Pest Management Advisory Council June 12th - 13th, 2006 *Delta Hotel, Ottawa* Meeting Report

The Pest Management Advisory Council (PMAC) met in Ottawa on June 12th - 13th, 2006. Appendix A contains a list of all meeting attendees. Appendix B is a summary of action items that resulted from the meeting.

Opening of the Meeting

Mr. Ambrose Hearn, Chair of PMAC opened the meeting. The agenda was reviewed and accepted.

Remarks by the Executive Director

Dr. Karen Dodds, Executive Director of the Pest Management Regulatory Agency (PMRA), discussed various key issues including the new Pest Control Products Act (PCPA) coming into force, the approach to responding to stakeholder concerns on PMRA's proposed decisions, and the importance of transparency and effective stakeholder engagement.

Council members emphasized the necessity for clarity and consistency regarding PMRA's communications. To ensure efforts are ongoing and continuous in this area, Council members were informed that future PMAC meeting agendas would hold a place for updates on Communications at the PMRA.

The New Pest Control Products Act: Implementation

Dr. Richard Aucoin, A/Chief Registrar, gave an overview of the implementation of the New Pest Control Products Act.

- Council members were supportive of the new Act coming into force.
- It was recommended that the Agency utilize clearer and consistent terminology with respect to distinguishing between new data that must be submitted to allow a product registration, and confirmatory data. Under the new Act, the PMRA has the authority to ask for further data from registrants, if information received is deemed unacceptable or incomplete.
- A new process is under development that will allow maximum residue limits to be set under the new PCPA. PMRA indicated that they will be consulting on a refined process

and will be addressing how emergency registrations will be handled.

- An expedited process and shorter time lines for reduced risk pesticides has already been developed by the PMRA, including a definition and criteria for reduced risk pesticides. With respect to lower risk pesticides, PMRA continues to develop a new regulatory approach and stays abreast of what other countries are doing in this regard.
- The Government of Canada's Privy Council Office has published a Framework for the Application of Precaution in Science-Based Decision Making about Risk. PMRA will be consistent, and will operationalize what is stated in the Government of Canada policy.

The New Pest Control Products Act: Re-evaluation

John Worgan, Director, Re-evaluation Management Division, outlined the requirements of the new Act with respect to Re-evaluation.

The following is a summary of the discussion.

- Council Members appreciated the opportunity to understand the new transparency provisions of the new Act. PMRA confirmed that there are two types of confidential information: confidential business information (CBI) and confidential test data (CTD). CBI is not available to the public. The new Act specifies that CTD would be available in the reading room after the final re-evaluation decision on all uses of the product is made. Some PMAC members were interested in having access to as much information as possible, as soon as possible, and not just in Ottawa.
- The PMRA has been working closely with the US EPA on common risk assessment processes and approaches for several years. It was noted however, that certain policies differ. Most of the active ingredients are studied jointly, and there is sharing of work and information.
- The PMRA will consult broadly about proposed re-evaluation decisions which will provide an opportunity for any concerns about whether or not alternative tools are available to be raised. The new Act has a provision which allows for the delay of a re-evaluation decision until a suitable replacement product can be found.

The New Pest Control Products Act: Transparency

Dr. Valerie Robertson, Director, Submission Coordination Division, summarized the changes in the new Act with respect to Transparency.

The following are key points from the discussion.

• As decisions are made under the new Act, evaluation reports are put into the public registry. These reports incorporate data reviews as well as any additional information that

was considered in the evaluation of the product, and will be listed for easy reference. It was confirmed that there will be no time limit in the Reading Room (within business hours), and that taking notes will be permitted.

- It was discussed that much of the data PMRA reviews, particularly for new product submissions, is unpublished. In accordance with the Privacy Act, some information in unpublished studies such as the author's name will not be included, or published, in PMRA's reports or be available in the Reading Room.
- Unpublished studies submitted by registrants to support a registration must adhere to strict OECD standards, and Good Laboratory Practice, and are subject to audits in order to maintain a high standard of quality. In addition, PMRA scientists evaluate these studies against the established protocols, and analyse the data through a rigorous review and risk assessment process.
- For conditional registrations, the public can challenge a registration decision once any requested data has been received and reviewed, and when the conditional registration is converted to a full registration or the conditional registration is renewed. Should a concern be raised with regard to the safety of a conditionally registered product, the PMRA has the authority to withdraw a registration until the concern has been addressed and any necessary data is received, reviewed and the acceptability for continued registration has been determined.
- The new Act allows the PMRA to share more information with other government departments, facilitating joint reviews. Registrants are comfortable with the new provisions and respect the balance between making information publically available and protecting confidential business information.
- CTD will not be accessible at the time of consultation, but rather at the time of a final registration, or continued registration decision.

Evaluation Reports under the New PCPA: A Plain Language Approach

John Worgan, Director, Re-evaluation Management Division, presented a proposal for a clearer and more understandable approach to regulatory documents.

- Members agreed with the plain language approach. The new plain language summary document would be in addition to the more detailed report containing scientific detail on the risk assessment. It was suggested that PMRA use headings in their documents to highlight the information addressing how vulnerable sub-populations are protected.
- The plain language summary would demonstrate why particular label statements are used, which would reinforce the importance and necessity of reading product labels.

Update on Low Risk Pesticides

Karen Lloyd, Director, Environmental Assessment Division, provided an update, and path forward, on the recent work pertaining to low risk pesticides.

The following is a summary of the discussion.

- Council members were happy to see the work on low risk products moving forward.
- Clear criteria and defined data requirements including efficacy for low risk products are important. Low risk products will have a PCP registration number to enable proper compliance monitoring.
- The new PCPA provides the ability to perform comparative risk assessments and the PMRA is considering how to undertake this type of assessment.

Pesticide Research and Monitoring

Christine Norman, Health Evaluation Division, PMRA presented information on health-specific research and monitoring initiatives, and addressed some of the recommendations in the letter from PMAC to the Minister with regard to pesticide research and monitoring.

- Overall, there was positive support for the progress made on health related research and monitoring. Members were supportive of the new work undertaken through the Canadian Health Measures Survey.
- Council members were interested in initiatives such as the Canadian National Children's Study and would like to see more funding of research relating to pesticides by organizations such as CIHR. It was acknowledged that Health Canada is only at the discussion phase regarding the development of future longitudinal studies.
- Details of the Health Measures Survey were discussed including that a national cohort, representative of the country, is being surveyed. Children under 6 however, are not included in the study, presumably due to logistical reasons. It was recommended that the PMRA discuss geographic demographics with the Steering Group as not all cities/provinces have the same laws respecting pesticide use, and the data may vary depending on the timing of the pesticide use season in relation to when the samples are taken.
- The Health Measures Survey (HMS) is currently only funded for a single cycle (2007-2009), but it is hoped that funding will continue for this project. With respect to the organophosphate (OP) analysis, the data from the HMS will help PMRA more fully

assess the validity of biomonitoring data being generated in the U.S. to the Canadian population. Analytes selected for any future cycles will be determined based on the results of the first cycle as well as regulatory needs and may include OPs.

- The work of the industry sponsored exposure data development task forces was discussed including that the work of the Outdoor Residential Exposure Task Force (ORETF). ORETF research includes dermal transfer (turf to skin) as well as dissipation of residues from the surface of grass. General algorithms also include other inputs such as direct ingestion of soil, and/or granules of pesticides. Although consideration of residues tracked into the home are generally considered in the PMRA risk assessment, research on this phenomenon is not being specifically investigated by ORETF. Task force data is published in peer reviewed journals and the data is used to support regulatory decisions as appropriate.
- As the PMRA does not have funding for research, the PMRA must utilize research and monitoring data from other sources. PMAC, stakeholder groups and the public have the ability to emphasize the need for further research and monitoring to the government.

Update on the Own Use Import Program

Trish MacQuarrie, Director, Alternative Strategies and Regulatory Affairs Division, PMRA gave a status update on the Program, more specifically regarding pivotal issues and status of the final report.

• The final report of the OUI Task Force is expected in the near future.

Revocation of the 0.1 ppm Default Regulation for Residues

Trevor Satchwill, Health Evaluation Division provided an overview of the proposed policy relating to revoking the regulation pertaining to the 0.1 ppm default maximum residue limit of pesticides on foods.

- The proposal was well received and members were supportive of the approach.
- Under international law the PMRA is required to set tolerances for residues of pesticides or their break-down products being imported into Canada, provided that the health exposure assessment demonstrates acceptable risk. The PMRA needs to address the issue of competitiveness while ensuring that health and the environment remain protected. The importance of ensuring the PMRA utilizes a precautionary approach while ensuring Canadian producers remain competitive and have access to products was stressed.
- Council members were invited to provide comment on the regulatory proposal which was published on June 23rd.

Information Item: Re-evaluation

John Worgan, Director, Re-evaluation Management Division, was present for questions on the Re-evaluation Program.

The following is a summary of the discussion.

- Terminology was again discussed with respect to confirmatory data versus new data requirements to address data gaps. The information pertaining to data call-ins and confirmatory data for re-evaluations is contained in the various decision documents and letters to registrants, and a request was made regarding how many re-evaluations call for additional data to be submitted. In the case where data may be requested during or after a re-evaluation, additional safety factors are used to correct for uncertainties such as an incomplete data set in order to determine whether there is an acceptable level of risk. The new Act gives the PMRA the ability to require that registrants submit any necessary data.
- The PMRA uses U.S. EPA evaluations to supplement PMRA reviews, however for reevaluations done under Program 3, such as the organophosphates, the PMRA undertakes a comprehensive evaluation and assessment. For future re-evaluations, the PMRA indicated that it will be trying to harmonize the time lines with the U.S..

Information Item: Federal / Provincial / Territorial Initiatives

Lindsay Hanson, Sustainable Urban Pest Management Section, PMRA was present for questions relating to the work of the F/P/T Classification Implementation Working Group.

• It was recommended that GHS and the classification of domestic class products be placed on the agenda at a future meeting.

Information Item: Voluntary Reporting of Incidents - Human Health

Jean-Pierre Lachaine was present for questions on the PMAC Working Group on the Voluntary Reporting of Incidents relating to Human Health.

- Council members were reminded that the proposed incident reporting system is intended as a post-registration monitoring system.
- A system that would allow for the medical community to do long term follow up such as the ProdTox program would be of value.
- Members would support the restored funding of initiatives such as ProdTox that integrate, on a national level, data from poison control centres to better ensure that the medical and

public health community can do appropriate follow up.

Communications

- The PMRA communications continues to be a priority of the council, particularly in light of a recent situation where internal speaking points pertaining to 2,4-D were incorrectly provided to the landscape industry. The main concerns of the council included:
 - situations such as the one above are taken seriously by the Agency and that measures are put in place to avoid them in the future;
 - the timeliness of the PMRA's response to issues when they are raised;
 - perceptions that the PMRA does not treat all stakeholders equally;
 - the use of the word "safe" by PMRA; and
 - various issues over the years that have led to a mistrust of the PMRA by the Canadian public.

The PMRA responded to these concerns with the following information:

- as public servants, the PMRA serves all of the Canadian public, not any one sector more than others;
- when documents are to be distributed to all stakeholders, they will be distributed simultaneously, in a bilingual format and posted on the PMRA's website;
- the single-window approach for contacting the Agency is no longer in effect, but if people are unsure of who to speak with, the call line can help direct their call, and will continue to manage general public inquiries;
- the Agency is committed to the goal of fostering open communication and appreciates the need for direct contact and quick response times; and
- that the PMRA has been sensitized to the use of the word safe and will continue to stress appropriate messaging.
- The topic of Communications will be discussed at the November PMAC meeting which will provide the opportunity to follow up on the progress of the PMRA in this regard.
- Despite concerns raised by Council, members were satisfied with the recent direction the PMRA is taking with respect to improving stakeholder engagement. Members continue to support open communication between the PMRA and stakeholders, and wish to ensure that consultations are done broadly and with inclusivity of all stakeholders.

Compliance Program/OECD Workshop on Pesticide User Compliance

Karen McCullagh, Director, Compliance, Lab Services and Regional Operations Division, presented on the Compliance Program, the National Compliance Strategy, and provided an update on an international workshop on Pesticide User Compliance hosted by PMRA.

• The scope of the National Compliance Strategy was discussed noting that users, registrants and vendors are all considered in the Strategy. There is a focus on users as this

is in keeping with recommendations made by the Commissioner of the Environment and Sustainable Development.

• The proposed Compliance Policy (PRO 2006-01) was published on June 1st and PMAC members were invited to review the document and provide comments. In addition, PMAC members were invited to provide comments on the National Compliance Strategy once the document is published. PMRA indicated that there was no scheduled date of publication established, but PMAC would be advised when the document is published.

Other Business

Ambrose Hearn, Chair, PMAC, concluded the meeting with a few last business items.

- 1. The action items resulting from the November 2005 Meeting were reviewed.
- 2. The key messages from the meeting were summarized, and recommendations to the PMRA and to the Minister were reviewed as a group.

Recommendations/Key Points to the Minister:

- The Council is pleased that the new *Pest Control Products Act* is coming into force, and wishes to continue to see progress on the outstanding regulations and policies supporting the Act.
- Members continue to support the work on a new regulatory approach for products with lower risk.
- Members were supportive of the new work undertaken through the Canadian Health Measures Survey.
- Council members were interested in initiatives such as the Canadian National Children's Study and would like to have elements relating to pesticides incorporated into the study. Council members would like to see more research relating to pesticides by organizations such as CIHR.
- Members support the restored funding of initiatives such as ProdTox that integrate, on a national level, data from poison control centres in order to better ensure that the medical and public health communities can do appropriate follow up (recommendation also to go to PHAC).
- The Council is satisfied with the recent direction the PMRA is taking with respect to improving stakeholder engagement. Members continue to support open communication between the PMRA and stakeholders, and wish to ensure that consultations are done broadly and with inclusivity of all stakeholders.

Recommendations to the PMRA:

- The Agency should use clear and consistent terminology with respect to a) distinguishing between new data requirements versus confirmatory data, and b) the discontinuation of the use of the word safe with respect to pesticides.
- Consideration be given to having Reading Room locations other than Ottawa.
- Members expressed support for the plain language approach regarding scientific regulatory documents. There was a recommendation that the documents be clearer and include headings regarding how vulnerable sub-populations are considered in the risk assessments.
- 3. Council members were invited to recommend future agenda items. Items suggested include:
 - a. Continued discussions leading to full implementation of the new PCPA, including the remaining regulations, and policies
 - b. GHS
 - c. The classification of domestic products
 - d. Continued updates on research and monitoring
- 4. The date for the next PMAC meeting was confirmed as November 14-15, 2006.
- 5. Members were requested to complete the meeting evaluation form.

Appendix A:

PEST MANAGEMENT ADVISORY COUNCIL Participants - June 12 - 13, 2006

<u>CHAIR:</u> (1) Mr. Ambrose Hearn, Independent

COUNCIL MEMBERS: (12)

Dr. Claire Infante-Rivard, McGill University Dr. Richard Bélanger, Laval University Mr. Glen Sampson, Nova Scotia Agricultural College Mr. Bob Freisen, Canadian Federation of Agriculture Dr. Neil Arya, Ontario College of Family Physicians Mr. Henry Walthert, Wood Preservation Canada Mr. Drew Franklin, Canadian Consumer Specialty Products Mr. Gary Brown, Canadian Horticultural Council Mr. Alain Renaud, Druide Ms. Kathleen Cooper, Canadian Environmental Law Association Dr. Karen Dodds, Pest Management Regulatory Agency (Government Employee) Ms. Julia Langer, World Wildlife Fund

ALTERNATES: (5)

Mr. Peter MacLeod, CropLife Canada Dr. Don Spady, Canadian Pediatric Society Mr. Peter Isaacson, Canadian Nursery and Landscape Association Ms. Angela Rickman, Sierra Club Mme Marie Garon, F/P/T Representative

SECRETARIAT: (4) (Government Employees)

Ms. Trish MacQuarrie, Pest Management Regulatory Agency Ms. Lynn Skillings, Pest Management Regulatory Agency Ms. Carole Doucette, Pest Management Regulatory Agency Ms. Famida Devji, Pest Management Regulatory Agency

PRESENTERS: (Government Employees)

Dr. Richard Aucoin, Pest Management Regulatory Agency Mr. John Worgan, Pest Management Regulatory Agency Dr. Valerie Robertson, Pest Management Regulatory Agency Ms. Karen Lloyd, Pest Management Regulatory Agency Ms. Karen McCullagh, Pest Management Regulatory Agency Ms. Christine Norman, Pest Management Regulatory Agency Ms. Trish MacQuarrie, Pest Management Regulatory Agency Mr. Trevor Satchwill, Pest Management Regulatory Agency Ms. Edith Lachapelle, Pest Management Regulatory Agency Mr. Lindsay Hanson, Pest Management Regulatory Agency Mr. Rob Ward, Pest Management Regulatory Agency Mr. Jean-Pierre Lachaîne, Pest Management Regulatory Agency

OBSERVERS:

Ms. Jill Lane, Canadian Aerial Application Association Ms. Anne Fowlie, Canadian Horticultural Council Ms. Amy Thomson, Canadian Consumer Specialty Products Association Mr. Chris McCurdy, S. C. Johnson and Son, Limited Mr. Larry Hammond, 2,4-D Industry Task Force Mr. Chris Warfield, Bayer CropScience Canada Ms. Shannon Watt, Canadian Federation of Agriculture **Ms. Miriam Halevy,** *Pest Management Regulatory Agency* Mr. Craig Hunter, Canadian Horticultural Council Mr. Jamie Munro, Pest Management Regulatory Agency Mr. Jason Flint, Pest Management Regulatory Agency **Mr. Pierre Petelle,** *Pest Management Regulatory Agency* **Mr. Pierre Beauchamp**, Pest Management Regulatory Agency **Dr. Connie Moase**, *Pest Management Regulatory Agency* **Dr. Ariff Ally,** *Pest Management Regulatory Agency* Mr. David Quesnel, Pest Management Regulatory Agency **Mr. Pierre Leblanc,** *Pest Management Regulatory Agency* Mr. Aaron Carswell, Pest Management Regulatory Agency Mr. Basil Stapleton, Health Canada, Legal Services Ms. Neilda Sterkenberg, Pest Management Regulatory Agency Meg Sears, MEng, PhD

Appendix B:

List of Action Items:

- 1. Gary Brown to provide a list of world wide trading partners to PMRA.
- 2. PMRA to provide Council members with the standard presentations on role of PMRA that are given to municipal councils, when requested.
- 3. PMRA was requested to provide a report regarding the number of data call-ins resulting from re-evaluations.