Regulatory Directive DIR2016-03

Final Decision Regarding Conditional Registrations under the Pest Control Products Regulations

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Purpose

The purpose of this document is to inform Canadians and interested stakeholders of Health Canada's Pest Management Regulatory Agency (PMRA) decision to discontinue the granting of new conditional registrations under the *Pest Control Products Act* and Regulations, effective 1 June 2016. This decision is further to the proposal to do so as communicated in the 19 January 2016 document NOI2016-01 *Notice of Intent Regarding Conditional Registrations under the Pest Control Products Regulations.* Please see Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Implementation

For the existing conditional registrations, PMRA will ensure that any outstanding information is received and reviewed in a timely manner. Due to commitments already made with respect to the generation of new studies, it is possible that a limited number of existing conditional registrations will need to be renewed. PMRA anticipates that all remaining conditional registrations will be resolved by 2017.

Appendix I Comments and Responses

Health Canada's Pest Management Regulatory Agency (PMRA) received comments in response to NOI2016-01, *Notice of Intent Regarding Conditional Registrations under the Pest Control Products Regulations*, from stakeholders including professional associations, non-governmental organizations and the public. The PMRA has consolidated and summarized the comments received and provides responses below.

The majority of stakeholders supported the discontinuation of granting new conditional registrations under the Pest Control Products Regulations. Below are some of the other comments received and the PMRA's response.

Conditional Registrations under the Pest Control Products Regulations

1. Comments regarding current conditional registrations

Many stakeholders supported cancelling conditional registrations or implementing further restrictions on current conditional registrations by setting strict time limits, with no extensions or renewals, and strict consequences for late delivery of the requested additional information.

PMRA Response

PMRA has developed a detailed work plan to review all remaining conditional registrations. PMRA is expecting to receive all outstanding information for conditional registrations within the next year. PMRA anticipates that all remaining conditional registrations will be resolved by 2017.

2. Comments relating to conditional registrations and neonicotinoid pesticides

Although approximately 1% of all pesticide registrations are conditional, a high percentage of those are neonicotinoid class pesticides. There was also concern expressed over the length of time some neonicotinoids pesticides have been conditionally registered.

PMRA Response

The information requested for many of the neonicotinoid conditional registrations has been received and is in the process of being reviewed by PMRA. As well, neonicotinoids are currently under re-evaluation. A status update for neonicotinoid insecticides is available on the Health Canada website.

3. Comments relating to openness and transparency

Concern expressed regarding conditional registrations being allowed for sale without a public consultation.

PMRA Response

PMRA is committed to transparency and openness to further strengthen confidence in its regulatory decisions. With the discontinuation of conditional registrations, a full public consultation will occur in a timely manner before each decision to register a new pesticide is made.

4. Comments relating to the type of data requested

Concern with the type of data required by a PMRA as a condition of the registration.

PMRA Response

Conditional registrations are granted only when the review of the scientific data and information is sufficient to determine that the risks of a pesticide are acceptable, but PMRA requires additional information, such as monitoring data after a product registration, to confirm the results of models used in the risk assessment.

5. Comments relating to the Commissioner of the Environment and Sustainable Development (CESD) 2015 Audit on Pesticide Safety

Stakeholder reiterated the findings of the 2015 CESD audit on the pesticide program.

PMRA Response

Health Canada's Response to the Commissioner of the Environment and Sustainable Development 2015 Audit on Pesticide Safety has been posted on the Health Canada website and provides responses, planned actions, specific deliverables to which Health Canada has committed and expected implementation dates. For more details, please see Health Canada’s response (http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/pesticide-safety-securite-pesticide/index-eng.php).

6. Comments relating to not supporting the discontinuation of the granting of conditional registrations

Stakeholder suggests that conditional registrations are useful and that agriculture would be adversely affected with their termination. Some form of “conditional” registration should remain in legislation to ensure access to pesticides and PMRA should ensure that the requested information is provided in a timely manner.

PMRA Response

PMRA is committed to ensuring that regulatory decisions for pesticides continue to be processed in a timely manner and that reviews are conducted within the established service standards and targets. PMRA's service standards and performance results are posted on the Health Canada website (http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/service/aepcp-aerpa-eng.php).

PMRA will be closely monitoring existing conditional registrations to ensure that the required information is received and will be reviewing this information and making a final registration decision by 2017.

PMRA is aware that conditional registrations may allow earlier access to pest control products. However, PMRA's primary mandate is to protect the health and safety of Canadians and their environment, and is committed to transparency and openness to further public and stakeholder confidence in its regulatory decisions. Therefore, given the delayed consultation associated with conditional registrations and other concerns raised, PMRA has decided to discontinue granting conditional registrations as of 1 June 2016.

7. Comments relating to the length of conditional registrations

PMRA should continue issuing conditional registrations but set stricter time limits for receipt of the requested information.

PMRA Response

In order to increase openness and transparency and to address issues raised by the Commissioner of the Environment and Sustainable Development, the Standing Committee on Health as well as non-governmental organizations, PMRA will discontinue granting conditional registrations.

8. Comments relating to the scientific review of data

All data in support of a pesticide should undergo a comprehensive scientific review and should be available to the public during consultation. The scientific data provided in support of a registration should be funded and developed by an independent body. An independent review of the scientific approach to approving pesticides is required. As well, concerns have been raised that PMRA has not been thoroughly examining the scientific data before granting a conditional registration.

PMRA Response

PMRA uses a scientific evidence-based approach to decision making. PMRA has approximately 270 highly qualified scientists. These scientists conduct a critical review of the pesticide applications, including the scientific data submitted, equivalent to an independent scientific peer-review body. The studies submitted by industry to PMRA are generally of very high quality. However, PMRA scientists can and do reject studies submitted by applicants that are deemed to be deficient due to deviations from the established study protocols. Industry-sponsored studies also lend themselves to a thorough, independent analysis of the raw data by PMRA's scientists.

Raw data must accompany each study; this translates into thousands of pages of data for a given compound that undergo thorough analyses and crosschecking between studies to ensure consistency. The PMRA can also request additional data to address concerns arising from the evaluation of the data submitted by applicants. All sources of published literature, as well as incident reports and other relevant information, are also considered by PMRA's scientists during a review.

9. Comments relating to the requirements for additional information

A stakeholder would like clarification on Health Canada's policy on "additional data requirements" following the discontinuation of conditional registrations, including the phase-in on any new requirements and how those requirements will be applied to applications currently in progress.

PMRA Response

As indicated in the Notice of Intent published on 19 January 2016, the Minister may require additional information related to the human health, safety, environment or value at any time.

This refers more specifically to Section 12 of the *Pest Control Products Act* which states:

12. (1) The Minister may, by delivering a notice in writing, require a registrant
(a) to compile information, conduct tests and monitor experience with the pest control product for the purpose of obtaining additional information with respect to its effects on human health and safety or the environment or with respect to its value; and
(b) to report the additional information to the Minister within the time and in the form specified in the notice.

If data requirements change in the future, PMRA will publish a consultation document for comment and will publish the final decision before implementing the new requirements.

10. Comments relating to pre-submission consultations

PMRA should adequately resource pre-submission consultations and administrative processes to ensure an efficient regulatory system.

PMRA Response

PMRA is committed to the pre-submission process. All registrants and applicants are encouraged to take advantage of this program to ensure that the data requirements are properly identified.

11. Comments relating to the timely identification of data gaps during the registration process

Request that PMRA identify data gaps as soon as possible in the registration process.

PMRA Response

PMRA notifies the applicant of any data gaps as soon as practicable in the registration process.

12. Comments relating to the precautionary principle

Health Canada is not applying the precautionary principle.

PMRA Response

Health Canada scientists rigorously review the detailed studies and tests provided by applicants in order to determine the risks to human health and the environment, and whether or not the product has value. The health risk assessment requires that consideration be given to sensitive sub-populations such as pregnant women, infants, children and seniors; the environmental risk assessment considers factors such as risks to non-target species. If a product is found to pose a concern to human health, future generations, or the environment, it is not registered for use in Canada.

13. Comments relating to the reading room

A stakeholder requested increased and remote access to reading room materials.

PMRA Response

The reading room is in Ottawa in order to allow access to scientific expertise, which may be required in the course of reviewing confidential test data, in order to provide further information on how the test data relates to the decision that was made. PMRA is also responsible for protecting the confidentiality of test data and for overseeing access to it.

14. Comments relating to products being used contrary to the label

Concerns over a pesticide being used contrary to label directions, and the public’s knowledge of products being used on public land. Also, a request was made to remove the registration of a product and impose action on municipalities.

PMRA Response

If a pest control product has not been used in accordance with label directions then PMRA should be informed so the incident can be investigated. Provided that a product is registered and is being used in accordance with the label directions, PMRA does not have the authority to force other jurisdictions to cease using or dispose of pest control products.

15. Comments relating to re-evaluation

Pesticides should not be used when they are under re-evaluation. The public needs to be better informed about the timing of a re-evaluation of a particular pesticide.

PMRA Response

All registered products, including conditionally registered products and products under re-evaluation, are allowed to be used in accordance with the conditions placed on their registration.

The *Pest Control Products Act* requires the PMRA to initiate re-evaluations of registered pesticides on a 15-year cycle, based on either its initial registration or the most recent major decision affecting the registration. In order to improve transparency and predictability, a revised work plan for re-evaluations and special reviews has been published on Health Canada's website. The work plan serves to inform interested stakeholders of the re-evaluation and special review work planned for the years 2015-2020.

16. Comments relating to post-market monitoring data

Will PMRA be eliminating the need for post-market monitoring data?

PMRA Response

Post-market information will continue to be required in some instances, using section 12 of the *Pest Control Products Act,* in order to ensure that the risks remain acceptable and that the product has value.

17. Comments relating to emergency registrations

The removal of conditional registrations may lead to an increased use of emergency registrations.

PMRA Response

Conditional registrations and emergency registrations are used in different circumstances and are not interchangeable. Under section 18 of the Pest Control Products Regulations, the Minister may register a control product, for a period not exceeding one year, for the emergency control of a seriously detrimental infestation.

An emergency is generally deemed to exist when the following criteria are met:

- a pest outbreak or pest situation occurs that can cause significant economic, environmental or health problems;
- there is no effective product or application method registered in Canada for the control of the pest; and
- there is no effective, alternative control method available.

18. Comments relating to openness and transparency

PMRA should provide more information to the public about the registration process in order to improve public confidence in the regulatory process.

PMRA Response

PMRA is currently developing a strategy to further engage and inform stakeholders and the public on our processes and decisions.

19. Comments relating to the publication process for PMRA documents

The translation and publication process is resulting in delays.

PMRA Response

PMRA is committed to openness and transparency in both official languages. Documents are being posted in a timely manner and PMRA will continue to monitor the situation.