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Gatineau, Québec K1A 0S5

Bid Fax: (819) 997-9776

SOLICITATION AMENDMENT MODIFICATION DE L'INVITATION

The referenced document is hereby revised; unless otherwise
indicated, all other terms and conditions of the Solicitation
remain the same.

Ce document est par la présente révisé; sauf indication contraire,
les modalités de l'invitation demeurent les mêmes.

Comments - Commentaires

Vendor/Firm Name and Address

Raison sociale et adresse du
fournisseur/de l'entrepreneur

Issuing Office - Bureau de distribution

Training and Specialized Services Division/Division de
la formation et des services spécialisés
Terrasses de la Chaudière 5th Floor
Terrasses de la Chaudière 5e étage
10 Wellington Street,
10, rue Wellington,
Gatineau
Québec
K1A 0S5

Title - Sujet Chemical Residue Testing Food Prod	
Solicitation No. - N° de l'invitation 39903-200178/E	Amendment No. - N° modif. 008
Client Reference No. - N° de référence du client 39903-200178	Date 2021-07-08
GETS Reference No. - N° de référence de SEAG PW-\$\$ZH-163-39367	
File No. - N° de dossier 163zh.39903-200178	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM Eastern Daylight Saving Time EDT on - le 2021-09-15 Heure Avancée de l'Est HAE	
F.O.B. - F.A.B. Specified Herein - Précisé dans les présentes Plant-Usine: <input type="checkbox"/> Destination: <input type="checkbox"/> Other-Autre: <input checked="" type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: MacNeil, Blaine	Buyer Id - Id de l'acheteur 163zh
Telephone No. - N° de téléphone (902) 403-3918 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction:	

Instructions: See Herein

Instructions: Voir aux présentes

Delivery Required - Livraison exigée	Delivery Offered - Livraison proposée
Vendor/Firm Name and Address Raison sociale et adresse du fournisseur/de l'entrepreneur	
Telephone No. - N° de téléphone Facsimile No. - N° de télécopieur	
Name and title of person authorized to sign on behalf of Vendor/Firm (type or print) Nom et titre de la personne autorisée à signer au nom du fournisseur/ de l'entrepreneur (taper ou écrire en caractères d'imprimerie)	
Signature	Date

Amendment 008

Please see the following questions and responses, and changes to the tender documents:

Questions 1-7 pertain to the analysis of dioxins (PCDD/F) and PCBs.

Q1. As the reference lab, does CFIA have a validated GC-MS/MS method for dioxin and PCBs?

A1. No

Q2. Why are you allowing the use of GC-MS/MS for dioxins and PCBs when there are no labs accredited by SCC or CALA for such a test?

A2. Only tests that are accredited by SCC or CALA will be acceptable as defined in the Statement of Work and MT3 in Attachment 1 to Part 4

Q3. Why are the method requirements different between the two programs (NCRMP and FSAP)?

A3. The two Programs (Dioxins/PCBS and Dioxin and Dioxin-like Congeners) have a different scope of analytes and different uses of the data.

Q4. Appendix 4A to Annex A states “the sensitivity and scope of the method SOP provided must meet and surpass the criteria detailed in the above table.” How do you evaluate detection limits for dioxins and PCBs on GC-MS/MS? Are they based on the lowest calibration standard as required in EU? EPA 1613b indicates that a sample detection limit is represented by a peak giving a signal/noise of 2.5x background noise. You cannot use this for MS/MS. The MS/MS on the market today do not have or have very little electronic noise, therefore S/N is useless. Your detection limit is only as good as your lowest calibration standard – called an Estimated Quantitation Limit (EQL). The Europeans have been clear that for MS/MS work, the EQL is used for the detection limit. For a 10 g sample taken to a final volume of 20 µL, using a CS-Lo standard of 0.1/0.5/1.0 pg/µL, the resulting EQL is 0.2 pg/g for TCDD/F (2 pg/g for OCDD/F and 1 pg/g for the rest). And for a sample with a 50% recovery of ¹³C-TCDD, the EQL would double!

A4. Evaluation of the detections limits is done during validation and accreditation by each laboratory. The established detection limits are additionally evaluated by the accrediting body. The evaluation of the method detection limits and applicability of the method for the scope of the requirement should be done in advance of bid submission. CFIA will review values provided in methods submitted and CFIA evaluation is based on the values submitted in the bid. Ongoing review and examinations of method performance will occur during client audits and contract evaluations as described in SOW

Q5. The EU has regulations on the “methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs” (Commission Regulation (EU) 2017/644 of 5 April 2017). Annex III lists for GC-HRMS and GC-MS/MS as acceptable for confirming compliance. Section 6.5 lists specific criteria for confirmatory methods. It is the last point that is most relevant. “Fulfilment of the further criteria as described in internationally recognized standards, for example, in standard EN 16215:2012 (Animal feed – Determination of dioxins and dioxin-like PCBs by GC/HRMS and of indicator PCBs by GC/HRMS) and/or in EPA methods 1613 and 1668 as revised, except the obligation to use GC-HRMS.” If GC-MS/MS is allowed for this contract, will you be following the guidance in these regulations?

A5. Yes

DELETE:

B12	Dioxin and Dioxin-Like Congeners	None Provided	For GC-HRMS; the resolution shall typically be greater than or equal to 10 000 for the entire mass range at 10 % valley. For GC-MS/MS: Monitoring of at least two specific precursor ions, each with one specific corresponding transition product ion for all labelled and unlabelled analytes in the scope of analysis. Maximum permitted tolerance of relative ion intensities of $\pm 15\%$ for selected transition product ions in comparison to calculated or measured values (average from calibration standards), applying identical MS/MS conditions, in particular collision energy and collision gas pressure, for each transition of an analyte.	Gas-chromatographic separation of isomers shall be sufficient (< 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF)	Dairy Egg Meat Processed Products	See Appendix 4d to Annex A	See Appendix 4a, 4b to Annex A	Confirmation using an acceptable MS technique is required. See Tasks/Technical Specifications	90	All Analytes are to be reported in (units) using the MS Excel template provided in ng/kg as illustrated in Appendix 4d to Annex A
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INSERT

B12	Dioxin and Dioxin-Like Congeners	None Provided	For GC-HRMS; the resolution shall typically be greater than or equal to 10 000 for the entire mass range at 10 % valley. For GC-MS/MS: Monitoring of at least two specific precursor ions, each with one specific corresponding transition product ion for all labelled and unlabelled analytes in the scope of analysis. Maximum permitted tolerance of relative ion intensities of $\pm 15\%$ for selected transition product ions in comparison to calculated or measured values (average from calibration standards), applying identical MS/MS conditions, in particular collision energy and collision gas pressure, for each transition of an analyte.	Gas-chromatography separation of isomers shall be sufficient (< 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF)	Dairy Egg Meat Processed Products	See Appendix 4d to Annex A	See Appendix 4a, 4b to Annex A	Confirmation using an acceptable MS technique is required. Confirmation shall adhere to the guidelines in Annex III of Commission Regulation (EU) 2017/644 of 5 April 2017	90	All Analytes are to be reported in (units) using the MS Excel template provided in ng/kg as illustrated in Appendix 4d to Annex A
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Q6. A recent government solicitation (5000056811) has a requirement to prove three years' worth of verifiable practical experience with the methods. Why does that not apply here?

A6. CFIA has an ongoing need for emerging hazards, such a requirement would have to be applied to all methods in the requirement not just this one, this would limit the ability of CFIA to move into those area. In the solicitation cited, it is not clear that the actual test method must be accredited, only the testing facility. CFIA has agreements with both accrediting bodies to provide technical assessors for the accreditation process and with the complex nature of this solicitation, 59 separate tests to evaluate versus a single one, and CFIA leverages that technical review process.

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Q7. Why are methods being changed from previous contracts – especially when there is no failure in the current methods?

A7. CFIA is evolving with the available technology and current practices globally

Q8. Amendment #5, Answer 2 – indicates updates to reference methods for the Sulfonamides program, addressing the required compounds and required LOQ/MDL. However, the compound lists in the updated reference methods (from ACC-056 to CVDR-M-3031 and CVDR-M-3039) do not match “Appendix 1 to Annex A” nor “Attachment 1 to Part 4 – Technical Criteria”. Which compound list is correct?

A8. The compound list in Appendix 1 to Annex A is correct. The table has been updated to clarify the LOQ/MDLs for the compounds.

DELETE

A14	Sulfonamides	<p>CFIA Saskatoon CVDR-M-3031.11 (Dairy, Egg)</p> <p>CFIA Saskatoon CVDR-M-3039.01 (Honey)</p>	<p>Sample, containing protein (egg and dairy), are cleaned up by protein precipitation, extraction with acetonitrile followed by SPE clean-up. Samples high in sugars are extracted with dilute acid and allowed to stand overnight to free sulfa drugs from sugar complexes. Instrumental analysis is by LC/MSD.</p>	<p>The SOP for the honey food group must include a step for extraction with dilute acid and standing overnight in order to free sulfa drugs from sugar complexes.</p>	<p>Dairy Egg Honey</p>	<p>Sulfabenzamide, Sulfacetamide, Sulfachloropyridazine Sulfadiazine Sulfadimethoxine Sulfadoxine Sulfaethoxypyridazine, Sulfaguanidine Sulfamerazine Sulfamer Sulfamethazine Sulfamethizole Sulfamethoxazole Sulfamethoxypyridazine Sulfamonomethoxine Sulfamoxole Sulfanilamide Sulfaphenazole Sulfapyridine Sulfaquinolaline Sulfathiazole Sulfisoxazole Dapsone Ormetoprim Trimethoprim</p>	<p>See Appendix A of the reference method</p>	<p>See Appendix A of the reference method</p>	<p>Confirmation using an acceptable MS technique is required. See Tasks/Technical Specifications</p>	<p>60</p>	<p>The "ANALYTE" is to be reported as "Sulfa Screen" and the "AMOUNT" is to be "0" for a negative and a "1" for a positive for one or more of the analytes. In the event of a positive, the analyte(s) found to be positive is/are to be reported as a separate entry and the amount as the actual value confirmed, in mg/kg.</p>
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A14	Sulfonamides	<p>CFIA Saskatoon CVDR-M- 3031.11 (Dairy, Egg)</p> <p>CFIA Saskatoon CVDR-M- 3039.01 (Honey)</p>	<p>Sample, containing protein (egg and dairy), are cleaned up by protein precipitation, extraction with acetonitrile followed by SPE clean-up. Samples high in sugars are extracted with dilute acid and allowed to stand overnight to free sulfa drugs from sugar complexes. Instrumental analysis is by LC/MSD.</p>	<p>The SOP for the honey food group must include a step for extraction with dilute acid and standing overnight in order to free sulfa drugs from sugar complexes.</p>	<p>Dairy Egg Honey</p>	Sulfabenzamide	0.005	0.01	<p>Confirmati on using an acceptabl e MS technique is required. See Tasks/Tec hnical Specificati ons</p>	60	<p>The "ANALYTE" is to be reported as "Sulfa Screen" and the "AMOUNT" is to be "0" for a negative and a "1" for a positive for one or more of the analytes. In the event of a positive, the analyte(s) found to be positive is/are to be reported as a separate entry and the amount as the actual value confirmed, in mg/kg.</p>
						Sulfacetamide	0.01	0.015			
						Sulfachloropyridazine	0.005	0.01			
						Sulfadiazine	0.005	0.01			
						Sulfadimethoxine	0.005	0.01			
						Sulfadoxine	0.005	0.01			
						Sulfaethoxyypyridazine	0.005	0.01			
						Sulfaguanidine	0.01	0.015			
						Sulfamerazine	0.005	0.01			
						Sulfamer	0.005	0.01			
						Sulfamethazine	0.005	0.01			
						Sulfamethizole	0.005	0.01			
						Sulfamethoxazole	0.005	0.01			
						Sulfamethoxyypyridazine	0.005	0.01			
						Sulfamonomethoxine	0.005	0.01			
						Sulfamoxole	0.01	0.015			
						Sulfanilamide	0.015	0.03			
						Sulfaphenazole	0.005	0.01			
						Sulfapyridine	0.005	0.01			
						Sulfaquinoxaline	0.005	0.01			

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				Sulfathiazole	0.005	0.01			
				Sulfisoxazole	0.005	0.01			
				Dapsone	0.005	0.01			
				Ormetoprim	0.005	0.01			
				Trimethoprim	0.01	0.015			

In Attachment 1 to Part 4

DELETE

A14	SULFONAMIDES	Dairy Egg Honey	Sulfabenzamide Sulfacetamide Sulfachloropyridazine Sulfadiazine Sulfadimethoxine Sulfadoxine Sulfathioxypridine Sulfaguanidine Sulfamerazine Sulfamer Sulfamethazine Sulfamethizole Sulfamethoxazole Sulfamethoxypridine Sulfamonomethoxine Sulfamoxole Sulfanilamide Sulfaphenazole Sulfapyridine Sulfaquinolone Sulfathiazole Sulfisoxazole Dapsone Ormetoprim trimethoprim	The scope of the analytical method and SOP must cover the sulfa drugs listed in APPENDIX A of the reference method at or below the detection limit (DL) indicated to be counted. Sulfa drugs not listed but deemed to be of value by the evaluation committee will be accepted towards the total analytes submitted Unable to assess Methods that do not meet the DL and LOQ requirements listed for at least 20 analytes DL and LOQ is equal to or lower than those listed for 20 to 21 of the listed analytes DL and LOQ is equal to or lower than those listed for 22 - 23 of the listed analytes DL and LOQ is equal to or lower than those listed for 24 of the listed analytes DL and LOQ is equal to or lower than those listed for all 25 of the listed analytes	0 2 3 4 5	5	2	
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INSERT:

A14	SULFONAMIDES	Dairy Egg Honey	Sulfabenzamide Sulfacetamide Sulfachloropyridazine Sulfadiazine Sulfadimethoxine Sulfadoxine Sulfathoxypyridazine Sulfaguanidine Sulfamerazine Sulfamer Sulfamethazine Sulfamethizole Sulfamethoxazole Sulfamethoxypyridazine Sulfamonomethoxine Sulfamoxole Sulfanilamide Sulfaphenazole Sulfapyridine Sulfaquinolaxaline Sulfathiazole Sulfisoxazole Dapsone Ormetoprim trimethoprim	Sulfa drugs not listed but deemed to be of value by the evaluation committee will be accepted towards the total analytes submitted	0	2	3	4	5	5	2	
				Unable to assess								
				Methods that do not meet the DL and LOQ requirements listed for at least 20 analytes								
				DL and LOQ is equal to or lower than those listed for 20 to 21 analytes								
				DL and LOQ is equal to or lower than those listed for 22 - analytes								
				DL and LOQ is equal to or lower than those listed for 24 analytes								
				DL and LOQ is equal to or lower than those listed for 25 + analytes								

Q9. Can you please clarify if each company need only submit one response for all of the testing? Or does each laboratory location need to submit one response for the tests conducted within that laboratory?

A9. One company can submit a combined response, if so desired. The response must clearly indicate which tests apply to each location.

Please see the revised Attachment 10 v3 (separately attached)

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As a reminder (Amendment 002), please contact cfia.labcoordination-coordinationdeslaboratoires.acia@canada.ca to obtain copies of the official methods. Note that USDA methods can be obtained by the link provided, and are only available in the language of the official publication.

All other terms and conditions remain unchanged.