PEST MANAGEMENT ADVISORY COUNCIL

MEETING REPORT

January 17, 2000

Introduction / Review of Agenda / Progress of Legislation - No changes to the agenda were made. It was suggested that future agenda should include an item for business arising from the previous meeting.

Council members requested the Chair to ensure that their advice was provided to the Minister of Health as quickly as possible once agreed upon by the members. New input from any member should not delay provision of advice already agreed upon.

John Dossetor, Office of the Minister of Health, informed the Council that the Minister intended to introduce the new pesticide legislation into Parliament during this session but that the exact timing had not yet been determined. Mr. Dossetor assured the Council that their support for the initiative was crucial and that their views on the proposals would be taken into account in finalizing the legislation.

Council members requested the Minister to attend the next meeting and to inform the Council on which issues he would like to receive their advice.

Decision-Making Framework for Identifying, Assessing and Managing Risks - Diane Kirkpatrick, Senior Branch Advisor, and William Ross, Director, DMF (Decision-Making Framework) Project, both of the Health Protection Branch, Health Canada, presented an overview of the initiative to develop a departmental decision-making framework and policy development process (see Appendix C).

The following summarizes issues raised and points of view expressed by Council members and the presenters during the discussion.

It may be difficult to reconcile scientific judgement with public perceptions, especially in cases where there is a lack of scientific certainty. In some cases, public opinion could prejudice objective scientific decision-making.

Public input is important at all stages of the process, particularly in identifying the issue and its context, and should not be confined to consultation on the science issues. The degree and form of public involvement will vary on a case-by-case basis. For example, in urgent situations there may only be time to keep the public informed as opposed to being able to consult. It is particularly important to disseminate information early in order to assure the public that the government is dealing with the issue. Consultation could follow later once the immediate urgency is under control.

Science and policy teams need to gather as much information as possible, including information from external sources such as adverse effects reports.

A well defined policy development process will serve to alleviate internal staff discontent, as well as building public confidence.

Public involvement will lead to increased public awareness of the government's role in ensuring the safety of products and processes such as biotechnology.

The Chair observed that the issue of public involvement could be a topic for discussion at a future Council meeting.

Diana Somers, a\Director, Health Evaluation Division, Pest Management Regulatory Agency (PMRA), outlined a draft PMRA risk assessment and risk management decision-making framework (see Appendix D).

Action: Council members were invited to provide comments to the Secretariat by February 29, 2000. These comments will be distributed to all Council members, unless a member requests otherwise.

Dan Krewski, consultant to Health Canada, described his role in advising on the development and implementation of risk assessment

and risk management decision-making frameworks in Health Canada and the individual organizations within it. Dr. Krewski is involved with initiatives in this area being conducted by the Centre for Population Health Risk Assessment, University of Ottawa, which liaises with a number of Schools of Public Health in the United States.

Dr. Krewski reported that he is confident that the PMRA risk assessment and risk management decision-making framework is an appropriate adaptation of the Health Canada framework, that it embodies current and appropriate risk assessment and risk management approaches and that it is consistent with the latest international developments. He further assured the Council that methodologies used by the PMRA for both cancer and non-cancer risk assessment were compatible with the latest approaches used in other countries, such as those developed jointly in the United States through government (Environmental Protection Agency) and academia (e.g., John Hopkins University, The International Life Sciences Institute) to implement the *Food Quality Protection Act of 1996*.

The following summarizes issues raised and points of view expressed by Council members and the presenters during the discussion.

Documenting the PMRA's decision-making framework provides predictability and accountability and serves to refute any public misconceptions.

The PMRA framework encompasses environmental, as well as health, risk assessment. The same framework is used for initial registration decisions as well as decisions following re-evaluation.

Important factors to include are reports of adverse effects, availability of alternative pest management products and strategies, and results of routine and special monitoring surveys.

Mechanisms to obtain adverse effects reports from doctors need to be developed; the strategy for this may need to include medical school training. A framework for adverse effects reporting is in the initial stages of development within the PMRA and will include liaison with poison control

centres. This information would be taken into account during re-evaluation and special review.

Electronic systems should be implemented to the extent possible in order to increase the efficiency of the decision-making process.

Decision-making for health risk management has evolved more internationally than has decision-making for environmental risk management.

Some Council members suggested that future Council discussions could focus on the details underlying the decision-making framework, e.g., what data are required for risk assessment, how are formulants handled, how do international trade issues influence the assessment of value, how is the acceptability of risk and value determined, how precautionary is the approach behind risk management decisions, how is public input factored in. Collaboration among PMRA and other government departments in the development of risk management policy could also be discussed.

Formulants Policy - Roy Lidstone, Head, Submission Screening Section, PMRA, described progress in developing a new PMRA formulants policy (see Appendix E). The objective is to develop a policy that would be harmonized with that of the U.S. Environmental Protection Agency. Once the draft policy is prepared, a Regulatory Proposal will be distributed for consultation.

Action: Council members were invited to provide comments on the proposed policy as presented, for consideration in the preparation of the Regulatory Proposal.

Some council members expressed support for the general direction of the policy development. The following summarizes major themes raised during the discussion.

Consideration should be given to developing a means of tracking the overall use of individual formulants.

More consideration needs to be given to the degree of risk assessment required for different types of formulants. For

example, this might depend on the function of the chemical in the formulation.

Disclosure of formulants is a very important and controversial issue. At present, there does not seem to be consensus on whether the toxicity of the formulant should be the trigger for disclosure. The U.S. Environmental Protection Agency has established a government/ industry working group to explore this issue. The PMRA will be participating in the discussion. Options could be presented to the Council for discussion at a future meeting. The Council would need more information on current Canadian legislation and policies prior to such a discussion. Council members declined an invitation from PMRA to participate directly in the working group.

Developing Innovative Approaches to Pest Management - Wendy Sexsmith, Director, Alternative Strategies and Regulatory Affairs Division, PMRA, introduced the next three agenda items. These all relate to the PMRA's strategic objective #1, namely, to protect health, safety and the environment from the risks of pesticides through the use of sound progressive science, including innovative approaches to sustainable pest management. The PMRA pursues this objective through:

registration of pest control products that reduce risk, e.g., reduced risk chemicals and biopesticides;
integrated pest management programs in concert with users and others;
Sustainable Development Strategy.

Biopesticides - Ms. Sexsmith described how the PMRA facilitates access to biopesticides (see Appendix F). The following summarizes issues raised and points of view expressed by Council members and the presenter during the discussion.

Canada reviews efficacy data whereas the United States does not. However, the U.S. does expect that efficacy trials will have been conducted by the applicant. This difference in approach has not proven to be a barrier to harmonization and work sharing. When joint Canada/U.S. reviews are conducted, the U.S. considers the Canadian efficacy review

in its decision-making.

The joint review project focuses on reduced risk pest control products. A prerequisite to applying this to biopesticides was the harmonization of data requirements. The availability of the joint review option, and the possibility of a larger market upon registration, provides an incentive to companies to develop new biopesticides. At present, there are two new microbials undergoing joint review.

Genetically-modified microbial pest control products are regulated by the PMRA, with appropriate additional data being requested.

One Council member expressed concern that the cost of generating the required data would preclude the development of new products or would lead to the use of unregistered products. On the other hand, it was pointed out that data requirements are tailored to individual cases through pre-submission consultations.

The data requirements for biopesticides cover environmental, as well as health, risks.

Joint reviews for reduced risk products, including biopesticides, have a shorter performance standard than other submission streams. The registration of biopesticides is also encouraged through the URMUR (User-Requested Minor Use Registration) program.

Integrated Pest Management - John Smith, Senior Project Manager, Alternative Strategies and Regulatory Affairs Division, PMRA, described the PMRA's integrated pest management (IPM) partnership projects (see Appendix G).

Many Council members expressed strong support for the IPM partnership projects. Some Council members would be interested in discussing the criteria for prioritizing these projects at a future Council meeting. Another topic of discussion could be the establishment of goals and measurement of progress in IPM adoption.

In addition to developing IPM strategies, the partnership projects also identify research needs. Because organizations responsible for conducting research, such as Agriculture and Agri-Food Canada and growers' associations, participate on the project teams, they are made aware of these research needs and can consider addressing them. Some Council members expressed concern with the level of funding for IPM research and the fact that the PMRA itself does not have any funds dedicated to research. Other members cautioned against putting PMRA in the awkward position of being both regulator and advocate of new pest management technology.

The Council decided to advise the Minister of Health that it supports the IPM Partnership Projects and that the PMRA should be encouraged to develop a proposal for the consideration of the Council with regard to the adoption of IPM in two pilot areas (canola and one other), including the identification of barriers, measurement techniques, funding issues, the need for enhanced collaboration with other departments and recommendations for additional pilots.

The Council also decided to urge the Minister of Health to work with his Cabinet colleagues to ensure adequate resources to support IPM research and advance its adoption.

Sustainable Development and the PMRA - Laura Doliner, Senior Project Manager, Alternative Strategies and Regulatory Affairs Division, PMRA, presented a status report on sustainable development and the PMRA (see Appendix H). Development of Health Canada's updated Sustainable Development (SD) Strategy, due December 15, 2000, will provide a forum in which to position IPM issues and needs and to discuss interdepartmental collaboration.

The following summarizes major themes raised during the discussion.

The Commissioner of the Environment and Sustainable Development has instructed departments that their updated SD strategies should include more measurable outcomes than did the ones prepared in 1997. Departments will need to find ways of demonstrating continuous improvement. This could involve the allocation of resources to data gathering surveys. Determining an appropriate balance of resource

allocation between activities and measurement will be challenging.

PMRA measurement tools could include progress in harmonization and the registration of reduced risk products. In the longer term, pesticide risk indicators being developed by the OECD will provide a more comprehensive measure of progress in risk reduction.

SD strategies recognize responsibilities of and linkages with other levels of government. Departments are being encouraged to build partnerships in order to fulfill their SD objectives.

Fisheries Act - Wendy Sexsmith outlined the relationship between the federal *Pest Control Products Act* and the federal *Fisheries Act* (see Appendix I). Once a federal position has been determined based on legal advice from the Department of Justice, it is proposed that a draft policy be distributed for consultation with stakeholders and provinces/territories.

Next Meeting - It was proposed that the Council meet next in late spring 2000. The following suggestions for future agenda were made.

Public involvement in decision-making
Government's role in communication to build/increase public confidence
Health Canada and PMRA decision-making frameworks
- examples of how they work in practice
- values behind decision-making (e.g., how precautionary)
- data requirements
- formulants
- risk assessment of genetically modified pest control products
- ecological risk assessment
- endocrine disruption
- collaboration with other departments, e.g., Agriculture and Agri-Food Canada, Environment Canada

Disclosure of formulants

IPM partnership projects: adoption, measurement
Performance indicators, including SD scorecard
PMRA enforcement program: role, capacity, objectives
Re-evaluation
- status of Regulatory Proposal
- process for re-evaluation of organophosphate pesticides / opportunities for public input

Action items to respond to report of Commissioner of the Environment and Sustainable Development
Cost recovery and its impact on the development of new pest control technology
PMRA budget and resource allocation

Council members requested that material on which advice is sought be distributed in advance of the meeting.

Appendices

Appendix A - Agenda for the meeting of January 17, 2000

Appendix B - Participants at the meeting of January 17, 2000

Appendix C - Presentation: Building Confidence in Decision Making: A Policy Development Process

Appendix D - Presentation: Risk Assessment and Risk Management in the Pest Management Regulatory Agency

Appendix E - Presentation: Formulants Policy (Update on Policy Development)

Appendix F - Presentation: Improved Access to Biopesticides

Appendix G - Presentation: Integrated Pest Management Partnership Projects

Appendix H - Presentation: Sustainable Development and the PMRA

Appendix I - Presentation: Relationship between the

Federal *Pest Control Products Act* and the Federal *Fisheries Act*