assessment that focus on achievement of results enabling contractors to determine initiatives best suited to their organization in order to achieve employment equity objectives.

5.8.2 Agreement to Implement Employment Equity

Contractors who bid on an initial goods and services contract, a standing offer, or a supply arrangement estimated at \$1 million or more (including applicable taxes) with the Government of Canada must first certify their commitment to implement employment equity by signing the [Agreement to Implement Employment Equity \(LAB1168\)](#) prior to contract award.

Once the goods and services contract, the standing offer, or the supply arrangement is awarded to the contractor, the contractor is assigned a unique Agreement to Implement Employment Equity number and is informed by Labour Program that they are now subject to the FCP. Contractors are then required to implement employment equity and, if representation gaps exist, to make all reasonable efforts most appropriate within the context of their specific organizational environment and structural needs to close any identified gaps. This obligation is on-going and not only subject to the period of the contract, including future contracts.

- 5.8.3 By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "[FCP Limited Eligibility to Bid](#)" list (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/list/inelig.shtml) available from [Human Resources and Skills Development Canada \(HRSDC\) - Labour's](#) website

Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the "[FCP Limited Eligibility to Bid](#)" list at the time of contract award.

Canada will also have the right to terminate the Contract for default if a Contractor, or any member of the Contractor if the Contractor is a Joint Venture, appears on the "[FCP Limited Eligibility to Bid](#)" list during the period of the Contract.

By submitting the present information to the RFP Authority, the Bidder certifies that the information provided is true as of the date indicated below. The certifications provided to Canada are subject to verification at all times. The Bidder understands that Canada will

declare a bid non-responsive, or will declare a contractor in default, if a certification is found to be untrue, whether during the bid evaluation period or during the contract period. Canada will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply with such request by Canada will also render the bid non-responsive or will constitute a default under the Contract.

For further information on the Federal Contractors Program for Employment Equity visit [HRSDC-Labour's website](#).

Date: _____ (YYYY/MM/DD)

Complete both A and B.

A. Check only one of the following:

- A1. The Bidder certifies having no work force in Canada.
- A2. The Bidder certifies being a public sector employer.
- A3. The Bidder certifies being a federally regulated employer being subject to the Employment Equity Act.
- A4. The Bidder certifies having a combined work force in Canada of less than 100 employees (combined work force includes: permanent full-time, permanent part-time and temporary employees [temporary employees only includes those who have worked 12 weeks or more during a calendar year and who are not full-time students]).
- A5. The Bidder has a combined workforce in Canada of 100 or more employees; and
- A5.1. The Bidder certifies already having a valid and current Agreement to Implement Employment Equity (AIEE) in place with HRSDC-Labour.

OR

- A5.2. The Bidder certifies having submitted the Agreement to Implement Employment Equity (LAB1168) to HRSDC-Labour. As this is a condition to contract award, proceed to completing the form Agreement to Implement Employment Equity (LAB1168), duly signing it, and transmit it to HRSDC-Labour.

B. Check only one of the following:

- B1. The Bidder is not a Joint Venture.

OR

() B2. The Bidder is a Joint venture and each member of the Joint Venture must provide the Contracting Authority with a completed appendix Federal Contractors Program for Employment Equity - Certification. (Refer to the Joint Venture section of the Standard Instructions)

5.9 DETERMINING THE POTENTIAL FOR COMMERCIAL EXPLOITATION OF THE INTELLECTUAL PROPERTY

Is there potential for commercial exploitation of any Intellectual Property that may be generated by the resulting contract?

- () Yes
- () No

5.10 SIGNATURE AND CERTIFICATION

By submitting a bid, the Bidder certifies that the information submitted by the Bidder in response to the above requirements is accurate and complete.

Signature

Date

Print Name and Capacity

APPENDIX 1 – RESULTING CONTRACT CLAUSES**1. GENERAL INFORMATION****1.1. Contact Information****1.1.1. Contracting Authority**

The Contracting Authority is identified in section C1, page 1, of the Contract.

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.

1.1.2. Project Authority

The Project Authority is:

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

Phone number: _____
Email: _____

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 the day-to-day management of the Contract.

NOTE: Invoices must not to be sent to the Project Authority directly. Invoices must be sent to the address indicated on page 1 of the Contract, section C8.

1.1.3. Contractor's Authorized Representative

The Contractor's Authorized Representative is:

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

Phone number: _____
Email: _____

1.2. PERIOD OF THE CONTRACT

The initial period of the Contract is identified in section C3, on page 1 of the Contract.

The Contractor hereby grants to Canada the irrevocable option to extend the period of the Contract by up to **one** additional year period under the same terms and conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable terms set out in the Basis of Payment.

Canada may exercise this option at any time by sending a written notice to the Contractor before the end date of the Contract. The option may only be exercised by the Contracting Authority and will be evidenced for administrative purposes only, through an amendment to the Contract.

1.3. SECURITY REQUIREMENTS

There is no security requirement applicable to this Contract.

1.4. BASIS OF PAYMENT

Refer to Annex B

1.5. METHOD OF PAYMENT

1.5.1. MILESTONE PAYMENTS

Canada will make milestone payments in accordance with the Schedule of Milestones detailed in the Contract and the payment provisions of the Contract if:

- i. an accurate and complete claim for payment, and any other document required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
- ii. all work associated with the milestone and as applicable any deliverable required has been completed and accepted by Canada.

Health Canada has adopted electronic direct deposit as their method for paying invoices. Suppliers are asked to register for electronic direct deposit and to provide their account information upon request. For help with online registration, send an email to: DD@hc-sc.gc.ca.

1.6. INVOICING INSTRUCTIONS

One (1) copy of each invoice must include the following:

- a. the Contract title, number and financial code;
- b. the date;
- c. a description of the Work performed;

- d. timesheets (if payment is based on hourly/per diem rates);
- e. evidences of actual Cost (Cost Reimbursable Elements);
- f. the amount of the progress payment being claimed; and the amount of any tax (including GST/HST)
- g. (Not applicable) Reimbursable travel.

2. GENERAL CONDITIONS

GC1. Interpretation

- 1.1. In the Contract,
 - 1.1.1. “Contracting Authority” means the officer or employee of Canada who is designated by the Articles of Agreement and includes a person authorized by the Contracting Authority to perform any of the Contracting Authority's functions under the Contract;
 - 1.1.2. “Cost” means Cost determined according to Public Works and Government Services Canada (PWGSC) Contract Cost Principles (CCP) 1031-2 as revised to the date of the bid solicitation or, if there was no bid solicitation, the date of the Contract. CCP 1031-2 are found on the PWGSC website at the following address: <https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual/3/1031-2>
 - 1.1.3. “Minister” includes a person acting for, or if the office is vacant, in place of the Minister and the Minister's successors in the office, and the Minister's or their lawful deputy and any of the Minister's or their representatives appointed for the purpose of the Contract;
 - 1.1.4. “Work”, unless otherwise expressed in the Contract, means all the activities, services, goods, equipment and things required to be done, delivered or performed by the Contractor under the Contract.

GC2. Date of Completion of Work and Description of Work

- 2.1. The Contractor shall, between the start date and the end date specified in section C3 (Contract Period of the Articles of Agreement), perform and complete with care, skill, diligence and efficiency the Work that is described in the Statement of Work (Annex A).

GC3. Successors and Assigns

- 3.1. The Contract is to the benefit of and binds the successors and permitted assignees of Canada and of the Contractor.

GC4. Subcontractors

- 4.1. Subcontractors must obtain the equivalent level of screening or clearance as deemed required for the Contractor.
- 4.2. All contracts and subcontracts with outside parties which contain security requirements are not to be awarded without prior written permission from the Contracting Authority.

GC5. Assignment

- 5.1. The Contractor must not assign the Contract without first obtaining the written consent of the Contracting Authority. Any assignment made without that consent is void and will have no effect. The assignment will be effective upon execution of an assignment agreement signed by the Parties and the assignee.
- 5.2. Assignment of the Contract does not relieve the Contractor from any obligation under the Contract and it does not impose any liability upon Canada.

GC6. Time of the Essence and Excusable Delay

- 6.1. It is essential that the Work be performed within or at the time stated in the Contract.
- 6.2. A delay in the performance by the Contractor of any obligation under the Contract that is caused by an event that:
 - a. is beyond the reasonable control of the Contractor;

- b. could not reasonably have been foreseen;
 - c. could not reasonably have been prevented by means reasonably available to the Contractor; and
 - d. occurred without the fault or neglect of the Contractor, will be considered an “Excusable Delay” if the Contractor advises the Contracting Authority of the occurrence of the delay or of the likelihood of the delay as soon as the Contractor becomes aware of it. The Contractor must also advise the Contracting Authority, within fifteen (15) working days, of all the circumstances relating to the delay and provide to the Contracting Authority for approval a clear work around plan explaining in detail the steps that the Contractor proposes to take in order to minimize the impact of the event causing the delay.
- 6.3. Any delivery date or other date that is directly affected by an Excusable Delay will be postponed for a reasonable time that will not exceed the duration of the Excusable Delay.
 - 6.4. However, if an Excusable Delay has continued for thirty (30) days or more, the Contracting Authority may, by giving notice in writing to the Contractor, terminate the Contract. In such a case, the Parties agree that neither will make any claim against the other for damages, Costs, expected profits or any other loss arising out of the termination or the event that contributed to the Excusable Delay. The Contractor agrees to repay immediately to the Minister the portion of any advance payment that is unliquidated at the date of the termination.
 - 6.5. Unless Canada has caused the delay by failing to meet an obligation under the Contract, Canada will not be responsible for any Costs incurred by the Contractor or any of its subcontractors or agents as a result of an Excusable Delay.

GC7. Indemnification

- 7.1. The Contractor shall indemnify and save harmless Canada, the Minister and their employees, servants and agents from and against all claims, losses, damages, costs, expenses, actions and other proceedings, made, sustained, brought, prosecuted, threatened to be brought or prosecuted, in any manner based upon, occasioned by or attributable to any injury to or death of a person or damage to or loss of property arising from any wilful or negligent act, omission or delay on the part of the Contractor, the Contractor's employees, servants, agents or subcontractors in performing the Work or as a result of the Work.
- 7.2. The Contractor shall indemnify and save harmless Canada, the Minister and their employees, servants and agents from all costs, charges and expenses whatsoever that Canada sustains or incurs in all claims, actions, suits and proceedings for the use of the invention claimed in a patent, or infringement or alleged infringement of any patent or any registered industrial design or any copyright or other intellectual property right resulting from the performance of the Contractor's obligations under the Contract, and in respect of the use of or disposal by Canada of anything furnished pursuant to the Contract.
- 7.3. The Contractor's liability to indemnify, save harmless or reimburse Canada under the Contract shall not affect or prejudice Canada from exercising any other rights under law.
- 7.4. The Contractor agrees that Canada shall not be liable for, and agrees to protect, indemnify and save harmless Canada, the Minister and their employees, servants and agents with respect to, any injury or damage (including death) to the Contractor or to the person of any officer, servant or agent of the Contractor or for the loss of or damage to the

property of the Contractor or its officers, servants or agents in any manner based upon, occasioned by, or in any way attributable to the performance of the said Work unless the injury, loss or damage is caused by the negligence of an employee, servant or agent of Canada while acting within the scope of his or her employment.

GC8. Notices

- 8.1. Where in the Contract any notice, request, direction, or other communication is required to be given or made by either Party, it shall be in writing and is effective if delivered in person, sent by registered mail, facsimile or electronic mail addressed to the Party for whom it is intended at the address mentioned in the Contract and any notice, request, direction or other communication shall be deemed to have been given by registered mail, when the postal receipt is acknowledged by the other Party; and facsimile or electronic mail, when transmitted. The address of either Party may be changed by notice in the manner set out in this provision.

GC9. Termination for Convenience

- 9.1. At any time before the completion of the Work, the Contracting Authority may, by giving notice in writing to the Contractor, terminate for convenience the Contract or part of the Contract. Once such a notice of termination for convenience is given, the Contractor must comply with the requirements of the termination notice. If the Contract is terminated in part only, the Contractor must proceed to complete any part of the Work that is not affected by the termination notice. The termination will take effect immediately or, as the case may be, at the time specified in the termination notice.
- 9.2. If a termination notice is given pursuant to subsection 9.1, the Contractor will be entitled to be paid, for Costs that have been reasonably and properly incurred to perform the Contract to the extent that the Contractor has not already been paid or reimbursed by Canada. The Contractor will be paid:
- on the basis of the Contract Dollar Value, for all completed Work that is inspected and accepted in accordance with the Contract, whether completed before, or after the termination in accordance with the instructions contained in the termination notice;
 - the Cost to the Contractor plus a fair and reasonable profit for all Work terminated by the termination notice before completion; and
 - all Costs incidental to the termination of the Work incurred by the Contractor but not including the Cost of severance payments or damages to employees whose services are no longer required, except wages that the Contractor is obligated by statute to pay.
- 9.3. The Minister may reduce the payment in respect of any part of the Work, if upon inspection, it does not meet the requirements of the Contract.
- 9.4. The total of the amounts, to which the Contractor is entitled to be paid under this section, together with any amounts paid, due or becoming due to the Contractor must not exceed the Contract Dollar Value. The Contractor will have no claim for damages, compensation, loss of profit, allowance arising out of any termination notice given by Canada under this section except to the extent that this section expressly provides. The Contractor agrees to repay immediately to Canada the portion of any advance payment that is unliquidated at the date of the termination.

GC10. Termination Due to Default of Contractor

- 10.1. The Minister may, by notice to the Contractor, terminate all or any part of the Work if:

- 10.1.1 the Contractor becomes bankrupt or insolvent, makes an assignment for the benefit of creditors, or takes the benefit of any statute relating to bankrupt or insolvent debtors, or if a receiver is appointed under a debt instrument or a receiving order is made against the Contractor, or an order is made or a resolution passed for the winding down of the Contractor, the Contracting Authority may, to the extent permitted by the laws of Canada, by giving written notice to the Contractor, immediately terminate for default the Contract or part of the Contract; or
- 10.1.2 the Contractor fails to perform any of the Contractor's obligations under the Contract, or, in the Minister's view, so fails to make progress as to endanger performance of the Contract in accordance with its terms.

- 10.2. In the event that the Minister terminates the Work in whole or in part under GC10.1, the Minister may arrange, upon such terms and conditions and in such manner as the Minister deems appropriate, for all or part of the Work to be completed that was so terminated, and the Contractor shall be liable to Canada for any excess costs relating to the completion of the Work.
- 10.3. Upon termination of the Work under GC10.1, the Minister may require the Contractor to deliver and transfer title to Canada, in the manner and to the extent directed by the Minister, any finished Work which has not been delivered and accepted prior to such termination and any materials or Work-in-process which the Contractor has specifically acquired or produced for the fulfilment of the Contract. Canada shall pay the Contractor for all finished Work delivered pursuant to the direction of, and accepted by, the Minister, the Cost to the Contractor of the finished Work plus the proportionate part of any fee fixed by the Contract and shall pay or reimburse the Contractor the fair and reasonable Cost to the Contractor of all materials or Work-in-process delivered pursuant to the direction. Canada may withhold from the amounts due to the Contractor the sums that the Minister determines to be necessary to protect Canada against excess Costs for the completion of the Work.
- 10.4. The Contractor shall not be entitled to be reimbursed any amount which, taken together with any amounts paid or becoming due to the Contractor under the Contract, exceeds the Contract Dollar Value applicable to the Work or the particular part of the Work.

GC11. Records to be Kept by Contractor

- 11.1. The Contractor shall keep proper accounts and records of the cost of the Work and of all expenditures or commitments made by the Contractor including invoices, original receipts and vouchers, which shall at reasonable times be open to audit and inspection by the authorized representatives of the Minister who may make copies and take extracts.
- 11.2. The Contractor shall afford facilities for audit and inspection and shall furnish the authorized representatives of the Minister with such information as the Minister or they may from time to time require with reference to the documents referred to in GC11.1.
- 11.3. The Contractor shall not dispose of the documents referred to in GC11.1 without the written consent of the Minister, but shall preserve and keep them available for audit and inspection for the period of time specified elsewhere in the Contract or, in the absence of such specification, for a period of six years following completion of the Work.

GC12. Conflict of Interest

12.1. The Contractor acknowledges that individuals who are subject to the provisions of the *Conflict of Interest Act*, 2006, c. 9, s. 2, the *Conflict of Interest Code for Members of the House of Commons*, the *Values and Ethics Code for the Public Service* or all other codes of values and ethics applicable within specific organizations cannot derive any direct benefit resulting from the Contract.

GC13. Contractor Status

13.1. This is a Contract for the performance of services and the Contractor is an independent contractor engaged by Canada to perform the Work. Nothing in the Contract is intended to create a partnership, a joint venture or an agency between Canada and the other Party or Parties. The Contractor must not represent itself as an agent or representative of Canada to anyone. Neither the Contractor nor any of its personnel is engaged as an employee or agent of Canada. The Contractor is responsible for all deductions and remittances required by law in relation to its employees.

GC14. Conduct of the Work

14.1. The Contractor represents and warrants that:

- a. it is competent to perform the Work;
- b. it has everything necessary to perform the Work, including the resources, facilities, labour, technology, equipment, and materials; and
- c. it has the necessary qualifications, including knowledge, skill, know-how and experience, and the ability to use them effectively to perform the Work.

14.2. The Contractor must:

- a. perform the Work diligently and efficiently;
- b. except for Government property, supply everything necessary to perform the Work;
- c. use, as a minimum, quality assurance procedures, inspections and controls generally used and recognized by the industry to ensure the degree of quality required by the Contract;
- d. select and employ a sufficient number of qualified people;
- e. perform the Work in accordance with standards of quality acceptable to Canada and in full conformity with the specifications and all the requirements of the Contract; and
- f. provide effective and efficient supervision to ensure that the quality of workmanship meets the requirements of the Contract.

14.3. The Work must not be performed by any person who, in the opinion of Canada, is incompetent, unsuitable or has conducted himself/herself improperly.

GC15. Member of Parliament

15.1. No Member of Parliament shall be admitted to any share or part of this Contract or to any benefit to arise from this Contract.

GC16. Protection of Work

16.1. The Contractor shall keep confidential all information provided to the Contractor by or on behalf of Canada in connection with the Work, including any information that is confidential or proprietary to third parties, and all information conceived, developed or produced by the Contractor as part of the Work where copyright or any other intellectual property rights in such information (except a licence) vests in Canada under the Contract. The Contractor shall not disclose any such information to any person without the written permission of the Minister, except that the Contractor may disclose to a subcontractor information necessary for the performance of the

subcontract, on the condition that the subcontractor agrees that it will be used solely for the purposes of such subcontract. Information provided to the Contractor by or on behalf of Canada shall be used solely for the purpose of the Contract and shall remain the property of Canada or the third party, as the case may be. Unless the Contract otherwise expressly provides, the Contractor shall deliver to Canada all such information, together with every copy, draft, working paper and note thereof that contains such information, upon completion or termination of the Contract or at such earlier time as the Minister may require. This section does not apply to any information that:

- 16.1.1. is publicly available from a source other than the Contractor; or
- 16.1.2. is or becomes known to the Contractor from a source other than Canada, except any source that is known to the Contractor to be under an obligation to Canada not to disclose the information.

16.2. When the Contract, the Work, or any information referred to in GC16.1 is identified as TOP SECRET, SECRET, CONFIDENTIAL or PROTECTED by Canada,

- 16.2.1. the Contractor shall, at all times, take all measures reasonably necessary for the safeguarding of the material so identified, including any other instructions issued by the Minister; and
- 16.2.2. the Minister shall be entitled to inspect the Contractor's premises and the premises of a subcontractor at any tier for security purposes at any time during the term of the Contract, and the Contractor shall comply with, and ensure that any subcontractor complies with, all written instructions issued by the Minister dealing with the material so identified, including any requirement that employees of the Contractor or of any subcontractor execute and deliver declarations relating to reliability screenings, security clearances and other procedures.

GC17. Contingency Fees, Auditing and Public Disclosure

17.1. The Contractor declares that the Contractor has not, directly or indirectly, paid or agreed to pay, and will not, directly or indirectly, pay a Contingency Fee to any individual for the solicitation, negotiation or obtaining of this Contract if the payment of the fee would require the individual to file a return under section 5 of the *Lobbying Act* R.S.C., 1985, c. 44 (4th Supp.).

17.2. All accounts and records relating to any payment by the Contractor of fees or other compensation for the solicitation, obtaining or negotiation of the Contract shall be subject to the accounting and auditing provisions of this Contract.

17.3. The Contractor consents, in the case of a contract that has a value in excess of \$10,000, to the public disclosure of basic information - other than information described in any of paragraphs 20(1)(a) to (d) of the *Access to Information Act* - relating to the Contract.

17.4. If the Contractor makes a false declaration under clause 17.1 or 21.1 or fails to comply with the terms set out in clause 17.2 or 17.3, it is an act of default under the Contract and the Contractor agrees, in addition to any other remedies that may be available against the Contractor, to immediately return any advance payments and agrees that the Contracting Authority may terminate the Contract in accordance with the default provisions of this Contract.

17.5. In this section, "Contingency Fee" means any payment or other compensation that is contingent upon or is

calculated upon the basis of a degree of success in soliciting or obtaining a government contract or negotiating the whole or any part of its terms.

GC18. Work Force Reduction Programs

- 18.1. The Contractor acknowledges and agrees that any person, including the Contractor, carrying out this Contract, shall make available to the Contracting Authority any details of the status of the person with respect to cash out benefits as well as details of any pension payments under work force reduction programs.
- 18.2. The Contractor shall, if asked in writing and where necessary, sign or cause to have signed on behalf of any person, a waiver of privacy with respect to any and all information in relation to any such benefits and payments.

GC19. Amendments

- 19.1. No amendment of the Contract nor waiver of any of the terms and provisions shall be deemed valid unless effected by a written amendment. For greater certainty, to be effective, any amendment to the Contract must be done in writing by the Contracting Authority and the authorized representative of the Contractor.

GC20. Replacement Personnel

- 20.1. The Contractor shall provide the services of the persons named in its bid and any additional persons necessary to perform the Work and provide the services required under this Contract, unless the Contractor is unable to do so for reasons beyond the Contractor's control.
- 20.2. Should the Contractor, at any time, be unable to provide their services, the Contractor shall be responsible for providing replacements who shall be of similar ability and attainment and who shall be acceptable to the Contracting Authority. In such case the Contractor shall notify the Contracting Authority in writing and provide:
- 20.2.1. the reason for the removal of the named person from the project;
- 20.2.2. the name of the proposed replacement;
- 20.2.3. an outline of the qualifications and experience of the proposed replacement; and
- 20.2.4. an accepted security clearance certificate, if applicable.
- 20.3. The notice shall be sent at least seven (7) days in advance of the date upon which the replacement is to commence Work. Any change in the terms and conditions of this Contract which result from a replacement of personnel shall be effected by a contract amendment.
- 20.4. Notwithstanding the foregoing, the Contractor is required to perform the Work and provide the services in accordance with the terms of this Contract.

GC21. Criminal Code of Canada

- 21.1. The Contractor agrees to comply with the Code of Conduct for Procurement (the "Code") and to be bound by its terms. The Code can be accessed at the following Internet address: <http://www.tpsgc-pwgsc.gc.ca/app-acq/cndt-cndct/contexte-context-eng.html> Furthermore, in addition to the Code, the Contractor must comply with the terms set out in this section.
- 21.2. The Contractor declares and it is a term of this Contract that the Contractor has, and any of the Contractor's employees assigned to the performance of the Contract have, not never been convicted of an offence, other than an offence for which a pardon has been granted under the following sections of the *Criminal Code* of Canada:
- 21.2.1. Section 121, Frauds on the government;
- 21.2.2. Section 124, Selling or purchasing office; or
- 21.2.3. Section 418, Selling defective stores to Canada.

GC22. Inspection/Acceptance

- 22.1. All the Work is subject to inspection and acceptance by Canada. Inspection and acceptance of the Work by Canada does not relieve the Contractor of its responsibility for defects or other failures to meet the requirements of the Contract. Canada will have the right to reject any Work that is not in accordance with the requirements of the Contract and require its correction or replacement at the Contractor's expense.

GC23. Taxes

- 23.1. Federal governments and agencies are to pay Applicable Taxes.
- 23.2. Applicable Taxes will be paid by Canada as provided in the Invoice Submission section. It is the sole responsibility of the Contractor to charge Applicable Taxes at the correct rate in accordance with applicable legislation. The Contractor agrees to remit to appropriate tax authorities any amounts of Applicable Taxes paid or due.
- 23.3. The Contractor is not entitled to use Canada's exemptions from any tax, such as provincial sales taxes, unless otherwise specified by law. The Contractor must pay applicable provincial sales tax, ancillary taxes, and any commodity tax, on taxable goods or services used or consumed in the performance of the Contract (in accordance with applicable legislation), including for material incorporated into real property.
- 23.4. In those cases where Applicable Taxes, customs duties, and excise taxes are included in the Contract Price, the Contract Price will be adjusted to reflect any increase, or decrease, of Applicable Taxes, customs duties, and excise taxes that will have occurred between bid submission and contract award. However, there will be no adjustment for any change to increase the Contract Price if public notice of the change was given before bid submission date in sufficient detail to have permitted the Contractor to calculate the effect of the change.
- 23.5. Tax Withholding of 15 Percent – Canada Revenue Agency Pursuant to the *Income Tax Act*, 1985, c. 1 (5th Supp.) and the *Income Tax Regulations*, Canada must withhold 15 percent of the amount to be paid to the Contractor in respect of services provided in Canada if the Contractor is not a resident of Canada, unless the Contractor obtains a valid waiver from the *Canada Revenue Agency*. The amount withheld will be held on account for the Contractor in respect to any tax liability which may be owed to Canada.

GC24. Title

- 24.1. Except as otherwise provided in the Contract including the intellectual property provisions, and except as provided in subsection 24.2, title to the Work or any part thereof shall vest in Canada upon delivery and acceptance thereof by or on behalf of Canada.
- 24.2. Except as otherwise provided in the intellectual property provisions of the Contract, upon any payment being made to the Contractor for or on account of materials, parts, Work-in-process or finished Work, either by way of progress payments or accountable advances or otherwise, title in and to all materials, parts, Work-in-process and finished Work so paid for shall vest in and remain in Canada unless already so vested under any other provision of the Contract.
- 24.3. Notwithstanding any vesting of title referred to in this section and except as otherwise provided in the Contract, the risk of loss or damage to the materials, parts, Work-in-process or finished Work or part thereof so vested shall remain with the Contractor until their delivery to Canada in accordance with the Contract. The Contractor shall be

- liable for any loss or damage to any part of the Work caused by the Contractor or any subcontractor after such delivery.
- 24.4. Any vesting of title referred to in subsection 24.2 shall not constitute acceptance by Canada of the materials, parts, Work-in-process or finished Work, and shall not relieve the Contractor of its obligation to perform the Work in accordance with the Contract.
- 24.5. Where title to any materials, parts, Work-in-process or finished Work becomes vested in Canada, the Contractor shall, upon the Minister's request, establish to the Minister's satisfaction that the title is free and clear of all claims, liens, attachments, charges or encumbrances and shall execute such conveyances thereof and other instruments necessary to perfect that title as the Minister may request.
- 24.6. If the Contract is a defence contract within the meaning of the *Defence Production Act*, R.S. 1985, c. D-1, title to the Work or to any materials, parts, Work-in-process or finished Work shall vest in Canada free and clear of all claims, liens, attachments, charges or encumbrances, and the Minister shall be entitled at any time to remove, sell or dispose of it or any part of it in accordance with section 20 of that Act.
- GC25. Entire Agreement**
- 25.1. The Contract constitutes the entire and only agreement between the Parties and supersedes all previous negotiations, communications and other agreements, whether written or oral, unless they are incorporated by reference in the Contract. There are no terms, covenants, representations, statements or conditions binding on the Parties other than those contained in the Contract.
- GC26. Harassment in the Workplace**
- 26.1. The Contractor acknowledges the responsibility of Canada to ensure, for its employees, a healthy work environment, free of harassment. A copy of the Policy on the Prevention and Resolution of Harassment in the Workplace, which is also applicable to the Contractor, is available on the Treasury Board Secretariat of Canada website.
- 26.2. The Contractor must not, either as an individual, or as a corporate or unincorporated entity, through its employees or subcontractors, harass, abuse, threaten, discriminate against or intimidate any employee, contractor or other individual employed by, or under contract with, Canada. The Contractor will be advised in writing of any complaint and will have the right to respond in writing. Upon receipt of the Contractor's response, the Contracting Authority will, at its entire discretion, determine if the complaint is founded and decide on any action to be taken.
- GC27. No Bribe or Conflict**
- 27.1. The Contractor declares that no bribe, gift, benefit, or other inducement has been or will be paid, given, promised or offered directly or indirectly to any official or employee of Canada or to a member of the family of such a person, with a view to influencing the entry into the Contract or the administration of the Contract.
- 27.2. The Contractor must not influence, seek to influence or otherwise take part in a decision of Canada knowing that the decision might further its private interest. The Contractor must have no financial interest in the business of a third party that causes or would appear to cause a conflict of interest in connection with the performance of its obligations under the Contract. If such a financial interest is acquired during the period of the Contract, the Contractor must immediately declare it to the Contracting Authority.
- 27.3. The Contractor warrants that, to the best of its knowledge after making diligent inquiry, no conflict exists or is likely to arise in the performance of the Contract. In the event the Contractor becomes aware of any matter that causes or is likely to cause a conflict in relation to the Contractor's performance under the Contract, the Contractor must immediately disclose such matter to the Contracting Authority in writing.
- 27.4. If the Contracting Authority is of the opinion that a conflict exists as a result of the Contractor's disclosure or as a result of any other information brought to the Contracting Authority's attention, the Contracting Authority may require the Contractor to take steps to resolve or otherwise deal with the conflict or, at its entire discretion, terminate the Contract for default. Conflict means any matter, circumstance, interest, or activity affecting the Contractor, its personnel or subcontractors, which may or may appear to impair the ability of the Contractor to perform the Work diligently and independently.
- GC28. Government Property**
- 28.1. The Contractor must take reasonable and proper care of all Government property while it is in its possession or subject to its control. The Contractor is responsible for any loss or damage resulting from its failure to do so other than loss or damage caused by ordinary wear and tear.
- GC29. Suspension of Work**
- 29.1. The Contracting Authority may at any time, by giving written notice, order the Contractor to suspend or stop the Work or part of the Work under the Contract. The Contractor must immediately comply with any such order in a way that minimizes the cost of doing so.
- GC30. Right of Set-Off**
- 30.1. Without restricting any right of set-off given by law, the Minister may set-off against any amount payable to the Contractor under the Contract, any amount payable to the Government of Canada by the Contractor under the Contract or under any other current contract. The Minister may, when making a payment pursuant to the Contract, deduct from the amount payable to the Contractor any such amount payable to the Government of Canada by the Contractor which, by virtue of the right of set-off, may be retained by the Government of Canada.
- GC31. Powers of Canada**
- 31.1. All rights, remedies, powers and discretions granted or acquired by Canada under the Contract or by law are cumulative, not exclusive.
- GC32. International Sanctions**
- 32.1. Persons in Canada, and Canadians outside of Canada, are bound by economic sanctions imposed by Canada. As a result, the Government of Canada cannot accept delivery of goods or services that originate, either directly or indirectly, from the countries or persons subject to economic sanctions.
- 32.2. The Contractor must not supply to the Government of Canada any goods or services which are subject to economic sanctions.
- 32.3. The Contractor must comply with changes to the regulations imposed during the period of the Contract. The Contractor must immediately advise Canada if it is unable to perform the Work as a result of the imposition of economic sanctions against a country or person or the addition of a good or service to the list of sanctioned

goods or services. If the Parties cannot agree on a work around plan, the Contract will be terminated for the convenience of Canada in accordance with section GC9.

GC33. Transportation Costs

33.1. If transportation Costs are payable by the Minister under the Contract and the Contractor makes the transportation arrangements, shipments must be made by the most direct and economical means consistent with normal shipping practice. The Costs must be shown as a separate item on the invoice.

GC34. Contract administration and dispute resolution

34.1. In the event that concerns or issues arise regarding the application of the terms and conditions of a contract, or regarding its administration, the Contractor should contact the contracting officer identified in the Contract to schedule a meeting by phone or in person to discuss and/or resolve any disagreements or misunderstandings. After this initial meeting has taken in place, and if needed, contractors will be provided with information on other dispute resolution options available to them such as the Office of the Procurement Ombudsman (OPO) or other appropriate recourses.

34.2. At the request and consent of both Parties, the Office of the Procurement Ombudsman may be requested to participate in an alternative dispute resolution process to resolve any dispute between the Parties respecting the interpretation or application of the terms and conditions of the resulting Contract and their consent to bear the costs of such a process. The Office of the Procurement Ombudsman may be contacted by phone at 1-866-734-5169 or by email at boa.opo@boa.opo.gc.ca.

GC35. Transportation Carriers' Liability

35.1. The Government of Canada's policy of underwriting its own risks precludes payment of insurance or valuation charges for transportation beyond the point at which ownership of goods passes to the Government of Canada (determined by the FOB point of Incoterms). Where increased carrier liability is available without charge, the Contractor must obtain the increased liability for shipment.

GC36. Integrity Provisions in Contracts

36.1 Statement

- a. The Contractor must comply with the [Code of Conduct for Procurement](#) and must comply with the terms set out in these Integrity Provisions.
- b. The Contractor confirms that it understands that convictions of certain offences, a false declaration in its bid, a false declaration under the Contract or failing to maintain up-to-date information requested may lead to a termination for default. If the Contractor or any of its Affiliates fail to remain free and clear of any convictions and any conditional or absolute discharges specified in these Integrity Provisions during the contract period, Canada may, following a notice period, terminate for default. The Contractor understands that a termination for default will not restrict Canada's right to exercise any other remedies that may be available against the Contractor and agrees to immediately return any advance payments.

36.2 List of Names

The Contractor must immediately inform Canada in writing of any changes affecting the list of names of directors and owners during the contract period.

36.3 Information Verification

The Contractor certifies that it is aware, and its Affiliates

are aware, that Canada may verify at any time during the contract period, the information provided by the Contractor, including the information relating to the acts or convictions and any conditional or absolute discharges specified in these Integrity Provisions. Canada may request additional information, validations from a qualified third party, consent forms and other evidentiary elements proving identity and eligibility to contract with Canada.

36.4 Lobbying Act

The Contractor certifies that neither it nor its Affiliates have directly or indirectly, paid or agreed to pay, and will not, directly or indirectly, pay a contingency fee to any individual for the solicitation, negotiation or obtaining of the Contract if the payment of the fee would require the individual to file a return under section 5 of the [Lobbying Act](#).

36.5 Canadian Offences Resulting in Legal Incapacity

- a. The Contractor has certified that neither it nor any of its Affiliates have been convicted of or have pleaded guilty to an offence under any of the following provisions, which result in legal incapacity under section 750(3) of the [Criminal Code](#), and for which they have not been pardoned or received a record of discharge under the Canadian Pardons subsection:
 - i. paragraph 80(1)(d) (*False entry, certificate or return*), subsection 80(2) (*Fraud against Her Majesty*) or section 154.01 (*Fraud against Her Majesty*) of the [Financial Administration Act](#), or
 - ii. section 121 (*Frauds on the government and Contractor subscribing to election fund*), section 124 (*Selling or Purchasing Office*), section 380 (*Fraud*) for fraud committed against Her Majesty or section 418 (*Selling defective stores to Her Majesty*) of the [Criminal Code](#), or
- b. the Contractor has not been convicted of or pleaded guilty to the offences described in paragraph (a) and has certified that it has not directed, influenced, authorized, assented to, acquiesced in or participated in the commission or omission of the acts or offences that would render that Affiliate ineligible to be awarded a contract under (a).

36.6 Canadian Offences

The Contractor has certified that:

- a. it and its Affiliates have not, in the last three years, from the date of contract award, been convicted of or pleaded guilty to an offence under any of the following provisions for which it would be ineligible for contract award under these Integrity Provisions and for which they have not been pardoned or received a record of discharge under the Canadian Pardons subsection:
 - i. section 119 (*Bribery of judicial officers, etc*), section 120 (*Bribery of officers*), section 346 (*Extortion*), sections 366 to 368 (*Forgery and other offences resembling forgery*), section 382 (*Fraudulent manipulation of stock exchange transactions*), section 382.1 (*Prohibited insider trading*), section 397 (*Falsification of books and documents*), section 422 (*Criminal breach of contract*), section 426 (*Secret commissions*), section 462.31 (*Laundering proceeds of crime*) or sections 467.11 to 467.13 (*Participation in activities of criminal organization*) of the [Criminal Code](#), or
 - ii. section 45 (*Conspiracies, agreements or arrangements between competitors*), section 46 (*Foreign directives*), section 47 (*Bid rigging*), section 49 (*Agreements or arrangements of federal financial institutions*), section 52 (*False*

- or misleading representation), section 53 (*Deceptive notice of winning a prize*) of the [Competition Act](#), or
- iii. section 239 (*False or deceptive statements*) of the [Income Tax Act](#), or
- iv. section 327 (*False or deceptive statements*) of the [Excise Tax Act](#), or
- v. section 3 (*Bribing a foreign public official*), section 4 (*Accounting*), or section 5 (*Offence committed outside Canada*) of the [Corruption of Foreign Public Officials Act](#), or
- vi. section 5 (*Trafficking in substance*), section 6 (*Importing and exporting*), or section 7 (*Production of substance*) of the [Controlled Drugs and Substance Act](#), or
- b. the Contractor has not been convicted of or pleaded guilty to the offences described in paragraph (a) and has certified that it has not directed, influenced, authorized, assented to, acquiesced in or participated in the commission or omission of the acts or offences that would make that Affiliate ineligible for contract award.
- 36.7 Foreign Offences**
The Contractor has certified that:
- a. it and its Affiliates have not, in the last three years, from the date of contract award, been convicted of or pleaded guilty to an offence in a jurisdiction other than Canada of having committed an act or omission that would, in Canada's opinion, be similar to an offence referenced in the Canadian Offences Resulting in Legal Incapacity and the Canadian Offences subsections and for which it would be ineligible for contract award under these Integrity Provisions and for which they have not been pardoned or received a record of discharge under the Foreign Pardons subsection:
- i. the court before which the Contractor or the Affiliate of the Contractor appeared acted within the court's jurisdiction;
- ii. the Contractor or the Affiliate of the Contractor appeared during the court's proceedings or submitted to the court's jurisdiction;
- iii. the court's decision was not obtained by fraud; and
- iv. the Contractor or the Affiliate of the Contractor was entitled to present to the court every defence that the Contractor or the Affiliate of the Contractor would have been entitled to present had the proceeding been tried in Canada; or
- b. it has not been convicted of or pleaded guilty to the offences described in paragraph (a) and has certified that it has not directed, influenced, authorized, assented to, acquiesced in or participated in the commission or omission of the acts or offences that would render that Affiliate ineligible to be awarded a contract under (a).
- 36.8 Ineligibility to Contract with Canada**
a. The Contractor confirms that it understands that if after contract award they have been convicted of certain offences, as described in the Canadian Offences Resulting in Legal Incapacity, the Canadian Offences and the Foreign Offences subsections, they will be ineligible to contract with Canada. If, after contract award, a Contractor becomes ineligible for contract award, Canada may, following a notice period, declare the Contractor to be ineligible and, to the extent that a contract has been awarded:
- i. terminate the contract for default; or
- ii. require the Contractor to enter into an Administrative Agreement with the Minister of PWGS on such terms and conditions as are necessary to safeguard the integrity of the procurement process.
- b. The Contractor confirms that it understands that where its Affiliate has been convicted of certain offences, as described in the Canadian Offences Resulting in Legal Incapacity, the Canadian Offences and the Foreign Offences subsections, the Affiliate is ineligible to contract with Canada. If, after contract award, an Affiliate of a Contractor becomes ineligible to contract with Canada, Canada may, following a notice period, declare the Contractor to be ineligible and, to the extent that a contract has been concluded:
- i. terminate the contract for default if, in the opinion of Canada, there is evidence that the Contractor directed, influenced, authorized, assented to, acquiesced in or participated in the commission or omission of certain acts or offences that make that Affiliate ineligible; or
- ii. require the Contractor to enter into an Administrative Agreement with the Minister of PWGS on such terms and conditions as are necessary to safeguard the integrity of the procurement process.
- c. The Contractor confirms that it understands that where it has been declared to be ineligible to contract with Canada under the [Ineligibility and Suspension Policy](#), it is also ineligible to contract with Canada under these Integrity Provisions for the duration of the period that has been determined by the Minister of PWGS. Where the Contractor has been declared to be ineligible under the [Ineligibility and Suspension Policy](#) after contract award, Canada may, following a notice period:
- i. terminate the contract for default; or
- ii. require the Contractor to enter into an Administrative Agreement with the Minister of PWGS on such terms and conditions as are necessary to safeguard the integrity of the procurement process.
- d. The Contractor confirms that it understands that where it or its Affiliates have been held responsible for breaches under the Lobbying Act subsection, it is ineligible to contract with Canada under these Integrity Provisions for the duration of the period that has been determined by the Minister of PWGS. Where the Contractor has been declared to be ineligible under the [Ineligibility and Suspension Policy](#) after contract award, Canada may, following a notice period:
- i. terminate the contract for default; or
- ii. require the Contractor to enter into an Administrative Agreement with the Minister of PWGS on such terms and conditions as are necessary to safeguard the integrity of the procurement process.
- 36.9 Declaration of Offences Committed**
The Contractor understands that it has a continuing obligation to immediately declare all convictions to Canada under the Canadian Offences Resulting in Legal Incapacity, the Canadian Offences and the Foreign Offences subsections.
- 36.10 Period of Ineligibility**
The following rules determine the period for which a Contractor or its Affiliate that has been convicted of certain offences is, ineligible to contract with Canada:
- a. for all offences referenced under the Canadian Offences Resulting in Legal Incapacity subsection for which a Contractor or its Affiliate has pleaded guilty to or has been convicted of, the period of ineligibility

- to be awarded a contract is indefinite, subject to the Canadian Pardons subsection;
- b. subject to an Administrative Agreement, for all offences referenced under the Canadian Offences and Foreign Offences subsections for which a Contractor or its Affiliate has pleaded guilty to or been convicted of, as the case may be, in the last three years, the period of ineligibility to contract with Canada is ten years from the date of determination by the Minister of PWGS, subject to the Canadian Pardons and Foreign Pardons subsections;
 - c. subject to an Administrative Agreement, for all breaches under the Lobbying Act subsection for which a Contractor or its Affiliate has been found responsible, in the last three years, the period of ineligibility to contract with Canada is ten years from the date of determination by the Minister of PWGS.
- 36.11 Canadian Pardons**
A determination of ineligibility to contract with Canada will not be made or maintained by the Minister of PWGS under these Integrity Provisions, in respect of an offence or act that gave rise or that could give rise to a determination of ineligibility, if the Contractor or its Affiliate has:
- a. been granted an absolute discharge in respect of the offence, or has been granted a conditional discharge in respect of the offence and those conditions have been satisfied;
 - b. been granted a pardon under Her Majesty's royal prerogative of mercy;
 - c. been granted a pardon under section 748 of the [Criminal Code](#);
 - d. received a record of suspension ordered under the [Criminal Records Act](#); and
 - e. been granted a pardon under the [Criminal Records Act](#), as that Act read immediately before the day section 165 of the [Safe Streets and Communities Act](#) comes into force.
- 36.12 Foreign Pardons**
A determination of ineligibility to contract with Canada will not be made or maintained, as the case may be, by the Minister of PWGS in respect of matters referenced in the Foreign Offences subsection and with respect to an

offence or act that gave rise or will give rise to a determination of ineligibility, if the Contractor or its Affiliate, has at any time, benefited from foreign measures that are similar to Canadian pardons at the sole discretion of Canada, conditional discharges, absolute discharges, records of suspension, or restoration of legal capacities by the Governor in Council.

36.13 Period of Ineligibility for Breaching Administrative Agreements

The Contractor confirms that it understands that where it has concluded an Administrative Agreement and that it has breached any of its terms and conditions, the Minister of PWGS will lengthen the period of ineligibility for a period to be determined by the Minister of PWGS.

36.14 Obligations on Subcontractors

The Contractor confirms that it understands that to the extent that it relies on a subcontractor(s) to perform the Contract, the Contractor will not enter into a subcontract with a company that has been convicted of or pleaded guilty or an Affiliate of the company has been convicted of or pleaded guilty, as the case may be, to any of the offences referenced in the Canadian Offences Resulting in Legal Incapacity, the Canadian Offences and the Foreign Offences subsections for which no pardon or equivalent has been received under the Canadian Pardons and Foreign Pardons subsections, without the prior written approval of the Minister of PWGS. Where the Contractor has entered into a contract with an ineligible subcontractor and for which no prior written approval has been received by Canada, the Minister of PWGS will declare the Contractor to be ineligible to contract with Canada for a period of five years.

GC37. Entire Agreement

37.1 The Contract constitutes the entire and only agreement between the Parties and supersedes all previous negotiations, communications and other agreements, whether written or oral, unless they are incorporated by reference in the Contract. There are no terms, covenants, representations, statements or conditions binding on the Parties other than those contained in the Contract.

3. TERMS OF PAYMENT

TP1. Payment

- 1.1. Payments under this Contract, except advance payments, shall be conditional upon performance, completion and delivery of the Work, or any part of the Work to the satisfaction of the Minister but subject to the submission and receipt by Canada of a claim for payment.
- 1.2. Subject to parliamentary appropriation of funds and to TP1.1, payment by the Minister for the Work shall be made:
 - 1.2.1. in the case of an advance payment, within thirty (30) days of the signing of this Contract by both Parties or within thirty (30) days of receipt of an invoice requesting payment, whichever is later,
 - 1.2.2. in the case of progress payment, within thirty (30) days following the date of receipt of a duly completed Work or progress report or within thirty (30) days of receipt of an invoice requesting payment, whichever is later, and
 - 1.2.3. in the case of a final payment, within thirty (30) days following the date of receipt of the completed Work or within thirty (30) days of receipt of an invoice requesting payment whichever is later.
- 1.3. For purposes of this Contract, a full day is any period of seven and one half (7.5) hours within any twenty-four (24) hour period.
- 1.4. If the Contractor is engaged in the performance of the Work for any period that exceeds or is less than a full day, the Contractor will be paid a pro-rata portion of the firm daily rate that corresponds to the number of hours during which the Contractor was so engaged.
- 1.5. If Canada has any objections to the form of the invoice or the substantiating documentation, within fifteen (15) days of its receipt, Canada shall notify the Contractor of the nature of the objection.
- 1.6. "Form of the invoice" means an invoice which contains or is accompanied by such substantiating documentation as Canada requires. Failure by Canada to act within fifteen (15) days only results in the date specified in TP1.1 of the clause to apply for the sole purpose of calculating interest on overdue accounts.
- 1.7. Notwithstanding any other provision of the Contract, no payment shall be made to the Contractor unless and until, with respect to all parts of the Work in respect of which payment is claimed, the Contractor, where required to do so, establishes to the satisfaction of the Minister that such parts of the Work will be free from all claims, liens, attachments, charges or encumbrances.

TP2. Interest on Overdue Accounts

- 2.1. For the purposes of this section:
 - (a) "average rate" means the simple arithmetic mean of the bank rates in effect at 4:00 p.m. Eastern Standard Time each day during the calendar month which immediately precedes the calendar month in which payment is made, where the "bank rate" means the rate of interest established from time to time by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association;
 - (b) "date of payment" means the date of the negotiable instrument drawn by the Receiver General for Canada and given for payment of an amount due and payable;
 - (c) an amount is "due and payable" when it is due and payable by Canada to the Contractor in accordance with the terms of the Contract; and
 - (d) an amount becomes "overdue" when it is unpaid on the first day following the day upon which it is due and payable.

- 2.2. Canada shall be liable to pay to the Contractor simple interest at the average rate plus three (3) percent per annum on any amount that is overdue, from the date such amount becomes overdue until the day prior to the date of payment, inclusive. Interest shall be paid without notice from the Contractor except in respect of payment which is less than 15 days overdue. No interest will be payable or paid in respect of payment made within such 15 days unless the Contractor so requests after payment has become due.
- 2.3. Canada shall not be liable to pay interest in accordance with this clause if Canada is not responsible for the delay in paying the Contractor.
- 2.4. Canada shall not be liable to pay interest on overdue advance payments.

TP3. Appropriation

- 3.1. In accordance with section 40 of the *Financial Administration Act*, payment under the Contract is subject to there being an appropriation for the particular service for the fiscal year in which any commitment hereunder would come in course of payment.

TP4. Travel and Living Expenses

Travel and living expenses incurred by the Contractor are entirely subject to the content of the current National Joint Council Travel Directive (<http://www.njc-cnm.gc.ca/directive/travel-voyage/index-eng.php>) and the Treasury Board Secretariat Special Travel Authorities, Section 7, "Persons on Contract" (http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/statb-eng.asp). Travel and living expenses are considered to be part of the total Cost of the Contract. Expenses which exceed the Directive will not be paid. Prior authorization for projected travel and living expenses is required.

4.1. General

- 4.1.1. Travel and living expenses are to be claimed at actual Cost but are not to exceed current National Joint Council Travel Directive.
- 4.1.2. A statement indicating the names of travellers; places visited; dates and length of visits; and purpose of travel must be submitted with each claim for travel and living expenses.
- 4.1.3. Insurance for all methods of travel; accidents; illness; cancellations; immunizations; and other obligations are the sole responsibility of the Contractor.

4.2. Method of Transportation

- 4.2.1. Air travel. The standard for air travel is economy class only. Upgrades to Business or First class are the sole financial responsibility of the Contractor.
- 4.2.2. Rail Travel. The standard for rail travel is the next higher class after the full economy class.
- 4.2.3. Rental vehicle. The standard for rental vehicles is mid size. Vehicle rental must be pre-approved by the Project Authority.
- 4.2.4. Private vehicle. The Contractor may claim only for distances necessarily driven solely on government business, using the most direct, safe and practical road routes. The rate per kilometre which is payable is specified in the current National Joint Council Travel Directive. Insurance is the responsibility of the Contractor. Canada will not assume responsibility for deductible amounts related to comprehensive or collision coverage.

4.3. Meal, accommodation, transportation and other allowances

- 4.3.1. For same day travel, with no overnight stay, the applicable meals allowance is paid, as specified in the current National Joint Council Travel Directive. Receipts are not required.
- 4.3.2. For same day travel, with no overnight stay, the applicable transportation allowance is paid, as specified in the current National Joint Council Travel Directive. Copies of the receipts must be provided, except when private, non-commercial accommodation is used. Original receipts may be requested at any time by Canada, if so, the Contractor must provide original receipts prior to any payment being made.
- 4.3.3. For travel of two (2) or more consecutive days, the applicable meal allowances, and the incidental expenses allowances per day are paid, as specified in the current National Joint Council Travel Directive. Receipts are not required.
- 4.3.4. For travel of two (2) or more consecutive days, the applicable travel and accommodation allowances

per day are paid, as specified in the current National Joint Council Travel Directive. Copies of the receipts must be provided, except when private, non-commercial accommodation is used. Original receipts may be requested at any time by Canada, if so, the Contractor must provide original receipts prior to any payment being made.

- 4.3.5. Meal allowances are not paid in respect of meals included in a fare (e.g. airplane or club-car ticket), or provided free of charge in a government mess, or included as part of the Cost of an event or other function.
- 4.3.6. Professional fees, or similar equivalent Costs cannot be claimed for travel time.
- 4.3.7. Receipts and vouchers for accommodation and transportation are required to be submitted with each claim, except when private, non-commercial accommodation is used. Luxury accommodation is not permitted. Original receipts may be required upon request from Canada, if so, the Contractor must provide original receipts.
- 4.3.8. Entertainment is not an allowable expense.

4. INTELLECTUAL PROPERTY

IP1. Contractor to Own Intellectual Property Rights

1.0 Interpretation

In the Contract,

- 1.1 “Background Information” means all Intellectual Property that is not Foreground Information that is incorporated into the Work or necessary for the performance of the Work and that is proprietary to or the confidential information of the Contractor, its subcontractors or any other third party;
 - 1.2 “Firmware” means any computer program stored in integrated circuits, read-only memory or other similar devices within the hardware or other equipment;
 - 1.3 “Foreground Information” means all Intellectual Property first conceived, developed, produced or reduced to practice as part of the Work under the Contract;
 - 1.4 “Intellectual Property” means any information or knowledge of an industrial, scientific, technical, commercial, literary, dramatic, artistic or otherwise creative nature relating to the Work, whether oral or recorded in any form or medium and whether or not subject to copyright; this includes but is not limited to any inventions, designs, methods, processes, techniques, know-how, show-how, models, prototypes, patterns, samples, schematics, experimental or test data, reports, drawings, plans, specifications, photographs, manuals and any other documents, Software and Firmware;
 - 1.5 “Intellectual Property Right” means any intellectual property right recognized by law, including any intellectual property right protected by legislation such as patents, copyright, industrial design, integrated circuit topography, and plant breeders’ rights, or subject to protection under the as trade secrets and confidential information;
 - 1.6 “Software” means any computer program whether in source or object code (including Firmware), any computer program documentation recorded in any form or upon any medium, and any computer database, and includes modifications to any of the foregoing.
- 2.0 **Records and Disclosure of Foreground Information**
- 2.1 During and after the performance of the Contract, the Contractor must keep detailed records of the Foreground Information, including details of its creation, ownership and about any sale or transfer of any right in the Foreground Information. The Contractor must report and fully disclose to the Minister all Foreground Information as required by the Contract. If the Contract does not specifically state when and how the Contractor must do so, the Contractor must provide this information when requested by the Minister or a representative of the Minister, whether before or after completion of the Contract.
 - 2.2 The Contractor must, in each disclosure under this section, indicate the names of all subcontractors at any tier, if any, who contributed to the development of the Intellectual Property Rights in the Foreground Information.
 - 2.3 Before and after final payment to the Contractor, the Contractor must provide the Minister with access to all records and supporting data that the Minister considers pertinent to the identification of Foreground Information.
 - 2.4 For any Intellectual Property that was developed or created in relation to the Work, the Minister will be entitled to assume that it was developed or created by Canada, if the Contractor’s records do not list that Intellectual Property or do not indicate that it was created by the Contractor, or by someone on behalf of the Contractor, other than Canada.
- 3.0 **Contractor to Own Intellectual Property Rights in Foreground Information**

- 3.1 All Intellectual Property Rights in the Foreground Information belong to the Contractor as soon as they come into existence.
 - 3.2 Despite the Contractor’s ownership of all the Intellectual Property Rights in the Foreground Information, Canada has unrestricted ownership rights in any prototype, model, custom or customized system or equipment that is a deliverable under the Contract, including manuals and other operating and maintenance documents. This includes the right to make them available for public use, whether for a fee or otherwise, sell them or otherwise transfer ownership in them.
 - 3.3 Any personal information, as defined in the *Privacy Act*, R.S. 1985, c. P-21, collected by the Contractor in the execution of the Work under the Contract becomes the property of Canada immediately upon collection and must be used only for the performance of the Work. The Contractor has no right in any such personal information.
 - 3.4 If the Work under the Contract involves the preparation of a database or other compilation using information or data supplied by Canada or any personal information referred to above, the Intellectual Property Rights in the database or compilation containing such information will belong to Canada. The Contractor’s Intellectual Property rights in the Foreground Information are restricted to those capable of being exploited without the use of the information or data supplied by Canada or the personal information. Unless the Contract otherwise expressly provides, the Contractor shall deliver to Canada all such information, data or personal information, together with every copy, draft, working paper and note thereof that contains such information, data, or personal information, upon the completion or termination of the Contract or at such earlier time as the Minister may require.
- 4.0 **Licenses to Intellectual Property Rights in Foreground and Background Information**
- 4.1 As Canada has contributed to the cost of developing the Foreground Information, the Contractor hereby grants to Canada a non-exclusive, perpetual, irrevocable, world-wide, fully-paid and royalty-free license to exercise the Intellectual Property Rights in the Foreground Information for Canada’s activities. Subject to any exception described in the Contract, this license allows Canada to do anything that it would be able to do if it were the owner of the Foreground Information, other than exploit it commercially in competition with the Contractor and transfer or assign ownership of it. The Contractor also hereby grants to Canada a license to use the Background Information to the extent that it is reasonably necessary for Canada to exercise fully all its rights in the deliverables and in the Foreground Information. These licenses cannot be restricted in any way by the Contractor providing any form of notice to the contrary, including the wording on any shrink-wrap license or any other kind of packaging, attached to any deliverable.
 - 4.2 For greater certainty, Canada’s licenses include, but are not limited to:
 - a. the right to disclose the Foreground and Background Information to third parties bidding on or negotiating contracts with Canada and to sublicense or otherwise authorize the use of that information by any contractor engaged by Canada solely for the purpose of carrying out such contracts. Canada will require these third parties and contractors not to use or disclose that information except as may be necessary to bid on, negotiate or carry out those contracts;

- b. the right to disclose the Foreground and Background Information to other governments for information purposes;
- c. the right to reproduce, modify, improve, develop or translate the Foreground and Background Information or have it done by a person hired by Canada. Canada, or a person designated by Canada, will own the Intellectual Property Rights associated with the reproduction, modification, improvement, development or translation;
- d. without restricting the scope of any license or other right in the Background Information that Canada may otherwise hold, the right, in relation to any custom-designed or custom-manufactured part of the Work, to exercise such of the Intellectual Property Rights in the Background Information as may be required for the following purposes:
- i. for the use, operation, maintenance, repair or overhaul of the custom-designed or custom-manufactured parts of the Work;
 - ii. in the manufacturing of spare parts for maintenance, repair or overhaul of any custom-designed or custom-manufactured part of the Work by Canada if those parts are not available on reasonable commercial terms to enable timely maintenance, repair or overhaul;
- e. for Software that is custom designed for Canada, the right to use any source code the Contractor must deliver to Canada under the Contract and to reproduce, use, modify, improve or translate the Software.
- 4.3 The Contractor agrees to make the Background Information, including in the case of Software, the source code promptly available to Canada for any purpose mentioned above. The license does not apply to any Software that is subject to detailed license conditions that are set out elsewhere in the Contract. Furthermore, in the case of commercial off-the-shelf software, the Contractor's obligation to make the source code promptly available to Canada applies only to source code that is within the control of or can be obtained by the Contractor or any subcontractor.
- 4.4 Where the Intellectual Property Rights in any Foreground Information are or will be owned by a subcontractor at any tier, the Contractor shall either obtain a license from that subcontractor that permits compliance with subsections IP 4.1 and IP 4.2 or arrange for the subcontractor to convey directly to Canada the same rights by execution of the form provided for that purpose by the Minister, in which case the Contractor shall deliver that form to the Minister, duly completed and executed by the subcontractor, no later than the time of disclosure to Canada of that Foreground Information.
- 4.5 The Contractor represents and warrants that it has the right to grant to Canada the licenses and any other rights to use the Foreground and Background Information. If the Intellectual Property Rights in any Foreground or Background Information are or will be owned by a subcontractor or any other third party, the Contractor must have or obtain promptly a license from that subcontractor or third party to grant promptly any required license directly to Canada.
- 4.6 Any information supplied by Canada to the Contractor for the performance of the Work remains the property of Canada. The Contractor must use Canada's information only to perform the Contract. If the Contractor wants to use any information owned by Canada for the commercial exploitation or further development of any of the Foreground Information, the Contractor must obtain a license from the Minister. In its request for a license to the Minister, the Contractor must explain why the license is required and how the Contractor intends to use the information. If the Minister agrees to grant a license, its terms will be negotiated between the Contractor and the Minister and may include the payment of a compensation to Canada.
- 5.0 **Transfer or License of Contractor's Rights**
- 5.1 During the Contract, the Contractor must not sell, transfer, assign or license the Foreground Information without first obtaining the Contracting Authority's written permission.
- 5.2 After the Contract, the Contractor is not required to obtain Canada's permission to transfer ownership in the Foreground Information but any transfer must be subject to all Canada's rights to use the Foreground Information. Furthermore, after the Contract, if the Contractor grants a license or any other right (other than a transfer of ownership) to a third party to use the Foreground Information, the Contractor is not required to notify Canada, but the license or right granted must not affect Canada's rights in any way. If the Contractor at any time transfers ownership or grants rights in the Foreground Information that interfere in any way with Canada's rights to use the Foreground Information, the Contractor must, if requested by Canada, immediately take all steps necessary to restore Canada's rights. If the Contractor is not successful in doing so, within the time reasonably required by Canada, the Contractor must immediately reimburse Canada for all costs Canada incurs to do so itself.
- 5.3 The Contractor shall promptly notify Canada of the name, address and other pertinent information in regard to any transferee (including the conditions of the transfer), assignee or licensee referred to in this subsection and shall ensure that such party is required to do the same with regard to any subsequent transferee, assignee or licensee.
- 5.4 If Canada terminates the Contract in whole or in part for default, or if the Contractor fails to disclose any Foreground Information in accordance with section IP 2.1, the Minister may, by giving notice to the Contractor, require the Contractor to convey to Canada all the Intellectual Property Rights in the Foreground Information or, in the case of a notice based on failure to disclose, all of the Intellectual Property Rights in the Foreground Information not disclosed, including the rights owned by subcontractors. In the case of Intellectual Property Rights in the Foreground Information that have been sold or assigned to a third party, the Contractor must pay to Canada on demand, at Canada's discretion, the fair market value of the Intellectual Property Rights in the Foreground Information or an amount equal to the payment received by the Contractor from the sale or assignment of the Intellectual Property Rights in the Foreground Information.
- 5.5 In the event of the issuance of a notice by the Minister, the Contractor must, at its own expense and without delay, execute such documents relating to ownership of the Intellectual Property Rights as the Minister may require. The Contractor must, at Canada's expense, provide all reasonable assistance in the preparation of applications and in the prosecution of any applications for any registration of any Intellectual Property Rights in any jurisdiction, including the assistance of the inventor in the case of an invention.
- 5.6 If the Contractor uses the Foreground Information to develop any new product or any improvement in any existing product, the Contractor agrees that, if Canada wishes to purchase such new or improved product, the Contractor must sell them to Canada at a discount off the lowest price for which it has sold those products to other customers, to recognize Canada's financial contribution to the development of those products.

6.0 Waiver of Moral Rights

6.1 If requested by Canada, during and after the Contract, the Contractor must provide a written permanent waiver of moral rights, as defined in the Copyright Act, R.S. 1985, c. C-42, from every author that contributes to any Foreground Information subject to copyright protection that is a deliverable to Canada under the Contract. If the Contractor

is an author of the Foreground Information, the Contractor permanently waives the Contractor's moral rights in that Foreground Information.

Dermal Absorption Testing of Existing and New Priority Chemicals under the Chemicals Management Plan

1. Scope

1.1. Title

Dermal Absorption Testing of Existing and New Priority Chemicals under the Chemicals Management Plan

1.2. Introduction

Health Canada is responsible for helping Canadians protect, maintain, and improve their health, while respecting individual choices and circumstances. To achieve this goal, Health Canada relies on high-quality scientific data as the basis for its work.

The Canadian Environmental Protection Act, 1999 (CEPA 1999) required the Ministers of the Environment and of Health to categorize all substances on the Domestic Substances List (DSL) that are persistent and/or bioaccumulative based on the Persistence and Bioaccumulation Regulations, are inherently toxic to humans or other organisms, or that present the greatest potential for human exposure in Canada. Substances found to meet the categorization criteria are subject to a screening assessment and, if determined to meet the criteria under section 64, may be subject to risk management measures. The Government of Canada completed this categorization exercise in 2006. Of the approximately 23,000 substances subject to categorization, about 4,300 were identified as priorities for further action. These substances became a focus for further work under Canada's Chemicals Management Plan (CMP), launched on December 8, 2006. The Ministers of the Environment and of Health have committed to addressing these substances by 2020, to ensure that chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment.

Of the 4,300 substances identified as priorities for further action, approximately 2,800 have been addressed in the first and second phases of the CMP. The Government of Canada is currently launching the third phase during which approximately 1,500 substances will be addressed.

As part of an initial screening of the substances to be addressed in the third phase of the CMP, the Existing Substances Risk Assessment Bureau (ESRAB) has determined that several of these substances (listed below) are present in personal-care products, cosmetics, paints, or household cleaning products and are potentially associated with high hazard. As well, the Consumer Product Safety Directorate (CPSD) has occasional need for data on dermal absorption which can be a main route of exposure to these substances. Often, data on chemical-specific dermal absorption are not available. Additional data would aid in refining certain assessments as well as enhancing the confidence of modelled dermal absorption predictions.

As the Healthy Environments and Consumer Safety Branch lacks the capacity to perform dermal absorption testing internally, Health Canada is seeking the services of a Contractor for the undertaking of laboratory studies to investigate the dermal absorption capabilities/potential of

prioritized chemical substances. The results of this study will support risk assessment activities under the CMP.

1.3 Objectives of the Requirement

The main objective of the requirement is to test the dermal absorption capabilities of identified priority substances in support of risk assessment activities under the CMP. The ultimate goal of the study is to generate data to derive dermal absorption rate for the specified chemicals. The study data and results provided by the Contractor will be evaluated by Health Canada for accuracy, appropriate quality assurance/quality control (QA/QC) measurements employed, and reporting standards.

1.4 Background and Specific Scope of the Requirement

The Government of Canada has committed to the safe management of chemical substances through its CMP, a three-phased initiative which provides a triaged approach to chemical management. Categorization of the Domestic Substances List (DSL) was completed in 2006, and 4,300 substances were identified for further evaluation under the CMP. With CMP Phases 1 and 2 complete, risk assessments of some 2,800 chemicals have been completed and risk management and ongoing monitoring strategies initiated. Yet much work remains if Canada is to fulfil the commitments it made to complete the assessment of all CMP priority chemicals by 2020. This work will support Health Canada's assessment of the potential human health effects and exposure of the specified chemical substances under the Canadian Environmental Protection Act (CEPA) 1999.

For those substances which are selected as priorities for testing by ESRAB, the data generated from the dermal absorption studies will be used by evaluators in the screening assessments generated under the third phase of the CMP. For example, the data may be used in a case where reliable empirical data on dermal absorption of a substance do not exist and the toxicological profile of that substance is mainly based on studies describing effects on animals dosed via the oral route. This data will be needed upon commencement of the drafting phase of the screening assessment, which is roughly estimated to be between Spring 2016 and Winter 2018. These timelines will be refined and confirmed as ESRAB finalizes the workplan and priority setting for CMP-3.

The Contractor shall conduct dermal absorption testing of chemicals and provide the results to the Scientific and Technical Authority at Health Canada. The timing will be subject to the specific requirements of the project, as determined exclusively by Health Canada.

In each report the Contractor will provide evidence that the method used has been validated and that the data are supported by appropriate quality assurance procedures.

The contractor will be required to complete dermal absorption testing of chemical substances 1 to 4 (see list below) by March 2017. In option year one, Health Canada will require dermal

absorption testing of chemical substances 5 and 6 to be completed by approximately December 2018.

1. Benzenesulfonic acid, dodecyl-, compd. with 2-propanamine (1:1) - (CAS#26264-05-1)
2. Acetic acid, propyl ester - (CAS#109-60-4)
3. 2-Ethyl-1-hexanol - (CAS#104-76-7)
4. N,N-Dimethylhexadecylamine - (CAS RN 112-69-6)
5. Trixylenyl phosphate - (CAS RN 25155-23-1)
6. Isopropylated triphenyl phosphate - (CAS RN 68937-41-7)

Ethical and Privacy Considerations

The dermal absorption experiments to be conducted in this project will make use of human skin tissue samples. The use of these samples will have prior approval of Health Canada's Research Ethics Board. However, the project itself will not collect or generate any personal data or identifying information relating to the human skin samples. Accordingly, there are no confidentiality or privacy issues or concerns.

See also sections 1.2 and 1.3 for related information on the background and scope of the Requirement.

2. Requirements

2.1. Tasks, Activities, Deliverables and Milestones

Tasks or Activities:

The Contractor shall:

1. Assess the specified chemicals for their dermal absorption capabilities;
2. Evaluate the generated data for accuracy and quality assurance/quality control (QA/QC) standards, and
3. Prepare a draft project report including the detailed methodology, validation standards, QA/QC standards applied and the results. The report should be finalized after consulting with the Scientific and Technical Authority at Health Canada. In the event of unforeseen methodological problems or delays in carrying out the work, the Contractor will provide a progress report and modified dates for completion of the work. Please refer to section 2.6 for more details on any changes in the scope of work.

Specifically:

At the beginning of the project, the Contractor shall provide Health Canada with information on the analyses to be conducted - i.e., its standard operating protocols for analysis, including instruments, a method description, certified or standard reference materials with a clear indication when adjusted, limits of detection for each analysis, precision of the transmitted results. In addition, the documents (a letter) concerning Research Ethics Board approval obtained to use Human skin tissue samples should be submitted to Health Canada.

The Contractor shall conduct dermal absorption studies of the above mentioned (6) chemicals prioritized by ESRAB for dermal absorption testing and assessment in accordance with Organization for Economic Cooperation and Development (OECD) test guideline 428 and SCCS 2010.

It has been verified that all chemicals specified are easily available and will be procured by the Contractor. The Contractor shall verify the chemical identity and purity of the test substance and its specific activity.

The Contractor shall be responsible for procuring the radio-labelled chemicals from its own suppliers. Radio-labelling of the chemicals is preferred to avoid method-sensitivity issues and to offset the cost of conducting dermal absorption studies using a non-labelled chemical. For those chemicals, where radiolabelling is not possible due to the instability of radiolabelled chemicals or substances lacking carbon, non-labelled chemicals will be tested. The exact methodologies and strategies for testing non-radiolabelled chemicals will be decided by Health Canada in consultation with the contractor.

The Contractor shall perform dermal absorption testing, including chemical and/or radiological analysis of the receiver solution samples, the skin, and the tape strip, and send the results to Health Canada within the timeline specified in the contract; the Contractor shall continue to do so for the duration of the contract.

Dermal Absorption Testing of Priority Substances:

- 1) The contractor shall conduct the entire study including preparation of study reports in accordance with OECD TG 428 and principles of Good Laboratory Practice (GLP).
- 2) Prior to conducting the study, the contractor should demonstrate adequate solubility in receptor fluid, and ability to quantify the unabsorbed volatilised dose where necessary such as in the case of volatile substances. The Contractor shall conduct dermal absorption (in vitro) studies to assess the percutaneous absorption of the specified chemical substances through human skin (fresh or frozen) in accordance with OECD Test Guideline 428 and SCCS 2010, as directed by Health Canada. Viable barrier-integrity-assessed, split-thickness human skin using eight (8) evaluable samples originating from one (1) to four (4) donors (SCCS 2010) will be mounted in flow-through diffusion cells. Absorption will be assessed over a period of 72 hours, with receptor fluid fractions collected hourly from 0 to 6 hours and at regular intervals (e.g., every 2 hours) from 6 hours onwards.
- 3) At 24 to 72 hours post-dose terminal procedures including full mass balance will be conducted in accordance with OECD Test Guideline 428 and SCCS 2010 (terminal post-exposure time point may vary depending on substance and formulation). This will include but not limited to the following: the cells will be dismantled, the skin dried, the stratum corneum removed by tape stripping, and the unexposed skin (skin under the cell flange) cut away from the exposed skin. Depending on whether substances are radio-labelled or non-radio-labelled, appropriate analytical methods (e.g., liquid scintillation counting, high performance liquid chromatography (HPLC) or gas chromatography (GC) should be

- used for quantitation in fractionated skin and receptor fluid. The validity, sensitivity, and detection limits of the method should be clearly documented in the project report.
- 4) The Contractor shall apply quality assurance/quality control (QA/QC) measures to the test results and summarize these results in Microsoft Excel format.
 - 5) The Contractor shall prepare and submit periodic status/progress reports during the course of the contract.
 - 6) The Contractor shall prepare and submit draft and final project reports that include information on the chemical substances tested in the dermal absorption studies - including details on vehicle, formulation, and concentration - the type of skin used (part of the body from where the skin tissue was obtained), the laboratory methods employed, the results of the data analyses and other specifications as outlined in OECD Test Guideline 428 and SCCS 2010. The Contractor shall submit the draft and final project reports to Health Canada via secured electronic data transfer in in Microsoft Word format. Where appropriate, quantitative data should be presented in Microsoft Excel format.

Milestones and Deliverables:

The Contractor shall submit to the Scientific and Technical Authority any or all deliverables as specified in this contract. The deliverables may include, but are not necessarily limited to, a description of the laboratory method(s), analytical study results, periodic debriefings, progress or status reports, and documented QA/QC results. Deliverables shall be provided in the format described above.

Milestones	Timeline by Fiscal Year
1. Provide Health Canada the required documents to obtain Health Canada Research Ethics Board approval to use human skin tissue samples.	July/August 2016
2. Provide Health Canada with information on the details of the analyses to be conducted - i.e., standard operating procedures, instruments used, method description, reference materials used, limits of detection for each analysis, the participation schedule of inter-laboratory proficiency testing programs for each measurement and the QA/QC applied.	July/August 2016
3. Procurement of radioinert and radiolabelled chemicals where necessary for chemicals 1 to 4, see section 1.4., and completion of assessment of chemicals for their dermal absorption potential/capabilities.	Dec 2016
4. Completion of evaluation of the data for accuracy and adherence to QA/QC standards.	Jan 2017
5. Completion of analysis and interpretation of the study results and preparation of draft report.	Feb 2017
6. Completion of final report.	Mar 2017

Milestones for option years	Timeline by Fiscal Year
Option year 1 1. Provide Health Canada with information on the details of the analyses to be conducted - i.e., standard operating procedures, instruments used, method description, reference materials used, limits of detection for each analysis, the participation schedule of inter-laboratory proficiency testing programs for each measurement and the QA/QC applied 2. Procurement of radioinert and radiolabelled (if possible) chemicals for chemicals 5-6, see section 1.4. 3. Completion of assessment of chemicals for their dermal absorption potential/capabilities. 4. Completion of evaluation of the data for accuracy and adherence to QA/QC standards. 5. Completion of analysis and interpretation of the study results and preparation of draft report. 6. Completion of final report.	April 2017 June 2017 Sept 2017 Oct 2017 Nov 2017 Dec 2017

Refer also to Section 4.2 for related details on deliverables.

2.2. Specifications and Standards

QA/QC measures must be implemented and documented. QA/QC measures should meet the requirements stated in OECD TG 428 and SCCS 2010. Quality controls appropriate for the analytical method and the parameters to be analyzed may include:

1. Laboratory blanks, certified reference materials and commercial control samples (if available), depending on the analyte in question;
2. Conduct the appropriate duplicate sample testing as required to estimate precision;
3. Multipoint calibration performed with each batch of samples;
4. Method Detection Limit as per call-up;
5. Results of most recent proficiency tests (including inter-laboratory comparisons studies) specific to each analyte being tested.
6. Provide analytical method documentation and QA/QC results.

Refer also to Section 2.4 relating to specifications on how the work is to be delivered and measured as completed. See also the deliverables outlined above.

2.3. Technical, Operational and Organizational Environment

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

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

2.4. Method and Source of Acceptance

The Scientific and Technical Authority at Health Canada 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 10 working days whether a specific deliverable has been accepted, and will identify any required changes to the deliverable. The Contractor will have 10 working days to revise the deliverable unless both parties agree to an alternative deadline. At that point, the Scientific and Technical Authority at Health Canada will re-review the deliverable and determine if it is acceptable or requires revision (at no cost to Health Canada).

2.5. Reporting Requirements

The Contractor shall deliver the services using the methods agreed upon, in the format requested, and within the timelines established in this contract. The Contractor shall submit one (1) electronic copy of each deliverable (i.e., draft project reports, and final reports) to the Scientific and Technical Authority. The Contractor shall submit periodic progress/status reports, with each report outlining the accomplishments for the given period, any open issues, and upcoming milestones. Refer to Section 2.1 for associated details on reporting requirements.

2.6. Project Management Control Procedures

The 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. Any changes in Scope identified by the Contractor will need to be presented in writing for consideration and agreement by the Scientific and Technical Authority. In identifying a suggested change in the Scope or any element of the Statement of Work, the Contractor will need to identify why it is recommending the change, the estimated cost of the change, the impact on the resources of the Contractor and the Crown, and the impact on the time line for the work. The Scientific and Technical Authority will indicate within five (5) working days if it wishes to approve the change. At that point a formal proposal will be received from the Contractor for review and acceptance by Health Canada and the contract will be amended accordingly.

The Contractor shall ensure that all deployed personnel are qualified and trained to fulfil their responsibilities in the conduct and management of this project. In addition, the Contractor shall ensure that all its assigned personnel are operating at all times in accordance with all applicable legislation, regulations, and codes as well as requirements specified by the Research Ethics Board.

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

2.7 Change Management Procedures

Any changes to the statement of work will be upon mutual agreement and in the form of a written contract amendment.

2.8 Ownership of Intellectual Property

“Intellectual Property” (IP) includes patents, copyright, industrial design, integrated circuit design, topography, plant breeders’ rights, or any rights subject to protection under the law as trade secrets and confidential information. Current Treasury Board “Policy on Title to Intellectual Property Arising Under Crown Procurement Contracts” states that IP ownership developed under government contracts will remain with the Contractor.

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

3.1 Authorities

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

To be announced at time of contract award.

Scientific and Technical Authority The Scientific and Technical Authority (or delegated representative) is responsible for all matters concerning the scientific/technical content of the work under the contract. Any proposed changes to the scope of the work are to be discussed with the Scientific and Technical Authority, but any resulting changes can only be confirmed by a Contract Amendment issued by the aforementioned Departmental Representative.

To be announced at time of contract award.

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

To be announced at time of contract award.

3.2 Health Canada’s Obligations

Health Canada shall:

- a) Health Canada’s representatives will establish a clear statement of tasks, activities, deliverables and milestones.
- b) Health Canada’s representatives will communicate with the contractor as required to review the testing protocol, verify details for completeness and to assess progress.

- c) Provide guidance on how to report study results, including the early results reporting protocol (if applicable)
- d) Provide comments on draft reports and final reports to the Contractor within ten (10) working days.

3.3 Contractor's Obligations

- a) The Contractor shall be responsible for the purchase of chemical substances in their radioinert and radiolabelled format as required, laboratory supplies required for the performance of the work outlined in this contract.
- b) Unless otherwise specified, the Contractor shall supply its own equipment and software for the performance of the work.
- c) The Contractor shall provide the services described in this contract in accordance with the specific delivery requirements described herein, which may include sample reception (under certain time and temperature conditions), sample preparation, and special sample and data destruction procedures.
- d) The Contractor shall provide all the personnel required for carrying out the work outlined in this contract, and shall conduct its activities in accordance with the current occupational health and safety guidelines applicable in its laboratory.
- e) The Contractor shall store the study samples until final approval of the results by Health Canada.
- f) The use of human skin must have prior approval of the appropriate research ethics board, and must specifically include approval from Health Canada's Research Ethics Board.

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

3.4 Location of Work, Work Site and Delivery Point

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

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

3.5 Language of Work

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

3.6 Special Requirements and Security Requirements

The bidder is required to be GLP compliant as recognized by the respective national GLP compliance monitoring authority. The contractor is required to have appropriate licenses, permits, protocols and approvals in place for the handling of radiolabelled substances and the conduct of dermal testing in human skin. The contractor must have experience with the relevant test guidelines published by the OECD and/or any other documents outlining guidance on the conduct of dermal testing: the OECD Test Guidelines 428 and SCCS 2010.

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

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

3.7 Use, Storage and Retention of Information

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

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

3.8 Insurance Requirements

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

3.9 Travel and Living

Not applicable.

4. Project Schedule

4.1 Expected Start and Completion Dates

The services of the Contractor will be required for a period of approximately eight (8) months commencing on or about the 18th of July 2016, with the option of renewal for one (1) year (fiscal year 2017-18) to be exercised at Health Canada's discretion. The expected completion

date of this project is the 31st of March, 2017. Should the option year be exercised, the expected completion date for the option year is the 31st of March, 2018.

4.2 Schedule and Estimated Level of Effort (Work Breakdown Structure) Time Schedule for Completion of Each Milestone

Refer to Milestone Table in section 2.1

5. Required Resources or Types of Roles to be Performed

- 5.1 The Contractor shall provide sufficient resources to complete the tasks, activities, and milestones identified in section 2.1. The work outlined requires the services of a team of skilled research professionals who possess the specific expertise needed to carry out the work. Additionally, to complete this work, the Contractor must have:
- a) The bidder is required to be GLP compliant as recognized by the respective national GLP compliance monitoring authority;
 - b) Analytical laboratory equipment to conduct dermal absorption experiments;
 - c) A comprehensive quality assurance (QA) program and a designated quality assurance officer;;
 - d) Analytical staff with training, experience, and expertise in conducting dermal absorption studies and analyses using the appropriate/approved analytical methods;
 - e) Demonstrated experience in conducting dermal testing in accordance with OECD Guidelines;
 - f) Expertise necessary to communicate dermal absorption data for environmental chemicals.;

6. Applicable Documents and Glossary

6.1. Applicable Documents

For more details on the Government of Canada's Chemicals Management Plan please consult <http://chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>

6.2. Relevant Terms, Acronyms and Glossaries

CEPA:	Canadian Environmental Protection Act
CMP:	Chemicals Management Plan
DSL:	Domestic Substance List
ESRAB:	Existing Substances Risk Assessment Bureau
HC:	Health Canada
GLP:	Good Laboratory Practice
OECD:	Organization for Economic Co-operation and Development
QA:	Quality Assurance
QC:	Quality Control
RFP:	Request for Proposal

SCCS: Scientific Committee on Consumer Safety

ANNEX B – BASIS OF PAYMENT

1. BASIS OF PAYMENT

- 1.1.** Canada will pay the Contractor for the satisfactory performance of the agreed to services an all-inclusive firm lot price of \$_____”, inclusive of all expenses, customs and duties, and applicable taxes.
- 1.2.** All prices and amounts of money in the Contract are exclusive of the Goods and Services Tax (GST) or Harmonized Sales Tax (HST), whichever is applicable, unless otherwise indicated. GST or HST, to the extent applicable, will be incorporated into all invoices and progress claims for goods supplied or work performed and will be paid by Canada. The Contractor agrees to remit to Canada Revenue Agency any GST or HST paid or due.
- 1.3.** No increase in the total liability of Canada or in the price of Work resulting from any design changes, modifications or interpretations of specifications made by the Contractor will be authorized or paid to the Contractor unless such changes, modifications or interpretations have been approved in writing by the Contracting Authority prior to their incorporation into the Work. The Contractor is not obliged to perform any Work or provide any service that would cause the total liability of Canada to be exceeded without the prior written approval of the Contracting Authority. The Contractor will notify the Project Authority in writing as to the adequacy of this sum:
- a. when it is seventy five percent (75%) committed, or
 - b. four (4) months prior to the Contract expiry date, or
 - c. if the Contractor considers the funds provided to be inadequate for the completion of the Work, whichever comes first.

In the event that the notification refers to inadequate funds, the Contractor will provide to the Project Authority, in writing, an estimate for the additional funds required. Provision of such notification and estimate for the additional fund does not increase the liability of Canada.

2. PRICE BREAKDOWN

2.1. PROFESSIONAL SERVICES

For professional services, the Contractor will be paid an all-inclusive lump sum amount based on the following table. These rates include overhead and profit but do not include GST and HST.

Labour resources	Per diem (CAD \$)	Level of effort (number of days)	Total price (CAD \$)

Resource #1 (name, labour category)			\$_____
Resource #2 (name, labour category)			\$_____
Resource #3 (name, labour category)			\$_____
Other resources (name, labour category)			\$_____
Other expenses			\$_____
Subtotal (excluding GST/HST)			\$_____
Estimated applicable taxes			\$_____
TOTAL			\$_____

2.2. Travel and Living Expenses

Not applicable.

2.3. Miscellaneous expenses (*if applicable*)

ANNEX C – SECURITY REQUIREMENTS

THERE IS NO SECURITY REQUIREMENT