

**MEMORANDUM OF UNDERSTANDING
BETWEEN**

**AUSTRALIAN PESTICIDES AND
VETERINARY MEDICINES AUTHORITY**

AND

**PEST MANAGEMENT REGULATORY AGENCY
CANADA**



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AUTHORITY
AND
PEST MANAGEMENT REGULATORY AGENCY, CANADA**

1) BACKGROUND

The Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Pest Management Regulatory Agency (PMRA) of Health Canada are responsible for the regulation of pesticides in their respective countries. The agencies have a strong record of cooperation in various international forums to advance the effective regulation of pesticides and a history of ad hoc direct cooperation on technical regulatory matters from time to time. Both organisations recognise that there is mutual advantage to increasing the scope of, and strengthening the framework for, such cooperation.

2) AUTHORITY

- 2.1. APVMA, a statutory authority established under the *Australian Agricultural and Veterinary Chemicals Code Act 1994 (the Code Act)*, and the PMRA, an Agency consolidating responsibilities for the regulation of pesticides in Canada, established within Health Canada in 1995, have similar approaches to regulation of pesticides in the broad sense and at the practical level in relation to the type of data required by both organisations.
- 2.2. This Memorandum of Understanding (MOU) is comprised of this document and its amendments and schedules, as amended from time to time.

3) PURPOSES AND OVERVIEW

- 3.1. This MOU establishes an arrangement between APVMA and PMRA. APVMA and the PMRA (the Parties) do not intend this MOU to create legally binding obligations between them. However, the Parties intend to strengthen exchange of knowledge and expertise to enhance the efficiency and effectiveness of their respective roles.
- 3.2. This MOU will focus on cooperation in relation to the operational aspects of pesticide regulation and will not cover broader government regulatory policy.
- 3.3. Subject to the confidentiality provisions outlined in paragraph 6, the Parties will exchange information on risk assessment and risk management options in respect of pesticides that they jointly cover, and to work concurrently and exchange information to conduct scientific risk assessments in relation to

specific projects. The MOU specifies a number of aspects of the working relationship between the Parties to fulfil these general objectives.

3.4. The exchange of information and cooperative action between the Parties relates to pesticides regulatory matters of mutual interest, with focus on the following elements:

- (i) A system for early information exchange on upcoming pesticides regulatory issues that may impact on Australia and Canada.

This would involve, but not be limited to, exchange of information on routine pesticide issues and agency initiatives that may be of mutual interest such as pesticide quality, issues of public concern, sustainable pest management, risk reduction, minor uses, cost recovery and efficiency measures;

- (ii) Promote scientific exchange and staff involvement in cooperative efforts to the fullest extent possible;
- (iii) A mutual determination to take advantage of international forums, such as the Codex Committee on Pesticide Residues, OECD and other international meetings as appropriate, for face-to-face meetings between staff, as an important mechanism for advancing the work program that the Parties mutually determine;
- (iv) Routinely exchange lists of new pesticides under evaluation and existing pesticides under re-evaluation. Exchange assessment reports prepared for pesticides of common interest;
- (v) Information and experience in relation to information technology, particularly in the area of electronic data submission and templates;

4) WORK PLAN

- 4.1. The development of a joint work program with a set of defined milestones over a three (3) year period. The work program will aim towards achieving common approaches to risk assessment methods and processes and conducting a joint assessment of applications for approval/registration or re-evaluation of pesticides;
- 4.2. As a first step, the Parties will cooperate on at least one assessment of a pesticide regulatory matter identified under paragraph 3.4. It is envisioned that this particular project will begin in early 2005 and may be completed by end 2005; and
- 4.3. As further elements of the work program are developed and mutually determined by officers responsible for this MOU, these will be exchanged in writing.

5) ACKNOWLEDGEMENT

- 5.1 The Parties to this MOU acknowledge that under the Agvet Codes all information provided by an applicant in support of an application to APVMA, except for confidential commercial information, is once the application has been disclosed by the APVMA, a matter of public record and is subject to requests under the *Freedom of Information Act 1982*. Similarly, all of APVMA's assessment reports, including the safety assessment reports, are also a matter of public record. APVMA is acting in accordance with its legislative framework in committing to provide such information to the PMRA and is not committed to inform the applicant about the provision of such information. However, as a matter of good practice, it will generally do so.
- 5.2 The Parties to this MOU acknowledge that the current Pest Control Products Act does not contain any provision concerning the disclosure of confidential information. The matter is governed by the *Access to Information Act*. Section 13 of that Act requires that the PMRA refuse to disclose any record that contains information received in confidence from the government of any foreign state or an institution thereof.

However, the new Pest Control Products Act will deal with the public disclosure of confidential information. Any information, which is used to support a registration decision, is to be placed in the Register where it may be subject to public disclosure. If it meets the statutory definition of "confidential business information" it will not be subject to public disclosure. If it meets the statutory definition of "confidential test data" the public will be permitted to inspect it in a reading room but will not be entitled to obtain a copy.

Information that is received in confidence from a source other than an applicant or registrant, and that is used in making a registration decision, is subject to the foregoing requirement for placement in the Register and public access. However, a regulatory proposal is currently being developed under which such public access would be limited to a reference to that information in the product monograph. A request for a copy of, or access to that information would have to be made to the source from which it was obtained. It cannot be said at this time that the regulatory proposal will be effected.

6) ROLES AND RESPONSIBILITIES

6.1 APVMA

- 6.1.1 Subject to paragraph 7.1, APVMA will notify the PMRA of applications received or proposals initiated relating to, but not limited to, those areas listed under paragraph 3.4. Notification will involve APVMA providing an

information summary to the PMRA describing the nature of the application or proposal.

6.1.2 At the request of the PMRA, and subject to paragraph 7.1, APVMA will provide further information to the PMRA regarding APVMA's assessment of any application or proposal formally notified under paragraph 6.1.1. Further information may include the following:

- (i) full copies of APVMA's assessment reports;
- (ii) information about the type and scope of data submitted with the application, and
- (iii) discussions with the assessing officers regarding issues of concern that arose during an assessment.

6.1.3 APVMA will provide information under paragraph 6.1.2 free of charge.

6.2 PMRA

6.2.1 Subject to paragraph 7.2, the PMRA will notify APVMA of any applications received relating to, but not limited to, those areas listed under paragraph 3.4. Notification will involve the PMRA providing an information summary to APVMA describing the nature of the application, consistent with current and new PCPA.

6.2.2 At the request of APVMA, and subject to paragraph 7.2, the PMRA will provide further information to APVMA regarding the PMRA's assessment of an application notified under paragraph 6.2.1. Further information may include the following:

- (i) full copies of the PMRA's assessment reports, including safety assessment information;
- (ii) information about the type and scope of data submitted with the application, including copies of specific study reports; and
- (iii) discussions with the assessing officers regarding issues of concern that arose during an assessment.

6.2.3 The PMRA will provide such information under paragraph 6.2.2 free of charge.

7) CONFIDENTIALITY

7.1 APVMA

- 7.1.1** APVMA will not disclose to the PMRA confidential commercial information, as defined in sub-section 3(1) of the Agvet Codes, without first obtaining the consent of the person whose information it is to the provision of such information in accordance with this MOU. When seeking such consent to provide the information to the PMRA, APVMA will inform the person of the purposes for which the PMRA might use the information and that, under the current PCPA in Canada, the PMRA will protect the confidential information from disclosure, in so far as the information is not already in the public domain, unless the APVMA consents to such disclosure. Under the new Act confidential information received from the APVMA that is used to support a registration decision, other than confidential business information as defined in that Act, may be subject to public disclosure or access.
- 7.1.2** APVMA will inform the PMRA of the person's response to a request under paragraph 7.1.1.
- 7.1.3** Unless otherwise required by law APVMA will take all reasonable efforts to protect the confidentiality of any information provided to it by the PMRA from disclosure to any third parties and will not release it to any person other than APVMA staff members or contractors who need to know the information for work purposes, except with written consent from the PMRA or written confirmation from the PMRA that the information has been made public in Canada. APVMA will take all reasonable efforts to ensure that staff members and contractors receiving access to such information will protect its confidentiality.
- 7.1.4** Refusal of an applicant to share information as outlined in this MOU will not preclude APVMA from evaluating its application.

7.2 PMRA

- 7.2.1** Before releasing any information, including confidential information, to APVMA the PMRA will obtain the consent of the applicant to the provision of such information to APVMA in accordance with this MOU. When seeking the consent of the applicant, the PMRA will inform the applicant of the purposes for which APVMA might use the information and APVMA will take all reasonable efforts to keep any such information confidential, in so far that the information is not already in the public domain.

The PMRA will inform APVMA of the applicant's response to a request under paragraph 7.2.1.

- 7.2.2** Unless otherwise required by law, the PMRA will take all reasonable efforts to protect the confidentiality of any information provided to it by APVMA from disclosure to any third parties and will not release it to any other

person other than the PMRA members or contractors who need to know the information for work purposes, except with the written consent from APVMA or written confirmation from APVMA that the information has been made public. The PMRA will take all reasonable efforts to ensure that staff members and contractors receiving access to such information will protect its confidentiality.

7.2.3 Refusal of the applicant to share information as outlined in this MOU will not preclude the PMRA from evaluating its application.

8) ADMINISTRATIVE ARRANGEMENTS

8.1 Changes by either Party in legislation, operational policies, practices and procedures which relate to matters covered by the MOU, and which would impact on the operations of the MOU, will be notified to the other Party and any consequential changes necessary to the MOU will be subject to consultation between the Parties.

8.2 Either Party may propose a variation to the provisions of this MOU, but any variation must be mutually determined in writing by both Parties of this MOU.

8.3 The officers responsible for the administration of this MOU are:

(i) the person holding the position of Chief Executive Officer, APVMA;
and

(ii) the person holding the position of Executive Director, PMRA.

8.4 The officers responsible for the day-to-day operations under this MOU are:

(i) The person holding the position of Program Manager Pesticides, APVMA;
and

(ii) the person holding the position of Chief Registrar, PMRA.

8.5 Changes to contact officers will be notified within 10 working days and transitional arrangements put in place to deal with correspondence received in the interim. The Parties will assist each other when requested to identify sources of expertise to review applications or to review or provide other information.

9) REVIEW OF THIS MOU

9.1 On, or shortly after, the first anniversary of the date of this MOU, representatives of the Parties will review the flow of information between the Parties, the costs incurred by each Party in providing information, and the


scope of the MOU and consider, if appropriate, amendment of this MOU. Thereafter, periodic review of this MOU may take place on request from either Party.

9.2 Nothing in paragraph 10.1 precludes the Parties from mutually determining to amend this MOU at any time.

10) COMMENCEMENT AND TERMINATION OF THIS MOU

10.1 The MOU will commence on the day on which it is signed by both Parties.

10.2 Either Party may terminate this MOU by written notice to the other Party. The MOU will terminate 30 calendar days after the date upon which the other Party receives written notice of the intention to terminate.



Executive Director
Pest Management Regulatory Agency
Canada



Chief Executive Officer
Australian Pesticides and Veterinary
Medicines Authority
Australia

Sept 15-04
Date

15 Sept 2004
Date