ANNEX A

STATEMENT OF WORK (SoW)

DRAFT

1. TITLE

Chemical Residue Testing in and on Food Products for Canadian Food Inspection Agency (CFIA)

2. DEFINITIONS AND TERMINOLOGY

Analytical Method	Method described by the Contractor in its Standard Operating Procedure (SOP) for a chemical residue of interest to CFIA.
Annual Sampling Plan	A detailed scheme (in MS Excel) outlining the analytical testing to be carried out on each sample by the designated laboratory.
CALA	Canadian Association for Laboratory Accreditation Inc.
Canadian Action Level	A maximum level of a Chemical Residue of Interest that is applied for administrative purposes in the absence of an MRL
CFIA	Canadian Food Inspection Agency
Chemical Residue of Interest to CFIA	Appendix 1 to this Annex lists chemical residues of interest to CFIA.
Commodity	Federally registered food commodities; specifically, Meat, Honey, Egg, Fresh Fruit and Vegetables, Processed Products, and Dairy products.
Food	As defined in the *Canadian Food and Drug Act*, “any article manufactured, sold or represented for use as a food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.”
LOD (Limit of Detection)	The lowest concentration of a chemical residue of interest that can be detected with reasonable certainty for a given analytical method in parts per million (µg/g), or otherwise noted.
LOQ (Limit of Quantitation)	The lowest concentration of a chemical residue of interest that can be determined quantitatively with suitable precision and accuracy for a given analytical method in parts per million (µg/g), or otherwise noted.
MRL	Maximum Residue Limit
NCRMP	National Chemical Residue Monitoring Program
Product Type	Description used by the Project Authority to describe a group of similar products, e.g. Spinach, Lamb, Cheese, etc.
Reference Method	An analytical method provided by the CFIA to which the Contractor’s method must be deemed equivalent.
SCC	Standards Council of Canada
SFCR	Safe Food for Canadians Regulations
SOP	The standard operating procedure for laboratory testing and handling of samples from sample reception to disposal, that the Contractor provided in its bid for a particular CFIA chemical residue of interest. Note that this term is used to describe the detailed analytical method and quality assurance criteria associated with the laboratory method.
SSF	Sample Submission Form
TEQ	Toxic Equivalents
Test Accreditation	The formal recognition by the SCC Program Specialty Area for Agriculture and Food Products (PSA-AFP) or CALA of the capability of a laboratory to perform a specific list of tests in specialty areas.
Trace Contaminant Analyses Group	Detection limits and where applicable, analytes, are listed in the Attachments to Appendix 1 to Annex A.
Turnaround Time (Analysis)	For each assigned test, the period from the receipt of the sample at the Contractor’s laboratory until the completion of the analysis, including confirmation if applicable, in calendar days.
Turnaround Time (Reporting)	For each assigned test, the period from the receipt of the sample at the Contractor’s laboratory until the result is reported to the Project Authority or designate, in calendar days.

3. OBJECTIVE

The objective is to provide the CFIA with testing services for chemical residue contaminants in or on Food on an “as and when required” basis, in accordance with the Chemical Residues of Interest to CFIA Requirements which are listed in Appendix 1 to this Annex.

4. BACKGROUND

The CFIA is a federal regulatory agency with a mandate to safeguard food, animals and plants to enhance the health and well-being of Canada’s people, environment and economy. One way the Agency achieves this is by the sampling and testing of food products through various chemical residue surveillance programs.

The chemical residue surveillance programs of the CFIA consist of several well-defined testing components. Refer to www.inspection.gc.ca/english/fssa/microchem/terme.shtml for details. The majority of residue testing falls under the following four components:

i. Monitoring Program – probes the food supply for potential contamination and is managed under the National Chemical Residue Monitoring Program (NCRMP);
ii. Targeted Surveys – special or pilot surveys focused on gathering information about the potential occurrence of hazards in specific commodity types and/or geographical areas;
iii. Directed Sampling – focuses on identified chemical contamination issues; and
iv. Compliance Sampling – seeks removal of food in violation of standards from the marketplace.

The CFIA requires analytical testing support for the monitoring program portion of the CFIA surveillance activities.

The National Chemical Residue Monitoring Program (NCRMP) of the CFIA has been in place since 1978. The program allows for continued consumer confidence in food safety by providing up to date information on residue levels in the food supply. The data collected is evaluated to determine both immediate and potentially long term risks to consumers. The identification of products in violation of Canadian standards allows the CFIA to undertake directed interventions and follow up inspections with producers to ensure compliance. Health Canada uses the data collected to establish new standards and monitor the appropriateness of those already in place.

The NCRMP consists of a statistically randomized sampling plan and schedule, the Annual Sampling Plan, which is developed by the CFIA Food Safety Science Services Division. Sampling and testing resources are allocated based on potential risk. As such, food items consumed in greater quantities by Canadians, those that are more contaminated or those contaminated with more toxic components are sampled and tested in the greatest quantities. Foods posing a lesser risk are sampled at a lower frequency and may not be included in the monitoring program every year. The sampling schedule identifies to CFIA inspection staff the time and place that a sample is to be taken as well as the accredited laboratory which is to receive and test the sample.

Data generated by the residue testing is crucial in establishing the safety of the food supply and provides the support for the continued acceptance of foods from Canada in the international marketplace. To this end, test results and testing plans are shared annually with responsible officials in other nations which accept Canadian exports. The NCRMP requires that both imported and domestic foods are tested and held to the same high standards for compliance.

The CFIA may be required to take regulatory action under any or all of the Acts it administers or enforces by virtue of section 11 of the *Canadian Food Inspection Agency Act*, or under any other applicable law, on the basis of any information received or obtained in the course of performing the Work under this Standing Offer.

The direct impact of testing on the health and safety of consumers, as well as international trade, makes it essential that Contractors strictly adhere to all quality assurance criteria.

5. APPLICABLE AND REFERENCE DOCUMENTS

The following documents complement and support the content of this SoW and will serve as a standard baseline for the duration of the Standing Offer (SO)

a) Standards Council of Canada (SCC) http://www.scc.ca/en/about-scc/publications/criteria-and-procedures

b) the Canadian Association for Laboratory Accreditation (CALA) http://www.cala.ca/accred_program.html

c) Canadian Maximum Residue Limits (MRL) for Chemical Contaminants. https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants.html

d) Maximum Residue Limits for Pesticides https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/pesticides-food/maximum-residue-limits-pesticides.html

e) "Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results" http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002D0657

f) AOAC PT Program https://www.aoac.org/aoac_prod_imis/AOAC/AOAC_Member/LPTP/PT_M.aspx

g) Inter-laboratory Comparison on Dioxins in Food organised by the Department of Exposure and Risk Assessment, Norwegian Institute of Public Health, Oslo, Norway. http://www.fhi.no.

6. SCOPE

The Contractor must provide the following services, on an “as and when required” basis:

6.1. Analytical Testing

6.1.1. Analytical testing services must be performed in a laboratory located in Canada and accredited under the Standards Council of Canada (SCC) under the Program Specialty Area for Agriculture and Food Products (PSA-AFP) or the Canadian Association for Laboratory Accreditation (CALA).

6.1.2. The Contractor must provide analytical testing services in accordance with analytical methods and Standard Operating Procedures (SOP) that have been accredited by the SCC in the Program Specialty Area for Agriculture and Food Products, or accredited by CALA for food testing.

6.1.3. The Contractor must maintain current Standard Operating Procedures (SOP) for all analytical areas of testing covered by the Standing Offer. The analytical methodology used in the testing services provided by the Contractor must be as described in the Contractor’s SOP(s). In turn, the Contractor’s SOP(s) must be based upon, but need not be identical to, the Reference Methods provided by the Project Authority or designate. The Reference Methods are cited by name in Appendix I to Annex A. Specific Reference Methods are not provided by the CFIA when:

- The test is “off the shelf” as part of a manufacturer’s kit; or
- The test is widely available in scientific literature and many approaches will be acceptable (i.e. metals and elements); or
- The test requires such sensitivity that the Contractor must have flexibility to broadly tailor the approach in order to achieve the required detection limits (i.e. Benzopyrene and other PAH by MS detection, Dioxin TEQ in fatty foods, and trace PCB in fatty foods).

6.1.4. The Contractor must perform analytical testing services on food in accordance with the Annual Sampling Plan established by the CFIA under its NCRMP.

6.2. Turnaround Time

The required laboratory "turnaround time" must be no more than that indicated in Appendix 1 to Annex A. The laboratory ‘turnaround time’ is the period from the receipt of the sample at the Contractor’s laboratory until the completion of all tests assigned to the sample, in calendar days. There is an additional period of time allowed to provide the CFIA with the reported results.

6.3. Notification

The Project Authority or designate must be notified via email within 24 hours of being confirmed of sample results which exceed the Canadian MRL (where one exists). In cases where no Canadian MRL exists, the Project Authority or designate must be notified via email within 24 hours of being confirmed of sample results which meet the following criteria:

- Pesticides: All results that are greater than 0.08 µg/g.
- Veterinary Drugs: All results that are above the stated LOQ of the Laboratory SOP.
- Banned Substances: All positive/detected results.

6.4. Sample Retention and Disposal

After all of the required testing on a specific sample is completed and reported, the Contractor's laboratory must continue to hold any remaining sample material under appropriate conditions to prevent spoilage, for an additional 90 calendar days from the date all required test(s) is(are) reported. After 90 calendar days, if no additional action has been requested by the Project Authority or designate, the remaining sample portions may be disposed by the Contractor at the Contractor's expense in accordance with the applicable federal, provincial and municipal laws and regulations.

7. TASKS/TECHNICAL SPECIFICATIONS

The Contractor is responsible for performing the tasks identified in each call-up in the manner specified for the following:

7.1. Sample Receipt

Following receipt of the sample(s) at the testing laboratory, the Contractor must perform the Work as specified in the Call-up. The services must include the following:

7.1.1. The Contractor must inspect the condition of each sample upon arrival. Samples must be in good condition, i.e. not spoiled or otherwise compromised. Retail samples must be in the original unopened package and must arrive at the testing facility in the same state as would be expected at retail.

7.1.2. The Contractor must compare the details on the sample submission form (SSF) against the details of the Annual Sampling Plan and any relevant guidance or specific instructions issued by the Project Authority or designate.

7.1.3. The Contractor must document any deviations from the details of the sample plan and any samples which arrive in a compromised condition. The Contractor must report deviations in writing to the Project Authority or designate within 48 hours. The Contractor must not begin analysis until clarification from the Project Authority or designate has been received.

7.1.4. The Contractor must store samples from arrival to disposal in a manner that ensures sample integrity is maintained throughout.

7.2. Analytical Testing

Once sample acceptance is confirmed, the Contractor must perform the Work as specified in the Call-up. The services must include the following:

7.2.1. Sample Preparation and Analysis

7.2.1.1. The Contractor must perform all analytical activities, including sample preparation, at the following location:

(Location to be inserted as identified in offer submission)

The Project Authority or designate must be notified by the Contractor in writing of any change to laboratory location or address at least 30 calendar days in advance.

7.2.1.2. The Contractor, where practical, must finely homogenize the entire edible contents of the package(s) to ensure the portion available for testing is uniform and representative. Following homogenization, the sample must be stored in a container and under conditions that will maintain the integrity of the sample until disposal.

7.2.1.3. The Contractor must analyze the samples in accordance with the tests detailed in the Annual Sampling Plan as per the specifications provided in Appendix 1 to Annex A and any relevant documents or specific instructions issued by the Project Authority or designate.

7.2.1.4. Samples must be prepared and analyzed in accordance with the Standard Operating Procedures (SOP) approved at Standing Offer issuance or subsequently approved by the Project Authority or designate. In the event new scientific evidence arises, the Project Authority will provide additional guidance on sample preparation and testing in writing. Any and all such guidance must be adhered to in cases it applies.

7.2.1.5. In the event that a sample matrix is not covered within the scope of the accredited method, validation records must be submitted to the Project Authority or designate for review. Analytical activity must not be carried out before the validation is accepted by the Project Authority or designate.

7.2.1.6. In cases where new matrices are added or a potential interference is identified, the Project Authority, or designate, may require SOP re-evaluation or modification. This must be conducted by the Contractor without additional cost.

7.2.1.7. A copy of a revised SOP must be sent by the Contractor to the Project Authority or designate, electronically in searchable PDF format within 14 calendar days, whenever an update occurs.

7.2.1.8. The Contractor must not, in any event, allow the proposed revised Standard Operating Procedure (SOP) to be utilized for analytical testing until it is reviewed and approved in writing by the Project Authority or designate. If the Contractor cannot perform the Work using the SOP originally identified as part of the offer, all work requiring that particular SOP must cease immediately. The Contractor must, as soon as possible, give notice to the Project Authority or designate of the reason for replacing the SOP and provide supporting documentation including validation data for this proposed SOP.

7.2.2. Confirmation of Analytical Results

7.2.2.1. In the absence of specific instructions in Appendix 1, results requiring confirmation are all those producing quantitative values which are greater than 80% of the level of the current Canadian Maximum Residue Limits (MRL).

7.2.2.1.1. In cases where a Canadian Action Level is available and provided either in Appendix 1 to Annex “A” or in writing by the Project Authority, confirmation requirements identified in 7.2.2.1 shall apply.

7.2.2.1.2. In cases where no Canadian MRL exists, the sample must be confirmed when the following criteria is met:

7.2.2.1.2.1. Pesticides: All results that are greater than 0.08 µg/g.
7.2.2.1.2.2. Veterinary Drugs: All results that are above the stated LOQ of the Laboratory SOP.
7.2.2.1.2.3. Banned Substances: All positive/detected results

7.2.2.2. Confirmation requirements:

7.2.2.2.1. Must include a minimum of one <u>repeated</u> result that the laboratory has processed from the original sample material if the confirmation method used is the same as the original test method.

7.2.2.2.2. If the confirmation method is different than the original test method, there must be a minimum of two repeated results that have been processed from the original sample material.

7.2.2.2.3. Any positive sample result that meets the above criteria must not be reported without a minimum of two corroborating quantitative results.

7.2.2.2.4. Any result reported must be within the determined calibration range of the analysis.

7.2.2.2.5. All confirmations must be completed using matrix matched calibration, unless the Contractor has clearly demonstrated in method validation that there is no significant matrix enhancement or matrix suppression between the sample matrix and the one used for calibration.

7.2.2.3. For analytical methods that use mass spectral analysis, all confirmed results must meet the following requirements:

7.2.2.3.1. All monitored and reported transitions used for quantitation and confirmation must be appropriate and structurally distinct from each other.

7.2.2.3.2. The Contractor must perform valid mass spectral confirmation procedures approved in writing by the Project Authority or designate. These may be based either on the suggestions in the Reference Methods specified in Appendix I to Annex A, or developed on the Contractor’s initiative. Acceptable mass spectral confirmation criteria and approaches can be found in the Official Journal of the European Communities, "Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results"

7.2.2.4. No additional charge will be paid for confirmation tests.

7.2.2.5. All reported results must be the average of the results obtained where they cannot be excluded through a statistical test.

7.2.2.6. Confirmed results must be reported to the Project Authority or designate via email within twenty four (24) hours of being confirmed. This includes:

- All banned substance results which have been detected and confirmed;
- All results which are over the Canadian MRL where one exists; and
- Where no MRL exists – Pesticides: All results greater than 0.08 µg/g; Veterinary Drugs: All results that are above the stated LOQ of the Laboratory SOP.

7.3. Reporting of Analytical Results

7.3.1. The Contractor must provide a monthly (or bi-weekly) Report #2 (at their discretion) to the Project Authority or designate as specified in Article 10 Deliverables.

7.3.2. The Analyte reported is to be presented exactly as indicated under “Analytes” in Appendix I to Annex A.

7.3.3. All results above the LOD are to be reported as a numeric value.

7.3.3.1. For substances that are on Health Canada’s list of Banned Drugs, all values that meet requirements for confirmation will be reported.

7.3.4. Numerical results must be reported to the significant figures indicated in the Contractor’s SOP for all levels greater than the limit of detection cited in the SOP for the analytical method being used.

7.3.5. Unless otherwise specified, the units for the reported values are to be in parts per million: i.e. µg/g, mg/kg, or mg/L as indicated in Appendix I to Annex A.

7.3.6. Whenever an analyte is absent (i.e. levels less than the detection limit for the method), the result is to be reported numerically as zero, "0".

7.3.7. If confirmation is required, only analytical results which have been confirmed as per section 7.2.2 are to be reported to the Project Authority or designate unless otherwise instructed.

7.4. Sample Results Follow-up

7.4.1. The Project Authority or designate may request review of results for reasons including anomalous results or non-compliant values. The laboratory must review all records for quality assurance/control and data associated with the sample in question to ensure the reported result is consistent and representative of the sample. If additional confirmation of the sample is required, the Contractor will undertake the analysis at the Contractor’s expense.

7.4.1.1. For inquires related to notification of confirmed positive results (see 6.3 Notification), the review must be completed and a response provided to the Project Authority or designate within 48 hours.

7.4.1.2. For routine inquiries, the review must be completed and a response provided to the Project Authority or designate within 14 calendar days.

7.4.2. Where the review uncovers a deviation within the laboratory quality system the deviation must be investigated, a corrective action report (CAR) opened, and a completed report provided to the Project Authority or designate within 60 calendar days.

7.5. Quality Assurance

7.5.1. Sample Receipt

The Contractor must maintain and implement an SOP for internal verification procedures to ensure the sample information records are accurate and complete, and the samples collected meet the specifications provided in the call-up or other guidance provided by the Project Authority or designate.

7.5.2. Analytical Testing

The Contractor must ensure that the testing laboratory maintains its technical ability to analyze the product types included in each call-up in accordance with accredited analytical methods and Standard Operating Procedures approved at Standing Offer issuance or subsequently approved by the Project Authority or designate. This may be subject to verification by the CFIA. The Contractor must be prepared to submit performance summaries and raw data that demonstrate method suitability based on various method performance criteria for the product types specified in the call-up at the request of the Project Authority or designate.

7.6. Reports of Analyses (RoA)

Reports of Analysis must be available when requested by the Project Authority or designate. A copy must be submitted to the Project Authority or designate within seven (7) calendar days following the date requested in writing by the Project Authority or designate.

7.7. Web Access

The Contractor must have a secure web page or web-based application which can be accessed by the Project Authority or designate. This would allow the Project Authority or designate to search and view analytical results, as well as any information related to the submitted sample based on the CFIA assigned sample ID number and print reports of analysis. There are regular requests for copies of the sample submission form which could be accommodated by the Project Authority or designate accessing and downloading a scanned copy of this form through the web access. The website must provide limited access rights so that only the Project Authority or designate, or those authorized by the Project Authority or designate, are able to access this information. The information on the date sampled and date received must be posted online within seven (7) calendar days of the sample being received in the Contractor's laboratory. Analytical results must be posted online within 14 calendar days of test completion.

7.8. Security and controlled substances

The Contractor is responsible for obtaining and maintaining a valid license in cases where a controlled substance is required to deliver the analytical services.

8. SUPPORT PROVIDED BY CANADA

8.1. The Project Authority or designate will provide an Annual Sampling Plan in support of the NCRMP of the CFIA. The Plan will provide estimates to the Contractor of the commodity types that are planned for submission to their facilities during the year, the time of year that each sample is planned to be provided and the required tests on the submissions received. The Plans must not be construed as contracts or call-ups, are subject to change and will form the basis of any call-ups issued under this Standing Offer. The level of services in any Annual Sampling Plan is only an approximation of requirements given in good faith.

8.2. The CFIA will be responsible for the delivery of samples by prepaid courier or otherwise to the Contractor's laboratory facility. The Contractor will be informed of all the specific tests required to be carried out on each sample submitted. Generally speaking, each sample will require a unique set of tests identified in advance by the CFIA and relayed electronically to the Contractor. These test requirements will be provided to the Contractor shortly after the issuance of the Standing Offers, and on or before April 1st of subsequent years. The scheduled samples will be submitted to the Contractor throughout the year according to the estimated predetermined schedule.

8.3. Contractors are advised that the Annual Sampling Plan may include samples which for specific reasons, beyond the control of the CFIA, are unavailable for delivery during the year. For example a slaughter establishment may be closed down by company officials or a crop failure may reduce imports from certain countries. Under these circumstances, the samples scheduled for submission to a Contractor laboratory may not materialize and call-ups will be adjusted to reflect this lack of sample submissions. In addition, a change in the priorities of CFIA could affect the estimated level of sample delivery.

9. CONSTRAINTS

9.1. Turnaround Times

9.1.1. Notwithstanding the stated turnaround times in Appendix I, all assigned tests for each sample must be completed within a maximum of one hundred twenty (120) calendar days of reception of the sample. Tests analyzed after this time will be rejected and the Government of Canada will not be responsible for any costs incurred for the tests.

9.1.2. Notwithstanding the above, all results must be reported to the Project Authority or Designate within an additional thirty (30) days or a maximum of one hundred fifty (150) days of sample reception.

9.2. Analytical Testing and Documentation

9.2.1. The Contractor must validate methods in accordance with the Contractor's validation guidelines for all sample matrices described in each call-up prior to testing. Validation records must be made available to the Project Authority or designate upon request. Results generated for matrices without validation data will not be accepted.

9.2.2. Samples must be prepared and analyzed in accordance with the Standard Operating Procedures approved at Standing Offer issuance or subsequently approved by the Project Authority or designate. Charges associated with results obtained from a method other than the approved will not be accepted.

9.2.3. Analytical Results with failed Quality Control, without a record of the raw analytical data, or which cannot be confirmed upon request by the Project Authority or designate will not be accepted.

9.2.4. Analytical Results must be generated from the laboratory location approved by Project Authority or designate or the results will be rejected.

9.2.5. Updates to SOP's that involve a change to the laboratory procedures that may be deemed significant by the Project Authority such as: sample preparation, extraction procedures, instrument parameters (including columns) that may or may not affect detection limits, number of reported analytes, and applicable matrices, must be approved by the Project Authority. The changes shall be accompanied by validation data to demonstrate equivalency to the prior version. The Project Authority may request additional data to substantiate the validation if the information provided is insufficient.

9.3. Proficiency Testing (PT) Program Participation

9.3.1. Proficiency Testing Programs are mandatory for the food commodities listed below:

9.3.1.1. Contractors responsible for testing one or both of the fresh or processed fruit & vegetable products food groups, must participate in the AOAC Laboratory Proficiency Testing Program, **P01 Pesticide Residues in Fruits & Vegetables.** Contractors responsible for testing any of the three food groups: meat, dairy, and egg must participate in the program from the Proficiency Testing Unit/Centre for Veterinary Drug Residues/CFIA Saskatoon Laboratory. Information pertaining to enrollment in this program is available from the Project Authority or designate.

9.3.1.2. Contractors responsible for testing for Persistent Organic Pollutants (POPs) must participate in the Inter-laboratory Comparison on Dioxins in Food organised by the Department of Exposure and Risk Assessment, Norwegian Institute of Public Health, Oslo, Norway.

9.3.2. For the remaining food groups, the Contractor must participate in proficiency testing programs where those programs are available from organizations such as the Food Analysis Performance Assessment Scheme (FAPAS) and AOAC. Or, in the absence of a proficiency testing program for an analytical method being performed by the Contractor's laboratory, a blind check sample must be developed and completed by the laboratory and a report provided to the Project Authority or designate.

9.3.3. The Contractor must provide the Project Authority or designate with a copy of the final report received from the proficiency testing administrators. If the final report does not identify the Contractor's laboratory by name, the Contractor must provide the code for their laboratory to the Project Authority or designate.

9.3.4. The Contractor must provide the Project Authority or designate with PT reports quarterly at a minimum. Each quarter is defined as the period of April-June, July-September, October-December, and January-March. In the event that no participation of proficiency testing occurred in the quarter, notification of such must be reported.

9.3.5. If the final report provided to the Project Authority or designate indicates an unsatisfactory result for the Contractor's laboratory, a corrective action report (CAR) must be opened, and the completed report submitted to the Project Authority or designate within 60 calendar days.

9.4. The Project Authority or designate may, at its discretion, randomly submit blind check samples as part of the Annual Sample plan. These samples will be used as a proficiency indicator of the Contractor. In the event of an unsatisfactory test determination, the Project Authority or designate will notify the Contractor to initiate an investigation and provide a corrective action report at no cost to Canada.

9.5. Samples may be submitted and assigned testing under any combination of the following Chemical Residues of Interest: EBDC(CS2), EBDC(EDA), and EBDC(ETU). Results for these tests must be reported together within each monthly report as described in section 10 Deliverables.

9.6. Any subcontracting is subject to prior written consent of the Project Authority or designate and must conform to subcontracting criteria of the accrediting body.

9.7. All data and information generated from this testing is considered to belong to the CFIA. Third party access to the findings, records or data of preliminary or final test result information on the CFIA testing must not be permitted. Results are only to be released to the Project Authority or designate. Use of any part of the information provided with the samples, in whole or in part for any purpose outside of the Standing Offer's scope of Work without the expressed written consent of the Project Authority or designate is strictly prohibited.

9.8. Any breach of security involving data systems containing information or data belonging to the CFIA must be reported to the Project Authority or designate within 12 hours of the breach being identified by the Contractor's IT department. Within 30 calendar days of the security breach, a report

identifying the details of the security breach, corrective actions taken, and details of the information affected must be sent to the Project Authority or designate. Where the report details cannot be completed or are unavailable prior to these 30 calendar days, the deadline for the report may be extended with the written permission of the Project Authority or designate.

9.9. Audit of Facilities

9.9.1. Representatives of the CFIA or agents of Canada will conduct a facility site audit to verify that the technical capabilities, human and material resources of the Contractor are adequate to perform the requirements of the Standing Offer. For example, method validation, turnaround times, sampling and reporting requirements, confirmatory testing decisions and procedures, data management criteria and any other activities which fall under the scope of the Standing Offer may be verified. The Contractor must submit to and participate fully in these audits.

9.9.1.1. Under normal circumstances, such audits will occur annually, but may be scheduled more frequently if problems are identified. Facility audits may be scheduled or unscheduled.

9.9.1.2. The Project Authority or Designate will provide an assessment report for each audit carried out. The report will include detailed findings, expected actions and timelines for corrective measures.

9.9.2. The National Chemical Residue Monitoring Program (NCRMP) is audited by representatives of Health Canada [paragraph 11(4) of the *Canadian Food Inspection Agency Act*], the Auditor General of Canada and foreign countries (*Meat Inspection Act*). To the extent that participating laboratories undertake testing in support of the residue program, the Contractor must agree to submit to and participate fully in such inspections and audits as they occur.

10. DELIVERABLES

10.1. The Contractor must report deviations noted upon sample receipt in writing to the Project Authority or designate within 48 hours of sample arrival

10.2. Confirmed results must be reported to the Project Authority or designate via email within twenty four (24) hours of being confirmed.

10.2.1.1. CFIA Requested Review (see 6.3 Notification), the review must be completed and a response provided to the Project Authority or designate within 48 hours.

10.3. Routine inquiries, the review must be completed and a response provided to the Project Authority or designate within 14 calendar days.

10.4. All PT reports must be provided to Project Authority or designate, at least quarterly.

10.5. Upon Request, the Contractor will provide a Report of Analysis that meets the requirements of the Accreditation body under which it is accredited.

10.6. The Contractor will deliver final analytical data for samples submitted for analysis, to the Project Authority or designate identified in the Call-up, for review and acceptance.

10.7. The Contractor must submit the following deliverables on a bi-weekly or monthly basis to the Project Authority or designate identified in the call-up for review and acceptance:

- Report #1 – Samples Received
- Report #2 – Results

10.8. Reports must be submitted no more than ten (10) calendar days from the beginning of the month.

10.9. Reports must be submitted electronically in Microsoft Office Format, preferably in Excel or Access format. The results are to be reported in batches at intervals of either two (2) weeks or one month depending on the volume of data generated. Each report should not exceed 5000 lines.

10.10. The submitted reports must use the field names as indicated in the tables below for Report#1 and Report#2, with no exceptions.

10.11. During the period of the Standing Offer, Reporting requirements may change to accommodate some modernization processes, whereby the Contractor will provide and upload files through a secure web portal. Frequency and content will be adjusted depending on volume to provide CFIA with a more accurate account of samples and testing

10.12. Report#1 (Samples Received)

This report must contain the following information for all samples received for this project for the month: i.e. for the March Report (to be submitted by April 10), all the samples received by the Contractor up to, and including the last day of March. The filename must be in the format "{*lab_identifier*}_SamplesReceived_{*yyyymmdd*}.{*ext*}"

Field ID	Field Name	Field Type	Field Length	List	Required/ Optional	Notes
1	SAMPLE_NO	String	20		Required	The sample number identified on the sample submission form (SSF). This should correlate with an equivalent sample number in the Sample Plan provided.
2	REGION	String	10	WEST ONTARIO QUEBEC ATLANTIC	Required	Reflects the Area the sample was sampled on the SSF.
3	PickUpCity	String	30		Optional	
4	PickUpProv	String	2	BC AB SK MB ON QC NB NS NB PE	Required	Reflects the Province the sample was sampled on the SSF.
5	PLAN_CODE	String	15		Required	Provided in the Sample Plan for each sample and should be identified on the SSF.
6	COMMODITY	String	20		Required	Provided in the Sample Plan for each sample and should be identified on the SSF.
7	Domestic/Import	String	10	Domestic Import Unknown	Required	This is to reflect the origin of the sample, where identified
8	Country/Origin	String	50	List to be provided	Required	
9	ProductType	String	50	List to be provided	Required	Provided in the Sample Plan for each sample.
10	SampleDescription	String	255		Required	Description or common name of the sample, to be filled in by the Contractor. In the case of Any ambiguity, the Project Authority or designate must be consulted. For veal samples, please indicate whether it is red (grain- or grass-fed) or white (milk-fed).
11	Organic	Boolean		True False	Required	
12	Process	String	25		Required	Description of the processing applied to the product (if any). A list will be provided with the Sample Plan.
13	EST_NO	String	10		Required	Registered ID of the meat establishment.

Field ID	Field Name	Field Type	Field Length	List	Required/ Optional	Notes
					for Meat	Note; this may expand to include the Registration ID under the SFCR
14	INSP_NO	Numeric	10			Where available, the ID number of the submitting CFIA inspector.
15	System ID	String	30			Where available on submission by CFIA inspectors
16	LabNo	String	30		Required	The internal number assigned and used by the Contractor's Laboratory
17	DateSample	Date/Time			Required	The date the sample was picked up, entered as YYYY-MM-DD. This should be on the SSF.
18	DateRecd	Date/Time			Required	The date/{time} the sample is received by the Contractor's Laboratory, entered as YYYY-MM-DD {hh:mm:ss}.
19	Destination Lab	String			Required	This code will be assigned to the Contractor Laboratory by CFIA and must be used on all reports.
20	Sample_Comment	String	250		Optional	Report any deviations of the sample from the sample plan, such as change of country of origin, region is different, guidance provided by the Project Authority or designate, etc.

10.13. Report#2 (Results)

This report must contain the following information for all results reported for the month. The filename must be in the format "{*lab_identifier*}_Results_{*yyyymmdd*}.{*ext*}"

Field ID	Field Name	Field Type	Field Length	List	Required/ Optional	Notes
1	SAMPLE_NO	String	20		Required	The sample number identified on the sample submission form (SSF). This should correlate with an equivalent sample number in the Sample Plan provided.
2	COMMODITY	String	20		Required	Provided in the Sample Plan for each sample and should be identified on the

Field ID	Field Name	Field Type	Field Length	List	Required/ Optional	Notes
						SSF.
3	PROGRAM	String	40	List will be provided	Required	The name of the CFIA Program under which the test falls. This is identified in the Sample Plan and will correspond to the Chemical Residues of Interest to CFIA as identified in Appendix 1 to Annex A.
4	ANALYTE	String	50	List will be provided	Required	The name of the analyte being tested, exactly as provided for each test
5	AMOUNT	Numeric			Required	The amount of the analyte determined in µg/g, unless otherwise specified in Annex A
6	ReportUnit	String	10		Required	Actual units the reported results are in.
7	TissueID	String	20	EYES FAT HEPATOPANCREAS INJ.SITE KIDNEY LIVER MUSCLE URINE VISCERA N/A	Required	
8	DateAnalyze	Date/Time			Required	The date testing is complete and finalized in the Contractor's laboratory.
9	DateRept	Date/Time			Required	The date the result is reported to the Project Authority or designate.
10	Result_Comment	String	255		Optional	Include any comments worth noting regarding the analysis or result,