



Health Canada

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Health Canada's Response to the Commissioner of the Environment and Sustainable Development 2015 Audit on Pesticide Safety

The Commissioner of the Environment and Sustainable Development (CESD), under the authority of the Auditor General, recently conducted an audit of the Pest Management Regulatory Agency (PMRA).

Recommendations from the [Report 1 Pesticide Safety](#) are listed below in addition to Health Canada's response, the planned actions, the specific deliverables to which we are committing and the expected implementation dates.

Some of the deliverables have already been achieved and are noted. As additional work is completed, this page will be updated.

Recommendations

1. PMRA should ensure that registrants respect the timelines specified in conditional registrations for providing required information. It should also assess the data within its established two year timeline to determine the continued acceptability of pest control products and active ingredients.

The Agency's Response

Agreed. Since 2008, PMRA has taken action to limit the number of conditional registrations, which are used only where risks have been deemed acceptable and where additional, confirmatory information has been

considered desirable. Currently, 1% of pesticide registrations are conditional in nature; most of these have been conditional for less than 5 years. Some pesticides have been conditionally registered for longer periods, mainly because PMRA has required information that would take multiple years to generate (for example, new types of scientific studies to be carried out).

PMRA believes it could be possible to eliminate the use of conditional registrations, and is developing options towards that goal. Stakeholders will be consulted on any proposed change in policy.

For the remaining conditional registrations, on a bi-annual basis, PMRA will post a status report on conditional registrations, including whether the requested information has been received, the actions that have been taken, and the performance in reviewing the data within the 2 year timeline. Where necessary, PMRA will use existing authorities in the *Pest Control Products Act* to ensure that the requested information is provided according to the established timelines.

Planned Management Actions

- Finalize decision on whether to eliminate the future use of conditional registrations
- Improve transparency of remaining conditionally registered products
- Use existing authorities, where appropriate, and engage in more active oversight in an effort to ensure that requested information is provided according to the established timelines

Deliverables

- **COMPLETED** : [List of pesticides conditionally registered](#) including the conditions of registration
- Publish a bi-annual status report to clearly identify which products are conditionally registered, the conditions of registration, when confirmatory data is due / received, outcome of review, and review performance (September 2016 and ongoing)
- **COMPLETED** : [Consultation document on whether to eliminate the use of conditional registrations](#)

- Publish a final decision on whether to eliminate the future use of conditional registrations (June 2016)

2. PMRA should finalize and apply the methodology required to ensure that it considers cumulative health effects of pesticides in its re-evaluations, as required by the *Pest Control Products Act*.

The Agency's Response

Agreed. The Pest Management Regulatory Agency agrees with the recommendation and the importance of ensuring that the cumulative effects of pesticides are considered where necessary.

This is an emerging area in the science used to regulate pesticides and PMRA is actively working with international partners to understand how to best apply these principles to protect the health and safety of Canadians. Most countries, including Canada, are working on a cumulative risk assessment methodology for pesticides. However, the international scientific community has not yet reached a consensus on how to best assess the cumulative effects of pesticides.

PMRA anticipates having its own methodology for cumulative risk assessments in place in the 2017-2018 fiscal year.

Planned Management Actions

- Complete and apply a methodology for cumulative risk assessments by 2017-2018

Deliverables

- **COMPLETED** : [PMRA's approach to assessing cumulative effects of pesticides](#)
- Publication of a methodology document for public consultation related to conducting cumulative risk assessments (September 2017)
- Implementation of the methodology (March 2018)

3. PMRA should establish realistic timelines for completing re-evaluations of active ingredients registered before 1995, and should complete them accordingly.

The Agency's Response

Agreed. PMRA has completed the majority of its re-evaluations of active ingredients registered before 1995 and is committed to completing the remainder of the re-evaluations by 2020. PMRA continues to make progress on the remaining 46, and where necessary, has implemented interim measures to further protect health and the environment during the review process.

The Minister of Health's multi-stakeholder Pest Management Advisory Council (PMAC) recently supported PMRA's three-year re-evaluation work plan. PMRA will update the current work plan, in collaboration with the Council, in order ensure that the remaining 46 re-evaluations are completed by 2020. In completing the re-evaluations, PMRA will collaborate with other foreign regulators, as appropriate, including the US Environmental Protection Agency (U.S. EPA).

PMRA will continue to report on progress on an annual basis.

Planned Management Actions

- Consult PMAC on the updated multi-year re-evaluation workplan, and revise accordingly
- Publish a revised multi-year re-evaluation workplan, to be updated annually
- Collaborate with other foreign regulators, including U.S. EPA, as appropriate
- Report on the progress of the re-evaluation of the remaining active ingredients registered before 1995 in PMRA's annual report to Parliament

Deliverables

- Present the revised multi-year re-evaluation workplan at the next [Pest Management Advisory Council](#) meeting (February 17-18, 2016)
- Publish the new multi-year re-evaluation workplan (March 2016), and update annually
- Ongoing engagement and collaboration with stakeholders
- Provide a progress update in [PMRA's Annual Report](#) (Corporate Plans And Reports, December 2015 and annually)

4. With respect to its overall work planning for re-evaluations, PMRA should ensure that its schedule of work is complete and up-to-date.

The Agency's Response

Agreed. The Pest Management Regulatory Agency will publish updated work plans in early 2016 and update them on a yearly basis. These will include clear expectations for timelines, as well as the expected publication date of the final re-evaluation decision.

PMRA's current approach to re-evaluation favours receipt of new information, including incident reports, from any and all stakeholders even where this material might arrive very late in the review process. While this approach helps ensure re-evaluations are based on the latest and most complete set of information available, it unfortunately often delays the final decision as PMRA must then reconsider its assessment. To address this challenge and to meet pre-established timelines, PMRA will consult on and develop a policy with clear rules and criteria for submitting information in order to make timely decisions.

Planned Management Actions

- The revised multi-year re-evaluation workplan mentioned at [Recommendation 3](#) will include clear timelines for all re-evaluations (of active ingredients registered before 1995 and cyclical re-evaluations) and special reviews to the final decision stage

- Develop a policy to ensure the timely submission of information in support of re-evaluation decisions

Deliverables

- Publish and update annually the multi-year re-evaluation workplan mentioned at [Recommendation 3](#)
- Publish a consultation document on the proposed rules and criteria for submission of information in support of re-evaluations (March 2016)
- Publication of the final policy document (August 2016)

5. When the Pest Management Regulatory Agency determines that the risks posed by a pesticide are unacceptable for all uses, it should act promptly to cancel the pesticide's registration.

The Agency's Response

Agreed. The Pest Management Regulatory Agency agrees that unacceptable risks presented by pesticides should be addressed promptly.

Where unacceptable risks are identified but can be appropriately addressed through mitigation measures, PMRA acts promptly to require such measures. These can range from cancellation of certain uses, to the enhancement of the use of personal protective equipment by workers, to the implementation of additional application restrictions. Where risks are imminent and no appropriate mitigation measures exist, PMRA's policy is to cancel all uses.

In some circumstances where risks are only considered unacceptable in the context of very long-term usage, and where mitigation measures can be put in place as an effective interim solution, PMRA may implement a phase-out period commensurate with the level of risk. This approach ensures the protection of human health and the environment and provides lead-time for improved products to be introduced. The use of orderly product phase-outs, where risks can be mitigated in the interim, is a widely accepted practice in use by the United States Environmental Protection Agency and other advanced economies.

In 2016, to improve transparency, PMRA will consult publicly on its current approach for establishing a phase-out of products (including extensions).

Planned Management Actions

- Analyze, develop and consult on PMRA's approach for establishing phase-out schedules

Deliverables

- Consult publicly on its current approach for establishing a phase-out of products (including extensions) (June 2016)
- Publication of the final approach document (August 2016)

6. PMRA should maintain its public register of pest control products as required by the *Pest Control Products Act* to clearly communicate which products are conditionally registered and what their associated conditions of registration are.

The Agency's Response

Agreed. At present, while some information on which products are conditionally registered and their associated conditions is currently available on PMRA's website, other information is provided to members of the public upon request.

Recognizing the importance of promoting greater transparency in the regulation of pesticides, PMRA is constantly striving to find ways to more effectively communicate information on conditional registrations with regulated parties, affected stakeholders and all Canadians. In 2016, all conditions associated with conditional registrations will be published on the Health Canada website.

Planned Management Actions

- The public registry will be updated, and will include all necessary information on conditionally registered products.

Deliverables

- An updated public registry which includes all conditionally registered pesticides, associated end use products, and conditions of use (March 2017)

7. To ensure that end users can make informed decisions on pesticide use, PMRA should consistently communicate timely and readily accessible information on : which products it has decided to remove from the market, which uses it has decided to prohibit, what mitigation measures it has decided to put in place, and when these changes will take effect.

The Agency's Response

Agreed. PMRA acknowledges that the current communication of the information can be improved by clearly identifying which products (rather than active ingredient) are implicated. Recently, PMRA has increased the clarity of its regulatory documents by including timelines for the implementation of regulatory decisions.

In 2016, PMRA will identify further opportunities to improve communication with stakeholders and the Canadian public regarding the removal of pesticides or their uses, and the associated timelines. PMRA will also revise decision documents to provide a clear summary of the products it has decided to remove from the market, what uses it has decided to cancel, what mitigation measures it has decided to put in place, and when these changes will take effect.

Planned Management Actions

Improve the communications of re-evaluation decisions by :

1. Amending new regulatory decision documents in order to better identify :
 - which products are removed from the market

- what uses are prohibited
- new mitigation measures
- when changes will take effect

2. Improve the communication of regulatory decisions

Deliverables

- **COMPLETED** : New [mobile app that allows users to access pesticide labels](#)
- Consult with the Pest Management Advisory Council (PMAC) to explore options for enhanced communications and outreach regarding re-evaluation outcomes (March 2016)