Ministerial Agreement for Data Protection under the *Pest Control Products Act*

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Table of Contents

Foreword

This document outlines the Agreement that is prescribed by the Minister under section 66 of the *Pest Control Products Act*. The Agreement has to be entered into when an applicant wishes to follow the formal process specified in the *Pest Control Products Regulations* to rely on a registrant's compensable data to register a generic product. The Agreement is to be used in conjunction with the *Pest Control Products Act* and *Pest Control Products Regulations*.

THIS AGREEMENT made in duplicate the day of , 201...

BETWEEN : (Name of registrant data provider)
(hereinafter referred to as "the Registrant")

AND: (Name of generic product applicant)
(hereinafter referred to as "the Applicant")

WHEREAS the Registrant is the owner of a registration under the *Pest Control Products Act* (PCPA) of a pest control product known as (name of product):

AND WHEREAS the Applicant is the owner of a pest control product known as (name of product), the active ingredient of which has been determined by the Minister of Health ("the Minister") under the PCPA to be equivalent to the active ingredient in (name of registrant's product);

AND WHEREAS the Applicant wishes to obtain the right to use or rely on data provided by the Registrant under the PCPA in relation to (name of Registrant's product) in support of the Applicant's application to register (name of Applicant's product) by complying with the *Regulations Amending the Pest Control Products Regulations* - SOR/2010-0119 – under the PCPA ("the regulations") regarding the payment of compensation;

AND WHEREAS the Applicant wishes to enter into negotiations with the Registrant in accordance with the regulations for the purpose of determining the compensation that would have to be paid in accordance with the regulations to register the Applicant's product using or relying on the data identified in Appendix "A" if the Applicant should decide to continue pursuing that application;

AND WHEREAS the Registrant wishes to comply with the requirements of the regulations regarding the determination of the compensation to be paid by the Applicant to the Registrant in compliance with the regulations for the right to use or rely on those data;

NOW THEREFORE the Applicant and Registrant covenant and agree as follows:

Article 1 No obligations created

This Agreement does not impose on the Applicant an obligation to continue pursuing the registration of a pest control product. The determination of compensation payable and the method of such payment is intended only to enable the Minister to decide what the Applicant must do to satisfy the regulatory requirements if the Applicant decides to continue pursuing the registration application.

Article 2 Negotiations Period

During the period of one hundred and twenty (120) days beginning on the day after the date of the delivery of this Agreement in accordance with the regulations, or any extended time on which the parties have agreed, the parties shall enter into negotiations for the purpose only of determining the compensation payable and the method and security of such payment for the right to use or rely on the data identified in Appendix "A".

The 120-day period specified in the previous paragraph is reduced to 60 days from the day after the date of the delivery of this Agreement in the circumstances specified in the Transitional Section 3 of the regulations.

Article 3 Conduct of Negotiations

The parties may elect to enter into direct negotiations for the whole duration of the negotiations period or for a limited period. The parties may decide to seek the assistance of a third party neutral to facilitate their negotiations, including through mediation, at any time during the period of direct negotiations.

The parties shall follow the steps described in Appendix "B", unless the parties agree otherwise, for the conduct of their negotiations within the time period determined in accordance with Article 2.

Article 4 Negotiated Settlement

Where a settlement is reached through the conduct of negotiations in accordance with Article 3, the parties shall sign a settlement agreement.

Article 5 Arbitration

If the parties fail to conclude a negotiated settlement within the time period determined in accordance with Article 2, the applicant may deliver to the registrant a written notice requiring that the determination of the compensation payable and the method, and security, of such payment be submitted to binding arbitration.

Article 6 Arbitration Period

Where written notice has been delivered, the arbitration begins on the day after delivery of the written notice in accordance with the regulations. The arbitration ends when the parties reach a negotiated settlement or an arbitral award is issued.

The duration of the arbitration shall not exceed 120 days since commencement of the arbitration period unless the parties agree to an extension. The arbitrator when informed of the parties' agreement on an extension may delay the delivery of an arbitral award until the extended period expires.

Article 7 Conduct of arbitration

The Applicant and the Registrant shall conduct the arbitration in accordance with the rules prescribed in Appendix "C", unless the parties agree otherwise.

Article 8 Confidentiality and Privacy

The parties shall comply with the confidentiality and privacy requirements set out in Appendix "D" unless the parties agree otherwise, except with respect to matters provided in section 5.

Article 9 Delivery of Information to the Minister

When a negotiated settlement is reached or an arbitral award is issued, if the Registrant has not provided a letter of access and the Applicant wishes to pursue the registration, the Applicant may deliver proof to the Minister of compliance with the settlement or arbitral award for the purpose of administering sections 16(4)(*e*) and 17.94(2) of the regulations.

Article 10 Compensation Principles

The parties shall have regard to the document attached as Appendix "E".

Article 11 Last Offers

For purposes of the regulations, a party's last offer will be presented in the form provided in Appendix "F".

Article 12 Proprietary Interest in Data

The Applicant will not claim a proprietary interest in data which they obtained the right to use or rely on in accordance with the regulations.

Article 13 Applicable Law

Except as otherwise indicated herein, this Agreement shall be subject to, and construed in accordance with, the laws in _____ (*specify the name of the Canadian jurisdiction).* If the parties fail to specify a Canadian jurisdiction the laws in Ontario apply.

IN WITNESS THEREOF, the parties have signed

Executed on behalf of the Applicant by: In the presence of:

_____ _____

(Name and title of signatory) (Witness)

Date:

Executed on behalf of the Registrant by: In the presence of:

_____ _____

(Name and title of signatory) (Witness)

Date:

List of Appendices

Appendix A: List of Compensable Data

Appendix B: Conduct of Negotiations

Appendix C: Rules of Arbitration

Appendix D: Confidentiality and Privacy

Appendix E: Compensation Principles

Appendix F: Last Offers Form

Appendix A Compensable Data

The parties will provide here the list of compensable data for which a letter of access will be requested.

Appendix B Conduct of Negotiations

PART A: DIRECT NEGOTIATIONS

First Meeting

1. The parties will convene their first direct negotiations meeting within 10 days after the delivery of the agreement in accordance with the regulations unless the parties agree otherwise.

Organizational Matters

2. Before the first scheduled meeting, the parties will discuss and attempt to reach agreement on organization matters (e.g. time, date, location and participants) that will facilitate their direct negotiations.

3. No transcript or recording will be kept of the direct negotiations, but this does not prevent a party from keeping its own notes of the negotiations.

Role of the Parties

4. The parties will attempt to obtain a negotiated settlement by
   a. identifying underlying interests;
   b. isolating points of agreement and disagreement;
   c. exploring alternative solutions;
   d. considering compromises or accommodations; and
   e. taking any other measures that will assist in the determination of the compensation payable by the Applicant to the Registrant.

5. The parties undertake to communicate and exchange information during the negotiation process and make serious efforts to obtain a negotiated settlement in accordance with Article 3.

Termination of Direct Negotiations

6. Direct negotiations are terminated when any of the following occurs:
   a. the negotiation period (120 days) or as extended by agreement of the parties , expires and no settlement has been reached ;
   b. the parties agree in writing to submit the matter to arbitration in accordance with the agreement prior to the expiration of the negotiation period; or
   c. the parties reach a settlement and sign a written agreement resolving the determination of the compensation payable by the Applicant to the Registrant and the method, and security, of payment.

Suspension of Direct Negotiations

7. The parties may agree to suspend their direct negotiations if they decide to seek the assistance of a third party neutral to facilitate their negotiations, including through mediated negotiation as provided in Part B.

Costs of Direct Negotiations

8. Each party shall bear its own costs with respect to the conduct of direct negotiations. Any common costs will be shared equally between the parties.

Last Offers

9. When the direct negotiations between the parties are terminated pursuant to section 6 paragraphs a and b, each party may present a last offer in writing to the other party in accordance with the regulations. It is agreed that the last offers will be made in the form annexed hereto as Appendix F.

Negotiated Settlement

10. For the purposes of sections 16(4)(*e*) and 17.94(2) of the regulations an applicant may deliver to the Minister a redacted version of a settlement agreement that shall disclose the identities of the parties, the identity of the registrant's product, the amount and method, and security, of payment of the compensation payable, the identities and signatures of the signatories and the date of execution of the settlement agreement for the purpose of providing proof of compliance with the settlement.

PART B: MEDIATED NEGOTIATION

Choice of Mediator

11. Further to the parties' agreement to suspend their direct negotiations in accordance with section 7 above, the parties have appointed _____ / will appoint a third party neutral to assist them in their negotiations and act as mediator within five days if the suspension of the negotiations. Where the parties cannot agree upon the choice of a mediator at the expiration of the 5-day period, the parties shall apply within the next 10-day period to the ADR Institute of Canada for the appointment of a mediator.

First Mediated Negotiation Session

12. The mediator will convene the parties to a mediated negotiation session within 10 days of being appointed unless the parties agree otherwise.

Role of the Mediator and the Parties

13. The mediator's duty is to facilitate the negotiations between the parties and assist them to reach their own settlement. The mediator has no duty to assert or protect the legal rights of any party, to raise any issue not raised by the parties themselves, or to determine who should participate in the mediated negotiation.

14. The parties undertake to communicate and exchange information during the mediated negotiation process and make serious efforts to obtain a negotiated settlement in accordance with Article 3. The parties and/or their representatives attending the mediated negotiation will have the authority to reach a settlement in this matter, or will have the means to readily and rapidly obtain that authority.

15. No transcript or recording will be kept of the negotiations during the mediated negotiation, but this does not prevent a party or the mediator from keeping their own notes. Any notes prepared or written by the mediator shall be destroyed at the time of the termination of the mediated negotiation.

Termination of the Mediated Negotiation

16. (1) The mediated negotiation is terminated when any of the following occurs:

a. the negotiation period (120 days) or as extended by agreement of the parties, expires and no settlement has been reached;
b. the parties agree in writing to submit the matter to arbitration in accordance with the agreement prior to the expiration of the negotiations period; or
c. the parties reach a settlement and sign a written agreement resolving the determination of the compensation payable by the Applicant to the Registrant and the method, and security, of payment.

(2) The mediated negotiation can also be terminated when a party engaged in the mediated negotiation either advises the other party and the mediator in writing of its intention to withdraw from the mediated negotiation or is deemed by the mediator to have abandoned the process. The termination does not terminate the direct negotiations unless the negotiation period (120 days) or as extended by agreement of the parties has expired and no settlement has been reached.

Costs

17. The parties agree to share equally the mediator's fees and the costs of the mediated negotiation session, such as the mediator's travel expenses and rental costs. Each party shall bear its own costs with respect to the conduct of the mediated negotiation.

Last Offers

18. When the mediated negotiation is terminated pursuant to section 16 (1), a or b, each party may present a last offer in writing to the other party in accordance with the regulations. It is agreed that the last offers will be made in the form annexed hereto as Appendix F.

Appendix C Conduct of arbitration

1. Scope of the Rules

1.1 The Rules on the conduct of arbitration set out in this Appendix apply to the arbitration of disputes between the parties arising under the *Pest Control Products Act* (PCPA) in relation to the use of or reliance on compensable data for the purposes authorized or permitted by the PCPA.

1.2 The *Commercial Arbitration Act* (CAA) shall apply to the arbitration process conducted under the Rules set out in this Appendix or any other rules the parties may agree on for the purpose of the arbitration. In the event that any such rule is in conflict with the provisions of the CAA, the provisions of the CAA shall prevail.

2. Appointment of Arbitral Tribunal

2.1 The parties shall designate an Arbitral Tribunal, consisting of either a single arbitrator or more than one arbitrator, to preside over the arbitration process within 5 days, unless the parties agree otherwise, of the delivery by the Applicant of the notice in writing to submit to binding arbitration in accordance with the regulations. Where the parties agree upon a single arbitrator but cannot agree upon the identity of that arbitrator at the expiration of the 5-day period, the parties shall apply within the next 10-day period, unless the parties agree otherwise, to the ADR Institute of Canada, or alternatively, to a judge of the Federal Court of Canada for the appointment of an arbitrator.

2.2 In accordance with Article 10(2) of the *Commercial Arbitration Code* appended to the *Commercial Arbitration Act*, where the parties are unable to agree upon the number of arbitrators the number of arbitrators shall be three, and each party shall appoint one arbitrator within 5 days, unless the parties agree otherwise, of the delivery by the Applicant of the notice to submit to binding arbitration. Those two arbitrators so appointed shall jointly appoint a third arbitrator within 5 days of their appointment, or failing their agreement at the expiration of the 5-day period, the parties may apply within the next 10-day period, unless the parties agree otherwise, to the ADR Institute of Canada, or alternatively, to a judge of the Federal Court of Canada for the appointment of a third arbitrator. The appointed third arbitrator shall act as chair of the Arbitral Tribunal.

2.3 Where an Arbitral Tribunal consists of more than one arbitrator, the parties may agree or the Arbitral Tribunal may decide, after hearing the submissions of the parties, to delegate the determination of some or all pre-hearing procedural matters to the chair of the Arbitral Tribunal.

2.4 Unless otherwise agreed by the parties, a person appointed to Arbitral Tribunal shall be and remain at all times wholly independent and shall not act as an advocate for any party to the arbitration.

2.5 Every arbitrator shall, before accepting an appointment, sign and deliver to the parties a statement declaring that he or she knows of no circumstances likely to give rise to a reasonable apprehension of bias and that he or she will avoid and disclose to the parties any such circumstances arising after that time and before the arbitration is concluded.

2.6 Any arbitrator who is unable to serve or to continue to serve due to disqualification, death or disability shall be replaced in the same manner as his or her original appointment.

3. Binding Arbitration Method

3.1 Final offer arbitration shall be the binding arbitration method used by the Arbitral Tribunal to determine awards under these rules. The Arbitral Tribunal shall have regard to Appendix E.

3.2 The last offers provided by the parties in accordance with the regulations at the termination of the negotiation period pursuant to Appendix B are their final offers for purposes of the arbitration.

3.3 If either party fails to provide a last offer in accordance with the regulations that party shall provide a final offer for purposes of the arbitration within 5 days of the appointment of the Arbitral Tribunal, unless the parties agree otherwise. It is agreed that the final offer will be made in the form annexed hereto as Appendix F.

3.4 The Arbitral Tribunal shall, in conducting a final offer arbitration, have regard to the information provided to the arbitrator by the parties in support of their final offers and, unless the parties agree to limit the amount of information to be provided, to any additional information that is provided by the parties at the Arbitral Tribunal's request.

3.5 The decision of the Arbitral Tribunal in conducting final offer arbitration shall be the selection by the arbitrator of the final offer of either of the parties, including the terms and conditions for the payment of compensation. If there is more than one arbitrator, the decision of the Arbitral Tribunal shall be made by a majority of all its members.

4. Communications

4.1 Any notification or communication to the Arbitral Tribunal or to a party or its designated Representative may be delivered by certified or registered mail, or any other method that would provide proof of delivery at a location identified for such purpose by the Arbitral Tribunal and each party.

4.2 No party or person acting on behalf of a party may communicate *ex parte* with the Arbitral Tribunal, except as directed by the Arbitral Tribunal, or where the communication is initiated by the Arbitral Tribunal for the purposes of administrative coordination of the arbitration.

5. Case management procedure or procedural conference

5.1 The Arbitral Tribunal may convene a procedural conference within 5 days, unless the parties agree otherwise, of the appointment of the Arbitral Tribunal, and, where the Arbitral Tribunal consists of more than one arbitrator, of the last member of the Arbitral Tribunal to resolve procedural or administrative issues. A procedural conference agenda may be created to assist any discussions involving the identification and clarification of the issues in dispute. The questions to be addressed at a procedural conference may include:

1. Should the hearing be oral or based on submitted documents and written interrogatories posed to the parties by the Arbitral Tribunal?
2. If an oral hearing is not required how much time will be required for the production of documents and responses?
3. If an oral hearing is required how much time will be required and where should the oral hearing be held?
4. If an oral hearing is required should the evidence be pre-filed in written form under statutory declaration to facilitate cross-examination? Where multiple witnesses will be cross-examined is it appropriate to allow for cross-examination of a panel of witnesses?
5. To what extent, and pursuant to what procedure, will there be any disclosure and production of facts and documents?
6. Should time be scheduled for the hearing of any issues with respect to pre-hearing disclosure?
7. Are there any specific issues of confidentiality that the Arbitral Tribunal should address?
8. Are the parties willing to jointly prepare briefs or legal authorities for use in the arbitration?
9. Can the parties agree on time limits and a schedule for the introduction of *viva voce* evidence?
10. Will expert evidence be required? Are any special rules relating to experts required?
11. What language will be used in the arbitration?
12. Should final argument be oral or written? If oral argument is necessary should there be a time limit? Should there be a timetable for delivery of written argument? Should there be any special procedures for reply argument by the applicant on any new point raised by the registrant?
13. Should the parties agree on a provisional timetable with timelines other than the ones provided in these Rules?

5.2 Procedural conferences will take place by telephone conference call, unless otherwise agreed.

5.3 The Arbitral Tribunal shall issue a procedural order and record any agreement made at any procedural conference and shall promptly send a copy of such order or record to each of the parties.

6. Compliance with the provisional timetable

6.1 The Arbitral Tribunal and the parties should make all reasonable efforts to comply with the provisional timetable provided in these Rules or the one they have agreed upon. Extensions and revisions of the timetable can be made by the parties or by the Arbitral Tribunal within the 120-day arbitration period or as extended by the parties.

6.2 The Arbitral Tribunal shall conduct the arbitration process as expeditiously as possible and, subject to the timetable to in Section 6.1, in the manner the Arbitral Tribunal considers appropriate having regard to the circumstances of the matter.

7. Written proceedings only

7.1 The Arbitral Tribunal may dispense with an oral hearing if the parties agree that an oral hearing is unnecessary given the issues in dispute. In such case, the Arbitral Tribunal shall set timelines for the presentation of written evidence and submissions.

7.2 Where a documents-only arbitration is convened in accordance with section 7.1, each party may direct interrogatories to the other seven (7) days after having received communications from the Arbitral Tribunal or the other party, and the other party shall answer the interrogatories within fourteen (14) days, unless the parties agree otherwise.

7.3 The deadline for any final written evidence and submission should be within twenty (20) days after the interrogatories are done unless the parties agree otherwise. Written evidence shall be submitted pursuant to a statutory declaration.

8. Need for a hearing

8.1 If an oral hearing is required, then following the first procedural conference the Arbitral Tribunal shall determine if further procedural conferences are required and either set the dates for those procedural conferences, or establish the timelines for any other procedural matters and the date for an oral hearing for the arbitration, which date should be within forty (40) days of the first procedural conference unless the parties agree otherwise.

8.2 In the case where an oral hearing is required, then, unless the Arbitral Tribunal otherwise directs or unless the parties agree otherwise:

1. Sworn statements of evidence shall be filed in advance of the hearing in lieu of examination-in-chief and witnesses shall be subject only to cross-examination and re-examination in accordance with timelines to be set following the first procedural conference;
2. The oral hearing, including oral arguments, shall be completed within five (5) days unless the parties agree otherwise; and
3. No transcripts of the proceedings shall be required.

8.3 The parties may agree that an oral hearing of the arbitration may also take place by telephone conference call.

9. Additional Evidence

9.1 At any time during the arbitration process, the Arbitral Tribunal may, subject to section 3.4, request any party to provide further evidence or submissions in such a manner as it determines.

9.2 The Arbitral Tribunal may, at any time, seek independent advice on any matter in dispute from any person or review and take notice of relevant facts or law provided that the parties shall be given notice and provide input as well as have the opportunity to review the content of the advice and make submissions thereon. At the request of a party, the Arbitral Tribunal may require that the person providing such advice attend the hearing and answer questions posed by any party or the Arbitral Tribunal.

10. Termination of the arbitration

10.1 The arbitration is terminated by a final award issued by the Arbitral Tribunal or the entering into a settlement agreement by the parties.

11. The Award

11.1 The Arbitral Tribunal will render its award within a reasonable time period after the close of the oral hearing, or the presentation of written Reply argument but no later than 120 days from the commencement of the arbitration or as extended by the parties.

11.2 The award shall set out the nature of the issues in dispute, the final decision regarding the final offers presented, the terms and conditions for the payment of compensation, including the payment of compensation in accordance with a schedule of payments, any order or further direction with respect to costs and interest on the award, and the facts and the law to the extent the Arbitral Tribunal deems them necessary to explain its award. When money has been put in escrow, the Arbitral Tribunal shall direct that funds be released to the Registrant in accordance with the award.

11.3 When issuing an award the Arbitral Tribunal shall also provide the parties with a signed copy of a summary of, or extract from, the award which shall include the identities of the parties to the arbitration, the identity of the registrant's product, the amount and method, and security, of payment of the award and the date on which the award was issued.

11.4 When providing the Minister with proof of compliance with an award for the purpose of administering sections 16(4)(e) and 17.94(2) of the regulations, an applicant may include the summary or extract that was provided by the Arbitration Tribunal in accordance with section 11.3.

12. Costs of Arbitration

12.1 The costs of the arbitration including facility costs, independent advisor fees, translation costs, and the fees and disbursements of the Arbitral Tribunal shall be fixed by the Arbitral Tribunal and shall be allocated between the parties in equal shares. The parties shall be jointly and severally responsible for the payment of all costs fixed by the Arbitral Tribunal, unless the parties and the Arbitral Tribunal have otherwise agreed and have confirmed those arrangements in writing.

12.2 The legal fees and disbursements incurred by the parties may be allocated by the Arbitral Tribunal based on the merits of the dispute. The Arbitral Tribunal shall apply the principle that parties shall each bear their own legal fees and disbursements but the Arbitral Tribunal may vary that allocation in its discretion, taking into account the subject matter in dispute, the outcome, and the conduct of the parties prior to and during the arbitration.

Appendix D Confidentiality and Privacy

Confidentiality and Privacy

1. Any direct or assisted negotiation or arbitration convened pursuant to this Agreement is confidential and private. Only the parties, their representatives and advisors may attend the negotiation or arbitration. Other persons may only attend with the consent of the parties.
2. Any person involved in a negotiation or arbitration in accordance with section 1 shall agree to be bound by this Appendix or any other similar undertaking.
3. The mediator or arbitrator shall not be compelled to disclose such records or to testify in any adversarial or judicial forum. The parties agree not to subpoena or require the testimony of the mediator or arbitrator or to produce records or notes.

Inadmissibility of Information Disclosed in Negotiation or Mediated Negotiation

4. The parties will not rely on or introduce as evidence in any proceeding, including an arbitration under this Agreement whether or not that arbitration relates to the subject matter of the negotiations, any oral or written information disclosed in or arising from a direct or mediated negotiation under this Agreement, including:

a. any documents of other parties produced in the course of the direct or mediated negotiation that are not otherwise produced or producible;
b. any views expressed, or suggestions made, by any party in respect of a possible settlement of the matter;
c. any admissions made by any party in the course of the direct or mediated negotiation, unless otherwise stipulated by the admitting party; and
d. the fact that any party has indicated a willingness to make or accept a proposal for settlement.

Exception to Non Disclosure

5. No oral or written information concerning the existence of the direct or assisted negotiation or arbitration, or anything which occurs or is disclosed within the direct or assisted negotiation or arbitration shall be disclosed or used outside of that process, or for any other purpose by a party except:

a. for any administrative purpose in conducting a direct or assisted negotiation or arbitration;
b. in connection with an application to a court for interim relief or to set aside, recognize or enforce an agreement or an arbitral award;
c. to the Minister in relation to the enforcement or administration of the Act;
d. where a party is required to do so by law or by a court or competent regulatory body;

and in the case of an arbitral award,

e. to assist future Arbitral Tribunals as set out in accordance with the Act ; or
f. to an independent expert for the sole purpose of assisting an arbitral tribunal in its understanding of the issues under its jurisdiction.

Supplementary Confidentiality Agreement

6. The parties may enter into a specific confidentiality agreement governing the disclosure of oral or written information to be used by the parties in negotiation or arbitration, subject to the rule provided in section 4.

Ruling on Confidentiality by the Arbitral Tribunal

7. An Arbitral Tribunal may at any time determine a procedure to rule upon a claim by any party that certain information must be kept confidential and may rule upon how that information will be treated during and after the arbitration process.

Appendix E Compensation Principles

Introduction

These compensation principles are for consideration in the determination of financial compensation under the regulations for data protection. These principles are intended as a tool for use by arbitrators in rendering decisions with respect to the amount of financial compensation to be awarded during the arbitration process as well as to aid parties in reaching a negotiated settlement. These principles are not formally binding on any party. The arbitrator will retain discretion under the final offer binding arbitration process in deciding which party's compensation offer to accept.

The compensation principles seek to balance the range of stakeholder interests that may be affected, directly or indirectly, by the functioning of the data compensation process. While each process may raise unique issues, it is expected that certain questions regarding compensation – in particular, on what basis data costs should be determined; the sharing of data costs between parties; and whether and how other potential adjustments should be addressed – will arise regularly during data compensation processes. The purpose of compensation principles is to encourage consistency and predictability in how such issues are considered in the determination of financial compensation.

The absence of wording on other potential principles or factors should not be construed as deterring parties from raising them for consideration. It is expected that these principles will evolve as experience is gained with the pesticide data compensation system.

Compensation Principles

Eligible Data Costs and Calculation of Costs

The scope of compensable data costs should reflect the broad range of activities undertaken by the data owner to develop and conduct studies, and to analyse data that are used in support of a registration. These may include costs incurred for review by senior scientific experts, overhead, and regulatory submission costs, as well as costs for the development of data, including pilot studies and repeated studies, if valid reasons for the repetition can be demonstrated.

Use of reasonable methods to estimate costs are considered appropriate in instances where actual, historic cost information (e.g., invoice records) is unavailable or incomplete.

Note that in some situations, data may be relied upon by PMRA – and therefore be subject to compensation – long after it was originally generated. Discounting costs based on the age of data is not recommended. Instead, where these circumstances arise, it may be appropriate to determine compensation based on a reasonable estimate of the present day costs that would be incurred if this data were to be re-generated.

Basis of Compensation

Compensation should be determined on the basis of the cost of data rather than the value of the data. “Value-based” claims for compensation – based on such factors as the market share that an applicant anticipates securing; the “early entry” benefits that may accrue to applicants when they rely on data rather than generating their own data; or “lost” revenues of data owners expected as a result of the entry of a generic competitor – should be discouraged.

Adjustments to data costs

A recommended approach for addressing key adjustments is as follows:

> *Inflation* – adjusting compensation by applying an established index (e.g., Consumer Price Index) from the period the compensable data was generated may be appropriate.
>
> *Interest on studies* – Where an applicant's registration precedes the determination of a compensation award, an interest charge accrued from the point at which the compensable data is relied upon -- normally the date of the applicant's registration -- may be appropriate. In the case of re-evaluation where a registrant wishes to rely on data submitted by another registrant to support continued registration, interest may accrue: on the basis of when the data costs were incurred (where data was generated in response to a data call-in); or on the basis of when the data was submitted to PMRA (where data had already been generated but had not been provided to PMRA).
>
> *Financial/Investment Risk Premium* – Taking a broad approach to the scope of compensable costs (as recommended in Eligible Data Costs above) represents an appropriate method to recognize the activities and efforts undertaken by data owners. Claims for an additional adjustment to the cost of compensable data to reflect financial risks borne by data owners to successfully obtain or maintain a registration should generally be discouraged. However, an adjustment may be appropriate in the context of data generated in response to re-evaluation – in particular, where a registrant opts not to partner with other registrant(s) to generate data, such that the registrant has enjoyed continuous access to the market without assuming the costs borne by other registrants in generating the data.

Cost Sharing

Compensation should be based on an equitable sharing of costs between a data owner and follow-on applicants, to the extent possible. Where data compensation for the same data has already been paid by another generic previously, an award in a subsequent process could be based on the determined cost of data divided by the number of applicable parties (e.g., the data owner, the generic that paid compensation in the first process, and the applicant in the subsequent process).

Arbitration decisions may include provisions regarding future adjustment to the compensation amounts paid in the event that another party subsequently provides compensation for the same data. Since the data subject to compensation may vary over time, it would be important to identify data compensation awarded by specific study in order for this approach to be practicable.

Appendix F Form of Last Offer for use in relation to a generic application

IN THE MATTER of the *Pest Control Products Act* and
the Regulations thereunder

LAST OFFER

WHEREAS subsection 17.91 (2) of the regulations provides for the presentation by the registrant and applicant to one another of their last offers in writing where the negotiations end without a settlement of the compensation payable having been reached;

AND WHEREAS the negotiations between (identity of registrant) and (identity of the applicant) have ended without a settlement having been reached;

AND WHEREAS the (the registrant or applicant, as the case may be) wishes to comply with that subsection;

AND WHEREAS it is acknowledged that this last offer will be the final offer for purposes of arbitration in accordance with Appendix C if the matter is submitted to arbitration

NOW THEREFORE (identity of the registrant or applicant) presents hereby its last offer to (identity of applicant or registrant) as the compensation to be paid by the applicant for the right to rely on the compensable data identified in Appendix A, as follows:

1. The amount of the offer is .....payable in ..(Canadian or US).. currency .

2. The payment is to be made in a lump sum.

OR

3. (a) The payment is to be made in ...(Number) ... equal annual installments on the anniversary of the first such payment ,.

OPTIONAL

(b) Security in the form of...(type)...is to be provided in relation to future installments, and

(c) Interest at the rate of ..... on future installments is to be paid at the time of payment of an installment .

IN WITNESS WHEREOF, this last offer has been

Executed on behalf of the (registrant or applicant) by: In the presence of:

_____ _____

(Name and title of signatory) (Witness)

Date: