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# Consultation on the Proposed Ministerial Agreement for Data Protection under the *Pest Control Products Act*

*(publié aussi en français)*

**26 November 2009**

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## **Foreword**

This document outlines the Ministerial Agreement that would be prescribed by the Minister under section 66 of the *Pest Control Products Act*. The Agreement would have 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. A similar Agreement would be used when the Minister requests data for a re-evaluation or special review. The Agreement is intended to be used in conjunction with the *Pest Control Products Act* and Pest Control Products Regulations.

Please forward written comments on the proposed Agreement to Regulatory Affairs by 29 January 2010 (see contact information on cover page).



## 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 are 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 of such payment for the right to use or rely on the data identified in Appendix "A".

## 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" 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 which sets out the compensation payable and the method of such payment.

## 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 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.

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".

Article 8      Confidentiality and Privacy

The parties shall comply with the confidentiality and privacy requirements set out in Appendix "D".

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 a copy of the settlement or arbitral award to the Minister for the purpose of determining what the Applicant must do in accordance with the regulations in order to obtain a registration.

Article 10     Data Compensation Guideline

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 of the Province of Ontario.

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 Data Compensation Guideline

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.*



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## **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.

#### **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 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.

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## Part B: Mediated Negotiation

### Choice of Mediator

9. 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.

### First Mediated Negotiation Session

10. The mediator will convene the Parties to a mediated negotiation session within 10 days of being appointed.

### Role of the Mediator and the Parties

11. 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.
12. 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.
13. 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

14. (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. a Party engaged in the mediated negotiation advises the other Party and the mediator in writing of its intention to withdraw from mediated negotiation at a later date that is not sooner than 60 days after the commencement of the negotiation period;
  - c. a Party engaged in the mediated negotiation is deemed by the mediator to have abandoned the process for failure to participate in a scheduled meeting or otherwise, without explanation, but not sooner than 60 days after commencement of the negotiation period;
  - d. 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
  - e. 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 of payment.
- (2) Termination of the mediated negotiation in accordance with paragraph b or c of subsection (1) does not terminate the direct negotiations.

**Costs**

15. The Parties agree to share 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.



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## Appendix C Conduct of Arbitration

### 1. Scope of the Rules

- 1.1 The Rules on the conduct of arbitration apply to disputes between the Parties arising under the Act in relation to the use of or reliance on compensable data for the purposes authorized or permitted by the Act.
- 1.2 These Rules shall be interpreted liberally with the object that the Parties enter into arbitration in a manner that is as inexpensive and expeditious as reasonably possible, consistent with a process that is fair, and suitable to the circumstances of the particular case. Any procedural question or controversy on which the Parties are not in agreement may be resolved by the application of the discretion of the Arbitral Tribunal designated by the Parties in conducting the arbitration.
- 1.3 In applying the Rules, the Arbitral Tribunal shall have regard to the Appendix E.
- 1.4 Any procedures or time periods arising under these Rules may be modified by the written consent of both Parties, in their discretion.

### 2. Law of the Arbitration

- 2.1 The *Commercial Arbitration Act* (hereafter Law of the Arbitration) shall apply to arbitration procedures conducted under these Rules. In the event that any provision of these Rules or the Arbitration Agreement of the Parties with respect to the conduct of the arbitration is in conflict with any provisions of the Law of the Arbitration from which the Parties cannot derogate, the provisions of the Law of the Arbitration shall prevail.

### 3. Appointment of Arbitral Tribunal

- 3.1 The Parties shall designate an Arbitral Tribunal, consisting of either a single arbitrator or more than one arbitrator, to preside over the arbitration proceedings within 5 days 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 to the ADR Institute of Canada, or alternatively, to a judge of the Federal Court of Canada for the appointment of an arbitrator.
- 3.2 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 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 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.



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- 3.3 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.
  - 3.4 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.
  - 3.5 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.
  - 3.6 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.

#### **4. Binding Arbitration Method**

- 4.1 Final offer arbitration shall be the binding arbitration method used by the Arbitral Tribunal to determine awards under these rules.
- 4.2 The last offers provided by the Parties in accordance with the regulations are their final offers for purposes of the arbitration. It is agreed that the last offers will be made in the form annexed hereto as Appendix F.
- 4.3 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.
- 4.4 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.
- 4.5 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. If there is more than one arbitrator, the decision of the Arbitral Tribunal shall be made by a majority of all its members.

#### **5. Communications**

- 5.1 Any notification or communication to the Arbitral Tribunal or to a Party or its Representative may be delivered to its address identified below by certified or registered mail, or any other method that would provide proof of delivery. Such notification or communication shall be deemed to have been delivered on the date of receipt is acknowledged or the date that delivery is confirmed.

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Address for the Arbitral Tribunal:

Address of the Applicant:

Address of the Registrant:

- 5.2 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.

## **6. Case Management Procedure or Procedural Conference**

- 6.1 The Arbitral Tribunal may convene a procedural conference within 5 days 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?
  13. Should the Parties agree on a provisional timetable with timelines other than the ones provided in these Rules?

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

6.3 The Arbitral Tribunal shall record any agreement or orders made at any procedural conference and shall promptly send a copy of such record to each of the Parties.

## **7. Compliance with the Provisional Timetable**

7.1 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 should be made only when justified.

7.2 The Arbitral Tribunal shall conduct the arbitration proceedings as expeditiously as possible and, subject to the timetable to in Section 7.1, in the manner the Arbitral Tribunal considers appropriate having regard to the circumstances of the matter.

## **8. Written Proceedings Only**

8.1 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. The deadline for any final written evidence and submissions should be within twenty (20) days of the first procedural conference unless the Parties agree otherwise. Written evidence shall be submitted pursuant to a statutory declaration.

8.2 Where a documents-only arbitration is convened in accordance with Section 8.1, 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.

## **9. Need for a Hearing**

9.1 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.

9.2 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

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3. No transcripts of the proceedings shall be required.

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

## **10. Additional Evidence**

10.1 At any time during the arbitration process, the Arbitral Tribunal may, subject to Section 4.4, require any Party to provide further evidence or submissions in such a manner as it determines.

10.2 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.

10.3 The Arbitral Tribunal may request additional information from any of the Parties at any time. If a Party unreasonably withholds information that the Arbitral Tribunal subsequently deems to be relevant, the Arbitral Tribunal may draw an adverse inference from the decision of a Party not to provide the Arbitral Tribunal with the information that was requested.

## **11. Termination of the Procedures**

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

## **12. The Award**

12.1 The Arbitral Tribunal will render its award within fifteen (15) days of 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; however, the Arbitral Tribunal, for good reason, may extend the fifteen (15) days period after consultation and with the concurrence of the Parties in accordance with the Regulations.

12.2 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 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 may direct that funds amount be released to the Registrant in accordance with the award.

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12.3 Summaries or extracts from final decisions will be transmitted to the Minister by the Arbitral Tribunal and will be retained by the Minister solely to assist in the administration of the Act.

**13. Costs of Arbitration**

13.1 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.

13.2 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.

13.3 The Parties shall be jointly and severally responsible for the payment of all costs fixed by the Arbitral Tribunal pursuant to Section 13.1, unless the Parties and the Arbitral Tribunal have otherwise agreed and have confirmed those arrangements in writing.

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## 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.

### Inadmissibility of Information Disclosed in Negotiation or Mediated Negotiation

2. The parties will not rely on or introduce as evidence in any proceeding, including an arbitration process under this Agreement whether or not that proceeding 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 in that proceeding;
  - 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

3. (1) No 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 proceeding, or for any other purpose by a party except:
  1. for any administrative purpose in conducting a direct or assisted negotiation or arbitration;
  2. in connection with an application to a court for interim relief or to set aside, recognize or enforce an agreement or an arbitral award;
  3. to the Minister in relation to the enforcement or administration of the Act;
  4. 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,
  5. to assist future Arbitral Tribunals as set out in accordance with the Act ; or

6. to an independent expert for the sole purpose of assisting an arbitral tribunal in its understanding of the issues under its jurisdiction.
- (2) Where a Party makes disclosure as permitted by paragraph 3(1)2 it shall only do so:
1. by disclosing no more than what is legally required;
  2. by obtaining or providing, where possible, an undertaking or order of confidentiality consistent with this section; and
  3. by furnishing to the other Party (and to the Arbitral Tribunal if the disclosure takes place during the arbitration) details of the disclosure and an explanation of the reason for it.

#### **Supplementary Confidentiality Agreement**

4. Notwithstanding any provision of this Appendix, the parties may enter into a specific confidentiality agreement governing the disclosure of documents to be used by the parties in negotiation or arbitration.

#### **Ruling on Confidentiality by the Arbitral Tribunal**

5. 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 the proceedings.

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## Appendix E Pesticide Data Compensation Guideline

### Introduction

This guideline document outlines the compensation principles to be considered in the determination of financial compensation under the *Regulations Amending the Pest Control Products Regulations* for data protection. The guideline is 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. The guideline is not formally binding on any of the parties. The arbitrator will retain discretion under the final offer binding arbitration process in deciding which party's compensation offer to accept.

The compensation guideline was developed in consultation with pesticide industry representatives. The compensation principles recognize 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 this guideline is to encourage consistency in how such issues are considered in the determination of financial compensation.

### Compensation Principles

During the arbitration process, the arbitrator may refer to past arbitral awards.

### 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 is appropriate in instances where actual, historic cost information (e.g., invoice records) is unavailable or incomplete.

### 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.



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This is consistent with the predecessor policy, *Product Specific Registration*, where determination of the research that generic applicants were required to perform in return for relying on data owners' data was based on a survey of costs identified by independent laboratories.

### **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 would be appropriate.

*Interest on studies* – the data is not considered to be relied upon until a registration is granted and since a registration will not be granted until the negotiation and arbitration process is completed, an adjustment for interest is not necessary.

*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 to mitigate financial risks. An additional adjustment to the cost of compensable data to reflect the financial risks borne by data owners to successfully obtain or maintain a registration should be discouraged.

*Adjustment for data compensation already paid in other jurisdictions* – Adjusting the amount of the compensation may be considered where an applicant can clearly demonstrate that it has already paid compensation for the same data under the pesticide data compensation provisions of the United States *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA).

### **Cost Sharing**

Compensation should be based on sharing of compensable data costs between data owners and follow-on applicants. Multiple follow-on applicants may, separately and successively, seek to rely on a data owner's compensable data. Where a subsequent follow-on applicant relies on compensable data for which compensation has already been paid, it would be appropriate to adjust compensation in order to share costs across the multiple data owners and applicants.

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**Appendix F Form of Last offer**

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 parties 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 applicant) have ended without a settlement having been reached;

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

NOW THEREFORE (identity of registrant or applicant) presents hereby its last offer in the amount of (dollars Canadian or American) to (identity of applicant or registrant) as the compensation to be paid by the applicant for the right to use or rely on the compensable data identified in Appendix A.

IN WITNESS WHEREOF, this final offer has been

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

In the presence of:

\_\_\_\_\_  
(Name and title of signatory)

\_\_\_\_\_  
(Witness)

Date: