PEST MANAGEMENT ADVISORY COUNCIL

MEETING REPORT

June 3-4, 2003

June 3, 2003

Introductions/Review of Agenda

Richard Van Loon, Council chair, opened the meeting and had Council members introduce themselves. Council members were advised that Joanne Buth has agreed to serve as the vice-chair of the Council.

Revised copies of the agenda were distributed. The chair announced that under "Other Business", the Recommendations to the Minister would be the first item discussed.

New *Pest Control Products Act*

Overview

Geraldine Graham, Head of the Regulatory Affairs Section, Pest Management Regulatory Agency (PMRA) gave an overview (see Appendix C: *The New Pest Control Products Act* [PCPA]) of the new PCPA and the work plan for its implementation.

The following summarizes major themes raised during the discussion.

- Council members, overall, provided very positive feedback on the phased approach to implementing the new PCPA and the chart that showed the steps involved.

- In Phase II, PMRA will be working on a policy relating to the use of the precautionary principle. A statement of the precautionary principle is contained within the new *PCPA* and is consistent with the definition in CEPA.

- Re-evaluation time-lines are not linked with the time-lines for the phased approach to implementing the new PCPA, however, the new Act will give PMRA authority to take action if requested data are not provided which could expedite the re-evaluation process. It was suggested that a chart, similar to the one provided for the implementation of the new PCPA, showing plans and progress of the re-evaluation program would be useful.

- The consultation documents for the four key new regulations have a 30 day comment period. An additional comment period of 75 days will be provided when the proposed regulations are published in Canada Gazette Part I. It was suggested that any consultation documents should address resource implications to industry.

- The new Act and regulations do not change the way products of biotechnology are regulated. PMRA continues to regulate genetically modified organisms that have pest control properties, and CFIA continues to regulate any crop that has been genetically modified for resistance to certain pest control products or to incorporate certain pest control properties.

Presentation of the Proposed Content of New Regulations

Council members were advised that the chance to comment on the regulatory proposals at PMAC did not replace their opportunity to submit detailed written comments as part of the formal consultation process.

Reporting of Pesticide Sales Information

Cameron Laing, Project Manager, Regulatory Affairs Section, PMRA, presented an overview (see Appendix D: *Pesticide Sales Reporting*) of the proposed regulation regarding the reporting of pesticide sales information.

The following summarizes major themes and clarifications raised during the discussion.

- There was a discussion regarding the applicability of sales information to approximate actual use. It was felt by some Council members that what would be reported was actually sales to vendors, and that one weakness in this is the assumption that vendors are not stockpiling product. PMRA pointed out that the collection of actual use information through means such as a survey is very expensive and that the OECD considers collection of sales data to be a reasonable substitute. It was suggested that PMRA purchase sales data from A.C. Nielsen for stores such as Walmart.

- Council members representing industry expressed concern over the anticipated difficulties in collecting sales information by province. This issue of concern is that estimates would only be allowed for two years and that this is not enough time to establish the infrastructure necessary to collect this data. Council members representing industry requested that an extension of the time lines regarding the use of estimates be considered by PMRA.

- Council members representing industry were also concerned that public disclosure of information on the quantity of sales would result in the disclosure of monetary value. PMRA indicated that proposed policy on disclosure would prevent disclosure of monetary value through the roll-up of product sales to the active ingredient level and even further in instances where an active ingredient is found in only one product.

- Some council members were interested in learning how the sales information collected would be used by PMRA and how it would be used to estimate exposure.

Adverse Effects Reporting

Jean-Pierre Lachaîne, Health Evaluation Division, PMRA presented an overview (see Appendix E: *Adverse Effects Reporting*) of the proposed regulation regarding the reporting of adverse effects.

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

- A concern was raised regarding the inclusion of some serious effects such as seizures or miscarriage within the definition of moderate effects.

- A Council member felt that the 14 day notification period for death of an animal or human was too long. It was suggested that there should be a requirement to report that a death occurred immediately and allow time after for the investigation into how and why the death occurred. Concern was raised that in the interim period between initial reporting of an incident and investigation of the incident, great care must be taken by PMRA to only inform the public and the media once the full story is known and accurate information can be given.

- Many Council members felt that the PMRA should keep the focus of this system on the reporting of health and environmental effects. Many felt that the requirement to report efficacy failures would lead to undue burden on the registrants to report every single failure, and large data management issues within PMRA. It was suggested to revisit the definitions for reporting efficacy. Regarding the reporting of observed pesticide resistance, it was indicated that it takes several years of investigation to reach a conclusion that resistance is present and that this type of information should be considered under the “notification” system within PMRA, not under reporting.

- Some Council members emphasized the importance of the voluntary reporting of incidents by the medical community and Poison Control Centers. Several members volunteered to participate on a PMAC Working Group to establish appropriate linkages with these groups. Appropriate linkages must also be made to ensure certified applicators are trained regarding the reporting system requirements.

- It was pointed out by one Council Member that this system is not a substitute for the need for increased environmental monitoring.

- Some council members were interested in learning how the information that is collected would be used by PMRA and how and when it would be used in the health and environmental risk assessments. The Council was interested in how the PMRA will organize this information so that they are in a position to speak to the media regarding any incidents.

- The fact that the U.S. collects human bio-monitoring data and that Canada does not was raised. It was suggested that PMRA should arrange for bio-monitoring studies in Canada.

WHMIS Equivalent Provisions

Geraldine Graham, Head of the Regulatory Affairs Section, PMRA gave an overview (see Appendix F: *WHMIS Equivalent Provisions for Pesticides*) of the proposed regulation regarding WHMIS equivalent provisions.

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

- Some members were very pleased that WHMIS provisions are being incorporated into the pesticide regulations.

- Concern was raised by some Council members regarding the cost of attaching an MSDS on every pesticide container and that this was an excessive burden for industry. Many applicators buy multiple containers of the same product and only need one MSDS. It was pointed out that within the WHMIS system, under the Hazardous Products Act, it is the responsibility of the supplier to provide MSDSs to workplaces and the responsibility of the employer to make the MSDS available to the employees. It was suggested that products be sorted into risk categories and the higher risk products have the requirement for an MSDS, but that reduced risk products not need an MSDS. PMRA responded that they do not classify products by risk category.

- One member suggested that if the MSDS includes additional health information that is not currently on the label, the PMRA should not wait for the regulation to be in place, but should publish this information on a website. Also, if the MSDS includes additional health and safety information, an MSDS should be provided with domestic products as well as with restricted and commercial ones. PMRA responded that if there were unacceptable risks associated with domestic products, they would not be registered.

- It was pointed out that many applicators and pesticide workers across the country do not speak English and that the MSDS will be thrown away. Others felt that workers, and in many cases their spouses, were generally very receptive to health and safety information. It was also noted that PMRA has an obligation to provide essential health and safety information, and if the user throws the information out, that is the personal choice of the user.

- It was suggested that the requirement for the hatched border would take additional space on labels that are already tight for space.

Reconsideration of Decisions

Geraldine Graham, Head of the Regulatory Affairs Section, PMRA gave an overview (see Appendix G: *Reconsideration of Decisions*) of the proposed regulation regarding the reconsideration of decisions.

The following comments and clarifications were noted during the discussion.

- The discretion to decide whether to establish a review panel or not is consistent with the approach under CEPA. It is anticipated that certain positions within the PMRA will be designated as qualified to make that decision on behalf of the Minister.

- The review panel would be selected from a list of qualified individuals.

- Some members expressed concern that a single request might not be given approval for review by the panel, but that if there were a number of requests that dealt with the same type of issue, consideration of the issue, not just the individual request, should be given.

- It was discussed that EPA had the capacity to pull together a panel of experts for the purpose of discussing issues. It was suggested that PMRA utilize this approach as well.

PMRA Compliance Program and Update on AMPs

Karen McCullagh, Director of Compliance, Lab Services and Regional Operations Division, PMRA presented an overview (see Appendix H: *PMRA Compliance Program and Update on AMPS*) of the compliance program within PMRA and the Administrative Monetary Penalties (AMPs) system.

The following summarized comments and clarifications noted during the meeting.

- Clarifications pertaining to the amount of authority the PMRA has in its investigations

were given including that food can be seized if its linked to a misuse or violation, that private property including farmers' fields can be entered, and that compliance agreements can be negotiated in lieu of fines.

- CFIA and the provinces have responsibility for the monitoring of MRLs in food. When a violation is found it is PMRA's responsibility to determine why the violation occurred (e.g., whether this would be as a result of misuse or unregistered use).

- Up to thirty percent of compliance officers' time is spent dealing with issues that arise outside of the planning process.

Communication and Outreach

Overview, **Explaining the New Act to the Public, Web Based Communication**

Janice Hopkins, Director, Alternative Strategies and Regulatory Affairs Division, PMRA gave a presentation (see Appendix I*: Communications and Outreach - Overview*) outlining the communication strategy proposed for the new PCPA, and various communication activities ongoing within the PMRA. Geraldine Graham, Head, Regulatory Affairs Section, PMRA presented a document that will be used to communicate with the public regarding the new PCPA (see Appendix J: *Explaining the New PCPA to the Public*). Murray Gwyer, Director, Business Line Improvement and Technology Development Division, gave a presentation (see Appendix K: *Web Based Communication*) regarding the plans for a new look to the PMRA website.

The following summarizes major themes raised during the discussion.

- Overall the Council was pleased with the plans for communicating the new Act, the document targeted to the public and the look of the new website.

- Additional messages need to be added to the communication strategy including re-evaluation, the safety built in by the risk assessment process, that the PMRA is involved in public health issues such as West Nile Virus, the new adverse effects reporting system, that the public has a means to become engaged in pesticide decisions, and that pesticides contribute to a healthy forest. It was also thought that the annual report should be a key communication tool. Suggestions were made regarding additional audiences for the communication strategy including high schools and municipal governments.

- Considerable discussion took place concerning re-evaluation and that the PMRA needs to have a greater focus on communicating about the program itself and the progress it is making.

- The 1-800 call line number for the PMRA should be emphasized, and the standards for

response should be identified. Current standards for the call line are that everyone who calls will get a response within 24 hours, even if its just to say that their call was received (Clarification post meeting). PMRA should expect an increased use of the call line with the new communication activities.

- Suggestions were made to include additional information in the PCPA document, including international activities that the PMRA is working on, and additional information concerning re-evaluation activities. In addition, some parts of the document should be reviewed to ensure accuracy including the section on testing for endocrine disruptors, and neurotoxicity testing. Some Council members felt that there is still confusion around definitions of minor use, URMUR and URMULE, as well as joint reviews versus regular submission review procedures.

- A suggestion was made to pilot the public registry and learn from the experiences of CEPA and the Ontario government.

- Comments from Council members on the new PMRA website included that it should have a button that would put readers on a mailing list to receive similar documents as they become available. It was also felt that label information needs to be highly visible and that an appropriate search engine is used for searching the database. Organizing information by audience was viewed positively but it was strongly suggested that when referring to the public in the context of the web site, the term consumer should be avoided.

Reporting

Existing Reporting (within the Government of Canada), New Reporting Under the new PCPA, PMRA Annual Report (1998-2003)

Janice Hopkins, Director, Alternative Strategies and Regulatory Affairs Division, PMRA gave a presentation (see Appendix L: *Reporting*) outlining existing reporting structures within the federal government, what new reporting will be required by the new PCPA and an outline of what the PMRA Annual Report will look like.

The following summarizes major themes raised during the discussion.

- Overall Council members were pleased with the outline of the annual report. Council members want to ensure that quantitative information relating to the numbers of registrations, re-evaluations etc. is contained within the report. Council members also want to have a consistent style and outline of the annual reports from year to year so that readers can compare years.

- Some Council members suggested that PMRA should play a role in directing research on pesticide issues which would ultimately be of use in regulatory decision making.

- It was clarified that in order to keep the size of the report reasonable, web links would be used within the document to direct people who want more information on a particular subject area. It was also clarified that PMRA does not spend a lot of time on Access to Information Requests.

Wednesday, June 4, 2003

Remarks from the Office of the Chief Scientist (Health Canada)

Kevin Keough, Chief Scientist for Health Canada gave introductory remarks and explained the five main areas his office is focusing on including:

- Increasing the capacity of the Department to perform science.

- Ensuring excellence in what the Department does.

- Engaging in innovative partnerships to accomplish the goals of the Department.

- Enhancing the dialogue between science and policy making.

- Raising the profile of the science.

Minor Use - Update

Richard Aucoin, A/Chief Registrar, PMRA and Bill Boddis, Agriculture and Agri-Food Canada (AAFC) gave an update on minor use activities (see Appendix M: *Update on Minor Use Initiative).*

The following clarifications and comments were noted during the discussion.

- Minor Use submissions must meet the same health and safety standards as regular submissions.

- Some Council members wanted clarification on minor use versus minor sales. It was clarified that minor uses are small acreages, but that companies don't make the investment in producing data to support a minor use unless there is reasonable chance of profit from the investment. It was suggested that the definition of minor use include

acreages and an explanation that it constituted niche marketing. It was suggested that sales of minor use products be tracked through the sales database.

- AAFC and PMRA are cooperating on a risk reduction strategy that develops commodity-specific IPM solutions and crop profiles in conjunction with stakeholder groups. These programs also help identify gaps that would benefit from additional research into new tools and from development of new products.

Revocation of the 0.1 ppm Default Regulation for Residues

Frank Wandelmaier, Alternative Strategies and Regulatory Affairs Division, PMRA, presented an overview (see Appendix N: *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues*) of the proposal to revoke the 0.1 ppm default MRL regulation.

The following summarizes comments, clarifications and major themes raised during the discussion.

- Council members were pleased overall with the proposal and wanted assurance that all federal partners were on side and that PMRA will proceed with the proposal. PMRA indicated that federal departments including DFAIT, CFIA, AAFC and HC had been consulted prior to the release of the consultation document and that their comments were incorporated into the consultation document.

- The comments received will be taken into consideration in the preparation of the regulation. The time frame for the Gazette I notice is likely to occur in the next fiscal year.

- It was clarified that a product entering Canada with measurable residues for which no MRL is listed in Table II and the Food and Drug Regulations, would contravene the F&D Act, regardless of the country of origin.

- It was clarified that this policy would lead to more realistic estimates of residues being available and would reduce the potential to unnecessarily fill up the risk cup. This is important since the risk cups are diminishing in size because of aggregation and cumulation of exposure and risk. It was pointed out that this is a science based policy in line with the direction international communities involved in pesticide regulation have taken.

- The definition of no detectable residues was discussed. It was clarified that for pesticides, a quantifiable residue must be present as identified through reliable, routine analytical methods.

West Nile Virus

Richard Aucoin, A/Chief Registrar, PMRA gave a presentation (see Appendix O: *West Nile Virus: The Role of the Pest Management Regulatory Agency of Canada*) on what role PMRA played in developing the public health approach to dealing with the West Nile virus.

The following summarizes comments and clarifications that were noted during the discussion.

- It was explained that the choice of adulticides for mosquito control is malathion because there is a very current database with a high level of confidence in the data. Alternatively, resmethrin is only registered for ground control, not aerial control and the data that is available is not as recent. It was clarified that spraying would typically occur during the night so that there would be maximum exposure to the mosquitos and minimum exposure to humans.

- It was clarified that the decision to spray either a larvacide or adulticide is made by the medical officer of health at the municipal level.

- The information presented on one of the overheads was clarified. Of the 10,000 mosquitos collected, 3% carried West Nile Virus; this was Canadian data. It was added that 85-90% of the West Nile Virus detected was not in a form that can be transmitted to humans.

Non-Food Use Agriculture

Gordon Surgeoner, Ontario Agri-Food Technologies presented an overview of the current and future uses of agriculture to support non-food industries such as industrial fuels, personal medicines and animal feedstocks.

The following summarizes major themes that were raised during the discussion.

- The issue of how the industry will segregate different uses of crops and pesticide use within the crop was raised, e.g. corn whose major use is to produce fuel, but a byproduct may be used in cattle feed. Can the crop be segregated so that the pesticides used on the corn were only registered for non-food use corn? It was pointed out that no matter what the final purpose of the crop, the human impact may be different, but the environmental concerns of pesticide use remain the same.

- The issue of whether there would be interaction between plant pharmaceuticals and pesticide residues on the crops used to produce the pharmaceuticals was raised as something the industry needs to be aware of.

Recommendations to the Minister

The Council agreed on the following recommendations. These and recommendations arising from the November 2002 PMAC meeting will be conveyed to the Minister of Health in a letter from the Council chair which will accompany the meeting report. Council members will be given the opportunity to comment on a draft letter before it is finalized.

1. The Adverse Effects Reporting system should focus on health and the environment, with a lesser emphasis on efficacy. A Working Group reporting to PMAC should be struck and tasked with establishing strong linkages with the medical community and Poison Control Centers to encourage voluntary reporting of adverse effects.

2. The re-evaluation program within PMRA should have an overall higher profile within communication activities with an emphasis on the re-evaluation process, activities and progress.

3. The PMRA Annual Report should include a variety of quantitative information.

4. The PMRA Communications Strategy should include messages on re-evaluation, the adverse effects reporting system, the registration process and how the public can become engaged on pesticide issues.

5. Health Canada, Environment Canada, the Department of Fisheries and Oceans and Agriculture and Agri-Food Canada should direct funding towards pesticide research including bio-monitoring, residues on food and environmental monitoring.

6. The definition of minor use should be clarified and the minor use program should track the actual use of pesticides on these minor use crops. The emphasis of the minor use program should be on reduced risk products.

The meeting was adjourned. The recommendations for future agenda items and the date for the next meeting will be determined through e-mail after the meeting.

Appendices

Appendix A - Agenda for the meeting of June 3-4, 2003
Appendix B - Participants at the meeting of June 3-4, 2003
Appendix C - Presentation: The New Pest Control Products Act
Appendix D - Presentation: Pesticide Sales Reporting
Appendix E - Presentation: Adverse Effects Reporting
Appendix F - Presentation: WHMIS Equivalent Provisions for Pesticides
Appendix G - Presentation: Reconsideration of Decision
Appendix H - Presentation: PMRA Compliance Program and Update on AMPS
Appendix I - Presentation: Communications and Outreach - Overview
Appendix J - Presentation: Explaining the New PCPA to the Public
Appendix K - Presentation: Web Based Communication
Appendix L - Presentation: Reporting
Appendix M - Presentation: Update on Minor Use Initiative
Appendix N - Presentation: Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues
Appendix O - Presentation: West Nile Virus: The Role of the Pest Management Regulatory Agency of Canada