REPORT OF THE STAKEHOLDER MEETING CONCERNING THE RE-EVALUATION OF PESTICIDES IN CANADA

Hosted by the Pest Management Regulatory Agency
Crowne Plaza Hotel
Ottawa, Ontario
May 19, 2004

EXECUTIVE SUMMARY

More than forty stakeholders from representative areas and other government departments (participants list attached) met on May 19, 2004 to discuss management of the outcome of the pesticides re-evaluation process as a follow-up to a meeting to examine the impact of the US Food Quality and Protection Act, hosted by PMRA in 1998. A representative of the US Environmental Protection Agency also participated.

The purpose of the meeting was:

- to provide an overview of the PMRA's Re-evaluation program, and
- to discuss issues, actions, and potential approaches resulting from the re-evaluation of older pesticides in Canada, and
- to explore ways of working together better in the future.

Following presentations on the Re-evaluation program, work on international regulatory harmonization, and the new *Pest Control Products Act,* participants engaged in a round table discussion to identify key issues related to re-evaluation from their perspective. A key issue that emerged from the meeting was the need for improved communication on re-evaluation.

Based on the ideas discussed at the meeting, it is proposed that discussions continue with stakeholders on re-evaluation outcomes. Because physical participation may be a barrier to organisations with limited resources, teleconference participation and electronic updates to participants and interested parties will be made available.

There may be a need to call upon specific expertise among stakeholders where one product may be affected by re-evaluation outcomes.

I. INTRODUCTION

The Chair welcomed participants on behalf of the PMRA and encouraged full participation by stakeholders in examining the management of outcomes of the re-evaluation process.

The purpose of the meeting was:

- to provide an overview of the PMRA's Re-evaluation program, and
- to discuss issues, actions, and potential approaches resulting from the re-evaluation of older pesticides in Canada, and
- to explore ways of working together better in the future.

The Executive Director of PMRA noted how positive it was that a wide variety of stakeholders were participating, despite the timing of the meeting, which presented a challenge for growers. With more than 400 active ingredients to re-evaluate, the Agency needs stakeholder support and advice for an orderly transition.

The agenda included two presentations: one an update on key pesticide regulatory issues, and the second an outline of the re-evaluation program. The remainder of the meeting was devoted to input from stakeholders on issues associated with the re-evaluation program, and ways of working together to set out next steps on the management of re-evaluation decisions.

II BACKGROUND INFORMATION ON THE PESTICIDE RE-EVALUATION PROGRAM

The PMRA re-evaluation program was outlined, including timelines, which are linked closely with the EPA re-registration process. (appended).

The four re-evaluation programs are outlined in Regulatory Directive DIR2001-03. The re-evaluations of organophosphates are nearly completed, with the examination of carbamates to be undertaken next year.

Participants noted that cooperation with the EPA is very positive, and asked whether this cooperation can be extended to the EU or OECD. It was noted that the US EPA is very advanced globally with respect to re-evaluation of pesticides and thus the partnership with EPA was very appropriate while the PMRA is working to increase its ability to workshare more globally.

In response to a comment on the proposed revocation of the default MRL, it was noted that the re-evaluation process facilitated harmonization of MRLs/tolerances.

III KEY DEVELOPMENTS AT PMRA

Key changes related to the new *Pest Control Products Act* were presented (appended). Developments in harmonization were also presented and indication of the Agency's strong interest in submission of joint reviews as a critical element of the harmonization process.

Copies of the presentations are also available on PMRA's Web site http://www.hc-sc.gc.ca/pmra-arla

IV ROUND TABLE SYNOPSIS

Participants in the meeting were invited to briefly introduce themselves, and to identify their issues and concerns with respect to outcomes of the re-evaluation process.

COMMUNICATION

- Participants noted that they wished to know when active ingredients would undergo re-evaluation. A work plan is needed as soon as possible, so that pesticide companies could then have discussions with growers on availability of alternatives. It would be helpful to have an interactive database regarding re-evaluation on line. PMRA committed to publish a list of planned re-evaluations for fiscal year 2004-05 on our website.

- Trade barrier issues are a big concern for growers who must work in the global environment. There is a need to ensure that discussions are held on re-evaluation. Additionally, growers emphasized the importance of ensuring there is a viable alternative before something is taken off the market.

- There is a great deal of public concern regarding the use of pesticides. PMRA needs to be more active on communication.

- Consider preparation of a communications package for products used by homeowners. Target these for a lay person to help them understand the re-evaluation process and to understand the science better.

- It is difficult to search the PMRA web site. PMRA noted that the site was being redesigned.

- Communication is very important, not to sell the product, but to sell the system (of sound scientific review of pesticides). It is important to speak of the integrity of the PMRA system; it is a science-based system.

HARMONIZATION

- PMRA uses reviews from other OECD countries where possible and work closely to resolve any differences. Our data requirements are very similar to theirs. We also continue to work with industry so that we may share reviews more easily.

- Although US decisions in re-registration are being used, there are some cases for retaining Canadian use patterns.

- Concern was raised about the different zones for setting MRLs in Canada and differences related to provincial or regional registrations.

- Concern was expressed about products being submitted to the US for registration and not Canada. This could relate to market size. How does risk play a part in harmonization? The risk cup may be filled filled first with import Maximum Residue Limits. The PMRA encourages Joint Reviews so that the risk cup is not full before the product is registered in Canada.

- There is concern from growers with respect to both efficacy and effectiveness. The older products tend to be lower cost and their loss can impact on competitiveness internationally.

- The other big issue is harmonization of MRLs in the US, EU and Japan. Harmonization is critical for particular growers who don't want to be caught without products.

- To measure success: are we seeing synchronized approvals in Canada and the US? This is a key yardstick, but progress must continue. Why are companies not taking advantage of joint reviews? Is efficacy standing in the way, if it is, then we should discuss this.

PROCESS

- PMRA advised, in response to a query on the refusal of use expansion while an active ingredient is under re-evaluation, that use patterns may not be expanded or changed during the process, so that the basis on which the re-evaluation is undertaken can be held constant. This applies to active ingredients that are included in the 2003-04 workplan, or for which re-evaluation has been announced.
- Label improvements and translation requirements were discussed citing cost issues, with a query whether these activities be harmonized. NAFTA labels were discussed as a useful means of harmonization.
- Re-evaluation targets are ambitious. It will be important to announce if they cannot be met, recognizing that PMRA is tied to US progress. The re-evaluation process is fine, but it will be important to look at differences in

rates and consumption between the US and Canada, and keep a Canadian perspective.

- A consistent last date of sale date was requested, one day in the year would be easier (e.g. end of December). The EPA uses one date per year. This is not a formal policy, but seems to work well there.

- It was recommended that separate letters for example be sent to formulators and manufacturers to allow an approval involving formulators as early in the process as possible.

- The question whether risk benefit is assessed was raised and the potential importance related to West Nile Virus. Under the PCPA, risk is not weighed against benefit.

- When data is generated by a task force to support an end use or an active ingredient, if the member is part of the task force, the member pays for the cost recovery. Who then benefits from the registration? Typically, it is the task force members who benefit from the registration.

- There are impediments to sharing reviews with other countries. The Agency shares the reviews only with the permission of the registrant. Under the new PCP Act, the Agency will no longer need permission once the review is complete.

- More alternative products should be available. Another area of concern is linked to process. PMRA looks at one pesticide at a time. We recommend that you consider crop pest combinations where two or three products could be used. Be sure that all use patterns and combinations are considered in looking at alternatives. If we have to maintain one product for some time, let's keep the least risky.

- Forestry is looking at alternatives and wish to see alternatives registered. Most forestry pesticide products are minor use products.

OTHER

- The EPA noted that issues with stakeholders in Canada are similar to those in the United States. The re-registration process started in the late 70's and into the 80's. It has been a daunting process working to get all products reviewed. The entire schedule is on the web now through 2008. EPA has 850 plus staff, many of whom are designated to re-registration.

- Concern was expressed regarding the number of buffer zones on the label. What is the difference between ditch and stream, water courses? PMRA

considers buffer zones. With respect to vocabulary, it would be helpful to have definitions as to what wildlife habitats mean.

- Concern was expressed regarding resources for the overall amount of re-evaluation that must be done. The Commissioner of the Office of Sustainable Development noted that the biggest issue was with resources. Has there been an explicit reallocation of resources to meet deadlines? Could you make the prioritization criteria clear and publish them? PMRA noted that new resources have been provided for re-evaluation activity. PMRA's work plan has been published for 2003-2004 food use pesticides, with criteria for priority.

V SUMMARY FROM THE CHAIR

To highlight, some of the key messages that have been emphasized today are:

There has been considerable emphasis on communication regarding how the regulatory process operates, though there was not a consensus in this area. Communication should be clear, timely and science-based.

A number of comments have been made on predictability and the list of 401 active ingredients that are being re-evaluated. You want predictability and wish to have communication on what is coming up in the next period, characterizing the activities and predicting when decisions will be made. This contribution from PMRA will permit you to consider priorities with respect to minor use needs, and planning and facilitating a search for alternatives.

You expressed concerns regarding no use expansion while re-evaluation is underway. You can't meet other needs because the active ingredient is being re-evaluated.

There is strong support for harmonization and an expressed wish that decisions be the same to the extent that they can be, especially harmonized with the US, but also with the EU, Japan and other key trading partners. There is a drive for international harmonization.

We recognise that there are Canadian use patterns and that we can't always have the same products available as in the US. On zones, you asked whether their basis may be re-examined. The number of crop zones may contribute to a lack of products being submitted for Canadian registration.

People wish to see a connection between re-evaluation and the other activities in PMRA, for example, the connection with adverse effects. As we enter the 15-year cycle, new information may be added to contribute to the need for re-evaluation.

We have heard your recommendation for a single end date for product phase out.

We recognise that formulators must be included in the re-evaluation process.

There is a high interest in harmonizing MRLs in North America and in a number of other countries. In revoking the default MRL, there are a few points of view - following the US policy or supporting the EU approach of a much lower default.

The implementation of labelling changes need to be harmonized. The Agency is currently undertaking a label initiative.

We must consider the timing of the withdrawal of products post re-evaluation especially where no good alternatives exist. There is a need to plan well in advance, especially for minor use pesticides.

On pesticides for public health purposes, there is a lack of availability of some products in Canada. We are a small market. You have asked us to consider the risk/benefit rather than the risk management approach in the public health context.

We need yardsticks to measure our performance. You wish to have that information available. The re-evaluation process may be improved by using additional data such as water monitoring information and market basket studies. There are opportunities for cooperation as there are many players on the water monitoring side.

Collaboration with provincial and territorial colleagues is critical due to the number of initiatives underway. Some here called for national harmonization.

There is a wish for better information such as a database on products that are undergoing re-evaluation, and the decisions that are being made concerning them.

The need for reduced risk products, and for alternatives to pesticides was highlighted.

VI WHAT NEXT?

The cost of attending such meetings is a challenge for some groups. In order to make this a more open process, the PMRA should consider electronic communication such as an electronic bulletin board or a LISTSERV. There is an interest in receiving regular information, including publishing information on the website.

Face-to-face is good but only annually to serve as an update. The utility of the meeting is directly tied to the results. An action plan on a subject by subject basis from the meeting was encouraged.

VII FINAL COMMENTS FROM EXECUTIVE DIRECTOR

Many issues have been put on the table. The offers of support and willingness to work together are valued. The PMRA needs a process to work on the outcomes of re-evaluation that is not resource demanding of stakeholders and is iterative and transparent. There has been a call for increased communication especially on our progress and a forward workplan. These will be published on the web.

The PMRA will immediately investigate single dates for stop sales and stop use. Our stakeholders have asked for continuing input in the management of outcomes of re-evaluation decisions. That advice is encouraged, welcome and necessary for PMRA's management of re-evaluation of pesticides.

VIII OUTCOME

A report of the meeting will be drafted and sent for comments to participants. Following the receipt of any comments, the report will be finalized and published. PMRA will be following up on the recommendations that were made during the meeting.

- Review draft report - submit comments by **October 6, 2004**
- Print/post report on PMRA web site by end October, 2004
- Set quarterly conference call dates to discuss progress on re-evaluation and any specific issues.
- Brief conference call updates to be posted on the PMRA web site within one week of the call
- Set up any ad hoc groups to work on specific issues on an as needed basis.

IX. APPENDICES

1. List of participants
2. Comments from participants: Louison Fortin, Environnement Québec
3. Letter of invitation to stakeholders

Stakeholders' List

Attendees	Affiliation
Marcos Alvares	National Resources Canada
Rob Anderson	Manitoba Health
John Arseneau	Environment Canada
Suzanne Beattie	Nu-Gro Corp
Josée Beaudoin	Health Canada, PMRA
Joanne Buth	Canola Council of Canada
Kelly Butler	Health Canada, PMRA
Kristen Callow	Ontario Ministry of Agriculture & Food
Bill Chase	McLaughlin Gormley King Company
Mark Cohen	NCH Corp
Shannon Coombs	Canadian Consumer Specialty Products Association
Kathy Cooper	Canadian Environmental Law Assoc
Cam Dahl	Grain Growers of Canada
Danny Dempster	Canadian Produce Marketing Assoc
Louison Fortin	Ministere de l'Environnement
Anne Fowlie	Canadian Horticultural Council
Bob Friesen	Canadian Federation of Agriculture
Les Goczan	Wellmark International
Janice Hopkins	Health Canada, PMRA
Karla House	Canadian Federation of Agriculture
Charalyn Kriz	Health Canada, PMRA
Helene Langlois	Schering-Plough
Susan Lewis	US EPA Office of Pesticides
Peter MacLeod	Crop Life Canada
Trish MacQuarrie	Health Canada, PMRA
Don McCabe	AgCare

Theresa McClenaghan	Canadian Environmental Law Assoc
Al McFadden	Dow AgroSciences Canada Inc
Ben Moody	Natural Resources Canada
Norma C. Pangilinan	Bayer Environmental Science
Lorna Poff	Ontario Environment
Gail Schley	McLaughlin Gormley King Company
Wendy Sexsmith	Health Canada, PMRA
Alexander Shalin	Nova Scotia Dept of Ag & Fisheries
Judy Shaw	Syngenta
Robert J. Sloan	Lonza Inc
Diana Somers	Health Canada, PMRA
Gordon Surgeoner	Ontario Agri-Food Technologies
Alan Tomlin	Agriculture & Agri-Food Canada
Caroline Turcotte	MAPAQ
Patti Turner	Crompton Co
Patty Vandierendonck	BASF Canada
Chris Warfield	Bayer CropScience
Madeline Waring	BC Min of Agr & Fisheries
Richard Whate	Toronto Department of Health
John Worgan	Health Canada, PMRA

Buffer zones

PMRA mentions that risks are acceptable if the pesticides are used in accordance with directives on labels. However, one of the instructions to follow in order to limit the environment risks is the compliance of buffer zones. It is not easy to follow the directive because:

1. Some buffer zones are not quantified, no distance has been written.
    - Potential for contamination of sensitive **areas** as a result of runoff will be reduced by inclusion of **buffer-zones** at or near the bottom of slope. (Sensitive areas: example **aquatic systems** or wetlands) [Hexazinone 25225]
    - Leave an **adequate buffer zone** between treatment areas and **sensitive plants**
        - This herbicide may cause injury to desirable trees and plants, particularly soybeans, flowers, fruit trees, grapes, ornamentals, peas, potatoes, tomatoes, tobacco, and other broadleaf plants especially in their developmental and growing stage. Follow these precautions when spraying in the vicinity of **sensitive crops**. (Dicamba 23957)

2. **Buffer zones** to be respected are very diversified, from 75 to 10 m (more than 10 difference distances 10, 15, 25, 45, 50, 75) according to the products used, the sensitive areas to be protected, etc.

3. The vocabulary used to qualify the **sensitive areas** to be protected is very diversified, thus is no uniformity and is confusing;
    - Do not use this product within 10 meters of the above mentioned **water sources**. (**water sources** : wells, lakes, streams, ponds or **sink holes)** [Atrazine 14842]
    - For the protection of aquatic plants, overspray or drift to **important wildlife habitats** such as wetlands, sloughs or **dry slough borders** and water bodies should be avoided. Leave a buffer zone of 29 meters between the last spray swath and the edge of any of these **habitats [milieu fr.]** [S-metholachlore 25729]
    - To reduce down-slope movement of the herbicide or treated soil particles into **sensitive areas** (for example **aquatic systems** or wetlands) Hexazinone 25225
    - This product is very toxic to fish and aquatic organisms. Do not contaminate ponds, lakes, streams or rivers during sprayer filling or rinsing operations or while spraying. Do not apply within 15 metres of **productive fisheries water** ... (Lambda-cyhalothrine **24984)**

Questions

Is it realistic, to enforce the buffer zones for the growers with more than 10 different types of zone?

What is the difference between ditch and stream, water courses?

What are the definitions of **important wildlife habitats, sensitive crops, sensitive plants, sensitive areas, aquatic systems, productive fisheries water etc** ...?

What efforts does PMRA make to get compliance of the directives on the labels?

Only 350 out of 1530 commercial labels included buffer zone.

Does ARLA want to increase the instructions relating to the buffer zones on labels?

April 15, 2004 **Letter of Invitation**

Dear Colleague:

You are cordially invited to a one-day meeting with Health Canada's Pest Management Regulatory Agency (PMRA) on May 19, 2004, concerning the Canadian pesticide re-evaluation program. The meeting will be held in Ottawa at the Crowne Plaza Hotel from 9:00 a.m. to 5:00 p.m.

The purpose of the meeting will be:

- to provide an overview of the PMRA's Re-evaluation program, and
- to discuss issues, actions, and potential approaches resulting from the re-evaluation of older pesticides in Canada, and to explore ways of working together better in the future.

In 2001, following consultation, a new approach to re-evaluation was initiated by the PMRA. The approach maximizes the use of recent re-evaluations completed in other countries, particularly the United States. Using this approach, the PMRA will be able to complete the re-evaluations of older pesticides as soon as possible to ensure that Canadians' health and their environment continues to be protected.

Priorities for the re-evaluation program were established by considering pesticides used on food, areas where work can be done jointly with the U.S.; Canadian specific concerns and availability of US Environmental Protection Agency (EPA) reviews. Canadians were consulted on the overall approach to pesticide re-evaluation.

The phase-out periods that are established when a re-evaluated pesticide has been found to require withdrawal from the market depend on the nature and severity of risks and consideration of the amount of product that remains in the distribution chain. The phase-out schedule includes a date of last sale by registrants and a date on which the product can no longer be sold to users. These schedules are typically harmonized with the US schedules. The phase-out period is part of the "proposed acceptability for continuing registration" documents that are released for public consultation following the completion of a review of a pesticide.

The PMRA was committed to re-evaluate, by 2006, 405 pesticide active ingredients that were registered prior to 1995. The original number of 405 actives is reduced by 4 disinfectant actives that are no longer regulated under the *Pest Control Products Act*, therefore, the target is now 401 actives.

The EPA target was 2006 but, because of workload issues, has recently shifted their target to 2008 for non food uses and 2006 for food uses. Since the PMRA target for completion of the re-evaluation process for 401 pesticide active ingredients registered prior to 1995 is tied to that of the US re-registration program, the re-evaluation of those non food uses will be completed in the 2008-2009 time frame.

To assist in harmonization of approaches in North America, a project to provide for coordination among the US, Canada and Mexico on re-evaluation has been established under the North American Free Trade Agreement Technical Working

Group on Pesticides (NAFTA TWG). This provides for Canadian input into the US decision making process regarding impact of the *Food Quality Protection Act* on agriculture in Canada, and for joint work on some active ingredients. It is also recognized that under NAFTA there is an opportunity to try to minimize the trade barriers that could arise.

The PMRA is aware that re-evaluation decisions create some issues and challenges for stakeholders, including pesticide users and registrants, but also for other stakeholder groups and for federal and provincial colleagues. This meeting is intended to give you an opportunity to identify those issues, and to explore potential approaches and ways of working together in the future. The agenda (attached) provides an opportunity for each participant to share information in roundtable discussions. The session will be informal and it is hoped that all participants will provide comments from their perspective .

I recognize that this meeting is being organized at a very busy time for a number of stakeholders, but we hope that you or your representative will be able to attend, given the importance of this subject.

Please confirm your attendance by completing and returning the attached form by fax to Josée Beaudoin at 613-736-3699 or by e-mail at **Josee_Beaudoin@hc-sc.gc** by April 30, 2004. An agenda is attached for your information.

While your travel expenses and accommodation costs will not be reimbursed for this meeting, we are pleased to advise that lunch will be provided.

Please contact the hotel directly to make your room reservation. In order to obtain the special rate, please make your reservation by April 30, 2004, under "Health Canada, PMRA Meeting".

The Crowne Plaza Ottawa
101 Lyon Street North
Ottawa, Ontario K1R 5T9 Tel: 1-800-567-3600
Group Name: Health Canada, PMRA Meeting
Special Room Rate: $132.00

For further information, please contact Kelly Butler (tel.: (613) 736-3812, fax: (613) 736-3659, e-mail: Kelly_Butler@hc-sc.gc.ca).

Yours truly,
W.A. Sexsmith
Acting Executive Director
PEST MANAGEMENT REGULATORY AGENCY