Pest Management Regulatory Agency
Teleconference on Canada's Pesticide Re-Evaluation Process
Monday, December 20, 2004

Minutes

1. Introduction from the Chair

John Worgan, PMRA

The Chair welcomed and thanked everyone. A roundtable of introductions was made and the Chair reviewed the agenda. Over 40 stakeholders participated.

A brief summary of the May 19th, 2004 stakeholder meeting was provided. The meeting included an overview of the re-evaluation process, a presentation on harmonization and a solicitation of recommendations on management of the outcomes of the re-evaluation process.

From that meeting, stakeholders recommended that such meetings be held on a continuing basis but noted that ability to participate might be limited by financial constraints, so teleconferences and electronic updates would be used with face to face meetings held as necessary.

2. Update on Re-evaluation Status

John Worgan, PMRA

The Chair noted that the timelines on re-evaluation would be closely linked to the US EPA process. Therefore food uses are targeted to be completed by fiscal year 2006 - 07 while non-food uses are targeted for completion by 2008-09. Further information on the re-evaluation process and documents published to date is available at: http://www.pmra-arla.gc.ca/english/pubs/reeval-e.html.

The Chair noted that the PMRA web site has been updated since the May meeting. The web site should now be more user friendly. A re-evaluation button is now available and allows for quick navigation to Re-evaluation publications.

Current status

As of November 30, 2004, decisions or proposed decisions on 144 pesticide active ingredients have been published or companies have been notified. Of those:

- 71 were discontinued/phased out, i.e., the manufacturer chose not to support the continued use of the product;
- 8 have been phased-out (or proposed for phase-out) as a result of PMRA review;

- 62 have been accepted for continued use with modification to the way they are to be used (with updated worker or environmental protection);
- 3 actives were accepted for continued use without any label changes.
- In addition, preliminary risk assessments have been published for the heavy duty wood preservatives creosote and copper chromium arsenate (CCA).

For an additional 21 active ingredients, assessments have been completed and decisions proposed, but documents have not yet been translated/published or companies have not yet been notified. These 21 active ingredients have been found acceptable for continued use with modification to the way they are to be used. These documents will be published soon.

It was noted by the Chair that one should not extrapolate from the above numbers to the 401 actives. For example the percentage of discontinued actives is not unexpected upon initiation of the re-evaluation program. Other regulatory agencies also report that a high number of active ingredients are discontinued by registrants at initiation of a re-evaluation program.

Approximately 83% of all decisions (excluding voluntary decisions by manufacturers to discontinued) are essentially harmonized with decisions from the US EPA.

The workplan to April 2003-June 2004 included doing reviews on active ingredients resulting in the publishing of one of the following documents:

I) Preliminary risk assessment,
ii) Proposed Acceptability for Continuing Registration (PACR),
iii) Re-evaluation Decision Document (RRD)
iv) Re-evaluation Notes (REV).

A progress report on the April 2003-June 30, 2004 workplan is available at web site: http://www.pmra-arla.gc.ca/english/pdf/plansandreports/pmra_progressreport2003-e.pdf. This progress report identifies the PMRA document number for each publication.

April 2004/June 2005 Workplan

The 2004 - 05 workplan is now posted on the PMRA web site at: http://www.pmra-arla.gc.ca/english/pdf/rev/rev2004-06-e.pdf.

For actives on the 04/05 workplan PMRA targets completion of a review and the publishing of one of the following documents:

I) Preliminary risk assessment,
ii) Proposed Acceptability for Continuing Registration (PACR),
iii) Re-evaluation Decision Document (RRD)
iv) Re-evaluation Notes (REV).

The purpose of re-evaluation is to determine whether registered pesticides meet today's safety standards. If they do not, typically a phase out schedule is proposed, harmonized with the US where possible.

A process for *ad hoc* transition working groups is now in place so that PMRA, growers and the pesticide industry can work together to try to find appropriate replacement products. Because PMRA does not develop the pesticides, it is necessary to work together with both the users and the pesticide industry in order to find and have submitted potential replacement products. One such group has been established for apples in light of recent proposals and decisions on some OPs.

Other processes include the risk reduction strategies where growers work with PMRA, AAFC and other stakeholders on an Integrated Strategy for managing their crop, that could include replacing older pesticides with new technology and encouraging registrants to submit pesticide applications jointly to the US and Canada.

In addition, the Minor Use Program that provides for the development of data by AAFC to support a registration and for PMRA to carry out the risk assessment also results in replacement products for growers. PMRA's approach is to try to ensure that a replacement product is available if at all possible.

Stakeholder Comments and Questions

Q- A query was made about actives that are currently under re-evaluation but not listed on the workplan.

A- Only actives for which PMRA targets publication of a document during this period are listed on the 04/05 workplan. Work on some additional active ingredients is underway but is at an earlier stage. In early 2005, another PMRA document will be published listing the remaining actives of the 401 list that have not yet been announced or that are not on the published workplans. These actives are targeted to be re-evaluated between 2005 and 2009. CAS #s will be provided for ease of reference/identification.

A comment was made that the Minor Use group tries to identify alternatives with existing registrations that are already available in other countries.

3. 401 List - Discussion regarding what information should be included

All

Stakeholders expressed an interest in an "interactive" 401 list sorted by active ingredient. A presentation on the web might be more manageable and more widely available.

The potential content of such an interactive list was proposed:

- last date of manufacture,
- last date of sale,
- last date of use,
- initiation of re-evaluation date,
- proposed end of re-evaluation,

- date the PACR will be released,
- date the RRD will be or was published,
- What is needed is a "snapshot" of each ingredient. This is difficult currently since a number of documents may need to be consulted to obtain a picture of the status.
- For phase out periods, describe what risk is being tolerated while the phase out is going on. It was noted that the RRD should provide this information. A process document is also under development which will describe considerations based on factors described in.

It is an important to keep the 401 list manageable, and that there are not too many links to the list. Stakeholders would like to see a mock up of the list to enable them to provide comment to PMRA.

Stakeholder Comments and Questions

Q- A question was asked if it would be possible to have e-mail notification when a change to the 401 list occurs.

A- Stakeholders were advised that they can receive notices of updates to the PMRA web site.

Q- Another question was whether PMRA would publish a document for all the discontinued actives under re-evaluation or will stakeholders need to check with registrants to know what is happening to these actives.

A- A Re-evaluation note will be published noting that registration has been withdrawn or whether the registrant will be putting into place additional mitigative measures.

4. Renewal period for actives under re-evaluation - Current Approach
John Worgan, PMRA

There has been a change in the renewal periods for actives ingredients under re-evaluation. Previously, this period has typically been 1 to 3 years with the majority of new Program 1 actives receiving one year renewals.

Recognizing the additional resource renewals demand from both industry and PMRA, and taking into account the expected timeframe for completion of re-evaluation, actives in Program 1 that are under re-evaluation (but not yet at decision stage around the time of their renewal sign off), will receive a 2 year renewal to more closely reflect the expected time needed to complete them. This will be effective immediately.

Program 1 actives for which a decision has been communicated will have a 1 year renewal (as previously).

Actives in programs 2,3, and 4 will continue to have renewal periods determined on a case by

case basis but we will endeavour to ensure this period is reasonable given the stage of re-evaluation and to time the renewal paired with the expected completion date of re-evaluation.

In response to a concern: If there is an unfavourable re-evaluation decision, it will not mean that the product can no longer be used at the end of the renewal period. A phase out schedule would typically be established based on severity of risk, amount in chain of commerce, availability of alternatives.

5. Other Business

Stakeholder Comments and Questions

Q- An report on the status of lawn herbicides was requested.

A- Remaining lawn and turf actives are in the final stages of review. Heavy workload in 2003/04 and new data were factors in finalizing the PACRs. PACRs planned for publication in early 2005.

Q- Another question was asked on how long it takes to complete a decision document (RRD).

A- The timeline for a PACR is 60 days and for a RRD is generally another 60 days. The timeline for the RRD may be longer depending on the complexity of the comments and if new and/or complex data need to be considered.

Q.- There was a query on whether there will be a risk/benefit consideration for public health pesticides (e.g. WNV).

A- Legislation prevents that approach, as risk must be acceptable. A risk benefit tradeoff is not done.

PMRA ACTION ITEMS:

- Draft minutes and circulate for comment
- PMRA to verify if there are links from the 2003/04 progress report to the publications on the PMRA web site
- Identify what is wanted/feasible for inclusion on the 401 list document
- PMRA to create a 401 List mock-up and send to stakeholders for comment
- Teleconferences to be scheduled every 4 months.
- The next teleconference proposed for April 14, 2005 at 1:00 to 2:30 (EST)