PEST MANAGEMENT ADVISORY COUNCIL

MEETING REPORT

May 17-18, 2004

May 17, 2004

Introductions/Review of Agenda

Joanne Buth, A/Chair, opened the meeting. The agenda was accepted. Members agreed that at the end of each agenda item, the Chair would summarize any major items of discussion likely to lead to recommendations to the Minister.

Roundtable Discussion with the Minister of Health

Eric Lamoureux, Policy Advisor to the Minister of Health, opened the meeting on behalf of the Minister, who was not able to attend due to international commitments. He advised the Council that the Minister appreciates the Council's advice and recommendations, and looks forward to the Council's advice as the new *Pest Control Products Act* moves toward proclamation.

He acknowledged that the Council was without a Chair and thanked Joanne Buth for acting as Chair for this meeting. He also indicated that his office is presently considering the options for the position of Chair, and that a new Chair would be in place for the next meeting. Council members then introduced themselves and presented their key pesticide policy/regulation issues.

> John Borden, formerly the Director of Research and Development at Simon Fraser University and now working at the biotech company Aerotech expressed concern that the number of new registrations of reduced risk pesticides is not keeping pace with the number of older products that are removed from the market due to re-evaluation. There is concern over users not having the selection of products they need to control pests.
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> Pamela Welborne, Queens University, indicated that there is concern over the communication with undergraduate students regarding pesticides. The Pest Management Regulatory Agency (PMRA) needs to create understandable and accurate messages about pest management and pest control products and do a better job at delivering the messages, especially in light of the Report from the Ontario College of Family Physicians.

Gord Surgeonor, University of Guelph and President of Ontario Agri-Food Technologies, noted in his view, that the speed of new product registration in Canada is slow and it is having an impact on Canadian innovation. Companies apply to get a U.S. registration first and this results in Canadian farmers competing in international markets with limited access to new pesticide products.

John Cross, Philom Bios, indicated that in his view, there are no economic incentives to bring microbial or biocontrol pesticide products to market in Canada. Canada has the capacity to be a global leader in this area, but the registration system for this type of product needs to be streamlined and have the ability to give registrations faster.

Joanne Buth, Canola Council of Canada, advised that there is support for a strong, science-based regulatory system. Regarding the Maximum Residue Limits (MRLs) and global trade, there needs to be faster movement on the NAFTA acceptance of MRLs and the global harmonization of MRLs as we face trade issues with Japan. There is also an issue with the U.S. having access to more pesticide products than in Canada. In Canada we are losing products due to re-evaluation. There are too few new registrations and there are too few new products coming up through research and development. This lack of products inhibits Canadas ability to compete globally.

Dr. Whiting, Canadian Centre for Occupational Health and Safety, indicated that his role on PMAC was to ensure pesticide workers get adequate safety information to ensure safe working conditions and to promote the development of new technologies that will protect workers and bystanders.

Julia Langer from the World Wildlife Fund indicated that environmental issues are her main focus. She advised that law and policy reform are needed for the enhanced protection of the environment and wildlife. To this end, the new *Pest Control Products Act* should be proclaimed as soon as possible. The pace of the registration of low risk pesticides is too slow. Canada needs more alternative practices including IPM. There is still concern over wildlife protection, concern over re-evaluation and the need for a greater focus on environmental issues in the registration process.

Kathy Cooper, Canadian Environmental Law Association, indicated that the new *Pest Control Products Act* needs to be proclaimed as soon as possible. She strongly supports the municipal bylaws and the 2000 Supreme Court decision upholding the right of municipalities in Quebec to enact bylaws concerning pesticides. She also was involved with the College of Ontario Family Physicians Report with the goal of protecting children. She would like to see expedited reviews of reduced risk products. Lately her organization has been receiving more calls about people wanting access to lower risk products and wants this to be more of a focus in PMRA.

Dean Thomson, Canadian Horticultural Council, expressed the need to improve access to lower risk products by improving the registration system and examine how PMRA looks at risk and efficacy. There is support for the re-evaluation program, but concern over the need for replacement products. In particular, there is concern that we are going to be losing some of the main pesticide products as a result of re-evaluation, particularly with respect to apples. There is support for the revocation of the 0.1 ppm default regulation for residues, but the zone maps need more work within the context of a global marketplace.

Brian Tuffin, Consumer Chemical Specialty Products Association, advised that, given the recent media attention on pesticides, there is an opportunity to use the media to restore confidence in the pesticide registration system. There appears to be an absence of communication from PMRA and there needs to be more proactive communication from PMRA. He expressed interest in faster harmonization and joint reviews. A priority should be the education of consumers regarding the smart usage of products.

Len Ritter, University of Guelph, indicated that the largest issue is that the PMRA is delivering a rigorous science based registration system, but the public has less confidence in the registration system than ever before. His perception is that the public is confused by the messages they receive from the federal government and decisions made by the City of Toronto and the Province of Quebec. PMRA needs to take action and do something to restore public confidence.

Peter MacLeod, Croplife, noted that there is agreement that PMRAs communication activities need to be improved. The public does not know if pesticides are safe or not. There is a crisis in the confidence in the registration system. The harmonization efforts need to focus on the differences between the U.S. and Canada, in particular there are issues with MRLs resulting in the inability to trade some food commodities.

Bob Friesen, Canadian Federation of Agriculture, indicated that the pesticide file is a critical one for Canadian agriculture. He encouraged more consultation, communication, and partnership with user groups. There needs to be more focus on the Agricultural Policy Framework and more work with Agriculture and Agri-Food Canada (AAFC) to improve the future of agriculture in Canada. The speed of new registrations threatens competitiveness.

New *Pest Control Products Act*

Geraldine Graham, Head of the Regulatory Affairs Section, PMRA gave an update of the new PCPA and the status of the supporting regulations. Presentation materials were distributed at the meeting and are available on the PMRA website.

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

- There is an existing government wide policy on the precautionary approach, and the new Act also contains a specific reference to the precautionary principle. It is currently proposed that the PMRA will develop a policy related to this reference in the Act in 2005-2006.

- Significant fines exist for anyone violating the confidentiality of confidential test data.

- Any costs relating to a special review or the establishment of a review panel will be covered by the PMRA.

- The Council continues to support action, at the earliest possible time, to bring the new PCPA into force. The timing for proclamation is beyond the control of PMRA.

- The Council wishes to emphasize the importance of having new reduced risk pesticides (both chemical and biological) registered in Canada. Such products are important to reduce pesticide risks to health and environment, and for the ability of Canadian growers to compete. PMRA should look at how the European Union does its comparative risk assessments in light of the suggestion to include a list of which products a new pesticide is competing against within the published pesticide assessment. The comparative risk assessment should be used as a mechanism to substitute reduced risk products for older products.

Pest Control Products Sales Information Reporting Regulations

Geraldine Graham, Head of the Regulatory Affairs Section, PMRA gave a presentation on the Pest Control Products Sales Information Reporting Regulations that were published in *Canada Gazette Part I* on March 27, 2004. Presentation materials were distributed at the meeting and are available on the PMRA website.

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

- It was clarified that this regulation will only apply to products that are registered in Canada, including anything that has a PCP number, and not for products that are manufactured in Canada but only for sale in other countries.

- Current thinking is that the public will be provided access to the data rolled up by active ingredient by province where there is more than one product.

- Some Council members thought that the information gathered from the sales database should be used to track the sales of reduced risk products. It was also suggested that there should be an incentive within the system for registrants of reduced risk products.

- There was a discussion regarding the applicability of sales information to approximate actual use and that the information collected will be a surrogate for actual use. PMRA indicated that all types and sources of information were considered in the development of the regulation, including ACNeilson data which was very expensive and not always complete. It was noted that in the U.S., consumption data is collected and is only national in scope. Some Council members felt that it was unrealistic for PMRA to expect manufacturers to collect data after it leaves the warehouse as products go through many layers of sales and sales data can't be accurately collected on a provincial level. PMRA indicated that in some cases information is currently being provided to specific provinces on sales within their province, and that estimates of sales at the provincial level can be provided. It was noted that where registrants did not currently generate provincial level sales data, they would be allowed to provide estimates for the first five years.

- There was a discussion regarding the reporting provision for the sales database would allow for proper protection of confidential financial information. It was clarified that the key information being collected is the quantity of sales, not the monetary value and that where there is only one end use product, the numbers would be rolled up in a manner so as not to disclose the confidential information. There was an opinion that there needs to be at least five products on the market in order for the roll up of active ingredient data to prevent disclosure of the monetary value.

- It was discussed that the original purpose of the sales database was to help with re-evaluation and to track trends in risk reduction. It was noted that a federal/provincial/territorial working group worked on the development of the database over a five year period and that provinces were very interested in using the information. It was discussed that many people are interested in the information that will be collected and that PMRA should ensure the information is used for the purpose(s) intended.

- It was recommended that the Sales Database project undergo a formal evaluation four years after implementation. This evaluation would determine the costs to industry and to PMRA and that the costs be weighed against the benefits of the information.

- Council members were encouraged to submit detailed written comments as part of the formal consultation process through publication in *Canada Gazette, Part 1.*

Formulants Program

Brad Bergen, Head of the Formulants Section, PMRA gave a presentation on the PMRA Formulants Program. Presentation materials were distributed at the meeting and are available on the PMRA website.

There was very little discussion on this issue other than the following:

- There was general support for the program.
- It was clarified that the formulants on lists 2 and 3 will be priorities for re-assessment.

Action: An updated set of PMRA organizational charts should be provided to the Council.

Re-evaluation

John Worgan, Director of the Re-evaluation Management Division, PMRA gave a presentation on the re-evaluation program. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- PMRAs re-evaluation program considers what alternatives are on the market for pests, and whether the withdrawal of some uses due to re-evaluation will result in no products left to control the pest. Council members stressed that the importance of continued progress in re-evaluation, and of the availability of alternatives, when products are being phased out.
- Some Council members were concerned about the possibility that products may not be eligible for registration in Canada due to the existing MRLs on imported foods. It was indicated that joint reviews would prevent this situation from occurring, and registrants were encouraged to use the joint review process as often as possible.
- Some Council members expressed concern over PMRAs use of an additional safety factor in the protection of fetal effects. PMRA and the U.S. EPA apply additional factors to account for data deficiencies as well as for severe pre-and post-natal adverse effects. These practices are currently in use both in the U.S. and Canada. The new PCPA codify, to a large extent, this practice. One Council member indicated that the World Health Organization had convened a panel to look at the appropriateness of the additional safety factor and found that there was no justification for its use. PMRA agreed to investigate this further and report back to the Council on this.

- Council members appreciated the detailed reporting on the progress of the re-evaluation program and asked for more of this type of information and less summaries within PMRA's Annual Report. It was also suggested that the Annual Report indicate how many resources were directed to the re-evaluation program versus new product registration.

- It was clarified that the re-evaluation program typically included environmental assessments, and that some re-evaluation decisions were based on environmental issues. It was suggested that PMRAs re-evaluation program needed to have more consistent attention on wildlife and environmental issues and that there should be more follow up on the effectiveness of environmental risk mitigation efforts.

- It was discussed that the re-evaluation program has made significant progress and that this should be the focus of more proactive communication by the PMRA.

Delivering Transparency and "Doing Business" Electronically

Valerie Robertson, Director of the Submission Co-ordination Division, PMRA and Murray Gwyer, Director of the Business Line Improvement and Technology Development Division gave a presentation on how the PMRA is delivering transparency related to the new *Pest Control Products Act* and on continued progress towards an electronic work environment. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- It was discussed that appropriate security arrangements are being taken to protect the confidentiality of information within the proposed reading rooms including the signing of affidavits that information won't be misused, appropriate use of penalties under the PCPA as a deterrent, and that PMRA is working with information technology security specialists on the project.

- Some Council members expressed concern that the increased transparency will result in a company's business intentions being made available to the public. Other members indicated that this was not of concern to them as it is a similar situation to that of the United States where this type of information is in the public domain.

- It was clarified that all adverse effects that are submitted to the PMRA will be carefully considered prior to any action being taken.

- Some Council members expressed concern over the expense of investing in an electronic environment and that a comprehensive business case would be useful. It was indicated that the new PCPA requires that certain types of information be made available in an electronic public registry and that the cost of setting up an electronic capability will be off-set by efficiencies compared to alternative paper-based approaches. It was indicated that current electronic development builds on an electronic environment and capacity developed

progressively since PMRA's formation. Earlier development has positioned PMRA to take the next step towards an advanced on-line regulatory system in support of realizing operational efficiencies. PMRA is utilizing Government of Canada Secure Channel infrastructure thereby avoiding risks and costs associated with developing proprietary security solutions. Leveraging emerging Secure Channel capacity reduces the total electronic system cost allowing PMRA to focus application development resources on operational needs specific to the electronic regulatory environment.

- The PMRA is working closely with the U.S. through NAFTA and through OECD towards harmonisation of electronic submission form and format. The OECD is hosting a meeting to harmonize templates and associated information technology. PMRA has developed an electronic tool that supports the assembly of submissions in EPA, PMRA, and OECD formats. The Council emphasized that the PMRAs focus with the electronic environment should be towards harmonization. PMRA confirmed this is the case.

- It was discussed that the PMRA uses proper contracting procedures to ensure an appropriate paper trail exists for all expenditures. PMRA confirmed that this is done at all times.

2003 Report of the Commissioner of the Environment and Sustainable Development (CESD)

Trish MacQuarrie, Director of the Alternative Strategies and Regulatory Affairs Division at PMRA gave a presentation on the follow up to the 2003 CESD Audit. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- It was clarified that the Report did not contain a recommendation on timely access to pest control products.

- Health Canada is working with the provinces and territories to develop an improved approach to developing the water quality guidelines. The guidelines set acceptable limits for levels of chemicals within drinking water.

- One of the recommendations from the CESD Report was to address data gaps on pesticide exposure. The recent work of the interdepartmental committee, 5NR (Natural Resource) Working Group on Pesticides and Pest Management on addressing monitoring research was discussed. The Council wanted to ensure the work was well co-ordinated, properly funded and included health research, specifically the monitoring of human exposure.

- Some Council members were concerned about the issues raised in the Report, specifically the issues of data completeness, reliability, the re-evaluation backlog and compliance.

- The process of responding to an audit was discussed. The PMRA response was in the CESD Report. It was explained that there were many items within the Report that PMRA has taken action on and continues to make progress towards completing, and that all recommendations in the report have been or are being acted upon.

- PMRA was encouraged to give more information to PMAC members about any challenges the PMRA is facing so that the Council can recommend solutions.

Harmonization

Charalyn Kriz, A/Chief Registrar of the PMRA gave a presentation on the progress PMRA has made towards harmonization, efforts underway to increase harmonization and addressed the comments pertaining to harmonization within the CESD Report. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- Council members acknowledged that there had been progress towards harmonization, but indicated they want to see more. PMRA was encouraged to further address barriers to harmonization including work on efficacy requirements, worker exposure requirements and particularly, the residue trial zone maps. PMRA agreed to further explore the barriers, discuss the scientific issues with the U.S., and report back to PMAC.

- Council members representing industry explained that the choice to use the joint review process is based on profitability, and that even if joint reviews were further streamlined, industry could still choose to not do business in Canada. It was also discussed that if there are additional data requirements in Canada, it would be more costly to do business here.

- One Council member indicated that, in one case, it took 10 months to set up a preconsultation meeting for a joint review with PMRA and because of the long time lines to set up the meeting, the registrant chose not to pursue the joint review process. The PMRA asked for further information on this example and indicated that this is not the norm as the joint reviews are a priority within PMRA. (Further information has been provided directly related to this issue).

- Council members and PMRA encouraged the organizations representing registrants to utilize the joint review process as often as possible.

- It was clarified that the OECD standardizes test guidelines for toxicology studies, including a developmental neurotoxicology (DNT) study. It was further clarified that if the U.S. utilized data from a DNT study, the PMRA would likely use the data in a similar way. PMRA agreed to send the DNT documents to the interested Council member. (This has been done).

Human Resources Strategy

Pat Curry, Principal of the Continuous Learning Program at PMRA gave a presentation on the Human Resources Strategy with the PMRA. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- Overall, the Council expressed support for the Human Resources Strategy.

- It was clarified that the PMRA does have many staff with either a farming background or a degree in agriculture. In addition, the PMRA sends staff on field tours to ensure an understanding of the practices and challenges of pesticide use.

- It was explained that there are both qualitative and quantitative measures built into the employee evaluation system. It was explained that BI/CH Development program was a motivator for staff and that the first cycle of the program is complete with a 10% graduation rate.

- It was explained that the PMRA uses external experts at various times and an example of this was using the Canadian Pediatric Society as an expert during the re-evaluation of DEET.

Reporting

Janice Hopkins, Special Advisor to the Executive Director of PMRA gave a presentation on the reporting activities within PMRA. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- Council members noted that a lot of new reports will be produced (sales information, adverse effects, etc.), and there needed to be an integration of these smaller reports into one large report, or an understanding of how all of the reports fit together.

- Some Council members asked for quantitative information on the numbers of joint reviews and how many decisions per submission type there were, including detail such as the number of URMURs and URMULEs each year. Others asked that the same type of information be presented from year to year so that comparisons could be easily made, while allowing for special entries that may differ from year to year. A request was made for the reports to identify what percent of PMRA resources went to re-evaluation versus new product submissions. Some members wanted the report to not only include information, but an interpretation of the information as well.

- PMRA indicated that the annual report would be mailed to stakeholders and placed on the PMRA website. Some Council members thought that the PMRA should consider new and unique ways of marketing the report and engaging stakeholders in its creation.

PMRA Website

Murray Gwyer, Director of the Business Line Improvement and Technology Development Division of PMRA gave a presentation on the proposed new PMRA website. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- Council members were pleased with the easily accessible quick link to the label search engine.

- PMRA indicated that the decision on how to integrate the public registry on the website is still under discussion.

- It was clarified that the training being offered to industry in the fall of 2004 would be focussed on electronic processes, and the integration of technology and the new PCPA.

***In Camera* Session**

An *In Camera* session was held. A number of recommendations arose from this session and will be included in a separate letter from the A/Chair to the Minister.

Agricultural Risk Reduction

Jacques Drolet, Head of the Alternative Strategies Section at PMRA and Leslie Cass, Research Co-ordinator of the Risk Reduction Program at Agriculture and Agri-food Canada (AAFC) gave a presentation on the joint agricultural risk reduction initiative. Presentation materials were distributed at the meeting and are available on the PMRA website.

The following summarizes major areas of discussion and clarifications:

- Council members were interested in discussing how the success of the program would be measured. It was discussed that PMRA/AAFC are developing a mechanism to measure the level of IPM adoption with growers as well as working with FPT on using a pesticide risk indicator. Council members acknowledged the difficulty with choosing a risk indicator.

- Summaries of the various risk reduction projects are available on the environment page of the AAFC website and on the PMRA website. The

PMRA website is undergoing enhancement and will soon include the newer risk reduction activities and framework.

- The AAFC approach to crop profiles is consistent with the U.S. in an effort to harmonize through North America. The purpose of the crop profile was clarified as being a key piece of useful information for the risk reduction strategy and to provide contextual information to the re-evaluation process. PMRA and AAFC are working to further understand the use of the profiles and whether they need modifications in order to be published and not violate any confidentiality. It was suggested that Council members sign a confidentiality agreement and then look in detail at an example of a crop profile, or examine one crop at each meeting so that PMAC can better understand and input into this program.

- The growers response to the canola IPM strategy was positive, and there were many discussions on how to evaluate its success. The intent of the canola growers is to measure attitudes toward using IPM and measure what practices have been adopted.

- A concern was raised that not enough of a budget was allocated to the PMRA/AAFC risk reduction project, and therefore fewer commodities can be addressed.

- Some Council members wanted to have an update on the Action Plan on Urban Use Pesticides within PMRA. It was discussed that this would be an agenda item for the next meeting.

- Some Council members thought that PMAC should play a larger role in seeking solutions to any problems that may arise with the risk reduction projects, including the prioritization of commodities.

Pesticide Risk Reduction on Crops in Ontario

Gordon Surgeoner, from Ontario Agri-Food Technologies gave a presentation on pesticide risk reduction on crops in Ontario. Presentation materials were distributed at the meeting and are available on the PMRA website.

- Some Council members asked for a similar presentation to be given to F/P/T as there may be some information of use as it relates to the Agricultural Policy Framework and possibly to the urban scenario.

- It was clarified that PMRA does not have the resources to conduct public opinion research, but does undertake a wide range of communication

activities, as were discussed at the June 2003 PMAC meeting. Council members asked for another opportunity to discuss the PMRA Communications Strategy at the next PMAC meeting, specifically to discuss the communication efforts targeted towards municipalities.

Review of Previous PMAC Recommendations to the Minister

Lynn Skillings, a member of the PMAC Secretariat, presented a summary of the various recommendations that have arisen at previous PMAC meetings, and the relevant action that has been taken on each of them. The presentation material will be made available to members on the PMRA website.

Recommendations to the Minister

The Council agreed on the following recommendations at the open session of the meeting.

1) The Council continues to support action, at the earliest possible time, to bring the new PCPA into force.

2) The Council wishes to emphasize the importance of having new reduced risk pesticides (both chemical and biological) registered in Canada. Such products are important to reduce pesticide risks to health and environment, and for the ability of Canadian growers to compete.

3) An evaluation of the Sales Data regulation should be carried out at the end of four years, to determine whether the information being collected is meeting the intended purpose. This evaluation should include what the costs are to both industry and the PMRA.

4) Council members stressed that the importance of continuing progress in re-evaluation, and of the availability of alternatives, when products are being phased out.

5) Delivering transparency - Council members support progress being made in delivering transparency and, in particular, support progress in using information technology to improve the registration system.

6) Members stressed the importance of harmonization.

7) The Council is supportive of the direction the PMRA is taking on the the Formulants program, the Human Resources Strategy and the new look of the PMRA website.

8) Regarding the Risk Reduction Strategy, the Council recommends that:

- quantifiable measures of success be identified for this initiative, considering risk reduction from the program and economic benefits;

- priorities in this initiative take into account re-evaluation priorities;

- PMRA give attention to product registration issues of reduced risk and lower risk products.

9) The Council continues to support the revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues.

Recommendations arising from the *in camera* session of the meeting will be communicated to the Minister of Health through a separate letter.

Date for Next Meeting

It was discussed that the next meeting would be in September/October 2004. The specific dates will be established by e-mail.