PEST MANAGEMENT ADVISORY COUNCIL

MEETING REPORT

February 15-16, 1999

February 15, 1999

Introduction / Review of Agenda - Due to the illness of the Chair, Dr. Richard Van Loon, on February 15, Dr. John Jarrell, Council member, kindly agreed to chair the meeting on that day. It was decided to modify the agenda by moving the item on proposed amendments to the *Pest Control Products Act* to February 16 and the items on the U.S. *Food Quality Protection Act* and Re-evaluation to February 15.

Submission Review and Decision-Making - Presentations were made by Diana Somers, PMRA, on the submission review process and health risk assessment, by Ted Kuchnicki, PMRA, on environmental assessment, and by Wayne Ormrod, PMRA, on risk management and decision-making (see Appendices C, D and E, respectively). The presentations were in response to the interest expressed by Council members, at their first meeting in November 1998, in the PMRA's risk assessment / risk management policies and procedures. In addition, it was considered important that later discussions on legislation and re-evaluation be based on a common understanding of the current risk management approach to decision-making.

During the ensuing discussion, Council members expressed interest in the following issues, encouraging the Agency to ensure that they are adequately addressed in submission review and decision-making processes and policies:

- special consideration for children and other sensitive sub-populations in risk assessments;
- re-entry intervals;
- interactions among pesticides in the environment / cumulative effects;
- criteria for establishing restrictions on aerial application / control of drift from ground application;
- environmental issues related to indoor uses of pesticides;
- environmental assessment of formulated products;
- post-registration environmental monitoring;
- harmonization of Canadian data requirements with other countries / ability to request additional data as appropriate;

- criteria for acceptable efficacy;
- impact of evolving conditions in marketplace on value assessment, e.g., emerging trade issues that might decrease value;
- consideration of trade implications;
- public costs related to illness and lost productivity;
- incentives for the registration of alternatives to traditional chemicals;
- policies and processes for minor uses and minor formulation changes;
- relationship between pre-market review and post-market control, e.g., provincial certification of applicators;
- public access to documented risk assessment methodologies used by PMRA;
- documentation of the degree of uncertainty in risk assessments;
- distinction between risk assessment and risk management;
- public access to data supporting pesticide registrations.

A number of Council members reported that they found the presentations very useful.

The Council requested additional information on risk assessment methodologies utilized by the PMRA.

U.S. *Food Quality Protection Act* - Cheryl Chaffey, PMRA, presented an overview of the U.S. *Food Quality Protection Act of 1996* (FQPA), the implications for Canada and how implementation issues are being addressed, in particular the development of science policies, the impact on the Canadian re-evaluation program, and the impact of regulatory outcomes on industry and users (see Appendix F). Council members had expressed concerns about the impact of FQPA, especially on Canadian agriculture, at their first meeting.

The PMRA has been working closely with the U.S. Environmental Protection Agency (EPA) to ensure full understanding and appropriate Canadian input into the scientific issues around implementation of the FQPA. At this point, the PMRA agrees in principle with the approaches being taken by the EPA.

The following summarizes issues raised and points of view expressed by Council members.

- PMRA should attempt to influence the EPA FQPA science policies to the extent possible, but not be bound by the outcome if disagreement remains. [The PMRA indicated that the government will continue to make registration decisions based on scientifically based risk management principles and would not be bound by decisions made elsewhere. At the same time, efforts to harmonize with the U.S. will continue in order to avoid differences to the extent possible.]

- Registrants may not be willing to support minor uses in light of the new FQPA requirements.

- It will be important to identify critical uses and generate robust data on actual use and residues in food, so that risks are not overestimated. Lack of a national sales database is a serious problem in this regard.

- The need for a fast track for the review of applications for the registration of potential replacements for products affected by FQPA was raised. [The PMRA indicated that industry should be encouraged to submit joint U.S. / Canada applications for the registration of replacements.]

- Registrants are concerned with possible impacts on fees. [PMRA does not expect fees to change as a result of FQPA because data requirements will not change significantly.]

- Industry is concerned with the impacts on harmonization and trade. [PMRA is working closely with the Departments of Foreign Affairs & International Trade and Agriculture & Agri-Food and the Canadian Food Inspection Agency to flag potential trade issues.]

Re-evaluation - Janet Taylor, PMRA, presented an overview of the proposed re-evaluation program which had been distributed in advance. It had been agreed at the first Council meeting that a proposal would be distributed in early 1999 for discussion at the next meeting.

The goal of the proposed program is to re-evaluate all products registered up to December 31, 1994 by 2005/06. Resources for the program will be shifted from submission backlog review and will increase as improvements to the efficiency of submission review allow more resources to be shifted. Cost of the program will be minimized by relying heavily on the use of available international reviews. The program will be coordinated with tolerance reassessments being conducted in the U.S. as a result of implementation of the FQPA.

In addition to the Advisory Council, the Federal-Provincial-Territorial Committee on Pest Management and Pesticides, the Economic Management Advisory Committee and other federal government departments have been requested to submit written comments by March 15, 1999. The proposed program will then be revised, as appropriate, and distributed for broader consultation.

The following summarizes issues raised and points of view expressed by Council members.

- There was general support for the approach to base re-evaluations on international reviews whenever possible, as long as the Canadian context was taken into account. Use of other harmonized approaches, such as residue zone maps, was also encouraged.

- Some Council members would favour the development of criteria to prioritize the Canadian re-evaluation program, rather than simply adopting the schedules of other countries. [PMRA stated that because the proposed program would maximize the use of international reviews,

there is limited scope for establishing unique Canadian priorities. In addition, this could divert resources from conducting the re-evaluations.]

- Some Council members would encourage grouping the pesticides into clusters according to use for the purposes of re-evaluation. [PMRA explained that, in the component of the program that is coordinated with FQPA, pesticides would be clustered based on their mechanism of toxicity which, in some cases, results in use clusters.]

- Industry is concerned about the cost of the program and disagrees with it being funded in part through cost recovery, because they view it as a public good. [PMRA pointed out that the resourcing strategy for the re-evaluation program was agreed upon when the cost recovery regime was implemented, i.e., resources would be gradually shifted to re-evaluation once the backlog of submissions was eliminated and as efficiencies were realized.]

- Instead of shifting resources to re-evaluation, industry would prefer that improvements in submission review efficiency lead to lower fees and/or shorter performance standards. They assert that lower fees would lead to faster development of new, safer replacements for older products which would then not need to be re-evaluated. Other Council members pointed out that there would still need to be a legal mechanism to remove the older products from the market.

- Industry questioned the need to re-evaluate products registered as late as 1994 and the need to review data in addition to an international review. [PMRA explained that products registered in 1994 would likely not be addressed until the last years of the program, i.e., as late as 2005/06. Data requirements and assessment methodologies would be expected to evolve over a ten year period. In addition to international reviews, information on Canadian uses and on residues and environmental fate under Canadian conditions are often necessary.]

- The need to reassess efficacy was questioned. [PMRA explained that this would only be done when risks were determined to be unacceptable; in this case efficacy data might indicate that uses/rates could be reduced in order to reduce risks.]

- Concerns were expressed that the proposed schedule could not be met and that costs might exceed projections.

- The suggestion was made that, when data are submitted in response to a call-in, adverse effects should be flagged by the registrant.

The above issues will be considered, along with the written comments, as the proposal is refined for purposes of broader consultation.

Terms of Reference / Modus Operandi - The following recommendations were made and will be incorporated into revised terms of reference, as appropriate, subject to approval by the Minister.

Modus Operandi: ***The Council decided that process matters could be decided by a simple majority vote, provided a quorum of members was present.*** [Post-meeting note: Legal counsel has advised that, unless otherwise stated, a quorum would normally comprise 50% plus 1 members. The Council may wish to discuss whether this is adequate.]

Alternates: After some discussion, the following motion which was formulated by Lorne Hepworth and Julia Langer, moved by Barbara McElgunn and seconded by Darwin Lewis, was carried by a vote of 17 to 3.

Council members representing associations may nominate one permanent alternate, who will be listed on the membership list. The alternate will be required to complete the Conflict of Interest Disclosure Form. In setting meeting dates, the Secretariat will make every attempt to accommodate the availability of as many members as possible, especially those who are unable to name an alternate.

Observers: Meetings will continue to be open to any observers who indicate their attendance in advance. They will not be provided with the documentation provided to members. As indicated in the terms of reference, the Council may meet in closed session where necessary to discuss confidential information. The agenda will indicate any closed sessions.

Distribution of documents: Council members may distribute and/or discuss documentation provided in advance of meetings as necessary to properly represent their association or sector at the meeting. Any document that should not be distributed beyond Council members will be so marked.

Meeting report: For the November 23, 1998 meeting, the Secretariat prepared a draft report for review by Council members and then finalized the report after incorporating comments received. The Council agreed that this process was satisfactory.

Action items: The Council decided that a list of action items should be agreed upon at the end of each half-day.

Website: Meeting reports will be posted on the PMRA website after being finalized. There was not agreement to post the terms of reference of the Council.

Comments by Council members to the media or public / Statements by observers at Council meetings: These items were not discussed and will be carried forward to a future agenda.

Process for Establishing Future Agenda: The following process, proposed by the Secretariat, was accepted by the Council.

Council members will submit a list of issues that they would like to see addressed to the Secretariat, along with a brief explanation. The Secretariat will distribute the list to members, along with a proposed selection for the next meeting's agenda. A final agenda will be prepared by the Secretariat taking into account members' comments. Members who suggest issues included on the agenda will be expected to prepare background documents in advance of the meeting. The Secretariat will assist in preparation of background material, as necessary.

February 16, 1999

Proposed Amendments to the *Pest Control Products Act* - Geraldine Graham, PMRA, presented a detailed outline of the proposed amendments. The amended legislation is intended to provide a clear and modern legal foundation for the risk management approach to regulating pesticides. Council members had discussed the proposals at their first meeting and had requested more detailed information in order to help them formulate advice to the Minister on whether or not to proceed with the proposed amendments.

The following summarizes major themes raised during the discussion.

- In response to a question, the PMRA provided the following three primary reasons for proceeding with the amendments:
  - to significantly increase openness and transparency; this will benefit the public, provinces/territories, and other federal government departments, and will facilitate international harmonization;
  - to introduce/improve certain specific elements, e.g., mandatory reporting of adverse effects, authority to make regulations to implement a national sales database, and enhanced enforcement provisions;
  - to clarify the risk management approach to regulatory decision-making.

- Many Council members support proceeding with the amendments as quickly as possible. Some made specific suggestions for additions which will be detailed in their written comments.

- Other Council members are uncertain as to why the initiative is being undertaken and expressed concern that the legislation may not take sufficient account of future directions in pest management or is not sufficiently different from the current legislation to make it worth proceeding.

C The preamble of the proposed new Act will be an important vehicle to outline the context of pest management regulation in Canada. Some specific points that Council members thought should be recognized in the preamble are:
  - provinces/territories as co-regulators;
  - importance of timely access to new, safer pest management technology and competitiveness;
  - need to protect the most sensitive subpopulations, e.g., children, elderly;
  - uncertainties inherent in risk assessment;
  - health care costs if health is not adequately protected;
  - importance of international harmonization.

C Many Council members strongly support the objective of fostering public confidence in the regulatory system through increased openness and transparency, including public consultation on major registration decisions. Some members expressed concern about the impact that provisions for public consultation might have on the timely access to new technology if it is not conducted efficiently.

C Some Council members expressed strong concern with possible economic impacts of the legislative proposals, particularly on minor uses of pesticides.

C Differing views were expressed about the level of detail that should be included in the proposed new Act versus regulations and/or guidelines.

C Some Council members expressed concern about the lack of a delineated process, with clear responsibilities, for conveying information about pesticide poisoning incidents to the PMRA, and the relationship of this process with the proposed provisions for mandatory reporting of adverse effects in the new legislation.

The Council agreed to the following process as a path forward.

1. Members should provide any written comments on the legislative proposals by March 16, 1999 (addressed to the Chair, c/o Ms. Tanya Saunders, PMAC Secretariat). The comments should cover any substantive points in as much detail as desired. Letters from each Council member would be appreciated, even if simply a brief indication of support for proceeding or an indication to the contrary. No response will be interpreted as indicating support for proceeding with the proposed amendments.

2. By March 5, 1999, the Secretariat will prepare a draft summary of the February 16 discussion. This will be circulated to Council members for any comments, which should also be provided by March 16. By April 13, the Secretariat will also summarize the written comments, along with a PMRA response. The PMRA response will indicate

clearly which items will be addressed in legislation and/or regulations and will include a proposed preamble for the new Act.

3. The Chair will provide the above summary and response, as well as the letters from Council members, to the Minister. The Chair will ask the Minister whether he would like the Council to meet again specifically to formulate its advice to him or whether he would prefer to make a decision based on the material already before him.

4. In the event that a meeting is required, the Secretariat will prepare draft advice that could be presented to the Minister, for review and discussion by the Council.

Next Meeting / Items for Future Agenda - A meeting to finalize advice to the Minister on proposed amendments to the *Pest Control Products Act* has been tentatively scheduled for May 20, 1999. The Secretariat will canvass members for items for future agenda, although it may not be possible to discuss many of these at the next meeting which will focus primarily on legislation.

Appendices

Appendix A - Agenda for the meeting of February 15-16, 1999

Appendix B - Participants at the meeting of February 15-16, 1999

Appendix C - Presentation: Submission Review Process and Health Risk Assessment

Appendix D - Presentation: Environmental Assessment

Appendix E - Presentation: Risk Management and Decision-Making

Appendix F - Presentation: U.S. *Food Quality Protection Act* (FQPA) / Overview of Activities in U.S. and Canada