

**Generation of Data and Drafting of regulatory Reports in support of the
Licensing of Drugs for the Rabbit Industry in Canada**

Solicitation/Request for Proposal: 01B68-0068

Agriculture and Agri-Food Canada

February 12, 2014

Contracting Authority:

**David Hickman
Senior Contracting Officer
Agriculture and Agri-Food Canada
Professional Services Contracting Unit
1341 Baseline Road Tower 3, Floor 5, Room 336
Ottawa, Ontario K1A 0C5**

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GENERAL INFORMATION

1.0 PROJECT SUMMARY

Requirement is for the planning and conduct of trials and laboratory analysis for the generation of efficacy data, determination of withdrawal time, and drafting of associated reports to support the licensing of up to 7 drugs to be used in meat-producing rabbits. Laboratory analysis must be conducted under Laboratory Practices (GLP).

2.0 SECURITY REQUIREMENTS

There are no security requirements.

3.0 INTERPRETATION

In the RFP,

- 3.1 “Canada”, “Crown”, “Her Majesty”, “the Government” or “Agriculture and Agri-Food Canada” or “AAFC” means Her Majesty the Queen in right of Canada, as represented by the Minister of Agriculture and Agri-Food;
- 3.2 “Contract” or “Resulting Contract” means the written agreement between Agriculture and Agri-Food Canada and a Contractor, comprising the General Conditions (set out in Appendix A of this RFP) and any supplemental general conditions specified in this RFP and every other document specified or referred to in any of them as forming part of the Contract, all as amended by agreement of the Parties from time to time;
- 3.3 “Contracting Authority or authorized representative” means the AAFC official, identified in Article 5.0 of Part 3 of this RFP, responsible for the management of the Contract. Any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor is not to perform Work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from any government personnel other than the aforementioned AAFC official;
- 3.4 “Contractor”, means the person or entity whose name appears on the signature page of the Contract and who is to supply goods or services to Canada under the Contract;
- 3.5 “Minister” means the Minister of Agriculture and Agri-Food or anyone authorized to act on his behalf;
- 3.6 “Moral Rights” has the same meaning as in the Copyright Act, R.S.C. 1985, c. C-42;
- 3.7 “Project Authority or authorized representative” means the AAFC official, identified in Article 6.0 of Part 3 of this RFP, responsible for all matters concerning a) the technical content of the Work under the Contract; b) any proposed changes to the scope of the Work, but any resulting change can only be confirmed by a Contract amendment issued by the Contracting Authority; c) inspection and acceptance of all Work performed as detailed in the Statement of Work, and; review and inspection of all invoices submitted;
- 3.8 “Proposal” means an offer, submitted in response to a request from a Contracting Authority, that constitutes a solution to the problem, requirement or objective in the request;

- 3.9 “Proponent” means a person or entity submitting a Proposal in response to this RFP;
- 3.10 “Work” means the whole of the activities, services, materials, equipment, software, matters and things required to be done, delivered or performed by the Contractor in accordance with the terms of this RFP.

PART 1: PROPONENT INSTRUCTIONS, INFORMATION AND CONDITIONS

1.0 ACCEPTANCE OF TERMS AND CONDITIONS

Agriculture and Agri-Food Canada will only consider proposals which accept Agriculture and Agri-Food Canada's terms and conditions.

The General Conditions attached in Appendix A and those set out in Part 3 of this RFP shall form part of any resulting contract.

2.0 COST OF PROPOSAL PREPARATION

The cost to prepare the proposal will not be reimbursed by Agriculture and Agri-Food Canada.

No cost incurred before receipt of a signed Contract or specified written authorization from the Contracting Authority can be charged to any Resulting Contract.

3.0 ENQUIRIES - SOLICITATION STAGE

All enquiries or issues concerning this solicitation must be submitted in writing to the **Contracting Authority** named below as early as possible within the solicitation period.

Enquiries and issues must be received by the Contracting Authority no later than **ten (10) calendar days prior to the solicitation/bid closing date** specified herein to allow sufficient time to provide a response. Enquiries or issues received after that time may not be able to be answered prior to the solicitation/bid closing date.

To ensure consistency and quality of information provided to proponent, the Contracting Authority will provide, simultaneously to all proponents to whom this solicitation has been sent, any information with respect to significant enquiries received and the replies to such enquiries without revealing the sources of the enquiries.

All enquiries and other communications with government officials throughout the solicitation period are to be directed **ONLY** to the Contracting Authority named below. Noncompliance with this condition during the bid solicitation period may (for that reason alone) result in disqualification of a proposal.

Meetings will not be held with individual proponent prior to the closing date/time of this RFP.

Contracting Authority:

Agriculture and Agri-Food Canada
Professional Services Contracting Unit
1341 Baseline Road, Tower 3, Floor 5, Room 336
Ottawa, (Ontario) K1A 0C5
Attention: David Hickman
david.hickman@agr.gc.ca

4.0 RIGHTS OF CANADA

Canada reserves the right to:

- a) Accept any proposal in whole or in part, without prior negotiation with the selected proponent;
- b) Reject any or all proposals received in response to this Request for Proposal;
- c) Cancel and/or re-issue this requirement at any time;
- d) Ask the proponent to substantiate any claim made in the proposal;
- e) Enter into negotiations with one or more proponents on any or all aspects of their proposals;
- f) Award one or more contracts;
- g) Retain all proposals submitted in response to this RFP.

5.0 SOLE PROPOSAL - PRICE SUPPORT

In the event that the Proponent's offer is the sole responsive offer received, the Proponent must provide, on Canada's request, one or more of the following price justification:

- (a) a current published price list indicating the percentage discount available to Canada; or
- (b) a copy of paid invoices for the like quality and quantity of the goods, services or both sold to other customers; or
- (c) a price breakdown showing the cost of direct labour, direct materials, purchased items, engineering and plant overheads, general and administrative overhead, transportation, etc., and profit; or
- (d) price or rate certifications; or
- (e) any other supporting documentation as requested by Canada.

6.0 MANDATORY CLAUSES

Where the words “must”, “shall” or “will” appear in this RFP, the clause is to be considered as a mandatory requirement.

PART 2: PROPOSAL PREPARATION INSTRUCTIONS & EVALUATION PROCEDURES

1.0 APPLICABLE LAWS

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

Proponents may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the Canadian province or territory specified and inserting the Canadian province or territory of their choice. If no change is made, it is deemed that the applicable law specified above is acceptable to the Proponent.

2.0 ELECTRONIC SUBMISSIONS AND SUBMISSION OF PROPOSAL

Notice: Proposals submitted by Facsimile or other electronic means will not be accepted.

Due to the nature of this RFP, electronic transmission of proposals by such means as electronic mail or facsimile to the Department of Agriculture and Agri-Food is not considered to be practical and therefore will not be accepted.

The proposal MUST be delivered to and received by the Contracting Authority no later than 12:00 PM (local time) Tuesday March 25th, 2014 at the following location:

**Agriculture and Agri-Food Canada
Professional Services Contracting Unit
1341 Baseline Road, Tower 3, Floor 5, Room 336
Ottawa, Ontario K1A 0C5
Attention: David Hickman**

The onus for submitting proposals on time at the specified location rests with the Proponent. It is the Proponent's responsibility to ensure correct delivery of their proposal to the person named above.

The Proponent must also ensure that its name, return address, solicitation number 01B68-13-0068 and closing date appear legibly on the outside of the envelopes containing the technical and price Proposals.

The Proponents are advised that, due to security measures for building visitors, arrangements should be made in advance with the Contracting Authority for any planned in-person delivery of Proposals between 8:00 a.m. and 3:00 p.m. Monday through Friday except on Government holidays, and weekends. Failure to do so may result in late receipt of a Proposal.

Proposals submitted in response to this RFP will not be returned.

The Proponent may submit a proposal in either official language.

The **INDIVIDUAL TRIAL PROPORSAL(S)** must be structured in two **SEPARATELY BOUND parts** (A and B) as indicated below:

Part A - Technical Proposal(s) **with no reference to price.**

Part B - Financial Proposal(s). Bidders must fill the financial proposal template (see Appendix D, Annex 3) for each trial for which a bid is being submitted.

This RFP includes 16 trials involving seven active medicinal ingredients. The list of trials and associated requirements are found in:

Appendix B Annex 1 – Human Safety - Residue Depletion Trials

Appendix B Annex 2 – Efficacy and Animal Safety trials

Applicants are not required to bid on both the Human Safety - Residue Depletion / Efficacy and Animal Safety trials, but may do so if feasible.

Bidding will be evaluated for each trial separately.

Bidders should complete a Veterinary Drugs Trial Application Form (Appendix D - Annexes 1 and/or Annex 2) for each trial being bid upon.

The Technical Proposal(s) and attachment(s) including the completed trial application form(s) must be submitted in one (1) original and three (3) hard copies

The Financial Proposal form must be submitted in one (1) original and one (1) hard copy.

Each proposal will include the supplier's legal entity name, name of the authorized official and if different, the name of the company contact, and their address, telephone number, facsimile number, email address and Request for Proposal No. 01B68-13-0068

It is the responsibility of the proponent to obtain clarification of the requirements contained herein, if necessary, prior to submitting a proposal.

It is essential that the elements contained in a proposal be stated in a clear and concise manner. Failure to provide complete information as requested will be to the proponent's disadvantage.

The proposal must be properly completed and signed by the proponent or by an authorized representative of the Proponent. The proponent's signature indicates acceptance of the terms and conditions governing the resulting contract as stated herein. No modification or other terms and conditions included in the Proponent's proposal will be applicable to the resulting contract notwithstanding the fact that the Proponent's proposal may become part of the resulting contract.

3.0 PREPARATION OF TECHNICAL PROPOSAL

In the technical proposal(s), the proponents should demonstrate their understanding of the requirements of the Statement of Work in Appendix B.

The application forms for Human Safety - Residue Depletion Trials and Efficacy and Animal Safety Trials (Appendix D, Annex 1 and/or 2) must be completed for each respective trial for which a bid is being submitted.

The technical proposal(s) may be organized as follows:

1. General proposal information

- Company background, general information
- Personnel, copy of CV for each employee identified in the proposal
- Certifications as required in Appendix E

Note: If a bidder is submitting a bid for more than one trial, the information listed above, may be submitted only once.

4.0 PREPARATION OF FINANCIAL PROPOSAL

One Financial Proposal Template (Appendix D - Annex 3) must be completed listing all the trails for which a bid is being submitted with the respective cost as it applies for the individual trials.

In the Financial proposal template, the proponent shall include a cost summary of the services requested in accordance with **Appendix “B”, Appendix “C” and Appendix “D”**.

Costs shall not appear in any other area of the proposal except in the Financial Proposal.

All bids must be in Canadian dollars. Financial evaluations are calculated on the total cost of the project, excluding HST (if applicable). Only the Canadian currency value for the bid will be used in evaluating a proposal. The Canadian currency value for a bid is fixed at the time of the proposal, irrespective of future changes in currency rate.

The failure by a company to bid in Canadian dollars (a mandatory requirement of the solicitation) is sufficient to make its proposal non-compliant. AAFC will reject a company's bid made in any other currency than Canadian.

5.0 CERTIFICATION REQUIREMENTS

In order to be awarded a contract, the certifications attached in **Appendix “E”** will be required. The certifications should be submitted with the proposal. Canada may declare a bid non-responsive if the certifications are not submitted or completed as required. Where Canada intends to reject a proposal pursuant to this paragraph, the Contracting Authority will so inform the Proponent and provide the Proponent with a time frame within which to meet the requirement. Failure to comply with the request of the Contracting Authority and meet the requirement within that time frame period will render the proposal non-responsive.

Compliance with the certifications the proponent provides to Canada is subject to verification by Canada. The Contracting Authority shall have the right to ask for additional information to verify the Proponent's compliancy to the applicable certifications before and after award of a contract. If it is determined that any certification made by the Proponent is untrue, whether made knowingly or unknowingly, or any failure to comply with the certifications or comply with the request of the Contracting Authority for additional information, will render the bid non-responsive.

6.0 EVALUATION PROCEDURES

Proposals will be evaluated in accordance with the Evaluation Procedures and Criteria specified in **Appendix “D”**. Proposals received will be compared separately against the evaluation criteria identified therein for each individual trial of this request for proposal (RFP) and in conjunction with the accompanying Statement of Work, **Appendix “B”**.

An evaluation team composed of representatives of the Department of Agriculture and Agri-Food will evaluate the proposals on behalf of Canada.

The evaluation team reserves the right but is not obliged to perform any of the following:

- a) seek clarification or verify any or all information provided by the proponent with respect to this RFP;
- b) contact any or all of the references supplied and to interview, at the sole costs of the proponent, the proponent and/or all of the resources proposed by the proponent to fulfill the requirement, at Agriculture and Agri-Food Canada in Ottawa, Ontario, on 48 hours' notice, to verify and validate any information or data submitted by the Proponent.

7.0 PROPOSAL AMENDMENT(S)

Any amendments to the RFP will be through an addendum.

PART 3: RESULTING CONTRACT CLAUSES

Upon a Contract being awarded pursuant to RFP # 01B68-13-0068, the following Terms and Conditions shall form part of the Resulting Contract:

1.0 SECURITY REQUIREMENTS

There are no security clearance requirements.

2.0 GENERAL CONDITIONS

The General Conditions attached in **Appendix A** shall form part of any resulting contract.

3.0 REQUIREMENT

The contractor will provide the services identified in Appendix B, Statement of Work.

The Contractor shall maintain, for the duration of the Contract, a designated single point of contact, hereafter referred to as a Project Authority, dedicated to managing the Contract.

4.0 CONTRACT PERIOD

The Contract shall be valid from date of contract award to March 31st, 2016 with the possibility of an extension at the discretion of the Project Authority if required.

5.0 CONTRACTING AUTHORITY

The Contracting Authority is:

David Hickman
Senior Contracting Officer
Agriculture and Agri-Food Canada
Professional Services Contracting Unit
1341 Baseline Road Tower 3, Floor 5, Room 336
Ottawa, Ontario K1A 0C5
Canada
E-mail : david.hickman@agr.gc.ca

The Contracting Authority (or delegated representative) is responsible for the management of this Contract. Any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor is not to perform work in excess of or outside the scope of this Contract based on verbal or written requests or instructions from any government personnel other than the aforementioned Officer.

6.0 PROJECT AUTHORITY

6.1 *The contact information of the Project Authority will be provided at time of contract award.*

6.2 The Project Authority, or authorized representative, is responsible for:

1. All matters concerning the technical content of the Work under the Contract;
2. Defining any proposed changes to the scope of the Work, but any resulting change can only be confirmed by a Contract amendment issued by the Contracting Authority;
3. Inspection and acceptance of all Work performed as detailed in the Statement of Work and;
4. Review and inspection of all invoices submitted.

7.0 CONTRACTOR REPRESENTATIVE

7.1 *The contact information of the Contractor Representative will be provided at time of contract award.*

7.2 The duties and responsibilities of the Contractor Representative shall include the following:

1. Responsible for the overall management of the Contract;
2. Ensure that Contracts are administered in accordance with the terms and conditions of the Contract;
3. Act as a single point of contact to resolve any contractual disputes that may arise. The contractor must ensure that the Contract Representative has direct access to the level of management within the Contractor's organization vested with the decision-making authority for contractual matters;
4. Shall be established as the only recognized individual from the Contractor's organization to speak on behalf of the Contractor for purposes of Contract management;
5. Monitor all resources that are providing services/deliverables in accordance with the Contract;
6. Liaise with the Project Authority on all matters concerning technical aspects of the Work and performance of its resources; and
7. Manage the transition of any potential resource(s) turnover during the period of the Work.

8.0 PRIORITY OF DOCUMENTS

The documents specified below form part of and are incorporated into the Contract. If there is a discrepancy between the wording of any documents which appear on the list, the wording of the document which first appears on the list shall prevail over the wording of any document which subsequently appears on the list:

1. The Articles of Agreement of this RFP
2. The General Conditions, Appendix A of this RFP
3. The Statement of Work, Appendix B of this RFP
4. The Basis of Payment, Appendix C of this RFP including Annex 3 Financial Proposal Form
5. AAFC's Request for Proposal
6. Certification Requirements, Appendix E of this RFP
7. Annex 1 and 2 of Appendices B and D of this RFP
8. Contractor's Proposal dated (to be inserted at contract award)

9.0 **This section is intentionally left blank.**

10.0 BASIS OF PAYMENT

The contractor shall be paid in accordance with the attached **Appendix “C”** for work performed pursuant to the contract and upon submission of the deliverables.

For terminated projects contractors will be paid for the work conducted up to the time of termination and as per the schedule of payment described in Section 11.0. Payment will be calculated based on the work conducted up to the time of termination and should not exceed the percentage of payment as guided by the schedule of payment below (Section 11.0).

11.0 METHOD OF PAYMENT / PAYMENT SCHEDULE

Payment will occur upon acceptance of the respective deliverables (listed below) by the Project Authority, upon submission of an invoice and containing information specified in Article 12.0, Invoicing Instructions, herein.

Payment Schedule:

First invoice: Trial Set-up value of the contract upon submission of the following deliverables;

1. Work plan including the exact location of the trial;
2. Study Plan/Protocol for efficacy and animal safety trials for approval by AAFC before trial initiation;
3. Study Plan/ Protocol for human safety – residue depletion trial for approval by AAFC before trial initiation;
4. Protocol for laboratory analysis indicating the analytical method that will be used with justification and any modification on the method with associated justification for AAFC approval before initiation (for human safety – residue depletion trials only).

Second Invoice: Trial Conduct value of the contract upon submission of the following deliverables:

1. Status report describing the trial setup including the exact location and pictures of the trial;
2. Results of clinical trials before and after treatment with the veterinary drug
3. Results of lab analyses of human depletion trials samples.

Third Invoice (final): Final Reports value of the contract upon submission of the final deliverables as listed below:

1. Submission of all trial-related raw data.
2. Submission of final reports.

12.0 INVOICING INSTRUCTIONS

Payment will only be made upon submission of a satisfactory invoice duly supported by specified submission of deliverables called for under the Contract.

Invoices must be submitted on the Contractor's own invoice form and must be prepared to show:

- a) The date;
- b) Name and address of Agriculture and Agri-Food Canada;
- c) List deliverables and/or description of work;
- d) AAFC contract number
- e) The amount invoiced (exclusive of the Harmonized Sales Tax (HST) if applicable) and the amount of HST, as appropriate, shown separately.

One (1) original and one (1) copy of the invoice together with attachments shall be forwarded to the Project Authority at the address noted in Section 6.0 above.

13.0 MANDATORY CERTIFICATIONS

Compliance with the Certifications the Contractor has provided Canada is a condition of this Contract and subject to verification by Canada during the entire period of the Contract. In the event that the Contractor does not comply with any certification or that it is determined that any certification made by the Contractor is untrue, whether made knowingly or unknowingly, the Minister shall have the right, pursuant to the default provisions of the Contract, to terminate the Contract for default.

14.0 FOREIGN NATIONALS (the non-applicable clause will be deleted at contract award)

CANADIAN CONTRACTOR

The Contractor must comply with Canadian immigration requirements applicable to foreign nationals entering Canada to work temporarily in fulfilment of the Contract. If the Contractor wishes to hire a foreign national to work in Canada to fulfil the Contract, the Contractor should immediately contact the nearest Service Canada regional office to enquire about Citizenship and Immigration Canada's requirements to issue a temporary work permit to a foreign national. The Contractor is responsible for all costs incurred as a result of non-compliance with immigration requirements.

FOREIGN CONTRACTOR

The Contractor must comply with Canadian immigration legislation applicable to foreign nationals entering Canada to work temporarily in fulfilment of the Contract. If the Contractor wishes to hire a foreign national to work in Canada to fulfil the Contract, the Contractor should immediately contact the nearest Canadian Embassy, Consulate or High Commission in the Contractor's country to obtain instructions, information on Citizenship and Immigration Canada's requirements and any required documents. The Contractor is responsible to ensure that foreign nationals have the required information, documents and authorizations before performing any work under the Contract in Canada. The Contractor is responsible for all costs incurred as a result of non-compliance with immigration requirements.

15.0 INSURANCE REQUIREMENTS

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

APPENDIX A

GENERAL CONDITIONS

GC1. INTERPRETATION

1.1 In the contract,

1.1 "Canada", "Crown", "Her Majesty" or "the Government" means Her Majesty the Queen in right of Canada;

"Contractor" means the person, entity or entities named in the Contract to supply goods, services or both to Canada;

1.2 "Minister" means the Minister of Agriculture and Agri-Food Canada or anyone authorized;

1.3 "Party" means Canada, the Contractor, or any other signatory to the contract and "Parties" means all of them;

1.4 "Work" unless otherwise expressed in the Contract, means everything that is necessary to be done, furnished or delivered by the Contractor to perform the Contractor's obligations under the Contract.

GC2. Powers of Canada

All rights, remedies and discretions granted or acquired by Canada under the Contract or by law are cumulative, not exclusive.

GC3. General Conditions

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.

GC4. Conduct of the Work

4.1 The Contractor represents and warrants that:

(a) It is competent to perform the Work;

(b) It has the necessary qualifications, including knowledge, skill and experience, to perform the Work, together with the ability to use those qualifications effectively for that purpose; and

(c) It has the necessary personnel and resources to perform the Work.

4.2 Except for government property specifically provided for in the Contract, the Contractor shall supply everything necessary for the performance of the Work, including all the resources, facilities, labor and supervision, management, services, equipment, materials, drawings, technical data, technical assistance, engineering services, inspection and quality assurance procedures, and planning necessary to perform the Work.

- 4.3 The Contractor shall:
- (a) Carry out the Work in a diligent and efficient manner;
 - (b) Apply as a minimum, such quality assurance tests, inspections and controls consistent with those in general usage in the trade and that are reasonably calculated to ensure the degree of quality required by the Contract; and
 - (c) Ensure that the Work:
 - (1) is of proper quality, material and workmanship;
 - (2) Is in full conformity with the Statement of Work; and
 - (3) Meets all other requirements of the Contract.
- 4.4 Notwithstanding acceptance of the Work or any part thereof, the Contractor warrants that the Work shall be of such quality as to clearly demonstrate that the Contractor has performed the Work in accordance with the undertaking in subsection 4.3.

GC5. Inspection and Acceptance

- 5.1 The Work will be subject to inspection by Canada. Should any part of the Work whether it be a report, document, good or service not be in accordance with the Contract or not be done to the satisfaction of the Canada, as submitted, Canada will have the right to reject it or require its correction at the sole expense of the Contractor before making payment.
- 5.2 The Contractor will be in default of the Contract if the Work is rejected by Canada or if he fails to correct the Work within a reasonable delay.

GC6. Amendments and Waivers

- 6.1 No design change, modification to the Work, or amendment to the Contract shall be binding unless it is incorporated into the Contract by written amendment or design change memorandum executed by the authorized representatives of Canada and of the Contractor.
- 6.2 While the Contractor may discuss any proposed changes or modifications to the scope of the Work with the representatives of Canada, Canada shall not be liable for the cost of any such change or modification until it has been incorporated into the Contract in accordance with subsection 6.1.
- 6.3 No waiver shall be valid, binding or affect the rights of the Parties unless it is made in writing by, in the case of a waiver by Canada, the Contracting Authority and, in the case of a waiver by the Contractor, the authorized representative of the Contractor.
- 6.4 The waiver by a Party of a breach of any term or condition of the Contract shall not prevent the enforcement of that term or condition by that Party in the case of a subsequent breach, and shall not be deemed or construed to be a waiver of any subsequent breach.

GC7. Time of the Essence

It is essential that the Work be performed within or at the time stated in the Contract.

GC8. Excusable delay

- 8.1 Any delay by the Contractor in performing the Contractor's obligations under the Contract which occurs without any fault or neglect on the part of the Contractor its subcontractors,

agents or employees or is caused by an event beyond the control of the Contractor, and which could not have been avoided by the Contractor without incurring unreasonable cost through the use of work-around plans including alternative sources or other means, constitutes an excusable delay.

- 8.2 The Contractor shall give notice to the Minister immediately after the occurrence of the event that causes the excusable delay. The notice shall state the cause and circumstances of the delay and indicate the portion of the Work affected by the delay. When requested to do so by the Minister, the Contractor shall deliver a description, in a form satisfactory to the Minister, of work-around plans including alternative sources and any other means that the Contractor will utilize to overcome the delay and Endeavour to prevent any further delay. Upon approval in writing by the Minister of the work-around plans, the Contractor shall implement the work around plans and use all reasonable means to recover any time lost as a result of the excusable delay.
- 8.3 Unless the Contractor complies with the notice requirements set forth in the Contract, any delay that might have constituted an excusable delay shall be deemed not to be an excusable delay.
- 8.4 If an excusable delay has continued for thirty (30) days or more, Canada 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 Canada the portion of any advance payment that is unliquidated at the date of the termination.
- 8.5 Unless Canada has caused the delay by failing to meet an obligation under the Contract, Canada will not be responsible for any cost incurred by the contractor or any subcontractors or agents as a result of an excusable delay.
- 8.6 If the Contract is terminated under this section, Canada may require the Contractor to deliver to Canada, in the manner and to the extent directed by Canada, any completed parts of the Work not delivered and accepted before the termination and anything that the Contractor has acquired or produced specifically to perform the Contract. Canada will pay the Contractor:
- (a) The value, of all completed parts of the Work delivered to and accepted by Canada, based on the Contract price, including the proportionate part of the Contractor's profit or fee included in the Contract price; and
 - (b) The cost to the Contractor that Canada considers reasonable in respect of anything else delivered to and accepted by Canada.
- 8.7 The total amount paid by Canada under the Contract to the date of termination and any amounts payable under this subsection must not exceed the Contract price.

GC9. Termination of convenience

- 9.1 Notwithstanding anything in the Contract, the Minister may, by giving notice to the Contractor, terminate or suspend the Contract immediately with respect to all or any part or parts of the Work not completed.
- 9.2 All Work completed by the Contractor to the satisfaction of Canada before the giving of such notice shall be paid for by Canada in accordance with the provisions of the Contract and, for all Work not completed before the giving of such notice, Canada shall pay the Contractor's costs as determined under the provisions of the Contract in an amount representing a fair and reasonable fee in respect of such Work.

- 9.3 In addition to the amount which the Contractor shall be paid under section GC9.2, the Contractor shall be reimbursed for the Contractor's cost of and incidental to the cancellation of obligations incurred by the Contractor pursuant to such notice and obligations incurred by or to which the Contractor is subject with respect to the Work.
- 9.4 The Contractor shall have no claim for damages, compensation, loss of profit, allowance or otherwise by reason of or directly or indirectly arising out of any action taken or notice given by Canada under the provisions of section GC9 except as expressly provided therein.
- 9.5 Upon termination of the Contract under section GC9.1, Canada may require the Contractor to deliver and transfer title to Canada, in the manner and to the extent directed by Canada, any finished Work which has not been delivered prior to such termination and any material, goods or Work-in-progress which the Contractor specifically acquired or produced for the fulfillment of the Contract.

GC10. Termination due to Default of Contractor

- 10.1 Canada may by notice to the Contractor, terminate the whole or any part of the Contract:
- a) If the Contractor fails to perform any of the Contractor's obligations under the Contract or in Canada's view, so fails to make progress so as to endanger performance of the Contract in accordance with its terms;
 - b) To the extent permitted under law, if the Contractor becomes bankrupt or insolvent, or a receiving order is made against the Contractor, or an assignment is made for the benefit of creditors, or if an order is made or resolution passed for the winding up of the Contractor, or if the Contractor takes the benefit of a statute relating to bankrupt or insolvent debtors; or
 - c) If the Contractor makes a false declaration under GC 37 or GC 38 or fails to comply with the terms set out in GC 16.3 or GC 39.
- 10.2 Upon termination of the Contract under section GC10, the Contractor shall deliver to Canada any finished Work which has not been delivered and accepted prior to such termination, together with materials and Work-in-progress relating specifically to the Contract and all materials, texts and other documents supplied to the Contractor in relation to the Contract.
- 10.3 Subject to the deduction of any claim which Canada may have against the Contractor arising under the Contract or out of termination, payment will be made by Canada to the Contractor for the value of all finished Work delivered and accepted by Canada, such value to be determined in accordance with the rate(s) specified in the Contract, or, where no rate is specified, on a proportional basis.
- 10.4 If the contract is terminated pursuant to GC 10.1 (c), in addition to any other remedies that may be available against the Contractor, the Contractor will immediately return any advance payments.

GC11. Suspension of Work

- 11.1 The Minister may at any time, by 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.

GC12. Extension of Contract

- 12.1 Where the Minister determines that additional work of the same nature as the Work

described in this Contract is required, the Contractor shall do such work and where required the term of the Contract shall be extended accordingly and confirmed in writing between the parties.

- 12.2 Payment for the work described in subsection 1 shall be calculated and paid on the same basis as in section GC12 and where required prorated.
- 12.3 Where the Minister has determined that the Contractor shall be paid expenses related to the Work described in section GC12.1, the type of expenses and amounts shall be confirmed in writing between the parties.

TERMS OF PAYMENT

GC13. Method of Payment

- 13.1 Payment in the case of progress payments:
- a) Payment by Canada to the Contractor for the Work shall be made within thirty (30) days following the date on which a claim for progress payment is received according to the terms of the Contract; and
 - b) If the Minister has any objection to the form of the claim for payment or the substantiating documentation, shall, within fifteen (15) days of its receipt, notify the Contractor in writing of the nature of the objection.
- 13.2 Payment in the case of payment on completion:
- a) Payment by Canada to the Contractor for the Work shall be made within thirty (30) days following the date on which the Work is completed or on which a claim for payment and substantiating documentation are received according to the terms of the Contract, whichever date is the later;
 - b) If the Minister has any objection to the form of the claim for payment or the substantiating documentation, shall, within fifteen (15) days of its receipt, notify the Contractor in writing of the nature of the objection.

GC14. Basis of Payment

- 14.1 A claim in the form of an itemized account certified by the Contractor with respect to the accuracy of its contents shall be submitted to the Minister.
- 14.2 Travel and other expenses, where allowed by the Contract, shall be paid in accordance with Treasury Board Guidelines and Directives, certified by the Contractor as to the accuracy of such claim.

GC15. Interest on Overdue Accounts

- 15.1 For the purposes of this clause:
- (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;
 - (b) "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;

- (c) "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;
 - (d) 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
 - (e) An amount becomes "overdue" when it is unpaid on the first day following the day upon which it is due and payable.
- 15.2 Canada shall be liable to pay to the Contractor simple interest at the Average Rate plus 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 thirty (30) days overdue. No interest will be payable or paid in respect of payment made within such thirty (30) days unless the Contractor so requests after payment has become due.
- 15.3 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.
- 15.4 Canada shall not be liable to pay interest on overdue advance payments.

GC16. Records to be kept by Contractor

- 16.1 The Contractor must keep proper accounts and records of the cost of performing the Work and of all expenditures or commitments made by the Contractor in connection with the Work, including all invoices, receipts and vouchers. The Contractor must retain records, including bills of lading and other evidence of transportation or delivery, for all deliveries made under the Contract.
- 16.2 If the Contract includes payment for time spent by the Contractor, its employees, representatives, agents or subcontractors performing the Work, the Contractor must keep a record of the actual time spent each day by each individual performing any part of the Work.
- 16.3 Unless Canada has consented in writing to its disposal, the Contractor must retain all the information described in this section for six (6) years after it receives the final payment under the Contract, or until the settlement of all outstanding claims and disputes, whichever is later. During this time, the Contractor must make this information available for audit, inspection and examination by the representatives of Canada, who may make copies and take extracts. The Contractor must provide all reasonably required facilities for any audit and inspection and must furnish all the information as the representatives of Canada may from time to time require to perform a complete audit of the Contract.
- 16.4 The amount claimed under the Contract, calculated in accordance with the Basis of Payment provision in the Articles of Agreement, is subject to government audit both before and after payment is made. If an audit is performed after payment, the Contractor agrees to repay any overpayment immediately on demand by Canada. Canada may hold back, deduct and set off any credits owing and unpaid under this section from any money that Canada owes to the Contractor at any time (including under other Contracts). If Canada does not choose to exercise this right at any given time, Canada does not lose this right.

GC17. Invoice Submission

- 17.1 Invoices must be submitted in the Contractor's name. The Contractor must submit invoices for each delivery or shipment; invoices must only apply to the Contract. Each invoice must indicate whether it covers partial or final delivery.
- 17.2 Invoices must show:

- (a) the date, the name and address of the client department, item or reference numbers, deliverable and/or description of the Work, contract number, Client Reference Number (CRN), Procurement Business Number (PBN), and financial code(s);
 - (b) details of expenditures in accordance with the Basis of Payment, exclusive of Goods and Services Tax (GST) or Harmonized Sales Tax (HST) (such as item, quantity, unit of issue, unit price, fixed time labor rates and level of effort, subcontracts, as applicable);
 - (c) deduction for holdback, if applicable;
 - (d) the extension of the totals, if applicable; and
 - (e) if applicable, the method of shipment together with date, case numbers and part or reference numbers, shipment charges and any other additional charges.
- 17.3 If applicable, the GST or HST must be specified on all invoices as a separate item. All items that are zero-rated, exempt or to which the GST or HST does not apply, must be identified as such on all invoices.
- 17.4 By submitting an invoice, the Contractor certifies that the invoice is consistent with the Work delivered and is in accordance with the Contract.

GC18. Right of Set off

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 Canada by the Contractor under the Contract or under any other current contract. Canada may, when making a payment pursuant to the Contract, deduct from the amount payable to the Contractor any such amount payable to Canada by the Contractor which, by virtue of the right of set off, may be retained by Canada.

GC19. Assignment

- 19.1 The Contract shall not be assigned in whole or in part by the Contractor without the prior written consent of Canada and an assignment made without that consent is void and of no effect.
- 19.2 An assignment of the Contract does not relieve the Contractor from any obligation under the Contract or impose any liability upon Canada.

GC20. Subcontracting

- 20.1 The Contractor must obtain the consent in writing of the Minister before subcontracting.
- 20.2 Subcontracting does not relieve the Contractor from any of its obligations under the Contract or impose any liability upon Canada to a subcontractor.
- 20.3 In any subcontract, the Contractor will bind the subcontractor by the same conditions by which the contractor is bound under the Contract.

GC21. Indemnification

- 21.1 The Contractor shall indemnify and save harmless Canada 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 willful or negligent act, omission or delay on the part of the Contractor, the Contractor's servants, subcontractors or agents in performing the Work or as a result of the Work.

21.2 The Contractor's liability to indemnify or reimburse Canada under the Contract shall not affect or prejudice Canada from exercising any other rights under law.

GC22. Confidentiality

The Contractor shall treat as confidential, during as well as after performance of the Work, any information to which the Contractor becomes privy as a result of acting under the Contract. The Contractor shall use its best efforts to ensure that its servants, employees, agents, subcontractors or assigned observe the same standards of confidentiality.

GC23. Indemnification - Copyright

The Contractor shall indemnify Canada from and against all costs, charges, expenses, claims, actions, suits and proceedings for the infringement or alleged infringement of any copyright 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.

GC24. Indemnification - Inventions, etc.

The Contractor shall indemnify Canada from and against all costs, charges, expenses, 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 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.

GC25. Ownership of Copyright

25.1 Anything that is created or developed by the Contractor as part of the Work under the Contract in which copyright subsists belongs to Canada. The Contractor must incorporate the copyright symbol and either of the following notices, as appropriate:

© HER MAJESTY THE QUEEN IN RIGHT OF CANADA (year)

or

© SA MAJESTÉ LA REINE DU CHEF DU CANADA (année).

25.2 At the request of the Minister, the Contractor must provide to Canada, at the completion of the Work or at such other time as the Minister may require a written permanent waiver of Moral Rights, in a form acceptable to the Minister, from every author that contributed to the Work. If the Contractor is an author, the Contractor permanently waives the Contractor's Moral Rights.

GC26. Taxes

26.1 Municipal Taxes

Municipal Taxes do not apply.

26.2 Provincial Taxes

(a) Excluding legislated exceptions, federal government departments and agencies are not required to pay any sales tax payable to the province in which the taxable goods or services are

delivered. This exemption has been provided to federal government departments and agencies under the authority of one of the following:

- (i) Provincial Sales Tax (PST) Exemption Licence Numbers, for the provinces of:

Prince Edward Island OP-10000-250
Manitoba 390-516-0

- (ii) For Quebec, Saskatchewan, the Yukon Territory, the Northwest Territories and Nunavut, an Exemption Certification, which certifies that the goods or services purchased are not subject to the provincial/territorial sales and consumption taxes because they are purchased by the federal government with Canada funds for the use of the federal government.

(b) Currently, in Alberta, the Yukon Territory, the Northwest Territories and Nunavut, there is no general PST. However, if a PST is introduced in Alberta, the Yukon Territory, the Northwest Territories or Nunavut, the sales tax exemption certificate would be required on the purchasing document.

(c) Federal departments must pay the HST in the participating provinces of Newfoundland and Labrador, Nova Scotia, New Brunswick, Ontario and British Columbia.

(d) The Contractor is not exempt from paying PST under the above Exemption Licence Numbers or Exemption Certification. The Contractor must pay the PST on taxable goods or services used or consumed in the performance of the Contract (in accordance with applicable provincial legislation), including material incorporated into real property.

26.3 Changes to Taxes and Duties

If there is any change to any tax or duty payable to any level of government in Canada after the bid submission date that affects the costs of the Work to the Contractor, the Contract Price will be adjusted to reflect the increase or decrease in the cost to the Contractor. However, there will be no adjustment for any change that increases the cost of the Work to the Contractor 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 on its cost. There will be no adjustment if the change takes effect after the date required by the Contract for delivery of the Work.

26.4 GST or HST

The estimated GST or HST, if applicable, is included in the total estimated cost on page 1 of the Contract. The GST or HST is not included in the Contract Price but will be paid by Canada as provided in the Invoice Submission section above. The Contractor agrees to remit to Canada Revenue Agency any amounts of GST and HST paid or due.

26.5 Tax Withholding of 15 Percent

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 a non-resident, unless the Contractor obtains a valid waiver. The amount withheld will be held on account for the Contractor in respect to any tax liability which may be owed to Canada.

GC27. International Sanctions

27.1 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.

Details on existing sanctions can be found at:
http://www.dfait-maeci.gc.ca/trade/sanctions_en.asp.

- 27.2 The Contractor must not supply to the Government of Canada any goods or services which are subject to economic sanctions.
- 27.3 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 convenience in accordance with section GC9.

GC28. T1204 Government Service Contract Payment

- 28.1 Pursuant to regulations made pursuant to paragraph 221 (1)(d) of the Federal Income Tax Act, payments made by departments and agencies to Contractors under applicable services Contracts (including Contracts involving a mix of goods and services) must be reported on a T1204 Government Service Contract Payment. To enable client departments and agencies to comply with this requirement, Contractors are required to provide information as to their legal name and status, business number, and/or Social Insurance Number or other supplier information as applicable, along with a certification as to the completeness and accuracy of the information.

GC29. Successors and Assigns

The Contract shall enure to the benefit of and be binding upon the parties hereto and their lawful heirs, executors, administrators, successors and assigns as the case may be.

GC30. Conflict of Interest and Values and Ethics Codes for the Public Service

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, any applicable federal values and ethics code or any applicable federal policy on conflict of interest and post-employment shall not derive any direct benefit resulting from the Contract unless the provision or receipt of such benefit is in compliance with such legislation and codes.

GC31. No Bribe

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 entering into the Contract or the administration of the Contract.

GC32. Errors

Notwithstanding any other provision contained in this Contract, no amount shall be paid to the Contractor based on the cost of Work incurred to remedy errors or omissions for which the Contractor or his servants, agents or subcontractors are responsible, and such errors or omissions shall be remedied at the Contractor's cost, or, at the option of Canada, the Contract may be terminated and in that event the Contractor shall receive payment only as determined under section GC10.

GC33. Performance

The failure of Canada to require performance by the Contractor of any provision of this Contract shall not affect the right of Canada thereafter to enforce such provision, nor shall the waiver by Canada of any breach of any term of the Contract be taken or held to be a waiver of any further breach of the same or any other term or condition.

GC34. Gender

Whenever the singular or masculine is used throughout this Contract, it shall be construed as including the plural, feminine, or both whenever the context and/or the parties hereto so require.

GC35. Survival

All the Parties' obligations of confidentiality, representations and warranties set out in the Contract as well as any other the provisions, which by the nature of the rights or obligations might reasonably be expected to survive, will survive the expiry or termination of the Contract.

GC36. Severability

If any provision of the Contract is declared by a court of competent jurisdiction to be invalid, illegal or unenforceable, that provision will be removed from the Contract without affecting any other provision of the Contract.

GC37. Contingency Fees

The Contractor certifies that it has not, directly or indirectly, paid or agreed to pay and agrees that it will not, directly or indirectly, pay a contingency fee for the solicitation, negotiation or obtaining of the Contract to any person, other than an employee of the Contractor acting in the normal course of the employee's duties. In this section, "contingency fee" means any payment or other compensation that depends or is calculated based on a degree of success in soliciting, negotiating or obtaining the Contract and "person" includes any individual who is required to file a return with the registrar pursuant to section 5 of the Lobbying Act, 1985, c. 44 (4th Supplement).

GC38. Criminal Offense

The Contractor declares that the contractor has not been convicted of an offence, other than an offence for which a pardon has been granted, under section 121, 124 or 418 of the Criminal Code.

GC39. Public Disclosure

39.1 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.

39.2 The contractor consents, in the case of a contract with a former public servant in receipt of a Public Servant Superannuation (PSSA) pension, that the contractor'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 described in 39.1.

GC40. Notice

Any notice under the Contract must be in writing and may be delivered by hand, courier, mail, facsimile or other electronic method that provides a paper record of the text of the notice. It must be sent to the Party for whom it is intended at the address stated in the Contract. Any notice will be effective on the day it is received at that address. Any notice to Canada must be delivered to the Minister.

GC41. Accuracy

The Contractor represents and warrants that the information submitted with its bid is accurate and complete. The Contractor acknowledges that the Minister has relied upon such information in entering into this Contract. This information may be verified in such manner as the Minister may reasonably require.

GC42. Entire Agreement

The Contract constitutes the entire agreement between the Parties relative to the subject procurement 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 relative to the subject procurement binding on the Parties other than those contained in the Contract.

APPENDIX B **STATEMENT OF WORK**

1.0 Background:

In 2011, Canada's 2,792 rabbit farms sent almost 625,000 head for slaughter. This is an important, albeit small niche sector for many Canadian animal producers. However, there are very few drugs licensed for use in meat-producing rabbits. The lack of access to veterinary drugs has hampered efforts by producers to sustain and grow production. Further, several veterinary drugs are being used in an extra-label manner to treat diseases. The off-label use of these drugs has led to concerns over food safety, trade and animal production.

AAFC is requesting proposals to conduct clinical trials to demonstrate the efficacy and safety of specific veterinary drugs to treat enteric or respiratory diseases in rabbits under Canadian conditions, as well as associated residue depletion data for such drugs. The data generated by these trials will be used in regulatory submissions to the Veterinary Drugs Directorate (VDD) for approval for uses in rabbits. The tissue analysis must be conducted in accordance with OECD Good Laboratory Practice (GLP) standards.

2.0 Objective:

The objective is to conduct veterinary drug clinical efficacy and residue depletion trials of sufficient quality to meet data requirements for the registration of these products in rabbits. Only Health Canada approved products with a valid Drug Identification Number (DIN) are permitted to be used for the studies. Efficacy trials should be conducted preferably in accordance with principles of Good Clinical Practices. Residue trials must be conducted with high standards to meet the regulatory requirements. Analysis of tissue samples for incurred residues should be done in accordance with GLP standards. Please note that all live animal trials (clinical efficacy or residue depletion studies) where feasible should comply with the appropriate Animal Care Guidelines. (Guide to the Care and Use of Experimental Animals, by the Canadian Council on Animal Care (CCAC) (http://www.ccac.ca/en/_standards/guidelines)).

The list of trials and associated trial requirements are found in Appendix B - Annex 1 and Annex 2 of this RFP.

3.0 Scope of Work:

The contractor will carry out either or both of the following:

A. Efficacy and Animal Safety Trials:

- Locate a minimum of two Canadian commercial rabbit farms in which to perform the clinical efficacy trials;
- Identify a Study Monitor to oversee the day to day conduct of the trials;
- Identify a Principal Investigator who is responsible for relevant clinical trials and the writing of the final report including a comprehensive summary of the data, statistical analysis and an interpretation of the results;

- To develop a clinical trial protocol which is suitable to demonstrate efficacy and safety for in-field use of the drug product when used in rabbits (see Section 4.);
- File an Experimental Studies Application to Health Canada's Veterinary Drugs Directorate before trial initiation)*
- Oversee the conduct the clinical trial in accordance with the protocol developed; and
- Prepare and submit a final report to PMC.

B. Residue Depletion Studies Trials:

- To locate a research facility in which to perform the in-life phase of the residue depletion studies;
- To identify a Study Monitor to oversee the day to day conduct of the trials;
- To identify a Principle Investigator who is responsible for relevant residue depletion trials and the writing of final report including a comprehensive summary of the data and an interpretation of the results;
- To develop protocol appropriate for the Residue Depletion trial;
- File an Experimental Studies Application to Health Canada's Veterinary Drugs Directorate before trial initiation_*
- Oversee the conduct of the residue depletion trial in accordance with the trial procol;
- To locate an analytical laboratory in which to perform tissue residue analyses for the relevant marker residues, using validated assays for rabbit tissues under the GLP conditions; and
- Prepare and submit a final report to PMC.

* Successful bidders must submit an application for an Experimental Studies Certificate to Health Canada's VDD. Once the ESC has been reviewed, Health Canada will issue an Experimental Studies Certificate, pursuant to C.08.014 of the *Food and Drugs Act and Regulations*. More information pertaining to the Experimental Studies Certificate application, including fees for a food producing species, is provided at the following link:

4.0 Deliverables & Timelines:

Deliverables are to be submitted according to the schedule listed below.

Deliverable 1 – Set up phase: (To be completed within four weeks of contract signing)

1. Work plan including the exact location of the trial;
2. Study Plan/Protocol for efficacy trials for approval by AAFC before trial initiation;

3. Study Plan/ Protocol for human depletion trial for approval by AAFC before trial initiation;
4. Protocol for laboratory analysis indicating the analytical method that will be used with justification and any modification on the method with associated justification for AAFC approval before initiation (for human depletion trials only).

Deliverable 2 – Trial conduct: (To be completed within ten weeks after trial initiation)

1. Status report describing the trial setup including the exact location and pictures of the trial;
2. Results of clinical trials before and after treatment with the veterinary drug;
3. Results of lab analyses of human depletion trials samples.

Deliverable 3 – Reporting phase: (To be completed within twenty weeks after trial initiation)

1. Submission of all trial-related raw data;
2. Submission of final reports.

* Timelines are tentative and may be updated at the discretion of the Project Authority

5.0 Contract Duration

The contract will start at the signing of the contract until March 31st, 2016 but may be extended at the discretion of the Project Authority if required.

6.0 Location of Work and Travel

The work location will be at the contractor's premises. The contractor will be responsible for providing:

- Facilities for the trials, test animals, and drugs used;
- Laboratory facilities for residue analysis and all chemicals including reference items;
- Computer hardware and software for the preparation of and reports;
- Office supplies, courier services, specialized data processing hardware or software;
- Administrative support (word processing, photocopying etc.).

7.0 Language of Work

The working language for this contract is English.

8.0 Method of Payment

Upon approval of the deliverable(s), AAFC will accept invoices based on the instructions listed in Part 3.0, Section 11.0

9.0 Project Authority

The Project Authority for the Contract will be named at the time of contract award. The Project Authority is responsible for all matters concerning the technical content of the Work under this contract. Any proposed changes to the scope of the work are to be discussed with the Project Authority, but any resulting change can only be confirmed by a contract amendment issued by the Contracting Authority.

APPENDIX C
BASIS OF PAYMENT

The Contractor shall be paid in accordance with the following Basis of Payment for work performed pursuant to the resulting contract.

Note: The Basis of Payment shall be a FIRM FIXED PRICE CONTRACT OF \$ ___ * ___ (in Canadian dollars) FOR ALL AWARDED TRIALS INCLUSIVE OF ALL RELATED EXPENSES INCLUDING TRAVEL but excluding applicable taxes. Payment shall be in accordance with Article 11, of the terms and conditions, Method of Payment. The following terms shall form part of any resulting Payment Schedule.

1. All deliverables are F.O.B. Destination, and Canadian Customs Duty included, where applicable.
2. All payments are subject to Government Audit.
3. All prices and amounts of money in the Contract are exclusive of Goods and Services Tax (GST) or Harmonized Sales Tax (HST), as applicable, unless otherwise indicated. The GST or HST, whichever is applicable, is extra to the price herein and will be paid by Canada.

At time of contract award, a table identifying all awarded trials and the corresponding costs will be included in the Appendix.

(To be updated at time of contract award)*

APPENDIX D EVALUATION PROCEDURES & CRITERIA

TECHNICAL PROPOSAL

It is essential that the elements contained in the Proposal(s) be stated in a clear manner and in sufficient depth to allow for evaluation by the evaluation team.

1.0 METHOD OF SELECTION – HIGHEST COMBINED SCORE OF TECHNICAL MERIT AND PRICE FOR EACH TRIAL. ALL TRIALS WILL BE AWARDED SEPARATELY.

- 1.1 The evaluation process is designed to identify the most qualified contractor to provide services as stipulated in the Statement of Work (Appendix B).
- 1.2 This section comprises the detailed Proposal requirements that will be used to evaluate Proponents' responses to the Request for Proposal(RFP).
- 1.3 The mandatory requirements under section 2.0 will be evaluated on a compliant/non-compliant basis. The Proposals must include the necessary documentation to demonstrate this compliance.

Proponents must indicate whether they comply with the mandatory requirements below (section 2.0) and indicate the location (page, paragraph number, etc.) of the information provided in the technical proposal to support the requirements.

- 1.4 The selection of the responsive Proposal(s) will be made on the basis of the **HIGHEST OVERALL SCORE PER TRIAL** for both the technical and financial proposals. Highest overall score (per trial) will be determined by adding the technical and financial points obtained as demonstrated in section 1.5 below.

The Proponents' Technical and Financial proposals will be scored separately. An Overall Proposal Score will be determined by combining a Proponent's Technical Proposal Score and Financial Proposal Score in accordance with the following weights:

Technical Proposal = 90%

Financial Proposal = 10%

Overall Proposal = 100%

- 1.5 **To be considered responsive in each trial, a proposal must:**

- 1- Meet all the mandatory requirements specified in section 2.0 below;
- 2- Achieve a **minimum score of 70% in each of the rated criterion.**

The responsive Proposal(s) which receives the highest score of the combined points for the **Technical Proposal** rated requirements (**90%**) and the **Financial Proposal** rated requirements (**10%**) will be considered for contract(s) award in the related project(s).

$$\frac{\text{Technical Score} \times \text{Ratio (90)}}{\text{Max Points}} + \frac{\text{Lowest Price} \times \text{Ratio (10)}}{\text{Bidder's Price}} = \text{Combined Score}$$

Example of Method of Selection:

Highest Combined Rating Technical Merit (90%) and Price (10%)			
Calculation	Technical Points	Price Points	Total Points
Proposal 1 - Tech = 88/100 - Price = \$200.00	$\frac{88 \times 90}{100} = 79.2$	$\frac{*125 \times 10}{200} = 6.0$	= 85.2
Proposal 2 - Tech = 82/100 - Price - \$130.00	$\frac{82 \times 90}{100} = 73.8$	$\frac{125 \times 10}{130} = 9.62$	= 83.42
Proposal 3 - Tech = 76/100 - Price = \$125.00*	$\frac{76 \times 90}{100} = 68.4$	$\frac{125 \times 10}{125} = 10$	= 78.4
* Represents the lowest priced proposal Bidder 1 is successful with the highest combined rating of 85.2			

- 1.6 The cost of the Proposal(s) will be evaluated in CANADIAN DOLLARS, Goods and Services Tax (GST)/Harmonized Sales Tax (HST) excluded, FOB destination for goods/services, Customs Duties and Excise Taxes included.
- 1.7 Failure of a Proposal to provide information in sufficient detail and depth to permit evaluation against the identified criteria may render a Proposal non-responsive. **All proponents are advised that only listing experience without providing any supporting data to describe where and how such experience was obtained will not be considered to be “demonstrated” for the purpose of the evaluation. All professional experience must be fully demonstrated in the proposal (i.e., dates, number of years and months of experience). Valid contact information, related to the the example of experience, must be provided.**
- 1.8 The Proponents acknowledge and agree that Canada is not responsible to search for, and therefore evaluate, information that is not properly referenced or is not otherwise provided in accordance with the Proposal Preparation Instructions in Part 2, Article 3.0.
- 1.9 Proponents shall not place any conditions or make any assumptions that attempt to limit or otherwise modify the scope of Work pursuant to the Statement of Work (Appendix B).
- 1.10 In each respective trial and in the event that two or more responsive proposals achieve the identical COMBINED SCORE, the proposal with the **highest technical score** will be considered the successful proposal.
- 1.11 A contractor may bid on one or more trials. In order to be considered further, a proposal must meet all of the mandatory requirements and have at least the minimum points required for each of the rated criteria.

Among the proposals meeting these minima the highest-ranked combined score, for each trial, will be considered for contract award. **AAFC may award one or more trials to one proposer if that proposer was the highest ranked compliant proposer for each of the trials.**

2.0 MANDATORY REQUIREMENTS

THE FOLLOWING MUST BE PROVIDED FOR EACH TRIAL LISTED

Failure to comply with any of the mandatory requirements will render the Proposal non-compliant and the Proposal will receive no further consideration. The Proponent must include the necessary documentation to demonstrate this compliance.

Proponents should indicate the location (e.g. page, paragraph number, etc.) of the information provided in the Technical Proposal to support the mandatory requirements.

The mandatory and rated requirements for each of the two types of trials are described below.

1. Mandatories: Human Safety – Residue Depletion Trials

<p>M1. GLP compliance. The applicant must identify a GLP-compliant laboratory which is capable of quantifying the drug residue concentrations in rabbit tissues. The assay used by the contract laboratory must be validated, including matrix validation in rabbit tissues. Copy of GLP certification must be provided.</p>	<p>Evaluation based on GLP certification and all associated information as listed</p>
<p>M2. Study Facility. Provide evidence that a facility where the in-life phase of the study has been identified, and secured.</p>	<p>Evaluation will be based on statement indicating that the bidder has a site or document indicating with contact info that a facility for the study has been secured.</p>

2. Mandatories: Efficacy and Animal Safety Trials

<p>M1. Study Facility. Provide evidence that a facility where the in-life phase of the study has been identified, and secured.</p>	<p>Evaluation will be based on statement indicating that the bidder has a site or document indicating with contact info that a facility for the study has been secured.</p>
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3.0 POINT RATED REQUIREMENTS

*THE FOLLOWING MUST BE PROVIDED FOR EACH TRIAL LISTED

The Proponent must address the rated requirements and in sufficient detail so that an in-depth evaluation is possible. These criteria will be used by Agriculture and Agri-Food Canada to evaluate each Proposal. The assessment by AAFC will be based solely on the information contained in the Proposal. An item not addressed will be given zero (0) points under the point rated system. AAFC may, but is not obligated to, ask the Proponent for clarifications.

The rated requirements have been selected to provide evaluators the ability to assess bidder's capacity and ability to conduct the trial work for which a proposal has been submitted. The marking scheme reflects a balance between complexities of the criteria evaluated weighted towards the criteria deemed critical to the success of the trial (Each criteria will be marked according to completeness, clarity, and rationales provided).

**Total available points: Human Safety – Residue Depletion Trials – 100 points maximum
Efficacy and Animal Safety Trials – 100 points maximum**

Proponents should indicate the location (e.g. page, paragraph number, etc.) of the information provided in the Technical Proposal to support the rated requirements.

Human Safety – Residue Depletion Trials

<p>R1. Experience in the conduct of veterinary drugs residue depletion trials. If more than five previous trials are submitted, the first five listed will be used for evaluation purposes (<i>key participants in the team and their experience</i>)</p> <p>– 20 points maximum (14 min)</p>	<p>-20 points for having completed at least five trials. -17 points for having completed at least three trials -14 points having completed one trial.</p>
<p>R2. Understanding of the trial requirements (<i>in-life and analytical phases</i>)</p> <p>– 15 points maximum (10.5 min)</p>	<p>-5 points for clearly stating the trial objectives. -5 points for describing the requirement to generate the samples for analysis. -5 points for justifying the GLP nature of the trial and associated requirements.</p>
<p>R3. Constraints/challenges/risks and mitigation strategies (<i>inclusion/exclusion criteria, any adverse health effects</i>)</p> <p>– 15 points maximum (10.5 min)</p>	<p>-5 points for listing and describing adequately items that can influence the success of the trial. -5 points for describing how challenges and risks will be mitigated.</p>

<p>R4. Trial Conduct and conditions</p> <p><i>Please provide a brief description of the trial conduct, including test animals (breed, sex, ages, drug treatment (dose, duration, withdrawal period, etc.), animal husbandry procedure, feeding, and animal management) the use pattern, application type (e.g. drench, foliar, seed treatment), proposed equipment and harvest procedures and quantity.</i></p> <p>– 20 points maximum (14 min)</p>	<p>Full points will be awarded for explanation of trial conduct detail including all items described. (points will be deducted for missing information)</p> <p>-test animals (breed, sex, ages) 5 points</p> <p>-drug treatment (dose, duration, withdrawal period, etc.) 5 points</p> <p>-animal husbandry procedure 5 points</p> <p>-feeding and animal management 5 points</p>
<p>R5 Analytical phase</p> <p>– 35 points maximum (24.5 min)</p>	<p>-25 points for describing analytical method with a rationale for its use. Procedure for method validation and limits of detection and limit of quantification.</p> <p>-10 points for experience with the selected method.</p> <p>-7 points if experience is with related method only).</p>
<p>Total for rated requirements – 100 maximum</p>	

Efficacy and Animal Safety Trials

<p>R1. Experience in the conduct of veterinary drug's efficacy trials. If more than five previous trials are submitted, the first five listed will be used for evaluation purposes. (key participants in the team and their experience)</p> <p>– 20 points maximum (14 Min)</p>	<p>-20 points for having completed at least five trials.</p> <p>-17 points for having completed at least three trials</p> <p>-14 points having completed one trial.</p>
<p>R2. Describe your project team and their responsibilities and how they will be accountable.</p> <p>Include the following information:</p> <ul style="list-style-type: none"> • Identification of Principal Investigator, Test Site Manager and Quality Assurance auditor responsible for the specific trial • Describe previous experience with the drug (or related drug), <p>The following information should be attached to the proposal:</p> <ul style="list-style-type: none"> • Curriculum Vitae of Principal Investigator, Test Site Manager, Research Technicians and Quality Assurance personnel • One set of CV's is required per contractor in their proposal. It is not necessary to attach copies of cv's to each application form. <p>– 20 points maximum (14 min)</p>	<p>-10 points for a full team (PI, assistant) with roles defined.</p> <p>-5 points experience (5 or more years full points, less)</p> <p>-5 points for Quality assurance.</p>

<p>R3. Understanding of the trial requirements (<i>in-life and analytical phases</i>).</p> <p>– 15 points maximum (10.5 min)</p>	<p>-5 points for clearly stating the trial objectives. -5 points for trial design with justification, randomization. -5 points for describing how animals will be selected, etc.</p>
<p>R4. Constraints/challenges/risks and mitigation strategies (<i>inclusion/exclusion criteria, any adverse health effects</i>)</p> <p>– 15 points maximum (10.5 min)</p>	<p>-8 points for listing and describing adequately items that can influence the success of the trial. -7 points for describing how challenges and risks will be mitigated.</p>
<p>R5. Trial Conduct and conditions</p> <p>– 20 points maximum (14 min)</p>	<p>Full points will be awarded for explanation of trial conduct detail including all items described (points will be deducted for missing information). -test animals (breed, sex, ages) 5 points. -activity schedule (clinical exam, body -- weight, feed intake, etc.) 5 points. -animal husbandry procedure - 5 points. -feeding and animal management - 5 points.</p>
<p>R6 Efficacy assessment</p> <p>– 10 points maximum (7 min)</p>	<p>-5 points for a full description of assessment procedure with a justification. -5 points for describing statistical procedures and justification, using of controls, etc.) .</p>
<p>Total for rated requirements – 100 points maximum</p>	

4.0 FINANCIAL PROPOSAL

THE PROPONENT'S FINANCIAL PROPOSAL SHALL INCLUDE THE FINANCIAL PROPOSAL FORM ATTACHED TO THIS RFP AS APPENDIX D - ANNEX 3. THE FORM MUST BE PRINTED AND COMPLETED LISTING EACH TRIAL BEING BID UPON. THE TABLE MUST BE COMPLETED IN THE FORMAT AS INDICATED INCLUSIVE OF A COSTING BREAKDOWN AND A FINAL TOTAL COST OF THE TRIAL.

THE PROPONENTS COSTING (IN CANADIAN DOLLARS) IS FOR A FIRM, ALL INCLUSIVE PRICE COVERING ALL RELATED EXPENSES EXPECTED TO BE INCURRED IN THE COMPLETION OF THE PROPOSED WORK. ALL APPLICABLE TAXES MUST BE EXCLUDED, AS THESE WILL NOT BE USED IN THE PROPOSAL EVALUATION AND SELECTION PROCESS.

Note: The firm all-inclusive trial costing provided by the proponent must include all project related expenses such as; professional fees, materials, travel, facilities, long distance phone calls; printing / photocopying, sub-contracting, etc.

5.0 METHOD OF SELECTION

The selection of the contractor(s) will be made based on highest ranked compliant bid(s). The bidder that complies with the mandatory requirements, achieves a minimum score of 70 percent for each of the rated criteria and attains the highest combined score per trial will be considered for contract award.

APPENDIX E

CERTIFICATION REQUIREMENTS

The following certification requirements apply to this Request for Proposal (RFP) document. Proponents must include, with their proposal, a signed copy of this certification below.

A) ACCEPTANCE OF AGRICULTURE & AGRI-FOOD CANADA'S TERMS AND CONDITIONS

Proponents will accept Agriculture & Agri-Food Canada's terms and conditions.

The General Conditions in Appendix A and those set out in Part 3 of this RFP shall form part of the Resulting Contract

Name

Signature

Date

B) LEGAL ENTITY AND CORPORATE NAME (IDENTIFY CLEARLY WHETHER THE LEGAL ENTITY IS WITH THE UNIVERSITY/COLLEGE OR INDIVIDUAL)

Please certify that the Proponent is a legal entity, by indicating whether the Proponent is **i)** a sole proprietorship, partnership or corporate entity, **ii)** indicating the laws under which the partnership or corporate entity was registered or formed, **iii)** together with the registered or corporate name. Also identify **iv)** the country where the controlling interest/ownership (name if applicable) of your organization is located.

- i) _____
ii) _____
iii) _____
iv) _____

Any resulting Contract may be executed under the following **i)** corporate full legal name and **ii)** at the following place of business (complete address) **iii)** telephone and fax number and email:

- i) _____
ii) _____
iii) _____

Name

Signature

Date

C) EDUCATION/EXPERIENCE CERTIFICATION

We certify that all statements made with regard to the education and the experience of individuals proposed for completing the subject Work are accurate and factual, and we are aware that the Minister reserves the right to verify any information provided in this regard and that untrue statements may result in the proposal being declared **non-responsive** or in other action which the Minister may consider appropriate.

Name

Signature

Date

D) PRICE/RATE CERTIFICATION

"We hereby certify that the price quoted have been computed in accordance with generally accepted accounting principles applicable to all like services rendered and sold by us, that such prices are not in excess of the lowest prices charged anyone else, including our most favoured customer for like quality and quantity so the services, does not include an element of profit on the sale in excess of that normally obtained by us on the sale of services of like quality and quantity, and does not include any provision for discounts or commissions to selling agents".

Name

Signature

Date

E) VALIDITY OF PROPOSAL

It is requested that proposals submitted in response to this Request for Proposal be:

valid in all aspects, including price, for not less than one hundred and twenty (120) days from the closing date of this RFP; and,

signed by an authorized representative of the Bidder in the space provided on the RFP; and,

provide the name and telephone number of a representative who may be contacted for clarification or other matters relating to the Bidder's proposal.

Name

Signature

Date

F) AVAILABILITY AND STATUS OF PERSONNEL

The Proponent certifies that, should it be authorized to provide services under any contract resulting from this RFP, the employees proposed in its proposal will be available to commence performance of the work within a reasonable time from contract award, or within the time specified herein.

If the Proponent has proposed any person in fulfilment of this requirement who is not an employee of the Proponent, the Proponent hereby certifies that it has written permission from such person to propose the services of such person in relation to the work to be performed in fulfilment of this requirement and to submit such person's résumé to the Contracting Authority.

During the proposal evaluation, the Proponent MUST upon the request of the Contracting Authority provide a copy of such written permission, in relation to any or all non-employees proposed. The Proponent agrees that failure to comply with such a request may lead to disqualification of the Proponent's proposal from further consideration.

Name

Signature

Date

G) PUBLIC ORGANIZATIONS, UNIVERSITIES, NON-PROFIT AND CHARITABLE ORGANIZATIONS

Public organizations, universities, non-profit and charitable organizations who wish to submit a proposal for this requirement, must provide the following certification:

"We hereby certify that we have established ourselves as competing with the private industry in the normal course of business and are not given unfair competitive advantage either through subsidization or through the absence of any liability to pay corporate taxes."

Name

Signature

Date

H) FORMER PUBLIC SERVANT – STATUS AND DISLCOSURE

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

Definitions

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

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

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

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

Former Public Servant in Receipt of a Pension

As per the above definitions, is the Bidder a FPS in receipt of a pension?

Yes () No ()

If so, the Bidder must provide the following information, for all 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 report.

Work Force Reduction Program

Is the Bidder a FPS who received a lump sum payment pursuant to the terms of a work force reduction program? 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 reduction 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 the Goods and Services Tax or Harmonized Sales Tax.

Name

Signature

Date